ADDRESSING THE NEEDS OF MALAYSIAN POSTMENOPAUSAL WOMEN: A PHARMACIST-LED OSTEOPOROSIS SCREENING PROGRAMME IN A TEACHING HOSPITAL PRIMARY CARE CLINIC

TOH LI SHEAN

M.Pharm

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ABSTRACT

In Malaysia, the prevalence of osteoporosis in women age >45 years is approximately 1 in 4 making it a major public health concern. Osteoporosis is usually asymptomatic in its early stages. Consequently, women who may have osteoporosis remain unidentified. This may lead to unwanted fractures. Fractures are associated with a reduction in quality of life. There is a 3-fold increased risk of death within 5 years in those who fracture. It is therefore imperative to encourage prevention and screening programmes which aid in early detection of osteoporosis. Current research suggests that many individuals with fragility fractures do not undergo appropriate screening and do not engage in preventive health behaviours.

Pharmacists can work in collaboration with doctors to screen for osteoporosis, to educate patients on their osteoporosis risk, and to empower patients to take osteoporosis preventive measures. It is with this belief that we conducted this study to determine the effectiveness of a pharmacist osteoporosis screening programme in postmenopausal women.

This study design was developed based on the United Kingdom Medical Research Council's Framework of developing and evaluating complex intervention. Hence, this research project was divided into three phases: phase one was to explore the perceptions of the stakeholders for conducting an osteoporosis screening programme, phase two was to develop tools for the osteoporosis screening programme whilst phase three was to conduct the a feasibility study on the osteoporosis screening programme.

Phase one aimed to answer three research questions. The first research question was to explore the barriers and facilitators towards conducting an osteoporosis screening programme. Seven main barriers to the implementation of an osteoporosis screening programme were identified: governmental, organizational and management, work environment, team, task, individual and patient factors. The patient factors were targeted for our intervention.

The second research question explored the role of the Malaysian pharmacist in osteoporosis screening. Pharmacists were principally perceived by all participants to be suppliers of medication, although there was some recognition of roles in providing medication advice. Nonetheless, doctors, nurses and policy makers were eager for pharmacists to be more proactive via inter-professional collaboration in osteoporosis screening, prevention advice and disease management.

The third research question aimed to explore the components for an acceptable, practical and sustainable osteoporosis screening programme. We systematically identified four intervention (environment restructuring, education, persuasion, enablement) components to develop an acceptable, practical and sustainable osteoporosis programme. The "interventional package" consisted of counselling sessions, osteoporosis risk assessment and bone mineral density.

In phase two, the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP) and Osteoporosis Prevention and Awareness Tool (OPAAT) were developed and validated. Both the OPAAT and SQOP were found to be valid and reliable to

assess patients' knowledge of osteoporosis and patients' satisfaction towards the pharmacist screening programme. Additionally, six osteoporosis risk assessment tools were also validated among Malaysian postmenopausal women. Our results identified that the Osteoporosis Screening tool for Asians (OSTA) was the most suitable risk assessment tool as it had a sensitivity of 81.3% and specificity of 41.0% at an empirical cut-off point of ≤0. A pharmacist-led osteoporosis screening intervention package which consisted of the 'intervention package' and collaboration between the doctors and pharmacists was developed and finalized.

Phase three was a feasibility study of the developed pharmacist-led osteoporosis screening programme. Based on scientific, process, resources and management assessment the programme was found to be feasible in the Malaysian primary care setting. This was a good start for the implementation of a population-based osteoporosis screening programme in Malaysia as there was currently no such programme available. Future research should involve a randomized controlled trial to assess the effectiveness of the programme.

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FINANCE

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PUBLICATIONS

Journal publications

1. Toh, L. S., Lai, P. S. M., Wu, D. B. C., Wong, K. T., Low, B. Y., Anderson, C. (2015) "The development and validation of the Osteoporosis Prevention and Awareness Tool (OPAAT) in Malaysia," Plos One (Accepted on 31st March 2015) (Appendix 38)

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AWARDS

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LIST OF ABBREVIATIONS

Abbreviations	Definitions
ABONE	Age Bulk One of Never Estrogen
AUC	Area under the curve
BCT	Behaviour change technique
BCW	Behaviour change wheel
BMD	Bone mineral density
CEO	Chief executive officer
CMP	Care management problem
CT scan	Computed tomography scan
DDSM-Q	Diabetes Disease State Management Questionnaire
DMET	Diabetes Management Evaluation tool
DEXA	Dual-energy x-ray absorptiometry
EFA	Exploratory factor analysis
FOOQ	Facts on Osteoporosis
FN	False negative
FP	False positive
FRAX	WHO Fracture Risk Assessment tool
GI	Gastrointestinal
HBM	Health belief model
HEDIS	Healthcare Effectiveness Data and Information Set
HRT	Hormone replacement therapy
IOF	International Osteoporosis Foundation
IV	Intravenous

MOKT	Malaysian Osteoporosis Knowledge Tool
MOST	Malaysian Osteoporosis Screening Tool
MTAC	Medication Therapy Adherence Clinic
NETSCC	United Kingdom's National Institute for Health Research Evaluation, Trials and Studies Coordination Centre
NICE	National Institute for Health and Care Excellence
NIH	National Institute of Health
NOF	National Osteoporosis foundation
OKAT	Osteoporosis Knowledge Assessment Tool
OKT	Osteoporosis Knowledge Test
OKQ	Osteoporosis Knowledge Questionnaire
ONJ	Osteonecrosis of the jaw
OPAAT	Osteoporosis Prevention and Awareness Assessment Tool
OPQ	Osteoporosis Questionnaire
ORAI	Osteoporosis Risk Assessment Index
OPSAT-Q	Osteoporosis Patient Treatment Satisfaction Questionnaire
OPSQ	Osteoporosis Satisfaction questionnaire
OSOP	One sheet of paper
OSTA	Osteoporosis screening tool for Asians

PCP	Primary care physician
PSQ-AN	Patient Satisfaction Questionnaire for Anaemia Treatment
PSQ	Preference and Satisfaction Questionnaire
PTH	Parathyroid hormone
QUS	Quantitative ultrasound
RANK	Receptor activator of nuclear factors Kappa B
RCT	Randomized controlled trial
ROC	Receiving operating characteristic
RUKA	Primary care clinic
SCORE	Simple Calculated Osteoporosis Risk Estimation
SD	Standard deviation
SERM	Selective Estrogen Receptor Modulators
SQOP	Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)
TN	True negative
TP	True positive
UK	United Kingdom
UK MRC	United Kingdom Medical Research Council
UMMC	University Malaya Medical Centre
US	United States of America
WEIGHT	Body Weight

RESEARCH TEAM

Name of researchers	Initial
Toh Li Shean	TLS
Pauline Lai Siew Mei	PLSM
Claire Anderson	CA
Wong Kok Thong	WKT
Sajarathulnisah Othman	SO
Low Bee Yean	LBY
David Wu Bin Chia	DWBC
Alexander Tan Boon Tong	ATBT

1.0 CHAPTER 1: LITERATURE REVIEW

1.1   Definition

1.1.1 Osteoporosis

Osteoporosis is defined as a skeletal disorder characterized by low bone mass and microarchitectural deterioration of bone tissue predisposing a person to an increased risk of fractures (National Osteoporosis Foundation, 2010, Ministry of Health Malaysia, 2012).

1.1.2 Disease profile

Generally, osteoporosis is asymptomatic in nature (National Osteoporosis Foundation, 2010). Common clinical presentation includes: increasing dorsal kyphosis (Dowager's hump), loss of height and back pain (Ministry of Health Malaysia, 2012). However, its clinical significance is predisposing an individual (with osteoporosis) to an increased risk of fracture (National Osteoporosis Foundation, 2010). These "fragility" fractures occur when individuals with osteoporosis slip and fall from a standing height, which would usually be insufficient to fracture normal bone (World Health Organization Geneva, 1998).

1.1.3 Basic bone biology

Bone is either cortical or cancellous with the adult skeleton containing 80% cortical and 20% cancellous bone. The outer shell of the skeleton is formed by dense contical bone, whereas porous cancellous bone forms the interior structures in a honeycombed fashion (Koda-Kimble et al., 2009).

The bone remodelling process is a continuous process involving, a balance between osteoblast and osteoclast

activities as osteoclasts resorbs bones, whereas osteoblasts help reform bony surfaces and fill bony cavity. This process begins with bone resorption that is initiated by osteoclasts excavating lacuna found on the surface of cancellous bone, or it occurs when cavities are formed in cortical bone. This process produced enzymes and proteins that help dissolve bone mineral and protein. Next, bone formation occurs with the help of osteoblast which gradually refill spaces created during the resorption process. Bone collagen fills in the bone cavities which are then calcified (Koda-Kimble et al., 2009).

Figure 1.1 shows the bone remodelling cycle at the cellular level. The top panels are of normal adults, the bone removed by the osteoclasts (left) is replaced completely by the osteoblasts (right). However when there is a high-turnover bone loss (middle panels) such as in women after menopause, the osteoclasts create a deeper resorption cavity that is not refilled completely. In low-turnover bone loss (bottom panel) which occurs with aging the osteoclasts create a resorption cavity of normal or decreased depth but the osteblasts fail to refill it (Koda-Kimble et al., 2009).

Figure 1.1: The bone remodelling cycle t the cellular level

Normal
Bone
Balance

Osteoclast-
mediated
bone loss

Osteoblast-
mediated
bone loss

Old bone

New bone

Several hormones are involved in bone remodelling such as the parathyroid hormone (PTH), glucocorticoid hormones, calcitonin, estrogen and testosterone. Calcium and vitamin D are important nutrients required for bone growth. PTH and glucocorticoid hormones are involved in bone resoprtion whereas calcitonin, estrogen and testosterone have been associated with bone formation. The skeleton system serves as a reservoir for calcium, the small intestine is the site for the absorption of dietary calcium and the kidneys reabsorb calcium in the tubular system. Calcium is regulated by the actions of PTH, vitamin D and calcitonin. PTH is released by the parathyroid gland when there is low serum calcium. This facilitates the mobilization of calcium and phosphate from bone and stimulates reabsorption of calcium through the tubular system in the kidneys. Vitamin D aids in intestinal absorption of calcium as well as phosphorous and magnesium. Increases in vitamin D levels decreases PTH levels. Calcitonin is released in response to high serum calcium levels. Calcitonin decreases intestinal absorption of calcium and phosphorous, inhibits calcium excretion in the kidneys and prevents bone resorption (Koda-Kimble et al., 2009).

1.1.4 Bone Mass

Bone mass peaks during the third decade of life. Bone begins to gradually decreases 0.3% to 0.5% yearly at about age 35 for both men and women. However with menopause due to the decrease in 17β-estradiol concentrations bone loss is accelerates by 2% to 3% per year that is superimposed on age-related bone loss. This loss gradually decreases over the next 8 to 10 years (Koda-Kimble et al., 2009).

1.1.5 Classification of osteoporosis

Osteoporosis can be classified into primary and secondary osteoporosis(Koda-Kimble et al., 2009).

1.1.5.1 Primary osteoporosis

Primary osteoporosis can be further classified into type I or type II (Koda-Kimble et al., 2009).

1.1.5.1.1 Type I primary osteoporosis

Type I is known as postmenopausal osteoporosis which is an increase in bone loss resulting in increased bone resorption. This affects women in the first 3-6 years of menopause (Koda-Kimble et al., 2009).

1.1.5.1.2 Type II primary osteoporosis

Type II is known as senile osteoporosis which occurs in both women and men 75 years of age or older(Koda-Kimble et al., 2009).

1.1.5.2 Secondary osteoporosis

Secondary osteoporosis results from the use of various medications or the presence of particular disease states. This type of osteoporosis can affect a person at any age and is equally common in men and women (Koda-Kimble et al., 2009). About 5% of all osteoporosis cases are secondary osteoporosis and about 20%of all osteoporosis fractures are caused by secondary osteoporosis (Bartl and Frisch, 2004). Table 1.1presents the list of medical conditions and medications which may lead to secondary osteoporosis.

Table 1.1: Medical conditions and medications which may lead to secondary osteoporosis (Reid, 2011)

Type of medications	Type of diseases
Glucocorticosteroids	Chronic liver diseases
Thyroxine	Chronic renal failure
Anticonvulsants	Hyperthyroidism
Depo-provera	Primary hyperparathyroidism
Heparin	Cushing's syndrome
Lithium	Insulin dependent diabetes
Cytotoxic drugs	Gastrointestinal resection
Gonadothrpin-releasing	Malabsorption
Tamoxifen	Irritable bowel disease
Aluminum	Chronic obstructive pulmonary disease
Vitamin D toxicity	Acquired immune deficiency syndrome or human immunodeficiency virus
Hyperoxia	

1.1.6 Epidemiology of osteoporosis

1.1.6.1 Prevalence of osteoporosis worldwide

Approximately one-tenth of women aged 60, one-fifth of women aged 70, two-fifths of women aged 80 and two-thirds of women aged 90 will be affected by osteoporosis worldwide. It is estimated that osteoporosis will affect 200 million women worldwide (Kanis, 2007).

1.1.6.2 Prevalence of osteoporosis in Europe

In Europe, due to the changes in population demography the number of men and women with osteoporosis in Europe will rise from 27.5 million in 2010 to 33.9 million in 2025, corresponding to an increase in 23% (Hernlund et al., 2013). Data from 2010 showed that the United Kingdom has approximately 3.21 million people aged ≥50 with osteoporosis (Svedbom et al., 2013).

1.1.6.3 Prevalence of osteoporosis in United States (US)

Based on figures in 2013, the United States (US) estimated that more than 54 million women and men aged 50 and older was affected by osteoporosis and low bone mass (Wright et al., 2014, National Osteoporosis Foundation, 2014). The figure will climb to more than 71.2 million by 2030 (National Osteoporosis Foundation, 2014).

1.1.6.4 Prevalence of osteoporosis in Latin America

In Brazil, 10 million people which approximates to one person in every 17 has osteoporosis (Siqueira et al., 2005).

1.1.6.5   Prevalence of osteoporosis in Middle East

The prevalence in Egypt was also high with 53.9 of postmenopausal women have osteopenia while 28.4 have osteoporosis (Mohy Taha, 2011).

1.1.6.6   Prevalence of osteoporosis in Australia

Similarly in Australia, 2.2 million Australian are affected by osteoporosis (Sambrook et al., 2002).

1.1.6.7   Prevalence of osteoporosis in Asia

The elderly population is expected to increase in all regions and all countries (United Nations, 2011). Asia is no exception to this trend. It is estimated that in year 2050, Asia will be having 29% of its citizens to be more than 60 years of age as compared to 11% in year 2011 (United Nations, 2011). The rapid development of an aging society produces an increase in diseases specific to aging particularly osteoporosis. In year 2003-2006, China's prevalence was found to be 15.7% for individuals' age above 50; which means that about 69.4 million people are affected with osteoporosis (International Osteoporosis Foundation, 2009). Data from Japan and Pakistan indicate that 12 million and 9.91 million people, respectively are affected by osteoporosis (International Osteoporosis Foundation, 2009). Similarly, there is a high prevalence of osteoporosis in Taiwan at 38.3% (Lin and Pan, 2011).

1.1.6.8   Prevalence of osteoporosis in Malaysia

Malaysia (located at the South East region of the Asian continent) is projected to have three times the amount of individuals aged 60 years and above from 1.4 million in year 2000 to 3.3 million in year 2020 (Mafauzy, 2000). Similarly to

other Asian countries, Malaysia has a high prevalence of osteoporosis of 24.1 %(Lim et al., 2005). The prevalence of osteoporosis will almost certainly increase together with Asia's rapid growth in its aging population. Therefore, this study is focused on the Malaysian population.

1.1.7 Risk factors of osteoporosis

1.1.7.1   Non-modifiable risk factors

1.1.7.1.1   Age

The risk of fracture doubles approximately with each decade (The Royal Australian College of General Practitioners, 2010). Fracture risk is strongly affected by age for both genders (The Royal Australian College of General Practitioners, 2010).

1.1.7.1.2   Ethnicity

Black women of African ancestry typically have a higher BMD than do white and Hispanic women(The North American Menopause Society (NAMS), 2010). Asian and Caucasians tend to have a lower average bone mass and smaller bones (The Royal Australian College of General Practitioners, 2010).

1.1.7.1.3   Gender

Men have an approximately 50% lower risk of osteoporotic fractures than women at a comparable age and bone density T-score, using young reference ranged matched for gender (The Royal Australian College of General Practitioners, 2010).

1.1.7.1.4   Early menopause

Women with early menopause have significantly lower bone density which has been associated with a higher fracture risk. Women whom had early menopause at a particular young age

may not have reached the peak bone density and will therefore be at further risk for osteoporosis (Meeta, 2013).

1.1.7.1.5 Personal history of fragility fracture as an adult

There is a five-fold increase on subsequent vertebral fracture risk with a single vertebral fracture. Additionally the risk of hip fracture also increases after one or more spinal fracture. Evidence show that 46% of women and 30% of men suffered further fractures over the following seven years (The Royal Australian College of General Practitioners, 2010). After an initial low trauma fracture from a simple fall, both older men and women have an increased equivalent risk of all types of subsequent fractures, especially in the next 5-10 years (Center et al., 2007).

1.1.7.1.6 First degree relatives with fracture

It has been found that women with a first-degree relative with osteoporosis typically have low bone mass (Kanis et al., 2004b). It has been suggested that approximately 75% if the genetic effect on a person's chance to develop osteoporosis is owing to a particular gene (Morrison et al., 1994).

1.1.7.2 Modifiable risk factors

1.1.7.2.1 Calcium intake

More than 99% of the body's calcium is in the teeth and bones. At a young age, prolong low calcium intake causes a negative calcium balance with a compensatory increase in PTH-medicated bone resorption which results in attainment of low peak bone mass. This later increases age-related bone loss and in postmenopausal women contributes to osteoporosis (Daroszewska, 2012). Therefore, an adequate

amount of calcium intake is needed to help achieve and maintain optimal bone mass(Koda-Kimble et al., 2009).

1.1.7.2.2 Vitamin D intake

Exposure to sunlight causes the skin to synthesized vitamin D. However, many factors such as latitude, overcast sky, skin pigmentation and ageing, clothing and the use of sun blocks diminish this process. Vitamin D is necessary for effective calcium absorption from the gut. Vitamin D is important as it helps regulate calcium by a complex interaction that involved PTH, thereby having a direct effect on the bone (The North American Menopause Society (NAMS), 2010). Vitamin D has a role in strengthening the bones via calcium absorption. It is the cofactor that facilitates the intestinal absorption of calcium and facilitates reabsorption of filtered calcium from the glomerular tubules back into plasma within the kidney (Cosman et al., 2014). It also assists in increasing bone mass and decreases fracture rates (Koda-Kimble et al., 2009). Deficiencies of vitamin D in adults will manifest as osteoporosis.

1.1.7.2.3 Other dietary considerations

Other dietary considerations are a diet in high in caffeine, protein, phosphorous and sodium has been associated with an increased risk of fractures by adversely effecting calcium balance. However, patients with adequate calcium intake may negate the effects of these dietary risks (NIH consensus development panel on osteoporosis prevention, 2001).

1.1.7.2.4 Small body built or low body weight

Low bone mineral status and increased fracture risk is associated with low body weight and excessive dieting

(Nguyen et al., 1998). It is recommended to maintain a body mass index (BMI) of not less than 19kg/m^2 for the prevention of osteoporosis (WHO technical report series 843, 1994).

1.1.7.2.5 Exercise

Exercise plays an important role in building bone in youth and helps slow down bone lost in adults. It assist in reducing the risk of fall as it strengthens muscles, increases flexibility and improves coordination and balance (International Osteoporosis Foundation, 2006). Prolonged bed rest and immobility especially in the elderly has been associated with decreased bone mass (Gutin and Kasper, 1992).

1.1.7.2.6 Smoking

It has been found that cigarette smokers may have impaired calcium absorption and lower 17β-estradiol levels but the mechanisms of how it affects bone mass are unknown (The North American Menopause Society (NAMS), 2010). Nonetheless, women who smoke, especially those who are thin, have been found to have an increased risk for fractures compared with non smokers (Baron et al., 2001).

1.1.7.2.7 Alcohol

Consuming excessive alcohol by both men and women may predispose them to low bone mineral density (BMD). However, it is unclear whether moderate alcohol consumption has an effect on bone mass. Nonetheless consuming as few as two alcoholic drinks daily significantly increases the fracture risks (Kanis et al., 2004a). This may be due to the effect of alcohol on osteoblasts or it may be secondary nutritional compromise that could results in impaired calcium and vitamin D intakes with subsequent decrease in bone formation (Moniz, 1994).

Those who are alcoholics also may be at risk for increased falls (Koda-Kimble et al., 2009).

1.1.8 Screening strategies

Screening can be performed by administering questionnaires or by using a machine.

1.1.8.1 The administration of questionnaires

There are several tools available to assess the risk of osteoporosis (Lim et al., 2011, Koh et al., 2001b, Weinstein and Ullery, 2000, Cadarette et al., 2000, Lydick et al., 1998, Michaëlsson et al., 1996). Further details on these questionnaires will be discussed in Chapter 5. However we would like to highlight the osteoporosis screening tool for Asians (OSTA). OSTA is a simple method to assess if a person is at risk of osteoporosis. It asks information about the age and how heavy the patient is. Additionally it will ask if the patient has any risk factors for osteoporosis. A score will then be calculated and the patient can be categorized to high, medium or low risk for osteoporosis. If the patient is categorized to the high or medium risk group for osteoporosis, a BMD scan is recommended (Koh et al., 2001b).

1.1.8.2 Quantitative ultrasound scanning

Quantitative ultrasound scanning (QUS) is also a simple and painless heel ultrasound. The scanners are also smaller, transportable and less expensive. The shape, intensity and speed of the propagating wave are altered by the physical and mechanical properties of the bone. QUS can be used as a screening tool to identify women who are at risk of osteoporosis. However, it cannot be used to confirm the diagnosis of osteoporosis. Eventually like all other risk

assessment tools, a BMD scan will still have to be performed for the diagnosis of osteoporosis (The Royal Australian College of General Practitioners, 2010, Moayyeri et al., 2012, National Osteoporosis Society, 2001).

1.1.9 Diagnosis of osteoporosis

1.1.9.1   Bone mineral density (BMD)

According to the WHO, the gold standard in diagnosing osteoporosis is to have a BMD scan. BMD scans are conducted using a dual energy x-ray absorptiometry (DEXA) machines (Kanis, 2007, National Osteoporosis Foundation, 2010). It uses very small amounts of radiation to determine the BMD of the spine and hip which are the main areas for osteoporosis fractures. This is a non-invasive, painless procedure that takes less than 15 minutes (National Osteoporosis Foundation). The results of the BMD scan at the hip or spine will be compared to a reference range of young healthy adults with average bone density. The difference between this average and the patient's bone density is then calculated and expressed in terms of standard deviation (SD) called the T-score. Based on this the patient can be categorised into three main categories: osteoporosis, osteopenia or normal (National Osteoporosis Foundation, 2010). Table 1.2 displays the World Health Organization (WHO) working group classification of osteoporosis for postmenopausal women.

Table 1.2: The World Health Organization (WHO) Working group classification of osteoporosis for postmenopausal women (National Osteoporosis Foundation, 2010)

Classification of osteoporosis	T-score
Normal	$\geq$-1.0
Osteopenia	-1.0> T-score >-2.5
Osteoporosis	$\leq$-2.5
Severe/Established osteoporosis	$\leq$-2.5 with presence of 1 or more fragility fractures

As bones take a long time to change, it is recommended to perform another BMD testing one to two years after initiating medical therapy for osteoporosis and every two years thereafter (National Osteoporosis Foundation, 2010). However, more frequent BMD testing may be warranted in certain clinical situations or if there is a change in therapy (National Osteoporosis Foundation, 2010, The Royal Australian College of General Practitioners, 2010). Additionally, the interval between repeat BMD screenings may be longer for patients without major risk factors and who have an initial T-score in the normal or upper lower bone mass range (National Osteoporosis Foundation, 2010).

1.1.10   Prevention of osteoporosis

1.1.10.1   Calcium

1.1.10.1.1 Dietary calcium intake

An adequate amount of calcium intake is needed to help achieve and maintain optimal bone mass (Koda-Kimble et al., 2009). Increasing age and menopause increases the daily requirements of calcium [Table 1.3]. Calcium can be obtained from diet and supplements. Examples of food rich in calcium are milk, cheese, tofu, sardines, mussels, nuts and yoghurt [Table 1.4] (National Coordinating Commitee on Food and Nutrition, 2005, Ministry of Health Malaysia, 2012).

Table 1.3: Calcium daily requirements (National Coordinating Commitee on Food and Nutrition, 2005)

	Age	Recommended Intake
Infants	0 - 6 months	300 mg (breast-fed) 400 mg (non-breast-fed)
	6 - 12 months	400 mg
Children	1 – 3	500mg
	4-6	600mg
	7-9	700mg
Adolescents (boys & girls)	10 - 18	1000mg
Men	19 – 49	800 mg
	> 50 years	1000 mg
Women	19 – 49	800 mg
	> 50 years	1000 mg
Pregnant	Third trimester	1000 mg
Lactating		1000 mg

Table 1.4: Calcium content of some common foods (National Coordinating Commitee on Food and Nutrition, 2005)

Food	Calcium content (mg)
1 glass of high calcium milk (200 ml)	500
1 glass of skimmed milk (200 ml)	250
1 glass of full cream milk (200 ml)	220
1 cup of yoghurt (150 g)	200
1 piece of tofu (150 g)	200
1/2 cup of yellow dhal (100 g)	170
1 cup of spinach (56 g)	160
1 cup of ice-cream (156 g)	150
1 cup of watercress (sai-yong choy) (50 g)	100
1 piece of cheddar cheese (20 g)	100
1 cup of mussels (160 g)	100
1/2 cup of anchovies (dried without head & entrails) (20 g)	100
1 piece of canned sardine (40 g)	100
1 cup of baked beans (240 g)	100
1 cup of mustard green (sawi), cekur manis, kai lan or pucuk ubi kayu (green vegetables) (50 - 80 g)	100
1 piece of tempeh (70 g)	50
1 cup of soyabean milk (200 ml)	40
1 cup of broccoli (95 g)	40
10 almonds (15 g)	30

* 1 cup = 200 ml

1.1.10.1.2 Calcium supplements

The best way to meet the daily requirement of calcium is through the intake of high calcium foods. Dairy products are the best sources of calcium due to their high elemental calcium content, high absortive rate and relative low cost. However, individuals who are unable to obtain enough calcium from foods should take a supplement to meet these guidelines (Koda-Kimble et al., 2009). The absorption of calcium supplements can vary from 20-40% depending on formulation [Table 1.5] (Koda-Kimble et al., 2009). Calcium is best absorbed by the body when it is taken several times a day (Karkkainen et al., 2001). However doses exceeding 2500mg/day of elemental calcium can results in hylercalcemia, hypercalciuria and possibly urinary stones (Koda-Kimble et al., 2009). However, the typical American diet is low in calcium (Koda-Kimble et al., 2009). Similarly the Malaysian diet is low in calcium which is between 300-500mg daily (Chee et al., 1997).

Table 1.5: Percentage of calcium in various salts (Koda-Kimble et al., 2009)

Salt	% Calcium
Calcium carbonate	40
Tricalcium phosphate (calcium phosphate, tribasic)	39
Calcium chloride	27
Dibasic calcium phosphate dihydrate	23
Calcium citrate	21
Calcium lactate	13
Calcium gluconate	9

1.1.1.10.1.3 Calcium for prevention of osteoporotic fractures in postmenopausal women

Calcium have been shown to reduce BMD loss in postmenopausal women and reduce the risk of osteoporotic fractures (Cummings and Nevitt, 1997, Jackson et al., 2006, Robbins et al., 2014, Neelemaat et al., 2012, Shea et al., 2004). A meta-analysis reviewed the literature from 1996-1997 assessing the effectiveness of calcium supplementation and/or dietary calcium for the prevention of osteoporotic fractures in postmenopausal women. There were 14 studies of calcium supplements and 18 studies of dietary calcium. The analysis revealed relative risk reductions between 25% and 70% for osteoporotic fractures. Most of these trials reported an approximate 30% fracture reduction with an intake of approximately 1000mg/day of elemental calcium (Cummings and Nevitt, 1997).

Another meta analysis of 15 trials that randomized postmenopausal women to calcium supplementation or usual calcium intake in diet found that calcium alone caused a positive mean percentage on BMD change from baseline of 2.05% for total body bone density, 1.66% at the lumbar spine, 1.6% at the hip and 1.9% at the distal radius (Shea et al., 2004). These data from these studies indicate the vital role for calcium related to optimal bone health.

1.1.10.2   Vitamin D

1.1.10.2.1 Natural sources of Vitamin D

Adequate vitamin D can be obtained from exposure to sunlight and diet. Exposure of the hands, face and arms to sunlight for about 15 minutes a day should be adequate. Fairer persons will only need 5 minutes of exposure to the sun. Darker persons will probably need about 30 minutes of exposure. However prolonged exposure to the sun should be avoided. It is important to note that glass prevents the transmission of ultraviolet B radiation which is necessary for the skin to produce vitamin D. Sunscreens also reduce the transmission of ultraviolet B and should only be applied if exposure to the sun will be over a longer period of time. A smaller amount of vitamin D is from the diet such as margarine, butter, milk, salmon, tuna, eggs, breakfast cereal, liver and other fatty fish (Koda-Kimble et al., 2009, Holick, 2004). Most adults are unlikely to obtain more than 10-20% of their vitamin D requirement from dietary sources(Daroszewska, 2012). If this is not possible, multivitamin and vitamin D supplements are available as previously mentioned.

The National Osteoporosis Foundation (NOF) recommends an intake of 800 to 1,000 international units (IU) of vitamin D per day for adults age 50 and older (National Osteoporosis Foundation, 2010). The Institute of Medicine Dietary Reference Intakes for vitamin D are 600 IU per day until age 70 and 800 IU per day for adults age 71 years and older (Ross et al., 2011). It has been estimated that there is a 29% reduction of hip fracture in women who take calcium and vitamin D supplements as compared to women who have have vitamin D deficiencies (Jackson et al., 2006, Robbins et al., 2014). However the use of vitamin D alone is unclear and it

has been found that using higher than recommended doses could lead to increase risk including hypercalciuria and hypercalcemia (The North American Menopause Society (NAMS), 2010).

1.1.10.2.2 Vitamin D supplements

There are 2 types of vitamin D: vitamin D2 (ergocalciferol) and vitamin D3 (cholecalciferol). Vitamin D3 is formed from the skin through the action of ultraviolet B radiation and the main ingredient in supplements. Vitamin D2 is produced by plants. Supplements can come from either source (Sunyecz, 2008). Some calcium supplements and most multivitamin tablets also contain vitamin D (Cosman et al., 2014). Various studies have noted improvement in muscle strength and balance, reduction in bone loss as well as reduce risk of falls with vitamin D supplementation(The North American Menopause Society (NAMS), 2010, Neelemaat et al., 2012).

1.1.10.3   Other dietary considerations

Although some promote the use of magnesium and isoflavones in osteoporosis prevention, the current data are insufficient to support its use for this purpose (The North American Menopause Society (NAMS), 2010).

1.1.10.4   Exercise

Weight bearing exercises such as walking, running and lifting weights helps prevent bone loss. Exercise helps maintain skeletal mass and may help reduce bone loss in postmenopausal women. This is because exercise appears to stimulate osteoblastic activity to help maintain bone mass (Gutin and Kasper, 1992). Improvements of bone density and a reduced hip fracture risk in older women have been

associated with thirty minutes of weight bearing exercise three times a week. This study noted a 41% lower risk of hip fracture compared with postmenopausal women who conducted weight bearing exercise for less than one hour per week (Feskanich et al., 2002). Additionally, studies have shown that weight bearing exercises are able to increase the BMD at the femoral neck by 0.9-1.6% (Heinonen et al., 1996, Nelson et al., 1994) and 1.0-1.3% in the lumbar spine (Nelson et al., 1994, Hinton et al., 2015).

A systematic review by Howe et al (2011) that examined the effectivieness of exercise intervention in preventing bone loss and fractures in postmenopausal women found 47 RCTs. The results of this review suggest a relatively small, statistically significant but possibly important effect of exercise on bone density. They suggest that the most effective types of exercise on BMD for the neck of femur appear to be resistance strenght training such as leg press and shoulder press. However, for the BMD at the spine they recommended a combination of both weight bearing exercises and strength training (Howe et al., 2011). These exercises should be conducted regularly in order to maximize and maintain the bones (Koda-Kimble et al., 2009).

1.1.10.5   Smoking cessation

Smoking cessation should be encouraged for people with osteoporosis as smoking is associated with lowered BMD and increased fracture risk as well as other health problems (The North American Menopause Society (NAMS), 2010).

1.1.10.6   Fall prevention

Many older people fall in the home, so it is important to try to reduce hazards that could cause a trip and fall. Fall prevention measures should be adopted in the elderly because nearly 90% of fractures are precipitated by falling (Cummings and Melton, 2002). These measures include intrinsic, extrinsic and environment factors. Environmental factors refer to the removal of all loose wires, cords, loose rugs and carpets. It is important to ensure rugs are anchored and smooth. Halls, stairways and entrances should be well lid (Koda-Kimble et al., 2009). Bathrooms are another common area where falls occur. Grab bars and non skid tape in the tub and shower should be installed. Additionally stairs should have treads and rails. The elderly should take their time when using the stairs and hold on to the railings. Furniture should also be in its usual places and not moved around (Daroszewska, 2012).

Extrinsic factors refer to appropriate foot wear such as sturdy, rubber-soled shoes. The elderly should also avoid lifting heavy objects. Medication can sometimes cause the elderly to be dizzy or drowsy leading to falls. Examples of these medications are antidepressants, sleeping pills, antihypertensives, antiepileptics, pain killers, antiparkinson medication, antihistamines and antidiabetics (Koda-Kimble et al., 2009).

Intrinsic factors refer to balance, gait problems, visual or hearing impairment (Koda-Kimble et al., 2009). Annual checkups on eyesight and hearing should be conducted. Poor eyesight can increase the risk of falling and deafness can affect balance. It is also important to identify other health problems such as Parkinson's disease, arthritis or stroke are

common causes of fall (Ministry of Health Malaysia, 2012). Hence, fall risks should be evaluated at least annually (Koda-Kimble et al., 2009).

1.1.11 Treatment of osteoporosis
1.1.11.1 Medications

As the scope of the study is mainly on prevention, this will be a brief introduction to the types of osteoporosis medication. There are many well established medications currently available for the treatment of osteoporosis [Table 1.6]. These medications will help rebuilt the bones and prevent further bone loss.

Table 1.6: Types of osteoporosis medications (Koda-Kimble et al., 2009, Ministry of Health Malaysia, 2012)

Therapeutic class	Generic name
Bisphosphonates	Alendronate
	Ibandronate
	Risedronate
	Zoledronate
HRT	Oestrogen/Oestrogen + progesterone
SERMs	Raloxifene
r-PTH	Teriparatide
New generation drug	Strontium ranelate
Calcitonin	Calcitonin salmon
Human monoclonal antibody (IgG$_2$)	Denosumab

1.1.11.1.1 Hormone replacement therapy (HRT)

Oestrogen therapy (with or without progestin) is beneficial in the prevention and treatment of osteoporosis as it increases the BMD of the lumbar spine and femoral neck up to 7.6% and 4.5% respectively over 3 years. A reduction in the risk of spine, hip and other osteoporosis fractures was by 33-40% (Cauley et al., 2003, The Women's Health Initiative Steering committee, 2004). The concern with this type of HRT is the increased risk of stroke, myocardial infarction and breast cancer (Rossouw et al., 2013, Schairer et al., 2000, Henderson and Lobo, 2012, Grodstein et al., 2008). Hence, HRT is less likely to be prescribed for the sole purpose of osteoporosis prevention (Koda-Kimble et al., 2009).

1.1.11.1.2 Selective Estrogen Receptor Modulators (SERMs)

SERM are hormone related pharmacological agents that have estrogen agonist, antagonist or both activities in various tissues where estrogen receptors are present. Raloxifene is an example of a SERM that may be an alternative therapeutic choice for osteoporosis prevention and treatment. Raloxifene has an agonistic effect on bone and serum lipid profiles and antagonistic effects on endometrial and breast tissues. Its agonistic effect on bone tissues is believed to occur through a reduction of bone resorption and a decreased rate of bone turnover which results in an increased BMD. In a one year study of osteopenic patients, raloxifene increased the lumbar spine and hip BMD by 2.2% and 0.8% respectively (Sambrook et al., 2004). The concern with SERMs is the increase in vasomotor symptoms (flushing and palpitations). Other adverse effects include an increased risk for venous thromboembolic disease which is greatest during the first 4

months of therapy. To decrease the risk of thrombosis associated with immobilization, raloxifene should be discontinued 72 hours before immobilization (surgery) (Koda-Kimble et al., 2009).

1.1.11.1.3 Biphosphonates

Another alternative pharmacological agent for the prevention and treatment of osteoporosis is biphosphonates. Alendronate, risendronate and ibandronate have been approved for osteoporosis treatment and prevention in postmenopausal women. Alendronate is an aminobiphosphonate that works by decreasing bone resorption resulting in decreased fracture rates in postmenopausal women who are at risk for osteoporosis. In an osteoporosis prevention study for 2 years in postmenopausal women >60 years using a dose of 5mg/day of alendronate, there is an increase in lumbar spine, hip and total BMD by 3.5%, 1.9% and 0.7% respectively compared to placebo. A dose of 5mg/ day had a higher BMD increase as compared to a dose of 2.5mg/day (Hosking et al., 1994).

As for risendronate, a study of women 40-60 years of age with normal BMD received a dose of 5mg/day for 2 years had a BMD increase of 5.7% at the lumbar spine and 5.4% in the hip compared to women taking placebo (Mortensen et al., 1998). Ibandronate versus placebo has also shown benefits in increasing BMD. There was significant BMD increase in lumbar spine (1.9%) and total hip (1.2%) in early postmenopausal women after 2 years (McClung et al., 2003).

However, the adverse effect of biphosphonates includes gastrointestinal (GI) symptoms such as regurgitation,

oesophageal ulcer and gastritis. Hence patients need to sit upright for 30-60 minutes after ingestion. Another adverse effect is the osteonecrosis of the jaw (ONJ) or dead jaw which occur if blood loss in bone tissue is temporarily or permanently impaired resulting in the eventual collapse of the bone. However most ONJ cases are cancer patients receiving chemotherapy and concurrent intravenous (IV) biphosphonate therapy (Koda-Kimble et al., 2009).

1.1.11.1.4 Other pharmacological agents

Other pharmacological agents are available such as the recombinant human PTH 1-34(r-PTH), teriparatide is a potent anabolic agent and is indicated for individuals with severe osteoporosis (Ministry of Health Malaysia, 2012). It stimulates new bone formation and activates remodelling which results in an increased BMD and connectivity in trabecular bone more than cortical bone (Koda-Kimble et al., 2009).

Strontium ranelate reduces bone resorption while promoting bone formation (Meunier et al., 2004). Calcitonin on the other hand acts directly on osteoclasts to inhibit bone resorption primarily from vertebral and femoral sites. It can be administered via injection and the intranasal spray for the postmenopausal women who have been diagnosed for at least 5 years (Koda-Kimble et al., 2009). Denosumab is a IgG_2 that inhibits the formation, function and survival of osteoclasts by preventing RANK (receptor activator of nuclear factors Kappa B) ligand from activating its only receptor, RANK, thus reducing bone resorption (Whyte, 2006).

1.1.11.1.5 Activated vitamin D

Activated Vitamin D such as calcitriol and alfacalcidol has been shown to increase BMD in those with established osteoporosis and reduce vertebral fractures (Orimo et al., 1994, Richy et al., 2004b, Gallagher, 1990).

1.1.12   Impact of osteoporosis

1.1.12.1   Clinical considerations (Medical impact)

The end result of osteoporosis is a fragility fracture. Fragility fractures can occur in various sites most notably the hips, vertebrae and forearm (National Osteoporosis Foundation, 2010). The World Health Organization provides that the worldwide projection of hip fractures cases due to osteoporosis will rise from 1.7 million in 1990 to 6.3 million by 2050 with a steep increase to be observed in developing countries (World Health Organization Geneva, 1999). Correspondingly, Cooper et al (1992) projected that 51.1% of osteoporotic fracture will occur in Asia by year 2050 which is a 19.9% increase as compared to year 1990 (Cooper et al., 1992) The ultimate goal of osteoporosis management is the prevention of fractures.

1.1.12.1.1 Hip fractures

Hip fracture is considered the most serious osteoporosis fracture. It may occur following a fall from the standing position. A hip fracture is painful and most probably necessitates hospitalization (Kanis, 2007).

Hip fracture is a fracture of the proximal femur, either through the femoral cervix or through the trochanteric region. Trochanteric fractures are more commonly osteoporotic

fractures. There is a greater increase risk for age-specific and sex-specific risks for hip fractures at trochanteric region than for cervical region. It has been found that in many countries these two fractures occur with equal frequency. However, the average age of patients with trochanteric fractures is approximately five years older than for cervical fractures (Kanis, 2007).

1.1.12.1.1.1 Incidence of hip fractures globally

In the past decades studies have shown geographic variation in the incidence of hip fractures across continents. Hip fractures incidences are highest in Sweden and North America. In Asia and Latin American population the hip fracture rates are lower. However three-quarters of the world's population live in Asia and it is projected that Asian countries will contribute more to the pool of hip fractures in coming years (Dhanwal et al., 2011).

1.1.12.1.1.2 Incidence of hip fractures in Europe

The incidence rates of hip fracture vary from North to South Europe. Sweden and Norway had the highest rates of hip fracture and the lowest in France and Switzerland. In Norway, the reported age-standardizes annual incidence rate of hip fracture is 920/100 000 in women and in Switzerland is 346/100 000 (Dhanwal et al., 2011). In central Europe, the United Kingdom showed an increase incidence rates by 32% in women up to 1991-1992 and thereafter remained stable (Balasegaram et al., 2001). As for the German studies, the age incidence of hip fracture increased by 0.5% annually from 1995-2004 (Icks et al., 2008).

1.1.12.1.1.3   Incidence of hip fractures in United States of America

The US population has the highest hip fracture rates in the world. A study reported age-standardized annual incidence of hip fracture of 511/100 000 for women (Melton et al., 1998). However a more recent study showed that hip fracture increased from 1986-19995 and then steadily declined from 1995-2005 (Brauer et al., 2009). Canadian women's overall fracture rate was 30% lower than in US women in 2001 (Leslie et al., 2010, Dhanwal et al., 2011).

1.1.12.1.1.4   Incidence of hip fractures in Australia/New Zealand

Initially in New Zealand, there was a disproportionate increase in the number of fractures in relation to the increase in population size from year 1950-1987 (Rockwood et al., 1990). However a later study from 1988-1999 showed a significant drop in fracture rate for females in all age bands (Fielden et al., 2001).As for Australia, a study in 1989-2000 showed a significant reduction in the overall fracture incidence rate 45 per year in women (Chang et al., 2004).

1.1.12.1.1.5   Incidence of hip fractures in Asia

However, epidemiological information is more widely available for hip than for other sites, although fragility fractures in other sites significantly contribute to the burden of osteoporosis. For instance, mainland China previously had one of the lowest incidence of hip fracture in the world in 1988, at 10 per 10 000. However, this has noticeably increased at about 10% per year from 2002-2006 (International Osteoporosis Foundation, 2009, Xia et al., 2012). Similarly, in Hong Kong there is a 300% increase of hip fracture incidence from the 1960s to the

1990. However, the rates in Thailand and Malaysia increased 200% and 150% respectively (International Osteoporosis Foundation, 2009). As for Singapore, the hip fracture incidence was 5 times more from 1960 to 1998 (Koh et al., 2001a). In Japan, incidence of hip fractures increased by 1.6 fold in men and 1.5 fold in women from 1986-1998 (Hagino et al., 2005). Korea also shows an increase of more than 6 fold in women and 2.5 fold in men (Lim et al., 2008). The Philippines similarly noted an increase in the number of hip fractures from 28 000 in 2003 and 34 000 in 2005, expecting the number to reach 175 000 in 2050 (International Osteoporosis Foundation, 2009). Additionally, conservative estimates shows that the number of hip fractures occurring annually in India exceeds 140 000 (International Osteoporosis Foundation, 2009).

1.1.12.1.1.6   Impact of hip fractures

The trochanteric fracture has a greater morbidity and mortality when compared with the cervical fractures. Studies have shown that up to 20%of patients die in the first year following a hip fracture and less than half of survivors regain the level of function that they had prior to the hip fracture (Chapuy et al., 1994, Trivedi et al., 2003). It has been found that the mortality, morbidity and social burden of hip fractures in Asian countries are similar to those in the West. A Singaporean study has found that after a hip fracture, 20% of patients will die within two years , 33% remain ambulant without aids, 40% are ambulant with aids, and 10% are wheel chair or bed bound (Mitra et al., 1994).

1.1.12.1.2 Vertebral fractures

The most difficult osteoporosis-related fracture to define is vertebral fractures. This is because diagnosis is made on a change in the shape of the vertebral body. These deformities as a results from osteoporotic fractures are usually classified as a crush fracture (involving compression of the entire vertebral body), a wedge fracture (in which there is anterior height loss), and biconcavity (where there is relative maintenance of the anterior and posterior heights with central compression of the end-plate regions). However, there is a widely used clinical system to classify vertebral fractures. A 20-25% height loss is classified as mild vertebral fractures, moderate (>25-40% height loss) or severe (>40% height loss)(Kanis, 2007).

1.1.12.1.2.1   Incidence of vertebral fractures worldwide

Vertebral fractures are rarely reported as it is difficult to quantify accurately. In the UK the lifetime risk of symptomatic vertebral fracture for a 50 year old white women was calculated to be 11% (Cooper, 1993). In the US, it is estimated that there are 550 000 to 700 000 osteoporotic vertebral compression fractures annually (Black et al., 1999, Burge et al., 2007).

There is limited data on vertebral fractures in Asia. In Japan, the prevalence of vertebral fracture in a population-based sample was 5.7- 13.0% in people aged 60-69 years of age (Kitazawa et al., 2001). Chinese in Beijing showed a comparable prevalence of vertebral fractures in individuals age over 50 at 15% (International Osteoporosis Foundation, 2009). Vertebral fracture incidence in women and men aged

over 50 years in Thailand was 32.1/1000 and 54.5/1000 person-year respectively (Jitapunkul et al., 2008). Currently, there is no data on the incidence of vertebrae fracture in Malaysia.

1.1.12.1.2.2   Impact of vertebral fractures

It has been estimated that 28% of patients with a vertebral fracture will die in the first year (Johnell et al., 2004). Even if a fracture does not occur, spinal bones may get crushed/compressed resulting in back pain, height loss and difficulty in breathing since there is less space under the ribs (Kauffman et al., 2007, Cosman et al., 2014).

1.1.12.2   Other types of fractures

Colles fracture is the most common distal forearm fracture. It lies within 2.5cm of the wrist joint margin and is associated with dorsal angulation and displacement of the distal fragment of the radius. This fracture normally occurs from a fall on the outstretched hand. Wrist fractures normally cause less morbidity than hip fractures and are rarely fatal. However, its consequences are often underestimated. About 1% of patients with a forearm fracture become dependent as a result of fractures (Writing Group for the Women's Health Initiative, 2002). It often leads to pain, tenderness, stiffness and swelling of the hand and more rarely to frozen shoulder (Neer et al., 2001). Additionally the risk of other osteoporotic fracture in later life is much increased after Colles fracture (Bagger et al., 2004). It has been estimated that 6% of wrist fracture patients will die within a year (Johnell et al., 2004).

1.1.12.2.1 Economic impact

Osteoporosis takes a huge economic toll. The disability due to osteoporosis in Europe is greater than that caused by cancers except for lung cancer. Osteoporosis's disabilities is comparable or greater than that lost to a variety of chronic non-communicable diseases, such as rheumatoid arthritis, asthma and high blood pressure related heart disease (Johnell and Kanis, 2006).

1.1.12.2.1.1   The economic impact of osteoporosis in Europe

For example, the cost of osteoporosis, including pharmacological intervention in the EU in 2010 was estimated at €37 billion. This includes the costs of treating incident fractures represented 66%, pharmacological prevention 5% and long-term fracture care 29% (Hernlund et al., 2013).In year 2010, there were approximately 536,000 new fragility fractures each year in the United Kingdom. The economic burden of new and prior fractures was £ 3,496 (€ 5,408) million each year. It is predicted that by 2025 the burden will increase by 24 % to £ 5,465 (€ 6,723) million (Svedbom et al., 2013).

1.1.12.2.1.2   The economic impact of osteoporosis in the United States

In the US, there are two million fractures annually and are attributed to osteoporosis, causing more than 432,000 hospital admissions, almost 2.5 million medical office visits and about 180,000 nursing home admissions1. Currently, Medicare pays for approximately 80 percent of these fractures, with hip fractures accounting for 72 percent of fracture costs.

As the population ages, the cost of care is expected to rise to $25.3 billion by 2025 (NOF 2014).

1.1.12.2.1.3   The economic impact of osteoporosis in Latin America

The estimate direct cost in Latin Americans is $13 billion for year 2050. It is estimated that there will be 655,648 hip fractures (Johnell, 1997).

1.1.12.2.1.4   The economic impact of osteoporosis in Australia

As for Australia the total costs relating to osteoporosis are $7.4 billion per year of which $1.9 billion are direct costs (Sambrook et al., 2002).

1.1.12.2.1.5   The economic impact of osteoporosis in Asia

Similarly, China spent $1.5 billion in year 2006 treating hip fracture. This expenditure is estimated that this will rise to $12.5 billion in 2020 and by 2050 to more than $ 264.7 billion (Luo and Xu, 2005). The direct hospitalisation cost for hip fractures in Malaysia from year 1997 was estimated at RM22 million (~$6000 000). This is an underestimate as it does not include the cost incurred in rehabilitation and long term nursing care. Therefore, without proper intervention the cost will escalate as the population ages (Ministry of Health Malaysia, 2012).

1.1.13 Osteoporosis knowledge among patients and healthcare professionals

Osteoporosis knowledge among patients vary from country to country. Previous studies have found that the knowledge of osteoporosis in adult women aged 21-90 years in Europe (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Ungan and Tumer, 2001), Canada (Cadarette et al., 2007), United States (Ailinger and Emerson, 1998, Burke-Doe et al., 2008), Middle East (Baheiraei et al., 2005b), and Australia (Winzenberg et al., 2003) was low. Conversely, women and men aged 16-79 years in Norway were knowledgeable about osteoporosis (Magnus et al., 1996). In Asia, the knowledge of osteoporosis ranged from low to moderate for women aged 19-90 in Brunei (Liza et al., 2009), Singapore (Saw et al., 2003) and Malaysia (Abdulameer et al., 2013, Yeap et al., 2010, Khan et al., 2014). However, another study in Malaysia found that the knowledge of osteoporosis was moderate in women aged 49-84 (Lai et al., 2008).

Women in Europe had generally moderate knowledge regarding osteoporosis (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Ungan and Tumer, 2001). However, they had poor knowledge in the risk factors of osteoporosis, and its consequences if left untreated (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Ungan and Tumer, 2001). Conversely, a Canadian study showed that elderly women appear to be aware of osteoporosis risk factors, but had knowledge deficits regarding the consequences of osteoporosis and the treatment available to prevent further bone loss (Cadarette et al., 2007). On the other hand, studies in the United States and Middle East showed that patients had a lack of knowledge in osteoporosis risk factors and preventive

behaviour (Ailinger and Emerson, 1998, Burke-Doe et al., 2008, Baheiraei et al., 2005b). There was also a low level of osteoporosis knowledge in all areas for Australia (Winzenberg et al., 2003). Similarly in Asia, there were low levels of osteoporosis knowledge in all areas of osteoporosis such as the definition, risk factors, consequences of osteoporosis and treatment (Abdulameer et al., 2013, Yeap et al., 2010, Khan et al., 2014, Liza et al., 2009, Saw et al., 2003). However there was one study conducted in Malaysia where osteoporotic women had moderate knowledge on osteoporosis. This may me because these women had already been counselled on how to take medications by pharmacists as part of standanrd healthcare and the questionnaire used in these study consisted of general questions to test whether patients knew how to take their medications (Lai et al., 2008).

Additionally not only there is a lack of osteoporosis knowledge in patients but there is also a lack of osteoporosis knowledge in healthcare professionals (Guzman-Clark et al., 2007, Claesson et al., 2015, Chen et al., 2005) (Otmar et al., 2012, Jaglal et al., 2003, Duyvendak et al., 2011). These studies assessed the knowledge of primary care nurses (Guzman-Clark et al., 2007, Claesson et al., 2015, Chen et al., 2005), primary care physicians (Otmar et al., 2012, Jaglal et al., 2003, Duyvendak et al., 2011) and internal medicine specialist (Guzman-Clark et al., 2007),

The lack of osteoporosis knowledge in healthcare professionals may cause some osteoporosis cases to be missed even after a fragility fracture (Kim et al., 2011). Additionally a lack of osteoporosis knowledge may lead to healthcare professionals prioritizing other diseases instead of osteoporosis (Otmar et

al., 2012, Claesson et al., 2015). Another study by Jaglal et al (2003) involving primary care physicians had similar issues (Jaglal et al., 2003). Their analysis revealed that primary care physicians lack a rational for BMD testing and were confused about the recommended management of osteoporosis (Jaglal et al., 2003). In another study, they have noted that the lack of knowledge, especially concerning the use of BMD-results may led to the under-treatment of the presented patients (Duyvendak et al., 2011). This leads us to the gap in osteoporosis managment which is discussed in the next section.

1.1.14 Gaps in osteoporosis management

Although treatment for osteoporosis are available, cost effective, well-tolerated and effective to reduce fracture risk, only approximately 20 percent of women who have an osteoporosis-related fracture receive either a bone mineral density test or a prescription for a drug to treat osteoporosis in the six months after the fracture (Cosman et al., 2014, National Committee for Quality Assurance, 2014, Hajcsar et al., 2000).

Additionally, a systematic review by Giangregorio et al (2006) found that an osteoporosis diagnosis was reported in 1 to 45% of patients with fractures, laboratory test was ordered for 1-49% and 1 to 32% of patients had bone density scans. As for calcium/vitamin D and pharmacological treatment was reported in 2-62% and 1 to 65% of patients, respectively. However fall assessments were not often reported (Giangregorio et al., 2006). This gap in the osteoporosis management is persistent as a more recent prospective observational study of >60 000 women aged ≥55 years

recruited from 723 primary care practices in ten countries, reported that less than 20% of women with new fractures received osteoporosis treatment (Greenspan et al., 2012). To further emphasize the gap, a province-wide study in Canada demonstrated that post-fracture diagnosis and treatment rate have not substantially changed between year 1996/1997 and 2007/2008 (Leslie et al., 2011).

A systematic review from Elliot-Gibson et al (2004) revealed that the reason the care gap exist and persist is multi-factorial in nature. They identified several issues: cost concerns relating to diagnosis and treatment, time required for diagnosis and case finding, concerns relating to polypharmacy and lack of clarity regarding where clinical responsibility resides (Elliot-Gibson et al., 2004).

A systematic review by Ganda et al (2012) noted prevention measures and screening interventions to be cost effective and is able to slow down the progression of osteoporosis (Ganda et al., 2012). Therefore, prevention measures and screening which aid in early detection are the most effective and cost-effective ways to slow down the progression of osteoporosis and reduce the number of hospital admittance due to osteoporotic fractures (Hajcsar et al., 2000, Cranney et al., 2008, Davis et al., 2007, Richy et al., 2004a, Cooper et al., 2011, Ganda et al., 2012). It is indeed a challenge to translate knowledge into practice and should be multifaceted with efforts directed at patient, provider and the healthcare system in order to achieve a variable success at the population level.

1.1.15   Strategies for multi-faceted approach towards an osteoporosis screening programme

Early detection of osteoporosis can be conducted via screening of osteoporosis. Osteoporosis screening can be targeted at primary or secondary prevention. Primary prevention of osteoporosis is directed at identifying high risk non-osteoporotic individuals without a prior fragility fracture and are asymptomatic. Secondary prevention of osteoporosis refers to the detection of the disease and prevention of subsequent fragility fracture. These are individuals who had atleast one fragility fracture (Lundy and Janes, 2009).

Additionally, osteoporosis screening can be conducted using BMD scans alone or identifying high risk individuals for BMD scans using various screening tools as highlighted in section 1.1.8 and 1.1.9. However, screening the population using BMD test alone is not possible due to BMD tests being expensive and DEXA machines are not widely available. Due to this, patients are normally assessed for their osteoporosis risk before undergoing a BMD scan (International Osteoporosis Foundation, 2009).

The most common risk factor used to stratify patients at high risk of osteoporosis is if a patient has had a history of fragility fracture. Therefore, most efforts in osteoporosis screening are targeted at secondary prevention as it has been found to be cost effective (Hajcsar et al., 2000, Cranney et al., 2008, Davis et al., 2007, Cooper et al., 2011).A systematic review by Little et al (2011) identified nine randomized controlled trials (RCTs) targeted at secondary prevention conducted by other healthcare professionals such as clinical researchers, physicians, orthopaedic surgeons and nurses to tackle

osteoporosis screening (Cranney et al., 2008, Majumdar et al., 2008, Miki et al., 2008, Rozental et al., 2008, Davis et al., 2007, Majumdar et al., 2007, Solomon et al., 2007, Feldstein et al., 2006, Gardner et al., 2005, Jaglal et al., 2012). These studies designed interventions to modify the behaviour of healthcare professionals or implement service delivery changes in osteoporosis management in the primary care setting. All of these interventions had similar components such as an education component, osteoporosis risk assessment and reminders (Cranney et al., 2008, Majumdar et al., 2008, Miki et al., 2008, Rozental et al., 2008, Davis et al., 2007, Majumdar et al., 2007, Solomon et al., 2007, Feldstein et al., 2006, Gardner et al., 2005, Jaglal et al., 2012). This systematic review noted that although all interventions demonstrated a positive effect towards BMD scanning and osteoporosis treatment post fracture, only three were considered to be at low risk of bias (Little and Eccles, 2010, Miki et al., 2008, Cranney et al., 2008, Majumdar et al., 2007).

Further efforts have been made in year 2012 when the International Osteoporosis Foundation (IOF) launched a campaign called 'Capture the Fracture' (International Osteoporosis Foundation, 2012a, International Osteoporosis Foundation, 2012b). The aim of this campaign was to reduce the incidence of secondary fractures throughout the world by the establishment of a new standard of care for fragility fracture sufferers. Healthcare providers were urged to respond to the first fracture to prevent the second and subsequent fractures. It has been found that the most effective way to achieve this is through the implementation of coordinator-based, post fracture models of care which includes

identification, assessment and treatment of patients at high risk for osteoporosis as part of the service. To date various model known as 'Fracture Liaison Services' have been conducted in the United Kingdom (McLellan et al., 2003, Wright et al., 2005, Clunie and Stephenson, 2008, Premaor et al., 2009, Wallace et al., 2011), Europe (Boudou et al., 2011, Huntjens et al., 2010) and Australia (Cooper et al., 2011, Inderjeeth et al., 2010, Lih et al., 2011). In Canada these services are called 'Osteoporosis Coordinator Programmes' (Bogoch et al., 2006)and in the US it is called the 'Care Manager Programmes (Dell et al., 2008). Despite, the considerable progress made in terms of establishment of exemplar services in many countries (International Osteoporosis Foundation, 2012a), these services are currently only available in a very small proportion of facilities that receive fracture patient worldwide. These services are also the beginning of inclusion of secondary fracture prevention in national health policy (National Institute for Health and Clinical Excellence, 2012, Ström et al., 2011, Australian government, 2006). However, many governments are yet to create the political framework to support funding of these new services. Additionally these services only target the population who have had a previous history of fractures.

Due to this high risk patients with other risk factors or who are asymptomatic may be missed by efforts of secondary prevention. Therefore, there is a need to explore primary prevention using other methods such as using a risk assessment tools. A literature search revealed three RCTs targeting primary prevention conducted by pharmacists using a risk assessment tools to identify high risk patients to undergo the BMD scan. Each of these studies used a different

risk assessment method: the QUS and Canadian guideline risk factor checklist (Yuksel et al., 2010), risk assessment questionnaire (Crockett et al., 2008) and identifying patients who are using long term glucocorticoids (McDonough et al., 2005). These studies did not analyze the cost effectiveness of the intervention in terms of fracture reduction but there was an increase in BMD scans, osteoporosis treatment or calcium intake (Crockett et al., 2008, Yuksel et al., 2010, McDonough et al., 2005). Nonetheless, evidence already exists for fracture reduction with many of the current osteoporosis medications in patient at hight risk for fractures (Koda-Kimble et al., 2009, Papaioannou et al., 2010). To date, there has been no prospective study that systematically screens all postmenopausal women. However, a retrospective study using 4035 medical records of postmenopausal women ≥45 years suggest that primary prevention of osteoporosis using a risk assessment tool can be cost-effective (Richy et al., 2004a).

Several guidelines have been developed based on expert opinion, cost effectiveness criteria, systematic reviews and/or predictive models. The U.S. Service Task force (U.S. Preventive Service Task Force, 2014), the National Osteoporosis Foundation (Cosman et al., 2014), the Malaysian Clinical Guidance and Management of Osteoporosis (Ministry of Health Malaysia, 2012) and the North American Menopause Society (The North American Menopause Society (NAMS), 2010) suggests that all women ≥65 years should have a BMD scan and that women ≥50 should have a BMD scan based on their risk factor profile. Other guidelines such as the National Institute of Health (NIH) (NIH consensus development panel on osteoporosis prevention, 2001), The WHO task Force for osteoporosis (World Health Organization, 2004, Kanis, 2007),

the Canadian Medical Association (Papaioannou et al., 2010), and the National Osteoporosis Guideline Group UK(Compston et al., 2014) recommended selecting patients for BMD measurement based on particular risk factors.

Additionally, the osteoporosis risk assessment tools such as the questionnaires and QUS does not harm the patients (Lim et al., 2011, Koh et al., 2001b, Weinstein and Ullery, 2000, Cadarette et al., 2000, Lydick et al., 1998, Michaëlsson et al., 1996). The BMD scan is also a non invasive procedure (National Osteoporosis Foundation). As these test are not harmful, the benefits of preventing a fragility fracture outweighs the minimal risk pose by these test. Additionally, WHO has recommended that the use of clinical risk factors together with BMD provides a mechanism for the effective and efficient delivery of healthcare for individual at high risk of osteoporosis and the avoidance of unnecessary treatment to others (World Health Organization, 2004).

1.1.16   Pharmacists' role in osteoporosis management

There is a growing body of literature supporting the roles of pharmacists in osteoporosis. Studies conducted in various settings around the globe have shown those pharmacists' interventions improved adherence to osteoporosis medication. Some studies have also reported improvements in both clinical and economic outcome (Van Boven et al., 2014, Stuurman-Bieze et al., 2014, George et al., 2010, Lai et al., 2013).

Although, most pharmaceutical care services are mainly targeted at treatment of osteoporosis. A further literature search revealed that there are three randomized control trials

(RCTs) conducted overseas by community pharmacies to evaluate the impact of pharmacist's interventions on osteoporosis management (Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005). However, two of these studies were considered biased (Elias et al., 2011). The study by Crockett et al had a high risk of both selection and information bias as self-reported assessment was used (Elias et al., 2011, Crockett et al., 2008). As for the study by McDonough et al the study suffered from a high risk of selection bias as the recruitment size and followed up differed between groups (Elias et al., 2011, McDonough et al., 2005). The third study by Yuksel et al demonstrated low bias in both aspects (Elias et al., 2011, Yuksel et al., 2010). Nonetheless, all three studies provided attestation that the intervention of pharmacists increased the number of patients that had their BMD tested and calcium intake initiated, indicating that pharmacists may have a role to play in reducing the gap in osteoporosis management (Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005). To date, there have been no studies on a pharmacist-led osteoporosis screening programme using the OSTA in Malaysia.

1.1.17   The development of a pharmaceutical care service

1.1.17.1   Definition of pharmaceutical care

'Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality' (Hepler and Strand, 1990). The outcomes referred to in this definition are: cure of a disease, elimination or reduction of a patient's symptoms, arresting or slowing a disease process; or preventing a disease or symptom (Hepler and Strand, 1990). On the other hand,

Barber (2001) argued that the outcomes measures refer to the patient's clinical condition whereby the goals are stated in terms of disease. This led to the development of many other definitions (Barber, 2001).

From a humanistic perspective, Cipolle, Strand and Morley proposed a definition of 'Pharmaceutical care is a practice in which the practitioner take responsibility for a patient's drug-related needs and is held accountable for this commitment (Cipolle et al., 2004). This referred to pharmacists practicing in a patient-centred manner whereby pharmacists' decision should be made based upon the wants and needs of the patients, who may have specific drug-related needs. Pharmaceutical care should be part of a pharmacists' daily activity in addition to the traditional role of purchasing and dispensing medications.

1.1.17.2 Practice of pharmaceutical care in Europe and other developed countries

In the European setting, pharmaceutical care is seen to be the professional care for the individual patient in a pharmacy (Foppe van Mill et al., 2004). Pharmacists were to counsel individual patients about medication. This concept also includes medication surveillance, counselling and evaluation of all the outcomes of care.

Although there are various definitions, pharmaceutical care is generally the philosophy behind pharmacy practice in many countries across the globe (Foppe van Mill, 2004). There are various terminologies used to describe pharmacy services that embrace the concept of pharmaceutical care. An example would be from the United States, they use a term called

medication therapy management (MTM) services which refers to a strategy to incorporate the philosophy of pharmaceutical care into everyday pharmacy practice for a defined patient population of patients with certain diagnosis (McGivney et al., 2007, Pellegrino et al., 2009).

1.1.17.3   Practice of pharmaceutical care in Malaysia

In Malaysia pharmaceutical care services are provided but are referred to as Medication Therapy Adherence Clinic (MTAC) by the Malaysian Ministry of Health. MTACs are normally provided in public hospitals (Lim and Lim, 2010). Aside from MTAC, the concept of pharmaceutical care is also embedded in other clinical pharmacy services that are being provided in hospitals and community pharmacist in Malaysia.

1.1.17.4   Pharmaceutical care research

There is a need for an increase in pharmaceutical care research with its expansion to tackle a range of disease management. Pharmaceutical care research falls under the category of health services research. However, research in this area is context specific as it depends on the local health care system.

Foppe van Mill et al (2004) has suggested that it is vital to first conduct a needs assessment study as the first phase in developing a pharmaceutical care service. A needs assessment refers to basic research which tries to identify the types of pharmaceutical care required in a given patient which will eventually lead to the development of a proposal for a pharmaceutical care intervention. The second phase refers to impact assessment which investigate whether the provision of pharmaceutical care improves the patients' clinical, humanistic

and economic out comes. It has been found that most pharmaceutical care studies focus on the second phase of the research in determining whether the intervention has led to the expected outcomes. This lacks consideration or explanation given to the mechanisms by which those outcomes are mediated. An example of this is that the there is an assumption that the intervention worked as planned; that the pharmacists were comfortable with their new roles; that patients welcomed the service and that the necessary collaboration with other health care professionals had taken place. However, in reality there may be many barriers that hinder the provision of service. Due to this there is a need to understand the components that are most likely to affect the provision of the pharmaceutical care prior to finalizing the design of the pharmaceutical care intervention or in evaluating the outcome of the service.

Various factors contribute to the success of pharmaceutical care delivery and it is difficult to measure specific outcomes. This shows that pharmaceutical care is a 'complex intervention' (Tulip and Campbell, 2001, Medical Research Council, 2008). Some pharmaceutical care may involve the need to improve therapeutic outcomes while other components may work through psycho-social or behavioural modification in an individual patient through patient education and counselling (Wong, 2004). Further examples of this is that some components have an organisational nature whereby inter-professional communication between pharmacists, physicians and other health care professionals is important in the delivery of pharmaceutical care (Wong, 2004). This shows that pharmaceutical care interventions are multifaceted in nature.

1.1.18   Theoretical framework (United Kingdom Medical Research Council framework)

A complex intervention as defined by the UK Medical Research Council (MRC) is "interventions comprising of separate elements which seem essential to the proper functioning of the intervention although the active ingredient is difficult to specify (Medical Research Council, 2000). Not only the number of elements in the intervention package are complex, there are other dimensions of complexity which includes the range of possible outcomes the behavioural differences of those delivering and receiving the intervention and the variability in the target population (Craig et al., 2008).The active ingredients of pharmaceutical care may consists of difference elements such as the pharmacist's personality and expertise, skills, patient characteristics and behaviours, inter-professional relationship and organisational culture. Therefore research in pharmaceutical care should consider these elements (Tulip and Campbell, 2001).

The UK Medical Research Council's (MRC) Framework of developing and evaluating complex interventions was designed to improve healthcare services making it applicable to the field of pharmacy practice (Medical Research Council, 2008). Therefore, the current study will adopt this conceptual framework. The framework provides a flexible guideline which assists in developing a practical complex intervention (Medical Research Council, 2008). Complex interventions are interventions that contain various interconnecting components. There are four key elements of the MRC Framework [Figure 1.2] (Medical Research Council, 2008).

Figure 1.2: Key elements of the development and evaluation process

Feasibility/piloting
1. Testing procedures
2. Estimating recruitment/retention
3. Determining sample size

Development
1. Identifying the evidence base
2. Identifying/developing theory
3. Modeling process and outcome

Evaluation
1. Assessing effectiveness
2. Understanding change process
3. Assessing cost-effectiveness

Implementation
1. Dissemination
2. Surveillance and monitoring
3. Long term follow-up

1.1.19 Developing a complex intervention

The first step of the MRC framework is identifying the evidence base by carrying out a literature review or a systematic review (Medical Research Council, 2008). This will then allow for the identification or development of relevant theories resulting in a more effective intervention (Medical Research Council, 2008). The next step involves modelling of the process and outcomes which requires an understanding of a particular intervention and its possible effects (Medical Research Council, 2000). Modelling prior to a full scale evaluation will assist in providing information about the intervention design such as identifying weaknesses that may lead to refinements of the design (Medical Research Council, 2008). In this study, qualitative methods such as in depth interviews were employed to explore stakeholders' perspective in osteoporosis prevention as well as the feasibility to providing a pharmacist assisted osteoporosis screening programme. With this data, we developed and validated tools pertaining to patients' knowledge of osteoporosis and satisfaction towards the pharmacist screening programme. Additionally, we validated various osteoporosis risk assessment tools. These tools will be used in the complex intervention.

1.1.20 Assessing feasibility and piloting methods

The feasibility and piloting stage involves testing procedures for their acceptability, estimating likely rates of recruitment and retention, and the calculation of appropriate sample size (Medical Research Council, 2008). This may include both quantitative and qualitative methods (Medical Research Council, 2008). With regards to this study the feasibility of

providing a pharmacist assisted osteoporosis screening programme was examined.

1.1.21   Evaluating a complex intervention

All aspects of this stage should be tested in the previous stages and the complex intervention should have considered randomisation, appropriate outcomes, adequate statistical power, informed consent and other standard features of well-designed trials (Medical Research Council, 2008, Medical Research Council, 2000). The next stage is the understanding processes where a process evaluation nested within the trial can be used to assess reason for intervention failure, fidelity and quality of implementation, clarify causal mechanism and identify contextual factors associated with variation in outcomes (Medical Research Council, 2008). In addition, an economic evaluation should be included if possible to ensure that the cost of the study is justified by the potential benefits of evidence it will generate (Medical Research Council, 2008). However this phase is beyond the scope of this PhD project. Nonetheless, it will provide data that will facilitate future work concentrating in the implementation of a randomized control trial of a pharmacist assisted osteoporosis screening programme.

1.1.22   Implementation and beyond

The last stage of the complex intervention is dissemination which is getting the evidence translated into routine practice or policy (Medical Research Council, 2008). Although surveillance, monitoring and long term outcomes of complex interventions are uncommon, it is necessary to determine whether the short term changes persist and whether the

benefits previously documented can be sustained (Medical Research Council, 2008).

1.1.23   The problem statement

The World Health Organization projects that the worldwide rate of hip fractures cases due to osteoporosis will rise from 1.7 million in 1990 to 6.3 million by 2050 with a steep increase to be observed in developing countries(World Health Organization Geneva, 1999). Correspondingly, Cooper et al projected that 51.1% of osteoporotic fractures will occur in Asia by year 2050, which is a 19.9% increase as compared to year 1990(Cooper et al., 1992). In Malaysia, the prevalence of osteoporosis is 24.1% (Lim et al., 2005).

Due to the asymptomatic nature of osteoporosis, women who have osteoporosis are often not aware that they are at an increased risk of sustaining a fracture(International Osteoporosis Foundation, 2009). Fractures are costly to treat, increase morbidity and mortality(International Osteoporosis Foundation, 2009, Ministry of Health Malaysia, 2012). In 1997, hip fractures cost about RM 22 million (£3.35 million) to treat. This figure however does not include the costs incurred in rehabilitation and long term nursing care(Ministry of Health Malaysia, 2012). Hip fractures are also associated with a reduction in quality of life. Up to 20% will die within two years as compared to those who do not sustain fractures (Koh, 2007). Therefore, prevention measures and screening which aid in early detection are the most cost-effective ways to reduce the number of hospital admittance due to osteoporotic fractures (Hajcsar et al., 2000, Cranney et al., 2008, Davis et al., 2007, Richy et al., 2004a, Cooper et al., 2011, Ganda et al., 2012).

Currently, there is no osteoporosis screening programme or fracture liaison services available in Malaysia. As the Malaysian healthcare system is not integrated between different hospitals and clinics, it is difficult to obtain patients' complete fracture history. Therefore, this study focused on osteoporosis screening targeted at primary and secondary prevention using an osteoporosis risk assessment tool.

1.1.24   Rationale for study

The lack of an osteoporosis screening needs to be addressed in Malaysia . Therefore, this calls for the development of a pharmaceutical care service intervention to tackle the lack of an osteoporosis screening program. It is envisaged that this study could contribute to the body of knowledge in relation to:

- Policy makers, doctors, pharmacist, nurses and patients perception towards an osteoporosis screening programme
- Development of the osteoporosis screening programme and various tools needed for the intervention.
- The role of the pharmacist in the management of osteoporosis

1.1.25   How did I become interested in the topic?

I graduated with a Master of Pharmacy in 2008. Subsequently I worked as a clinical pharmacist in a tertiary hospital, the University Malaya Medical Centre (UMMC). There I coincidentally met one of my co supervisors (Dr Pauline Lai) while getting lost in one of the hospital's back stairs. I remembered this incidence in particular as she was telling me about her research on osteoporosis and how exciting research can be. This further confirmed my interest on doing some research of my own.

The following year I worked at a primary care clinic in a suburban area called Kuala Langat. I conducted many home visits and noticed that there were numerous patients who were bed ridden due to a fracture. However, no action was conducted to investigate for osteoporosis. At that time, facilities for a bone mineral density scan (BMD) was limited in this area. Hence, I decided to look back at my old work place

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UMMC where the BMD was available. Similarly to the suburban areas, investigations of fragility fractures were still low. Timely, I was awarded a scholarship after approaching another of my co supervisors (Associate Professor Mr Wong) from the University of Nottingham. Numerous discussions took place for tackling the gap in the current osteoporosis management from primary prevention, treatment to inpatient care. We finally decided that secondary prevention in primary care would be the best place to start in addressing the gap. Hence my journey for a PhD began.

1.1.26 Organization of study

This thesis is divided into five chapters. The current chapter provides a description on osteoporosis. Subsequently, it discusses the concept of pharmaceutical care and complex intervention. Then, it presents the literature review on the gaps in osteoporosis management, interventions by healthcare professionals, role of pharmacists in osteoporosis management. It then presents the rationale for the study and how I became interested in this issue.It ends with the presenting the aim and objectives of the study.

Chapter 2 describes the methodology underpinning phase one. It describes the qualitative methods that were chosen and how validity and reliability can be assessed. It illustrates the data collecting process and methods of analysis in detail. It then presents and discusses the findings for the three research questions.

Chapter 3 describes the methodology and methods used in phase two study. It provides the explanation on what tools were needed for the screening programme, detailing on the

development and validation process of the tools. The chapter also explains the development of the intervention package for the pharmacist-led osteoporosis screening programme.

Chapter 4 describes the methodology and methods used in phase three study. It discusses the feasibility of the pharmacist-led osteoporosis screening programme, highlighting the factors for improvement.

Chapter 5 summarises the overall findings and concludes with the implications for practice, policy and research.

1.1.27   Aims and objectives

1.1.27.1   Aims

To develop a pharmacist-led osteoporosis screening programme.

1.1.27.2   Objectives

- To identify the barriers and facilitators of conducting an osteoporosis screening programme
- To explore the pharmacist role in osteoporosis screening
- To develop the intervention package for the pharmacist-led osteoporosis screening programme
- To develop and validate a tool to assess the satisfaction of patients' towards the pharmacist-led osteoporosis screening programme
- To develop and validate a tool to assess the awareness and knowledge of osteoporosis in Malaysian postmenopausal women
- To validate and compare various osteoporosis risk assessment tools in a Malaysian setting
- To assess the feasibility of the pharmacist-led osteoporosis screening programme

2 CHAPTER 2: PHASE ONE: A QUALITATIVE STUDY EXPLORING THE PERSPECTIVES OF NURSES, DOCTORS, PHARMACISTS, PATIENTS AND POLICY MAKERS REGARDING AN OSTEOPOROSIS SCREENING PROGRAMME IN MALAYSIA

2.1 Introduction

In order to understand the relevant stakeholders' views of osteoporosis screening, we had three research questions:

- What are the barriers and facilitators encountered by nurses, doctors, pharmacists, patients and policy makers regarding an osteoporosis screening programme?
- Can Malaysian pharmacists expand their non-dispensing role in an osteoporosis screening?
- What are the components for an acceptable, practical and sustainable osteoporosis screening programme?

2.2   Aim

To identify the problems and needs of postmenopausal women as well as the views of policy makers, pharmacists, doctors and nurses in osteoporosis screening.

2.3   Objectives

The specific objectives of phase one were to:
- Understand the barriers and facilitators encountered by nurses, doctors, pharmacists, patients and policy makers regarding an osteoporosis screening programme
- Explore the current pharmacists' role and the expansion of their non-dispensing role in osteoporosis screening
- Identify the components for an acceptable, practical and sustainable osteoporosis screening programme

Phase one was divided into three sections to answer the above objectives.

2.4 What are the barriers and facilitators encountered by nurses, doctors, pharmacists, patients and policy makers regarding an osteoporosis screening programme?

2.4.1 Methods

To date, there is no existing population-based osteoporosis screening programme in Malaysia. A lack of reported evidence on stakeholder's perception on osteoporosis screening programme in Malaysia noted that there was a need to explore these issues in Malaysia. Hence, a qualitative research approach using in-depth interviews was chosen for this phase.

2.4.1.1 Study design

A qualitative research design was used as there were no prior information about the barriers and facilitators towards an osteoporosis screening programme in Malaysia. Qualitative interviews are the most commonly employed approach in health and pharmacy practice research (Smith, 2002). It enables the researcher to discover what people think of the world they live in, to evaluate their experience and to uncover why they behave the way they do (Murphy et al., 1998). As stated by Murphy and colleagues "If you want to understand what people do, believe and think, ask them."

2.4.1.2 Setting

The study was conducted at the primary care clinics of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia.

2.4.1.3 Period of study

Data collection occurred from October to December 2012.

2.4.1.4   Participants

2.4.1.4.1 Patient group

Included were English or Malay speaking postmenopausal women aged ≥ 50 years old who have not been diagnosed as osteopenia/osteoporosis. Excluded were those not well enough to participate in the study.

2.4.1.4.2 Healthcare professional group

2.4.1.4.2.1   Nurses

Included were registered nurses working at the primary care or osteoporosis clinic, UMMC and with more than one year of working experience. Excluded were nurses from other departments.

2.4.1.4.2.2   Pharmacists

Included were out patient pharmacists from the UMMC with more than one year of working experience. Excluded were pharmacists undergoing internship.

2.4.1.4.2.3   Doctors

Included were doctors with more than one year of working experience in the primary care clinics. Excluded were year one clinical master candidates as they were not on site.

2.4.1.4.2.4   Policy makers

Policy makers in our study were individuals who have the authority to influence the practice of the primary care clinic. We planned to recruit the head of the primary care clinic, head of the outpatient pharmacy, head of the store pharmacy, the chief pharmacist, head of in-patient pharmacy, matron, chief executive officer (CEO) of the hospital and deputy CEO of the

hospital were recruited. Excluded were policy makers from departments not related to activities in the primary care clinic.

2.4.1.5   Sample size

It is not required for qualitative research to have a large or statistically representative sample which is the norm for quantitative research (Bowling, 2009). Qualitative samples are concerned with the 'richness' of the data to increase our insight into a specific research question. Hence the samples recruited are generally small (Bowling, 2009). Nevertheless, it is important to have an effective sampling strategy in qualitative research.

2.4.1.6   Qualitative sampling

In relation to the selection of participants for interviews, a variety of sampling techniques have been described in the literature (Smith, 2002). These include purposive sampling, a technique where participants selected are believed to have particular characteristics relevant to the research. Convenience sampling involves selecting participants based on ease of accessibility or willingness to participate in the study. Snowballing involves asking participants to suggest others whom they know are in the target group and who could be invited to take part in the study (Bowling, 2009).

In this study, we wanted to explore the views and experiences of patients, pharmacists, nurses, doctors and policymakers towards conducting an osteoporosis screening programme at the primary care clinic. Hence, purposive and snowballing sampling strategies were adopted. Purposive sampling was used to select non-osteoporotic post menopausal women ≥50 years of age from the three main ethnics groups (the Malays,

Chinese, and Indians) in Malaysia. Initially, it was not intended to recruit patients using the snowballing method. However, many patients of Malay ethnicity declined participation. We then asked participants to recommend potential participants of Malay ethnicity. Therefore, in order to gain access to the Malay population we employed the snowballing method.

Purposive sampling was also used to recruit nurses, doctors and pharmacists. Nurses from the primary clinic with more than one year of working experience in the primary clinic were selected. We interviewed these nurses as they were involved with patient registration, screening and their medical records. These nurses provided information on the workflow of the clinic in general.

Similarly, doctors with more than one year of working experience in the primary clinic were selected using purposive sampling. The doctors were interviewed as they were involved with examining the patients. The information they provided allowed us to understand how osteoporosis could be incorporated into the consultations.

Pharmacists were also selected using purposive sampling. The outpatient pharmacy department was divided into four departments namely the main outpatient department, PharmCare which is the dispensary for long term medication patients, retail pharmacy and specialist item pharmacy. Pharmacist with at least one year of working experience in the outpatient pharmacy was selected. Pharmacists were interviewed as the patients would visit the pharmacy for their medications after their doctor's visit. The pharmacists were

able to provide information on the final stage of the patients' visit to the primary care.

We selected healthcare professionals with more than one year of working experience in the primary care clinic as they would have sufficient working experience and understanding of the primary care clinics barriers, facilitators and management issues.

As for policy makers, it was not possible to obtain thematic saturation as we were only able to identify eight policy makers that would contribute to our data. Therefore, policy makers who were believed to be able to produce 'rich' information were approached and recruited for in-depth interviews. We included the head of the primary care clinic as this participants' view would represent the views of the primary care doctors at a management level. We also included the head of the outpatient pharmacy, head of the store pharmacy, the chief pharmacist, head of in-patient pharmacy as they were all involved in the policy in medication purchasing. However, the matron, the CEO of the hospital and deputy CEO did not response to the invitation to participate in this study.

2.4.1.7　Instruments used

2.4.1.7.1 Baseline demographics

Baseline demographic information such as patients' medical history, lifestyle and medication history was collected (Appendix 1). Healthcare professionals' baseline information, work experience and education level were also collected (Appendix 2).

2.4.1.7.2 Topic guide

Three topic guides were developed to assist in the interviewing process: for patients (Appendix 3), healthcare professionals (nurses, pharmacists, doctors- Appendix 4) and policy makers (Appendix 5). Although all three topic guides essentially follow the same questions, each question was phrased according to the perspective of the targeted group. Additional questions were added for policy makers with regards to budgeting. In addition, questions regarding the experiences towards osteoporosis were removed for policy makers.

The topic guides were developed based on literature search as well as discussion with an expert panel involving a consultant endocrinologist and four pharmacists with many years of research and clinical experience. A pilot test was then conducted with three individuals (one for each topic guide) to fine tune the topic guide.

Translation of the topic guide for patients (Appendix-6) and healthcare professionals (nurses, pharmacists, doctors- Appendix 7) to Malay was performed as some interviews were conducted in Malay. Translation from English to Malay was performed by a pharmacist was also a native Malay speaker. The Malay version was translated back to English by another

pharmacist who understood both English and Malay. Differences were discussed with the researcher until a final Malay version was developed.

2.4.1.8   Data collection

2.4.1.9   Interview type

Qualitative interviews are commonly referred to as being structured, semi-structured or unstructured (Smith, 2002). Semi-structured and unstructured interviews may be referred to collectively as in depth interviews (Bryman, 2004). Structured interviews are conducted with the researcher having a pre-defined set of questions limiting the response of the participants (Bryman, 2004). In contrast, an unstructured interview is conducted with the researcher using at most a brief set of prompts to deal with a certain range of topic and allowing the participant to answer freely (Bryman, 2004).

The semi structured approach is one where the researcher has a list of questions or fairly specific topics to be covered and this is often referred to as an topic guide (Bryman, 2004). However, there is still a great deal of leeway on how participants can reply. It is also not necessary for the questions to be asked in the exact order as outlined by the topic guide and additional questions may be added for probing new emerging topics (Bryman, 2004, Bowling, 2009). This method allows for a fairly clear focus on the interview topic while allowing the participant to raise issues of personal relevance or concern (Bryman, 2004). The semi-structured in-depth interview was deemed the most appropriate method for this study based on these reasons.

Interviews can be conducted individually or in a group (Bryman, 2004). The latter, a group discussion or 'focus groups' has the advantage of exploring the dynamics of communication between the research participants (Bryman, 2004). However, individual in-depth interviews were chosen for this study as they enable individual respondents' perspectives to be explored in more detail as compared to using a focus group (Smith, 2002). Therefore, the discussion here focuses on issues pertaining to individual interviews.

2.4.1.10   Interview location

Eight patients were interviewed in a quiet location (e.g. an unused doctor's room, conference room or seminar room) that was suitable for an interview within the clinic setting. The other 12 patients were interviewed in their homes. All health care professionals and policymakers were interviewed in their respective offices or in the seminar room located at the primary care clinic except for one who chose to be interviewed in his home.

2.4.1.11   Procedure

Patients were recruited while they were waiting for their doctors' appointment. To ascertain that patients were not diagnosed with osteoporosis/osteopenia, the patients' medical notes were checked. A patient information sheet in English of Malay depending on preference (Appendix 8 and 9) was provided to selected patients. The purpose of the study and the process of the interview were explained to the participants using the research information sheet. Upon agreement to participate in the study, participant's written consent (Appendix 10 and 11) was obtained and permission to audio-record was sought. Demographic data were also collected

from each participant. They were also reminded that the information collected was strictly confidential and that they were not obliged to respond to any questions they were not comfortable with. They were also informed that they can withdraw from the study without giving a reason and that it would not affect their hospital care. It is hoped that this process would be able to provide the participants with a comfortable environment in order to encourage them to speak freely.

Depending on the patients' preference, the interview was conducted on the same day or at another time convenient to them. Patient recruitment and interview continued until new themes ceased to emerge. This was achieved after interviewing 20 patients.

Similarly, the nurses, doctors, pharmacists and policy makers identified. An information sheet in English of Malay depending on preference of the nurses (Appendix 12 and 13) was provided to patients identified. For the other healthcare professionals and policy makers only the English version of the information sheet was available (Appendix 14, 15 and 16). The purpose of the study and the process of the interview were then explained to the participants using the research information sheet. Upon agreement to participate in the study, participant's written consent (Appendix 17-21) was obtained and permission to audio-record was sought.

All patient, healthcare professional and policy maker interviews were conducted by the researcher (TLS), except for one patient interview where an experienced qualitative researcher (SO) conducted the interview. This was performed

as a teaching session for the novice researcher (TLS). In addition, for three policy maker interviews, one of the researcher's supervisors (a senior pharmacist and previously a policy maker himself) assisted (WKT). Refreshments were provided after each interview session with the patients, healthcare professionals and policy makers.

The researcher is bilingual and is able to speak English and Malay fluently. Sixteen patient interviews were conducted in English, two were conducted in both English and Malay, and two were conducted in Malay. Eight nurse interviews were conducted in both English and Malay, whilst two were conducted in English. Nine pharmacist interviews were conducted in English, whilst two were conducted in both Malay and English. Four doctor interviews were conducted in English, whilst six were conducted in both Malay and English. Lastly, all five interviews with the policy makers were conducted in a mix of English and Malay.

2.4.1.12   Theoretical framework: Framework of factors influencing clinical practice

Generally in healthcare, human error is routinely blamed for clinical incidents. However, these quick judgments obscure a more complex truth. A closer analysis usually reveals a series of events and departure from safe practice, each influenced by the working environment and the wider organizational context (Vincent et al., 2000).

We used the protocol for the investigation and analysis of clinical incidents for our analysis, as it ensures a systematic, comprehensive, and efficient investigation of incidents, to generate ways of assessing risk and to focus research on the

causes and prevention of adverse outcomes. This protocol
uses the framework of factors influencing clinical practice to
guide the analysis regarding the lack of a population based
screening programme in a primary care clinic in Malaysia
(Vincent et al., 2000, Vincent et al., 1999). Figure 2.1
summarizes the adapted investigation process (Vincent et al.,
1999).

Figure 2.1: The adapted investigation process based on the protocol for the investigation and analysis of clinical incidents

Identify a serious clinical incident or an incident as being fruitful in terms of organisational learning.

↓

Trigger the investigation procedure.

↓

Investigators will establish the circumstances as they initially appear and complete an initial summary. Decide which part of the process of care requires investigation and prepare an outline chronology of events. Identify any obvious Care Management Problems (CMPs)

↓

Interview staff using the structured approach:
- Establish the chronology of events.
- Revisit the sequence of events and ask questions about each of the clinical management problems identified at the initial stage
- Use the framework to ask supplementary questions about the reasons for the occurrence of each clinical management problem. Record each CMP and its contributory factors.

↓

Collate the interviews and assemble a composite analysis under each of the CMPs identified at the start. For each CMP identify both specific and, where appropriate, general contributory factors.

↓

Compile the report of the events, listing the causes of the CMPs and make recommendations to prevent recurrence.

↓

Submit report to senior clinicians and management according to local arrangements.

↓

Implement the action arising from the report and monitor progress.

Normally the protocol is used on a single clinical incident case. As there was no population based osteoporosis screening in our setting, we used the framework to investigate the lack of osteoporosis screening in the primary care clinic as a single case. The framework consists of seven main factors influencing clinical practice as shown in Table 2.1 (Vincent et al., 1999). The seven main factors are: governmental, organizational and management, work environment, team, task, individual and patient. The term "institutional context" was modified to "governmental context" as our setting is managed by the ministry of higher education.

Table 2.1: Framework of factors influencing clinical practices

FACTOR TYPES	INFLUENCING CONTRIBUTORY FACTORS
Governmental Factors	Economic and regulatory context
	National health service executive
	Clinical negligence scheme for trusts
Organisational and Management Factors	Financial resources & constraints
	Organisational structure
	Policy standards and goals
	Safety culture and priorities
Work Environment Factors	Staffing levels and skills mix
	Workload and shift patterns
	Design, availability and maintenance of equipment
	Administrative and managerial support
Team Factors	Verbal communication
	Written communication
	Supervision and seeking help
	Team structure (congruence, consistency, leadership)
Individual Factors	Knowledge and skills
	Competence
	Physical and mental health
Task Factors	Task design and clarity of structure
	Availability and use of protocols
	Availability and accuracy of test results
Patient Factors	Condition (complexity & seriousness)
	Language and communication
	Personality and social factors

The clinical incident investigated in this study was fractures due to undiagnosed osteoporosis. The first step in the investigation using the protocol was to identify the Care Management Problem (CMP). CMPs were active failures, unsafe acts or omissions which can have a direct of indirect effect on the eventual adverse outcomes for the patients. We identified the Care Management Problem (CMP) as failure to screen for osteoporosis. Figure 3.2 below demonstrates the chronology of events for a patient who visits the primary care clinic for a regular follow up appointment. Based on the Figure 2.2 we noted that several stakeholders were involved in this process: namely the nurses, doctors and pharmacists. We then conducted in-depth interviews with these stakeholders, as well as patients and policy makers.

Various factors contributing to the incident was identified. However, a further distinction between specific contributory factors and general contributory factors was needed. Specific contributory factor refer to factors that are relevant on a particular occasion whereas a general contributory factor refers to a factor that is quite frequent with more general implications. As our study investigated the primary care setting as a whole all factors identified were general contributory factors. Additionally, if a new CMP were to emerge during the interview it will be noted but would not be explored as it is beyond the scope of this study. Our study did not encounter new CMPs.

Figure 2.2: Chronology of events for a patient who visits the primary care clinic for their regular follow up appointment

(Time)

0700

| Waiting time 10 minutes-1 hour | Patient A arrives at the hospital and registers to see the doctor at the triage counter. Staff involved nurses. | → High risk patients not identified |

| Waiting time ~1-3 hours | Patient A waits for his/her turn to see the doctor. |

1000

| Consultation time ~15-30 minutes | Patient A sees the doctor. Staff involved doctors and nurses. | → High risk patients not identified ← Failure to screen for osteoporo-sis |

| Waiting time 10-15 minutes | Patient A makes an appointment for the next doctor's visit. Staff involved clerks. |

1100

| Waiting time 30 minutes-2 hours | Patient A collects medications from the outpatient pharmacy. Staff involved pharmacists. | → High risk patients not identified |

2.4.1.13 Data management

Interviews were audio recorded using a digital interview recorder. The audio files were downloaded to a personal computer and played using the Sony Memory stick Voice editor, to "slow" conversations, in order to facilitate transcribing.

2.4.1.14 Field notes

After each interview, the researcher jotted down field notes in a notebook. Feelings during the interview and main themes of the interviews were noted. This was referred to during data analysis as it assisted in highlighting immediate emerging themes.

2.4.1.15 Transcripts

All audio-recordings were transcribed verbatim. The first ten recorded interviews were transcribed by the researcher. Subsequent recordings were transcribed by undergraduate science students or pharmacists. In order to ensure that the data was rigorous and trustworthy, the transcripts performed by the researcher were checked by another pharmacist who was fluent in both languages. The transcripts performed by the undergraduate students or pharmacist were checked by the researcher for accuracy and completeness. All transcripts were offered to each interviewee to check for accuracy but they all declined.

2.4.1.16 Translations

Translation for this study is defined as the transfer of meaning from a source language (Malay) to a target language (English) (Esposito, 2001). It must be acknowledged that there is potential for intentional and unintentional modification of the

data through mistranslation, partial omission of oversimplification which is unavoidable during translation (Escott and Walley, 2005). However, the reliability of the translation to reflect the participants' intended response will influence the validity of the data (Escott and Walley, 2005). For this study, the translations were meant to capture the meaning of the statements, rather than giving a literal translation (Esposito, 2001). For example, a Malay participant was asked about the reasons why people do not care about osteoporosis, she mentioned "Sebab tak kena kat batang hidung." This can be translated to 'Because we, ourselves did not suffer from osteoporosis' and if this were to be literally translated from Malay it would be "Because we did not get it at the stick of our nose."

Based on Twinn et al recommendations all non-English transcripts were translated to English by one person (the researcher) to ensure consistency and reliability (Twinn, 1997). Consequently, the translation took a large amount of time taking nearly two to three hours to translate one page (Squires, 2008). Nonetheless, this was necessary as one of my supervisors was British (CA) and does not speak or understand Malay. Several factors may affect the quality of the translation. This includes the linguistic competency of the translator and the translator's knowledge of the people and environment under study (Wild et al., 2005). The researcher was a suitable choice as she was fluent in both languages and has previously worked in hospital understudy as a pharmacy intern.

Some researchers may suggest back translating translated interviews as a way to validate the translation (Chen and

Boore, 2009, Wild et al., 2005). Chen & Boore subsequently suggests the involvement of an expert panel in reaching the final agreement on the translation in order to gain conceptual equivalence (Chen and Boore, 2009). However, it has been disputed that back translation does not necessarily ensure the trustworthiness of the results incurring additional costs and time to the study (Squires, 2008). A bilingual individual competent in the qualitative researcher's discipline was considered adequate for validating the conceptual equivalence of the translation (Squires, 2008). Hence, back translation was not conducted in this study. Steps were taken to ensure accurate translation from Malay to English by verifying the translation with another Malay pharmacist who was fluent in both languages. The researcher revisited and retranslated some of the excerpts until agreement was reached between the researcher and the Malay pharmacist. Consensus validation was the finalization point.

Although all transcripts were translated to English for verification purposes, the original language was used during data analysis. Misinterpretation was reduced as this facilitated cross checking the data with the audio recordings when there was a need to consider voice modulations of the participants.

During data analysis, selected themes and sub-themes from Malay were translated to English. This repeat translation helped the researcher to reduce misinterpretation. The process allowed the researcher to check for discrepancies between the first version from the translated transcripts and the second version from translated selected themes. After comparing the first and second version of the translation the actual meaning was represented more appropriately in the

second version. Rendering it better to translate selected themes rather than translating the whole transcript. The study by Chen & Boore concurs that verbatim transcripts and data analysis can be conducted in the original language and only emergent concepts, themes and sub-themes needed translation to English (Chen and Boore, 2009).

2.4.1.17   Ethical approval

Prior to the commencement of the interviews, ethical approval was obtained from, the University Malaya Medical Centre Ethics Committee (approval number: 914.14, Appendix 22). All required documents were submitted and approval was obtained one month after submission. In accordance with the ethics committee requirements, a report upon completion form has been submitted. Ethical issues such as anonymity, confidentiality and informed consent were considered in this study.

2.4.1.17.1 Anonymity and confidentiality

Only the researcher and the supervisors had access to the audiotapes. All information were coded and anonymized. At the end of the PhD, the audiotapes will be destroyed. The information collected as paper copies were stored under lock and key, while the electronic data can only be accessed by the researcher and supervisors with a secure password. The data collected were used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. All information which is collected was confidential and any form of identity will not be included in any publications.

2.4.1.17.2 Informed consent

Prior to the start of any research activity, written informed consent for participating and audio recording of the interviews was obtained from each participant.

2.4.1.18　Data analysis

Thematic analysis informed by constant comparison was used to analyse the interview data (Boyatzis, 1998, Braun and Clarke, 2008). It involves analysing the data as a whole to find repeated patterns of meaning (Braun and Clarke, 2008, Boyatzis, 1998). The analysis of the data involved repeatedly reading the transcripts while listening to the audio recording, and emerging topics were coded and constantly compared and contrasted with other transcripts (Braun and Clarke, 2008).

QSR International Pty Ltd. NVivo version 10 for Windows, 2012 was used to aid in the analysis of the data. This software eases the handling of large data, facilitating constant comparison between interpretation and illustrative statements from the original transcripts (Bazeley, 2007). The documents containing the transcripts were imported from Microsoft Word to NVivo (Bazeley, 2007). These documents can then be opened in NVivo and coded for analysis (Bazeley, 2007). These codes are called 'nodes' in NVivo (Bazeley, 2007). There are three types of nodes: free nodes, tree nodes and case nodes (Bazeley, 2007). Analysis normally begins by identifying free nodes which are stand-alone nodes (Bazeley, 2007). Tree nodes can be used to show the relation between nodes as they can be organized into hierarchy (Bazeley, 2007). Case nodes can organize coding according to cases (Bazeley, 2007). In this study, tree nodes and free nodes were used.

Analysis began during data collection. At the end of each interview, the researcher wrote memos of interesting topics that were raised in the interview. All data was collected and analyzed by the same researcher enabling the researcher familiar with the data (Braun and Clarke, 2008). However, the entire interview was read through prior to generating initial codes (Braun and Clarke, 2008).

The researcher identified and labelled text that was related to a node. This process is called coding (Bazeley, 2007, Miles and Huberman, 1994). The coding of this research were 'data driven' meaning that the nodes formed depended on the data (Braun and Clarke, 2008). The transcripts were read line by line and key nodes were identified (Miles and Huberman, 1994). In some cases, the same texts were coded with different nodes as they may have had more than one meaning. A coding framework was developed using the identified nodes. This framework was used for coding subsequent data. Newly identified codes were added to the coding framework. The whole process was iterative and involved rereading, linking and connecting text to the represented nodes. Subsequently, previously coded texts were revisited and checked whether they represented the nodes that they were assigned to, otherwise they were transferred to a more suitable codes.

The next phase of analysis began by refocusing the analysis at a broader level of themes (Braun and Clarke, 2008). This involved sorting the themes into broader themes and collating all the relevant coded data extracts within the identified theme. The 'one sheet of paper' (OSOP) analysis as described by Ziebland and McPherson (2006) was used to progress the

analysis of the data. OSOP involved reading through each code and then noting on a piece of paper all issues that were raised and making connections between them (Ziebland and McPherson, 2006). This process allowed identification of deviant cases that did not fit into the emerging story. These deviant cases were than reanalysed and accounted for in the analysis (Bazeley, 2009). During these phase the tree nodes were arranged into parent nodes (themes) and child nodes (subthemes) (Braun and Clarke, 2008). Nvivo assisted in the illustration of the hierarchical organisation (Bazeley, 2007). This process continued until all transcripts had been analysed and the codes were compared until data saturation. Data saturation involves bringing new participants into the study until no new codes emerged (Bowen, 2008).

In our study, the analysis of each stakeholder: patients, pharmacists, nurses, doctors and policy makers were conducted separately. However, the themes which emerged within each group were similar and the analyses of all the stakeholders were combined.

The analysis was enriched by going back to the literature noting how other research and theories fitted and how it could further inform the analysis (Braun and Clarke, 2008). Themes and sub themes were further refined based on the literature. Finally the themes and sub themes were reviewed to ensure that they 'accurately' reflect the meaning evident in the data set as a whole.

The concept of reliability and validity is explored in the next section.

2.4.1.19   Reliability and validity of data and methods

Qualitative research is often criticized as biased, lacking generalisability, small scale, anecdotal, and/or lacking rigor (Anderson, 2010). Nonetheless, qualitative studies can be unbiased, in depth, valid, reliable, credible and rigorous when carried out appropriately (Anderson, 2010).

2.4.1.19.1 Validity

Validity of the research findings refer to the extent at which the findings are accurate representation of the phenomena or the 'truth' of the data (Smith, 2010). There are a number of methods to substantiate validity such as respondent validation, triangulation use of contradictory evidence, and constant comparison (Anderson, 2010, Mays and Pope, 2000). In our study we planned to use four validation methods: respondent validation, triangulation, constant comparison and cumulative validation. However, due to the circumstances which are explained below we were only able to use two methods: constant comparison and cumulative validation.

Respondent validation allows participants to read the data and analyses as well as provide feedback on the researcher's interpretations of their responses (Mays and Pope, 2000). This provides the opportunity for the researcher to re-analyze their data, checking for inconsistencies and challenging the researcher's assumptions (Mays and Pope, 2000) . Unfortunately, all participants declined to participate in this process. This may be due to the low literacy level of the patients and the lack of time by both patients and healthcare professionals. These findings were presented to the staff of the primary care department. Although not all participants were present, this provided an opportunity for the healthcare

professionals to raise issues during the question and answer session which guide the researcher to revisit the transcripts and field notes to confirm some of the issues.

Triangulation is defined by using two or more methods to study the same even (Mays and Pope, 2000). Initially, both individual interviews and focus groups discussions were meant to be conducted for this study. Unfortunately, due to the hectic working hours of the healthcare providers and accessibility barriers of the patients only individual interviews was feasible. However, contradictory evidence was sought out, examined and accounted for during the analysis to ensure that the researcher's bias has minimum interference with the data.

Constant comparison played a major role in this study. This involved looking at all the interviews as a whole rather than fragmenting it (Anderson, 2010). For example, an interview is compared with the previous data and not considered on its own enabling the researcher to identify emerging/unanticipated themes within the research project.

Another technique used in this study for the process of validation is cumulative validation in which the researchers may use literature to demonstrate whether the findings were consistent with existing knowledge of the subject (Smith, 2002). This led the researcher to revisit the transcripts to verify some issues.

In a qualitative study, validity may be compromised by the researcher who is responsible for data collection and analysis. Hence, it is vital to acknowledge the ways (i.e. interpretation and research experience) that the researcher may influence

the outcomes (Charmaz, 2006). Another way that validity can be compromised is whether participants felt comfortable in expressing their thoughts or opinions (Smith, 2002).

The location of the interview also plays and important part. Patients had the choice of being interviewed at their own homes or in the hospital depending on their preference. All healthcare professionals were interviewed in counselling or seminar rooms. However, at certain times some of their colleagues walked in and out of these rooms whilst the interview was going on. This might have prevented them from raising or discussing certain issues.

The inexperience of the researcher in interviewing may have compromised the validity of the study at the initial stages. A deeper understanding of qualitative research towards the end of study allowed the researcher to detect cues that were not grasped during the initial interviews. This could have led to further probing and gaining a deeper understanding about the phenomena.

In addition, the fact that participants knew the researcher is a pharmacist could have affected the way they responded to the questions. Most of the healthcare professionals and some of patients were previously acquainted with the researcher. This may have led patients to give socially acceptable answers to avoid being judged negatively. As for the healthcare professional, they might have expected the researcher to be aware of certain things and could have left out some of them. Nonetheless, these data are not considered invalid but it's potential influence of the context should be considered (Murphy et al., 1998).

2.4.1.19.2 Reliability

Reliability refers to the reproducibility of the findings. In an ideal situation, to ensure consistency in analysis the coding procedures should be undertaken by two or more researchers independently (Smith, 2002). However, this was time consuming. Therefore, to ensure reliability of the data analysis of this study, sections of the coded transcripts were presented to two supervisors independently (PLSM and CA). One supervisor was familiar with the field environment (PLSM) and the other supervisor was based in the UK independent of the field, and and experienced qualitative researcher (CA). Sections of the coded transcripts were presented to these supervisors on separate occasions to establish agreements on the codes assigned to each section of the data. Assessments were also made for the data within each code to confirm that the code represented the data.

The end stage of the analysis involved a presentation of the summary of all the interviews to the researcher's supervisors (CA, PLSM, WKT, SO and LBY). This allowed them to obtain a complete understanding of the study. The confirmation of the themes and matching of the transcribed quotes with the themes and sub-themes derived from the analysis was finalized using consensus validation.

The results will be presented in four sections: Participants' characteristics, barriers and facilitators to an osteoporosis screening programme, pharmacists' role in osteoporosis and development of the intervention using the behavioral wheel change.

2.4.2 Results

2.4.2.1   Participants' characteristics

Recruitment commenced until no new themes emerged this was achieved with a total of 20 patients, 10 nurses, 10 doctors, 11 pharmacists and five policy makers. It was noted that more information was needed to clarify some issues (workload of osteoporosis clinic and knowledge of osteoporosis) and therefore, nurses from the osteoporosis clinic were recruited in addition to the primary care nurses. An aid nurse was mistakenly interviewed instead of a staff nurse and was excluded in the data analysis. The characteristics of the participants are shown in Table 2.2.

Table 2.2: Participants characteristics

No	Participants	Age	Gender	Years of practice
1.	PT-1	58	Female	
2.	PT-2	66	Female	
3.	PT-3	55	Female	
4.	PT-4	60	Female	
5.	PT-5	61	Female	
6.	PT-6	72	Female	
7.	PT-7	64	Female	
8.	PT-8	52	Female	
9.	PT-9	63	Female	
10.	PT-10	62	Female	
11.	PT-11	63	Female	
12.	PT-12	59	Female	
13.	PT-13	65	Female	
14.	PT-14	59	Female	
15.	PT-15	55	Female	
16.	PT-16	70	Female	
17.	PT-17	58	Female	
18.	PT-18	57	Female	
19.	PT-19	57	Female	
20.	PT-20	62	Female	
21.	NUR-1	44	Female	>10
22.	NUR-2	51	Female	>10
23.	NUR-3	43	Female	>10
24.	NUR-5	45	Female	>10
25.	NUR-6	55	Female	>10
26.	NUR-7	52	Female	>10
27.	NUR-8	37	Female	>10
28.	NUR-9	42	Female	>10
29.	NUR-10	42	Female	>10
30.	NUR-11	40	Female	>10
31.	PHARM-1	26	Male	1-4
32.	PHARM-2	24	Female	1-4

33.	PHARM-3	25	Female	1-4
34.	PHARM-4	23	Male	1-4
35.	PHARM-5	29	Female	1-4
36.	PHARM-6	27	Female	1-4
37.	PHARM-7	25	Male	1-4
38.	PHARM-8	29	Female	5-10
39.	PHARM-9	27	Female	5-10
40.	PHARM-10	28	Male	1-4
41.	PHARM-11	28	Female	1-4
42.	DR-1	33	Male	5-10
43.	DR-2	30	Male	1-4
44.	DR-3	36	Female	5-10
45.	DR-4	38	Male	5-10
46.	DR-5	30	Male	5-10
47.	DR-6	48	Female	>10
48.	DR-7	28	Female	5-10
49.	DR-8	29	Female	5-10
50.	DR-9	30	Female	5-10
51.	DR-10	32	Male	5-10
52.	POL-1	50	Male	>10
53.	POL-2	51	Female	>10
54.	POL-3	57	Male	>10
55.	POL-4	45	Female	>10
56.	POL-5	44	Male	>10

Abbreviations: PT=patient, NUR= nurse, PHARM=pharmacist,

DR= doctor, POL= policy maker

2.4.2.2 Barriers and facilitators to an osteoporosis screening programme

Our study found that there is currently no population based osteoporosis screening programme in existence in our setting and in Malaysia. Based on the protocol for the investigation and analysis of clinical incidents, seven main factors as barriers leading to the failure to screen for osteoporosis were identified: governmental, organizational and management, work environment, team, individual, task, and patient factors.

On the other hand, participants focused on barriers and few issues regarding facilitators were raised. Therefore, these facilitators were discussed within the barriers. There was only one facilitator in each of these factors: organizational and management factor, patient factor, team factor and work environment factor. Table 2.3 presents a brief summary of the results where elaborations of the results can be found in the next section.

Table 2.3: Barriers towards an osteoporosis screening programme

Factors	Barriers
Governmental factors	• No dedicated executive at the Malaysian Ministry of Health for osteoporosis
Organizational and management factors	• Financial and resources constraints
	• Organization and structure constraints
	• Lack of policy standards and goals
Work environment	• Administrative and managerial support
	• Building and design
	• Education and training
	• Environment
	• Equipment and supplies
	• Staffing
	• Time constraint
	• Workload
Team	• General communication
Task	• Availability of protocol to staff
	• Availability and accuracy of test results
Individual	• Knowledge and skill

Patient	- Condition (complexity and seriousness) - Personality - Knowledge - Communication - Social factors - Difficulty to adhere to osteoporosis prevention measure

2.4.2.2.1 Governmental factors

2.4.2.2.1.1 No dedicated executive at the Malaysian Ministry of Health for osteoporosis

In Malaysia, there is currently no dedicated executive at the Malaysian Ministry of Health for osteoporosis. Hence, there is a lack of governmental policy for a population based screening for osteoporosis. Patients are currently screened for osteoporosis when they have experienced a low trauma fracture, are symptomatic, or on an ad hoc basis. The lack of policy for osteoporosis screening at the governmental level may be the reason why osteoporosis may be under diagnosed. In order for osteoporosis to be screened effectively a nationwide policy is required.

"… When…the government… adopt(s) (a) certain policy… for example… the immunization (policy)… (the) whole population is… screened. …this is actually very effective because everyone… (has) to do it." (DR-2/M/30y)

2.4.2.2.2 Organizational and management factors

Organizational and management factors can be further categorized into financial and resources constraints, organization and structure constraints, and lack of policy standards and goals.

2.4.2.2.2.1 Financial and resources constraints

According to the WHO, osteoporosis is diagnosed when the T score is ≤ -2.5 standard deviations. The gold standard to diagnose osteoporosis is via a BMD scan. In Malaysia, DEXA machines are primarily located in bigger urban hospitals, as smaller hospitals do not receive funding to purchase such expensive equipments. This then limits the number of patients that can be screened for osteoporosis. In order to perform a population based screening programme for osteoporosis, a specific budget should be allocated to ensure its success. At present, resources required to screen for osteoporosis is taken from existing financial resources (such as the medication budget), which is not ideal.

"I don't think there's any specific budget for prevention programmes."   *(POL-4/F/45y)*

2.4.2.2.2.2 Organizational and structure constraints

2.4.2.2.2.1 Lack of leadership to head the population based osteoporosis screening programme, people are disorganized

Currently, there is a lack of leadership from the healthcare professionals to conduct an osteoporosis screening programme. According to the policy makers, opportunities to improve health services were given but the response from the healthcare professionals (such as pharmacists and doctors) were poor. In recent years, several activities have been implemented in our hospital, such as the medication therapy adherence clinic for diabetes and warfarin. The successful implementation of these programmes shows that the hospital's upper management is supportive towards activities which would improve patient well being. Hence, participants felt that the attitude of the hospital's upper management was a facilitator, as they would not be opposed to a population based osteoporosis screening programme in the future.

"*All the bosses are ok... if you have anything (an idea), you just voice out, they will listen...*"   (PHARM-6/F/27y)

2.4.2.2.2.3 Policy standards and goals

2.4.2.2.2.3.1 There is no clinic policy to screen for osteoporosis

Currently, there is no clinic policy to screen for osteoporosis. Hence, the doctors at the primary care clinic are screening patients opportunistically. The doctors then compared osteoporosis screening to other screening programmes such as breast cancer screening. They perceived that a policy to screen for osteoporosis screening will aid in its success; noting the success of a policy for breast cancer screening. The doctors all agreed that there should be a new programme to screen for osteoporosis. However, they suggested that screening of osteoporosis should be conducted opportunistically and eventually shifting to systematically screening everyone. This is to ensure that the new programme is sustainable.

"... Especially in... menopause ladies… (when) the blood pressure is well controlled. Then we... ask for... other thing(s) that (are) related to menopause. That's how we captured them (osteoporosis cases)." (DR-1/M/33y)

2.4.2.2.2.3.2 Primary care practitioners are not allowed to prescribe osteoporosis medications (Prescribing restrictions)

Medications to treat osteoporosis are expensive. In our setting, the Drugs and Therapeutics subcommittee has decreed that only endocrinologists, gynaecologists and orthopaedic specialists are able to prescribe medications to treat osteoporosis. Primary care physicians are not able to prescribe these medications. This was seen by the primary care physicians as a hindrance to diagnose and treat

osteoporosis. In order for a successful osteoporosis screening programme to take place, doctors, nurses and pharmacists suggested a more flexible prescribing policy.

"I think they should make it (prescribing restrictions) a bit more flexible so that our doctors can also write (prescribe) it (osteoporosis medication). I don't know (if) it's a bit expensive... I'm not sure of the price, so these... medicines, our RUKA (Primary Care Clinic)... doctors can't write (prescribe). Somehow (the patients) have to go back to the osteoporosis clinic, see the.... specialist then get it (osteoporosis medications). (NUR-6/F/55y)

2.4.2.2.3 Work environment factors

The participants highlighted a range of barriers faced from the work environment factors. The list includes administrative and managerial support, building and design, education and training, environment, equipment or supplies, staffing, time constraints and workload.

2.4.2.2.3.1   Administrative and managerial support
2.4.2.2.3.1.1   Long waiting time for bone mineral density scan appointments

The difficulty in diagnosing osteoporosis arises from a long waiting time for the patient to obtain a bone mineral density appointment with the department of nuclear medicine (There was a 6-12 months waiting period). In addition, patients can only see their primary care doctors once they have had their BMD scan. Subsequently, patients who need to be treated for osteoporosis need to be referred to the osteoporosis clinic as primary care physicians are not allowed to prescribe osteoporosis medications. In addition, the waiting time to see

the specialist at the osteoporosis clinic was 6-12 months. Although the doctors noted a facilitator whereby the process ran smoothly, the long waiting time was cited by all participants as a barrier.

"I find that (it) is... too long (a) process. Because... to get to your osteoporosis (bone mineral density) done... It takes about six months... And then... (she has) to come back again (for clinic appointments)… They are not doing it very fast. Because once you take six months, the person who (is) suffering with that disease either will go chronic or… (I) don't know whether she'll... still (be) alive or not. (PT-7/F/64y)

2.4.2.2.3.2 Building and design
2.4.2.2.3.2.1 Lack of space to conduct osteoporosis screening

A specific room or partitioned area is required to conduct specialised services such as diabetic screening or counselling as it would provide a conducive environment. Participants' cited that having a dedicated space for osteoporosis screening was a factor as the clinic was crowded, and all available space has been utilised.

"… No one thought about it or there is no facility in terms of place." (POL-4/F/45y)

2.4.2.2.3.3 Education and training
2.4.2.2.3.3.1 Lack of education and training for healthcare professionals

A majority of continuous medical education focuses on topics such as diabetes and cardiovascular diseases. There seems to be a paucity of training programmes targeting osteoporosis,

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indicating a lack of emphasis to train or reinforce healthcare professionals' knowledge in managing osteoporosis. Nonetheless, the healthcare professionals were eager to attend an osteoporosis workshop should there be one.

"I always hear of urology for BPH, urology, diabetic workshop... I also go... for Alzheimer's, hypertension. Osteoporosis, I have never been. Psychiatry, I have been... to a workshop but osteoporosis I have never been."

(NUR-1/F/44y)

2.4.2.2.3.4 Environment
2.4.2.2.3.4.1 Primary care services are not elderly friendly

In order for any health promotional programme to succeed, it must be easily accessible to patients. Osteoporosis screening is targeted at the elderly. There should be ample ramps for wheelchair access, parking support bars and adequate signage. Despite the availability of these elderly friendly facilities at the primary care clinic, patients commented that a more personalized service would aid the elderly in undergoing osteoporosis screening. Patients felt that the services provided by the primary care clinic were not as elderly friendly compared to the private sector. This was seen as a barrier when visiting the hospital.

"... Went to KPJ (private hospital) because it was too painful to come here (RUKA) ... that day when I arrived here, I couldn't walk. My husband had to park (the car), I thought to myself 'how am I going to get down (to the clinic by myself)?' ... the nurses (at the private hospital) was waiting with a wheelchair, I then sat on the wheelchair. I was pushed on the

wheel chair to the therapy room, the nurse straight away sent me to physio. Even if I have to see the specialist... the nurse will send."

<div align="right">

(PT-5/F/61y)

</div>

2.4.2.2.3.5   Equipment or supplies

2.4.2.2.3.5.1   Lack of DEXA machines

While there are currently functional DEXA machine in this setting, many other smaller hospitals do not have DEXA machines. Despite osteoporosis being screened opportunistically, the waiting time is 6 months to a year. If a population based osteoporosis screening programme was started, the number of DEXA machines will not be able to cope with the amount of BMD scans ordered. Therefore the number of DEXA machines need to be increased so that it is available nationwide.

"... (If) we screen everyone for osteoporosis... certain place(s) don't have the BMD (Bone Mineral Density) measurements (machine)... Here got (we have)... but you know if everyone uses that facility then we're kind of swamp (ed)."

<div align="right">

(DR-7/F/28y)

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2.4.2.2.3.5.2   Lack of osteoporosis medications

Healthcare professionals were concerned that if osteoporosis population screening was provided, treatment should also be provided. The primary care clinic is part of a public hospital whereby the medication cost is heavily subsidized by the government. For example, government workers and pensioners are entitled to free medications where else private patients paid a nominal sum of RM20 per month. Nonetheless some of these patients are still unable to afford these fees.

However, social welfare funds are availably but only to the lower income population. Healthcare professionals feared that not only the patients cannot afford the medications but also the government would not be able to cope with the increase in demand of osteoporosis medication.

"And this thing (osteoporosis medication) is quite expensive... Because, if we go for... screening there is a cure. But the cure should be available for all... There is no point... telling a person (to do) a BMD (Bone Mineral Density)... and telling her that you are osteoporotic and she is not a government servant. She cannot afford the cost of it."

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(DR-6/F/48y)

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2.4.2.2.3.6   Staffing
2.4.2.2.3.6.1   Lack of workforce

There was a lack of workforce with regards to doctors, pharmacists and nurses. The hospital was seen to be barely coping with the daily services. This would lead to difficulty in conducting any new services such as the osteoporosis screening programme. Essentially there should be enough staff to replace a staff who may call in sick. Unfortunately, this is not possible with the current amount of staff.

"I supposed... the challenge; it would be the manpower... That would be our first... hurdle. Once we have that, the person, then it can... be done."   *(POL-2/F/51y)*

2.4.2.2.3.7   Time constraints

2.4.2.2.3.7.1   Short consultation time with all healthcare professionals

Currently the consultation with the doctors only involved addressing the chief complaint as the waiting time is about 1-3 hours. The screening of osteoporosis would increase the consultation time leading to an increased waiting time. Hence, patients perceived that time would be a barrier for doctors to routinely screen for osteoporosis.

"... Because most doctors are so busy, they won't spend (the) time talking about something not related to your condition."

(PT-9/F/63y)

2.4.2.2.3.7.2   Restrictive key performance indicator

The healthcare professionals raise the limitations of two key performance indicators (KPI). The first is the 15-30 minutes consultation time between the doctors and patients. The second is the 30 minute dispensing time which includes the waiting time between the pharmacists and the patients. These two KPIs were intended to ensure that the patients did not have a waiting time. However, these time restrictions made osteoporosis screening not possible as healthcare professionals only had enough time to address the chief complaint.

"But with the outpatient setting here in our hospital. I don't think we can talk so much to the patients...Because we need to meet our quality objectives... So, there're limitations."

(PHARM-6/F/27y)

2.4.2.2.3.7.3   Workload

There is a large amount of patients at UMMC. Because of this healthcare professionals have to multitask and may not be able to spend additional time with the patients to screen for osteoporosis.

"They (healthcare professionals) are very busy… they (have) a lot of patient (s)… waiting."   (PT-6/F/72y)

Conversely, osteoporosis clinic nurses described the workload in the osteoporosis clinic to be low. These nurses suggest that more osteoporosis clinic referrals are needed from the primary care clinic.

"The (osteoporosis) clinic does not have that many patients. A hundred is not many."   (NUR-7/F/52y)

2.4.2.2.4   Team factors
2.4.2.2.4.1   Lack of communication in the primary care department

A lack of communication between departments and healthcare professionals has resulted in poor teamwork among the healthcare teams. Examples of poor communication and teamwork were of patients going for their osteoporosis clinic appointment without their bone mineral density scan results, healthcare professionals conveying different information to the patients or the lack of trust between the healthcare professionals to carry out screening. Therefore, all the participants expressed the need for an inter-professional collaboration. Additionally, although communication with patients was considered poor by the participants, a facilitator was noted as a small group of patients had good

communication skills and was open to communicate with the healthcare professionals.

"… The nurse(s)… the communication, how good is the communication between the pharmacists and the doctors and the patient(s)… communication could be a barrier. Thus, if the pharmacists (are) thinking on a different line, the doctors thinking on a different level, then they would end up nowhere."   *(DR-6/F/48y)*

2.4.2.2.5 Task factors

The task factors could be divided to two barriers: availability of an updated osteoporosis guideline and availability and accuracy of an osteoporosis risk assessment tool.

2.4.2.2.5.1   Availability of an osteoporosis guideline

Some of the healthcare professionals were not aware that an osteoporosis guideline was available. Others noted that the guidelines were not updates. The osteoporosis guideline was not update since 2006. This led healthcare professionals to look for other sources of information such as overseas guidelines from the United Kingdom or United States of America.

"…I think... they do (have an osteoporosis guideline), (it) is mainly (on) non-pharmacological, promote weight-bearing exercises… But it's an old guideline. We have never updated our osteoporosis guidelines, I think, our CPG (Clinical Practice Guideline) is (updated a) long, long (time) ago."

(DR-9/F/30y)

2.4.2.2.5.2   Availability and accuracy of and osteoporosis risk assessment tool

Despite the limited number of DEXA machines, there is currently no osteoporosis risk assessment tool suitable for the Malaysian population. The participants identified that an osteoporosis risk assessment tool would aid in optimizing the usage of current resources by screening patients at high risk for osteoporosis to go for a BMD scan. This tool should be able to accurately screen patients quickly and cheaply. Additionally participants mentioned that a general screening booklet whereby they can record screening activities would aid in the monitoring of whether osteoporosis screening or other diseases have been conducted.

"...If there is a screening tool which is... available... affordable... feasible and reachable for everyone, it'll be very helpful... we can't expose everyone to the BMD..."

(DR-4/M/38y)

2.4.2.2.6   Individual factors

Individual factors refer to healthcare professionals and policy makers. It can be divided to two types of barriers: personality and knowledge.

2.4.2.2.6.1   Personality
2.4.2.2.6.1.1   Healthcare professionals are not initiative during work

The lack of initiative from the healthcare professionals to start a new programme may be a barrier to start osteoporosis screening. This was seen as a barrier based on the failure of the smoking cessation and the osteoporosis medication

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therapy adherence and compliance (MTAC) programme. Healthcare professionals were seen to not keep themselves up to date and took a nonchalant approach towards osteoporosis screening as it seen to be not part of their core job scope. Nonetheless, the healthcare professionals considered osteoporosis to be a rising problem and are supportive of the idea for an osteoporosis screening programme.

"...I've... send people for quit something (smoking) and yet why can't the pharmacist open up the quit smoking clinic here?... they are not able to do it... they say, they don't have enough energy, they don't have the passion?"

(POL-3/M/57y)

2.4.2.2.6.2   Knowledge

There was a lack of osteoporosis knowledge seen in the healthcare professionals. Policy makers, doctors, pharmacists and nurses had a basic knowledge on osteoporosis but this was not sufficient. The gap in the knowledge includes all areas such as: osteoporosis as a disease, risk factors, and consequences of untreated osteoporosis, symptoms, screening, prevention and treatment. Because of the lack of knowledge on the screening and diagnosis of osteoporosis inappropriate tests such as x-rays and blood calcium level have been used to screen for osteoporosis instead of using the BMD scan.

Additionally, the lack of knowledge on the consequences of untreated osteoporosis and its symptoms, osteoporosis was seen to be not life threatening and is not taken seriously. The effect of this has led the healthcare team to focus on the treatment of osteoporosis when a fracture has occurred or

prioritizing other diseases such as diabetes. Health efforts have also been directed to the younger generation due to the perception that osteoporosis will not have an impact on the society as it only effects the elderly. Therefore, it is imperative to ensure that the healthcare professionals are equipped with the knowledge and are made aware that prevention is better than cure. Table 2.4 demonstrates the areas of osteoporosis which lack knowledge.

Table 2.4 Quotes highlighting healthcare professionals lack of knowledge on osteoporosis

Areas with a lack of knowledge	Quotes
Consequences of untreated osteoporosis: Osteoporosis is not life threatening	*"... Osteoporosis (is) not urgent. Osteoporosis... cannot kill you)."* *(NUR-8/F/37y)*
Risk factors: Women who gave birth many times are at higher risk for osteoporosis	*"... Usually it will affect woman, old woman that... give birth more than a few times... Maybe more than four times... Then they are prone to get osteoporosis when they are getting older..."* *(PHARM-7/M/25y)*
Symptoms: Unaware osteoporosis is asymptomatic	*"... We don't really ... screen without any complain (symptoms)..."* *(POL-2/F/51y)*
Screening: Blood calcium levels can be used to screen for osteoporosis	*"The other one... (the doctors screened me with a) blood test, they (doctors) said the calcium level is good."* *(PT-20/F/62y)*
Diagnosis: BMD scan is high in radiation	*"So women who is in the reproductive age, we cannot... (be) exposed to the... BMD (Bone Mineral Density) and then the X-Rays. So the screening tool will be... helpful for that group of people where we can avoid certain exposure to X-Rays."* *(DR-2/M/30y)*
Prevention: Swimming can help strengthen bones	*"Like... brisk walk, brisk walk, swimming... if the patient willing.... maybe jogging."* *(DR-5/M/30y)*
Lack of focus on screening and prevention of osteoporosis	*"... Awareness and education... cause right now all we're doing is treatment... waiting for the thing to happen. So there isn't enough... on prevention..."* *(PHARM-8/F/29y)*
Treatment: Lack of osteoporosis medication knowledge	*"Plus they (primary care doctors) may not... have the experience required to treat and review osteoporotic patients from time to time. Primary care is basically quite raw, it's generalized medicine. They're probably the doorkeepers."* *(PHARM-11/F/28y)*

2.4.2.2.7 Patient factors

Barriers contributing to the patient factors can be broken down to smaller subthemes such as condition, communication, personality, social factors and difficulty to adhere to osteoporosis prevention measures. Based on our data an additional subtheme emerged which was a lack of osteoporosis knowledge.

2.4.2.2.7.1 Condition
2.4.2.2.7.1.1 Osteoporosis was perceived to be not serious

The first barrier contributing to patient factor was that patients perceived osteoporosis to be a condition that was not serious mainly because it is normally asymptomatic in nature. This led patients to prioritize other diseases such as diabetes or cancer screening.

"As far I know (osteoporosis) is not life threatening, so why bother? There are other many things to worry about."

                                    (PT-13/F/65y)

2.4.2.2.7.2 Personality
2.4.2.2.7.2.1 Nonchalant attitude towards osteoporosis

As osteoporosis was perceived to be not serious, patient had a nonchalant personality towards osteoporosis. Furthermore, there were some patients who were in denial and did not want to find out if they had osteoporosis. Conversely, there was a facilitators noted as there were patients who had a pro-active attitude of health seeking behavior. These group of patients believed that prevention is better than cure and are willing to conduct screening as necessary. In order to conduct and

sustain and osteoporosis screening programme the healthcare professionals urged patients to take ownership of their health. This referred to patients being proactive about their own health issues.

"Some are just ignorant to it... 'I'm getting old... it's normal to (get) it, so don't bother."

(PHARM-9/F/27y)

2.4.2.2.7.2.2   Unwilling to listen to healthcare professionals' advice

Another personality barrier was some patients' unwillingness to listen to the advice of other healthcare professionals such as pharmacists or nurses. They were only willing to listen to advice from doctors. There were also some patients who preferred to listen to the advice given by a specialist, over a primary care physician.

"... We're also having problems here... some of them... (will) say, "... What (kind of)... doctor are you?" "I'm a general doctor." "No, no, no, I don't want to see a general doctor, I want to see a specialist."   *(DR-2/F/30y)*

2.4.2.2.7.2.3   Negative perception towards healthcare professionals
2.4.2.2.7.2.3.1 Competence

There was a perception that patients perceived that some healthcare professionals were incompetent. Patients found that some of the healthcare professionals seemed inexperienced or not capable to conduct their duties. This perception came from experiences of friends or family whom previously had a bad experience in the hospital or patients

themselves receiving wrong information. These stories led patients to perceive that some healthcare professionals were incompetent, finding it unnecessary and risky to do non urgent test such as a BMD scan. This type of perception was seen towards doctors, nurses, radiologists and pharmacists.

"I backed out. I am very scared. Because you hear a lot of people said this (and)… that happens... our lab technician(s), are they capable of handling (all these tests)?"

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(PT-18/F/57y)

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2.4.2.2.7.2.3.2 Healthcare professionals do not conduct themselves professionally

In UMMC, teaching sessions are conducted with doctors as part of part of continuing education. This sometimes caused the doctors to be late for their clinic sessions. Therefore, stakeholders noted that patients perceived that the healthcare professionals did not conduct themselves professionally. This is because patients are unaware that doctors are required to attend teaching sessions, and believe that doctors are intentionally late. Some of the patients also commented that the doctors, nurses or pharmacists did not answer their questions satisfactorily or answered them in an unprofessional manner.

"... It (is) about one hour late (for the clinic session)… because they (doctors) say, they have to be in the ward. So (I) don't know (if it is) true or not."

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(PT-13/F/65y)

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2.4.2.2.7.3 Knowledge

The stakeholders unanimously agreed that another barrier was a lack of osteoporosis knowledge among patients. Patients had a basic knowledge to what was osteoporosis. However, knowledge beyond that was limited especially in the areas of the consequences of untreated osteoporosis. Other topics which patients had poor knowledge includes: osteoporosis in general, screening for osteoporosis, prevention of osteoporosis and treatment of osteoporosis. It was also mentioned that rural patients had less osteoporosis knowledge as compared to city patients. Various methods and strategies have been suggested by the stakeholders interviewed for the dissemination of osteoporosis information: group counselling, individual counselling, campaigns, pamphlets and media advertisement. Table 2.5 demonstrates the areas lacking in knowledge.

Table 2.5: Quotes highlighting patients lack of osteoporosis knowledge

Areas with a lack of knowledge	Quotes
Osteoporosis as a disease: Osteoporosis was perceived to be part of aging and confused with osteoarthritis	*"They thinks it's part of aging.... like.. (it's) normal."* (DR-7/F/28y) *"… It's because they have… knee pain, they thought (this) is osteoporosis"* (DR-3/F/36y)
Cause of osteoporosis: Patients did not know the cause of osteoporosis	*"Maybe it's got to do with... blood circulation slowing down."* (PT-11/F/63y)
Consequences of untreated osteoporosis: Osteoporosis is not life threatening	*"As far I know is not life threatening, so why bother? There are other many things to worry about."* (PT-13/F/65y) *"...People just do not know... the severity of having osteoporosis."* (PHARM-4/M/23y)
Risk factors: Women who gave birth many times and being overweight were thought to be at higher risk for osteoporosis	*"Don't be overweight... don't ah burden... your bones."* (PT-1/F/58y) *"During childbearing where... some say the calcium... taken up by the baby."* (PT-12/F/59y)
Symptoms: Unaware osteoporosis is asymptomatic	*"When your teeth start... decaying a little... you start losing teeth... that's another indicator."* (PT-11/F/63y) *"Osteoporosis affects the joint."* (PT-20/F/62y) *"I got a friend they don't know (that they have osteoporosis) until they do a BMD. (Then they realized) "Ey I got osteoporosis but they... look healthy."* (NUR-3/F/43y)
Diagnosis: BMD scan is high in radiation	*"Radiation, isn't it dangerous?"* (PT-18/F/57y) *"I don't know what (are the available) type of bone screening facility. If you just putting the foot there... I don't think that's accurate."* (PT-20/F/62y)
Prevention: Unaware of all areas of calcium supplements, exercise and other preventive methods	*"Cause you will get stones in your kidney."* (PT-14/F/59y) *"Maybe I take the wrong dose... I don't know."* (PT-18/F/57y) *"I don't think my exercises... I mean (it) cannot prevent osteoporosis."* (PT-17/F/58y) *"...When is the (best time for the absorption of) vitamin D at what time? I don't think they know."* (POL-3/M/57yr))
Treatment: Lack of osteoporosis medication knowledge	*"Here pain (points at shoulder) then the doctor (gave an) injection. Then 9 months, 1 year... injection again."* (PT-6/F/72y)

2.4.2.2.7.4 Communication

2.4.2.2.7.4.1 Language barrier

Communication gap between healthcare professionals and patients was seen as barriers by the stakeholders. Reasons for the communication gap may be due to language barrier. Malaysia is a multiracial country. Although Malay is the national language and English is widely spoken, not all elderly are able to communicate in these languages. Some elderly patients may only speak in Mandarin or Tamil making communication difficult for staff who do not know these languages.

"... Sometimes (there is a) language problem with the patients... patients doesn't understand what... we're trying to tell them (or) what we're going to do them (screening)..."
(NUR-6/F/55Y)

2.4.2.2.7.5 Social factors

2.4.2.2.7.5.1 Financial constraints

Financial constraints contribute to the patient factor. In Malaysia, government workers or government pensioners are entitled to free healthcare. However, the rest of the population would need to pay a minimum fee. Despite the government subsidy, the cost of medication, supplements and services were still seen to be unaffordable for some of the patients.

"They (patients) are all... financially constrain(ed). So when you tell them... Fosamax is RM70. It's not cheap."
(NUR-2/F/51y)

2.4.2.2.7.6 Time constraints

Time constraint was another barrier, due to the lack of the DEXA machines and manpower waiting time for clinics and medications can be long. The whole process from the clinic appointment to the collection of medications will take at least half a day. This has led to patients choosing not to go for their clinic appointment prioritizing jobs or chores until their condition becomes unbearable. Screening for osteoporosis was perceived to add on to their waiting time and further deter patients from coming to the primary care clinic. A facilitators to this, is that although some patients consider the clinic appointment to be time consuming, there were some patients who considered a clinic appointment to be a social outing where they could make new friends. Nonetheless, a short clinic waiting time would assist the successful clinic attendance of the patients.

"Yes I can go (for jogging or screening) but there are plenty of chores. Previously I wasn't looking after my grandchildren. How can I leave them at home?"

(PT-17/F/58y)

2.4.2.2.7.6.1 Short consultation time

Patients mentioned that there was not enough consultation time to address other issues such as prevention or screening aside from the chief complaint. The consultations seemed rushed and felt that they would be bothersome to their doctors if they asked additional questions.

"Doctors, they are so busy... if you are not sick... (and you) go and ask them... they won't spend much time with (you)... maybe 5 minutes... finish."   *(PT-1/F/58y)*

2.4.2.2.7.7   Family circumstances

Most of the elderly in Malaysia depend on their children to bring them to the hospital making multiple clinic appointments difficult to adhere to.

"… They (elderly) depend a lot on their children, even to come to (the) hospital… Their children have to take leave... if you want… them to do… screening… they will feel that it is very troublesome because... they don't want to come a few times... just for the test."   *(DR-3/F/36y)*

2.4.2.2.7.8   Difficulty to adhere to osteoporosis prevention measures

Osteoporosis prevention measures and screening were seen to be a difficult task to some patients. For example, some patients feel too unfit to exercise or fear of safety when exercising. Others have difficulty in swallowing the calcium tablets and difficulty in drinking milk. These topics are not well discussed; difficulties and confusions are not addressed leading to patients giving up on their prevention efforts.

"When I feel "cloudy", then I just… (take) a short nap. Then after that I won't do that (brisk walking/treadmill) everyday. Just... on(c)e (a) week… I do."
                    (PT-14/F/59y)

2.4.3 Discussion

This study highlights the range of barriers in conducting an osteoporosis screening programme as perceived by policymakers, doctors, pharmacists, nurses and patients in a primary care clinic. There were seven main factors that

contributed to the barriers of running an osteoporosis screening programme: governmental, organizational and management, work environment, team, task, individual and patient factors.

These barriers encountered in a multicultural, Asian country were similar to barriers reported in overseas studies (Guzman-Clark et al., 2007, Jaglal et al., 2003, Beaton et al., 2012, Duyvendak et al., 2011, Kim et al., 2011, Simonelli et al., 2002, Feldstein et al., 2008, Papa and Weber, 1997, Otmar et al., 2012, Taylor et al., 2001, Claesson et al., 2015). Thematic consistency is apparent between all these studies and our study, suggesting that these barriers are widely held ideas that the results of this study are generalisable.

However, barriers from the governmental and, organisational as well as management factors are specific to our study. A lack of an osteoporosis screening policy at the national level in Malaysia influenced the lack of policy to screen for osteoporosis at the clinic level. This led to organizational and management barriers where a lack of funding and leadership occurred. Therefore, it is crucial to ensure that policy makers are equipped with knowledge on the importance of osteoporosis screening. This is essential in order to gain their support as it will assist in securing resources to begin the osteoporosis screening programmes and to ensure their sustainability (Straus et al., 2011). The lack of literature in this area may be due to the lack of studies on the barriers for screening of osteoporosis at the policy maker level. Studies were mainly conducted on patients or healthcare professionals perspectives (Guzman-Clark et al., 2007, Jaglal et al., 2003, Beaton et al., 2012, Duyvendak et al., 2011, Kim et al., 2011,

Simonelli et al., 2002, Feldstein et al., 2008, Papa and Weber, 1997, Otmar et al., 2012, Taylor et al., 2001).

Another policy barrier under the organizational and management factor identified is that primary care practitioners were not allowed to prescribe osteoporosis medications (prescribing restrictions). This has become an obstacle to screening and treating osteoporosis cases. The pharmacists, doctors and nurses unanimously suggested for a more flexible 'prescribing restriction' policy. This was a similar situation in a Canadian study which eventually allowed primary care practitioners to prescribe osteoporosis medication, suggesting that this is the way forward in order to successfully conduct a population based osteoporosis screening programme (Guzman-Clark et al., 2007).

The lack of leadership and funds at the governmental, organizational and management levels, resulted in several work environment factors. The work environment factors in our study concurs to previous studies, such as the lack of: DEXA machines (Milsom et al., 2013) leading to a long waiting time, education and training in osteoporosis (Taylor et al., 2001, Feldstein et al., 2008), osteoporosis medications (Simonelli et al., 2002). Another barrier cited from the work environment factor was a lack of space to conduct osteoporosis screening. This may be because there was currently no osteoporosis screening programme. Hence, a location was not allocated. Lack of manpower leading to a high workload and short consultations time was a particular barrier highlighted in our study.

Further analysis of the data identified an issues which were only identified from our setting was a restrictive key performance indicator (KPI) whereby a doctors consultation time should not exceed 30 minutes and a pharmacists' dispensing duration should not exceed 30 minutes These KPIs were designed to ensure that patients did not have too long a waiting time at the clinic, and at the pharmacy. However, the downside of having this KPI is that doctors will only focus on the patient's chief medical complaint, and pharmacy staff will dispense medications as quickly as possible, so that the crowd can be cleared. Despite these KPIs, the waiting time for a patient to see a doctor can range from 1-3 hours, whilst the waiting time for their prescription to be filled can range from 30 minutes to 2 hours. This suggests that screening can be conducted during this waiting time period, so that the patient's time maybe used effectively.

Another barrier identified specifically for our setting was the lack of elderly friendly services at the primary care centre. Despite the availability of some elderly friendly facilities, hospital staff were not at hand to assist the elderly (such as pushing them in a wheel chair from the point where they are dropped off to the doctor's clinic) to assist the elderly. This in turn affected the patients' accessibility to the hospital.

As for the team factor, communication gaps between the healthcare professionals, departments and patients resulted in poor teamwork. One of the ways suggested to address this barrier was to conduct an inter-professional osteoporosis screening programme. Previous studies have shown that inter-professional collaboration improves communication and clinical

outcomes (Hjalmarson et al., 2013, Dolovich et al., 2008, Majumdar et al., 2008).

The barriers from the task factors were a lack of awareness towards the availability of an osteoporosis guideline. This was not a new barrier as previous studies have found that only 42% of general practitioners declared any awareness of an osteoporosis guideline (Taylor et al., 2001). Participants also cited that the guideline was not updated. However, the Malaysian osteoporosis guideline from year 2006 has now been updated in year 2012 (Ministry of Health Malaysia, 2012). Nonetheless this updates guideline does not mandate osteoporosis screening where as in Canada, guidelines have been released to ensure that all women >65 with a fracture should be screened for osteoporosis (Papaioannou et al., 2010).

Another barrier from the task factor cited specifically for our setting was a lack of an osteoporosis risk assessment tool, as it was difficult to access the DEXA machines. Several risk assessment tools have been developed (Koh et al., 2001b, Lim et al., 2011, Ministry of Health Malaysia, 2012). And previous studies have shown that the use of a risk assessment tools increased the number of BMD scans ordered and the number of osteoporosis cases detected (Yuksel et al., 2010, Crockett et al., 2008). In the Malaysian osteoporosis guidelines (2012), it was recommended that OSTA should be used as a screening tool. However, the OSTA has not been validated, whilst the MOST has been validated. Hence phase two of this study involved conducting a study to validate the OSTA in the Malaysian population and compared it to the MOST.

Individual factors noted a new theme called personality arose which was not part of the framework. This referred to perceptions of the personality of the healthcare professionals who did not show much initiative at work. Additionally, in the patient factor, patients' had a negative perception of the healthcareprofessional perceiving that they do not act professionally. Studies have shown that a high workload may lead to such behaviour of lack of initiative and lack of professionalism (Reader and Gillespie, 2013). Nonetheless, the healthcare professionals were supportive towards the idea of a screening programme. These healthcare professionals unanimously agreed that there is a growing demand for osteoporosis awareness. This indicates that the healthcare professionals are willing to take on the new osteoporosis screening programme which is essential for its success.

The most common barrier seen from the individual factors is the lack of osteoporosis knowledge of healthcare professionals (Guzman-Clark et al., 2007, Beaton et al., 2012, Kim et al., 2011, Claesson et al., 2015) (Sale et al., 2014). Similar results were found where some osteoporosis cases are missed even after a fragility fracture (Kim et al., 2011) or other diseases were prioritized due to the lack of osteoporosis knowledge (Otmar et al., 2012, Claesson et al., 2015). In our setting, healthcare professionals prioritized other diseases or treatment of osteoporosis when a fracture has occurred instead of screening osteoporosis which is more cost effective. Additionally, if patients find that their healthcare providers did not see osteoporosis as important, they were less likely to be tested for their BMD (Beaton et al., 2012). Another study by Jaglal et al (2003) involving healthcare providers had similar

issues raised by the participants in our study (Jaglal et al., 2003). Their analysis consist of focus group discussions with Ontario family physicians, revealing that family physicians lack a rational for testing and were confused about the recommended management of osteoporosis (Jaglal et al., 2003). Some of the principle barriers to osteoporosis care raised by the physicians were also described by the patients in their focus group: patient having too many co-morbidities, lack of knowledge regarding appropriate follow up. These concerns might all results at least in part from the limited time (Jaglal et al., 2003). Thus although patients are reliant on their doctors for directing their osteoporosis care, many physicians experience much the same uncertainty about the management of osteoporosis as patients. In another study, they have noted that the lack of knowledge, especially concerning the use of BMD-results may led to the under-treatment of the presented patients (Duyvendak et al., 2011). This was not an issued raise by our participants. Our PCPs seem to be confident to interpret the BMD results.

As for the patient factors, various studies were similar where they have noted that patients had poor knowledge on osteoporosis. They perceived it as a non serious disease as they could not link osteoporosis and fragility fractures (Beaton et al., 2012, Feldstein et al., 2008, Ha et al., 2014). Based on literature, the linking of osteoporosis and fractures is a difficult task as not only do non osteoporotic women have difficulty linking osteoporosis and fractures but women who are already diagnosed with osteoporosis are also unable to see the link (Besser et al., 2012). Beaton et al conducted a study involving focus group discussions with patients (men and women) who had fragility fractures echoed many of the issues raised by the

focus group participants in our study (Beaton et al., 2012). Similarly to the study by Beaton et al, our study shows that patients had a misconception that the BMD scan was an invasive procedure (Beaton et al., 2012). They feared that it was high in radiation.

Although this seems to be a common problem in osteoporosis, the patients' lack of osteoporosis knowledge is a new theme identified that was not part of the framework. However, for the effective prevention of osteoporosis and its fractures, patients should be equipped with the knowledge of the various prevention measures available. Hence, it was included as a theme in the patient factors. The lack of osteoporosis knowledge is perhaps the most modifiable barrier seen from the patient factors. Patients found themselves exposed to conflicting results and had difficulty accessing osteoporosis information. The study identified many specific misunderstanding that could be addressed by patient education. However, patients differed in their requirement of osteoporosis knowledge levels. This suggests the need for individualized patient-centred information that addresses their particular needs and enables them to develop a coherent mental representation of their illness and its management(Lorish et al., 1985).

The lack of osteoporosis knowledge and a perception that it is not serious led our patients to have a nonchalant attitude towards osteoporosis prioritizing other diseases. Similar findings were found by Beaton et al where other health conditions were noted as barriers to starting osteoporosis treatment (Beaton et al., 2012). Patients also were perceived to have difficulty in adhering to treatment and preventive

lifestyle measures. It was suggested that patient education can assist to manage this problem (Sedlak et al., 2000, Burke-Doe et al., 2008). However whether these interventions affect patient outcomes and future fracture incidence has not been well studied. In addition, even if osteoporosis educational materials are provided to the patients at risk for osteoporosis, this is often not enough to change knowledge, attitude and behaviours regarding prevention of osteoporosis (Etemadifar, 2013, Kasper et al., 1994). Nonetheless, knowledge of osteoporosis plays an important role in developing attitudes towards the disease which in turn impacts health care behaviours (Andersen, 1995).

Other findings, which have implications for future interventions in osteoporosis screening includes communication and the doctor-patient relationships. Previous studies have shown that the doctor-patient relationship were important to ensure that patients follow treatment advice (Haskard Zolnierek and DiMatteo, 2009, Lau et al., 2008). Patients from these studies commented that when they had a good relationship with their doctors, they wanted to follow their instructions which could possibly include advice on preventive measures. Improved doctors-patient communication can be incorporated into future interventions, including education for healthcare professionals. Relationships should also be supportive and address the fears and concerns that patients have about osteoporosis, but may have difficulty expressing. Feedback from BMD scans was crucial motivations of adherence for this group. Scans provide concrete information about disease progression which is fundamentally important in a condition which is asymptomatic and often invisible to patients (Besser et al., 2012).

Additionally, patient factor noted barriers such as the healthcare professionals were perceived to be incompetent. This may be because UMMC is a teaching hospital and some of the healthcare professionals are currently undergoing a family medicine training programme, and may not be as experienced as their senior colleagues. Another explanation to this would be the effect of a high workload may increase the probability of the healthcare professionals making errors leading to the perception of incompetency (Tully and Buchan, 2009).

Other patient factors include language barriers. Patients with limited language proficiency have problems with healthcare access, comprehension, adherence and receive lower quality of care overall. As prevention activities are not easily monitored an understanding of its importance is crucial to ensure it is practiced as necessary. Strategies to overcome language barriers in practice include employing diverse healthcare workforce and using translation services when necessary. Preparing healthcare professionals to serve in diverse communities can be done by offering medical language courses in medical schools to help familiarize students with medical terminologies they will encounter in different communities.

The cost of medications and BMD scans influenced the likelihood of patients going for osteoporosis screening(Ha et al., 2014). Conversely, a study in US found that the cost of medication and screening was not seen as a major problem for the patients (Feldstein et al., 2008). Nonetheless, in our study participants perceive that the cost of medications and screening procedures are expensive. However, UMMC is a

government clinic which means that the prices that patients are experiencing is a very minimal fee.

Another common issue noted by patient's in our and in other studies were time constraints whereby there was a lack of time for consultations between the patients and healthcare professionals (Beaton et al., 2012). It was mentioned that there was not enough time to address other issues such as prevention or screening aside from the chief complaint. Meadows and colleagues reported failure to communicate was a persistent barrier to osteoporosis treatment, as described in interviews conducted with women aged 45-65 years following a fragility fracture in an urban Canadian centre (Meadows et al., 2007). Other patients prioritize looking after grandchildren and their jobs instead of their doctors visit due to long waiting hours. This was similar in the study by Backett-Milburn where patients prioritize jobs as they needed to 'keep going' where dwelling on future health risk or illnesses were seen to be a diversion from getting on with the present (Backett-Milburn et al., 2000).

In addition, access to the clinic was a particular barrier in our study unlike the west where access was not seen as a major barrier (Feldstein et al., 2008). Most Malaysian elderly are dependent on their children for transport to their clinic appointments. This may be because of the Malaysian culture where children are expected to take care of their elderly. Additionally, public transport to the clinic is not elderly friendly. Nonetheless, this was seen as barrier for our setting as a survey conducted on primary care practitioners noted that they were more likely to treat independently living adults (Simonelli et al., 2002).

2.4.4 Strength of the study

The strength of our study was that we interviewed all relevant stakeholders for their views and opinions regarding an osteoporosis screening programme. Hence, we were able to gain an in depth understanding of the barriers towards this programme.

2.4.5 Limitations of the study

Only five policy makers were recruited out of a possible seven. However, the themes raised by the policy makers were similar to that raised of other healthcare professionals such as doctors, pharmacists and nurses suggesting that data saturation have occurred. We also did not include men in our study. It is possible that different factors will affect men in osteoporosis screening, which need to be explored by further research. An expansion to this study would be to include the perceptions of endocrinologist or orthopaedic surgeons.

2.4.6 Conclusion

Our study identified the various barriers and facilitators encountered by nurses, doctors, pharmacists, patients and policy makers regarding an osteoporosis screening programme. Barriers and facilitators occurred at seven different levels of the healthcare system: governmental, organizational and management, work environment, individual, team, task and patients. Tackling the issue of osteoporosis screening should not happen only at the work force level. A more comprehensive osteoporosis screening programme should be designed and developed involving upper management.

2.5 Research question 2: Can Malaysian pharmacists expand their non dispensing role in an osteoporosis screening?

2.5.1 Introduction

In order to answer this research question we began by exploring the relevant stakeholders' perception on the: current role of pharmacists, future pharmacists' role and the relevance of inter-professional collaboration. To the best of our knowledge, there is no study specifically exploring the role of the Malaysian pharmacist in osteoporosis. A lack of reported evidence on stakeholder's perception on the pharmacists' role noted that there was a need to explore these issues in Malaysia. Therefore, a qualitative research approach using in-depth interviews was chosen for this phase.

2.5.2 Method

The second research questions were explored concurrently with the first research question. The research methods, data management and analysis were conducted exactly the same way as described previously (section 3.4.1). However a different theoretical framework was used during the analysis of the relevance of was different. Hence, only the theoretical framework will be discussed for this section.

2.5.2.1   Theoretical framework: D'Amour Model

We used the D'Amour model as it was developed based on a model of collaboration, which applies to inter-professional and inter-organizational collaboration in healthcare organizations. It can be used to analyze the increasingly complex and heterogeneous multi level systems of personels collaborating such as in the primary care clinic. D'Amour et al developed this model following a study of inter-professional collaboration in a primary-healthcare setting and tested it in healthcare networks. This model allows us to determine the level of inter-professional collaboration and areas of improvement (D'Amour et al., 2008).

The D'Amour model suggest that collective action can be analyzed in terms of four dimensions operationalized by ten indicators. Figure 2.3 shows that the four dimensions are interrelated and influence each other. Two of the dimensions involve relationships between individuals: shared goals and visions and internalization. The other two dimensions (governance and formalization) involve organizational setting which influences collective action. Table 2.6 presents description of each dimension. These four dimensions and their interaction capture the processes inherent in collaboration. Nonetheless, they are subjected to influences such as resources, financial constraints and policies and should be taken into account as determinants of collaborative processes (D'Amour et al., 2008).

Figure 2.3: The D'Amour model of collaboration (D'Amour et al., 2008)

Governance
- Centrality
- Leadership
- Support for innovation
- Connectivity

Shared goals and vision
- Goals
- Client-centred orientation vs other allegiances

Formalization
- Formalization of tools
-Information exchange

Internalization
-Mutual acquaintanceship
-Trust
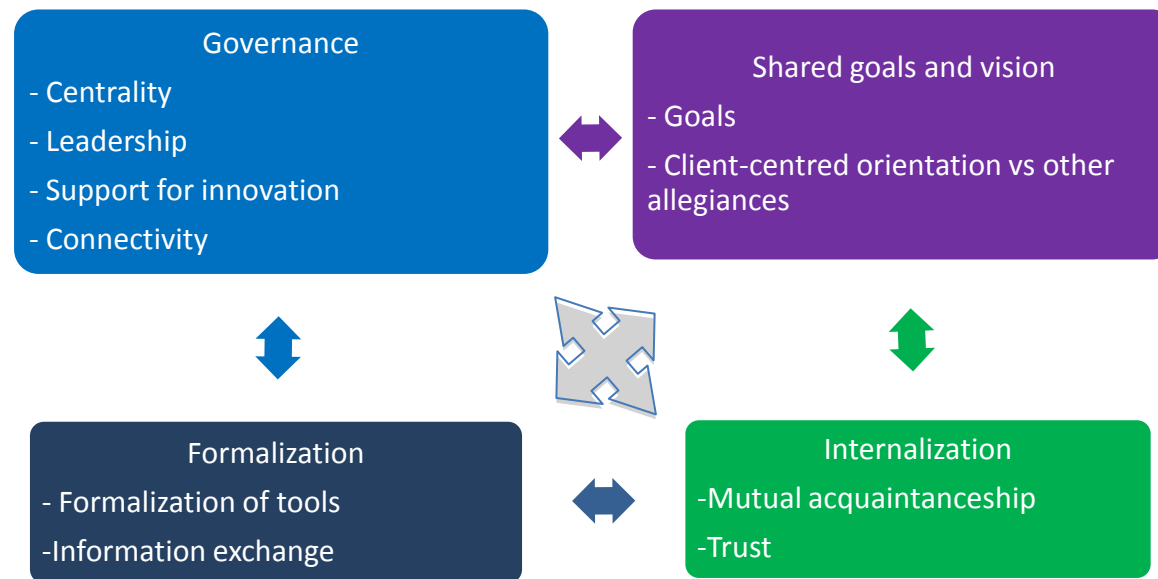
Table 2.6: Description of each dimension (D'Amour et al., 2008)

Dimension	Description
Shared goals and vision	The existence of common goal and appropriation by the team, the recognition of divergent motives and multiple allegiances and the diversity of definitions and expectations regarding collaboration
Internalization	Awareness by professionals of their interdependencies and of the importance of managing them. This translates into a sense of belonging, knowledge of each other's values and discipline and mutual trust
Governance	Leadership function that support collaboration by giving direction to and supports professionals as they implement innovations related to inter-professional and inter-organizational collaborative practices.
Formalization	Structuring clinical care by documented procedures that communicate desired outputs and behaviours exist are being used. It clarifies expectations and responsibilities

The 10 indicators can then be categorized to three levels representing the level of achievement of an indicator. Level three is called active collaboration which is the maximum level of achievement. It refers to a setting that has successfully established stable collaboration and is sustainable despite uncertainties in the health care system. Level two is called developing collaboration, it is collaboration that is not stable and may still be subjected to re-evaluation as a consensus has not been reached. Although progress on collaboration is being made, it would require more time to achieve an active collaboration. The minimum level of achievement is level one known as potential/latent collaboration. This level refers to collaboration that does not yet exist or has been blocked by conflicts that are so serious that the system cannot move forward. The level 1-3 for each indicator are explained in Table 2.7. Based on these levels, a visual representation of collaborations is possible (D'Amour et al., 2008).

Table 2.7: Indicators of collaboration according to levels (D'Amour et al., 2008)

Indicators	Active Collaboration LEVEL 3	Developing Collaboration LEVEL 2	Potential or Latent Collaboration LEVEL 1
Goals	Consensual, comprehensive goals	Some shared ad hoc goals	Conflicting goals or absence of shared goals
Client-centred orientation vs. other allegiances	Client-centred orientation	Professional or organizational interests drive orientations	Tendency to let private interests drive orientations
Mutual acquaintanceship	Frequent opportunities to meet, regular joint activities	Few opportunities to meet, few joint activities	No opportunities to meet, no joint activities
Trust	Grounded trust	Trust is conditional, is taking shape.	Lack of trust
Centrality	Strong and active central body that fosters consensus	Central body with an ill-defined role, ambiguous political and strategic role.	Absence of a central body, quasi absence of a political role.
Leadership	Shared, consensual leadership	Unfocused, fragmented leadership that has little impact	Non-consensual, monopolistic leadership
Support for innovation	Expertise that fosters introduction of collaboration and innovation	Sporadic, fragmented expertise	Little or no expertise available to support collaboration and innovation
Connectivity	Many venues for discussion and participation	Ad hoc discussion venues related to specific issues	Quasi-absence of discussion venues

Formalization tools	Consensual agreements, jointly defined rules	Non-consensual agreements, do not reflect practices or are in the process of being negotiated or constructed	No agreement or agreement not respected, a source of conflict
Information exchange	Common infrastructure for collecting and exchanging information	Incomplete information-exchange infrastructure, does not meet needs or is used inappropriately	Relative absence of any common infrastructure or mechanism for collecting or exchanging information

2.5.3 Results

Results were divided to three sections the current role of the pharmacists, the expansion of the pharmacists' role and the need for inter-professional collaboration.

2.5.3.1   Participants' characteristics

Please refer to section 3.4.2.1 and Table 3.2 for the participants' characteristics.

2.5.3.2   The current role of the pharmacists as perceived by the patients, nurses, doctors, pharmacists and policy makers

Pharmacists were principally perceived by participants to be suppliers of medication, although there was some recognition of roles in providing medication safety, medication costing and medication advice [Table 2.8].

Table 2.8: Current perceived pharmacists' role by patients, nurses, doctors, pharmacists and policy makers

Current perceived pharmacists role	Sub themes
Suppliers of medication	Dispensing of medications
	Approval of medication supply
Medication safety	Ensure patients receives the appropriate medications
Medication advice	Medication advice to patients
	Medication advice to other healthcare professionals
Medication costing	Budgeting of medication fund

2.5.3.2.1 Suppliers of medication

2.5.3.2.1.1   Dispensing medications

The supplying of medications by dispensing was seen to be the core duty of the pharmacists. Dispensing was perceived to be an activity where the pharmacists receives a prescription from the patients at the counter and supplies the appropriate medication. If it is a repeated prescription, the pharmacists would set another appointment date for the patients to collect the medication.

"So I take the (medication from the pharmacist for the) first time... (then) they give me another date to, replenish... (my medication in about) six months or one year... appointment. That's all..."   *(PT-16/F/70y)*

2.5.3.2.2 Approval of medication supply

Additionally, the supplying of medications also refers to the pharmacists' role in the UMMC Drugs and Therapeutics sub-committee whereby policies about medication usage are determined. Various policies are approved to only allow certain group of specialist to prescribe certain medications. For example, osteoporosis medications can only be dispensed if a BMD scan indicates osteoporosis and if it is prescribed by an endocrinologists, orthopaedics and gynaecologists. Therefore, the pharmacists would need to ensure the appropriate forms and procedures are conducted before the medication can be dispensed to the patients.

"So the pharmacists will assess if the patients can get the medication for free, whether the doctor can prescribe the medication or not. Because previously, Fosamax we had to attach the BMD report."   *(NUR-9/F/42y)*

2.5.3.2.3 Medication safety

2.5.3.2.3.1 Ensure patients receives the appropriate medication

The pharmacists were seen to be the final safety net before the patients take home their medications. As the primary care clinic has a lot of trainee doctors, the pharmacists' role to ensure that the patients receive the appropriate medication is crucial. To elaborate on this, the pharmacists play an important role to check the appropriateness of the medication in terms of: indication, dose and interaction.

"... At the moment the role... (is) making sure that... the med(ication), the patient is receiving is safe... The main focus is safety... whatever prescription that come in... (we ensure the) dose, the combination of products... is safe for the patient(s)..."   *(PHARM-8/F/29)*

2.5.3.2.4 Medication advice

2.5.3.2.4.1 Medication advice to patients

The pharmacists were also recognised for their role in giving medication advice. The pharmacists would dispense the medications and provide information to the patients regarding the medications. The information provided includes the indication, mode of action, side effects and method of taking the medications. The monitoring of the patients adherence and compliance is also part of this process. There were some patients who recognized the pharmacists' role in advice for minor ailments and supplements.

"Pharmacist, I think it's very important... the role would be to explain to the patients regarding the indication of the

medication, the mode of action and the proper way of taking

the medications."   *(DR-3/F/36y)*

2.5.3.2.4.2   Medication advice to other healthcare professionals

Apart from that, pharmacists were seen by the other healthcare professionals such as doctors and nurses to be medication experts. They would seek advice from the pharmacists regarding: side effects, interactions, dosage, approval to prescribe and availability. However this is not a common occurrence.

"But for me... the pharmacist relationship is... just to ask about the drugs side effects, the drugs whether (it) can be prescribe, about the dosage, everything..." (DR-8/F/29y)

2.5.3.2.5   Medication costing
2.5.3.2.5.1   Budgeting of medication fund

Pharmacists were seen to be involved in medication costing via the UMMC Drugs and Therapeutics sub-committee. The policy to only allow certain groups of specialist to prescribe certain medications is part of fund management. Due to the shortage of funds there was a shortage of medications. Hence, pharmacists at the upper management level would need to develop policies to ensure sufficient medication is available where as pharmacists at the frontline would need to ensure these policies are adhered too.

"(This policy is to) save cost because we have to ensure that the usage of the medication is not too high. Hence, we limited it to a certain amount of patients (whom are under the

*specialists' care). Therefore, we are forced to do screening of
prescribed medication this way."* (POL-5/M/44y)

2.5.3.3   The expansion of the pharmacists' non-dispensing role to osteoporosis screening as perceived by patients, nurses, doctors, pharmacists and policy makers

Nonetheless, doctors, nurses, patients, policy makers and
pharmacists themselves were eager for pharmacists to expand
their role beyond medication: supply, advice, costing and
safety. The stakeholders perceived that the pharmacists
should expand their role in terms of counselling, creating
awareness and screening of osteoporosis.

*"But I think we are actually well position to actually do... this
screening and in fact to do the counsel(ing) (and) educating
the public."* (POL-2/F/51y)

2.5.3.3.1 Counselling

Counselling was seen to be conducting activities such as the
current medication therapy adherence and compliance (MTAC)
clinic conducted for diabetic patients. This was an
individualized service provided by the pharmacists.
Pharmacists assist the patients in adjusting their insulin dose
and give lifestyle advice. Recommendations to doctor
regarding therapy were also given if necessary. However, this
service is only conducted for diabetics and patients on
warfarin. Therefore, stakeholders noted the possibility of this
kind of services to be extended to osteoporosis and other
diseases. Additionally, group counselling by *the pharmacists
was also suggested.*

"I want the MTAC osteoporosis to be implemented again in our hospital after proper planning... because... from here we can... reach out to the public because... my daily job. I think (it) is very... difficult for me to actually talk to them (patients)." *(PHARM-10/F/28y)*

2.5.3.3.2 Creating awareness of osteoporosis

The second area suggested was creating awareness on osteoporosis and public health in general. Stakeholders suggest various ways such as creating posters, campaigns or giving health talks during clinic session. However, this could also be done opportunistically. For example, pharmacists could casually mention to a postmenopausal women if she has undergone a BMD scan. Pharmacists were seen to be most accessible to patients at the community level. Therefore, pharmacists are in an ideal position to create awareness on osteoporosis and various diseases.

"I think they (primary care pharmacists) have (a) big role because... they are more... involved with community... they have a major role in screening, not only osteoporosis, other diseases as well. And then to educate patients also, they have... a big role." *(DR-5/M/30y)*

2.5.3.3.3 Screening of osteoporosis

Lastly, the pharmacists were seen to be in an ideal position to screen for osteoporosis. This is because pharmacists were seen to be more accessible. Patients would visit the pharmacists several times before their next doctor's appointment for their repeat prescriptions. This gives the pharmacists the opportunity to tap into screening and prevention of osteoporosis. Patients also perceived

pharmacists to be knowledgeable and trust pharmacist for advice.

"Pharmacist can explain to us... rheumatism (referring to osteoporosis)... what you (kind of supplements to) take... we.... trust the pharmacist." (PT-6/F/72y)

Currently, both the doctors and nurses are unable to screen for osteoporosis systematically due to the time constraint. If pharmacists were involved in osteoporosis screening it was seen as an improvement to the healthcare system. This facilitates the healthcare professionals to understand each others' scope of practice better leading to a more effective healthcare system. Additionally, the involvement of pharmacists in osteoporosis screening would lighten the workload of doctors and nurses. This in turn saves both the patients and healthcare professionals' time. The pharmacist would screen for osteoporosis and the doctors would focus on diagnosis and treatment. Hence, the pharmacists could play a part in osteoporosis screening alerting the doctors when a BMD scan may be needed. This will assists in detecting untreated osteoporosis.

"...Pharmacist can help to save (the) doctor's time... because some patient(s) (do not) need to (be) referred (to the) doctor. Waste both... (the) doctors' and patients' time... So if (the) pharmacists can do that (osteoporosis screening), it's good."
(PHARM-2/F/24y)

Interviewed pharmacists referred to their current role as 'robotic dispensers' and unanimously agreed for an expansion of the pharmacist role in osteoporosis screening. They felt that

they weren't contributing enough to the society and were not satisfied with their current job scope. Therefore, there is a need to expand the pharmacist non-dispensing role in osteoporosis screening.

"(We) dispense like (a) robot... you just push, push, push the thing (medication) out." (PHARM-6/F/27y)

Lastly, all the participants concurred that the expansion of the non-dispensing role of the pharmacists to osteoporosis screening was seen as progression for the profession. The pharmacists' skills were considered underutilized and shifting from a more medication-centred approach to a more patient-orientated approach. This emphasizes the need to expand the pharmacists' role to osteoporosis screening. Additionally, pharmacists were well equipped with the knowledge on the disease, treatment and prevention. Stakeholders noted the success of pharmacists' independent prescribing role overseas. They unanimously agreed that the pharmacists' role should be expanded to osteoporosis management.

"(The pharmacists') job scope is expanding all this time… I wouldn't be surprised if pharmacist (start) screening (for osteoporosis) since (there are) all ready… pharmacist prescribers (overseas)..." (PHARM-11/F/28y)

2.5.3.4 Need for inter-professional collaboration in osteoporosis screening

However, barriers to the expansions of the pharmacists' role to osteoporosis screening were noted. These barriers include patients perceiving pharmacists to be profit driven, inadequate staffing and infrastructure. Moreover, the Malaysian

pharmacists do not have access to patients' case notes and do not have the sole right to dispense medications with doctors currently dispensing is another challenge to overcome. These were some of the barriers but the main barrier noted by all stakeholders was the lack of an inter-professional collaboration in osteoporosis screening, prevention advice and disease management.

"Because... we don't understand our role and responsibility. I mean among the healthcare providers... We should actually clear... the doubts of the healthcare professionals... so that... everyone of us will be working quite closely together without much prejudice."   *(PHARM-10/M/28y)*

These findings were further examined using the D'Amour's structural model of collaboration which encompasses four main themes: shared goals and visions, internalisation, formalisation and governance. This model supports our data which highlights a lack of governance and formalisation, that fosters consensus, leadership, protocol and information exchange. Based on the D'Amour's model, this primary care clinic is described as developing towards an inter-professional collaboration in managing osteoporosis but is still in its early stages. The Kiviat graph [Figure 2.4] provides a schematic view of collaboration in our setting.

Figure 2.4: Kiviat graph lays out the schematic view of collaboration in the primary care setting.

Developing collaboration

- Goal
- Client-centred
- Mutual acquaintanceship
- Trust
- Centrality
- Support for innovation
- Connectivity
- Leadership
- Formalization tool
- Information exchange

Developing collaboration
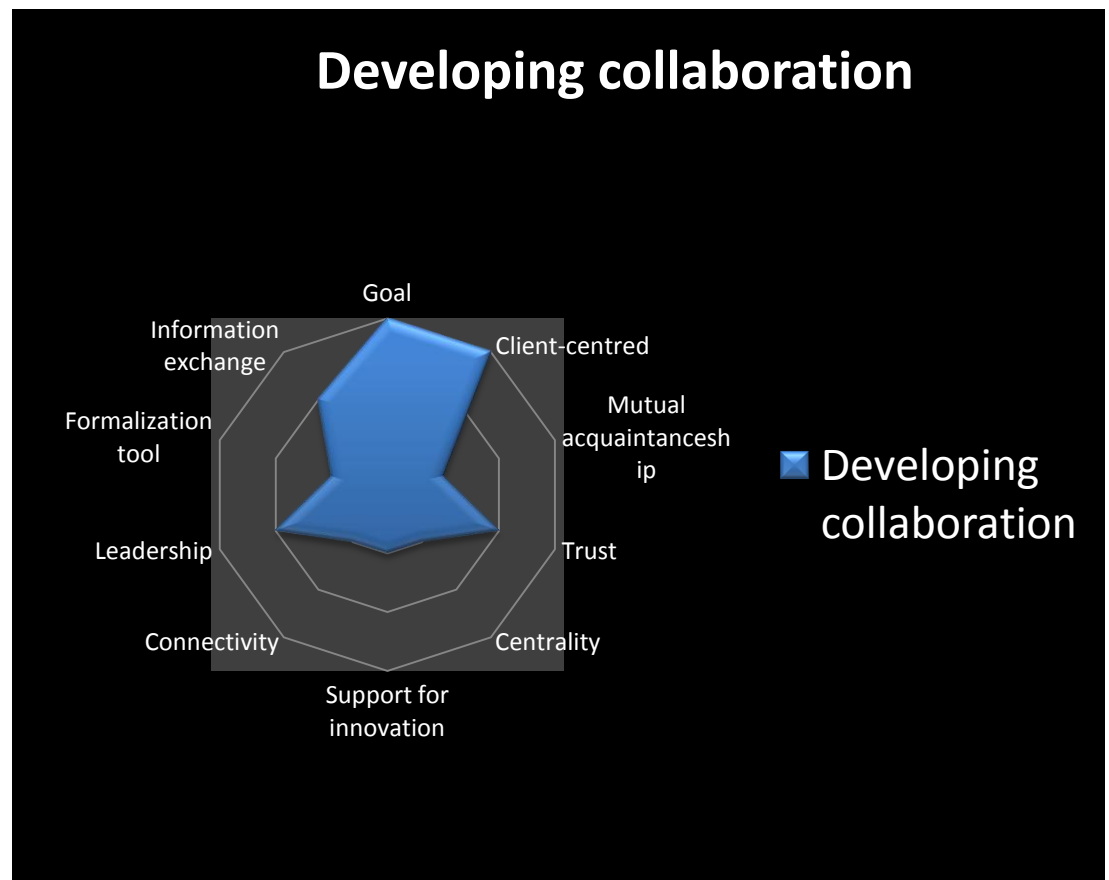
2.5.3.5 Share goals and vision

With respect to the shared goal and vision dimension, there were two indicators goals and client-centred orientation versus other allegiances. The analysis of the data showed that the healthcare professional team (nurses, pharmacists, doctors, policy makers) and patients had a common set of goals namely: to increase osteoporosis awareness and to increase osteoporosis screening.

Stakeholders were eager to increase the public's awareness of osteoporosis. They wanted to increase the public's awareness not only of osteoporosis but of other diseases such as hepatitis. The stakeholders were supportive in working more closely with the pharmacists, suggesting that the pharmacists conduct counselling, give lifestyle and preventive advice. On top of that, they suggested that osteoporosis awareness can also be improved via the pharmacists giving daily health talks at the clinics.

"If the pharmacist wants to do some counselling …. want(s) to give a talk… want(s) to do a video… to create awareness among the public, among the patients who are here in the clinic. … most welcome to…."   *(DR-9/F/30y)*

The second goal was to increase osteoporosis screening. To attain this goal stakeholder noted that the solution could be a pharmacist-led osteoporosis screening programme in collaboration with the doctors. This point is clearly expressed by the one of participants:

"I think probably the pharmacist can... detect the problem (osteoporosis)... then they can suggest to the physician

that... the patient will benefit from the BMD (scan). But... I don't think it should be... the pharmacist... ordering (the BMD scan) because... we (doctors)... suppose to co-relate with the clinical... condition and we're suppose to... advice (on the) appropriate treatment."   *(DR-4/M/38y)*

The results for the shared goals and vision showed that the stakeholders had common goals centred on client needs. They wanted to improve the healthcare system and the progression of the pharmacy profession to give better quality services to the patients. Therefore, these two indicators are achieved at level 3.

2.5.3.6   Internalization

Regarding the internalization dimension, there were two indicators namely mutual acquaintanceship and trust. The doctors, pharmacists, nurses, policy makers were not mutually acquainted with the pharmacists' role. Additionally, policy makers questioned if the pharmacists themselves understood their own role. Hence, the policy makers, doctors, nurses and pharmacists did not understand each others' scope of practice.

"I really (have) no idea what… (the pharmacist does)… (Laughs)."   *(DR-8/F/29y)*

Although the mutual acquaintanceship was low at level 1, the indicator trust achieved a moderate level 2. Despite not fully understanding the role of the pharmacists, stakeholders believed that the pharmacist had the knowledge and capabilities to conduct osteoporosis screening. However, other doctors' impression was that pharmacists were unable to

contribute in any manner except in medication supply and its cost.

"..certain doctors feel superior to (the) pharmacist... They (doctors) think all... (pharmacists)… know is just (the) names of the drugs and what is available here and how much it costs."   *(PHARM-5/F/29y)*

2.5.3.7   Governance

In relation to governance, the data showed weak centrality (level 1). There is a lack of directive from the upper management. According to the stakeholders interviewed upper management must become more involved to direct the implementation of a collective approach for an osteoporosis screening programme.

"It boils down to policy makers, what do they want us to do. Then we will do it."   *(PHARM-11/F/28y)*

There was no data to support innovation (level 1). Nor has it create the impression that there is expertise or funding to promote innovation in a collaborative process and thus provided the support needed to develop collaboration. Leadership exist but is unfocused and has little impact (level 2). The upper management gives the opportunity to the junior pharmacists to be innovative. However, the junior pharmacists are not ready to take up the opportunity.

"Our meeting ... (we) talked about (the) pharmacists' role and responsibilities and issues related to it… we want to see the young ones (pharmacists)… coming up.. we have to nurture them (young pharmacists)... But if they are not ready then it's going to be very difficult."   *(POL-3/M/57y)*

Connectivity is, as it were poor (level 1). Essentially there was a lack of communication between both the doctors and nurses with the pharmacists. Some of the interviewed participants mentioned that they have never spoken to a pharmacist and that the interviewer (TLS) was their first pharmacist encounter. Reasons identified were that pharmacists work mostly within the pharmacy area. They also were not integrated to participate in other hospital activities such as health awareness campaigns.

"... Our pharmacists (are) 'lock(ed) up' (at the pharmacy)."

(NUR-3/F/43y)

A similar situation was noted by the patients, there was minimum communication with the pharmacists. Communication was limited to the dispensing of medications. Some patients perceived the pharmacists to unapproachable as they were too busy.

"The pharmacist... I don't communicate with them, just by the numbers only, whatever... but the dispensing... is ok."

(PT-18/F/57)

2.5.3.8   Formalization

Analysis of the formalization dimension shows that there was no clear guideline pertaining to osteoporosis screening or protocol on the division of responsibilities between the healthcare professionals (level 1). Stakeholders mentioned that the guidelines were outdated. Protocols and directives on who should conduct screening were unavailable making healthcare professionals confused on what can be done.

"... Screening... I don't know... what... legislation... says about pharmacists... to educate people."

(DR-4/M/38y)

The channels for exchanging information were level 1 as there were separate divisional meetings. The meetings were held together with junior and senior staff. However, meeting were either held with pharmacists or nurses or doctors only. There was no inter-professional meeting. Therefore, this only resolves issues within the pharmacy and not aid in inter-professional collaboration.

"Our meeting is professional... irrespective of grade (junior/senior)... (we) talk about pharmacy role and responsibilities and issues related to it."(POL-3/M/57y)

To sum up this primary care clinic is in its early stages of inter-professional collaboration in osteoporosis management. It achieved level 2 in the sense that it is evolving but remains incomplete.

2.5.4 Discussion

Pharmacists were principally perceived by all participants to be suppliers of medication, although there was some recognition of roles in providing medication advice. Nonetheless, all the stakeholders were eager for pharmacists to be more proactive via inter-professional collaboration in counselling, creating awareness and screening of osteoporosis. Based on the D'Amour's model, this primary care clinic is described as developing towards an inter-professional collaboration in managing osteoporosis but is still in its early stages.

To our knowledge, there are no studies reporting on the perception of patients, nurses, pharmacists, doctors and policymakers with regard to the pharmacist's role in osteoporosis screening at the primary care setting. However there are numerous studies on community pharmacist perceptions on their role in osteoporosis screening which found similar results to our study. A study published in 1996 from Canada using a mailed survey found that only a few pharmacists reported routinely conducting prevention activities. However, over 90% believed it is important to integrate prevention into practice (O' Loughlin et al., 1999). Similarly another Canadian web based survey reported that pharmacists spend most of their time on dispensing duties but over 60% believed that the time had come to expand their role in areas such as disease prevention and health promotion (Jorgenson et al., 2011). This shows that the progression of the Malaysian pharmacists is similar to that of its overseas counterpart.

Various studies also concur that pharmacists are considered credibly for counselling as they are more easily accessible

(Chandra et al., 2003). They also have various knowledge and skill regarding various public health issues (Chandra et al., 2003, Anderson et al., 2009, MacLaughlin et al., 2005).

Additionally, a systematic review conducted on the beliefs and attitudes of pharmacist in relation to pharmaceutical public health showed that although most view public health services as important and part of their role, various organizational barriers (lack of time, integration, staff and trust) limit their involvement (Eades et al., 2011, George et al., 2010). Therefore, these results confirm that the profession largely accepts changing the role of pharmacists from traditional dispensing duties to include greater involvement in health promotion and prevention. Another interesting point is that perceptions of pharmacists have not changed much in more than 10 years. Although pharmacists largely believe that they should be doing more minimal changes to the profession has occurred over the past 10 years (Eades et al., 2011).

Conversely another survey where pharmacists were similarly questioned about public health issues, the majority of the respondents considered they should be involved in hypertension (82%), diabetes (76%) and smoking cessation (84%), only 44% and 34 % thought the same for osteoporosis and risk of fall respectively. These finding suggest that pharmacists may not regard osteoporosis and fall risk as being the highest importance (Laliberté et al., 2012). Indeed, the stakeholders in the present study admitted osteoporosis is not a priority. Given the demonstrated benefits of greater involvement in the management of osteoporosis, better ways must be found to translate this evidence based knowledge into the primary health care system (Laliberté et al., 2011).

Several studies have evaluated the effectiveness of primary care intervention to improve the management of osteoporosis. A recent meta analysis showed that these intervention (targeting at-risk patients, primary care physician and community pharmacists) may improve the management of osteoporosis but improvements are often modest (Laliberté et al., 2011). A Canadian study using self-administered questionnaires to community pharmacists and public health officers noted that although a majority of the pharmacists believed that they should be involved in osteoporosis screening (46.6%) and fall prevention (50.3%); however only 17.4% of the pharmacies reported being involved in this activity. The barriers noted in this study were similar to our study such as the lack of time (78.8%) and lack of coordination with other healthcare professionals (54.5%) (Laliberté et al., 2013). This suggests that the development of these intervention where health care professionals work as individual groups does not appear to be an efficient option to optimize health care .Therefore, the results of the present study provide important information on the development of osteoporosis care using inter-professional collaboration.

Although, research has shown that pharmacists can indeed improve the quality of health care delivery in areas such as improving prescribing, reduce healthcare utilization and medication cost and contributes to clinical improvements in many chronic medication conditions such as cardiovascular and diabetes (Dolovich et al., 2008, Machado et al., 2007a, Machado et al., 2007b, Nkansah et al., 2010). Even in the management of osteoporosis, integrating community pharmacists into osteoporosis management has results in an

increase in bone mineral density scan and calcium intake (Yuksel et al., 2010, McDonough et al., 2005, Crockett et al., 2008, Liu et al., 2007, Barris Blundell et al., 2006, Law and Shapiro, 2004, Goode et al., 2004). However, the pharmacists are not well integrated into primary care.

The areas for improvement based on the D'Amour model should be noted in order for an efficient osteoporosis screening programme to be established. At this point, we suggest that internalization (mutual acquaintanceship and trust), governance (connectivity) and formalization (information exchange) may be addressed by conducting a pharmacists-led osteoporosis screening programme. A study conducted by Dolovich et al (2008) integrated the pharmacists into the primary care practice to prevent drug-related issues. Feedbacks from the physicians were that they were able to recognize the benefits of working with pharmacists directly integrated into their practice. Physicians showed an increase perception and understanding towards the pharmacists' role. Pharmacists on the other hand recognized the need to improve their skills, be more proactive and improve communication with their fellow healthcare team members (Dolovich et al., 2008). An osteoporosis screening programme will foster opportunities to address these issues.

Other areas for improvement include governance (centrality and support for innovation) and formalization (no clear guidelines). We hope that with the success of the programme it will render more centrality, support for innovation and a clear guideline on osteoporosis screening. This is known as the bottom-up approach which has been shown to be effective in a study where leaders and professionals developed

interdependency, measured collective performances and communicated feedback. Such approach makes managers aware of the need for inter-professional collaboration. It helps facilitate leadership, increased transparency and collective control with benefits for both patients and providers (Hjalmarson et al., 2013). Given the increasing stress on the healthcare system due to an aging population and the consequent rise in the prevalence of osteoporosis, a more marked shift toward a wider public health role for pharmacists is indeed possible by incorporating inter-professional collaboration.

2.5.5 Conclusion

Although pharmacists were primarily seen as medication experts, the stakeholders unanimously agree that the pharmacy profession should shift towards being more patient-orientated approach. Inter-professional collaboration is needed to facilitate the expansion of the non-dispensing role in osteoporosis screening. Based on the D'Amour model our setting achieved level 2 which is developing towards inter-professional collaboration in managing osteoporosis but it is still in its early stages. There is room for improvement in the areas of internalization, governance and formalization. The pharmacy profession in Malaysia is gradually moving in the direction of its overseas counterparts where inter-professional collaboration in osteoporosis management is currently being practised. Efforts extending to awareness and acceptance towards the pharmacists role will be crucial for a successful change. Important changes cannot be envisioned without a real integration of community pharmacists into the public health primary care system.

2.6 Research question 3: Can a practical and sustainable osteoporosis screening programme be developed?

2.6.1 Introduction

We wanted to develop an acceptable, practical and sustainable osteoporosis screening programme. In order to answer this research question we used the theory of behaviour change wheel to design the intervention.

2.6.2 Methods

The third research question was explored concurrently with the first and second research question, as described previously. Although the research methods, data management and analysis were conducted exactly the same way, a different theoretical framework was used during the analysis. Hence, only the theoretical framework will be discussed for this section.

2.6.2.1 Theoretical framework: Behaviour change wheel (BCW)

The behaviour change wheel (BCW) theory was utilized as we wanted to develop an intervention to improve implementation of evidence-based health care. The changing of behaviour of the healthcare professionals, policy makers and others working within and with the healthcare system can improve the implementation of a complex intervention such as the osteoporosis screening programme. The BCW is a framework for analyzing target behaviours in the context of the setting and considering the full range of intervention functions and policy categories that may be relevant to the intervention problems [Figure 2.5] (Michie et al., 2011).

Figure 2.5: The behaviour change wheel (Michie et al., 2011)
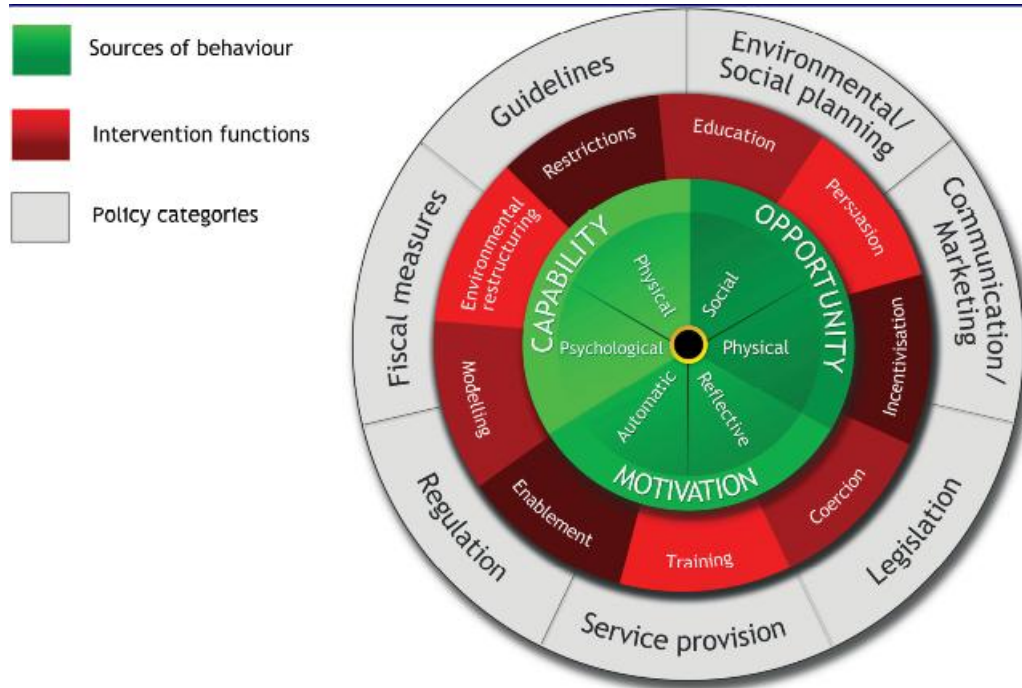
A systematic review of 19 published frameworks was used to derive the framework, none of the published frameworks were found to contain all the intervention functions known to be relevant to designing a behaviour change intervention. Therefore, the BCW was developed to provide a basis for identifying what it would take to achieve the desired behaviour change in terms of changes to capability, opportunity and motivation. This was called the COM-B system [Figure 2.6].

The definition of capabilities is an individual's psychological and physical capacity to engage in the activity concerned. It includes having the necessary knowledge and skills. For example, the capacity to engage in the necessary thought process such as comprehension and reasoning is a form of capability. As for opportunity it is defines as all factors that lie outside the individual that make the behaviour possible or prompt it. There were two types, physical opportunity and social opportunity. An example of this is cultural milieu that dictates the way the people think about things such as words and concepts that make up our language. With regard to motivation, it is defined as all those brain processes, emotional responses as well as analytical decision-making. Motivation is further distinguished from the reflective processes (involving evaluations and plans) and automatic processes (involving emotions and impulses that arise from associative learning and/or innate disposition). In Figure 2.6 the double arrows represents potential influence between the components of the system. To elaborate on this opportunity can influence motivation as can capability; enacting behaviour can alter capability, motivation, and opportunity (Michie et al., 2011).

Figure 2.6: The COM-B system- a framework for understanding behaviour (Michie et al., 2011)
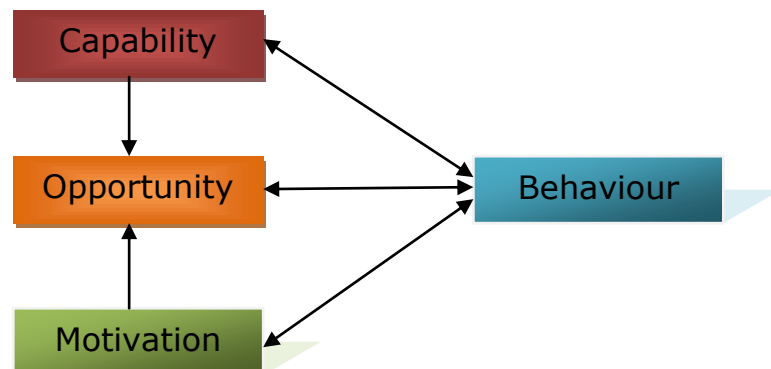
It then links this to nine intervention functions (education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement) and seven types of policy that could be used to implement these intervention functions (mass-media/marketing legislation, fiscal policy, service provision, guideline development, regulation and environmental/social planning). It forms the basis of a systematic analysis of how to make the selection of intervention and policies. Therefore, this assists in selecting the intervention function or functions most likely to be effective in changing the target behaviour. Table 2.9 presents the definition of the interventions and policies (Michie et al., 2011).

Table 2.9: Definitions of interventions and policies (Michie et al., 2011)

Intervention	Definition
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability or opportunity1

Policies	Definition
Communication/marketing	Using print, electronic, telephonic or broadcast media
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision
Fiscal	Using the tax system to reduce or increase the financial cost
Regulation	Establishing rules or principles of behaviour or practice
Legislation	Making or changing laws
Environmental/social planning	Designing and/or controlling the physical or social environment
Service provision	Delivering a service

1 Capability beyond education and training; opportunity beyond environmental restructuring.

The intervention strategy can then be provisionally established and specific types of behaviour change technique can be selected, guided by evidence, theory and practicalities to deliver the intervention [Table 2.10] (Michie et al., 2013).

Table 2.10: Taxonomy of 93 behaviour change techniques based on 16 clusters (Michie et al., 2013)

Cluster	Behaviour change technique (BCT)
Scheduled consequences	Punishment
	Response cost
	Chaining
	Extinction
	Discrimination training
	Shaping
	Negative reinforcement
	Counter-conditioning
	Thinning
	Differential reinforcement
Reward and threat	Social reward
	Material reward
	Self-reward
	Non-specific reward
	Threat
	Anticipation of future rewards or removal of punishment
	Incentive
Repetition and substitution	Behaviour substitution
	Habit reversal
	Habit formation
	Graded task
	Overcorrection
	Behavioural rehearsal/practice
	Generalization of a target behaviour
Antecedents	Restructuring the physical environment
	Restructuring the social environment
	Avoidance/changing exposure to cues for the behaviour
	Distraction
Associations	Discriminative (learned) cue
	Time out
	Escape learning
	Satiation
	Exposure
	Classical conditioning
	Fading
	Prompts/cues
Covert learning	Vicarious reinforcement
	Covert sensitisation
	Covert conditioning
Natural consequences	Health consequences
	Social and environmental consequences
	Salience of consequences

	Emotional consequences
	Self-assessment of affective consequences
	Anticipated regret
Feedback and monitoring	Feedback and behaviour
	Biofeedback
	Other (s) monitoring and awareness
	Self-monitoring of outcome of behaviour
	Self-monitoring of behaviour
Goals and planning	Action planning (including implementation intentions)
	Problem solving/ coping planning
	Commitment
	Goal setting (outcome)
	Behavioural contract
	Discrepancy between current behaviour and goal standard
	Goal setting (behaviour)
	Review behaviour goal(s)
	Review outcome goal(s)
Social support	Social support (practical)
	Social support (general)
	Social support (emotional)
Comparison of behaviour	Modelling of the behaviour
	Information about others' approval
	Social comparison
Self-belief	Mental rehearsal of successful performance
	Self-talk
	Focus on past success
	Verbal persuasion to boost self-efficacy
Comparison of outcomes	Persuasive arguments
	Pros and cons
	Comparative imagining of future outcomes
Identity	Identification of self as role model
	Self-affirmation
	Identity associated with changed behaviour
	Reframing
	Cognitive dissonance
Shaping knowledge	Reattribution
	Antecedents
	Behavioural experiments
	Instructions on how to perform a behaviour
Regulations	Regulate negative emotion
	Conserving mental resources
	Pharmacological support
	Paradoxical instruction

The authors recommend to start by understanding the problem, identifying key specific behaviours (often several) by asking questions of who needs to do what differently, when, where and how. Behavioural change can occur at different levels in healthcare such as with patients, with healthcare professional and at an organisational level. Next they recommended understanding the behaviours in the context whereby the COM-B model can be used to answer questions such as why the behaviours are as they are and what needs to change for the desired behaviour to occur (Michie et al., 2011).

Subsequently the developers need to consider the full range of possible intervention using the behaviour change wheel to select broad categories of intervention type. Then identify specific behaviour change techniques that can be selected to achieve the behaviour change (Michie et al., 2011).

The developers then need to decide on the mode of delivery which could be face-to-face (individually/group) or distance (population level using media or individually tailored such as phone calls). Additionally, when selecting an intervention, mode of delivery and policy categories, issues such as evidence of effectiveness, local relevance, practicability, affordability and acceptability (public, professional and political) should be considered. Figure 2.7 summarizes this process. This model is well tested and has been shown to be useful in evaluating the 2010 English government tobacco control strategy and the National Institute for Health and Care Excellence (NICE) obesity guideline. Therefore, we have decided that this is the most suitable theory to develop the

pharmacists-led osteoporosis screening programme (Michie et al., 2011).

Figure 2.7: Summary of approach to developing behaviour change intervention

Target behaviour	Design intervention	Deliver intervention

```
┌──────────────┐
│ Select target│
│  behaviour   │
└──────────────┘
        │
        ▼
   ┌──────────────┐
   │   Specify    │
   │ (Who, what,  │
   │ where, how)  │
   └──────────────┘
           │
           ▼
      ┌──────────────┐
      │  Understand  │
      │    (Why)     │
      └──────────────┘
              │
              ▼
         ┌──────────────┐
         │ Intervention │
         │  functions   │
         └──────────────┘
                 │
                 ▼
            ┌──────────────┐
            │  Behaviour   │
            │   change     │
            │  techniques  │
            └──────────────┘
                    │
                    ▼
               ┌──────────────┐
               │   Mode of    │
               │   delivery   │
               └──────────────┘
                       │
                       ▼
                  ┌──────────────┐
                  │   Policy     │
                  │  categories  │
                  └──────────────┘
```

171
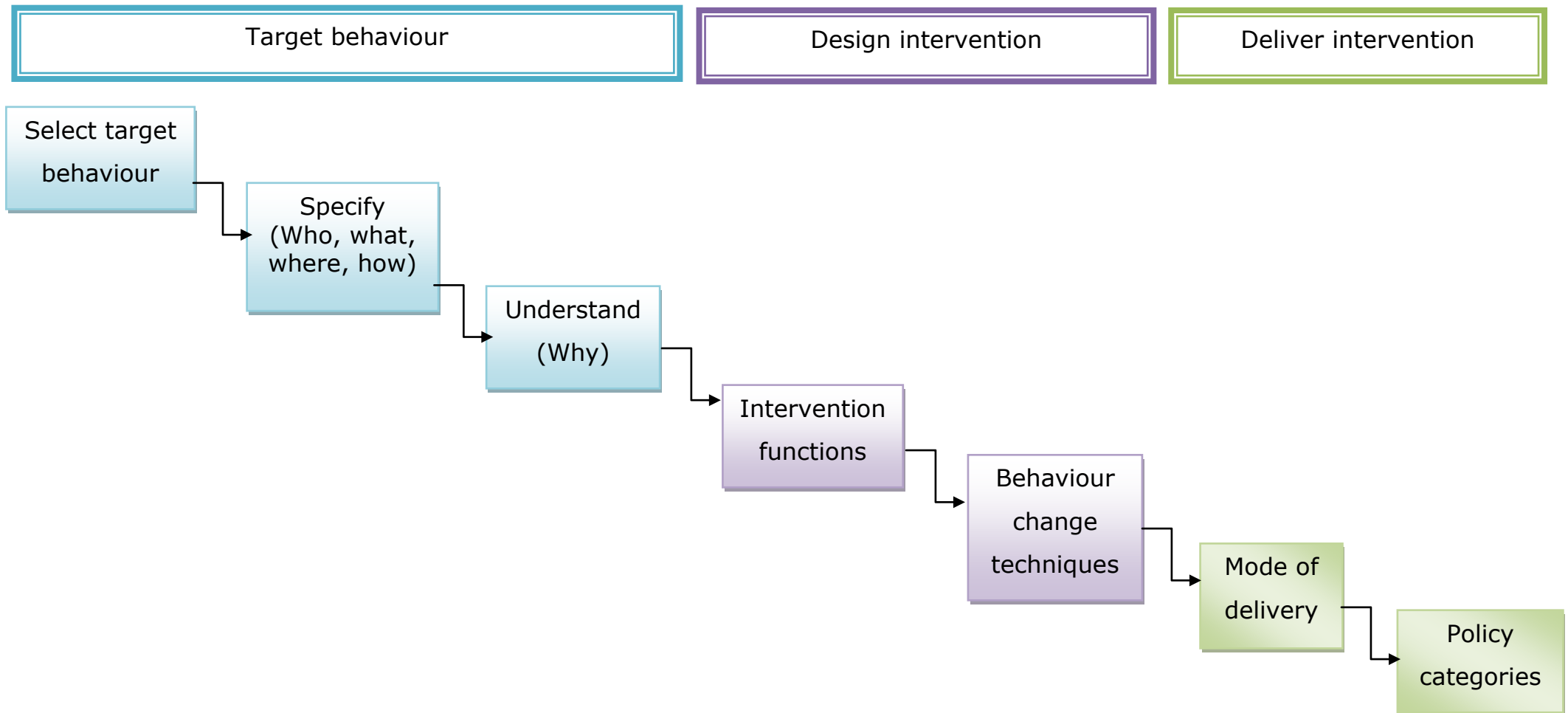
2.6.3 Results

2.6.3.1   Participants' characteristic

Please refer to section 3.4.2.1and Table 3.2 for the participants' characteristics.

2.6.3.2   The development of a pharmacist-led osteoporosis screening programme

For our study, the intervention efforts are targeted at the barriers of patient factors. Based on the framework of factors influencing clinical practice, patient factors most directly influence the practice and outcome and the probability of an incident (Vincent et al., 1999). Additionally targeting other levels of the healthcare system would be beyond the scope of this PhD. Table 2.11 displays the barriers from the patient factors, the target behaviours derived from the barriers followed by identification of the cause using the COM-B model. The BCW was then used to pick the intervention functions, specific behaviour change techniques and policy category.

Table 2.11: Intervention functions, behaviour change techniques and policy categories used to address the patient factors

Patient factors	Target behaviour	Understanding of the behaviours based on the COM-B model	Intervention function	Behaviour change technique	Policies category
Condition (complexity and seriousness)					Environmental/ social planning
• Osteoporosis is perceived to be not serious	• Patients to understand that untreated osteoporosis can be life threatening	• Psychological capability • Reflective motivation	• Education • Environmental restructuring	Shaping knowledge • Provide information on consequences of untreated osteoporosis Antecedents • Restructuring the physical and social environment by implementing an osteoporosis screening	• Developing a practical and sustainable osteoporosis screening programme
Personality					
• Nonchalant attitude towards osteoporosis	• Patients willing to conduct osteoporosis screening and prevention measures	• Psychological capability • Automatic motivation	• Education • Persuasion • Environmental restructuring	Shaping knowledge • Provide information about osteoporosis Comparison of outcomes • Persuasive arguments on benefits of	

				screening and prevention Antecedents Restructuring the physical and social environment by implementing an osteoporosis screening	
Unwilling to listen to the healthcare professionals advice	Patients to trust healthcare professionals	Social opportunity	Environmental restructuring	Antecedents Restructuring the physical and social environment by implementing an osteoporosis screening programme	
Knowledge					
Lack of knowledge	Improve all aspects patients knowledge towards osteoporosis	Psychological capability	- Education - Environmental restructuring	Shaping knowledge - Provide information about osteoporosis Antecedents - Restructuring the physical and social environment by implementing an osteoporosis screening	

Communication					
• Language barrier	• Create opportunities to communicate information regarding osteoporosis	• Social opportunity • Physical opportunity	• Environmental restructuring	Antecedents • Restructuring the physical and social environment by implementing an osteoporosis screening	
Social factors					
• Financial constraints	• Affordable osteoporosis screening and medications	• Reflective motivation • Physical opportunity	• Environmental restructuring • Enablement	Antecedents • Restructuring the physical and social environment by implementing an osteoporosis screening Social support • Social support (financial)	
• Time constraints	• Ensure the osteoporosis screening programme is conducted at a time convenient for the patients	• Reflective motivation • Physical opportunity	• Environmental restructuring • Enablement	Social support • The osteoporosis screening programme to be conducted at a practical time for the patients Antecedents • Restructuring the physical and social environment by	

				implementing an osteoporosis screening	
• Short consultation time	• Ensure sufficient time for consultation regarding osteoporosis	• Social opportunity • Physical opportunity	• Environmental restructuring • Enablement	Social support • Sufficient consultation time Antecedents • Restructuring the physical and social environment by implementing an osteoporosis screening	
• Family circumstances	Ensure that the osteoporosis screening programme is accessible to the patients	• Physical opportunity	• Environmental restructuring • Enablement	Social support • The osteoporosis screening programme to be conducted at a practical time for the patients Antecedents • Restructuring the physical and social environment by implementing an osteoporosis screening	

Difficulty to adhere to osteoporosis prevention measure					

Difficulty to adhere to osteoporosis prevention measure	• Ensure patients difficulty to adhere to osteoporosis prevention measure is addressed	• Physical capability
		• Reflective motivation
		• Automatic motivation
			• Education
			• Enablement
			• Environmental restructuring
				Shaping knowledge
				  • Provide instruction on how to perform preventive measures
				Goals and planning
				  • Prompt barrier identification
				Antecedents
				  • Restructuring the physical and social environment by implementing an osteoporosis screening	

2.6.3.3   Intervention function
2.6.3.3.1 Environment restructuring

We addressed all the patient factors using the intervention function environmental restructuring via the BCT antecedents. Antecedents involved restructuring the physical and social environment of the primary care clinic by implementing a pharmacists-led osteoporosis screening programme. Restructuring of the physical environment of the primary care clinic refers to incorporating the programme as one of the clinic services. This restructures the social environment by allowing both patient and healthcare professionals to communicate regarding osteoporosis screening. The osteoporosis screening programme was tailored to execute various BCT directed at the patients' factors which will be elaborated in sections below.

Additionally, the BCT antecedent allows the healthcare professionals to address the issue of language barriers which are caused by the lack of physical and social opportunity (COM-B model). Physical opportunity refers to the lack of a physical opportunity for the patients to undergo osteoporosis screening. Social opportunity refers to the lack of opportunity for the patients to communicate with the healthcare professionals. By conducting an osteoporosis screening programme, the health care professionals will be able to prepare the osteoporosis information in various languages and communicate with a larger population. The patients will have an opportunity to conduct osteoporosis screening.

"... So (we) have to address (this)... larger ethnic groups, that are maybe Mandarin, or... English, then BM (Malay), Tamil (speaking)... So that... they can read and maybe they would understand, after that they can do something about it."

(DR-2/M/30y)

Another barrier which was addressed by this BCT was the patients' unwillingness to listen to the healthcare professionals' advice. By conducting the osteoporosis screening programme, the healthcare professionals will be able to communicate with the patients more addressing the lack of social opportunity. Therefore, they can gain the patients' trust by proving their capabilities and creating rapport with the patients, increasing their willingness to listen to advice.

"... A bonding... So they will tell us all these things. So they will come." (DR-6/F/48y)

2.6.3.3.2 Education

We found that other aspects of the patient factors: condition, knowledge, personality and difficulty to adhere to osteoporosis preventive measure can be addressed in more detail using an educational intervention via the BCT of shaping knowledge. Based on the COM-B model we evaluated that the patients' lack of osteoporosis knowledge factor was affected by the lack in psychological capability. A lack of psychological capability in this case refers to the lack of osteoporosis knowledge. We aimed to improve all aspects of the patients' osteoporosis knowledge.

As for the patient factor condition, patients perceived osteoporosis as not to be serious condition. We evaluated it to be caused by the patients' lack of psychological capability and reflective motivation from the COMB-B model. Due to the lack of knowledge on the consequences of untreated osteoporosis, patients evaluated osteoporosis to be a not serious condition. This in turn affected the patients' personality whereby they took a nonchalant attitude towards osteoporosis. We evaluated this issue to be due to the lack of psychological capability and automatic motivation from the COM-B model. As a lack of osteoporosis knowledge led to patients acting nonchalantly due to an innate dispositions such as perceiving osteoporosis to be not life threatening.

Correspondingly, patients' difficulties in adhering to osteoporosis preventive measures may be caused by a lack of psychological capability, physical capability, reflective motivation and automatic motivation. To elaborate on this, patients may have had difficulty to conduct weight-bearing exercises. Hence, it became an unpleasant activity as patients may feel pain leading to a reduction in motivation. Patients will then evaluate the preventive measures to be too difficult to adhere too. Educating patients will equip them with the knowledge on osteoporosis preventive measures suitable for their physical condition overcoming its difficulties.

Therefore, based on stakeholders' suggestions we developed a counselling session that was delivered by the pharmacist. Patients would receive 30 minutes of verbal counselling. Topics

covered during the counselling session were the definition of osteoporosis, consequences of untreated osteoporosis, risk factors for osteoporosis, the role of the BMD scan (its function, what the results mean, accessibility and the frequency a patient has to go for a BMD scan), other tests used in osteoporosis screening [quantitative ultrasound scanning, x-ray, blood test and the Osteoporosis Screening Tool for Asians (OSTA)], lifestyle changes (calcium intake, vitamin D intake, weight bearing exercise and fall prevention), and treatment of osteoporosis. Additionally particular emphasis was given to the consequences of untreated osteoporosis and how to conduct osteoporosis preventive measures.

"I think you should counsel, counsel people because sometimes people are not aware of the importance of osteoporosis."

(PT-10/F/62y)

Strategies to conduct the counselling session include using lay terms, pictorial descriptions and providing the patients with an osteoporosis booklet. Therefore during the counselling session an osteoporosis booklet was provided to the patients. This information booklet also allowed the pharmacists to engage the patients and assist the patients to visualize the information. Additionally, the patients were able to take the leaflet home with them and reread the information. Please refer to Appendix 24 for the osteoporosis booklet.

"(I need osteoporosis information) pamphlets, simple thing that we can understand. Not too scientific." (PT-15/F/55y)

2.6.3.3.3 Persuasion

We used the intervention function persuasion to address the additional aspect of the patients' nonchalant attitude caused by the automatic motivation. This was achieved using the BCT whereby we compared the outcomes and use persuasive arguments on the benefits of osteoporosis screening and prevention specific to a patient. Stakeholders believed that an individualize counselling session would increase the effectiveness of the counselling session as it is easier for the patients to communicate as compared to a group counselling session. By individualizing the counselling sessions we can tailor the session based on the patients' education background and address personal issues regarding osteoporosis screening and prevention.

"If one to one session, I think they will... want to do it (osteoporosis preventive measure)... (it is) different... when we (compare with) dispens(ing) at the counter and (when) we talk to them personally. They will easily open up. They will tell us the problem." (PHARM-3/F/25y)

2.6.3.3.4 Goals and planning: Prompt barrier identification

Additionally, in order to address the aspect of reflective and automatic motivation from the factor 'difficulty to adhere to preventive measures'. We used another intervention function called enablement where we used the BCT 'prompt barrier identification when conducting an osteoporosis preventive measure.' The pharmacist would discuss potential barriers (pain

while exercising, funding, lactose intolerant etc) of conducting the osteoporosis preventive measure with the patients. This enables the pharmacists to tailor an osteoporosis preventive regimen suitable to the patient.

"When patients... asks 'Should I take calcium?' 'Should I take vitamin D?'… If you are wealthy enough, you want to take tablets, go ahead... If you are not so wealthy, you have... ten tablets to take… I would say enough. But if you can actually cope with your amount of medication... why not?" (PHARM-9/F/27y)

2.6.3.3.5 Social support

2.6.3.3.5.1   Social support: Osteoporosis risk assessment tools

We evaluated the financial constraints that were influenced by physical opportunity and reflective motivation. We addressed the lack of physical opportunity by using the intervention function enablement. The issue with the financial constraints is the cost of the BMD scan and medication. Therefore we provided an osteoporosis risk assessment tool which screens for patients who are at high risk for osteoporosis. The risk assessment tool is a simple and quick calculation using the patients' weight and age. This allows the hospitals resources such as the BMD scan and funding for the scans and medications to be used more effectively leading to more accessible osteoporosis screening for these patients. By giving the patients the opportunity to go for a free screening they will then evaluate that their finances can afford an osteoporosis scan thereby addressing the aspect of reflective motivation.

"If it's free... if you give me (a chance to go for osteoporosis screening). I don't mind going."   *(PT-20/F/62y)*

2.6.3.3.5.2   Social support: The osteoporosis screening programme to be conducted at a practical time for the patients

Similarly, the barrier of patients' time constraints and family circumstances to attend the screening programme was affected by physical opportunity and reflective motivation. We addressed the lack of physical opportunity by using the intervention function enablement. Therefore, we decided to conduct the osteoporosis screening programme during the waiting time for the doctor's appointment. The waiting can be one to three hours. By using this time frame we did not extend the patients' time at the hospital nor did we need the patient to come to the hospital multiple times. This will hopefully lead to the patients positively evaluating the feasibility of going for the osteoporosis screening addressing the aspect of reflective motivation.

"There should be (information and osteoporosis screening), maybe at the clinic while we (are) wait for the doctor ('s) (appointment)." (PT-15/F/55y)

2.6.3.3.5.3   Social support: Sufficient consultation time

One of the patient factors was the lack of consultation time. We evaluated this to be caused by the lack of social opportunity and physical opportunity. Therefore by conducting a pharmacist-led

osteoporosis screening programme during the waiting time for the doctor's appointment we would have created an opportunity for the patients to discuss issue pertaining to osteoporosis. The pharmacists will be able to spend the time to communicate and address any issues that the patients may have. We allocated about 15-30 minutes per patients.

"... The patient comes in, first (they) see the pharmacist, catch them, do the risk assessment... Just write in there (case notes) high risk, so the doctor is aware. Because we usually as doctors we don't so much... time with the patient, with the work load especially. So it will be a good thing." (DR-6/F/48y)

2.6.3.4   Policy category
2.6.3.4.1 Environmental/social planning: Developing a practical and sustainable osteoporosis screening programme

For our study the type of policies that can be used to implement the pharmacist osteoporosis screening programme is the policy category environmental/social planning. This involves designing and/or controlling the physical and social environment. Stakeholders emphasized that the planning of the programme was crucial. We needed to develop a practical, acceptable and sustainable osteoporosis programme. They suggested that in order for the programme to be a success upper management approval and support was essential.

"That's why must speak to the specialist, we must, make an appointment to go and see this osteoporosis specialist, talk to

them, encourage them to have this type of campaign... Only
these people who can start these campaigns." (NUR-6/F/55y)

2.6.4 Discussion

Using the behavioural change wheel to address barriers from the patients' factors we identified four key intervention components: environment restructuring, education, persuasion and enablement. This referred to the restructuring of the environment that was the need to develop and implement an osteoporosis screening programme by empowering the patient with osteoporosis knowledge. The programme should also be conducted one-on-one with the patient to incorporate the persuasion aspect of the intervention and conducted a time convenient to patients without burdening the patients financially. All these key intervention components were used to develop an acceptable, practical and sustainable osteoporosis screening programme in a primary care clinic.

We compared the BCW to other approaches such as the Theory of Planned Behaviour and Health Belief Model (Ajzen, 1991, Rosenstoack et al., 1988). We agreed with the BCW authors that both these theories do not address the important role of impulsivity, habit, self-control, associative learning and emotional processing. The BCW model includes automatic processing which broadens the understanding of behaviour beyond the reflective, systematic cognitive process that is normally focused of most behavioural research in implementation science and health psychology (Michie et al., 2011). These aspects have been

considered in the BCW making it a comprehensive theory used for intervention design.

Additionally, the behavioural change wheel may be incorporated into the context very naturally. By context we mean the 'opportunity' component of the model. This means that the behavioural can only be understood in relation to context making it a good starting point (Michie et al., 2011).

The BCW was then compared to other frameworks such as MINDSPACE. MINDSPACE is a checklist for policymakers of the most important influences on behaviour from the UK's Institute of Government (Institute for Governement, 2010). However this framework recognises two systems by which human behaviour can be influenced, the reflective and automatic. But it focused on the automatic part of the human behaviour and does not attempt to link influences on behaviour with these two systems making it incoherent. The BCW manages to link these two systems using the COM-B model (Michie et al., 2011).

As for intervention mapping, a key difference between this and the BCW approach is that the intervention mapping aims to map behaviour on to its 'theoretical determinants' in order to identify potential levers for change (Bartholomew et al., 2011). However the BCW approach recognises that the target behaviour system can in principle arise from combinations of any of the components of the behaviour system (Michie et al., 2011).

A search of published literature found several randomized controlled trials (RCTs) for osteoporosis screening services. These RCTs were conducted by various healthcare professionals such as primary care physicians,(Gardner et al., 2005, Rozental et al., 2008) orthopaedic surgeons, (Rozental et al., 2008, Miki et al., 2008) pharmacists (Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005) and nurses.(Majumdar et al., 2007). All of these interventions had similar components to our interventions in the sense that they all had an education component, osteoporosis risk assessment; the services were provided for free at a time convenient to the patients. However, the rationale for the intervention used was often unclear. Only four studies reported that the intervention was tailored to identified barriers (Gardner et al., 2005, Majumdar et al., 2007, Majumdar et al., 2008, Cranney et al., 2008). Nonetheless, all interventions demonstrated a positive effect towards bone mineral density (BMD) scanning and osteoporosis treatment post fracture. (Majumdar et al., 2007, Miki et al., 2008, Rozental et al., 2008, Gardner et al., 2005, Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005).

Strengths of this study were that our intervention was informed by a theory. It has been hypothesised that interventions informed by psychological theory show greater efficacy than non-theory based studies. This is because theory driven interventions are more likely to target theoretically consistent or empirically supported mechanisms of behaviour change (Craig et al., 2008). However, interventions described as theory-based often have an unclear foundation (Michie et al., 2009). Although guidelines

from the UK MRC framework for complex intervention advocates drawing on theory in intervention design, it does not specify how to select and apply theory(Craig et al., 2008). There is often no analysis undertaken to guide the choice of theories. Therefore, we found the BCW to be a systematic and comprehensive theory enabling us to clearly outline which intervention affects a specific behaviour.

Limitations of this study include that we have tailored it specifically to the local setting and it may not be generalizable to other setting. Another criticism is that the area of intervention is too complex and the constructs may still be too ill-defined to be able to establish useful, scientifically based evidence. The authors of the BCW also note that no framework can address the level of detail required to determine what will or will not be an effective intervention. However, they suggest that these are empirical questions and there is already evidence that character intervention by BCT can aid in the understanding and identifying which intervention are more or less effective (Michie et al., 2009, Michie et al., 2011, West et al., 2010).

2.6.5 Conclusion

In conclusion, based on the BCW we have systematically identified four intervention (environment restructuring, education, persuasion, enablement) components to develop an acceptable, practical and sustainable osteoporosis programme.

3 CHAPTER 3: PHASE TWO DEVELOPMENT AND VALIDATION OF TOOLS AND INTERVENTION PACKAGES USED FOR THE PHARMACIST-LED OSTEOPOROSIS SCREENING PROGRAMME

3.1 Introduction

This chapter is divided into four sections. It describes the development and validation of the Satisfaction Questionnaire for Osteoporosis (SQOP) and the Osteoporosis Prevention and Awareness Tools (OPAAT) which were used to evaluate the pharmacist-led osteoporosis screening programme. Additionally, this chapter presents the validation and comparison of six osteoporosis risk assessment tools for the Malaysian postmenopausal women. Then, it explains the development of a pharmacist-led osteoporosis screening.

3.2 Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

3.2.1 Introduction

3.2.1.1 Importance of measuring satisfaction

Patient satisfaction may potentially be used to evaluate current preventive efforts and to predict patients' adherence to preventive advice (Pascoe, 1983). The shift from healthcare provider centred care to more patient centred care emphasizes the need to evaluate humanistic outcomes such as patient satisfaction.(Gourley and Duncan, 1998). The rating of

satisfaction by patients is a personal evaluation of healthcare services and providers (Hardy et al., 1996, Ware et al., 1983). Patient satisfaction serves as an important determinant of the viability and sustainability of health care services (Johnson et al., 1997).

Due to the asymptomatic nature of osteoporosis, women who have osteoporosis are often not aware that they are at an increased risk of sustaining a fracture (International Osteoporosis Foundation, 2009). Prevention measures and screening which aid in early detection are the most cost-effective ways to reduce the number of hospital admittance due to osteoporotic fractures. Evidence shows that satisfied patients are more likely to continue using healthcare services, value and maintain relationships with health care providers, follow the advice of the healthcare professionals, adhere to treatment and have better health outcomes which in this case is a reduction in fracture rates (Locker and Dunt, 1978, Pascoe, 1983).

Evaluating satisfaction can also assist healthcare professionals to provide healthcare services more effectively. Patient evaluations will help identify patients' needs, perceptions, concerns and areas of service failure. This in turn may encourage health care providers to be accountable for the quality of service delivered which ensures continuous monitoring and improvement in health care delivery (Ford et al., 1997).

3.2.1.2 Randomized controlled trials performed on osteoporosis screening services

A search of published literature found several randomized controlled trials (RCTs) for osteoporosis screening services. These RCTs were conducted by various healthcare professionals such as primary care physicians,(Gardner et al., 2005, Rozental et al., 2008, Majumdar et al., 2008, Feldstein et al., 2006, Mudano et al., 2013) orthopaedic surgeons, (Rozental et al., 2008, Miki et al., 2008) pharmacists (Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005) and nurses.(Majumdar et al., 2007). All interventions demonstrated a positive effect towards bone mineral density (BMD) scanning and osteoporosis treatment post fracture (Majumdar et al., 2007, Miki et al., 2008, Rozental et al., 2008, Gardner et al., 2005, Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005).

However, only four studies assessed patient satisfaction. Of these studies, only two studies used a validated tool. One of the tools used was the Patient Satisfaction Questionnaire (PSQ-18) (Majumdar et al., 2008) it was a generic satisfaction questionnaire. The second tool used was the Osteoporosis Patient Satisfaction Questionnaire (OPSQ)(Lai et al., 2010), whilst the other studies did not provide information on how they measured patient satisfaction(Feldstein et al., 2006, Mudano et al., 2013). This highlights two facts, many studies did not assess patients' satisfaction using a validated tool and many studies did not assess patient satisfaction as an outcome (Lai et al., 2013, Majumdar et al., 2008).

3.2.1.3 Tools to assess satisfaction in osteoporosis

Three tools have been developed globally to assess satisfaction pertaining to osteoporosis and its treatment (Gold et al., 2011, Flood et al., 2006, Lai et al., 2010). Of which, two were developed and validated in the United States (Flood et al., 2006, Gold et al., 2011), whilst one was developed in Malaysia (Lai et al., 2010). The Osteoporosis Patient Treatment Satisfaction Questionnaire (OPSAT-Q) contains 16-items with four domains: convenience, confidence with daily activities, side effects and overall satisfaction. OPSAT-Q was used to evaluate patients' satisfaction towards biphosphonates treatment for osteoporosis and osteopenia. Convenience, confidence with daily functioning and overall satisfaction are rated on a 7-point Likert-like scale where as side effect was rate on a 5-point bother scale.

The second tool was called the Preference and Satisfaction Questionnaire (PSQ) to evaluate the preference, satisfaction and bother with a weekly oral tablets versus a once every 6 months subcutaneous injection for treatment of postmenopausal bone loss. The PSQ was a 20-item questionnaire with five domains: pill satisfaction, injection satisfaction, pill bother, injection bother and preference for pill or the injection.

The Osteoporosis Patient Satisfaction Questionnaire (OPSQ) was a 16-items questionnaire developed to assess the opinion of postmenopausal osteoporosis women towards pharmaceutical care. It has two domains (satisfaction on delivery of pharmaceutical care and usefulness of the counselling session)

and used a five-point Likert-like scale. However, all these satisfaction tools were not suitable to assess the satisfaction of patients of an osteoporosis screening and prevention programme, as their focus was on osteoporosis and its treatment.(Lai et al., 2010, Gold et al., 2011, Flood et al., 2006) To date, no instrument has been developed and validated specifically to assess patients' satisfaction towards an osteoporosis screening and prevention programme in Malaysia.

3.2.2 Objectives

To develop and validate the English version of the SQOP to evaluate patients' satisfaction towards an osteoporosis screening and prevention programme in Malaysia.

3.2.3 Methods

Based on the UK MRC framework, it is imperative to assess the effectiveness of an intervention conducted. Therefore, this section presents the development and validation of a satisfaction questionnaire called the SQOP will be used as one of the methods to evaluate the osteoporosis screening and prevention programme.

3.2.3.1 Quantitative methods

Quantitative methods are employed to investigate frequencies of events involving calculation of summary statistics, to establish the proportion of a population who hold certain views or have had particular experiences or to compare differences in outcomes between groups (Smith, 2010).

In our study we needed an instrument to measure the satisfaction level of patients' towards an osteoporosis screening and prevention programme. Such a tool is currently unavailable. In the following section, I shall discuss the quantitative research method that was adopted to develop and validate the questionnaire.

3.2.3.2 Questionnaires

Survey research using questionnaires provides a quantitative or numeric description of trends, attitudes, or opinions of a population by studying a sample of that population (Creswell, 2009). The strength of survey research using questionnaires are useful for collecting factual information from large samples relatively cheaply in a reasonably short time, well structured questionnaires can collect the relevant information in a systematic way(Smith, 2010). Structured questionnaires involve questioning respondents in a highly standardized manner using a precise sequence and wording of questions. The methods of recording answers are specified in advance on the questionnaire (Campbell et al., 1999). Survey questionnaires should be acceptable and attractive to potential respondents by being reasonable in length and well-presented (Smith, 2002).

Surveys can be designed to measure events, behaviour and attitudes of the population of interest. These types of surveys are called descriptive surveys, as the information is collected from the population and descriptive measures are calculated. Data collected from the population at one point in time are called cross sectional surveys. Most cross sectional studies collect data by

recalling the past and are known as retrospective surveys. However, retrospective studies are frequently criticised for potential recall bias where respondents may be selective in recalling the past. Nonetheless, descriptive surveys are a relatively cheap data collection method in terms of time and resources, as large numbers of people can be surveyed relatively quickly, compared to longitudinal studies in which a sample is followed up over a period of time (Bowling, 2009).

Another type of survey aims to investigate casual associations between variables and is carried out at more than one point in time. These types of analytical surveys are called longitudinal surveys. Most longitudinal surveys collect data prospectively over a specified period of time. Prospective, longitudinal surveys require careful definitions of the study group, variables for measurement, data collection frequency of time intervals and response rates need to be high. This method is of value for studying the effects of new interventions (Bowling, 2009).

Surveys can be conducted via self-administration, personal interview, telephone, postal or internet (Smith, 2010, Bowling, 2009). Self-administering questionnaires often use closed ended questions and if well constructed they are easier and quicker for respondents to answer and are also easier for the researcher to code and incorporate into quantitative analysis (Smith, 2010). Personal interviews are normally used for less structured instruments which often comprises of open ended questions allowing for more complex questions, flexibility and clarifications of misunderstanding (Smith, 2010, Vaus, 2002). However,

interviews are more laborious. In addition, there are several limitations that needs to be considered including the cost, issue of anonymity, unwillingness of respondents to reply honestly to certain questions and an inability to control behaviour which interviewers may introduce reporting bias (Vaus, 2002, Campbell et al., 1999, De Leeuw, 2005). Many questionnaires that are designed for self-completion can also be used in interviews to optimize respond rates (Smith, 2010, De Leeuw, 2005).

Questionnaires can also be administered via the telephone or mail. In general, these types of methods are more suited for a structured questionnaire. Administration over the telephone has an advantage over postal administration as they data can be collected quicker, than waiting for the questionnaires to arrive by post. Telephone interviews are best arranged in advance at a time convenient for the interviewee. Email and internet are options that have become increasingly used as a data collection method (Smith, 2010).

For this phase of the study, we needed a questionnaire to measure the satisfaction level of the patients towards an osteoporosis screening and prevention programme. Therefore, we developed and validated a structured longitudinal questionnaire for self-administration. Self-administration was chosen to ensure that it is practical to be used in future daily practice. The researcher assisted participants who encountered difficulty in reading the questionnaire themselves. At retest, the questionnaire was administered over the telephone, so that

participants need not make a second trip to the hospital just to answer the questionnaire (De Leeuw, 2005).

3.2.3.3 Development of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

The SQOP was developed based on modifications from the Osteoporosis Patient Satisfaction Questionnaire (OPSQ) and findings from Phase one qualitative study which examined the barriers and needs towards an osteoporosis screening and prevention service in Malaysia.

3.2.3.3.1 Language

The SQOP was developed in English. Despite Malay being the national language of Malaysia, postmenopausal women aged 50 years residing in Malaysia are more fluent in English as schooling was only conducted in the English language then.

3.2.3.3.2 Modification from the Osteoporosis Patient Satisfaction Questionnaire (OPSQ)

Of the 16 items in the OPSQ, 9 items were removed. Eight of these items were on satisfaction related to osteoporosis medication, whilst one item was on a follow up visit. Four items from the OPSQ were rephrased. In item 2, the word 'session' was used instead of 'appointment' as we did not set appointments with the participants. For item 7 'How useful was the service provided by the pharmacist in this study?' was considered leading and was rephrased to 'How would you rate the advice given by the pharmacist?' The word overall was added to item 9: 'How would you rate the 'overall' quality of service that was

given by the pharmacist to you?' to make the question more specific. The original question for item 18 was 'How would you rate your understanding of osteoporosis since you participated in the study?' was modified to 'How would you rate your understanding of osteoporosis now?' as we wanted the questionnaire to be used in clinical practice after the completion of our study. Three items were retained from the OPSQ without any modifications.

3.2.3.3.3   Development of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP) based on the qualitative data in Phase one

Based on the results from our qualitative findings (Phase one: Barriers to an osteoporosis screening programme) we categorized the factors to the following domains which may influence patients' satisfaction when utilizing an osteoporosis screening and prevention service: outcomes/efficacy, accessibility/convenience, technical quality, interpersonal relationship, finance and continuity.

A literature search noted that these domains were similar to those recommended by Ware et al. (1983) they developed a 55 item Patient Satisfaction Questionnaire (PSQ) to measure patient satisfaction in general with specific feature of care. The PSQ represents the content of characteristics of providers and services described most often in the literature and in response to open ended-questions. However, the model developed by Ware et al. (1983) had an additional domain (physical condition and

availability). Hence, the domain of physical condition was also included in the SQOP. However, the domain availability was not included as the service was not yet available at the current setting and will not be relevant to our participants. Table 3.1 displays the definition of each domain.

Table 3.1: The definition of the domains of the Satisfaction
Questionnaire for Osteoporosis Prevention (SQOP) and the
factors addressed based on Phase one results

Domain	Definition	Factors addressed
Outcomes/ efficacy	The results of medical care encounters (e.g., helpfulness of medical care providers in improving or maintaining health).	Patient factor: Osteoporosis is perceived to be not serious Osteoporosis is perceived to be not serious Knowledge Difficulty to adhere to osteoporosis prevention measure
Accessibility/con venience	Factors involved in arranging to receive medical care (e.g., time and effort required to get an appointment, waiting time at office, ease of reaching care location)	Patient factor: Time constraints Short consultation time Family circumstances
Technical quality	Competence of providers and adherence to high standards of diagnosis and treatment (e.g., thoroughness, accuracy, unnecessary risks, making mistakes).	Individual factor: Knowledge Competence Patient factor: Unwilling to listen to healthcare professionals advice
Interpersonal relationship	Features of the way in which providers interact personally with patients (e.g., Concern, friendliness, courtesy, disrespect, rudeness).	Patient factor: Language barrier Individual barrier: Healthcare professional do not conduct themselves professionally
Finance	Factors involved in paying for medical services (e.g.,	Patient factor: Financial constraint

	reasonable costs, alternative payment arrangements, comprehensiveness of insurance coverage).	
Continuity	Sameness of provider and/or location of care (e.g., see same physician).	Patient factor: Nonchalant attitude towards osteoporosis
Physical condition	Features of setting in which care is delivered (e.g., orderly facilities and equipment, pleasantness of atmosphere, clarity of signs and directions).	Work environment factor: Primary care services are not elderly friendly

Therefore 16 new items were added. The final SQOP consists of 23 items, and was divided into 7 domains. Each item had a five-point Likert-like response. Please refer to Appendix 23 for the finalized version of the SQOP.

3.2.3.4   Validation of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

Before a research instrument such as a questionnaire can be used to measure what it intends to measure, it needs to be validated. A questionnaire is valid only after successfully undergoing a validation process which gauges the validity measure of a concept (Smith, 2002, Bryman, 2004). The validation process involves testing the instrument, in its entirety or by selecting individual questions for which it is to be used to ensure that the responses are a true reflection of the variables or attributes of interest. A validated tool is necessary as it ensure the validity and the reliability of the results.

The process of validation also ensures that the cultural differences and language used are suitable for its local population. This ensures that the questionnaire can effectively collect the data required, eases data processing, data analysis and the scientific robustness such as the validity and the reliability of the instrument used (Smith, 2010, Smith, 2002, Lai, 2013). Figure 3.1 displays the summary of the validation process.

Figure 3.1 Summary of validation process
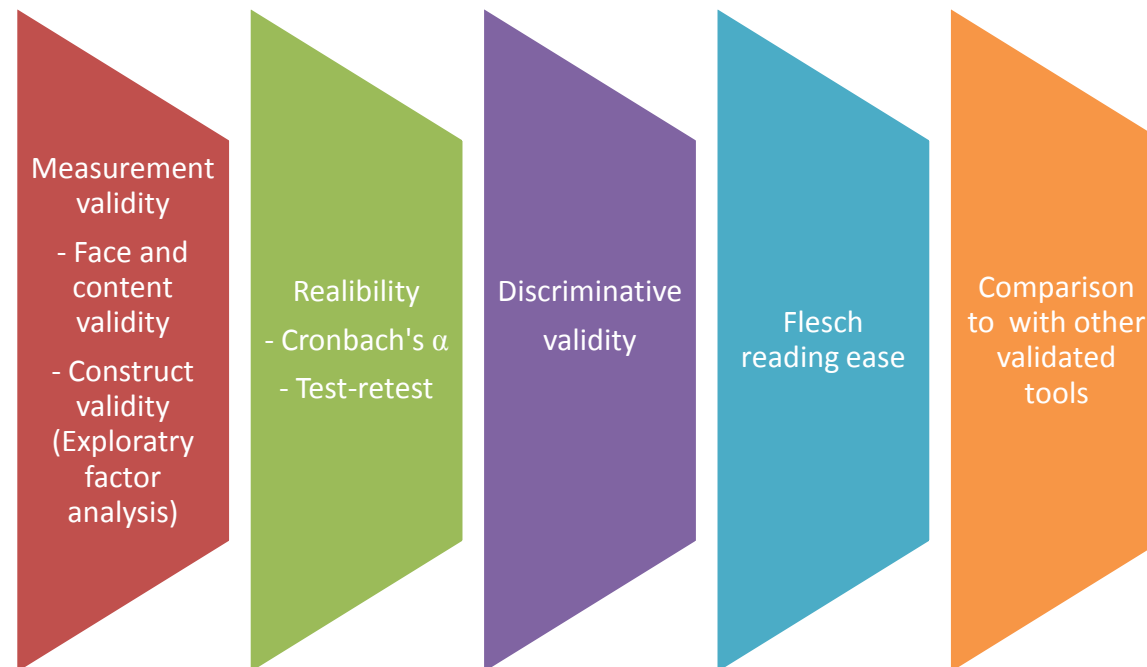
3.2.3.4.1   Validity

Validity refers to the questionnaire measuring the object of desire. For the development and validation of the SQOP, this phase is concerned with the measurement validity (face, content and construct validity) and discriminative validity. The measurement validity of a questionnaire refers to the extent to which the questions collect accurate data relevant to the study objectives (Smith, 2002, Bryman, 2004).

3.2.3.4.1.1   Face validity

This is generally the first test of validity (Smith, 2002). Face validity indicates whether, on the face of it, the instrument appears to be assessing the desired qualities. It represents a subjective judgement based on a review of the measure itself by one or more experts and rarely uses any empirical approaches. Participants from the target population such as patients can also be used to critically review the content of the scale. Alternatively, a more formal approach such as focus groups and in-depth interviews may be conducted to explore whether the questionnaire is covering all aspects of the topic relevant to patients. Occasionally, cognitive interviews can be used where respondents verbalize their reaction to each question as they answer them to indicate the questionnaire perceived by the respondents. Linguistics can also be tested to indicate whether the phrasing of the questions were clear (McDowell, 2006). Face validity aims to uncover problems such as identification of questions which respondents may be unable or reluctant to answer, questions that might be ambiguous or misinterpreted or

questions that might not be an accurate reflection of the variable of interest (Smith, 2002).

3.2.3.4.1.2 Content validity

Content validity is concerned with the comprehensiveness or whether the questions selected are representative of all relevant issues that were specified in the conceptual definition of its scope (McDowell, 2006). This is generally obtained from preliminary fieldwork such as qualitative interviews which aims to uncover the perspective of the population of interest leading to the development of the instrument (Smith, 2002).

3.2.3.4.1.3 Construct validity

For assessing variables such as pain, happiness and satisfaction, gold standards do not exist and thus validity testing becomes more challenging. Therefore, for such abstract constructs, "construct validation" can be used (McDowell, 2006). This begins with a conceptual definition of the topic (or construct) to be measured. This will give an indication of the internal structure of its components and the way it relates to other constructs. Construct validity involves testing a scale not against a single criterion but in terms of theoretically derived hypotheses concerning the nature of the underlying variable or construct (Pallant, 2011). The main types of methods to determine construct validity include correlational evidence such as factor analysis and evidence for the ability of measure to discriminate among different groups (McDowell, 2006).

3.2.3.4.2   Factor analysis

Factor analysis is an analytical tool in describing the correspondence of alternative indicators to the underlying concepts that they may record. It uses the pattern of inter-correlations among replies to questions. Factor analysis then analyses and forms the questions into groups or factors that appear to measure common themes, each factor being distinct from the others. Factor analysis can also be used to describe the underlying conceptual structure of an instrument. It can show how far the items accord in measuring one or more common themes guiding the selection of items on the basis of their association with the trait of interest. It can also indicate the association among subscales component of measurement or even complete measures. A scale measuring the same topic would be expected to be grouped by the analysis onto the same factor (McDowell, 2006).

Factors analysis can be divided into two parts: a structural model and measurement model. The structural model posits underlying constructs to be measured. The measurement model presents the relationship between variables recorded (answers to questions) and the underlying concepts. It can be further divided to confirmatory factor analysis and exploratory factor analysis. Confirmatory factor analysis begins with the structural model and is used to test how far the empirical data support the proposed conceptual structure. On the other hand, exploratory factors analysis begins with the measured variables and shows how they cluster together to represent underlying constructs even where these have not been formally defined (McDowell, 2006).

3.2.3.4.3   Discriminative validity

For the purpose of this study, discriminative validity was referred to as the extent to which the classification system (in our case the SQOP) was able to differentiate between participants with and without the 'intervention package' (Streiner and Norman, 2008).

3.2.3.4.4   Reliability

Reliability of a survey instrument refers to the extent to which the findings are reproducible (Smith, 2002). Two frequently used indicator for reliability is internal reliability and test-retest (Pallant, 2011, Smith, 2002). We conducted the Cronbach's α and test-retest to assess the internal consistency and stable reliability of the questionnaire, respectively.

3.2.3.4.4.1   Internal reliability

Internal reliability is the degree to which the items that make up the scare are all measuring the same underlying attribute (Pallant, 2011). Cronbach's α is the most common statistics used to measure internal consistency which provides an indication of the average correlation among all the items that make up the scale. A value of zero indicates no correlation among the items, whereas a value of one would indicate perfect correlation among the items (McDowell, 2006).

3.2.3.4.4.2   Test-retest

Test-retest is assessed by administering the questionnaire to the same people on two different occasions and calculating the correlation between the two scores obtain. The questionnaire is

considered reliable if the correlations between results are high (Pallant, 2011). The researcher needs to consider how long to wait before administering the retest. On average, a maximum of two to four weeks is a reasonable period of time between the initial and follow-up administration of the questionnaire to minimize the possibility of real or random change occurring (Aday and Cornelius, 2006).

3.2.3.5   Study design

The validation process was a randomized controlled trial.

3.2.3.6   Setting

The study was conducted at the primary care clinics of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia.

3.2.3.7   Period of study

The data collection began in September 2013 and went on until Dec 2013.

3.2.3.8   Participants
3.2.3.8.1   Inclusion/exclusion criteria

English or Malay speaking postmenopausal women aged ≥ 50 years old who had not previously been diagnosed with osteopenia/osteoporosis were included. Eligible participants who were feeling too unwell to participate in the study were excluded.

3.2.3.9   Sampling procedure

The first consideration of any researcher is the identification of, and access to the population of interest. There are a variety of sampling methods such as random sampling. Random sampling is defined as a method in which every member of the population has an equal chance of being selected. This normally involves a sampling frame which consists of a list of all members of the population. Based on this list, a random sample can be selected using random numbers or a systematic procedure such as the selection of every tenth person on the list can be employed if there is no order to the entries On the other hand, convenience sampling selects the most readily accessible participants. These are cheap and quick ways to obtain the data but jeopardizes representativeness of the findings (Smith, 2002).

In this study, random sampling was used as it allows for generalisation to the population from which the sample is drawn. Additionally, the random sampling procedure was used as there was only one researcher making it not possible to recruit all patients or conduct convenience sampling. The researcher screened for potential participants by using a 1:2 systematic random sampling procedure. Participants were recruited at the clinic's waiting area while they were waiting to see their doctor. Randomization of participants to either the control or intervention group was performed by drawing pieces of paper stating control or intervention from a bag, while participants were filling up the demographic form.

3.2.3.10 Sample size

In quantitative studies a statistically representative sample is required. The sample size required for survey research is determined by the degree of accuracy desired when the estimate base on the sample is applied to the wider population (Smith, 2010). For validation studies, the sample size can be calculated based on a 5:1 subject to item ratio for factor analysis (Gorsuch, 1983). Additionally, the anticipated response rate must be considered. In general, a larger sample size leads to a more accurate estimate and the narrower the confidence intervals (Smith, 2010). Hence, the sample size should be calculated at the design stage of the study to ensure it is statistical power (a measure of how likely the study is to produce a statistically significant result) (Bowling, 2009). Our sample size was calculated based on a 5:1 subject to item ratio for factor analysis (Gorsuch, 1983). Allowing for a 20% loss to follow up, the total number of participants required was 70 in each arm.

3.2.3.11 Instruments used

3.2.3.11.1 Baseline demographics

Baseline demographic information such as participants' medical history, lifestyle and medication history was collected. Healthcare professionals' baseline information, work experience and education level were also collected (Appendix 1).

3.2.3.11.2 Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

The final SQOP consists of 23 items, and was divided into 7 domains (outcomes/efficacy, accessibility/convenience, technical

quality, interpersonal relationship, physical condition, finance and continuity). Each item had a five-point Likert-like response. One indicates the lowest satisfaction for that item and five indicates the highest satisfaction. Scores ranged from 30 to 150, and was converted to percentage, ranging from 0-100%. Zero indicates the lowest level of satisfaction, whilst 100 indicates the highest.

3.2.3.12   Intervention package provided

Intervention participants received 30 minutes of verbal counselling and an osteoporosis booklet (Appendix 24). Topics covered during the counselling session were the definition of osteoporosis, consequences of untreated osteoporosis, risk factors for osteoporosis, the role of the BMD scan (its function, what the results mean, accessibility and the frequency a patient has to go for a BMD scan), other tests used in osteoporosis screening [quantitative ultrasound scanning, x-ray, blood test and the Osteoporosis Screening Tool for Asians (OSTA)], lifestyle changes (calcium intake, vitamin D intake, weight bearing exercise and fall prevention), and treatment of osteoporosis.

Control participants received standard care. Standard care involved a regular visit to the doctor. Any counselling on osteoporosis by the doctor was opportunistic and at the doctors' discretion.

3.2.3.13   Procedure

Eligible participants were first screened and then randomly recruited by the pharmacist at the waiting area. The study was explained to participants using the patient information sheet

(Appendix 25). Informed consent and the participants' baseline demographic data were obtained (Appendix 26). Subsequently, the participants were randomly allocated to the control or intervention group. The intervention group received the 'intervention package' and the control group received the standard care. The SQOP was then administered to both groups. Participants answered the questionnaire themselves. However, for those who experienced some difficulty in reading the questions themselves, the researcher read the questions out for them and assisted them in filling the questionnaire. The researcher ensured that all questions have been answered. All questionnaires and intervention were administered by the researcher. The researcher was trained by one of the supervisor who was well versed in osteoporosis to deliver the counselling.

Two weeks after baseline, a telephone follow up was conducted to administer the SQOP to both groups. The control group was provided the intervention package over the phone and were mailed the osteoporosis booklet at the end of the study. Figure 3.2 presents the validation process.

Figure 3.2 Validation process

| Baseline | No. of participants recruited (n=140) |

Informed consent and baseline information obtained.

Randomly allocated

Control group
N=70

Intervention group
N=70

Counselling session +
osteoporosis booklet
provided

SQOP was administered

SQOP was administered

1st Follow up
(Two weeks
later)

SQOP was administered over
the phone

SQOP was administered over
the phone

Counselling session provided
over phone + osteoporosis
booklet was provided via mail.

Abbreviations:
PIS=Patient information sheet
SQOP= Satisfaction questionnaire for
osteoporosis prevention

3.2.3.14   Source of data

The source of data varied from medical registers, medical records, observations to observe if patients were too unwell to participate in the study, interviews, questionnaire and informal discussions to find out informally if patients have osteoporosis during recruitment. Some of the data such as participants' clinical information were obtained from medical records prior to the provision of service, whilst other data were obtained during the counselling session with the pharmacist.

3.2.3.15   Ethics approval

Ethical approval from the University Malaya Medical Centre Ethics Committee was obtained prior to the study (ref no. 920.27) (Appendix 27). All required documents were submitted and approval was obtained one month after submission. In accordance with the ethics committee requirements, a report upon completion form has been submitted. Ethical issues such as anonymity, confidentiality and informed consent were considered in this study.

3.2.3.15.1   Anonymity and confidentiality

Only the researcher and the supervisors had access to the questionnaire. All information were coded and anonymized. The information collected as paper copies were stored under lock and key, while the electronic data can only be accessed with a secure password. The data collected were used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. All

information which is collected was confidential and any form of identity will not be included in any publications.

3.2.3.15.2   Informed consent

Prior to the start of any research activity, written informed consent for participating was obtained from each participant.

3.2.3.16   Data analysis

All data was entered into the IBM$^{®}$ SPSS$^{®}$ version 20 (IBM Corporation, Armonk, NY, US). Baseline demographic data of the control and intervention group was compared using chi square test for categorical variables or the independent t-test for continuous variables. Non-parametric test were used since the data obtained was not of normal distribution. A p-value < 0.05 was considered as statistically significant.

3.2.3.17   Face and content validity

The face and content validity of the SQOP was established via consultation with an expert panel (a consultant endocrinologist and four pharmacists with many years of research and clinical experience). Comprehension of the questionnaire was tested on 10 postmenopausal women who understood English. This involved asking the participants for their opinions about the phrasing, format and content of the instrument. This resulted in a change of item 8 from 'Has the advice given by the pharmacist affected your life in general?' to 'How would you rate the advice given by the pharmacist?' as participants commented that it was difficult to gauge the effect of newly given advice.

3.2.3.18 Exploratory factor analysis (EFA)

EFA was performed to provide information about the validity of the items within each domain and to explore the appropriateness of the factor structure of the current questionnaire. It is important to note that the control group were not required to answer items 19-23 as these items were specifically assessing the satisfaction of the intervention conducted. However, all items (i.e. items 1-23) in the EFA were included for 2 reasons. Firstly, although the control group did not answer items 19-23, it still is represented as one of the seven domains. Secondly if control participants were excluded from the EFA, then we would not have satisfied the minimum number of participants require (i.e. 100 participants) where there are more than six factors present (Mundform et al., 2005). The extraction method used was maximum likelihood and the rotation method was promax. To determine how many factors were retained a criterion of eigenvalue greater than 1.0 was considered. Corrected item-total correlations were used to identify items which did not measure the same main component as the other items. A value of less than 0.3 indicates that the item is measuring a different component from the scale as a whole.

3.2.3.19 Cronbach's α

The mean score ± S.D. was calculated for each item.. The results for intervention and control were combined to test for internal reliability (Cronbach's α). Cronbach's α greater than or equal to 0.70 indicates good internal reliability(Cronbach, 1951).

3.2.3.20 Test retest

To assess test-retest reliability, the Wilcoxon-signed rank test and the Spearman's correlation was used. The higher the correlation indicates a higher reliability (Pallant, 2011).

3.2.3.21 Discriminative validity

Discriminative validity was performed on the control and intervention group to assess if the SQOP was able to differentiate between the satisfaction levels of the two groups. Since, the control group was not required to answer items 19-23, the total score of both control and intervention group were converted into percentages. The Mann Whitney U test was then used to analyse if the SQOP was able to discriminate between the control and intervention group using their percentages.

3.2.3.22 Flesch reading ease

Microsoft Office Word 2007 was used to calculate the Flesch reading ease. Flesch reading ease was performed to assess the reading comprehension level necessary to understand the written document. An average document should have a score of 60-70 (Flesch, 1948).

3.2.4 Results (Phase two- Satisfaction Questionnaire for Osteoporosis Prevention (SQOP))

3.2.4.1 Participants

A total of 173 participants were approached: 33 declined and 140 participants (80.9%) were recruited (control= 70 and intervention=70). No significant differences were found between the control and intervention group in all demographic aspects [Table 3.2].

Table 3.2: Baseline demographic characteristics of participants

Characteristics		Control (n=70)	Intervention (n=70)	t-value/ chi2a,c	p-value
Mean age ± S.D (years) [range], Median		58.51±7.06 [50-77], 56.00	60.57±7.26 [50-77], 60.00	-1.700	0.091
Age range (years) [n (%)]					
<65		56 (80.0)	50 (71.4)	1.398	0.237
≥ 65		14 (20.0)	20 (28.6)		
Ethnicity [n (%)]					
	Malay	13 (18.6)	17 (24.3)		
	Chinese	31 (44.3)	29 (41.4)	2.467	0.495
	Indian	24 (34.3)	19 (27.1)		
	Others	2 (2.9)	5 (7.1)		
Mean BMI ± S.D., Median		25.33±6.50, 23.52	25.32±5.75, 23.63	0.003	0.997
BMI [n (%)]					
<18.5 (underweight)		5 (7.1)	5 (7.1)	0.833	0.841
18.5-24.9 (normal)		37 (52.9)	32 (45.7)		
25.0-29.9 (overweight)		17 (24.3)	19 (27.1)		
≥30.0 (obese)		11 (15.7)	14 (20.0)		
Level of education [n (%)]					
Primary(6 years of education)		4 (5.7)	3 (4.3)		
Secondary (11-13 years of education)		33 (47.1)	28 (40.0)		
Diploma/Technical (12-14 years of education)		15 (21.4)	14 (20.0)	1.727	0.631
Tertiary/Postgraduate (15-21 years of education)		18 (25.7)	25 (35.7)		

Abbreviations:S.D. = standard deviation; BMI=body mass index
[a] Chi square test was used for all categorical variables whilst the independent t-test was used for all continuous variables.
[b] Others include four Eurasian, one Portuguese and one Thai.
[c] Fisher's exact test was used as the number of cells with expected count less that 5 is more than 20% of the total number of cells

3.2.4.2 Factor analysis and psychometric properties of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

EFA extracted seven domains with a criterion of eigenvalue greater than 1.0. This explains the 79.1% of the cumulative variances. The eigenvalue and the proportion of variance explain are shown in Table 3.3. The factor loading of the items to each factor are shown in table 3.4 (0.118-0.977). All items had a factor loading of more than 0.3 except item 17 which had a factor loading of 0.118. However this item was maintained due to its importance based on findings from the qualitative study. Correlations between the factors resulting from the rotation were similar and the residuals ranged from -0.184-0.167are shown in Table 3.5.

Table 3.3: Eigenvalue of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP) and the proportion of variance explained using promax and maximum likelihood

| Factor | Before rotation | | | After rotation | | |
	Eigenvalue	Percentage of variances	Cumulative percentage of variances	Eigenvalue	Percentage of variances	Cumulative percentage of variances
Factor 1	3.520	15.30	15.30	7.548	32.82	32.82
Factor 2	2.981	12.96	28.27	2.908	12.64	45.46
Factor 3	2.364	10.28	38.54	1.977	8.56	54.05
Factor 4	2.363	10.27	48.81	1.768	7.69	61.74
Factor 5	2.287	9.94	58.76	1.523	6.62	68.36
Factor 6	1.631	1.09	65.85	1.354	5.89	74.25
Factor 7	1.122	4.88	70.73	1.112	4.84	79.09

Table 3.4: Factor loading of items in the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7
Q1	.037	.339	.283	.034	.373	.417	.423
Q2	.428	.304	.340	.108	.040	.914	.163
Q3	.078	.392	.141	.063	.977	.078	.004
Q4	.109	.462	.277	.173	.379	.166	-.120
Q5	.122	.046	-.004	.188	-.058	.082	.451
Q6	-.169	.125	.052	-.035	.826	-.130	-.001
Q7	.502	.427	.298	.387	-.079	.545	.170
Q8	.451	.199	.593	.462	.041	.555	.222
Q9	.590	.703	.472	.114	.430	.153	-.035
Q10	.761	.232	.403	.049	.066	.258	.008
Q11	.788	.225	.603	.433	.036	.472	.384
Q12	.519	.250	.383	.367	-.063	.378	.110
Q13	.530	.622	.669	.434	.080	.565	.430
Q14	.714	.318	-.035	.338	-.053	.562	.240
Q15	.841	.400	.350	.520	-.019	.365	.210
Q16	.432	.315	.563	.910	.164	.094	.010
Q17	-.311	.037	-.633	-.239	.118	-.112	.106
Q18	.363	.675	.338	.164	.227	.404	.243
Q19	.331	.701	.159	.178	.257	-.017	-.286
Q20	-.014	.762	.027	.135	.125	.265	.355
Q21	.384	.669	.771	.467	.287	.358	.175
Q22	.191	.288	.351	.924	.084	.368	.536
Q23	.308	.660	.818	.406	.401	.475	.452

Table 3.5 Correlations between the factors resulting from the rotation using promax and maximum likelihood

Correlation	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23
Q1	1.000	.320	.351	.336	-.095	.196	.167	.221	.242	.142	.221	.221	.238	.150	.019	.000	.000	.360	.074	.216	.353	.188	.381
Q2	.320	1.000	.104	.231	-.116	-.131	.526	.539	.240	.367	.411	.382	.470	.515	.317	.021	-.207	.368	.084	.109	.334	.078	.367
Q3	.351	.104	1.000	.390	-.055	.808	-.016	.038	.435	.082	.038	-.035	.064	.087	.051	.174	.190	.247	.306	.152	.242	.109	.331
Q4	.336	.231	.390	1.000	-.110	.170	.193	.154	.448	-.082	.000	.139	.127	.044	.202	.248	-.195	.131	.515	.140	.451	.109	.378
Q5	-.095	-.116	-.055	-.110	1.000	-.136	.198	.137	.021	-.004	.239	.013	.228	.211	.226	.082	.150	.081	-.115	.051	-.027	.317	.125
Q6	.196	-.131	.808	.170	-.136	1.000	-.155	-.101	.147	-.090	-.101	-.122	-.167	-.161	-.132	.076	.298	-.143	.084	.031	.155	.047	.192
Q7	.167	.526	-.016	.193	.198	-.155	1.000	.471	.353	.198	.471	.462	.486	.436	.542	.317	-.113	.316	.352	.237	.348	.324	.366
Q8	.221	.539	.038	.154	.137	-.101	.471	1.000	.243	.438	.576	.440	.427	.283	.386	.481	-.449	.337	.051	-.046	.420	.429	.522
Q9	.242	.240	.435	.448	.021	.147	.353	.243	1.000	.521	.398	.341	.532	.288	.524	.301	-.218	.435	.574	.351	.557	.031	.508
Q10	.142	.367	.082	-.082	-.004	-.090	.198	.438	.521	1.000	.666	.531	.350	.511	.478	.184	-.240	.431	.204	-.064	.375	-.046	.280
Q11	.221	.411	.038	.000	.239	-.101	.471	.576	.398	.666	1.000	.440	.603	.524	.759	.481	-.449	.337	.051	-.046	.420	.429	.522
Q12	.221	.382	-.035	.139	.013	-.122	.462	.440	.341	.531	.440	1.000	.411	.452	.411	.374	-.272	.189	.115	-.017	.509	.292	.316
Q13	.238	.470	.064	.127	.228	-.167	.486	.427	.532	.350	.603	.411	1.000	.370	.640	.455	-.347	.559	.232	.352	.697	.462	.722
Q14	.150	.515	.087	.044	.211	-.161	.436	.283	.288	.511	.524	.452	.370	1.000	.690	.175	.144	.301	.165	.207	.170	.291	.148
Q15	.019	.317	.051	.202	.226	-.132	.542	.386	.524	.478	.759	.411	.640	.690	1.000	.513	-.250	.285	.301	.110	.397	.433	.382
Q16	.000	.021	.174	.248	.082	.076	.317	.481	.301	.184	.481	.374	.455	.175	.513	1.000	-.416	.176	.288	.021	.606	.777	.507
Q17	.000	-.207	.190	-.195	.150	.298	-.113	-.449	-.218	-.240	-.449	-.272	-.347	.144	-.250	-.416	1.000	-.026	-.025	.301	-.289	-.127	-.319
Q18	.360	.368	.247	.131	.081	-.143	.316	.337	.435	.431	.337	.189	.559	.301	.285	.176	-.026	1.000	.478	.562	.447	.183	.447
Q19	.074	.084	.306	.515	-.115	.084	.352	.051	.574	.204	.051	.115	.232	.165	.301	.288	-.025	.478	1.000	.472	.395	.018	.292
Q20	.216	.109	.152	.140	.051	.031	.237	-.046	.351	-.064	-.046	-.017	.352	.207	.110	.021	.301	.562	.472	1.000	.307	.235	.372
Q21	.353	.334	.242	.451	-.027	.155	.348	.420	.557	.375	.420	.509	.697	.170	.397	.606	-.289	.447	.395	.307	1.000	.432	.804
Q22	.188	.078	.109	.109	.317	.047	.324	.429	.031	-.046	.429	.292	.462	.291	.433	.777	-.127	.183	.018	.235	.432	1.000	.492
Q23	.381	.367	.331	.378	.125	.192	.366	.522	.508	.280	.522	.316	.722	.148	.382	.507	-.319	.447	.292	.372	.804	.492	1.000

Reproduced correlation	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23
Q1	.382[a]	.320	.351	.169	.089	.242	.152	.198	.213	.086	.195	.086	.310	.135	.089	.008	.037	.289	.039	.263	.271	.187	.422
Q2	.320	.999[a]	.104	.232	-.115	-.131	.526	.539	.240	.367	.411	.382	.469	.515	.317	.021	-.207	.368	.084	.109	.334	.078	.367
Q3	.351	.104	.999[a]	.389	-.055	.808	-.016	.039	.435	.083	.038	-.035	.064	.087	.051	.174	.190	.246	.306	.153	.243	.109	.331
Q4	.169	.232	.389	.368[a]	-.150	.238	.179	.159	.365	.072	.027	.111	.238	.040	.091	.258	-.071	.286	.397	.249	.395	.108	.351
Q5	.089	-.115	-.055	-.150	.319[a]	-.046	.061	.036	-.012	.057	.250	.064	.158	.213	.237	.086	.099	.065	-.123	.130	-.002	.317	.101

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23
Q6	.242	-.131	.808	.238	-.046	.746ᵃ	-.209	-.087	.186	-.095	-.116	-.170	-.124	-.157	-.160	.076	.186	.034	.094	.004	.069	.047	.170
Q7	.152	.526	-.016	.179	.061	-.209	.489ᵃ	.408	.318	.328	.438	.383	.505	.497	.493	.318	-.173	.371	.258	.255	.398	.324	.365
Q8	.198	.539	.039	.159	.036	-.087	.408	.594ᵃ	.228	.347	.579	.415	.522	.307	.431	.480	-.434	.235	.025	-.047	.481	.429	.501
Q9	.213	.240	.435	.365	-.012	.186	.318	.228	.778ᵃ	.517	.414	.288	.504	.308	.489	.302	-.159	.518	.597	.332	.565	.031	.528
Q10	.086	.367	.083	.072	.057	-.095	.328	.347	.517	.679ᵃ	.641	.377	.422	.455	.584	.182	-.310	.292	.203	-.076	.309	-.046	.292
Q11	.195	.411	.038	.027	.250	-.116	.438	.579	.414	.641	.884ᵃ	.501	.627	.542	.738	.480	-.413	.306	.031	-.060	.455	.429	.516
Q12	.086	.382	-.035	.111	.064	-.170	.383	.415	.288	.377	.501	.370ᵃ	.442	.379	.480	.377	-.296	.250	.154	.043	.369	.292	.338
Q13	.310	.469	.064	.238	.158	-.124	.505	.522	.504	.422	.627	.442	.753ᵃ	.391	.570	.455	-.321	.515	.291	.368	.672	.462	.716
Q14	.135	.515	.087	.040	.213	-.157	.497	.307	.308	.455	.542	.379	.391	.836ᵃ	.673	.174	.076	.344	.188	.205	.131	.291	.134
Q15	.089	.317	.051	.091	.237	-.160	.493	.431	.489	.584	.738	.480	.570	.673	.806ᵃ	.515	-.224	.374	.286	.142	.412	.433	.381
Q16	.008	.021	.174	.258	.086	.076	.318	.480	.302	.182	.480	.377	.455	.174	.515	.990ᵃ	-.418	.174	.288	.020	.603	.777	.507
Q17	.037	-.207	.190	-.071	.099	.186	-.173	-.434	-.159	-.310	-.413	-.296	-.321	.076	-.224	-.418	.612ᵃ	-.024	.010	.290	-.397	-.127	-.335
Q18	.289	.368	.246	.286	.065	.034	.371	.235	.518	.292	.306	.250	.515	.344	.374	.174	-.024	.508ᵃ	.422	.485	.475	.184	.500
Q19	.039	.084	.306	.397	-.123	.094	.258	.025	.597	.203	.031	.154	.291	.188	.286	.288	.010	.422	.715ᵃ	.453	.433	.018	.288
Q20	.263	.109	.153	.249	.130	.004	.255	-.047	.332	-.076	-.060	.043	.368	.205	.142	.020	.290	.485	.453	.791ᵃ	.329	.235	.365
Q21	.271	.334	.243	.395	-.002	.069	.398	.481	.565	.309	.455	.369	.672	.131	.412	.603	-.397	.475	.433	.329	.784ᵃ	.432	.770
Q22	.187	.078	.109	.108	.317	.047	.324	.429	.031	-.046	.429	.292	.462	.291	.433	.777	-.127	.184	.018	.235	.432	1.000ᵃ	.492
Q23	.422	.367	.331	.351	.101	.170	.365	.501	.528	.292	.516	.338	.716	.134	.381	.507	-.335	.500	.288	.365	.770	.492	.865ᵃ

Residual	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23
Q1		.000	.000	.167	-.184	-.047	.015	.023	.029	.056	.026	.135	-.072	.016	-.069	-.008	-.037	.071	.035	-.047	.082	.000	-.041
Q2	.000		.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000
Q3	.000	.000		.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.001	.000	.000	.000	.000
Q4	.167	.000	.000		.040	-.068	.014	-.005	.083	-.154	-.027	.029	-.111	.003	.112	-.009	-.124	-.155	.117	-.109	.056	.000	.027
Q5	-.184	.000	.000	.040		-.090	.137	.101	.033	-.061	-.011	-.051	.070	-.002	-.011	-.004	.051	.015	.008	-.079	-.025	.000	.024
Q6	-.047	.000	.000	-.068	-.090		.054	-.013	-.039	.005	.016	.049	-.042	-.005	.028	.000	.112	-.178	-.010	.026	.086	.000	.023
Q7	.015	.000	.000	.014	.137	.054		.063	.035	-.130	.033	.079	-.019	-.060	.049	-.001	.060	-.055	.094	-.018	-.050	.000	.000
Q8	.023	.000	.000	-.005	.101	-.013	.063		.016	.091	-.003	.025	-.095	-.023	-.045	.001	-.014	.103	.025	.001	-.061	.000	.021
Q9	.029	.000	.000	.083	.033	-.039	.035	.016		.004	-.016	.054	.028	-.020	.036	-.002	-.060	-.082	-.023	.019	-.008	.000	-.020
Q10	.056	.000	.000	-.154	-.061	.005	-.130	.091	.004		.024	.153	-.072	.056	-.106	.002	.069	.139	.001	.012	.066	.000	-.013
Q11	.026	.000	.000	-.027	-.011	.016	.033	-.003	-.016	.024		-.061	-.024	-.018	.021	.000	-.036	.031	.020	.014	-.035	.000	.006
Q12	.135	.000	.000	.029	-.051	.049	.079	.025	.054	.153	-.061		-.031	.074	-.069	-.003	.024	-.061	-.038	-.060	.140	.000	-.022
Q13	-.072	.000	.000	-.111	.070	-.042	-.019	-.095	.028	-.072	-.024	-.031		-.021	.070	.001	-.026	.045	-.059	-.015	.025	.000	.005
Q14	.016	.000	.000	.003	-.002	-.005	-.060	-.023	-.020	.056	-.018	.074	-.021		.018	.001	.068	-.042	-.022	.002	.039	.000	.014
Q15	-.069	.000	.000	.112	-.011	.028	.049	-.045	.036	-.106	.021	-.069	.070	.018		-.002	-.026	-.089	.015	-.032	-.015	.000	.001
Q16	-.008	.000	.000	-.009	-.004	.000	-.001	.001	-.002	.002	.000	-.003	.001	.001	-.002		.001	.003	.000	.001	.003	.000	.000
Q17	-.037	.000	.000	-.124	.051	.112	.060	-.014	-.060	.069	-.036	.024	-.026	.068	-.026	.001		-.001	-.035	.011	.108	.000	.016
Q18	.071	.000	.001	-.155	.015	-.178	-.055	.103	-.082	.139	.031	-.061	.045	-.042	-.089	.003	-.001		.056	.076	-.028	.000	-.052
Q19	.035	.000	.000	.117	.008	-.010	.094	.025	-.023	.001	.020	-.038	-.059	-.022	.015	.000	-.035	.056		.020	-.038	.000	.004
Q20	-.047	.000	.000	-.109	-.079	.026	-.018	.001	.019	.012	.014	-.060	-.015	.002	-.032	.001	.011	.076	.020		-.023	.000	.007
Q21	.082	.000	.000	.056	-.025	.086	-.050	-.061	-.008	.066	-.035	.140	.025	.039	-.015	.003	.108	-.028	-.038	-.023		.000	.035
Q22	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000		.000
Q23	-.041	.000	.000	.027	.024	.023	.000	.021	-.020	-.013	.006	-.022	.005	.014	.001	.000	.016	-.052	.004	.007	.035	.000	

3.2.4.3   Cronbach's α

The items representing each domain are shown in Table 3.6. The Cronbach's α of each domain are shown in Table 4.6 ranging from 0.531-0. 812. All items had a corrected item-total correlation of more than 0.3.

Table 3.6: Psychometric properties of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

Items	Questions	Corrected item-total correlation	Cronbach's α if item deleted	Cronbach's α	Domains
1	The service was conducted at a time that _____ (fill in the blank) for you.	0.508	0.527	0.661	Accessibility/ convenience
2	During the session, what did you think about the time given to discuss your problems with the pharmacist?	0.486	0.549		
3	How would you rate the location of this service?	0.432	0.618		
4	How would you rate the comfort of the location?	0.363	-	0.531	Physical
12	If you have questions about osteoporosis, would you ask the pharmacist?	0.363	-		
5	Was the pharmacist easy to talk to?	0.378	-	0.535	Technical quality
9	How would you rate the service provided by the pharmacist?	0.378	-		
*6	How would you rate the advice given by the pharmacist?				Interpersonal relationship
7	How would you rate the overall quality of service that was given by the pharmacist	0.439	0.801	0.812	Outcomes/ Efficacy

	to you?		
8	This pharmacist service should _____ (fill in the blank)	0.426	0.803
10	What do you think about having the same pharmacist to see you for subsequent osteoporosis care?	0.263	0.813
13	Pharmacist in other hospitals should _____ (fill in the blank) this service	0.574	0.788
14	How would you rate the amount of information provided to prevent falls?	0.500	0.797
15	How would you rate the amount of information provided to change your diet to prevent bone loss?	0.480	0.799
18	How would you rate the amount of information provided on the exercises to help strengthen bones?	0.551	0.791
19	Would you pay for a pharmacist counselling service?	0.421	0.802
20	If yes, how much are you willing to pay for each visit to the pharmacist? If you are not willing to pay anything for the service, please proceed to question 18.**	0.509	0.794

21	How would you rate your understanding of osteoporosis now?	0.440	0.801	
22	Explanation of osteoporosis	0.446	0.800	
23	Explanation of consequences of untreated osteoporosis	0.543	0.793	
*11	Explanation on how osteoporosis can be prevented via lifestyle change(s)			Continuity
*16	Explanation on the available methods to screen for osteoporosis			Finance
#17	Osteoporosis booklet provided			

Notes:
*There was only one item in these domains. Hence Cronbach's α could not be conducted.
This was an optional questions. Hence it was excluded from calculating the Cronbach's α
** Please refer to Appendix one for the full questionnaire

3.2.4.4   Test retest

At retest, eight participants (5.7%) dropped out from the study: three (2.1%) were overseas and five (3.6%) could not be contacted, leaving 132 (94.3%) at retest. Results from the control and intervention group were analyzed separately. All test-retest scores were significantly correlated for both the control ($p<0.05$) and intervention ($p<0.05$) group. No significant difference was found for all items in the control group except for items five and six [Table 3.7]. For the intervention group, no significant difference was found for all items except for items four, five, 13, 20, 21 and 23 [Table 3.7].

Table 3.7: Test and retest reliability of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

Group	Control							Spearman's
	Test (n=70)		Retest (n=70)		Wilcoxon-signed rank test			correlation test*
	Mean±SD	Median	Mean±SD	Median	Mean/rank	z-value	p-value	
Items								
1	3.17±0.72	3.00	3.13±0.78	3.00	4.00/4.00	-1.134	0.257	0.938
2	2.90±0.98	3.00	2.91±1.03	3.00	1.00/2.00	-0.447	0.655	0.978
3	3.73±1.23	4.00	3.74±1.21	5.00	4.00/4.00	-0.378	0.705	0.949
4	3.59±1.17	4.00	3.63±1.17	5.00	9.33/8.00	-0.688	0.491	0.877
5	3.26±1.37	3.00	3.31±1.37	4.25	0.00/2.50	-2.000	0.046*	0.983
6	3.49±1.13	4.00	3.23±1.22	4.00	8.32/4.50	-2.508	0.012*	0.745
7	3.59±0.81	4.00	3.63±0.85	4.00	3.00/3.00	-1.342	0.180	0.958
8	3.29±0.95	3.00	3.13±1.06	4.00	8.61/5.50	-1.639	0.101	0.726
9	3.14±0.97	3.00	3.11±0.93	4.00	3.50/3.50	-0.816	0.414	0.955
10	3.36±0.84	3.00	3.41±0.83	4.00	3.50/5.10	-1.100	0.271	0.908
11	3.91±1.03	4.00	3.86±0.92	5.00	5.25/4.50	+1.155	0.248	0.925
12	3.33±0.78	3.00	3.33±0.78	3.25	1.50/1.50	0.000	1.000	0.996
13	2.41±1.10	3.00	2.31±0.96	3.00	11.09/8.50	-1.170	0.242	0.802
14	2.20±0.97	2.00	2.19±1.01	3.00	9.00/8.00	-0.229	0.819	0.862
15	2.20±0.97	2.50	2.13±0.95	3.00	11.82/12.28	-0.923	0.356	0.796
16	2.01±1.35	1.00	1.99±1.29	3.00	3.33/2.50	-0.707	0.480	0.947
17	3.25±1.71	4.00	3.73±1.61	5.00	0.00/1.00	-1.000	0.317	0.726
18	3.01±0.12	3.00	3.00±0.00	3.00	1.00/0.00	-1.000	0.317	0.981
#19								
#20								
#21								
#22								
#23								
Total	61.87±8.76	61.18	61.23±8.96	61.77	29.79/24.41	-1.580	0.114	0.941

Group	**Intervention**							
	Test (n=70)		Retest (n=62		Wilcoxon-signed rank test			Spearman's correlation test
	Mean±SD	Median	Mean±SD	Median	Mean/rank	t-value	p-value	
Items								
1	4.49±0.79	5.00	4.55±0.92	5.00	7.50/5.00	-1.387	0.166	0.818
2	4.47±0.85	5.00	4.50±0.99	5.00	4.50/4.50	-1.414	0.157	0.849
3	4.67±0.76	5.00	4.69±0.78	5.00	3.50/3.50	-0.816	0.414	0.868
4	4.49±0.68	5.00	4.63±0.73	5.00	5.50/5.50	-2.530	0.011*	0.794
5	4.27±1.01	5.00	4.35±0.98	5.00	0.00/3.50	-2.333	0.020*	0.900
6	4.97±0.17	5.00	4.97±0.18	5.00	1.50/1.50	0.000	1.000	0.483
7	4.60±0.49	5.00	4.68±0.47	5.00	4.00/4.00	-1.890	0.059	0.769
8	4.83±0.38	5.00	4.84±0.37	5.00	2.50/2.50	0.000	1.000	0.762
9	4.31±0.60	4.00	4.39±0.58	4.00	3.00/3.60	-1.667	0.096	0.815
10	4.81±0.46	5.00	4.79±0.48	5.00	2.50/2.50	0.000	1.000	0.794
11	4.51±0.78	5.00	4.42±0.90	5.00	2.50/1.00	-1.069	0.285	0.910
12	4.66±0.66	5.00	4.69±0.64	5.00	3.00/3.00	-1.342	0.180	0.822
13	4.43±0.75	5.00	4.50±0.74	5.00	0.00/3.50	-2.449	0.014*	0.869
14	4.40±0.75	5.00	4.45±0.74	5.00	5.50/5.50	-1.265	0.206	0.751
15	4.46±0.76	5.00	4.47±0.76	5.00	2.50/2.50	-1.000	0.317	0.915
16	2.76±1.47	3.00	2.28±1.48	3.00	0.00/1.00	-1.000	0.317	0.967
17	3.25±1.48	4.00	3.23±1.42	3.50	1.00/0.00	-1.000	0.317	0.987
18	4.64±0.54	5.00	4.69±0.50	5.00	0.00/2.00	-1.732	0.083	0.929
19	4.20±4.67	4.00	4.29±0.49	4.00	3.50/3.50	-1.633	0.102	0.785
20	4.06±0.59	4.00	4.19±0.62	4.00	6.00/6.00	-2.111	0.035*	0.798
21	4.26±0.50	4.00	4.37±0.52	4.00	4.50/5.06	-2.309	0.021*	0.699
22	4.19±0.55	4.00	4.23±0.64	4.00	3.50/3.50	-1.633	0.102	0.849
23	4.44±0.50	4.00	4.77±0.42	5.00	0.00/11.50	-4.690	0.000*	0.459
Total	88.10±5.87	88.18	89.36±5.98	89.09	13.79/25.79	-4.995	0.000*	0.948

Notes:
*Statistically significant at $p < 0.05$
**Item 17 was excluded from the total score calculation as it was an optional question.
The control group were not required to answer items 19-23 as these items were specifically assessing the satisfaction of the intervention conducte

3.2.4.5   Discriminative validity

The instrument in this study showed that the intervention group had a significantly higher participant satisfaction compared to the control group (88.10±5.87 versus 61.87±8.76, $p<0.05$). Thus the SQOP was able to discriminant between a group with higher satisfaction and lower satisfaction. This also demonstrated that our intervention had an effect on participants' satisfaction level [Table 3.7].

3.2.4.6   Flesch reading ease

Flesch reading ease was 62.9.

3.2.4.7   Comparison of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP) with other validated instruments

The psychometric properties of the SQOP were similar to that of other validated instruments for measuring participant satisfaction [Table 3.8].

Table 3.8: Comparison of psychometric properties of the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP) to other validated patient satisfaction instruments

	SQOP	OPSQ	OPSAT-Q	PSQ	PSQ-An	DMET	DDSM-Q	PEQD
No. of subjects	140	180	104	1583	312	202	114	1472
Mean age ± S.D. (years)	59.5±7.2	65.6±9.3	65.1 ±10.3	65.4	60.2±11.8	55.7	61.9±9.4	51.0±16.0
Type of study	RCT	RCT	Observational	RCT	Observational	Observational	Observational	RCT
No. of items	23	16	16	20	11	73	31	12
No. of domains	7	2	4	6	2	2	3	4
Cronbach's α	0.81	0.86	0.72-0.89	0.61-0.93	0.83	0.79-0.95	-	0.73-0.84
Factor analysis: no. of components	7	1	-	5	-	13	3	-
No. of times administered	Twice	Once	Twice	Once	Twice	Once	Once	Twice (n=202)
Interval between administration	2 weeks	NA	2 weeks	NA	4 weeks	N A	NA	Mean= 66 ± 14 days
Test-retest reliability (intraclass correlations)	0.46-0.98	NA	0.62-0.81	NA	0.45-0.67	NA	NA	0.66-0.83

Abbreviations:
DDSM-Q= Diabetes Disease State Management Questionnaire;(Krass et al., 2009) DMET= Diabetes Management Evaluation tool;(Paddock et al., 2000) NA= Not applicable; OPSAT-Q= Osteoporosis Patient Treatment Satisfaction Questionnaire;(Flood et al., 2006) OPSQ= Osteoporosis Patient Satisfaction Questionnaire;(Lai et al., 2010) PEQD= Patients' Evaluation of the Quality of Diabetes Care;(Pouwer and Snoek, 2002) PSQ= Preference and Satisfaction Questionnaire;(Gold et al., 2011) PSQ-An= Patient Satisfaction Questionnaire for Anaemia Treatment;(Nordyke et al., 2006) RCT= Randomized Controlled Trial; SQOP= Satisfaction Questionnaire for Osteoporosis Prevention

3.2.5 Discussion

The SQOP performed satisfactorily in both the EFA and psychometric properties. This indicates that the SQOP is suitable to assess patient satisfaction towards an osteoporosis screening and prevention service in Malaysia.

EFA showed that there were seven domains of satisfaction being measured within the main component to assess patients' satisfaction towards an osteoporosis screening and prevention programme in Malaysia. This was as expected, as the researchers initially designed this tool to assess seven domains, namely: outcomes/efficacy, accessibility/convenience, technical quality, interpersonal relationship, finance, physical condition and continuity. The seven domains were deemed to be significant to assess patients' satisfaction as it concurred with the themes from a previous qualitative study (Ware et al., 1983).

The domains measured by SQOP were then compared to that of other satisfaction tools related to osteoporosis. For example, the OPSQ measured convenience, time, trusts and usefulness of the counselling session.(Lai et al., 2010) The OPSAT-Q measured convenience, confidence with daily activities, side effects and overall satisfaction (Flood et al., 2006). PSQ on the other hand measured preference, bother or satisfaction (Gold et al., 2011). It was difficult to compare the domains of the OPSAT-Q, PSQ and OPSQ as these tools were targeted at osteoporosis treatment instead of prevention. However, there were similarities in terms of some of the domains measured such as convenience and usefulness.

Corrected item-total correlations showed that all items measured the same main component which is satisfaction. SQOP was designed as a multi-dimensional tool rendering an overall Cronbach's α unsuitable. Hence the Cronbach's α was conducted for each domain. The physical and technical quality domains had a low Cronbach's α of 0.531 and 0.535 respectively due to the small number of items in each domain (George and Mallery, 2003). Nonetheless, the other two domains had an acceptable and good Cronbach's α of 0.661 (accessibility/convenience) and 0.812 (outcomes/efficacy) (George and Mallery, 2003). However, Cronbach's α was not computed for the domains: interpersonal relationship, continuity and finance as these domains only had one item. These domains comprise a total of 4 items out of the 23 items. Flesch reading ease was satisfactory at 62.9 as this represents the standard level reading of documents for adults.

The SQOP performed satisfactorily at test-retest indicating that the SQOP achieved stable reliability. Only items five and item six 'was significantly different at test-retest for control participants. This may be because participants may have been more "satisfied with the service" provided by the pharmacist.

As for the intervention group, there was no significant difference in item scores between test and retest except items four, five, 13, 20, 21 and 23. Item four was regarding 'How would you rate the comfort of the location?' This difference may be due to participants having more time to reflect on the programme and realizing that they were "more satisfied" leading to viewing the

overall comfort more positively. Item five was regarding 'If you have questions about osteoporosis, would you ask the pharmacist?' Several of the participants changed to a more positive answer during the retest and this may be because of their intervention experience with the researcher who is a pharmacist. Items 13, 20, 21 and 23 were regarding 'How would you rate the amount of information provided?' 'Explanation of consequences of untreated osteoporosis,' 'Explanation on how osteoporosis can be prevented via lifestyle changes 'and 'Osteoporosis booklet provided', respectively. A possible explanation for this positive change could be because participants may have had more time to consider the information provided, found it useful, and hence were more satisfied. This in turn improved the overall score of intervention participants significantly.

The SQOP was able to differentiate between participants who were expected to be more satisfied as they received an additional service 'the intervention' as compared to those who did not receive the intervention, indicating that the items in SQOP were specific in addressing the different attributes of participant satisfaction towards an osteoporosis screening and prevention service in Malaysia.

Currently, there are only a limited number of studies that have validated instrument to measure patient satisfaction. (Gold et al., 2011, Lai et al., 2010, Krass et al., 2009, Flood et al., 2006, Nordyke et al., 2006, Pouwer and Snoek, 2002, Paddock et al.,

2000) The psychometric properties of the SQOP were similar to previous satisfaction tools.

3.2.6 Strengths

Surveys research using questionnaires are useful for collecting large samples relatively cheaply and in a reasonably short time. Most participants required about 10-15 minutes to complete the questionnaire. This method is suitable for collecting factual information which requires short answer and closed questions. Additionally, structured questionnaires can collect the relevant information in a systematic way(Smith, 2010).

3.2.7 Limitations

Our research used a mixed mode survey administration, where we used self-administration of the survey and interviewed participants who had difficulty in answering the questions at baseline. Subsequently, the follow up survey was administered using telephones interviews. We used the mix mode to optimize response rate and cost. However, mixing the survey administration mode increases the probability that the participants will give different answers due to the difference in administrations mode rather than in opinion (Check and Schutt, 2012). Nonetheless, we have carefully designed the survey to ensure that the survey was equivalent across modes (De Leeuw, 2005). Additionally, the researcher was also trained to reduce interviewer bias (Check and Schutt, 2012).

A limitation of this study was that SPSS Analysis of Moment Structure (AMOS) was not used to conduct confirmatory factor

analysis as five of the seven domains were developed with two items or less (Finance, physical condition, interpersonal relationship, continuity and technical quality). This was because the questionnaire was designed so that participants would only take approximately 5 minutes to complete, to ensure the practicality of its usage in daily practice. The numbers of items per domain was determined based on the patients' emphasis towards the domain during the IDIs. Nonetheless, EFA showed that there were seven components measuring patients' satisfaction.

Another limitation of this study was that SQOP was designed to measure the satisfaction of patients towards a pharmacist conducted osteoporosis screening and prevention service. Hence, wordings such as 'Was the pharmacist easy to talk to?' was used. The implementation of this questionnaire is limited to services provided by a pharmacist. Minor modifications of the SQOP will be required if used to assess satisfaction provided by other healthcare professionals.

Participants in our study were mainly Chinese (42.9%) and Indians (30.7%). This does not represent the ethnic distribution of Malaysia. It only represents the ethnicity of patients who sought treatment in our study site, meaning that our results cannot be considered population-based. Future validation studies of our tool to Malay and Mandarin, and enrolment of participants from multi-sites would be more representative of the Malaysian population.

3.2.8 Conclusion

The English version of the SQOP was found to be a reliable and valid instrument for assessing patient satisfaction towards an osteoporosis screening and prevention programme in Malaysia. Future studies should include the translation of the SQOP into Malay and Mandarin to assess patient satisfaction for Malaysians that are not fluent in English.

3.3 Osteoporosis Prevention and Awareness Tool (OPAAT)

3.3.1 Introduction

3.3.1.1 Importance of knowledge

Knowledge of osteoporosis plays an important role in developing attitudes towards the disease which in turn impacts upon health care behaviors (Andersen, 1995). Patients' health beliefs are defined by attitudes, values and knowledge about health and health services. Although knowledge is not the only component attributed to behavioural changes in patients, it is one of the essential components. Therefore patients should be equipped with the knowledge of the various prevention measures available to increase the likelihood of osteoporosis prevention and its fractures. This includes knowledge on physical activity, adequate calcium intake, adequate vitamin D intake, fall prevention and screening of osteoporosis (Ministry of Health Malaysia, 2012).

Primary prevention of osteoporosis is directed at identifying high risk non-osteoporotic individuals, while secondary prevention of osteoporosis refers to the early detection of the disease and prevention of subsequent fragility fracture. Both primary and secondary prevention involve osteoporosis preventing behaviours (Lundy and Janes, 2009). Therefore, it is important to educate patients on the importance of screening and prevention, as studies have found that early detection of osteoporosis is the most cost-effective ways to reduce the number of hospital admittance due to osteoporotic fractures (Hajcsar et al., 2000, Cranney et al., 2008, Davis et al., 2007, Richy et al., 2004a).

Although there are many methods to increase osteoporosis preventive behaviour such as patient reminder(Heyworth et al., 2014), physician reminders (Cranney et al., 2008) and screening programmes (Yuksel et al., 2010), patient education has been found to be an effective component in increasing knowledge and frequency of osteoporosis preventive behavior (Nielsen et al., 2008, Gaines and Marx, 2011, Jensen et al., 2013, Burke-Doe et al., 2008, Werner, 2005, Yu and Huang, 2003, Baheiraei et al., 2005a). A study by Burke-Doe noted that an increase in osteoporosis knowledge was associated with an increased confidence to perform preventive measures (Burke-Doe et al., 2008). Similarly, studies in Iran, Norway and Singapore have shown a significant relationship with knowledge scores and preventive practice (Saw et al., 2003, Magnus et al., 1996, Jalili et al., 2007). Women in Iran have noted that women who have insufficient knowledge on osteoporosis, have a negative attitude to the preventive actions (Jalili et al., 2007).

However, some studies suggest otherwise (Etemadifar, 2013, Kasper et al., 1994). The differences in these studies' methodologies make it difficult to generalize results, as some studies used qualitative methods (Terrio and Auld, 2002) whilst others used quantitative methods (Etemadifar, 2013, Burke-Doe et al., 2008, Kasper et al., 1994). The variations in the results also suggest that knowledge is not the only component that affects behavioural change. Beliefs, attitudes and values may also be a barrier to implementing osteoporosis preventive efforts (Andersen, 1995). Nonetheless, knowledge plays an important component towards osteoporosis prevention and screening.

Hence a reliable and validated tool to assess osteoporosis prevention and screening knowledge in postmenopausal women at risk for osteoporosis is necessary.

3.3.1.2   Tools to assess osteoporosis knowledge

Seven knowledge tools for osteoporosis have been developed and validated: the Facts on Osteoporosis (FOOQ) (Ailinger et al., 2003, Ailinger et al., 1998, Ailinger and Emerson, 1998), the Osteoporosis Knowledge Assessment Tool (OKAT) (Winzenberg et al., 2003), the Osteoporosis Questionnaire (OPQ) (Pande et al., 2000), the Osteoporosis Knowledge Test (OKT) (Kim et al., 1991), the Osteoporosis and You (Cadarette et al., 2007), the Osteoporosis Knowledge Questionnaire (OKQ) (Curry and Hogstel, 2001), and the Malaysian Osteoporosis Knowledge Tool (MOKT) (Lai et al., 2008). Table 3.9 summarizes the characteristics of the seven tools. Although these tools have been validated they were focused mainly on assessing knowledge of osteoporosis and its treatment (Lai et al., 2008, Kim et al., 1991, Ailinger et al., 2003, Ailinger et al., 1998, Ailinger and Emerson, 1998, Winzenberg et al., 2003, Pande et al., 2000, Cadarette et al., 2007, Curry and Hogstel, 2001).

Table 3.9: Summary of validated tools to measure osteoporosis knowledge.

Instruments	Scale type	No. of items	Domains assessed	Validated in which country	Validated in what language?
FOOQ (Ailinger et al., 1998) (Ailinger and Emerson, 1998, Ailinger et al., 2003)	True or false	25 items	Risk factors and preventive behaviours associated with osteoporosis	US	English
OKAT (Winzenberg et al., 2003)	True, false and do not know	20-items	Osteoporosis in general. This includes the cause of osteoporosis, risk factors and some questions on prevention and treatment	Australia	English
OPQ(Pande et al., 2000)	Multiple-choice	20-items	General information of osteoporosis, risk factors and consequences of untreated osteoporosis	United Kingdom	English
OKT (Kim et al., 1991)	Multiple-choice	24-items	Calcium and exercise	US	English
Osteoporosis and You (Cadarette et al., 2007)	5-point Likert scale	10-items	Osteoporosis risk factors, consequences of untreated osteoporosis, prevention and treatment	Canada	English
OKQ (Curry and Hogstel, 2001)	Multiple-choice	12- items	Osteoporosis risk factors	US	English
MOKT (Lai et al., 2008)	5-point Likert scale	40-items	General information about osteoporosis, consequences of untreated osteoporosis, risk factors of osteoporosis and its treatment	Malaysia	English

Abbreviations: FOOQ- Facts on osteoporosis; OKAT- Osteoporosis knowledge assessment tool; OPQ- Osteoporosis questionnaire; OKT- Osteoporosis Knowledge test; OKQ- Osteoporosis knowledge questionnaire and MOKT- Malaysian osteoporosis knowledge too

In Malaysia, the MOKT (Lai et al., 2008) and the Malay version of the OKT (Abdulameer et al., 2013, Kim et al., 1991) have been validated. However, we wanted to assess the knowledge of osteoporosis and its prevention. Hence, these tools were unsuitable for use in our study as the MOKT assessed knowledge on osteoporosis and its treatment, while the OKT assessed osteoporosis knowledge by asking participants to rate the likelihood of getting osteoporosis based on the type of preventive measure taken (Kim et al., 1991, Lai et al., 2008). Hence, the aim of our study was to develop and validate the English version of the Osteoporosis Prevention and Awareness Tool (OPAAT) in Malaysia.

3.3.2 Objectives

To develop and validate Osteoporosis Prevention and Awareness Tool (OPAAT) in Malaysia.

3.3.3 Methods

This section presents the development and validation of a satisfaction questionnaire called the OPAAT which will be used as one of the methods to evaluate the osteoporosis screening and prevention programme. Issues relating to quantitative methods and questionnaires have been previously discussed in section 3.1.3.1 and 3.1.3.2.

3.3.3.1 Development of the Osteoporosis Prevention and Awareness Tool (OPAAT)

The OPAAT was developed based on modifications from the Malaysian Osteoporosis Knowledge Tool (MOKT) and findings from Phase one qualitative study which examined the barriers and needs towards an osteoporosis screening and prevention service in Malaysia.

3.3.3.1.1 Language

Despite Malay being the national language of Malaysia, postmenopausal women aged 50 years and above are more fluent in English as schooling was only conducted in the English language then. Hence, the OPAAT was developed in English.

3.3.3.1.2 Modification from the Malaysian Osteoporosis Knowledge Tool (MOKT)

We took 10 out of the 50 items from the MOKT, as the other items were related to assessing knowledge on risk factors of osteoporosis, osteoporosis medication or misconceptions about osteoporosis. Items about risk factors and misconceptions were removed as our qualitative results highlighted risk factors and other misconceptions which were more relevant to our population. Items on osteoporosis medications were removed as this questionnaire aimed to assess osteoporosis screening and prevention. Six items were rephrased. For item 1, we added the word "fracture" in parenthesis to emphasize that the word "broken bones" means fracture. For item 5, "early on" was removed as patients were unaware that osteoporosis was asymptomatic and the phrase "early on" may confuse them (Toh

et al., 2012). As for item 13 and 16, we combined the original four questions to develop two questions; as "a loss of height" and "hunchback" were essentially assessing the same thing, and "joint pain" and "swelling of the fingers" were both referring to symptoms of osteoarthritis. Four items from the MOKT were used in its original format.

3.3.3.1.3 Development of the Osteoporosis Prevention and Awareness Tool (OPAAT) based on the qualitative data in Phase one

Results from the qualitative study found that patients, nurses, general practitioners, pharmacists and policy makers lacked knowledge in the following areas: osteoporosis in general, consequences of untreated osteoporosis and osteoporosis prevention (Toh et al., 2012). Further details can be found in chapter 3, section 3.4.2.2.7.3. Therefore 22 new items were added. The final OPAAT consists of 30 items, and was divided into three domains: osteoporosis in general (domain A), consequences of untreated osteoporosis (domain B) and osteoporosis prevention (domain C).

3.3.3.2 Validation of the Osteoporosis Prevention and Awareness Tool (OPAAT))

3.3.3.3 Study design

The validation process was a cross sectional study.

3.3.3.4 Setting

The study was conducted at the primary care clinics of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia.

3.3.3.5 Period of study

The data collection began in October 2013 to January 2014.

3.3.3.6 Participants

3.3.3.6.1 Patient

English speaking postmenopausal women aged 50 years and above, who had not been diagnosed with osteoporosis/osteopenia were included (This information was obtained from the patient's medical records). Participants who were feeling too unwell to participate in the study were excluded. The OPAAT was administered to the patient group at baseline and 2 weeks later to assess for reliability.

3.3.3.6.2 Professional group

To assess discriminative validity, pharmacists were recruited from the same tertiary hospital. Pharmacists were expected to have a higher knowledge of osteoporosis than patients. The OPAAT was administered to the pharmacists only once, as we

wanted to assess the instrument's ability to discriminate between the knowledge scores of patients and healthcare professionals at baseline.

3.3.3.7 Sampling procedure

A 1:2 systematic random sampling method was used to recruit participants, as it was not possible for one researcher to recruit all the eligible participants at the clinic. The medical folders of eligible participants were labelled from 1-40, and a number was randomly drawn from a bag to determine the starting number at the start of each day. This was performed to ensure that sampling was random. Subsequently every 2nd medical folder was selected for recruitment.

Additionally, 11 participants were also recruited using the "snowballing" method. As the project went on, participants began to refer their friends and family. Although this was a non-randomized method of recruiting patients, only 11 (7.3%) participants were recruited in this manner.

3.3.3.8 Sample size
3.3.3.8.1 Patient group

Sample size was calculated based on a 5:1 participant ratio for factor analysis (Gorsuch, 1983). Since the OPAAT had 30 items, the total number of participants needed was 150. Allowing for a 20% loss to follow up, the final number of participants required was 180.

3.3.3.8.2 Professional group

The total number of pharmacists recruited was based on the number of pharmacists working in the hospital understudy. This group of participants was excluded from factor analysis.

3.3.3.9   Instruments used

3.3.3.9.1   Baseline demographics

Baseline demographic information such as patients' medical history, lifestyle and medication history was collected (Appendix 1). Healthcare professionals' baseline information, work experience and education level were also collected (Appendix 2).

3.3.3.9.2   Osteoporosis Prevention and Awareness Tool (OPAAT)

The OPAAT consist of 30 items with three domains: osteoporosis in general, consequence of untreated osteoporosis and osteoporosis preventive measure (Appendix 28). A score of one was given for a correct response and zero for an incorrect or do not know response. The total score was converted into percentage ranging from 0-100. Each domain score was also analyzed.

3.3.3.10   Procedure

Patients were recruited at the waiting area outside the general practitioner's consultation room as the waiting time to see the general practitioner's appointment ranges from one to two hours. Utilising this period of waiting allowed the research team to collect data without extending the duration of the patient's visit to the hospital.

The study was explained to the participants using an information sheet. Patient's written consent was obtained (Appendix 29 and 30). Baseline demographic information such as patients' medical history, lifestyle and medication history was collected. Patients answered the questionnaire themselves. For those who experienced some difficulty in reading the questions, the researcher assisted them. The researcher then checked the questionnaire to ensure that all questions were answered. This took approximately 10 minutes. The OPAAT was administered again to the same group of patients after two weeks to assess for reliability. A duration of two weeks was selected for retest, as this time interval is generally accepted to be long enough for participants not to have remembered their original responses, and not long enough for their knowledge of the subject to have changed (DeVon et al., 2007). Patients were questioned if any significant changes or events occurred within the past two weeks, and all changes were documented.

Pharmacists' baseline information, work experience and education level were also collected using a baseline information form specific for pharmacist. The OPAAT was administered to the pharmacists only once at baseline (Appendix 31 and 32).

3.3.3.11   Source of data
The source of data varied from medical registers, medical records, observations to observe if patients were too unwell to participate in the study, interviews, questionnaire and informal discussions to find out informally if patients have osteoporosis

during recruitment. Some of the data such as patients' clinical information were obtained from medical records prior to the provision of service, whilst other data were obtained during the counselling session with the pharmacist.

3.3.3.12   Ethics approval

The University Malaya Medical Centre Ethics Committee was obtained prior to the study (ref no. 920.27, Appendix 27). All required documents were submitted and approval was obtained one month after submission. In accordance with the ethics committee requirements, a report upon completion form has been submitted. Ethical issues such as anonymity, confidentiality and informed consent were considered in this study.

3.3.3.12.1   Anonymity and confidentiality

Only the researcher and the supervisors had access to the questionnaire. All information were coded and anonymized. The information collected as paper copies were stored under lock and key, while the electronic data can only be accessed with a secure password only accessible by the researcher and supervisors. The data collected were used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. All information which is collected was confidential and any form of identity will not be included in any publications.

3.3.3.12.2   Informed consent

Prior to the start of any research activity, written informed consent for participating was obtained from each participant.

3.3.3.13 Data analysis

All data was entered into the IBM® SPSS® version 20 (IBM Corporation, Armonk, NY, US). Flesch reading ease was calculated using Microsoft Office® Word® 2007 (Microsoft Corporation, Redmond, WA, US). Non-parametric tests were used since data obtained were not normally distributed. A p-value <0.05 was considered as statistically significant.

3.3.3.14 Face and content validity

Face and content validity of the OPAAT was established via consultation with an expert panel consisting of four pharmacists with many years of research and clinical experience. Comprehension of the questionnaire was tested on 10 postmenopausal women who understood English. This involved asking the patients for their opinions about the phrasing, format and content of the tool. The patients encountered no difficulty in answering the questionnaire. Hence, no further changes were made.

3.3.3.15 Factor analysis

The construct validity of OPAAT was examined using exploratory factor analysis (EFA). Traditionally, factor analysis such as EFA and confirmatory factor analysis (CFA) can only be performed when data are of a continuous scale (Harrington, 2009, Kim and Mueller, 1978). However, Bruin (2006) developed a new algorithm of EFA to account for categorical data. In this study, EFA was performed on three separate domains to explore the appropriateness of factor structure (Bruin, 2006). Factors with

eigenvalues greater than one were considered as having significant contribution in explaining the overall model variation and were retained (Kaiser, 1960, Harman, 1976).

3.3.3.16 Cronbach's α

Cronbach's α coefficient is a tool used to assess internal consistency. Cronbach's α value: >0.9- Excellent, >0.8- Good, >0.70- Acceptable, >0.6- Questionable, >0.5 – Poor and <0.5- Unacceptable (George and Mallery, 2003). If omitting an item increases Cronbach's α significantly, then excluding the item will increase the homogeneity of the scale (Cronbach, 1951).

3.3.3.17 Test retest

For test- retest, categorical data were analysed using the kappa measure of agreement and the Mc Nemar's test. In order to define inter-rater reliability, a kappa measure of agreement was calculated for each item. A kappa value of 0.5 represents moderate agreement, above 0.7 represents good agreement and above 0.8 represents very good agreement (Peat, 2001). Mc Nemar's test was used to examine the test-retest reliability on the individual items. Continuous data of the individual items and total domain scores were analyzed using the Wilcoxon signed-rank test and Spearman's rho correlation coefficient. According to Cohen 1988, a value of 0.10-0.29 showed a low correlation, 0.30-0.49 moderate correlation and 0.50-1.00 high correlation (Cohen, 1988).

3.3.3.18   Discriminative validity

To assess discriminative validity, the chi square test was used on categorical data of the individual items to detect the difference between the patient group and professional group. The Mann-Whitney U test was used for continuous data of the individual items and total domains score to compare if there was any significant difference between the patient and professional group.

3.3.3.19   Flesch reading ease

Flesch reading index is a tool used for estimating the reading comprehension level necessary to understand a written document based on the average number of syllables per word and the average number of words per sentence. The Flesch reading ease was calculated using the formula below: Flesch reading ease= 206.835- (1.015x average sentence length) - (84.6 x average number of syllables per word).

The Flesch reading score (which range from 0 to 100) indicates the level of difficulty in understanding the document. The lower the score, the greater the difficulty. An average document should have a score of 60-70 (Flesch, 1948).

3.3.3.20   Factors associated with knowledge

Linear multiple regression was used to identify factors associated with knowledge. It used to estimate the linear relationship between a dependent variable (knowledge score) and one or more independent variables (demographic variables).

3.3.4 Results (Phase two- Osteoporosis Prevention and Awareness Tool (OPAAT))

3.3.4.1 Participants

A total of 253 patients were approached, 19 declined. 234 participants were recruited (patients=203, hospital pharmacists=31), [patient response rate=91.4%, pharmacists response rate= 100.0%]. Patients' demographic data are shown in Table 3.10. Pharmacists recruited worked in different areas of the pharmacy, with working experience ranging from 1-10 years.

Table 3.10: Baseline demographic characteristics of patients

Characteristics	Patients (n=203)
Mean age ± S. D. (years) [range] (Median)	62.1±7.2 [50-79] (61.0)
Age range (years) [n (%)]	
<65	120 (59.1)
≥ 65	83 (40.9)
Ethnicity [n (%)]	
Malay	30 (14.8)
Chinese	126 (62.1)
Indian	44 (21.7)
Eurasian	3 (1.5)
Mean BMI (kg/m^2) ± S.D. (Median)	24.2±4.6 (23.3)
BM I (kg/m^2) [n (%)]	
<18.5 (underweight)	10 (4.9)
18.5-24.9 (normal)	118 (58.1)
25.0-29.9 (overweight)	55 (27.1)
≥30.0 (obese)	20 (9.9)
Level of education [n (%)]	
Primary (6 years of education)	10 (4.9)
Secondary (11-13 years of education)	78 (38.4)
Diploma/Technical school training (12-14 years of education)	39 (19.2)
Tertiary/Postgraduate (15-21 years of education)	76 (37.4)
Income per month [n (%)]	
<RM1000 (<$ 310.7)	36 (17.7)
RM1000-1999 ($ 310.7-621.0)	25 (12.3)
RM2000-2999 ($ 621.3- 931.7)	23 (11.3)
RM3000-3999 ($ 932.0- 1242.3)	21 (10.3)
RM4000-4999 ($ 1242.6-1553)	17 (8.4)
>RM5000 (>$1553.3)	81 (39.9)

S.D. = standard deviation; BMI=body mass index; $= US dollar

3.3.4.2 Factor analysis and psychometric properties of the Osteoporosis Prevention and Awareness Tool (OPAAT)

As shown in Table 3.11 (a), for domain A, EFA yielded one factor with an eigenvalue of 4.04 which contributed to 81.0% of total variation. Ten items within this domain have factor loadings greater than 0.3 in Table 3.12 (a), suggesting substantial contribution in explaining the overall variation. In Table 3.11 (b),for domain B, EFA also produced only one factor with an eigenvalue greater of 1.9, which explained 87.3% of the total variation. All five questions within this domain had factor loadings greater than 0.3 as shown in Table 3.12(b). In Table 3.11(c), for domain C, EFA generated only one factor with an eigenvalue greater than one (4.4). This factor contributed to 69.4% of total variation. Table 3.12 (c) showed that the factor loadings of all 12 items within this domain were above 0.3. Overall, the data from the three EFAs suggested the adequacy of one factor for each domain [Table 3.11 and 3.12].

Table 3.11: Eigenvalues of the domains in the Osteoporosis
Prevention and Awareness Tool (OPAAT) using exploratory factor
analysis (EFA)

(a) Eigenvalues of domain A

Domain A	Eigenvalue
Factor1	4.04065
Factor2	0.80586
Factor3	0.50583
Factor4	0.22203
Factor5	0.11458
Factor6	0.01873
Factor7	-0.02871
Factor8	-0.10657
Factor9	-0.16125
Factor10	-0.19727
Factor11	-0.22522

(b) Eigenvalues of domain B

Domain B	Eigenvalue
Factor1	1.8924
Factor2	0.74467
Factor3	-0.04495
Factor4	-0.19105
Factor5	-0.23417

(c) Eigenvalues of domain C

Domain C	Eigenvalue
Factor1	4.36008
Factor2	0.84406
Factor3	0.56791
Factor4	0.44087
Factor5	0.31589

Factor6	0.26055
Factor7	0.17115
Factor8	0.01055
Factor9	-0.04459
Factor10	-0.15964
Factor11	-0.21151
Factor12	-0.27104

Table 3.12: Factor loadings of the Osteoporosis Prevention and Awareness Tool (OPAAT) using exploratory factor analysis (EFA)

(a) Factor loadings of domain A

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8
ITEM1	0.3207	0.2394	-0.1778	0.1858	0.2448	0.2203	-0.0682	0.0334
ITEM2	0.3641	-0.2981	0.389	0.1759	0.1214	-0.05	-0.177	-0.0281
ITEM3	0.6867	0.4137	-0.0234	-0.2121	-0.1167	0.0259	-0.1924	0.0187
ITEM4	0.5165	-0.277	0.1993	0.0702	-0.2318	0.104	-0.0083	0.0588
ITEM5	0.7448	0.2325	0.057	0.3106	-0.1576	-0.1444	-0.0722	-0.0153
ITEM6	0.4156	0.4079	0.0697	0.27	0.0308	-0.0044	0.2128	-0.012
ITEM7	0.6944	-0.1801	0.1375	-0.04	0.1071	0.2178	0.0844	-0.0266
ITEM8	0.3345	0.1019	0.359	-0.1986	0.0684	0.0893	0.1261	0.019
ITEM9	0.6472	0.0113	-0.1588	-0.1892	-0.1781	0.172	-0.0105	-0.0556
ITEM10	0.6949	-0.3275	-0.3495	0.0851	0.1654	0.0115	-0.04	0.0059
ITEM11	0.7208	0.0986	0.0598	-0.2682	0.2446	-0.256	0.0009	0.0059
ITEM12	0.8021	-0.264	-0.1945	-0.0087	-0.1141	-0.1628	0.1512	0.0155

Only the factor loadings (represented as eigenvalue) greater than 1 were selected (Harman, 1976)

(b) Factor loadings of domain B

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8
ITEM12	0.3207	0.2394	-0.1778	0.1858	0.2448	0.2203	-0.0682	0.0334
ITEM13	0.3641	-0.2981	0.389	0.1759	0.1214	-0.05	-0.177	-0.0281
ITEM14	0.6867	0.4137	-0.0234	-0.2121	-0.1167	0.0259	-0.1924	0.0187
ITEM15	0.5165	-0.277	0.1993	0.0702	-0.2318	0.104	-0.0083	0.0588
ITEM16	0.7448	0.2325	0.057	0.3106	-0.1576	-0.1444	-0.0722	-0.0153

Only the factor loadings (represented as eigenvalue) greater than 1 were selected (Harman, 1976)

(c) Factor loadings of domain C

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8
ITEM17	0.3207	0.2394	-0.1778	0.1858	0.2448	0.2203	-0.0682	0.0334
ITEM19	0.3641	-0.2981	0.389	0.1759	0.1214	-0.05	-0.177	-0.0281
ITEM20	0.6867	0.4137	-0.0234	-0.2121	-0.1167	0.0259	-0.1924	0.0187
ITEM21	0.5165	-0.277	0.1993	0.0702	-0.2318	0.104	-0.0083	0.0588
ITEM22	0.7448	0.2325	0.057	0.3106	-0.1576	-0.1444	-0.0722	-0.0153
ITEM23	0.4156	0.4079	0.0697	0.27	0.0308	-0.0044	0.2128	-0.012
ITEM24	0.6944	-0.1801	0.1375	-0.04	0.1071	0.2178	0.0844	-0.0266
ITEM25	0.3345	0.1019	0.359	-0.1986	0.0684	0.0893	0.1261	0.019
ITEM26	0.6472	0.0113	-0.1588	-0.1892	-0.1781	0.172	-0.0105	-0.0556
ITEM27	0.6949	-0.3275	-0.3495	0.0851	0.1654	0.0115	-0.04	0.0059
ITEM29	0.7208	0.0986	0.0598	-0.2682	0.2446	-0.256	0.0009	0.0059
ITEM30	0.8021	-0.264	-0.1945	-0.0087	-0.1141	-0.1628	0.1512	0.0155

Only the factor loadings (represented as eigenvalue) greater than 1 were selected (Harman, 1976)

3.3.4.3   Difficulty factors

The mean ± SD accuracy rate was 0.60±0.22 (range: 0.26-0.94). Four out of 30(13.3%) items had values <0.3 and 11/30(36.7%) items had values of >0.75. The remaining 15/30(50.0%) items had values between 0.3-0.75 [Table 3.13].

3.3.4.4   Cronbach's α

Cronbach's α was analyzed for the three domains. All domains had a Cronbach's α of ≥0.6 except for domain B (0.286). Thirteen out of 30 items had corrected item –total correlations <0.3 [Table 3.13].

Table 3.13: Psychometric properties of the Osteoporosis Prevention And Awareness Tool (OPAAT)

Domains	Item Number		Difficulty factor	Cronbach's α	Corrected Item correlation	Cronbach's α if item deleted
	1	Makes bones weaker, more brittle and more likely to break (fracture)	0.91		0.421	0.639
	2	Everybody will get osteoporosis as it is part of aging	0.32		0.173	0.672
Osteoporosis in general (A)	3	Osteoporosis occurs because bone is removed faster than it is formed	0.52	0.668	0.176	0.673
	4	Osteoporosis and osteoarthritis are different names we can use to describe the same disease	0.58		0.455	0.619
	5	Osteoporosis usually has no symptoms	0.48		0.065	0.693
	6	Postmenopausal women are not at risk for osteoporosis	0.72		0.416	0.629
	7	Osteoporosis is an untreatable disease.	0.56		0.232	0.663
	8	A bone mineral density test is used to diagnose osteoporosis	0.76		0.428	0.628
	9	I do not need a bone mineral density test unless I fracture my bones.	0.79		0.555	0.608
	10	A bone mineral density test is high in radiation	0.45		0.321	0.646
	11	A bone mineral density test should be performed monthly to monitor bone loss	0.60		0.407	0.629

	12	Results in back pain	0.72		0.272	0.095
Consequences of untreated osteoporosis (B)	13	Loss of height or hunchback	0.88		0.235	0.173
	14	Loss of mobility (unable to move around myself)	0.78	0.286	0.164	0.215
	15	Results in tooth loss	0.26		0.006	0.373
	16	Results in joint pain or swelling of fingers	0.27		0.056	0.319
	17	The recommended daily intake for calcium in women above 50 years of age is 1000mg	0.61		0.274	0.744
	18	It is too late to increase calcium intake after the age 50	0.55		0.417	0.727
	19	Glucosamine can help prevent osteoporosis	0.29		0.181	0.753
	20	Calcium supplements can help prevent osteoporosis	0.85		0.397	0.731
Osteoporosis prevention (C)	21	The regular dose of calcium supplements can cause kidney stones.	0.26	0.748	0.264	0.744
	22	Foods such as milk, tofu, anchovies (*ikan bilis*), yellow dhal and spinach are rich in calcium	0.90		0.398	0.73
	23	You can obtain your recommended daily intake of vitamin D via exposing your skin to sunlight for about 15 minutes a day	0.87		0.300	0.739
	24	Increasing coffee and tea intake can help in osteoporosis prevention	0.67		0.479	0.719
	25	Weight bearing exercise (such as brisk walking and line dancing) can decrease bone loss.	0.68		0.248	0.747
	26	Exercise will wear out bones	0.78		0.459	0.723
	27	Certain medications (such as sleeping tablets or	0.57		0.421	0.726

No	Statement				
	high blood pressure medications) may reduce the risk of falling				
28	To prevent falls, comfortable shoes with a good grip should be used.	0.94		0.524	0.728
29	Poor vision may lead to falls	0.92		0.380	0.734
30	Being under weight helps prevent osteoporosis	0.60		0.490	0.718
Total Cronbach's α			0.820		

3.3.4.5 Test retest

At retest, 9 (4.4%) patients could not be contacted. Hence, only 194 participants were included at retest (response rate = 95.6%) [See table 3.14]. The Kappa measurement of agreement for 29/30 items (96.7%) were ≥0.8, and 1/30 items (3.3%) was ≥0.7. The McNemar's test showed no significant differences for all 30 items at test retest. The Wilcoxon signed-rank test showed no significant difference for all domain scores except for the domain on the 'consequences of untreated osteoporosis.' However, the total score showed no significant difference. All domains and items were significantly correlated using the Spearman's rho correlation coefficient (0.760-0.990, $p<0.05$) [Table 3.14].

Table 3.14: Test and retest reliability of the individual items for the Osteoporosis Prevention And Awareness Tool (OPAAT)

Domain	Item number	Test (n=203)			Retest (n=194)			McNemar's test p-value	Kappa measurement of agreement** P-value	Spearman's rho correlation coefficient*	Wilcoxon signed-rank test		
		Mean±SD	Median	No. of correct responses [n (%)]	Mean±SD	Median	No. of correct responses [n (%)]				Mean/rank	z-value	P-value
Osteoporosis in general (A)	1	0.91±0.28	1.00	185 (91.1)	0.89±0.32	1.00	172 (88.7)	0.219	0.833	0.838			
	2	0.32±0.47	0.00	64 (31.5)	0.30±0.46	0.00	58 (29.9)	0.250	0.964	0.964			
	3	0.52±0.50	1.00	105(51.7)	0.52±0.50	1.00	101 (52.1)	1.000	0.979	0.979			
	4	0.58±0.50	1.00	117 (57.6)	0.57±0.50	1.00	110 (56.7)	1.000	0.958	0.958			
	5	0.48±0.50	0.00	97 (47.8)	0.48±0.50	0.00	94 (48.5)	1.000	0.990	0.990			
	6	0.72±0.45	1.00	147 (72.4)	0.71±0.46	1.00	137 70.6)	0.508	0.886	0.887			
	7	0.56±0.50	1.00	113 (55.7)	0.54±0.50	1.00	105 (54.1)	0.453	0.927	0.928			
	8	0.76±0.43	1.00	155 (76.4)	0.74±0.44	1.00	144 (74.2)	0.219	0.917	0.918			
	9	0.79±0.41	1.00	160 (78.8)	0.78±0.42	1.00	152 (78.4)	1.000	0.970	0.970			
	10	0.45±0.50	0.00	92 (45.3)	0.46±0.50	0.00	90 (46.4)	0.219	0.938	0.938			
	11	0.60±0.49	1.00	121 (59.6)	0.60±0.49	1.00	118 (60.8)	0.754	0.892	0.893			
	Domain score (%)	60.7±22.2	63.64		60.0±23.8	63.63				0.953	14.54/11.33	-0.724	0.469
Consequences of untreated	12	0.72±0.45	1.00	147 (72.4)	0.72±0.45	1.00	140 (72.2)	1.000	0.923	0.923			
	13	0.88±0.33	1.00	178 (87.7)	0.89±0.31	1.00	173 (89.2)	0.250	0.925	0.927			
	14	0.78±0.42	1.00	158 (77.8)	0.78±0.41	1.00	152 (78.4)	0.500	0.970	0.971			

		Mean±SD	Median	n (%)	Mean±SD	Median	n (%)	p	Kappa		Mean rank	z	p
osteoporosis (B)	15	0.26±0.44	0.00	52 (25.6)	0.27±0.45	0.00	53 (27.3)	0.453	0.908	0.908			
	16	0.27±0.44	0.00	54 (26.6)	0.29±0.45	0.00	56 (28.9)	0.219	0.923	0.924			
	Domain score (%)	58.0±21.3	60.00		59.2±21.7	60.00				0.909	7.50/10.27	-2.216	0.027*
Prevention of osteoporosis (C)	17	0.61±0.49	1.00	123 (60.6)	0.60±0.49	1.00	116 (59.8)	0.687	0.935	0.936			
	18	0.55±0.50	1.00	112 (55.2)	0.55±0.50	1.00	106 (54.6)	1.000	0.948	0.948			
	19	0.29±0.46	0.00	59 (29.1)	0.28±0.45	0.00	55 (28.4)	1.000	0.962	0.962			
	20	0.85±0.36	1.00	173 (85.2)	0.83±0.38	1.00	161 (83.0)	0.250	0.943	0.945			
	21	0.26±0.44	0.00	52 (25.6)	0.26±0.44	0.00	51 (26.3)	0.375	0.932	0.933			
	22	0.90±0.30	1.00	183 (90.1)	0.88±0.32	1.00	171 (88.1)	0.375	0.869	0.872			
	23	0.87±0.34	1.00	176 (86.7)	0.85±0.36	1.00	165 (85.1)	0.453	0.852	0.854			
	24	0.67±0.47	1.00	137 (67.5)	0.68±0.47	1.00	131 (67.5)	0.727	0.905	0.905			
	25	0.68±0.47	1.00	138 (68.0)	0.65±0.48	1.00	126 (64.9)	0.070	0.908	0.910			
	26	0.78±0.41	1.00	159 (78.3)	0.76±0.43	1.00	148 (76.3)	0.289	0.882	0.884			
	27	0.57±0.50	1.00	116 (57.1)	0.55±0.50	1.00	106 (54.6)	0.405	0.760	0.761			
	28	0.94±0.24	1.00	191 (94.1)	0.92±0.28	1.00	178 (91.8)	0.125	0.846	0.856			
	29	0.92±0.28	1.00	186 (91.6)	0.90±0.30	1.00	174 (89.7)	0.250	0.910	0.914			
	30	0.60±0.49	1.00	122 (60.1)	0.59±0.49	1.00	115 (59.3)	1.000	0.947	0.947			
	Domain score (%)	67.8±20.2	71.42		66.4±22.6	71.43				0.937	21.17/19.50	-1.339	0.171
Total OPAAT score (%)		63.6±17.4	66.67		62.9±19.1	66.67				0.950	28.98/27.05	-0.107	0.914

*Statistically significant at p<0.05. Wilcoxon signed-rank test and Spearman's rho correlation coefficient was used for continuous variables.

McNemar's test and Kappa measurement of agreement was conducted for categorical variables

3.3.4.6 Discriminative validity

The overall total knowledge score for the pharmacist group was significantly higher than the patient group (80.9±8.7 vs 63.6±17.4, p<0.001) [Table 3.15]. No significant difference was seen for 16/30(53.3%) items.

Table 3.15: Knowledge scores of the patient and pharmacist group at test and retest

Domains	Item Number	Patients(n=203)			Pharmacist(n=31)			Mann-Whitney U-test			p-value [a]
		Mean±SD	Median	Participants that answered correctly [n (%)]	Mean±SD	Median	Participants that answered correctly [n (%)]	Mean/rank	Z-value	p-value	
Osteoporosis in general (A)	1	0.91±0.28	1.00	185 (91.1)	0.97±1.80	1.00	30 (96.8)				0.482 [b]
	2	0.32±0.47	0.00	64 (31.5)	0.58±0.50	1.00	18 (58.1)				0.007*
	3	0.52±0.50	1.00	105(51.7)	0.90±0.30	1.00	28 (90.3)				0.000*
	4	0.58±0.50	1.00	117 (57.6)	0.94±0.25	1.00	29 (93.5)				0.000*
	5	0.48±0.50	0.00	97 (47.8)	0.55±0.51	1.00	17 (54.8)				0.590
	6	0.72±0.45	1.00	147 (72.4)	1.00±0.00	1.00	31 (100.0)				0.002*
	7	0.56±0.50	1.00	113 (55.7)	0.68±0.48	1.00	21 (67.7)				0.284
	8	0.76±0.43	1.00	155 (76.4)	0.94±0.25	1.00	29 (93.5)				0.052
	9	0.79±0.41	1.00	160 (78.8)	0.97±0.18	1.00	30 (96.8)				0.033*
	10	0.45±0.50	0.00	92 (45.3)	0.48±0.51	0.00	15 (48.4)				0.900
	11	0.60±0.49	1.00	121 (59.6)	0.77±0.43	1.00	24 (77.4)				0.088
	Domain score (%)	60.7±22.2	63.64		79.8±12.6	81.82		109.23/171.68	-4.834	0.000*	

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	Item	Mean±SD	Median	n (%)	Mean±SD	Median	n (%)				p
Consequenc es of untreated osteoporosis (B)	12	0.72±0.45	1.00	147 (72.4)	0.77±0.43	1.00	24 (77.4)				0.713
	13	0.88±0.33	1.00	178 (87.7)	0.84±0.37	1.00	26 (83.9)				0.565 [b]
	14	0.78±0.42	1.00	158 (77.8)	0.81±0.40	1.00	25 (80.6)				0.905
	15	0.26±0.44	0.00	52 (25.6)	0.51±0.51	1.00	16 (51.6)				0.006*
	16	0.27±0.44	0.00	54 (26.6)	0.74±0.44	1.00	23 (74.2)				0.000*
	Domain score (%)	58.0±21.3	60.00		73.6±17.4	80.00		110.98/160.21	-4.086	0.000*	
Prevention of osteoporosis (C)	17	0.61±0.49	1.00	123 (60.6)	0.58±0.50	1.00	18 (58.1)				0.944
	18	0.55±0.50	1.00	112 (55.2)	0.84±0.37	1.00	26 (83.9)				0.005*
	19	0.29±0.46	0.00	59 (29.1)	0.78±0.43	1.00	24 (77.4)				0.000*
	20	0.85±0.36	1.00	173 (85.2)	0.94±0.25	1.00	29 (93.5)				0.271 [b]
	21	0.26±0.44	0.00	52 (25.6)	0.61±0.50	1.00	19 (61.3)				0.000*
	22	0.90±0.30	1.00	183 (90.1)	1.00±0.00	1.00	31 (100.0)				0.084 [b]
	23	0.87±0.34	1.00	176 (86.7)	0.81±0.40	1.00	25 (80.6)				0.405 [b]
	24	0.67±0.47	1.00	137 (67.5)	0.94±0.25	1.00	29 (93.5)				0.006*
	25	0.68±0.47	1.00	138 (68.0)	0.71±0.46	1.00	22 (71.0)				0.900
	26	0.78±0.41	1.00	159 (78.3)	0.84±0.37	1.00	26 (83.9)				0.638
	27	0.57±0.50	1.00	116 (57.1)	0.94±0.25	1.00	29 (93.5)				0.000*
	28	0.94±0.24	1.00	191 (94.1)	0.97±0.18	1.00	30 (96.8)				1.000 [b]
	29	0.92±0.28	1.00	186 (91.6)	1.00±0.00	1.00	31 (100.0)				0.138 [b]
	30	0.60±0.49	1.00	122 (60.1)	0.87±0.34	1.00	27 (87.1)				0.007*

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Domain score (%)	67.8±20.2	71.42		84.3±10.5	85.71	109.14/172.26	-4.876	0.000*
Total (%)	63.6±17.4	66.67		80.9±8.7	83.33	107.67/181.84	-5.694	0.000*

* Statistically significant at p<0.05, The Mann-Whitney U-test was conducted for continuous variables and the chi square was conducted for categorical variables.
[a] Chi-square test [b] Fisher's exact test was used as the number of cells with expected count less that 5 is more than 20% of the total number of cells

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3.3.4.7   Flesch reading ease

Flesh reading ease was 59.2.

3.3.4.8   Factors associated with knowledge

Knowledge was higher in patients who completed their high school education, and patients who conducted fall prevention activities ($R^2=0.208$, F=3.949, df=18, $p<0.001$). These two factors explained 27.9% of the variances.

3.3.4.9   Comparison of the Osteoporosis Prevention and Awareness Tool (OPAAT) with other validated instruments

The OPAAT had a similar Flesch reading ease as the MOKT. The Cronbach's α of the OPAATs domain was 0.29, 0.67 and 0.75. Two of OPAAT's domains had similar Cronbach's α to the MOKT, Osteoporosis and you, OKAT and FOOQ which ranged from 0.60-0.82. This shows that the psychometric properties of the OPAAT were similar to that of other validated instruments for measuring patients' knowledge [Table 3.16].

Table 3.16: Comparison of psychometric properties of the Osteoporosis Prevention And Awareness Tool (OPAAT)

	OPAAT	MOKT	Osteoporosis and You	OKAT	FOOQ	OKQ	OPQ
Age (years)	50-79	49-84	65-90	25-44	-	≥ 60	≥ 50
Number of subjects	203	88	871	467	256	188	50
Number of items with low difficulty level (%)	4(13.3)	19 (47.5)	6 (60)	3(15)	-	-	(44)
Flesch reading ease	59.2	57	-	45	81-90	-	74.3
Cronbach's α or Kuder Richardson (KR)	0.27-0.75	0.82	0.60	0.70	0.76	0.80 (KR)	0.84 (KR)
Mean score (%)	63.6	69.0	37.7	44.0	-	57.4	-

OPAAT: Osteoporosis Prevention And Awareness Tool; MOKT: Malaysian Osteoporosis Knowledge Test (Lai et al., 2008), Osteoporosis and You (Cadarette et al., 2007); OKAT: Osteoporosis Knowledge Assessment Tool (Winzenberg et al., 2003); FOOQ: facts on Osteoporosis Quiz (Ailinger et al., 1998, Ailinger et al., 2003); OKQ: Osteoporosis Knowledge Questionnaire (Curry and Hogstel, 2001); OPQ: Osteoporosis Questionnaire (Pande et al., 2000)

3.3.5 Discussion

The OPAAT performed satisfactorily in its psychometric properties and was able to discriminate between knowledge level of patients and pharmacists. This indicates that the English version of OPAAT is suitable to assess knowledge of postmenopausal women about osteoporosis prevention in Malaysia.

EFA confirmed that there were three domains (osteoporosis in general, consequences of untreated osteoporosis and osteoporosis prevention) in the OPAAT to assess patient's knowledge on osteoporosis and its prevention. This provides support for the construct validity of our tool. To the best of our knowledge no other osteoporosis knowledge assessment tool has validated the construct of their tool via this method.

Flesch reading ease was at 59.2. This indicates the OPAAT can be understood by patients who have completed primary education. Since all of our participants have completed primary education, they were able to complete the OPAAT without any problems. The mean ± SD accuracy rate was 0.60±0.22 (range:0.26-0.94). Out of the 30 items, four items were considered difficult (accuracy rates <0.3) and five considered easy (accuracy rates >0.7). The optimum difficulty level would be 0.5. This indicates that the OPAAT was moderately easy for the participants to answer.

The construct of the tool was considered to be multi-dimensional and an overall Cronbach's α was unsuitable. We then analyzed the Cronbach's α by domain. All domains demonstrated good and acceptable internal reliability except the domain on the 'consequences of untreated osteoporosis'

with a Cronbach α value of 0.286. This could be because there were only 5 items in this domain, and knowing the correct answer for one item may not necessarily mean that they knew the correct answer for the next item. However, increasing the number of items within the domain would have made the questionnaire too lengthy reducing the likelihood of completion. Corrected item-total correlations showed that all items measured the same main component which was satisfactory except items 13/30(43.3%). However all items were retained as removing any of the items did not improve the overall Cronbach's α significantly.

All 30 items performed satisfactorily at test-retest. Kappa measurement of agreement showed that 29/30 items (96.7%) were in very good agreement, and 1/30 items (3.3%) was in good agreement. As for the domains all domains performed satisfactorily except for the domain on "consequences of untreated osteoporosis." Patients may have forgotten the answer they selected at test (as they might have been guessing) as opposed to knowing the right answer. This led to a significant difference in this domain score as it had a small number of items. Although this limits how well this domain can measure the knowledge on the consequences of untreated osteoporosis, the guessing of answer reflects actual practice. Nonetheless, there was no significant difference in the overall scores. This indicates the OPAAT has achieved stable reliability. The domains and items had a high Spearman's rho correlation coefficient ranging from 0.760-0.990. They were all significantly correlated at $p<0.05$. Therefore, all items were retained.

Although pharmacists were expected to have a higher score than patients for all items, there were three items (items no. 13, 17 and 23) where no significant difference was found. This may be because more than 80.0% of both patients and pharmacists correctly answered items no. 13 and 23, indicating that their knowledge level for these items were high. As for item no. 17 which was pertaining to calcium intake, less than 60.6% of patients and pharmacists answered this item correctly. This concurs with our previous qualitative findings that found that both patients and pharmacists lacked knowledge in this area. (Toh et al., 2012). Nonetheless, the overall score and all domain scores of the OPAAT showed a significant difference between the patient and pharmacist group. This indicates that the OPAAT has achieved discriminative validity.

Previous studies have found that the knowledge of osteoporosis in adult women aged 21-90 years in Europe (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Ungan and Tumer, 2001), Canada (Cadarette et al., 2007), United States (Ailinger and Emerson, 1998, Burke-Doe et al., 2008), Middle East (Baheiraei et al., 2005b), and Australia (Winzenberg et al., 2003) was low. Conversely, women and men aged 16-79 years in Norway were knowledgeable about osteoporosis (Magnus et al., 1996). In Asia, the knowledge of osteoporosis ranged from low to moderate for women aged 19-90 in Brunei (Liza et al., 2009), Singapore (Saw et al., 2003) and Malaysia (Abdulameer et al., 2013, Yeap et al., 2010, Khan et al., 2014). However, another study in Malaysia found that the knowledge of osteoporosis was moderate in women aged 49-84 (Lai et al., 2008). In our study, patients' overall knowledge score was 63.6±17.4, which indicate that

their knowledge level was moderate. Our results were similar to a previous study conducted in Malaysia which assessed knowledge on osteoporosis and its prevention (Lai et al., 2008). This may be because both studies were conducted in the same setting. In addition, participants in both studies were mainly health seeking urban patients.

However, we would like to highlight that the cohort of patients used in the Lai et al (2008) study were patients who had osteoporosis, whilst our cohort were patients who did not have osteoporosis (Lai et al., 2008). This shows that there was no difference in knowledge in patients with or without osteoporosis. Another tool, the Osteoporosis Knowledge Questionnaire (OKQ) assessed knowledge on osteoporosis risk factors, diagnosis, prevention and treatment in female population aged 60 and above scored 57.4% (Curry and Hogstel, 2001). The OKQ score was similar to the OPAAT as they assessed non-osteoporotic postmenopausal population of a similar age group. Additionally, we would like to highlight the lack of knowledge on osteoporosis occurs in women who have not experienced a fracture, as well as those who had a previous fracture (Beaton et al., 2012). The different tools used to assess knowledge and the different cohorts in which the tool was administered to (Lai et al., 2008, Abdulameer et al., 2013, Khan et al., 2014, Yeap et al., 2010) made comparison between studies difficult. In addition, most studies did not report the use of validated tools to assess knowledge levels (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Ungan and Tumer, 2001, Burke-Doe et al., 2008, Liza et al., 2009, Yeap et al., 2010, Khan et al., 2014, Kasper et al., 1994, Etemadifar, 2013, Magnus et al., 1996).

Patients' knowledge was lowest on the domain on the 'consequences of untreated osteoporosis.' This concurs with findings from our qualitative research which indicates that there is a need to educate patients in this area (Toh et al., 2012). Correspondingly, Osteoporosis and You noted a deficit in knowledge in the area of consequences of untreated osteoporosis (Cadarette et al., 2007). These tools were developed mainly to assess the knowledge of domains of osteoporosis in general and treatment, the OPAAT was developed specifically to evaluate osteoporosis prevention.

In our study, factors with a positive correlation to the knowledge score includes patients with a secondary or higher education level, and patients who conducted fall prevention activities. Similarly, a Greek and Turkish study noted an association with knowledge and level of education (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Khan et al., 2014). Additionally, Khan et al's (2014) findings concurred with our study as they noted a significant association between knowledge and ethnicity (Khan et al., 2014). Conversely, Ailinger et al stated neither education level, age nor the menopause status increase osteoporosis knowledge (Ailinger and Emerson, 1998). Patients who conduct fall preventive measure had more knowledge of osteoporosis. This further justifies the importance of a higher knowledge level about osteoporosis prevention to ensure its implementation.

3.3.6 Strengths

The strength of our study was that we developed the OPAAT based on literature review as well as findings from a previous qualitative study. By utilising findings from our qualitative data, we were able to identify the areas in which knowledge of osteoporosis was low in our population.

3.3.7 Limitations

One of the limitations of our study was that convergent validity could not be performed. This was because during the period of our study, no such tool exists. The participants that we recruited also did not represent the ethnic distribution of Malaysia, but it represented the patients who sought treatment in our study site. Nonetheless, a large proportion of our patients had a monthly household income above $1553 (39.9%) which was representative of the married Malaysian household population income (Department of statistics Malaysia, 2013). Seventy six percent of our participants were married. (Department of statistics Malaysia, 2013). This shows that our participants income were representative of the Malaysian population.

Another limitation of our study was that we used mixed methods of administration. At baseline, majority of participants answered the OPPAT themselves, whilst a minority (2.5%) required assistance. At retest, the OPAAT was administered over the telephone as we wanted to optimize response rates. There is a possibility that participants may answer the items differently due to the mixed modes of administration (Check and Schutt, 2012). However, this effect would be applicable to all participants, hence its effects on the calidation process would be negated.

Additionally, our study used a mixed method of recruitment. Eleven (7.3%) of the participants was recruited using the snowballing method instead of random sampling. This was an error by the researcher. Although this was a non-randomized method of recruiting the patients, it only comprised of 7.3% of the participants in our study and should not affect the outcomes as 15% of the sample size was allocated for drop out.

3.3.8 Conclusion

The English version of the OPAAT was found to be a reliable and valid instrument for assessing patient knowledge on osteoporosis and its prevention in Malaysia. OPAAT can subsequently be used to evaluate the effectiveness of the education efforts provided. Future studies, using Bahasa Malaysia and Mandarin versions of the questionnaire are required to assess patient knowledge for Malaysians that are not fluent in English.

3.4 Validation of osteoporosis risk assessment tools

3.4.1 Introduction

3.4.1.1 Importance of screening for osteoporosis

Despite its medical and economic impact only 17-20% of women with a fragility fractures were screened for osteoporosis (Hajcsar et al., 2000, Greenspan et al., 2012). It is therefore important to identify postmenopausal women who are at risk for developing osteoporosis to prevent unwanted fractures. The end result of osteoporosis is a fragility fracture. Fragility fractures can occur in various sites most notably the hips, vertebrae and forearm (National Osteoporosis Foundation, 2010). The World Health Organization provides that the worldwide projection of hip fractures cases due to osteoporosis will rise from 1.7 million in 1990 to 6.3 million by 2050 with a steep increase to be observed in developing countries (World Health Organization Geneva, 1999).

According to the World Health Organization (WHO), osteoporosis is diagnosed when the T-score at the hip or spine is ≤ -2.5 (National Osteoporosis Foundation, 2010). This becomes a problem for a newly industrialized country like Malaysia as the dual-energy x-ray absorptiometry (DEXA) machine is costly and not widely available (Ministry of Health Malaysia, 2012, International Osteoporosis Foundation, 2009). Therefore, screening which aid in early detection are the most effective and cost-effective ways to slow down the progression of osteoporosis.

3.4.1.2   Screening strategies

We have previously discussed the available screening strategies such as the BMD, QUS and questionnaires in section 1.7.3 and 1.7.4. In this chapter we would like to focus on the screening strategies using questionnaires. There are currently six validated risk assessment tools. The Simple Calculated Osteoporosis Risk Estimation (SCORE) (Lydick et al., 1998), the Osteoporosis Risk Assessment Index (ORAI) (Cadarette et al., 2000), the Age Bulk One or Never Estrogen (ABONE) (Weinstein and Ullery, 2000) , the Body Weight (WEIGHT) (Michaëlsson et al., 1996), the Malaysian Osteoporosis Screening Tool (MOST) (Lim et al., 2011) and the Osteoporosis Screening Tools for Asians (OSTA) (Koh et al., 2001b) have been developed to perform an "initial screen" to determine if the patient requires a bone mineral density (BMD) scan [Table 3.17]. They do not replace the need for a BMD scan, but rather, these tools can be used to screen a larger number of women who potentially may require a BMD scan.

Table 3.17: Summary on the types of screening strategies using questionnaires

Name of questionnaire	Country developed	Development cohort	Specificity	Sensitivity	Primary outcome measured	Country validated
SCORE (Lydick et al., 1998)	US(Lydick et al., 1998)	1424 community-dwelling postmenopausal women aged ≥45 years (white, black, Hispanic) (Lydick et al., 1998) from 106 centres	50.0% (Lydick et al., 1998)	89.0% (Lydick et al., 1998)	Femoral neck T-score ≤-2 (Lydick et al., 1998)	United States of America (Lydick et al., 1998, Geusens et al., 2002), Netherlands(Geusens et al., 2002), Belgium (Sedrine et al., 2001, Richy et al., 2003, Gourlay et al., 2005) and Singapore (Chan et al., 2006)
ORAI (Cadarette et al., 2000)	Canada(Cadarette et al., 2000)	The database of the Canadian Multicentre Osteoporosis Study comprising of 926 non-institutionalized female subjects aged	45.1%(Cadarette et al., 2000)	90.0% (Cadarette et al., 2000)	Either femoral neck of lumbar spine T-score ≤-2(Cadarette et al., 2000)	Canada (Cadarette et al., 2000), Singapore (Chan et al., 2006), Belgium (Gourlay et al., 2005, Richy et al., 2003), United States of

		≥45 years from three centres(Cadarette et al., 2000)				America(Geusens et al., 2002) and the Netherlands (Geusens et al., 2002)
ABONE (Weinstein and Ullery, 2000)	US (Weinstein and Ullery, 2000)	1610 postmenopausal white women using a questionnaire using logistic regression (Weinstein and Ullery, 2000)	The sensitivity and the specificity of this tool was not published (Weinstein and Ullery, 2000)		T-score ≤-2.5 of either the total hip, femoral neck or spine (Weinstein and Ullery, 2000)	Singapore (Chan et al., 2006).
WEIGHT (Michaëlsson et al., 1996)	Sweden (Michaëlsson et al., 1996)	175 randomly-selected women aged 28-74 years in Sweden(Michaëlsson et al., 1996)	36.0%(Michaëlsson et al., 1996)	94.0%(Michaëlsson et al., 1996)	Femoral neck T-score <-2.5. (Michaëlsson et al., 1996)	Singapore (Chan et al., 2006)
			38.0%(Michaëlsson et al., 1996)	89.0%(Michaëlsson et al., 1996)	T-score <-2.5 of the lumbar spine(Michaëlsson et al., 1996)	
MOST(Lim et al., 2011)	Malaysia(Lim et al., 2011)	Secondary analysis from a large scale study involving a lifestyle intervention	61.6%(Lim et al., 2011)	73.2% (Lim et al., 2011)	T-score ≤-2 of the either the femoral neck of the lumbar spine	Malaysia (Lim et al., 2011)

		programme. A total of 514 healthy Malaysian women aged ≥45 were recruited. (Lim et al., 2011)				(Lim et al., 2011)
OSTA (Koh et al., 2001b)	China, Taiwan, Hong Kong, Korea, Malaysia, Singapore, Thailand and Philippines (Koh et al., 2001b)	860 postmenopausal Asian women from 21 clinics in eight countries (Koh et al., 2001b)	45.0%(Koh et al., 2001b)	91.0%(Koh et al., 2001b)	Femoral neck T-scores ≤-2.5(Koh et al., 2001b)	Japan (Saetung et al., 2008) Belgium (Gourlay et al., 2005, Richy et al., 2003), United States of America (Geusens et al., 2002), Netherlands (Geusens et al., 2002), Taiwan (Li, 2008), Thailand (Geater et al., 2004), Philippines (Li-Yu et al., 2005), Hong Kong (Kung et al., 2003) and Singapore (Chan et al., 2006)

3.4.1.3 The availability of osteoporosis risk assessment tool in Malaysia

A literature search noted that these tools have been validated in the United States of America (Lydick et al., 1998, Geusens et al., 2002), Canada (Cadarette et al., 2004), Belgium (Richy et al., 2003, Gourlay et al., 2005), Netherlands (Geusens et al., 2002), Philippines (Li-Yu et al., 2005), Japan (Fujiwara et al., 2001), Korea (Park et al., 2003), Thailand (Saetung et al., 2008, Geater et al., 2004), Taiwan (Li, 2008), Hong Kong (Kung et al., 2003) and Singapore (Chan et al., 2006). The validation of an instrument is crucial to ensure that the difference in the population are accounted for and the instrument measure what is was designed to measure (Smith, 2002, Lai, 2013). Despite being widely applied in the Caucasian and Asian population, these tools were not validated in the Malaysia except the MOST. However, the validation of the MOST was conducted with a small sample size of 72 participants. The OSTA was recommended by the Malaysian clinical practice guideline for osteoporosis as the OSTA's development involved the Malaysian population (Koh et al., 2001b). However, it has only been validated in the Malay population where else, the Malaysian population comprises of Malays, Chinese and Indians (Muslim et al., 2012).

3.4.2 Objectives

Therefore, this study aimed to determine the validity and reliability of six risk assessment tools in Malaysia.

3.4.3 Methods

3.4.3.1   Study design

This was a cross sectional study.

3.4.3.2   Setting

The study was conducted at the primary care clinics of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia.

3.4.3.3   Period of study

Data was collected from October 2013 until January 2014.

3.4.3.4   Participants

3.4.3.5   Patient identification and recruitment

English speaking postmenopausal women aged 50 years and above, who have not been diagnosed with osteoporosis/osteopenia were included. Participants who were feeling too unwell to participate in the study were excluded.

3.4.3.6   Sampling procedure

This study was conducted concurrently with the validation of the Osteoporosis Prevention and Awareness Tool (OPAAT) the sampling procedure as explained in section 4.2.3.8.1.

3.4.3.7   Sample size

As the validation of the osteoporosis risk assessment tools was part of the validation of the Osteoporosis Prevention and

Awareness Tool (OPAAT),the sample size was calculated based on a 5:1 participant to item ratio required for factor analysis to be performed for the OPAAT (Gorsuch, 1983). Since the OPAAT had 30 items, the total number of participants needed was 150.

3.4.3.8 Primary outcome

To assess the validity and reliability of six osteoporosis risk assessment tools in the Malaysian population.

3.4.3.9 Secondary outcomes

3.4.3.9.1 Sensitivity and specificity

Sensitivity was defined as the proportion of women with osteoporosis that tested positive using the risk assessment tools. Specificity was defined as the proportion of women without osteoporosis who tested normal using the risk assessment tools.

3.4.3.9.2 Optimal cut-off point

The ability of the risk assessment tool to discriminate low BMD as defined by T-score ≤ -2.5 was evaluated using the receiving operating characteristic (ROC) curve.

3.4.3.10 Instruments used

3.4.3.10.1 Baseline demographics

This instrument was used to collect baseline demographic information such as patients' medical history, lifestyle and medication history (Appendix 1).

3.4.3.10.2 Osteoporosis risk assessment tools

Six risk assessments tools were used in this study. Table 3.18 is a summary of the published cut-off points and the scoring system of the risk assessment tools:

3.4.3.10.2.1　The Simple Calculated Osteoporosis Risk Estimation (SCORE)

The final model of SCORE is a simple additive scoring system using six questions: age, weight, race, fracture history, rheumatoid arthritis history and estrogen use. A score of ≥6 classified participants as having an increased risk for osteoporosis (Lydick et al., 1998).

3.4.3.10.2.2　Osteoporosis Risk Assessment Index (ORAI)

The three item additive scoring system of ORAI includes: age, weight and current estrogen use (yes or no) were the three items used. A score of ≥9 classified participants as having an increased risk for osteoporosis (Cadarette et al., 2000).

3.4.3.10.2.3　Age Bulk One of Never Estrogen (ABONE)

Any women with ≥2 score was recommended for a BMD scan based on the ABONE. One point was given for each of these categories: ≥ 65 years old, <63.5kg or have not used estrogen for > 6 months. (Weinstein and Ullery, 2000).

3.4.3.10.2.4　Body Weight (WEIGHT)

The tool specifies that a weight under or 70kg shows a risk for osteoporosis (Michaëlsson et al., 1996).

3.4.3.10.2.5   Malaysian Osteoporosis Screening Tool (MOST)

The MOST was an additive scoring system based on age, years of menopause, body mass index (BMI) and hip circumference. A score of ≥4 classified participants as having an increased risk for osteoporosis. (Lim et al., 2011).

3.4.3.10.2.6   Osteoporosis Screening Tools for Asians (OSTA)

The final model had 11 items but eventually all except age and weight were dropped. OSTA involves a calculation as follows: weight in kilograms were deducted with age in years and multiplied by -0.2. Participants with a score of ≤-1 were classified as having an increased risk for osteoporosis. The OSTA further classified the osteoporosis risk to low, moderate and high. An index of >-1 indicated a very low risk for osteoporosis where as a score of -1 to -4 indicated moderate risk and a score of <-4 was classified as high risk. (Koh et al., 2001b).

Table 3.18: Published cut-off points and scoring system of the six risk assessment tools

Tool	Published cut-off point	Scoring system
SCORE	Score ≥ 6	Race: 5 if not black Rheumatoid arthritis: 4 if applicable History of minimal trauma fracture after age 45 years: 4 for each fracture of the wrist, hip, or ribs (12 point maximum) Age: 3 times of the first digit of age in years Estrogen therapy: 1 if never used Weight:-1 times the weight in pounds 2.2 x kg (lb) divided by 10 and truncated to an integer
ORAI	Score ≥ 9	Age: 15 ≥ 75 years 9 if 65-74 years 5 if 55-64 years Weight: 9 if < 60 kg 3 if < 60.0- 69.9kg Estrogen use: 2 if not currently taking estrogen
ABONE	Score ≥ 2	Age: 1 if >65 years Weight: 1 if <63.5kg Estrogen use: 1 if never used oral contraceptive or estrogen therapy for at least 6 months
WEIGHT	≤70kg	Weight ≤70kg
MOST	Score ≥4	Age: 20if >61 years 6 if 56-60 years 2 if 51-55 years 0 if <50 years Years post menopause 22 if >10years 6 if 6-10 years 4 if 1-5 years 0 if 0 years BMI : 4 if <19 kg/m^2 2 if 19-24 kg/m^2 0 if > 24 kg/m^2 Hip circumference 2 if <90cm 0 if >90 cm
OSTA	Score ≤ -1	0.2 x (body weight (kg) – age (years))

3.4.3.10.2.7 Dual energy X-ray absorptiometry (DEXA) machine

DEXA was used to measure the left femoral neck and lumbar spine (L1-L4) BMD. The brand of manufacturer was IDXA model by GE Lunar (Milwaukee, US). The T-scores were calculated using the peak reference ranges for young healthy Asian women. The mean and precision error for femoral neck and lumbar spine (L1-L4) was 0.936 (1.4%CV) and 1.184 (1.1%CV) respectively. All BMD measurements were conducted by two qualified radiologist.

3.4.3.11 Procedure

Participants were recruited while they were waiting for their doctor's appointment using a 1:2 systematic random sampling procedure or the snowballing method. One out of every two postmenopausal women was asked if they were willing to participate in the study (Appendix 29 and 30, patient information sheet and consent form). Random sampling was used to give an equal chance to all eligible participants to be selected for inclusion in our sample [Figure 3.3].

Figure 3.3: The validation process of the various osteoporosis risk assessment tool

| 1st visit- (Baseline) | The researcher screened for potential participants (N=224) |

↓

Informed written consent and baseline information was obtained from all participants. (N=164)

↓

Participants were interviewed for risk factors using OSTA, SCORE, ORAI, WEIGHT, MOST and ABONE. Participants' weight, height and hip circumference were measured using a digital weighing machine, a mechanical height scale and measuring tape.

↓

Researcher arranged the BMD scan appointment for participants

↓

Participants went for their BMD scan (N=150)

↓

| Follow up via phone (Two weeks) | Researcher informed the participants of their BMD results via telephone. Questions regarding the BMD results and osteoporosis prevention were answered. |

↓

Participants with a T-score ≤-2.5 were advised to visit their doctor

Abbreviations:

OSTA- Osteoporosis Screening Tool for Asians

SCORE- Simple Calculated Osteoporosis Risk Estimation

ORAI- Osteoporosis Risk Assessment Index

WEIGHT- Body Weight

ABONE- Age Bulk One of Never Estrogen

BMD- Bone Mineral Density

MOST- Malaysian Osteoporosis Screening Tool

3.4.3.12　Source of data

The source of data varied from medical registers, medical records, observations to observe if patients were too unwell to participate in the study, interviews, questionnaire and informal discussions to find out informally if patients have osteoporosis during recruitment. Some of the data such as patients' clinical information were obtained from medical records prior to the provision of service, whilst other data were obtained during the counselling session with the pharmacist.

3.4.3.13　Ethics approval

This study was approved by the Medical Ethics Committee of the University Malaya Medical Centre (approval no: 920.27, Appendix 27). All required documents were submitted and approval was obtained one month after submission. In accordance with the ethics committee requirements, a report upon completion form has been submitted. Ethical issues such as anonymity, confidentiality and informed consent were considered in this study.

3.4.3.13.1 Anonymity and confidentiality

Only the researcher and the supervisors had access to the questionnaire. All information were coded and anonymized. The information collected as paper copies were stored under lock and key, while the electronic data can only be accessed with a secure password. The data collected were used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. All information which is collected was confidential and any form of identity will not be included in any publications.

3.4.3.13.2 Informed consent

Prior to the start of any research activity, written informed consent for participating was obtained from each participant.

3.4.3.14   Data analysis

All data was entered into the IBM® SPSS® version 20 (IBM Corporation, Armonk, NY, US). The primary outcome measure considered in this study was femoral neck T-score. Although no single level of BMD should be used as the sole basis for treatment, the femoral neck T-score is the most reliable measure for predicting hip fracture risk (Johnell et al., 2005, Marshall et al., 1997). However, the combination of femoral neck and lumbar spine (L1-L4) BMD was also presented as participants were diagnosed as having osteoporosis if the T-score at any given site was ≤-2.5.

In our study we calculated the true positives, false negatives, true negative and false positives. A true positive is if the participant was osteoporotic and was classified as at risk for osteoporosis. If the participant was osteoporotic but was classified as not at risk for osteoporosis it is considered as a false negative. A true negative was a non osteoporotic participant classified as not at risk for osteoporosis. If a non osteoporosis participant was classified as at risk for osteoporosis, it is a false positive.

Sensitivity and specificity were calculated based on the original published cut-off points [Table 4.18]. Sensitivity was analyzed as the proportion of women with osteoporosis (T-score ≤-2.5 at the femoral neck) who tested positive on the risk assessment (i.e., having a value in the range determined by the tool as an increased risk for osteoporosis). Specificity

was analyzed based on the proportion of women without osteoporosis (T-score ≤-2.5 at the femoral neck) who tested normal on the risk index assessment (i.e., having a value in the range determined by the tool as low risk for osteoporosis). The sensitivity and specificity of the tools were also analyzed using the combination of either a T-score ≤-2.5 at the femoral neck or lumbar spine. The formulas used to calculate the sensitivity and specificity are as below:

Sensitivity (%) = [True positives/ (False negatives+ true positives)] x 100

Specificity (%) = [True negatives/ (False positives+ true negatives)] x 100

The ROC curves which plot sensitivity against (1-specificity) were generated to empirically determine the tools' optimal cut-off points, sensitivity and specificity in the same study sample. It is not necessary that a risk assessment tool have both high sensitivity and specificity when the tool is free and causes no harm. Therefore the primary purpose of the tools is to identify most patients at risk among women whom BMD can then be used to obtain a definite diagnosis. We identified the tool with the best balance between a high sensitivity and a moderate specificity. The top left-hand corner of the ROC curve was identified as the empirical optimal cut-off point for the tools. The area under the curve (AUC) was calculated using logistic regression, was used to compare the diagnostic performance of the two tests. In general a realistic classifier should not have an AUC <0.500 (Fawcett, 2006).

3.4.4 Results (Phase two- Validation of osteoporosis risk assessment tools)

3.4.4.1 Participants

Figure 4.4 demonstrated the recruitment process, a total of 224 participants were approached: 60 declined and 164 participants were recruited (73.2%). However, 14 out of the 164 did not perform the BMD [Figure 3.4]. Table 3.19 summarises participants' demographic characteristics A total of 16/150 (7.1%) was found to be osteoporotic based on either a T-score ≤-2.5 of the total femoral or the spine.

Figure 3.4: Recruitment process
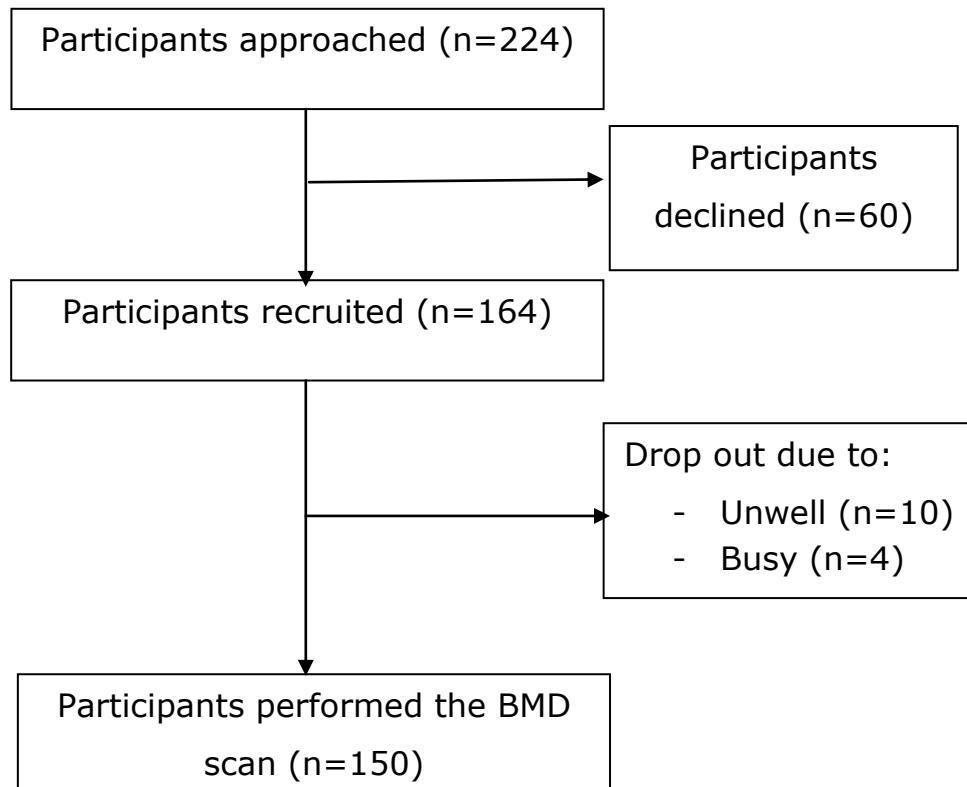
Table 3.19: Demographics characteristics of participants

Characteristics	Patients (n=150)
Mean Age ± S.D. (years) [range] (Median)	62.0±7.0 [50.0-82.0] (62.0)
Ethnicity [n (%)]	
Malay	12 (8.0)
Chinese	108 (72.0)
Indian	28 (18.7)
Eurasian	2 (1.3)
Mean weight ± S.D. (kg) [range] (Median)	57.9±10.0 [40.0-91.0] (55.8)
Mean hip circumference (cm) [range] (Median)	93.4 ± 6.8 [78.7-121.9] (94.0)
Mean BMI ± S.D. (kg/m^2) [range] (Median)	23.8±3.8 [15.6-35.4] (23.0)
BM I (kg/m^2) [n (%)]	
<18.5 (underweight)	5 (3.3)
18.5-24.9 (normal)	97 (64.7)
25.0-29.9 (overweight)	37 (24.7)
≥30.0 (obese)	11 (7.3)
Household income per month [n (%)]	
<RM1000 (<$ 310.7)	29 (19.3)
RM1000-1999 ($ 310.7-621.0)	12 (8.0)
RM2000-2999 ($ 621.3- 931.7)	15 (10.0)
RM3000-3999 ($ 932.0- 1242.3)	17 (11.3)
RM4000-4999 ($ 1242.6-1553)	12 (8.0)
>RM5000 (>$1553.3)	65 (43.3)
Level of education [n (%)]	
Never been to school	1 (0.7)
Primary (6 years of education)	12 (8.0)
Secondary (11-13 years of education)	47 (31.3)
Diploma/Technical school training (12-14 years of education)	31 (20.7)
Tertiary/Postgraduate (15-21 years of education)	59 (39.3)
Mean bone mineral density ± S.D. (g/cm^2) [range] (Median)	
Femoral neck	0.78 ± 1.78 [-0.89-1.16] (0.80)
Lumbar spine L1-L4	1.05 ± 0.15 [0.64-1.46] (1.05)
Mean T-score ± S.D. [range] (Median)	
Femoral neck	-0.87 ± 0.93 [-2.80-

Lumbar spine L1-L4	2.00] (-0.95)
	-0.53 ± 1.28 [-3.90-
	2.90] (-0.50)
Status of bones femoral neck BMD [n (%)]	
Normal	78 (34.8)
Osteopenia	66 (29.5)
Osteoporosis	6 (2.7)
Status of bones based on either femoral neck or lumbar spine (L1-L4) BMD [n (%)]	
Normal	69 (30.8)
Osteopenia	65 (29.0)
Osteoporosis	16 (7.1)

S.D. = standard deviation; BMI=body mass index; $= US dollar; BMD= bone mineral density

3.4.4.2   Sensitivity, specificity and published cut-off points

The sensitivity and specificity was calculated based on the published cut-off points of the indices [Table 3.20]. Based on the femoral neck T-score, the SCORE, the ORAI, the WEIGHT and the MOST achieved a sensitivity of 100%, but had low specificity (2.1%-19.4%). The ABONE also had high sensitivity (83.3%), but low specificity (27.1%). The OSTA had the lowest sensitivity (50.0%) in comparison with the other instruments, but had the highest specificity (49.3%).

We then calculated the sensitivity and specificity of the indices using the published cut-off points [Table 3.20]. Based on either the femoral neck or lumbar spine (L1-L4) T-score, the SCORE, the WEIGHT and the MOST achieved a sensitivity of 100%, but had low specificity (2.2%-12.7%). ABONE and ORAI also had a high sensitivity (ABONE=87.5%, ORAI=93.8%) and a low specificity (ABONE=28.4%, ORAI=20.2). OSTA on the other hand had the lowest sensitivity of 68.8% in comparison with the other instruments, but had the highest specificity of 51.5%.

Table 3.20: Results of the six risk assessment tools using published cut-off points when compared with femoral neck bone mineral density T-score ≤-2.5 and either femoral neck or lumbar spine T-score ≤-2.5

	Femoral neck					Femoral neck or lumbar spine (L1-L4)				
	T-score		Sensitivity (%)	Specificity (%)	Total	T-score		Sensitivity (%)	Specificity (%)	Total
	≤-2.5	>-2.5				≤-2.5	>-2.5			
SCORE										
High risk ≥ 6	6 (TP)	133 (FP)	100.0	7.6	139	16 (TP)	123 (FP)	100.0	8.2	139
Low risk <6	0(FN)	11 (TN)			11	0(FN)	11 (TN)			11
ORAI										
High risk ≥ 9	6(TP)	116(FP)	100.0	19.4	122	15(TP)	107(FP)	93.8	20.2	122
Low risk <9	0(FN)	28(TN)			28	1(FN)	27(TN)			28
ABONE										
High risk ≥ 2	5(TP)	105(FP)	83.3	27.1	110	14(TP)	96(FP)	87.5	28.4	110
Low risk <2	1(FN)	39(TN)			40	2(FN)	38(TN)			40
WEIGHT										
High risk ≤70kg	6(TP)	127(FP)	100.0	11.8	133	16(TP)	117(FP)	100.0	12.7	133
Low risk <70kg	0(FN)	17(TN)			17	0(FN)	17(TN)			17
MOST					2.1					2.2
High risk ≥ 4	6(TP)	141(FP)	100.0		147	16(TP)	131(FP)	100.0		147
Low risk < 4	0(FN)	3(TN)			3	0(FN)	3(TN)			3
OSTA										
High risk ≤ -1	3(TP)	73(FP)	50.0	49.3	76	11(TP)	65(FP)	68.8	51.5	76
Low risk <-1	3(FN)	71(TN)			74	5(FN)	69(TN)			74

TP= true positive; FN=false negative; FP= false positive; TN= true negative; SCORE=Simple Calculated Osteoporosis Risk Estimation; ORAI= Osteoporosis Risk Assessment Index; ABONE= Age Bulk One of Never Estrogen; WEIGHT= Body Weight; MOST= Malaysian Osteoporosis Screening Tool; OSTA= Osteoporosis Screening Tool for Asians; BMD= Bone Mineral Density

ROC curves were generated based on the femoral neck T-score are presented in Table 3.21 and Figure 3.5. Based on the femoral neck T-score, AUC values ranged from 0.519-0.661, with the WEIGHT, the ORAI and the OSTA having the highest AUC values. Using different cut-off points the tools were able to achieve a sensitivity of 66.7%-100.0% and specificity of 27.1%-50.7%. There were three tools with a high sensitivity and moderate specificity: the ORAI, WEIGHT and OSTA.

Based on either the femoral neck or lumbar spine (L1-L4) T-score, AUC values ranged from 0.569-0.663, with the WEIGHT, the ORAI, the SCORE and the OSTA having the highest AUC values [Table 3.21 and Figure 3.6]. Using different cut-off points the tools were able to achieve a sensitivity of 75.0%-93.6% and specificity of 28.4%-53.0%. Similarly to the results based on femoral neck T-score, there were three tools with a high sensitivity and moderate specificity: the SCORE, ORAI, ABONE and OSTA. A lower cut-off value for OSTA and WEIGHT represents higher risk for osteoporosis (low BMD). As for the other indices: SCORE, ORAI. ABONE and MOST, higher values indicate higher risk for developing osteoporosis.

Table 3.21: Empirically-determined cut-off points, sensitivity and specificity based on receiver operating characteristics (ROC) curves for identifying osteoporosis subjects using only femoral T-score ≤ -2.5 and either femoral neck or lumbar spine T-score ≤ -2.5

Tool	Femoral neck T-score ≤ -2.5					Femoral neck or lumbar spine T-score ≤ -2.5				
	Empirical cut-off points	Sensitivity	Specificity	Area under curve (95% CI)	p-value	Empirical cut-off points	Sensitivity	Specificity	Area under curve (95% CI)	p-value
SCORE	Score ≥ 9	66.7	34.0	0.558 (0.312-0.805)	0.628	Score ≥ 9	81.3	35.8	0.627 (0.482-0.772)	0.097
ORAI	Score ≥ 12	100.0	41.0	0.644 (0.496-0.792)	0.232	Score ≥ 12	93.6	43.3	0.663 (0.545-0.782)	0.033*
ABONE	Score ≥ 2	83.3	27.1	0.586 (0.357-0.815)	0.475	Score ≥ 2	87.5	28.4	0.653 (0.511-0.795)	0.046
WEIGHT	≤57kg	83.3	45.1	0.661 (0.449-0.874)	0.181	≤58kg	81.3	41.0	0.592 (0.465-0.719)	0.232
MOST	Score ≥ 31	66.7	50.7	0.519 (0.284-0.753)	0.878	Score ≥ 31	75.0	53.0	0.569 (0.434-0.704)	0.368
OSTA	Score ≤ 0	83.3	36.8	0.603 (0.387-0.819)	0.393	Score ≤ 0	81.3	41.0	0.627 (0.505-0.748)	0.098

*Statistically significant a p <0.05

Figure 3.5: Receiver operating characteristic curve based on femoral neck bone mineral density T-score ≤ -2.5 (n=150). a Simple Calculated Osteoporosis Risk Estimation (SCORE). b Osteoporosis Risk Assessment Instrument (ORAI). c Age, Bulk, One or Never Estrogen (ABONE). d Body Weight criterion (WEIGHT). e Malaysian Osteoporosis Screening Tool (MOST). f Osteoporosis Screening Tool for Asians (OSTA)

d. Body weight criterion (WEIGHT)

Diagonal segments are produced by ties.

e Malaysian Osteoporosis Screening Tool (MOST)

Diagonal segments are produced by ties.

f Osteoporosis Screening Tool for Asians (OSTA)

Diagonal segments are produced by ties.

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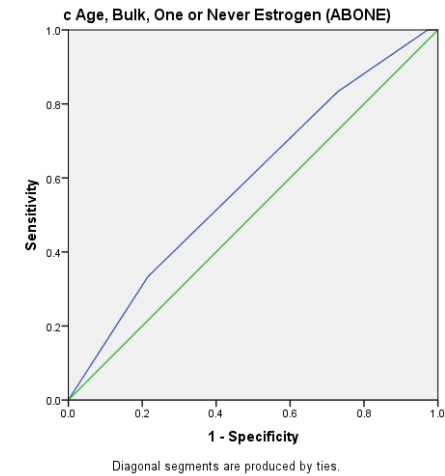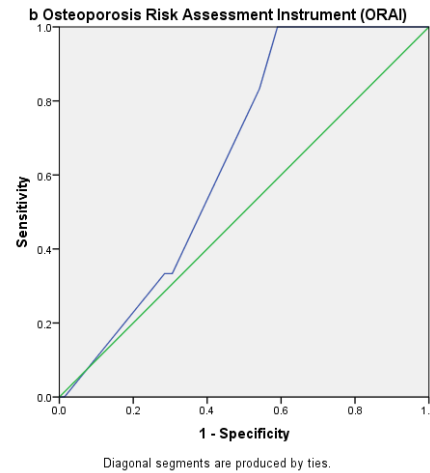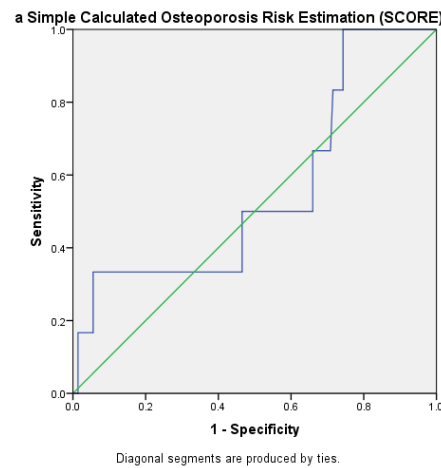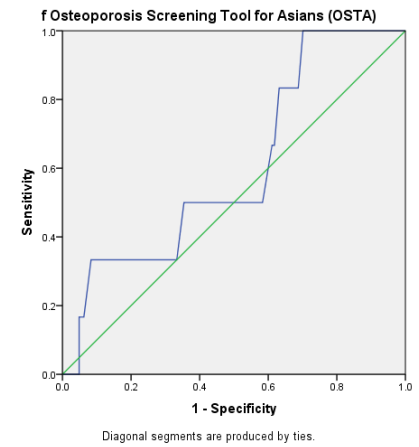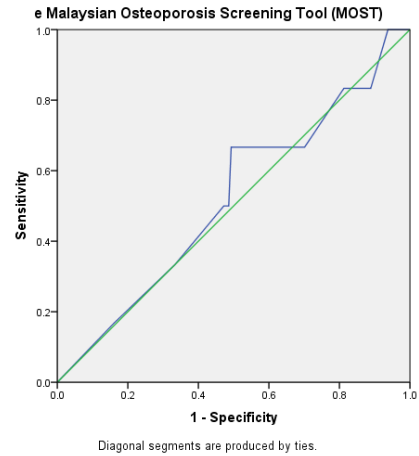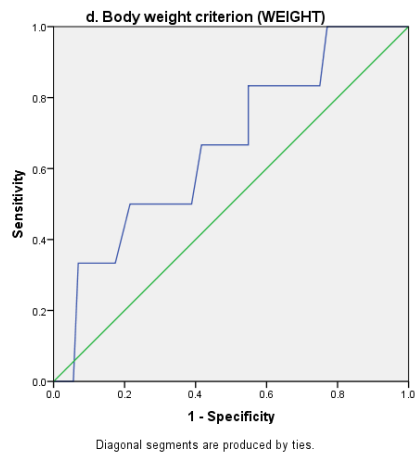
Figure 3.6: Receiver operating characteristic curve based on either femoral neck or lumbar spine (L1-L4) bone mineral density T-score ≤ -2.5 (n=150). a Simple Calculated Osteoporosis Risk Estimation (SCORE). b Osteoporosis Risk Assessment Instrument (ORAI). c Age, Bulk, One or Never Estrogen (ABONE). d Body Weight criterion (WEIGHT). e Malaysian Osteoporosis Screening Tool (MOST). f Osteoporosis Screening Tool for Asians (OSTA)

d. Body weight criterion (WEIGHT)

Diagonal segments are produced by ties.

e Malaysian Osteoporosis Screening Tool (MOST)

Diagonal segments are produced by ties.

f Osteoporosis Screening Tool for Asians (OSTA

Diagonal segments are produced by ties.

311
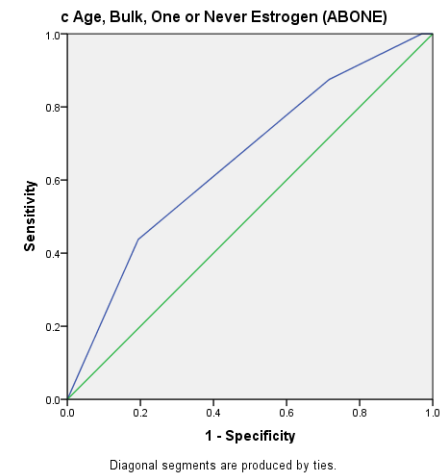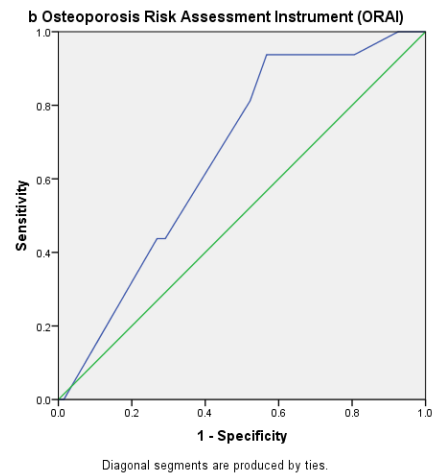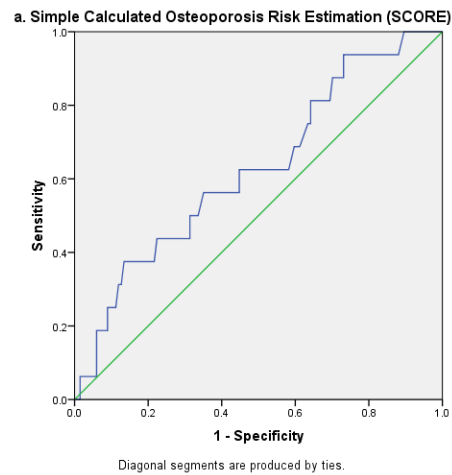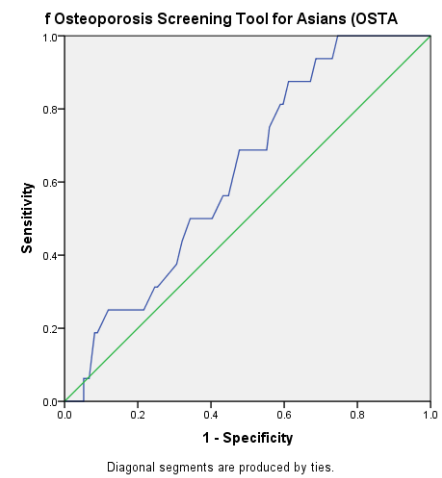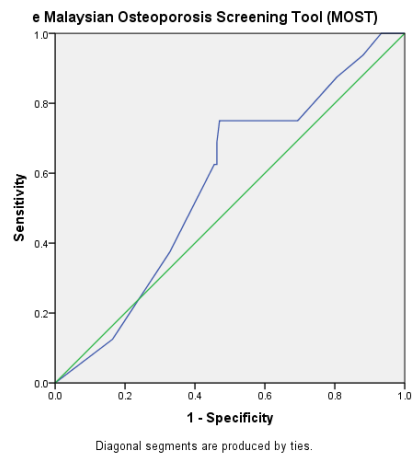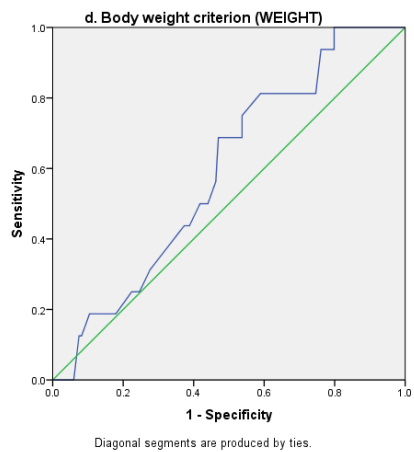
3.4.5 Discussion

This study showed that the various osteoporosis risk assessment tools namely: SCORE, ORAI, ABONE, WEIGHT, MOST and OSTA were valid, reliable and useful in identifying Malaysian postmenopausal women with osteoporosis. Based on the published cut-off points and T-score ≤-2.5, the sensitivity was high for all of the indices which was above 83.3% with the exception of OSTA which had the lowest sensitivity of 50.0% (T-score femoral neck) and 68.8% (T-score femoral neck and lumbar spine (L1-L4)). However, the specificity was low for most of the tools ranging from 2.1% to 51.5%. In order to optimize the tools, the empirical optimum cut-off points were identified by generating ROC curves. The sensitivity of the tools improved ranging from 66.7%-100.0%. Specificity on the other hand ranged from 27.1%-53.0%. Our study found the OSTA to have the best balance between the sensitivity, specificity and practical usability.

Our study compared the sensitivity and specificity of the six tools with the T-score of femoral neck alone and either femoral neck or lumbar spine (L1-L4) using the published cut-off points. Based on our results the sensitivity and specificity of all six tools were similar for all six tools using both outcomes. This suggests that these risk assessment tools can be used to screen for osteoporosis using femoral neck T-score only when using the published cut-off points.

We then identified the optimal cut-off points for all six tools using the ROC curve. A high sensitivity is crucial as it provides reliable evidence for physicians to start early treatment for patients at risk of osteoporosis. Numerically, OSTA yielded an AUC of 0.603, with sensitivity and specificity of 83.3% and

36.8% at the empirically identified optimal cut-off point of ≤0 using the T-score of the femoral neck. This AUC generated was lower as compared to the ORAI (AUC=0.644) and WEIGHT (AUC=0.661). However, the OSTA was considered to be more suitable for daily clinical use as it is a simple tool. The OSTA requires only the age and body weight to screen for the risk of osteoporosis. This is an important feature because other tools such as the ORAI require more detailed information such as oestrogen use which are more time consuming to obtain. A comparable tool to OSTA's simplicity was the WEIGHT which yielded a higher AUC of 0.661 (sensitivity= 83.3%, specificity=45.1%). Therefore the WEIGHT would be the suitable tool to assess osteoporosis risk based on T-score of the femoral neck.

Based on either the femoral neck or lumbar spine (L1-L4) T-score, the ORAI, ABONE, SCORE and OSTA had the highest AUC of 0.663, 0.653, 0.627 and 0.627 respectively. Similarly, we found the OSTA to be most suitable tool to use during daily clinic practice as the SCORE requires more details to assess the risk such as estrogen use, history of fractures and rheumatoid arthritis. On the other hand the ORAI and ABONE require the history of estrogen use which may difficult to obtain as the Malaysian healthcare system is not integrated between hospitals and clinics. Therefore, the OSTA would be the most suitable to assess osteoporosis risk based on the T-score of either femoral neck or lumbar spine.

Overall, based on both the T-score of femoral neck alone or either femoral neck or lumbar spine, we found the OSTA with a cut-off ≤-0 to be the most suitable tool to assess osteoporosis risk in the Malaysian population. This is because

although the WEIGHT was easier to use than the OSTA, it did not perform as well as the OSTA when assessing the overall osteoporosis risk when compared to T-score of either the femoral neck or lumbar spine. However the OSTA had a high AUC when assessing the osteoporosis risk based on both the T-score of femoral neck alone and either the T-score of femoral neck or lumbar spine. Additionally, although OSTA was more complicated than WEIGHT, studies in Singapore and Hong Kong which validated various risk assessment tools including OSTA (Chan et al., 2006, Kung et al., 2003) and WEIGHT (Chan et al., 2006) suggest that the OSTA would be the most practical and accurate tool for daily use when assessing osteoporosis risk based on femoral neck T-score.

We would like to highlight that the empirically identified optimum cut-off points by generating the ROC curves were higher than the published results for SCORE, ORAI, OSTA and MOST whether comparing with only the femoral neck T-score or with either the femoral neck or lumbar spine (L1-L4) T-score. Conversely, a lower empirically identified optimum cut-off points were noted for WEIGHT. As for ABONE the optimum cut-off point identified was similar to the published cut-off of ≥2. The difference of cut off points for SCORE and ORAI may be because the cohort in our study was of mixed ethnicity of Malay (8.0%), Chinese (72.0%), Indian (18.7%) and Eurasian (1.3%) whereas SCORE and ORAI were mainly developed for the Caucasian population (Lydick et al., 1998, Cadarette et al., 2000). A study of 135 Chinese postmenopausal women similarly noted higher cut-off points for the SCORE (≥8) and ORAI (≥20). (Chan et al., 2006). The difference in cut-off points for OSTA and MOST may also be explained by demographic differences in the samples. The cohort in our

study was of women ≥50 years of age where else the original OSTA and MOST study included younger women ranging from ≥45 years. As for the WEIGHT cut off point was lower compared to the recommended 70kg this could be because Malaysian women has a lower mean body weight of 58.44kg. Therefore, the empirical cut-off point was 57-58kg (Azmi et al., 2009). This demonstrates that the tools' optimal cut-off points may vary with different age and ethnic groups.

Different risk assessment tools were developed and validated using different T-score at different sites (Cadarette et al., 2004, Lydick et al., 1998, Koh et al., 2001b, Lim et al., 2011, Weinstein and Ullery, 2000, Michaëlsson et al., 1996). Agreement on a single risk assessment tool and a single type or types of T-score for comparison should be identified to ease clinician's decision to which is the most suitable tool. This will help fulfil the objective of identifying women at risk for osteoporosis.

The prevalence of osteoporosis in our study was low (7.1%) as compared to another study conducted in Malaysia which noted a prevalence of 24.1% (Lim et al., 2005). This may be because the participants recruited in this study were health seeking individuals as they were recruited from the primary care clinic and may have taken preventive measures against osteoporosis, the women conducted in the other study were community dwelling women recruited via flyers (Lim et al., 2005).

3.4.6 Strengths
Our study fills the gap of the lack of a validated osteoporosis risk assessment tool by validating sic type of tools. The

strength of our studies was that we compared all six tools to identify the best tool for our population. We also identified the optimal cut-off point for our population.

3.4.7 Limitations

The limitation of our study was the small sample size. This may be the reason for the low AUC results for all the tools. Nonetheless, based on the estimated sample size for multi-observer ROC studies by Obuschowski (2008), a sample size of 288 is required in order to achieve 80% of statistical power.

Additionally, some participants (11 participants) were also recruited using the "snowballing" method as the validation of the osteoporosis risk assessment tools was conducted concurrently with the validation of an osteoporosis knowledge questionnaire called Osteoporosis Prevention and Awareness Tool (OPAAT). As the awareness of the project spread the participants began to refer their friends and family. Although this is a non-randomized method or recruiting the patients, it only comprise of 7.3% of the participants in our study and should not affect the outcome as 15% of the sample size was allocate for drop-outs.

Inaccuracies of in self-reported data may have reduced the ability of these risk assessment tools to predict the osteoporosis risk. However, if this is the case, our results may underestimate the potential value of these tools for identifying women with low BMD, but are probably representative of the results that would be seen in clinical practices. Aside from that out study cohort was mainly 72.0% Chinese, this does not reflect the Malaysian population which consist of Malays as a majority. Nonetheless, these findings are useful as the

prevalence of osteoporosis is higher in the Chinese population (Koh et al., 2001b). Our results were also based on the Malaysian population and would not be generalized to women in other countries. Further studies should be carried out in larger samples, different ethnicity and of different age groups. This will assist in a more conclusive answer to the tools' generalisability and applicability may be derived.

3.4.8 Conclusion

This study showed that the various osteoporosis risk assessment tools namely: SCORE, ORAI, ABONE, WEIGHT, MOST and OSTA were valid, reliable and useful in identifying Malaysian postmenopausal women with osteoporosis. The OSTA was the simplest and most well balance tool for daily clinical use. However, further studies should be conducted in a larger sample with different age range and ethnicity to ensure it applicability.

3.5 The development of a pharmacist-led osteoporosis screening and prevention programme

3.5.1 Introduction

This section summarizes the development of a pharmacist-led osteoporosis screening and prevention programme. This intervention was developed based on the principals of the UK MRC framework for complex interventions.

3.5.2 Objective

To develop a pharmacist-led osteoporosis screening and prevention programme for use among postmenopausal women in Malaysia.

3.5.3 Methods

3.5.3.1 Development of a complex intervention

The development of the intervention can be divided into three sections: identifying the evidence, identifying or developing the theory, and modelling the process and outcomes.

3.5.3.2 Identifying the evidence

An intervention must be developed to the point where it can reasonably be expected to have a worthwhile effect before a substantial evaluation is undertaken. The UKMRC framework recommends identifying what is already known about similar interventions and the methods that have been used to evaluate them. A high quality systematic review of relevant evidence should be conducted if there has been no recent evaluation (Craig et al., 2008). We conducted a literature review using Pubmed, Scopus and the Cochrane library using the search terms: systematic review, osteoporosis,

fragility/minimal/low trauma fracture, intervention, fracture liaison services, prevention and screening.

3.5.3.3   Identifying or developing theories

A number of psychological factors are involved in learning new behaviours and changing existing behaviours (Hardeman et al., 2005). Theories provide overarching frameworks that could assist in explaining behaviours. Subsequently, these behaviours can be targeted by an intervention (Hardeman et al., 2005, Craig et al., 2008). Our task was to develop a theoretical understanding of the best way to change behaviour. We achieved this by drawing on existing evidence and theory, supplemented with new primary research (Craig et al., 2008). As there was no behavioural intervention theory specifically targeting osteoporosis screening we conducted qualitative interviews with patients, nurses, pharmacists, doctors and policy makers as described in Chapter 3. We then reviewed a number of theory and behaviour change techniques that had shown some success in changing behaviour (Medical Research Council, 2008). We then used both methods to inform the development of our intervention. In Phase one, we have conducted qualitative studies using the theory of behavioural change wheel and behavioural change techniques. Using this theory we have identified the key components for the intervention (Michie et al., 2011). Further details on the methods and analysis of these three sections can be found in section 3.6.

3.5.3.4   Modelling process and outcomes

Modelling a complex intervention before a full scale evaluation can provide important information about the design of the intervention. The modelling process also allows for the

evaluation and identification of weaknesses leading to refinement. We used a causal modelling approach presented by Hardeman et al (2005). It is a modelling approach that focuses on the first two phases of the UKMRC framework which has been presented in section 1.7.12. The term causal modelling refers to the development of a specific causal model to guide the design of a programme to support behaviour change for RCT evaluation. Hardeman et al (2005) provided a generic model which contains four levels. Their causal model links behavioural determinant, casually through behaviour, to physiological and biochemical variables and health outcomes (Hardeman et al., 2005). This means that by targeting the intervention to the behavioural determinant, behaviour change can occur and in turn affect the physiological and biochemical variables which are used to measure the health outcomes.

We then applied this generic model to our study [Figure 3.7]. This allows for graphical representation on appropriate intervention and measurement points and behaviour changes techniques. We tailored the model to the characteristics of our target population (postmenopausal women), social context, target behaviour and health outcomes. In our study, behavioural determinant was referred to as the psychological factors involved in learning new behaviours and changing existing behaviours. Behaviour refers to the target behaviour needed to make the change. Physiological/biochemical refers to the measure used to determine the health outcome. As for health outcome, it refers to predictors used to determine the incidence of the disease. The generic process and outcomes measured were mapped onto the causal pathway [Figure 3.7]. For our study, both literature review and theories were used

to inform the causal model from behaviour determinants to health outcomes.

Figure 3.7: Causal modelling for the pharmacist-led osteoporosis screening programme

Level

1	Behavioural determinants

↓

2	Behaviour

↓

3	Physiological and biochemical variables

↓

4	Health outcomes
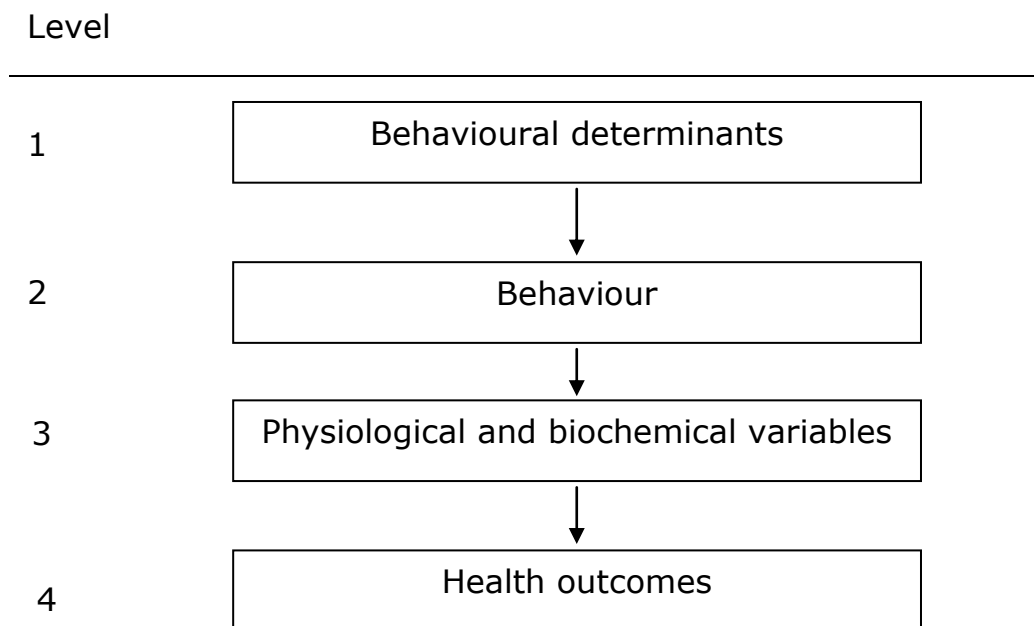
3.5.4 Results

3.5.4.1 Identifying the evidence

3.5.4.2 Systematic reviews of the effectiveness of intervention to improve osteoporosis screening and prevention

We found four systematic reviews relevant to osteoporosis screening and prevention. A systematic review in 2012 was conducted to evaluate the effectiveness of published models of care for the secondary prevention of osteoporotic fracture called the fracture liaison service. They identified 42 studies and categorized the types of intervention into four types. Type A involved identification, assessment and treatment of patients as part of the services. Figure 3.8 represents an overview of a type A model of care. Type B is similar to A, without treatment initiation; type C involved alerting patients plus primary care physicians; and type D involved patient education only. They concluded that Type A and B services were cost-effective, although definition of cost-effectiveness varied between studies. They suggested that a fully coordinated, intensive model of care for secondary fracture prevention was more effective in improving patient outcomes than approaches that involved alerts and/or education only (Ganda et al., 2012).

Figure 3.8: Structure of Type A osteoporosis screening programme (Ganda et al., 2012)
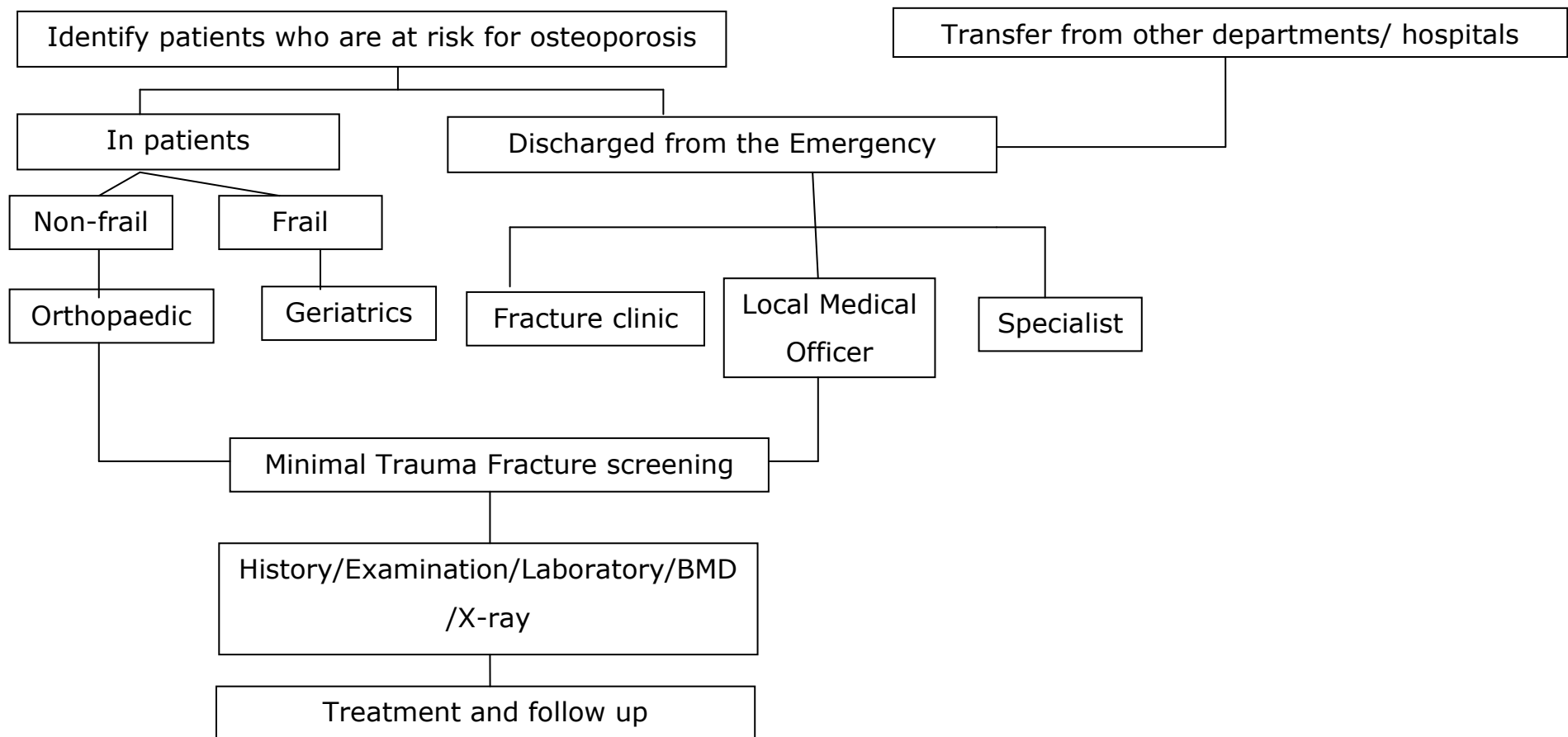
Sale et al (2011) systematically reviewed 57 studies that determined the effectiveness of osteoporosis investigation and treatment within post-fracture initiatives, in fracture clinics and other orthopaedic environment. Their findings were similar. They noted that the most effective intervention was when they had dedicated personnel to implement an intervention which included BMDs and/or treatment. (Sale et al., 2011, Ganda et al., 2012).

Little et al (2011) systematically assessed 9 studies to determine the effectiveness of an intervention to improve the investigation (BMD scan) and management of osteoporosis in patients following a fragility fracture. They found that all interventions reported a positive effect and measured outcomes of BMD scanning and osteoporosis treatment. However, there was only one study that showed statistical significance between intervention and control group. Other outcomes were measured such as osteoporosis diagnosis and percentage of patient undergoing BMD (Little and Eccles, 2010).

Elias et al (2010) examined the impact of pharmacist interventions in improving osteoporosis management. They included three randomized controlled trials. Although they noted that two of the studies were at high risk of bias, the results from the RCTs suggest that pharmacist interventions may improve bone mineral density testing and calcium intake among patients (Elias et al., 2011).

Our intervention was based on the type A model of care, whereby we provided osteoporosis risk assessment,

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individualized counselling (based on the patient's needs), recommendations to doctors, BMD scan and treatment if required (Ganda et al., 2012). All these activities were coordinated by a dedicated personnel (a pharmacist) (Ganda et al., 2012). We used these systematic reviews to determine our primary and secondary outcomes. The primary outcome for our intervention is the proportion of patients undergoing a BMD scan. Secondary outcomes include the proportion of patients diagnosed with osteoporosis, the proportion of patients started on osteoporosis medication, as well as the proportion of patients that conducted osteoporosis preventive measures. We also measured patients' osteoporosis knowledge and satisfaction towards the osteoporosis screening programme as or secondary outcomes.

3.5.4.3   Identifying theories

Results from the qualitative studies (Phase one) noted seven main barriers to conducting an osteoporosis screening programme: governmental, organizational and management, work environment, team, task, individual and patient factors. However, our intervention will be focusing at the patient factor as it most directly influences the practice, outcome and the probability of incident (Vincent et al., 1999). Interventions were targeted at these barriers using the theory of BCW. The BCW highlighted four key intervention functions: environmental restructuring, education, persuasion and enablement. In this phase we found the pharmacist to be the most suitable healthcare professional to lead the screening programme. Therefore, the qualitative data was used for the development of the pharmacist- led osteoporosis screening guided by the theory of behavioural change wheel as described in section 3.6.

3.5.4.4 Modelling process and outcomes

In our study, we targeted postmenopausal women above the age of 50 years who have not been diagnosed with osteoporosis as they were considered to be biggest cohort that are at high risk of having osteoporosis (Ministry of Health Malaysia, 2012).

3.5.4.5 Behavioural determinants

The behavioural determinants were identified as capability, opportunity and motivation using the BCW which were previously discussed in phase one, section 3.6.

3.5.4.6 Behaviour

Behaviour refers to patients undergoing a BMD scan and/or conducting osteoporosis prevention methods.

3.5.4.7 Physiological/biochemical variable

The physiological/biochemical variable in our study was the BMD results as it the gold standard to diagnose osteoporosis.

3.5.4.8 Health outcomes

As for health outcome, we measured various process measure such as proportion of patients going for BMD scan, proportion of patients started on osteoporosis medication, proportions of patients conducting osteoporosis preventive measures, number of patients diagnosed with osteoporosis, knowledge of osteoporosis and satisfaction towards the programme. We have mapped the process and outcomes of the intervention in Figure 3.9.

Figure 3.9: Pharmacist-led osteoporosis screening programme causal model

Intervention points and behavioural change techniques

Causal model

Outcome measures

Level 1- Behavioural determinants

-Environmental restructuring: Providing an osteoporosis screening program at the primary care clinic

- Enablement: Providing free osteoporosis risk assessment while patients are waiting for their doctor's appointment. Providing sufficient consultation time

-Education: Individualized counselling which provides knowledge on osteoporosis screening and prevention

- Persuasion: Individualized counselling which prompt barrier identification on osteoporosis screening and prevention

Level 3- Physiological variables

Level 2-Behaviour

Past behaviour

Have not attended osteoporosis screening

Capability

Opportunity

Motivation

(Based on behavioural change wheel)

Undergo DEXA scan and/or conduct osteoporosis preventive measures

-Proportion of patient who attended a DEXA scan

-Osteoporosis Knowledge

-Satisfaction towards the osteoporosis screening program

Level 4-Health outcomes

-Number of patients diagnosed with osteoporosis

-Proportion of patients started on osteoporosis medication

-Proportion of patients started on osteoporosis preventive measures

Knowledge questionnaire (OPAAT) and baseline demographics

-BMD results

-Knowledge questionnaire (OPAAT)

- Satisfaction questionnaire (SQOP)

-Primary care physician evaluation

-Patient self report

In our intervention, we evaluated patients' knowledge and satisfaction. Validated measures exist to measure knowledge and satisfaction pertaining to osteoporosis. However, they focused on treatment of osteoporosis. This led us to develop and validate two tools the OPAAT and SQOP (section 4.1 and 4.2). Additionally, there was no osteoporosis risk assessment tool validated in our population. Therefore we evaluated and compared six different types of osteoporosis risk assessment tools. Based on our study, we used the OSTA as the screening tool because the OSTA was the simplest and most well balance tool for daily clinical use (section 4.3).

3.5.5 Discussion

A pharmacist-led osteoporosis screening and prevention programme was developed specifically for postmenopausal women aged 50 and above, at a primary care clinic in Malaysia. Using the first phase of the UK MRC framework we were able to develop an evidence and theory-based intervention, based on literature review, qualitative findings and theories. Our intervention component involved environment restructuring, education, persuasion and enablement. The causal model was established to finalize the intervention. Careful attention to the design of the programme means that we have developed an osteoporosis screening programme that would generate evidence on the effectiveness of a replicable intervention.

We compared the UK MRC framework to other approaches such as the RE-AIM evaluation model. The RE-AIM evaluation model was mainly for public health impact interventions. This includes aspects such as reach, efficacy, adoption,

implementation and maintenance (Glasgow et al., 1999). Although this might seems to be a better fit for our intervention, the aspects included in the RE-Aim model has been incorporated into the MRC UK phases. Another approach was the Precede-Procede which involves needs assessment; this was also considered in the MRC UK framework in the development phase (Green and Kreuter, 1999). Intervention mapping was another method that could be considered. It describes five phases of programme development from definition of programme objectives to process and effect evaluation (Bartholomew et al., 2001). Similarly the Logic model links inputs and activities to programme (Conrad et al., 1999). However, these aspects were also considered by the MRC UK framework. Therefore, we found the UK MRC framework to be a comprehensive and systematic method to develop our intervention.

We used the causal modelling approach. The strength of the causal model is that it specifies steps involved in developing causal models and specifying measures along the causal pathway. Additionally it provides for a concise, one-page representation of theory and evidence based causal pathway linking the intervention components and measures. The causal model guides the choice of intervention point and measures when it hypothesizes the causal pathways. This aids in preventing measuring variables that do not affect the intervention. It also assists in the choice of BCT, making it possible to examine why interventions are effective or not. It also allows the assessment of the extent intervention targeted the behavioural determinants and applies specific technique. Lastly it enables statistical modelling of relationship between the measured behaviours and distant health outcomes.

However for our study the short follow up does now allow for the assessment of the relationship between undergoing a BMD scan and fracture (Hardeman et al., 2005). However, literature has shown that using similar measure can help reduce fracture (McLellan et al., 2011, Lih et al., 2011).

Although the UK MRC framework enabled us to use a rigorous method to develop our intervention that is likely to be accepted in the setting in which it is to be delivered and tested, the process has some disadvantages. The UK MRC framework posed a number of challenges such as time and resources needed. This challenges were similar to other two other studies which used the UK MRC framework to develop an intervention on prevention of childhood obesity (Lakshman et al., 2014) and secondary prevention of coronary heart disease in primary care (Byre et al., 2006). Significant amount of resources are normally allocated for the development of pharmacological and other biochemical intervention but the development of public health intervention which do not involve the generation of intellectual property does not receive as much funding. Funding bodies need to consider if public health interventions are to follow a rigorous development and evaluation process (Lakshman et al., 2014).

A limitation of our study is that the intervention was refined and tailored to the local setting making the generalizability to other settings difficult. However, by linking the intervention components to a theoretical framework it may provide an effective way to allow our finding to be generalizable. This may also avoid duplicating efforts for subsequent research.

3.5.6 Conclusion

We developed an evidence and theory-based pharmacist-led osteoporosis screening programme using the MRC UK framework. This innovative approach has made the intervention more likely to be acceptable and deepens the understanding of how such a complex intervention performs in primary care.

4 CHAPTER 4: PHASE THREE- FEASIBILITY STUDY OF A PHARMACIST-LED OSTEOPOROSIS SCREENING PROGRAMME

4.1 Introduction

4.1.1 Feasibility and pilot study

Various factors affect the internal, external, construct, and statistical validity of the design, implementation and results of a randomized controlled trial (RCT) intervention. Feasibility and pilot studies are designed to build the foundation of the planned intervention, to ensure that the implementation of the intervention is practical, to assess the potential for a successful implementation of the intervention studies and to reduce threats to the validity of the study (Tickle-Degnen, 2013).

 "Feasibility studies are pieces of research done before a main study (i.e randomized controlled trial) in order to answer the question 'Can this study be done?'... It is used to estimate important parameters that are needed to design the main study." Feasibility studies are different from pilot studies. A pilot study is " A version of the main study that is run in miniature to test whether the components of the main study can all work together ... (and resembles) the main study in many respects, includes an assessment of the primary outcome (National Institute for Health Research, 2012)." Hence, a feasibility study tries out parts of the intervention, whereas a pilot study tries out the operation of all parts of the planned intervention. The outcomes of most feasibility and pilot studies should be measured using descriptive statistics,

qualitative analysis and compilation of basic data related to administrative and physical structure (Tickle-Degnen, 2013) (Lancaster et al., 2004, Grimes and Schulz, 2002).

However, our feasibility study is different to published feasibility studies of drug trials where a single "active" ingredient is being tested, which is the causal effect of the intervention outcome. Our intervention is based on qualitative findings and behavioural change techniques (such as the behavioural change wheel) which involves "blended" active ingredients; a theoretical perspective that reflects an understanding of performance and outcomes as being at the intersection of person, environment and a measurement paradigm based on constructs and continua; and client-centres, individualized intervention. Therefore, we used a typology developed by Tickle-Dengen which has been used in occupational therapy, and are typically derived from "blended" active ingredients, like our study (Tickle-Degnen, 2013).

Tickle-Dengen (2013) modified a typology by Thabane et al. (2010) developing a systematic and comprehensive typology to outline four primary purposes for both pilot and feasibility studies: to test the (1) process, (2) resources, (3) management, and (4) scientific basis of planned intervention Process assessment refers to the expected response rates, follow-up rates, adherence to study intervention and attendance. It also assesses the suitability of the eligibility criteria, data collection methods including amount of data collected, time and capacity to collect the data. Examples of resources assessments refer to whether the researchers have the capacity to communicate and coordinate patients; whether there is adequate time to conduct each step at each stage,

and whether there is sufficient equipment. As for management assessments, it refers to finding out the challenges and strengths faced by the investigator to conduct the planned activities such as to accurately enter the data on to the computer and the management of the ethics of the research. Scientific assessment on the other hand refers to the safety of the intervention, estimates the intervention effect and the reliability, validity of the assessment used for the target population (Tickle-Degnen, 2013, Thabane et al., 2010).

4.1.1.1 Importance of feasibility studies in osteoporosis

Feasibility studies can be used to build the foundation for a planned intervention study (Tickle-Degnen, 2013). They can assist in identifying potential bias or problems that may occur in various aspects of the study such as the processes, resources, management and scientific aspects (Tickle-Degnen, 2013).

Three randomized control trials (RCTs) have been conducted internationally by community pharmacists to evaluate the impact of pharmacist's interventions on osteoporosis management (Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005). All three studies showed that pharmacist intervention increased the number of patients that had their BMD tested and calcium intake initiated, indicating that pharmacists have a role to play in reducing the gap in osteoporosis management (Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005). However, two of these studies were considered biased (Elias et al., 2011). The study by Crockett et al had a high risk of both selection and information bias, as self-reported assessment was used (Elias et al., 2011,

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Crockett et al., 2008). As for the study by McDonough et al. the study has a high risk of selection bias as the recruitment size and follow up differed between the control and intervention groups (Elias et al., 2011, McDonough et al., 2005). The third study by Yuksel et al demonstrated low bias in both aspects (Elias et al., 2011, Yuksel et al., 2010). These biases could have been minimised by conducting feasibility studies.

A search of published literature found five feasibility/pilot studies pertaining to osteoporosis screening: one in hospital (Ryder et al., 2007), two in community pharmacies (Cerulli and Zeolla, 2004, Elliot et al., 2002) and two in a primary care setting (Mudano et al., 2013, Pencille et al., 2009). These studies used feasibility studies to preliminary assess the effectiveness of their interventions (Pencille et al., 2009, Cerulli and Zeolla, 2004, Ryder et al., 2007) recruitment method (Pencille et al., 2009, Mudano et al., 2013), processes (time spent with patients, communication, acceptance of physicians) (Cerulli and Zeolla, 2004, Elliot et al., 2002) and project cost (Cerulli and Zeolla, 2004).

All four studies concluded that a feasibility study was informative in making decisions towards a successful implementation of the interventions (Cerulli and Zeolla, 2004, Elliot et al., 2002, Pencille et al., 2009, Mudano et al., 2013). For example, the studies performed in community pharmacies found that the planned process were suitable, and that these processes were positively accepted by the healthcare professionals involved (Cerulli and Zeolla, 2004, Elliot et al., 2002).The other two primary care studies were able to identify the most suitable recruitment method for their study, thus

reducing bias in their study methodology (Mudano et al., 2013, Pencille et al., 2009). Therefore, feasibility studies are critical to the successful implementation of RCTs and interventions. To date, there is a paucity of data of studies using the OSTA in an osteoporosis screening programme in the Malaysian primary care setting.

4.1.2 Objectives

To determine the feasibility of a pharmacist-led osteoporosis screening programme at a Malaysian primary care clinic.

4.1.3 Methods

4.1.3.1 Study design

This is a prospective, pre and post intervention study of a pharmacist-led osteoporosis screening programme.

4.1.3.2 Setting

The study was conducted at the primary care clinics of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia.

4.1.3.3 Period of study

Data were collected from June to August 2014.

4.1.3.4 Participants

English or Malay speaking postmenopausal women aged ≥ 50 years old who had not been diagnosed with osteopenia/osteoporosis were included. Those not well enough to participate in the study were excluded.

4.1.3.5 Sampling procedure

Randomization was not conducted as we wanted to assess if the components of the intervention could function well together in a practice setting. Therefore, convenience sampling was used to reflect daily clinic practice.

4.1.3.6 Sample size

A large sample size is not required for a feasibility study as adequate power statistics for null hypothesis testing is not required (Tickle-Degnen, 2013). We recruited a convenience sample of 50 patients.

4.1.3.7 Primary and secondary outcomes

We used the Tickle-Dengen modified typology by Thabane et al to categorize our primary and secondary outcomes which were: to test the (1) process, (2) resources, (3) management, and (4) scientific (Tickle-Degnen, 2013) (Thabane et al., 2010).

4.1.3.8 Primary outcome
4.1.3.8.1   Scientific assessment

Our primary outcome was to measure the proportion of patients who went for the BMD scan. We assessed this outcome by patient self-report and confirmed by obtaining the patients' BMD scan results. This outcome measured is consistent with the currently used HEDIS (Healthcare Effectiveness Data and Information Set) measures for quality of osteoporosis care adopted by the National Committee on Quality Assurance (National Committee for Quality Assurance (NCQA), 2004, National Committee for Quality Assurance, 2014).

4.1.3.9 Secondary outcomes measured

4.1.3.9.1   Scientific assessment

Four secondary outcomes were measured: the number of patients started on osteoporosis medications, the number of patients conducting lifestyle modifications namely: taking calcium supplements, increasing calcium in the diet and/or exercise, patients' osteoporosis knowledge and patients' satisfaction towards the pharmacist-led osteoporosis screening programme.

4.1.3.9.1.1   The number of patients that were started on osteoporosis medications

Similarly, this outcome measured is also consistent with the currently used HEDIS measures for quality of osteoporosis care adopted by the National Committee on Quality Assurance (National Committee for Quality Assurance (NCQA), 2004, National Committee for Quality Assurance, 2014). We measured this via patients' self report. Subsequently we confirmed the data by checking the patient's medical records.

4.1.3.9.1.2   The number of patients that made lifestyle modifications

We also measured the number of patients conducting lifestyle modifications namely: taking calcium supplements, increasing calcium in the diet and/or exercise. These were measured based on patient self report.

4.1.3.9.1.3   Patients' osteoporosis knowledge

Based on the UK MRC framework (Medical Research Council, 2008), it is imperative to assess the effectiveness of an intervention conducted. We measured the outcome of patient's pre and post osteoporosis knowledge scores as part of the

evaluation of the intervention. We used the OPAAT to measure this outcome. The development and validation of the OPAAT have been explained in section 4.2, Phase two.

4.1.3.9.1.4   Patients' satisfaction towards the pharmacist-led osteoporosis screening programme

The patients' satisfaction towards the osteoporosis screening programme was also measured as part of the evaluation of the intervention. This was measured using the SQOP which was previously described in section 4.3 of Phase two.

4.1.3.9.2   Process assessment

In this feasibility study we assessed the intervention's processes, including response rates, follow-up rates, suitability of the eligibility and exclusion criteria, data collection methods, patients' time and capacity to complete data collection procedures. This was assessed from the researcher's experience and documentation from the pilot.

4.1.3.9.3   Resources assessment

We also assessed the resources in terms of whether the researchers had the capacity to communicate and coordinate the patients and primary care physicians, physical condition, time to conduct each stage, sufficient equipment and documentation. This was assessed from the researcher's experience and documentation from the pilot.

4.1.3.9.4   Management assessment

This refers to accuracy when entering the data to the computer and adherence to ethics application. This was

measured by the researcher's experience and documentation from the pilot.

4.1.3.10 Instruments used

4.1.3.10.1 Baseline demographics

This instrument was used to collect baseline demographic information such as patients' medical history, lifestyle and medication history (Appendix 1).

4.1.3.10.2 Osteoporosis Screening Tools for Asians (OSTA)

The OSTA was used to screen the patients' risk for osteoporosis. It categorized the patients to low, moderate of high risk. The OSTA involves a calculation as follows: weight in kilograms were deducted with age in years and multiplied by -0.2. (Please refer to section 4.3 for further details).

4.1.3.10.3 WHO Fracture Risk Assessment tool (FRAX)

The FRAX was used to provide additional information of the patient's fracture risk to further aid the physician's in deciding if a BMD scan was needed. It was developed to evaluate the fracture risk of patients (Appendix 33). It was developed by WHO, based on individual patient models that integrate the risk associated with clinical risk factors as well as BMD at the femoral neck. The model calculates the risk of fractures of men or women by using age, height, weight, prior fragility fracture, parental history of hip fracture, current tobacco smoking, ever long-term use of oral glucocorticoids, rheumatoid arthritis, other causes of secondary osteoporosis and daily alcohol consumption of three of more units daily. Femoral neck BMD can additionally be entered for more accurate estimates. The FRAX algorithms output is a 10-year

probability of hip fracture and the 10-year probability of a major osteoporosis fracture (clinical spine, forearm, hip or shoulder fracture). As a FRAX model based on the Malaysian cohort has not been developed, we used the model based on the Singaporean population (Kanis, 2014, McCloskey, 2009).

4.1.3.10.4 Osteoporosis Prevention and Awareness Tool (OPAAT)

The validated OPAAT was used to assess the knowledge of patients as described in section 4.2 previously.

4.1.3.10.5 Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

The validated SQOP was used to assess the knowledge of patients as described in section 4.1 previously (Toh et al., 2014).

4.1.3.11 Intervention provided

Patients received an osteoporosis booklet (appendix 24), 30 minutes of verbal counselling, a fracture risk assessment using FRAX and an osteoporosis risk assessment using OSTA. Topics covered during the counselling session were the definition of osteoporosis, consequences of untreated osteoporosis, risk factors for osteoporosis, the role of the BMD scan (its function, what the results mean, accessibility and the frequency a patient has to go for a BMD scan), other tests used in osteoporosis screening (quantitative ultrasound scanning, x-ray, blood test and the OSTA), lifestyle changes (calcium intake, vitamin D intake, weight bearing exercise and fall prevention), and treatment of osteoporosis. A recommendation for a BMD scan (appendix 34) was made to

the doctors for patients who had a moderate or high risk for osteoporosis.

4.1.3.12 Procedure

Figure 5.1 demonstrates the workflow of the finalized pharmacists-led osteoporosis screening programme based on the behaviour change wheel. Eligible patients were first screened by nurses at the waiting area. Suitable patients were then recruited by the pharmacist. The study was explained to patients using the patient information sheet (Appendix 35). Informed consent and the patients' baseline demographic data were obtained (Appendix 36). Subsequently, the pharmacist assessed the patients' 10-year fracture risk using FRAX, conducted a counselling session and administered the OPAAT. Patients answered the questionnaire themselves. However, for those who experienced some difficulty in reading the questions themselves, the researcher read the questions out for them and assisted them in filling the questionnaire. The researcher ensured that all questions had been answered. Most patients required about 10-15 minutes to complete the questionnaire.

All questionnaires and interventions were administered by the researcher. The researcher was trained by one of the supervisors who was well versed in osteoporosis to deliver the counselling session. An osteoporosis risk assessment was then conducted. If the OSTA score indicated that the patient was at risk for osteoporosis (high risk, intermediate risk, low risk plus one risk factor), a recommendation was made to the doctor to order a BMD scan and a BMD scan appointment was prearranged pending the doctor's evaluation.

The patients were then evaluated by the doctor for the need for a BMD scan. An appointment for one month later was set. During this time, the patients would undergo a BMD scan if required. Two weeks after baseline, a telephone call was conducted to administer the SQOP and OPAAT. An independent postgraduate student was employed to use the SQOP to assess the patients' satisfaction and the OPAAT to assess the patients' knowledge during this follow up. The pharmacist reminded the patients of their next doctor's appointment and informed the patients of their BMD results and answered any queries that they may have.

The patient then attended their scheduled doctor's appointment. A second follow up (immediately after the doctor's appointment) was conducted to assess if the patient attended the osteoporosis clinic or was started on osteoporosis treatment/preventive measures. Figure 4.1 demonstrates the workflow of the finalized pharmacists-led osteoporosis screening programme based on the behaviour change wheel.

Figure 4.1: Flow chart on the pharmacist-led osteoporosis screening program


```
┌─────────────────────────────────────────────────────────────┐
│        Nurses will refer potential candidates to the pharmacist │
└─────────────────────────────────────────────────────────────┘
                              │
┌─────────────────────────────────────────────────────────────┐
│     Nurses/pharmacist will measure the participant's height and weight │
└─────────────────────────────────────────────────────────────┘
                              │
 ┌──────────┐  ┌─────────────────────────────────────────────┐
 │ Baseline │  │ Pharmacist will conduct the first counselling session which includes: │
 └──────────┘  │ obtaining baseline information, administering OPAAT and screening patients │
               │              using OSTA and FRAX (N=50)        │
               └─────────────────────────────────────────────┘
```

| Low risk | Low risk & 1 risk factor | Medium risk | High risk |

Pharmacist will recommend to the doctor to order a BMD scan using a form (Appendix 6.1)

Pharmacist to prearrange BMD scan appointment

Patients go for scheduled doctor's appointment

| BMD scan not necessary | BMD scan necessary |

Doctors to schedule the next appointment one month later and to pass the BMD form to patients

Patients go for their BMD scan*

Patients go for subsequent doctor's appointment where their BMD results will be reviewed

Follow up via phone will be conducted to administer SQOP and OPAAT. Pharmacist reminded the patients of their next doctor's appointment and informed the patients of their BMD results via telephone. Questions regarding the BMD results and osteoporosis prevention were answered.

Follow up via phone will be conducted to assess if patients attended the osteoporosis clinic or started on osteoporosis treatment/preventive measures.

*The patients will receive the hard copy of the results and the researcher will receive the softcopy

Abbreviations:
- BMD: Bone Mineral Density
- OSTA: Osteoporosis Screening Tool for Asians
- OPAAT: Osteoporosis Prevention and Awareness Assessment Tool
- SQOP: Satisfaction Questionnaire for Osteoporosis

4.1.3.13 Source of data

The source of data varied from medical registers, medical records, observations to observe if patients were too unwell to participate in the study, interviews, questionnaire and informal discussions to find out informally if patients have osteoporosis during recruitment. Some of the data such as patients' clinical information were obtained from medical records prior to the provision of service, whilst other data were obtained during the counselling session with the pharmacist.

4.1.3.14 Ethics approval

Ethical approval from the University Malaya Medical Centre Ethics Committee was obtained prior to the study (ref no. 920.26, Appendix 37).

4.1.3.15 Data analysis

All data was entered into the IBM® SPSS® version 20 (IBM Corporation, Armonk, NY, US). Descriptive statistics were used to present patient demographics, response rate, follow up rates, proportions of patients who went for BMD scans, outcomes of patients that went for BMD scan. Mc Nemar's test was used to examine the pre and post scores of the individual items in the OPAAT. Continuous data of the individual items and total domain scores of the OPAAT were analyzed using the Wilcoxon signed-rank. Non-parametric tests were used since data obtained were not normally distributed. A p-value <0.05 was considered as statistically significant.

To ascertain the feasibility of providing this service, the data gathered to assessed the process, resources and management in this study were described.

4.1.4 Results

4.1.4.1 Patients characteristics

A total of 55 patients were approached, 5 declined participation. Finally 50 patients were recruited, [response rate= 90.9%]. Patients' demographic data are shown in Table 4.1.

Table 4.1: Baseline demographic characteristics of patients

Characteristics	Patients (n=50)
Mean age ± S. D. (years) [range]	64.7±8.2 [51-83]
(Median)	(64.5)
Age range (years) [n (%)]	
<65	25 (50.0)
≥ 65	25 (50.0)
Ethnicity [n (%)]	
Malay	6 (12.0)
Chinese	30 (60.0)
Indian	14 (28.0)
Mean BMI ± S.D. (kg/m2)[range]	23.3±3.6 [15.4-
(Median)	35.6](23.5)
BMI (kg/m2) [n (%)]	
<18.5 (underweight)	3 (6.0)
18.5-24.9 (normal)	33 (66.0)
25.0-29.9 (overweight)	12 (24.0)
≥30.0 (obese)	2 (4.0)
Level of education [n (%)]	
Primary (6 years of education)	3 (6.0)
Secondary (11-13 years of education)	30 (60.0)
Diploma/Technical school training (12-14	11 (22.0)
years of education)	60 (12.0)
Tertiary/Postgraduate (15-21 years of	
education)	
Income per month [n (%)]	
<RM1000 (<$ 310.7)	10 (20.0)
RM1000-1999 ($ 310.7-621.0)	10 (20.0)
RM2000-2999 ($ 621.3- 931.7)	10 (20.0)
RM3000-3999 ($ 932.0- 1242.3)	7 (14.0)
RM4000-4999 ($ 1242.6-1553)	5 (10.0)
>RM5000 (>$1553.3)	8 (16.0)

S.D. = standard deviation; BMI=body mass index; $=US dollar

4.1.4.2 Proportion of patients who went for BMD scan

Using the OSTA, 27/50 (54.0%) patients were categorized into moderate to high risk groups. For the low risk group, 9/23 (39.1%) had more than one major clinical risk factor: 5/23 (21.7%) had a family history of osteoporosis, 2/23 (8.7%) had a previous fracture and 2/23 (8.7%) had a family history of osteoporosis as well as a previous fracture. A BMD scan was recommended for these patients [Figure 4.2].

Figure 4.2: Stratification of patients' osteoporosis risk based on OSTA
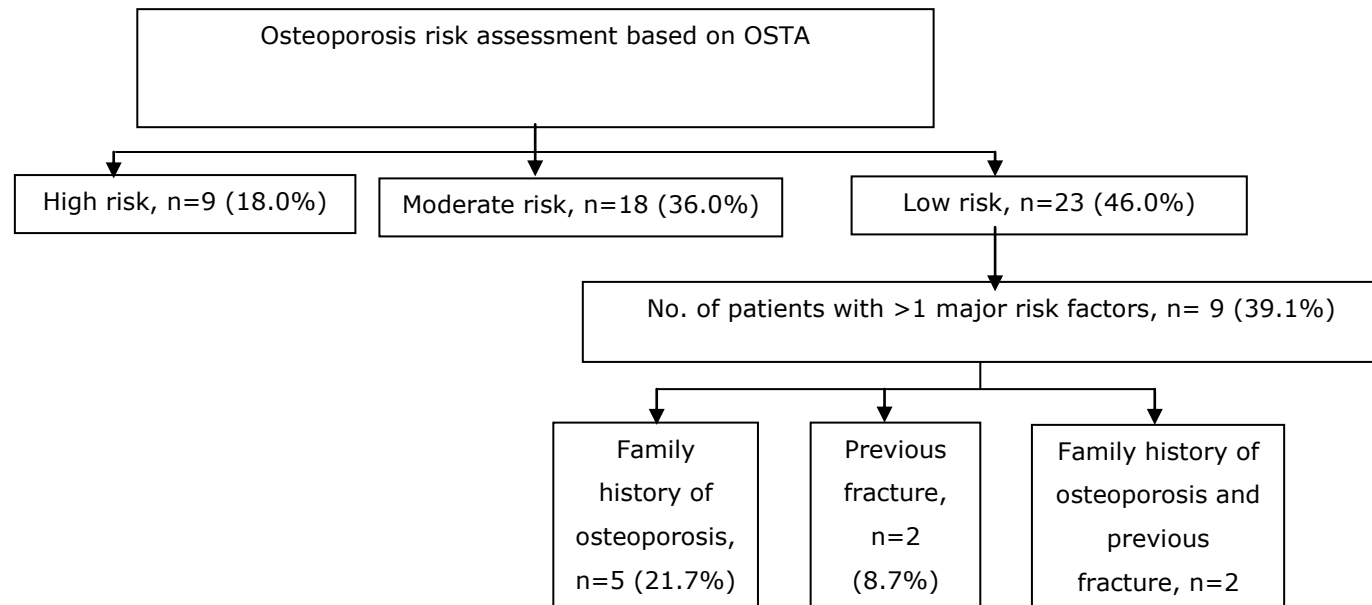
Out of 36 recommendations made by the pharmacists, 28 (77.8%) BMD scans were ordered. Reasons provided by the doctors on why BMD scans were not ordered were: 3/36 (8.3%) patients' x-ray results were normal; 1/36 (2.8%) doctor said that there were more urgent diseases to treat such as heart, endocrine and eye; 1/36 (2.8%) patient's blood calcium levels were normal; 1/36 (2.8%) patients was considered too young (58 years old), 1/36 (2.8%) patient's FRAX fracture risk was considered too low (11% major osteoporosis fracture and 2.2% for hip fracture) and 1/36 (2.8%) would be exposed to too much radiation as she had another appointment for a computed tomography (CT) scan. In addition, 3 extra BMD scans were ordered by the doctors even though it was not recommended by the pharmacist, as BMDs scans were provided free of charge by the research fund. Therefore a total of 31 BMD scans were ordered.

Ultimately, 26/31 (83.9%) went for a BMD scan: 3 /31 (9.7%) were busy, 1/31 (3.2%) was afraid of too much radiation as she was going for an electrocardiogram the next month and 1/31 (3.2%) was not contactable [Figure 4.3].

Figure 4.3: Results of feasibility study
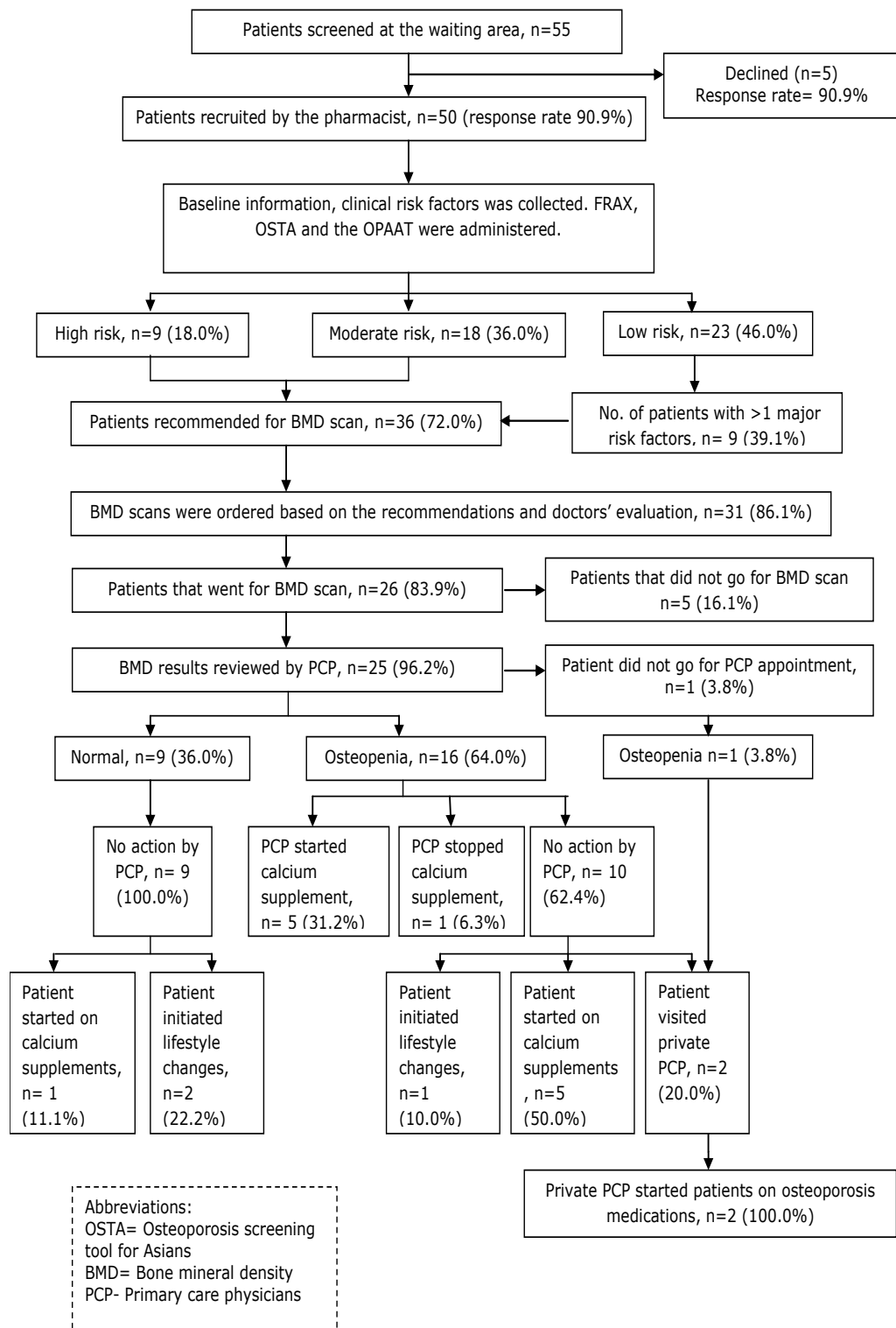
Outcome of patients that went for a bone mineral density scan

Seventeen out of 26 (65.4%) patients had osteopenia. BMD results were seen by primary care physicians in 25/26 (96.2%) patients. One (3.8%) patient did not come for a follow up visit as the waiting time was too long. Nonetheless, this patient visited a private practice primary care physician. She was found to be osteopenic.

4.1.4.3 Outcomes of patients started on osteoporosis medication or patients conducting lifestyle modifications

Out of the 16 osteopenic patients reviewed by the primary care clinic, five (31.3%) were started on calcium tablets and one (6.3%) was asked to stop their calcium supplements as her parathyroid blood test was out of range. No action was taken for the remaining ten (62.5%) patients. However out of these ten patients, five (50.0%) patients initiated calcium supplements on their own, one (10.0%) started some weight bearing exercises, whilst one (10.0%) patient visited a private practice primary care physician, who started her on 2g strontium ranelate daily. There was one (10.0%) patient who did not go for her primary care clinic appointment. However this patient visited a private practice primary care physician and was started on 2g strontium ranelate daily.

In our study, nine out of 26 (34.6%) of the patients had normal BMD results. Although the primary care physicians decided that no action was necessary, two (22.2%) patients initiated lifestyle changes (such as weight bearing exercises and increase dietary calcium intake) and one (11.1%) patient started taking calcium supplements.

In total, two out of 26 (7.7%) patients from this study were started on osteoporosis medications. Additionally, 11/26 (42.3%) patients started on calcium supplements and 3/26 (11.5%) initiated osteoporosis preventive lifestyle measure.

4.1.4.4 Knowledge score

After one month, only 46/50 patients answered the OPAAT again (response rate=92.0%): 2 (4.0%) were busy, 1 (2.0%) was afraid of radiation and hence was excluded since she did not go for the BMD, and 1 (2.0%) was patient could not be contacted. After the intervention provided by the pharmacist, there was an increase in knowledge for 27/30 (90.0%) items. The domain scores as well as the total score for the OPAAT were also significantly higher after intervention [Table 4.2].

Table 4.2: Patients' knowledge score at baseline and one month later.

Domain	Item number	Baseline (n=50)			One month later (n=46)			McNemar's test p-value	Wilcoxon signed-rank test		
		Mean±SD	Median	No. of correct responses [n (%)]	Mean±SD	Median	No. of correct responses [n (%)]		Mean/rank	z-value	P-value
Osteoporosis in general	1	0.64±0.48	1.00	18 (69.2)	0.89±0.31	1.00	23 (88.5)	0.002*			
	2	0.32±0.47	0.00	9 (34.6)	0.65±0.48	1.00	19 (73.1)	<0.001*			
	3	0.34±0.48	0.00	7 (26.9)	0.43±0.50	0.00	11 (42.3)	0.289			
	4	0.34±0.48	0.00	9 (34.6)	0.65±0.48	1.00	20 (76.9)	0.001*			
	5	0.36±0.48	0.00	8 (30.8)	0.76±0.43	1.00	22 (84.6)	<0.001*			
	6	0.64±0.48	1.00	16 (61.5)	0.78±0.42	1.00	23 (88.5)	0.016*			
	7	0.34±0.48	0.00	9 (34.6)	0.50±0.51	0.50	16 (61.5)	0.008*			
	8	0.48±0.50	1.00	15 (57.7)	0.89±0.31	1.00	25 (96.2)	<0.001*			
	9	0.54±0.50	1.00	17 (65.4)	0.76±0.43	1.00	21 (80.8)	0.006*			
	10	0.36±0.48	0.00	10 (38.5)	0.76±0.43	1.00	21 (80.8)	<0.001*			
	11	0.46±0.50	0.00	15 (57.7)	0.78±0.42	1.00	21 (80.8)	0.001*			
	Domain score (%)	44.72±28.03	45.45		73.54±26.04	81.82			14.50/19.13	-5.100	<0.001*
Consequences of untreated	12	0.66±0.48	1.00	15 (57.7)	1.00±0.00	1.00	26 (100.0)	#			
	13	0.76±0.43	1.00	19 (73.1)	1.00±0.00	1.00	26 (100.0)	#			

osteoporosis	14	0.68±0.47	1.00	18 (69.2)	0.96±0.21	1.00	25 (96.2)	0.007*			
	15	0.22±0.42	0.00	9 (34.6)	0.83±0.38	1.00	22 (84.6)	<0.001*			
	16	0.22±0.42	0.00	7 (26.9)	0.91±0.28	1.00	25 (96.2)	<0.001*			
	Domain score (%)	50.80±26.87	60.00		93.91±11.83	100.00			13.00/22.44	-5.476	<0.001*
Prevention of osteoporosis	17	0.40±0.49	0.00	9 (34.6)	0.93±0.25	1.00	25 (96.2)	<0.001*			
	18	0.32±0.47	0.00	8 (30.8)	0.89±0.34	1.00	24 (92.3)	<0.001*			
	19	0.26±0.44	0.00	7 (26.9)	0.52±0.51	1.00	17 (65.4)	0.019*			
	20	0.54±0.50	0.00	17 (65.4)	0.98±0.15	1.00	26 (100.0)	<0.001*			
	21	0.16±0.37	0.00	3 (11.5)	0.67±0.47	1.00	20 (76.9)	<0.001*			
	22	0.64±0.48	1.00	19 (73.1)	1.00±0.00	1.00	26 (100.0)	#			
	23	0.50±0.51	0.50	15 (57.7)	0.96±0.21	1.00	26 (100.0)	<0.001*			
	24	0.42±0.50	0.00	12 (46.2)	0.61±0.49	1.00	18 (69.2)	0.022*			
	25	0.28±0.45	0.00	9 (34.6)	0.80±0.40	1.00	24 (92.3)	<0.001*			
	26	0.50±0.51	0.50	15 (57.7)	0.74±0.44	1.00	23 (88.5)	0.013*			
	27	0.64±0.49	0.00	10 (38.5)	0.41±0.50	0.00	11 (42.3)	0.375			
	28	0.78±0.42	1.00	21 (80.8)	0.98±0.15	1.00	25 (96.2)	0.004*			
	29	0.78±0.42	1.00	20 (76.9)	0.89±0.31	1.00	24 (92.3)	0.344			
	30	0.52±0.50	1.00	15 (57.7)	0.76±0.43	1.00	21 (80.8)	0.013*			
	Domain score (%)	46.00±25.13	50.00		79.66±16.15	82.14			7.00/24.14	<0.001*	0.000*
Total OPAAT score (%)		46.33±21.36	46.67		79.06±14.26	81.67			8.00/23.70	-5.668	<0.001*

*Statistically significant p<0.05. Wilcoxon signed-rank test was used for continuous variables. McNemar's test was conducted for categorical variables.

Could not be calculated as all patients answered correctly one month later

4.1.4.5 Satisfaction level

The patients' satisfaction was not assessed during baseline. However the patients' satisfaction score at one month later was 89.75±12.44.

4.1.4.6 Process assessments

Based on the response rate of 90.9% we found the inclusion criteria to be suitable. The inclusion criteria were clear and sufficient enabling us to target postmenopausal women >50 years old who had not been diagnosed osteoporosis/osteopenia. The follow up rate was 26/31 (83.9%) during the first follow up and 26/26 (100%) for the second follow up.

However, modifications were made to the data collection method. Initially, the nurses were allocated to refer potential patients to the pharmacists. However, nurses did not perform this task. Hence, the pharmacist screened for potential patients herself. All patients had enough time and the capacity to complete the data collection procedure. Patients took approximately 15 minutes to complete the OPAAT and the SQOP. Therefore we have tested the timing and administrative aspect of the intervention and was found to be successful.

4.1.4.7 Resources assessment

The pharmacist initially found it difficult to communicate and coordinate with the doctors regarding the recommendations and procedures of the intervention. The doctors were not motivated and supportive to proceed with the intervention tasks. In order to resolve this, the pharmacist conducted individual sessions with the doctors before the clinic session, which aided in the coordination and communication of the

intervention. These individual sessions with the doctors involved a short briefing on the gap of osteoporosis, the aim and procedures of the research. There were no problems with communicating with the patients from baseline to follow up.

This intervention was conducted at the waiting area of the clinic. Currently, no room has been allocated for this intervention. Although the intervention proceeded smoothly, some patients commented that it would be more professional if a consultation room was allocated for the pharmacist or at least a table and chair should be stationed for the intervention.

As for time and capacity to conduct each stage, the pharmacist found that the risk assessment, counselling and administration of the two questionnaires took approximately 30 minutes for each patient. The time allocated was sufficient as patients waiting time for their doctor's appointment would normally be more than 30 minutes. For the first follow up session, administration of the OPAAT, SQOP and information on the BMD results was approximately 15-30 minutes depending on the number of questions the patients had. The second follow up needed about five minutes.

Documentation was successful, as the forms used by the pharmacists to make recommendations were documented into the patients' medical record. Equipment to measure height and weight were available throughout the intervention. DEXA machines were also available as needed during the patients' appointment.

4.1.4.8 Management assessment

The pharmacist was able to document all data and outcomes needed into SPSS daily. There were also no problems with managing the procedures based on the ethics application.

4.1.5 Discussion

To our knowledge, this is the first feasibility study of a pharmacist-led osteoporosis screening in a primary care clinic. The feasibility study was a success and can be taken to the next step which is the implementation of a large scale randomized controlled trial, to assess the effectiveness of the intervention. The current workflow was functional and able to assess both primary (proportion of patients that went for the BMD scan) and secondary outcomes (the number of patients started on osteoporosis medications, the number of patients conducting lifestyle modifications, patients' osteoporosis knowledge, patients' satisfaction towards a pharmacist-led osteoporosis screening programme, process assessment, resources assessment and management assessment).

We found the inclusion and exclusion criterion to be suitable as the osteoporosis screening programme was positively received by patients (response rate =90.9%). In our cohort, 26 (83.9%) patients went for a BMD density scan, which resulted in 17(65.4%) being diagnosed with osteopenia. Only 2(7.7%) patients were started on osteoporosis medications, 11 (42.3%) were started on calcium supplements and 3 (11.5%) initiated lifestyle modifications on their own accord. Additionally, the knowledge score of the patients significantly increased in all domains when compared to baseline. The overall OPAAT score increased significantly from 46.33±21.36 to 79.06±14.26. Patients were also satisfied with the

programme (satisfaction score=89.75±12.44). The current process, resource and management of the osteoporosis screening programme were also found to be suitable.

In our study, the reasons given by the doctors for not ordering BMD scans highlighted several misconceptions in the areas regarding osteoporosis screening, interpretation of FRAX, risk factors, radiation of the BMD scan and the lack of priority towards osteoporosis. This further supports our Phase one findings on the healthcare professionals' lack of osteoporosis knowledge in section 3.4.2.2.7.3.

Some of the BMD scans were not ordered because patients' x-ray results were normal. Similarly, in New Zealand there was a misconception to judge bone mineral density using the x-ray results (Sale et al., 2014). According to the Malaysian osteoporosis guidelines, radiological osteopenia is apparent in plain x-ray only after more than 30% of bone loss has occurred (Ministry of Health Malaysia, 2012).

Another reason the BMD scans were not ordered was because patients' blood calcium results were normal. Based on the National Osteoporosis Foundation (NOF) clinician's guide to prevention and treatment of osteoporosis 2014 blood calcium levels are not used to screen for osteoporosis but to rule out secondary causes of osteoporosis (Cosman et al., 2014) (Houillier et al., 2006). Therefore, tools such as the OSTA, FRAX and QUS are more suitable for osteoporosis screening (Cosman et al., 2014, Ministry of Health Malaysia, 2012) as both the x-ray results and blood calcium levels do not reflect the patients' osteoporosis risk.

The second misconception was with the FRAX. In our study, the FRAX was a useful tool in improving patients' perception of their osteoporotic risk. FRAX was also used in our study to provide additional information of the patients' fracture risk. Although, the OSTA score of a 64 year old patient showed that she was at low risk (-0.8) for osteoporosis, she was recommended for a BMD scan. This was because the patient reported that her parents had a previous hip fracture and was diagnosed as osteoporosis. However, this patient's BMD scan was not ordered as the risk of fracture based on FRAX was considered to be too low. The patient had an 11% probability of a major osteoporosis fracture and 2.2% probability for hip fracture. This suggest that there was a misinterpretation of the Malaysian osteoporosis guideline as they suggested that treatment should be started on osteopenic postmenopausal women above the age 50 years with > 20% probability of a major osteoporotic fracture or >3% probability of a hip fracture. However, this option was seen to be not cost effective(Ministry of Health Malaysia, 2012). There were no recommendations on when a patient should be referred for a BMD scan based on FRAX (Ministry of Health Malaysia, 2012). Based on the UK Osteoporosis Guideline Groups, a BMD scan is indicated for this patient so that the FRAX can be recalculated to aid the decision on whether medication is needed (McCloskey, 2009, Compston et al., 2014). Although, the threshold setting used in the UK guideline may differ from the Malaysian population but it serves as preliminary guide till a Malaysian model is developed.

Another misconception noted in the area of patient risk factors was highlighted as a patient aged 58 years old was considered too young to go for a BMD scan. This patient's OSTA score

was 0.4 which was categorized as low risk. The patient was recommended for a BMD scan due to a traumatic fracture at the wrist after the age 45. According to the National Osteoporosis Foundation (NOF) clinician's guide to prevention and treatment of osteoporosis 2014 this patient could have been a candidate for a BMD scan as she had a previous fracture history as an adult and was already above the age of 50 years (Cosman et al., 2014). However, there was insufficient detail in the current Malaysian guidelines.

The misconception of the BMD scan being high in radiation was also noted as one of the patient's BMD scan was not ordered for fear of being exposed to too much radiation as she also had a computer tomography (CT) scan appointment. Data has been published that a BMD scan radiation is very low and considered trivial (Cosman et al., 2014). Additionally, the benefits of conducting a BMD scan outweigh the risk of osteoporosis being undetected and subsequently suffering from fragility fractures.

In addition, there was one patient whose BMD scan was not ordered as she had other diseases to address such as cardiovascular, endocrine and the eye. This shows that there is a lack of priority towards osteoporosis. Our qualitative results noted that this was one of the barriers towards osteoporosis screening (Toh et al., 2012). Similarly, other studies have found that treatment and prevention of other diseases was prioritized instead of osteoporosis (Otmar et al., 2012, Jaglal et al., 2003).

Conversely, there were three patients who were not recommended for a BMD scan but were ordered one by the

primary care physician, as the BMDs scans were provided free of charge by the research fund. Although the primary care physicians concerned were only making use of the opportunity that a BMD scan was freely available to patients during the study period, this act was considered unnecessary and a waste of funds. This indicates that there is a lack of knowledge among primary care physicians with regards to osteoporosis screening. An educational or training session could assist in rectifying these misconceptions among primary care physicians, as shown in a previous study where student nurses showed an increase in osteoporosis knowledge after an education intervention (Zhang et al., 2012).

One patient did not want to go for the BMD scan as she was afraid of too much radiation as she was going for an electrocardiogram the next month. This was a misconception towards the BMD scan as a BMD scan's radiation is very low and considered trivial (Cosman et al., 2014). Another misconception was that an electrocardiogram does not involve radiation, it uses electrical impulses (Sarker, 2014). Based on this we suggest that the counselling session should not only mentioned that the BMD is low in radiation, we should also enforce that it is safe to go for a BMD scan together with any other scans that the patient may require. Additionally, the counselling session should reinforcement that the benefits of conducting a BMD scan outweighs the risk of osteoporosis being undetected and subsequently suffering from fragility fractures. This also reinforced the findings and discussion from our qualitative study in Phase one.

In our study, out of the 16 osteopenic patients reviewed by the primary care clinic, one of the patients was asked to stop

their calcium supplements as her parathyroid blood test was out of range. This action is appropriate as calcium supplements can affect parathyroid hormone levels (Riggs et al., 1998, Bilezikian et al., 2011). This reinforces the point made by the Phase one qualitative results; stakeholders enforced the importance of continuity of care. The importance of continuity of care is to ensure that the patient's condition is considered as a whole which includes other co-morbidities and social background. Therefore, an inter-professional collaboration was important to ensure the patient received the optimal care according to each healthcare professional's specialty (D'Amour et al., 2008).

We would like to highlight that two osteopenic patients visited a private practice primary care physician and was initiated on 2g strontium ranelate daily. One of the patients reported that her siblings had osteoporosis; the other patients surgically removed her uterus and ovaries at age 45. Therefore, based on the Malaysian guideline these patients were suitable candidate for osteoporosis treatment (Ministry of Health Malaysia, 2012). Similarly, this reinforces our qualitative findings in phase one where there was a lack of awareness of the Malaysian osteoporosis guidelines.

Our study showed that 83.9% of the patients went for a BMD scan, 7.7% patients were started on osteoporosis medications, 42.3% started on calcium supplements and 11.5% patients initiated lifestyle modifications This preliminary effect of our osteoporosis screening programme shows that our study has potential to improve the management of osteoporosis. Our results concurred with other osteoporosis screening programmes conducted by pharmacists which demonstrated

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an increase in BMD scans ordered, initiation of calcium supplements and/or treatment (Yuksel et al., 2010, Crockett et al., 2008, McDonough et al., 2005, McConaha et al., 2014).

The knowledge of the patients was assessed using the OPAAT. There were three items that did not show a significant difference. Item 3 (Osteoporosis occurs because bone is removed faster than it is formed) and item 27 (Certain medicines (such as sleeping tablets or high blood pressure medicines) may reduce the risk of falling). These questions may have been too technical for the patients and was only briefly mentioned during the counselling session. However, there was still an increase in the percentage of patients answering these questions correctly in this study was 26.9% to 42.3 % (item 3) and 38.5% to 42.3% (item 27) although not significant. Similarly, for item 29 (Poor vision may lead to falls) this was briefly mentioned in the counselling. However, most patients already knew the answer at baseline (76.9% patients answering correctly at baseline), and even more patients answered this item correctly post intervention (92.3%). Nonetheless, there was a significant increase in knowledge for the overall scores and all domains. These preliminary results demonstrated that the counselling programme is effective.

Additionally, the satisfaction score of the patients were 89.75±12.44. This score was similar to the score achieved by the intervention group of the SQOP validation study. Based on this previous study the cut-off score was defined as 61.00 as the control group in this study achieved a satisfaction score of 61.87±8.76 (Toh et al., 2014). Based on this we considered

patients in this study to be satisfied with the osteoporosis screening programme.

Based on the process assessments of the osteoporosis screening programme, modifications were made to the data collection method. Initially, the nurses were asked to refer potential patients to the pharmacists. This method was found to be inefficient as the nurses had difficulty in screening for the patients. Therefore, the pharmacist was then used to screen for potential patients. This may be because nurses in Malaysia are not trained and have a low level of osteoporosis knowledge. Therefore, it was difficult for them to screen for potential patients. Similar results were found in a US study where they compared a decentralized clinical-pharmacy-based osteoporosis management service intervening on postmenopausal women following fractures, while the comparison group utilized a centralized registered nurses to manage this population. This study found that the integrated pharmacist-run osteoporosis management service demonstrated a substantial increase in the rate of osteoporosis drug initiation among these postmenopausal women who experiences a fracture compared with a centrally located nurse run service. However, screening rates did not significantly differ between groups (Heilmann et al., 2012). This shows that in order to include the nurses as part of the osteoporosis screening, a training session pertaining to osteoporosis screening would need to be conducted targeted at the nurses.

4.1.6 Strengths

The strength of this study is that the osteoporosis screening programme was designed specifically for this setting following

a qualitative study. It was then supported by the use of the behavioural change wheel to ensure that the underlying psychological reason to conducting an osteoporosis screening programme was addressed. Additionally the tools used such as the OPAAT and SQOP was specifically developed and validated for this intervention. The OSTA was also validated for use in this population.

4.1.7 Limitations

As this was a feasibility study, the sample size used was small and results were not generalisable. Our study was also not able to detect any patient diagnosed with osteoporosis. However, the aim of this study was not to assess the effectiveness of the intervention. Therefore, we achieved the aim of our study which was to assess the feasibility of the developed osteoporosis screening programme.

The lack of a control group was another limitation, as changes in patient behaviour could have been affected by factors other than the intervention. In addition some results were based on patient self-reports and were not verified with the providers. Nonetheless this reflects realistic results of the daily clinical practice.

Another potential limitation was that this study contacted patients via telephone to determine their satisfaction with the osteoporosis screening programme. Results from the telephone interviews may have been skewed to appear more favourable as the survey was not blinded. However, this potential bias was decreased since an independent postgraduate student used the SQOP to assess the patients'

satisfaction; the pharmacist who performed the screening and education did not conduct the telephone follow-up.

Additionally, although Phase two, section 4.3 found that the best OSTA cut-off point for this population to be ≤0, the feasibility study used a cut-off point of ≤-1. This is because there was a preference from the primary care doctors to use the published cut-off points of ≤-1 to screen for the patients as our current data is unpublished and has not been peer reviewed. Currently, there are plans to publish the data from Phase two, section 4.3.

A further limitation of this study was the exclusion of men. It is possible that different psychological factors are related to the screening of osteoporosis in men, which need to be explore by further research. This may involve the validation of OSTA for men or the development of other risk assessment tool to screen for osteoporosis in men.

4.1.8 Conclusion

In conclusion, a pharmacist-led osteoporosis screening programme was demonstrated to be feasible in the Malaysian primary care setting. The study emphasizes that there is a need to conduct osteoporosis screening education sessions for healthcare professionals before commencing the programme. The results will inform the design of a larger trial that could provide more precise estimates of the effect of the osteoporosis screening programme. Further large scale studies need to be conducted to assess the generalisability of these finding towards reducing the gap in osteoporosis management.

5   CHAPTER 5: CONCLUSION

5.1   Summary of key findings

This study was divided into three phases applying the first two phases of the UK MRC framework for complex intervention as a theoretical guide to develop a pharmacist-led osteoporosis screening programme for postmenopausal women in a primary care clinic in Malaysia. The use of qualitative approaches in phase one helped to identify barriers for conducting an osteoporosis screening programme. Despite the need to address the barriers encountered for conducting the screening programme, the pharmacist was identified as the most suitable healthcare professional to conduct this programme. Pharmacists were seen to be knowledgeable specialist who are currently under utilised in the primary health care team. This study demonstrated that via inter-professional collaboration the pharmacists could expand their role to osteoporosis screening. Additionally, the intervention for the screening programme was developed based on the behavioural change wheel and data from the qualitative approach.

In phase two, several tools were developed and validated to be used in Phase three to evaluate the intervention. The OPAAT was found to be valid and reliable to assess patients' knowledge of osteoporosis; whilst the SQOP was found to be a valid and reliable tool to assess patients' satisfaction towards the pharmacist screening programme. Additionally, six osteoporosis risk assessment tools were also validated among postmenopausal women in Malaysia. Among these tools, the OSTA also had the best overall specificity (36.8% and 41.0%) and sensitivity (83.3% and 81.3%). Additionally, the OSTA was found to be the most suitable tool as it was cheap, and

easy to use. This tool was subsequently used in Phase three. The workflow for the pharmacist-led screening programme was developed finalized.

Phase three was a feasibility study. The feasibility study indicated that it is feasible to deliver a pharmacist-led osteoporosis screening programme in the Malaysian primary care setting.

5.2   Overall discussion

There is a need for quality research designs and clear description of the process of pharmaceutical care interventions to evaluate the impact of the interventions (Roughead et al., 2005). Pharmaceutical care interventions are complex intervention and research in this area should reveal the complexity of pharmacaceutical care (Tulip and Campbell, 2001). This present study has shown that pharmaceutical care interventions are indeed complex as not only did it involve preventing and screening of osteoporosis, it involved the need to establish relationships with patients and interprofessional collaboration with pharmacists, doctors, nurses and policy makers. The identification of these components was made possible with the application of the UK MRC framework for complex interventions. The UK MRC frameworks emphasised the imporatance of conducting qualitative and feasibility studies to identify components of a particular intervention prior to developing a definitive trial (Medical Research Council, 2008).

Some of the findings in this study such as barriers to conducting an osteoporosis screening program, SQOP, OPAAT,

validation of risk assessment tools might be transferable to other healthcare settings in Malaysia. However, the intervention itself is tailored specifically to the current location. Therefore, the degree of generalisability or transferability to other settings could only be determined by the reader as it is context specific. The reader needs to decide on the components that are relevant to their setting based on the description of the setting and methodologies provided. Nonetheless, this study could be taken as an example for investigating the role of pharmacist in screening. It might be useful as an example for conducting different kinds of screening as general problems pertinent to screening may be similar.

This study fills the gap of the lack of a satisfaction tool to assess patients' satisfaction towards an osteoporosis screening program (the SQOP), the lack of a tool to assess patients' knowledge towards osteoporosis prevention (the OPAAT) and the lack of a validated osteoporosis risk assessment tool by validating six type of tools. As these tools are validated in the Malaysian population they can now be used by future researchers or clinicians interested in this field.

5.3 Strengths

This study was developed rigorously using the UK MRC framework specifically targeted at the location. It identifies and addressed specific barriers to the setting ensuring the acceptability, practicalities and sustainability of the intervention. Additional, a feasibility study was conducted and has shown the program to be feasible.

5.4   Limitations

Overall, the participants that we recruited in this study did not represent the ethnic distribution of Malaysia. The participants of this study were mainly Chinese ranging from 41.0-72.0% of the participants. However, it represented the patients who sought treatment in our study site.

Additionally, this study did not directly involve patients during the development and implementation of the intervention. The concept of involving patients refers to, rather than using patients as the 'subjects' of research it is doing research 'with' or 'by' the patients. This can be done in various was such as having patient representative in the research group or via the internet. It has been found that interventions involving only healthcare professionals may miss perspectives of the patients. Patient input is needed in order to monitor the quality of decision making. It is important to understand what is important to the patients. Hence, recent intervention developments and implementation have involved patients (NHS Foundation Trust, 2006). Nonetheless, in this study the patients suggestions and input on the barriers were considered as we conducted in depth interviews with 20 patients during phase 1.

5.5   Recomendations

It is recommended that pharmacists should play a more proactive role in osteoporosis management and screening. In summary, although the pharmacist-led osteoporosis screening programme has contributed towards closing the gap in osteoporosis screening in postmenopausal women, there remains room for improvement. It is recommend that a randomized controlled trial is required to strengthen the

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evidence for pharmacist osteoporosis screening and to measure its effectiveness in terms of clinical outcomes (number of fractures, number of patients who started on osteoporosis medications, number of patients undergoing a BMD scan and number of patients conducting lifestyle modifications) and cost effectiveness.

However, based on this study there were several factors that may affect the sustainability of the pharmacist-led osteoporosis screening program. These include lack of staff, high workload, lack of space and lack of interprofessional relationship between pharmacists, nurses and doctors. In order to enhance and sustain the screening program, these issues need to be resolved.

Therefore, based on the experience of conducting the pharmacist-led osteoporosis screening program, some of the recommendations include conducting the screening program weekly instead of daily to reduce the workload on current staff. This frequency of conducting the program provides the opportunity for patients to utilize the new service but does not strain the staff as it is only conducted once a week. The staffs are able to handle the core work and conduct the screening program on less hectic days. Additionally, the weekly osteoporosis screening program would not increase the number of BMD scans dramatically which may be an issue if the program is conducted daily as there is a lack of DEXA machines. Currently, pharmacist-led diabetes and asthma clinics are being conducted on a weekly basis. These programs have now been conducted for several years showing the sustainability of this method.

The second recommendation that can be made is to provide patient education and counselling in a dedicated consulation area. As there are lack of rooms a partition can be used where the screening program can be conducted. It is important to listen, empathise, develop rapport and communicate with the patients. In order to do this, a certain amount of privacy is needed to ensure the patients feel comfortable to voice out their concerns.

It is also suggested to enhance collaboration between pharmacists, physicians and nurses. For example, in the beginning of the feasibility study, it was difficult to get the doctors to cooperate as they did not understand the program or the role of the pharmacist. Therefore, it is important to conduct workshops and meetings interprofessionally to provide opportunites for different kind of healthcare professionals to understand each others' role.

It is important to educate patients but it is also important to educate healthcare professionals. This study has found that not only there was a lack of osteoporosis knowledge in patients but also in healthcare professionals such as the doctors, pharmacists and nurses. Therefore, lectures and workshop targeting the areas of osteoporosis should be conducted more frequently.

5.6   Policy implications

As this study concluded at the feasibility of the pharmacist-led osteoporosis screening program, a full randomized controlled trial needs to be conducted to assess its effectiveness. Once the effectiveness of the intervention is assessed future plans to expand the project to other areas of Malaysia can be

considered with the support of policy makers. It is imperative to have the support of the policy makers in order for an intervention to make an impact on practice. Nonetheless, this study has established evidence that pharmacists have a role to play in osteoporosis screening through risk assessments, education and recommendations to the primary care physician.

5.7 Healthcare professional implications

The implication for pharmacists would be an expansion of their job scope and job satisfaction as they will be able to make recommendations to primary care physicians and be more involved in patients's care.

Other implications are a better interprofessional collaboration between healthcare professionals such as nurses, doctors and pharmacist. This intervention provides various opportunites for the healthcare professional to better understand each others' respective roles and to share the responsibilities of managing patients' care.

5.8 Implications for patients

Patients will benefit from this service as it provides an opportunity for patients to discuss their concerns about osteoporosis screening and prevention methods. This is also an opportunity for them to receive education, osteoporosis risk assessment and counselling. The osteoporosis risk assessment is beneficial for the patients as this may lead them to undergo a BMD scan and may prevent fragility fractures.

5.9   Research implications and future work

Phase one of this study has extensively studied the barriers to conducting an osteoporosis screening in a primary clinic. However this study was conducted in urban women and did not consider the perspective of women leaving in more rural areas. Future studies, should explore the perspective of rural women towards conducting an osteoporosis screening program.

In phase two, tools such as the SQOP and OPAAT were developed and validated in English. The English versions of these tools were sufficient for this study as most women who are postmenopausal were educated in English. However, the education system in Malaysia changed from English to Malay. Therefore a validated Malay, Mandarin and Tamil version of these tools would be required for future studies.

Phase three, was a feasibility study of the pharmacist-led osteoporosis screening program. Therefore, before the RCT is conducted a pilot of this program should be conducted. This is to further assess other areas of the RCT such as the randomization process.

As this study focuses on outpatients, future studies can be expanded to target inpatients such as patients who have already been warded for a fragility fracture and are at high risk of osteoporosis. Additionally, this study targeted women. Screening of osteoporosis should be expanded to men.

5.10   Conclusion

This study has successfully applied the UK MRC framework for complex intervention to develop a pharmacist-led osteoporosis

screening program in a primary clinic in a terriary hospital in Malaysia. It has laid the foundation for future work to be carried out in improving osteoporosis management via the expansion of the pharmacist role into osteoporosis screening. It has provided a thorough analysis of the challenges faced in the developmental phase prior to evaluating its effectiveness in a RCT.

REFERENCES

ABDULAMEER, S. A., SULAIMAN, S. A. S., HASSALI, M. A. A., SUBRAMANIAM, K. & SAHIB, M. N. 2013. Psychometric properties of osteoporosis knowledge tool and self-management behaviours among Malaysian type 2 diabetic patients. *J Community Health,* 38**,** 95-105.

ADAY, L. A. & CORNELIUS, L. J. 2006. *Designing and conducting health surveys: A comprehensive guide,* San Francisco, USA, Jossey-Bass A Wiley Imprint.

AILINGER, R. L. & EMERSON, J. 1998. Women's knowledge of osteoporosis.pdf>. *Applied Nursing Research,* 11**,** 111-114.

AILINGER, R. L., HARPER, D. C. & LASUS, H. A. 1998. Bone up on osteoporosis development of the facts on osteoporosis quiz. *Orthop Nurs,* 17**,** 66-73.

AILINGER, R. L., LASUS, H. A. & BRAUN, M. A. 2003. Brief report: revision of the factors on Osteoporosis Quiz. *Nurs Res,* 52**,** 198-201.

AJZEN, I. 1991. The theory of planned behavior. *Organizational behaviour and human decision processes,* 50**,** 179-211.

ALEXANDRAKI, K. I., SYRIOU, V., ZIAKAS, P. D., APOSTOLOPOULOS, N. V., ALEXANDRAKIS, A. I., PIPERI, C., KAVOULAKI, E., MYRIOKEFALITAKIS, I., KORRES, G. & DIAMANTI-KANDARAKIS, E. 2008. The knowledge of osteoporosis risk factors in a Greek female population. *Maturitas,* 59**,** 38-45.

ANDERSEN, R. M. 1995. Revisiting the behavioral model and access to medical care: Does it matter? *Journal of Health and Social Behavior,* 36.

ANDERSON, C. 2010. Presenting and evaluating qualitative research. *American Journal of Pharmaceutical Education,* 74**,** 1-7.

ANDERSON, C., BLENKINSOPP, A. & ARMSTRONG, M. 2009. *The contribution of community pharmacy' to improving the public's health: summry report of the literature review 1990-2007* [Online]. Available: www.pharmacyhealthlink.org.uk [Accessed 12 December 2014].

AUSTRALIAN GOVERNMENT 2006. PBS extended listing of alendronate for treating osteoporosis and Medicare extended listing for bone mineral density testing. . *In:* AGEING, D. O. H. A. (ed.). Canberra, Australia: Australian government,.

AZMI, M. Y., JUNIDAH, R., SITI MARIAM, A., SAFIAH, M. Y., FATIMAH, S., NORIMAH, A. K., POH, B. K., KANDIAH,

M., ZALILAH, M. S., WAN ABDUL MANAN, W. M., SITI HASLINDA, M. D. & TAHIR, A. 2009. Body mass index (BMI) of adults: Findings ofthe Malaysian adult nutrition survey (MANS). *Mal J Nutr,* 15**,** 97-119.

BACKETT-MILBURN, K., PARRY, O. & MAUTHNER, N. 2000. 'I'll worry about that when it comes along': osteoporosis, a meaningful issue for women at mid life. *Health Education Research,* 15**,** 153-162.

BAGGER, Y. Z., TANKÓ, L. B., ALEXANDERSEN, P., HANSEN, H. B., MØLLGAARD, A., RAVN, P., QVIST, P., KANIS, J. A. & CHRISTIANSEN, C. 2004. Two to three years of hormone replacement treatment in healthy women have long-term preventive effects on bone mass and osteoporotic fractures: the PERF study. *Bone,* 34**,** 728-735.

BAHEIRAEI, A., POCOCK, N. A., EISMAN, J. A., NGUYEN, N. D. & NGUYEN, T. V. 2005a. Bone mineral density, body mass index and cigarette smoking among Iranian women: implications for prevention. *BMC Musculoskeletal Disorders,* 6**,** 34.

BAHEIRAEI, A., RITCHIE, J. E., EISMAN, J. A. & NGUYEN, T. V. 2005b. Psychometric properties of the Persian version of the osteoporosis knowledge and health belief questionnaires. *Maturitas,* 50**,** 134-139.

BALASEGARAM, S., MAJEED, A. & FITZ-CLARENCE, H. 2001. Trends in hospital admissions for fractures of the hip and femur in England, 1989-1990 to 1997-1998. *J Public Health Med,* 23**,** 11-17.

BARBER, N. 2001. Pharmaceutical care and medicines management- is tere a difference? *Pharm World Sci,* 23**,** 210-211.

BARON, J. A., FARAHMAND, B. Y., E., W., MICHAËLSSON, K., ALBERTS, A., PERSSON, I. & LJUNGHALL, S. 2001. Cigarette smoking, alcohol consumption, and risk of hip fracture in women. *Arch Intern Med,* 161**,** 983-988.

BARRIS BLUNDELL, D., RODRIGUEZ ZARZUELO, C., SABIO SANCHEZ, B., GUTIERREZ ALVAREZ, J. L., NAVARRO VISA, E., VALDES MUNOZ, O., GARRIDO JIMENEZ, B. & SANCHEZ GOMEZ, R. 2006. Screening for osteoporosis among post-menopausal women in community pharmacy. *Pharmacy Practice,* 4**,** 95-101.

BARTHOLOMEW, L. K., PARCEL, G. S., KOK, G. & GOTTLIEB, N. H. 2001. *Intervention mapping: Designing theory- and evidence-based health promotion programs,* Mountain view, CA, Mayfield.

BARTHOLOMEW, L. K., PARCEL, G. S., KOK, G. & GOTTLIEB, N. H. 2011. *Planning health promotion programs: Intervention mapping,* San Francisco, USA, Jossey-Bass.

BARTL, R. & FRISCH, B. 2004. *Osteoporosis: Diagnosis, prevention, therapy: A practical guide for all physicians-from pediatrics to geriatrics,* Heidelberg, Germany, Springer.

BAZELEY, P. 2007. *Qualitative data analysis with Nvivo,* London, Sage publications.

BAZELEY, P. 2009. Analysing qualitative data: More than 'identifying themes'. *Malaysian Journal of Qualitative Research,* 2**,** 6-22.

BEATON, D. E., SUJIC, R., MCILROY BEATON, K., SALE, J., ELLIOT-GIBSON, V. & BOGOCH, E. R. 2012. Patient Perceptions of the Path to Osteoporosis Care Following a Fragility Fracture. *Qualitative Health Research,* 22**,** 1647-1658.

BESSER, S. J., ANDERSON, J. E. & WEINMAN, J. 2012. How do osteoporosis patients perceive their illness and treatment? Implications for clinical practice. *Arch Osteoporosis,* 7**,** 115-124.

BILEZIKIAN, J. P., KHAN, A., POTTS, J. T., BRANDI, M. L., CLARKE, B. L., SHOBACK, D., JÜPPNER, H., D'AMOUR, P., FOX, J., REJNMARK, L., MOSEKILDE, L., RUBIN, M. R., DEMPSTER, D., GAFNI, R., COLLINS, M. T., SLINEY, J. & SANDERS, J. 2011. Hypoparathyroidism in the adult: Epidemiology, diagnosis, pathophysiology, target-organ involvement, treatment, and challenges for future research. *Journal of Bone and Mineral Research,* 26**,** 2317-2337.

BLACK, D. M., ARDEN, N. K., PALERMO, L., PEARSON, J. & CUMMINGS, S. R. 1999. Prevalent vertebral deformities predict hip fractures and new vertebral deformities but not wrist fractures. Study of Osteoporotic Fractures Research Group. . *J Bone Miner Res,* 14**,** 821-828.

BOGOCH, E. R., ELLIOT-GIBSON, V., BEATON, D., JAMAL, S. A., JOSSE, R. G. & MURRAY, T. M. 2006. Effective initiation of osteoporosis diagnosis and treatment for patients with fragility fracture in orthopaedic environment. *J Bone Joint Surg Am,* 88**,** 25-34.

BOUDOU, L., GERBAY, B., CHOPIN, F., OLLAGNIER, E., COLLET, P. & THOMAS, T. 2011. Management of osteoporosis in fracture liaison service associated with long-term adherence to treatment. *Osteoporosis International,* 22**,** 2099-2106.

BOWEN, G. A. 2008. Naturalistic inquiry and the saturation concept: a research note. *Qualitative Research,* 8**,** 137-152.

BOWLING, A. 2009. *Research methods in health: Investigating health and health services,* Glasgow, McGraw Hill.

BOYATZIS, R. E. 1998. *Transforming qualitative information: Thematic analysis and code development,* Thousang Oaks, California, Sage publications.

BRAUER, C. A., COCA-PERRAILLON, M., CUTLER, D. M. & ROSEN, A. B. 2009. Incidence and mortality of hip fractures in the United States. *JAMA,* 302**,** 1573-1579.

BRAUN, V. & CLARKE, V. 2008. Using thematic analysis in psychology. *Qualitative research in psychology,* 3**,** 77-101.

BRUIN, J. 2006. *Newtest: command to compute new test* [Online]. UCLA: Statistical Consulting Group. Available: http://www.ats.ucla.edu/stat/stata/ado/analysis/ [Accessed 5th May 2014].

BRYMAN, A. 2004. *Social Research Methods,* Hampshire, UK, Ashford Colour Press.

BURGE, R., DAWSON-HUGHES, B., SOLOMON, D. H., WONG, J. B., KING, A. & TOSTESON, A. 2007. Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025. *Journal of Bone and Mineral Research,* 22**,** 465-475.

BURKE-DOE, A., HUDSON, A., WERTH, H. & D.G., R. 2008. Knowledge of osteoporosis risk factors and prevalence of risk factors for osteoporosis, falls and fracture in functionally independent older adults. *Journal of Geriatric Physical Therapy,* 31**,** 11-17.

BYRE, M., CUPPLES, M. E., SMITH, S. M., LEATHAM, C., CORRIGAN, M., BYRE, M. C. & MURPHY, A. 2006. Development of a complex intervention for secondary prevention of coronary heath disease in praimry care using the UK Medical Reseach Council framework. *American Journal of Managed Care,* 12**,** 261-266.

CADARETTE, S. M., GIGNAC, M. A. M., BEATON, D. E., JAGLAL, S. B. & HAWKER, G. A. 2007. Psychometric properties of the "Osteoporosis and You" questionnaire: osteoporosis knowledge deficits among older community-dwelling women. *Osteoporos Int,* 18**,** 981-989.

CADARETTE, S. M., JAGLAL, S. B., KREIGER, N., MCISAAC, W. J., DARLINGTON, G. A. & TU, J. V. 2000. Development and validation of the osteoporosis risk assessment instrument to facilitate selection of women for bone densitometry. *CMAJ,* 162**,** 1289-1294.

CADARETTE, S. M., MCISAAC, W. J., HAWKER, G. A., JAAKKIMAINEN, L., CULBERT, A., ZARIFA, G., OLA, E. & JAGLAL, S. B. 2004. The validity of decision rules for selecting women with primary osteoporosis for bone mineral density testing. *Osteoporos Int,* 15**,** 361-6.

CAMPBELL, O., CLELAND, J., COLLUMBIEN, M. & SOUTHWICK, K. 1999. Social science methods for research in reproductive health. *World Health Organization: Geneva*.

CAULEY, J. A., ROBBINS, J., CHEN, Z., CUMMINGS, S. R., JACKSON, R. D., LACROIX, A. Z., LEBOFF, M., LEWIS, C. E., MCGOWAN, J., NEUNER, J., PETTINGER, M., STEFANICK, M. L., WACTAWSKI-WENDE, J. & B., W. N. 2003. Women's Health Initiative investigators. Effects of estrogen plus progestin on risk of fractures and bone mineral density; the Women's Health Initiative randomised trial. *the journal of the American Medical Association,* 290**,** 1729-1738.

CENTER, J. R., BLIUE, D., NGUYEN, T. V. & EISMAN, J. 2007. Risk of subsequent fracture after low-trauma fracture in men and women. *The journal of the American Medical Association,* 297**,** 387-394.

CERULLI, J. & ZEOLLA, M. M. 2004. Impact and feasibility of a community pharmacy bone mineral density screening and education program. *J Am Pharm Assoc,* 44**,** 161-167.

CHAN, S. P., TEO, C. C., NG, S. A., GOH, N., TAN, C. & DEURENBERG-YAP, M. 2006. Validation of various osteoporosis risk indices in elderly Chinese females in Singapore. *Osteoporos Int,* 17**,** 1182-8.

CHANDRA, A., MALCOLM, N. & FETTERS, M. 2003. Practicing Health Promotion Through Pharmacy Counseling Activities. *Health Promotion Practice,* 4**,** 64-71.

CHANG, K. P., CENTER, J. R., NGUYEN, T. V. & EISMAN, J. A. 2004. Incidence of Hip and Other Osteoporotic Fractures in Elderly Men and Women: Dubbo Osteoporosis Epidemiology Study. *Journal of Bone and Mineral Research,* 19**,** 532-536.

CHAPUY, M. C., ARLOT, M. E., DELMAS, P. D. & MEUNIER, P. J. 1994. Effect of calcium and cholecalciferol treatment for three years on hip fractures in elderly women. *British Medical Journal,* 308**,** 1081-1082.

CHARMAZ, K. 2006. *Constructing grounded theory,* London, Sage.

CHECK, J. & SCHUTT, R. K. 2012. *Research methods in education,* California, USA, Sage.

CHEE, S. S., ISMAIL, M. N., NG, K. K. & ZAWIAH, H. 1997. Food intake assessment of adults in rural and urban

areas from four selected regions in Malaysia. *Mal J Nutr,* 3**,** 91-102.

CHEN, H. Y. & BOORE, J. R. P. 2009. Translation and back-translation in qualitative nursing research: Methodological review. *Journal of Clinical Nursing,* 19**,** 234-239.

CIPOLLE, R. J., STRAND, L. M. & MORLEY, P. C. 2004. *Pharmaceutical Care Practice,* New York, USA, McGraw-Hill.

CLAESSON, A., TOTH-PAL, E., PIISPANEN, P. & SALMINEN, H. 2015. District nurses' perceptions of osteoporosis management: a qualitative study. *Osteoporosis International*.

CLUNIE, G. & STEPHENSON, S. 2008. Implementing and running a fracture liaison service: An integrated clinical service providing a comprehensive bone health assessment at the point of fracture management. *Journal of Orthopaedic Nursing,* 12**,** 159-165.

COHEN, J. W. 1988. *Statistical power analysis for the behavioral sciences,* Hillsdale, NJ, Lawrence Erlbaum Associates.

COMPSTON, J., COOPER, A., COOPER, C., FRANCIS, R., KANIS, J. A., MARSH, D., MCCLOSKEY, E., REID, D. M., SELBY, P., DAVIES, C. & BOWRING, C. 2014. Guideline for the diagnosis and management of osteoporosis in postmenopausal women and men from the age of 50 years in the UK. *In:* GROUP, N. O. G. (ed.). Sheffield, UK.

CONRAD, K. J., RANDOLPH, F. L., KIRBY, M. W. & BEBOUT, R. R. 1999. Creating and Using Logic Models. *Alcoholism Treatment Quarterly,* 17**,** 17-31.

COOPER, C. 1993. Epidemiology and public health impact of osteoporosis. *Bailliere Clin Rheumatol Osteoporosis,* 7**,** 459-477.

COOPER, C., CAMPION, G. & J, M. L. 1992. Hip fracture in the elderly: A world-wide projection. *Osteoporos Int,* 2**,** 285-289.

COOPER, M. S., PALMER, A. J. & SEIBEL, M. J. 2011. Cost-effectiveness of the Concord Minimal Trauma Fracture Liaison service, a prospective, controlled fracture prevention study. *Osteoporosis International,* 23**,** 97-107.

COSMAN, F., LINDSAY, R., LEBOFF, M. S., JAN DE BEUR, S. & TANNER, B. 2014. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation.

CRAIG, P., DIEPPE, P., MACINTYRE, S., MICHIE, S., NAZARETH, I. & PETTICREW, M. 2008. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ,* 337**,** a1655.

CRANNEY, A., LAM, M., RUHLAND, L., BRISON, R., GODWIN, M., HARRISON, M. M., HARRISON, M. B., ANASTASSIADES, T., GRIMSHAW, J. M. & GRAHAM, I. D. 2008. A multifaceted intervention to improve treatment of osteoporosis in postmenopausal women with wrist fractures: a cluster randomized trial. *Osteoporos Int,* 19**,** 1733-40.

CRESWELL, J. W. 2009. *Research design: Qualitative, quatitative, and mixed methods approaches,* London, Sage.

CROCKETT, J. A., TAYLOR, S. J. & MCLEOD, L. J. 2008. Patient responses to an integrated service, initiated by community pharmacists, for the prevention of osteoporosis. *International Journal of Pharmacy Practice,* 16**,** 65-72.

CRONBACH, L. J. 1951. Coefficient alpha and the internal structure of tests. *Psychometrika,* 16**,** 297-334.

CUMMINGS, R. G. & NEVITT, M. C. 1997. Calcium for prevention of osteoporotic fractures in postmenopausal women. *Journal of Bone and Mineral Research,* 12**,** 1321-1329.

CUMMINGS, S. R. & MELTON, L. J. 2002. Epidemiology and outcomes of osteoporotic fractures. *The Lancet,* 359**,** 1761-1767.

CURRY, L. C. & HOGSTEL, M. O. 2001. Risk status related to knowledge of osteoporosis in older women. *J Women Aging,* 13.

D'AMOUR, D., GOULET, L., LABADIE, J.-F., MARTÍN-RODRIGUEZ, L. & PINEAULT, R. 2008. A model and typology of collaboration between professionals in healthcare organizations. *BMC Health Services Research,* 8**,** 188.

DAROSZEWSKA, A. 2012. Prevention and treatment of osteoporosis in women: an update. *Obstetrics, Gynaecology & Reproductive Medicine,* 22**,** 162-169.

DAVIS, J. C., GUY, P., ASHE, M. C., LIU-AMBROSE, T. & KHAN, K. 2007. Hip watch: Osteoporosis investigation and treatment after a hip fracture: A 6-month randomized controlled trial. *Journal of Gerontology,* 62A**,** 888-891.

DE LEEUW, E. D. 2005. To mix or not to mix data collection modes in survey. *Journal of Official Statistics,* 21**,** 223-255.

DELL, R., GREENE, D., SCHELKUN, S. R. & WILLIAMS, K. 2008. Osteoporosis Disease Management: The Role of the Orthopaedic Surgeon. *The Journal of Bone and Joint Surgery (American),* 90**,** 188-194.

DEPARTMENT OF STATISTICS MALAYSIA 2013. Salaries and wages survey report. *In:* MALAYSIA, D. O. S. (ed.). Putrajaya, Malaysia: Department of statistics Malaysia.

DEVON, H. A., BLOCK, M. E., MOYLE-WRIGHT, P., ERNST, D. M., HAYDEN, S. J., LAZZARA, D. J., SAVOY, S. M. & KOSTAS-POLSTON, E. 2007. A psychometric toolbox for validity n reliability. *Journal of Nursing Scholarship,* 39**,** 155-164.

DHANWAL, D. K., DENNISON, E. M., HARVEY, N. C. & COOPER, C. 2011. Epidemiology of hip fracture: Worldwide geographic variation. *Indian J Orthop,* 45**,** 15-22.

DOLOVICH, L., POTTIE, K., KACZOROWSKI, J., FARRELL, B., AUSTIN, Z., RODRIGUEZ, C., GAEBEL, K. & SELLORS, C. 2008. Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics. *Clinical Pharmacology and Therapeutics,* 83**,** 913-917.

DUYVENDAK, M., NAUNTON, M., VAN ROON, E. N. & BROUWERS, J. R. B. J. 2011. Doctors' beliefs and knowledge on corticosteroid-induced osteoporosis: identifying barriers to improve prevention. *Journal of Clinical Pharmacy and Therapeutics,* 36**,** 356-366.

EADES, C. E., FERGUSON, J. S. & O'CARROLL, R. E. 2011. Public health in community pharmacy: A systematic review of pharmacist and consumer views. *BMC Public Health,* 11**,** 582.

ELIAS, M. N., BURDEN, A. M. & CADARETTE, S. M. 2011. The impact of pharmacist interventions on osteoporosis management: a systematic review. *Osteoporos Int,* 22**,** 2587-96.

ELLIOT-GIBSON, V., BOGOCH, E. R., JAMAL, S. A. & BEATON, D. E. 2004. Practice patterns in the diagnosis and treatment of osteoporosis after a fragility fracture: a systematic review. *Osteoporosis International,* 15**,** 767-778.

ELLIOT, M. E., MEEK, P. D., KANOUS, N. L., SCHILL, G. R., WEINSWIG, P. A., BOHLMAN, J. P., ZIMPEL, C. L., JENSEN, B. C., WALTERS, D. R., SUTTER, S. L., PETERSON, A. N., PETERSON, R. M. & BINKLEY, N. C. 2002. Osteoporosis screening by community pharmacists: Use of National Osteoporosis Foundation resources. *J Am Pharm Assoc,* 42**,** 101-10.

ESCOTT, S. & WALLEY, S. 2005. Listening to those on the frontline: Lessons for community-based tuberculosis programmes from a qualitative study in Swaziland. *Soc Sci Med,* 61**,** 1701-1710.

ESPOSITO, N. 2001. From meaning to meaning: The influence of translation techniques on non-English focus group research. *Qualitative Health Research,* 11**,** 568-579.

ETEMADIFAR, M. R. 2013. Relationship of knowledge about osteoporosis with education level and life habits. *World Journal of Orthopedics,* 4**,** 139-143.

FAWCETT, T. 2006. An introduction to ROC analysis. *Pattern Recognition Letters,* 27**,** 861-874.

FELDSTEIN, A., ELMER, P. J., SMITH, D. H., HERSON, M., ORWOLL, E., CHEN, C., AICKIN, M. & SWAIN, M. C. 2006. Electronic medical record reminder improves osteoporosis management after a fracture: a randomized, controlled trial. *J Am Geriatr Soc,* 54**,** 450-7.

FELDSTEIN, A. C., SCHNEIDER, J., SMITH, D. H., VOLLMER, W. M., RIX, M., GLAUBER, H., BOARDMAN, D. L. & HERSON, M. 2008. Harnessing stakeholder perspectives to improve the care of osteoporosis after a fracture. *Osteoporosis International,* 19**,** 1527-1540.

FESKANICH, D., WILLETT, W. & COLDITZ, G. 2002. Walking and leisure-time activity and risk of hip fracture in postmenopausal women. *The journal of the American Medical Association,* 288**,** 2300-2306.

FIELDEN, J., PURDIE, G., HORNE, G. & DEVANE, P. 2001. Hip fracture incidence in New Zealand, revisited. *N Z Med J,* 114**,** 154-156.

FLESCH, R. 1948. A new readability yardstick. *Journal of Applied Psychology,* 32**,** 221-233.

FLOOD, E. M., BEUSTERIEN, K. M., GREEN, H., SHIKIAR, R., BARAN, R. W., AMONKAR, M. M. & CELLA, D. 2006. Psychometric evaluation of the Osteoporosis Patient Treatment Satisfaction Questionnaire (OPSAT-Q), a novel measure to assess satisfaction with bisphosphonate treatment in postmenopausal women. *Health Qual Life Outcomes,* 4**,** 42.

FOPPE VAN MILL, J. W. 2004. Proving the benefits of pharmaceutical care. *Pharm World Sci,* 26**,** 123.

FOPPE VAN MILL, J. W., SCHULZ, M. & TROMP, T. F. 2004. Pharmaceutical care, European developments in concepts, implementation, teaching, and research: a review. *Pharm World Sci,* 26**,** 303-311.

FORD, R. C., BACH, S. A. & FOTTLER, M. D. 1997. Methods of measuring patient satisfaction in health care

organizations. *Health care management review,* 22**,** 74-89.

FUJIWARA, S., MASUNARI, N., SUZUKI, G. & ROSS, P. D. 2001. Performance of Osteoporosis Risk Indices in a Japanese Population. *Curr Ther Res Clin Exp,* 62**,** 586-594.

GAINES, J. M. & MARX, K. A. 2011. Older men's knowledge about osteoporosis and educational interventions to increase osteoporosis knowledge in older men: A systematic review. *Maturitas,* 68**,** 5-12.

GALLAGHER, J. C. 1990. Metabolic effects of synthetic calcitriol (Rocaltrol) in the treatment of postmenopausal osteoporosis. *Metabolism,* 39**,** 27-29.

GANDA, K., PUECH, M., CHEN, J. S., SPEERIN, R., BLEASEL, J., CENTER, J. R., EISMAN, J. A., MARCH, L. & SEIBEL, M. J. 2012. Models of care for the secondary prevention of osteoporotic fractures: a systematic review and meta-analysis. *Osteoporosis International,* 24**,** 393-406.

GARDNER, M. J., BROPHY, R. H., DEMETRAKOPOULOS, D., KOOB, J., HONG, R., RANA, A., LIN, J. T. & LANE, J. M. 2005. Interventions to improve osteoporosis treatment following hip fracture. A prospective, randomized trial. *J Bone Joint Surg Am,* 87**,** 3-7.

GEATER, S., LEELAWATTANA, R. & GEATER, A. 2004. Validation of the OSTA index for discriminating between high and low probability of femoral neck and lumbar spine osteoporosis among Thai postmenopausal women. *J Med Assoc Thai,* 87**,** 1286-1292.

GEMALMAZ, A. & OGE, A. 2007. Knowledge and awareness about osteoporosis and its related factors among rural Turkish women. *Clinical Rheumatology,* 27**,** 723-728.

GEORGE, D. & MALLERY, P. 2003. *SPSS for Windows step by step: A simple guide and reference,* Boston, USA, Allyn and Bacon.

GEORGE, P. P., MOLINA, J. A. D., CHEAH, J., CHAN, S. C. & LIM, B. P. 2010. The evolving role of the community pharmacist in chronic disease management- A literature review. *Ann Acad Med Singapore,* 39**,** 861-867.

GEUSENS, P., HOCHBERG, M. C., VAN DER VOORT, D. J. M., POLS, H., VAN DER KLIFT, M., SIRIS, E., MELTON, M. E., TURPIN, J., BYRNES, C. & ROSS, P. D. 2002. Performance of Risk Indices for Identifying Low Bone Density in Postmenopausal Women. *Mayo Clin Proc,* 77**,** 629-637.

GIANGREGORIO, L., PAPAIOANNOU, A., CRANNEY, A., ZYTARUK, N. & ADACHI, J. D. 2006. Fragility Fractures and the Osteoporosis Care Gap: An International

Phenomenon. *Seminars in Arthritis and Rheumatism,* 35**,** 293-305.

GLASGOW, R. E., VOGT, T. M. & BOLES, S. M. 1999. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Publich Health,* 88**,** 1322-1327.

GOLD, D. T., HORNE, R., COON, C. D., PRICE, M. A., BORENSTEIN, J., VARON, S. F., SATRAM-HOANG, S. & MACARIOS, D. 2011. Development, reliability, and validity of a new Preference and Satisfaction Questionnaire. *Value Health,* 14**,** 1109-16.

GOODE, J. V. K., SWIGER, K. & BLUML, B. M. 2004. Regional osteoporosis screening, referral and monitoring program in community pharmacies: Findings from project imPACT: Osteoporosis. *Journal of the American Pharmacists Association,* 44**,** 152-160.

GORSUCH, R. L. 1983. *Factor analysis,* Hillsdale, NJ, Lawarence Erlbaum Associates.

GOURLAY, M. L., MILLER, W. C., RICHY, F., GARRETT, J. M., HANSON, L. C. & REGINSTER, J. Y. 2005. Performance of osteoporosis risk assessment tools in postmenopausal women aged 45-64 years. *Osteoporos Int,* 16**,** 921-7.

GOURLEY, G. A. & DUNCAN, D. V. 1998. Patient satisfaction and quality of life: Humanistic outcomes. *The American Journal of Managed Care,* 4**,** 746-755.

GREEN, L. W. & KREUTER, M. W. 1999. *Healt promotion planning: An educational and ecological apptroach,* Mountain View, CA, Mayfield.

GREENSPAN, S. L., WYMAN, A., HOOVEN, F. H., ADAMI, S., GEHLBACH, S., ANDERSON JR, F. A., BOONE, S., LACROIX, A. Z., LINDSAY, R., COEN NETELENBOS, J., PFEILSCHIFTER, J., SILVERMAN, S., SIRIS, E. S. & WATTS, N. B. 2012. Predictors of Treatment with Osteoporosis Medications After Recent Fragility Fractures in a Multinational Cohort of Postmenopausal Women. *J Am Geriatr Soc,* 60**,** 455-461.

GRIMES, D. A. & SCHULZ, K. F. 2002. Descriptive studies: what they can and cannot do. *The Lancet,* 359**,** 145-149.

GRODSTEIN, F., MANSON, J. E., STAMPFER, M. J. & REXRODE, K. 2008. Postmenopausal Hormone Therapy and Stroke. *Archives of Internal Medicine,* 168**,** 861-866.

GUTIN, B. & KASPER, M. J. 1992. Can vigorous exercise play a role in osteoporosis prevention? A review. *Osteoporos Int,* 2**,** 55-69.

GUZMAN-CLARK, J. R., FANG, M. A., SEHL, M. E., TRAYLOR, L. & HAHN, T. J. 2007. Barriers in the management of

glucocorticoid-induced osteoporosis. *Arthritis Rheum,* 57**,** 140-146.

HA, Y.-C., LEE, Y.-K., LIM, Y.-T., JANG, S.-M. & SHIN, C. S. 2014. Physicians' Attitudes to Contemporary Issues on Osteoporosis Management in Korea. *Journal of Bone Metabolism,* 21**,** 143.

HAGINO, H., KATAGIRI, H., OKANO, T., YAMAMOTO, K. & TESHIMA, R. 2005. Increasing incidence of hip fracture in Tottori Prefecture, Japan: trend from 1986 to 2001. *Osteoporos Int,* 16**,** 1963-8.

HAJCSAR, E. E., HAWKER, G. & BOGOCH, E. R. 2000. Investigation and treatment of osteoporosis in patients with fragility fractures. *CMAJ,* 16**,** 819-822.

HARDEMAN, W., SUTTON, S., GRIFFIN, S., JOHNSTON, M., WHITE, A., WAREHAM, N. J. & KINMONTH, A. L. 2005. A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. *Health Education Research,* 20**,** 676-687.

HARDY, G. E., WEST, M. A. & HILL, F. 1996. Components and predictors of patient satisfaction. *British Journal of Health Psychology,* 1**,** 65-85.

HARMAN, H. 1976. *Modern factor analysis,* Chicago, University of Chicago Press.

HARRINGTON, D. 2009. *Confirmatory factor analysis,* New York, USA, Oxford University Press, Inc.

HASKARD ZOLNIEREK, K. B. & DIMATTEO, M. R. 2009. Physician Communication and Patient Adherence to Treatment: A meta analysis. *Medical Care,* 47**,** 826-834.

HEILMANN, R. M. F., FRIESLEBEN, C. R. & BILLUPS, S. J. 2012. Impact of a pharmacist-directed intervention in postmenopausal women after fracture. *American Journal of Health-System Pharmacy,* 69**,** 504-509.

HENDERSON, V. W. & LOBO, R. A. 2012. Hormone therapy and the risk of stroke: perspectives 10 years after the Women's Health Initiative trials. *Climacteric,* 15**,** 229-234.

HEPLER, C. D. & STRAND, L. M. 1990. Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy,* 47**,** 533-542.

HERNLUND, E., SVEDBOM, A., IVERGÅRD, M., COMPSTON, J., COOPER, C., STENMARK, J., MCCLOSKEY, E. V., JÖNSSON, B. & KANIS, J. A. 2013. Osteoporosis in the European Union: medical management, epidemiology and economic burden. *Archives of Osteoporosis,* 8**,** 136.

HEYWORTH, L., KLEINMAN, K., ODDLEIFSON, S., BERNSTEIN, L., FRAMPTON, J., LEHRER, M., SALVATO, K., WEISS, T. W., SIMON, S. R. & CONNELLY, M. 2014. Comparison of

interactive voice response, patient mailing, and mailed registry to encourage screening for osteoporosis: a randomized controlled trial. *Osteoporosis International,* 25**,** 1519-1526.

HJALMARSON, H. V., AHGREN, B. & KJÖLSRUD, M. S. 2013. Developing interprofessional collaboration: A longitudinal case of secondary prevention for patients with osteoporosis. *Journal of Interprofessional Care,* 27**,** 161-170.

HOLICK, M. F. 2004. Sunlight and vitamin D for bone health and prevention of autoimmune diseases, cancers, and cardiovascular disease. *Am J Clin Nutr,* 80**,** Suppl 1, 1678-1688S.

HOSKING, D., CHILVERS, C., CHRISTIANSEN, C., RAVN, P., WASNICH, R., ROSS, P., MCCLUNG, M., BALSKE, A., THOMPSON, D., DALEY, M. & YATES, J. 1994. Prevention of bone loss with alendronate in postmenopausal women under 60 years of age. *The New England Journal of Medicine,* 338**,** 485-492.

HOUILLIER, P., FROISSART, M., MARUANI, G. & BLANCHARD, A. 2006. What serum calcium can tell us and what it can't. *Nephrology Dialysis Transplantation,* 21**,** 29-32.

HUNTJENS, K. M. B., VAN GEEL, T. A. C. M., BLONK, M. C., HEGEMAN, J. H., VAN DER ELST, M., WILLEMS, P., GEUSENS, P. P., WINKENS, B., BRINK, P. & VAN HELDEN, S. H. 2010. Implementation of osteoporosis guidelines: a survey of five large fracture liaison services in the Netherlands. *Osteoporosis International,* 22**,** 2129-2135.

ICKS, A., HAASTERT, B., WILDNER, M., BECKER, C. & MEYER, G. 2008. Trend of hip fracture incidence in Germany 1995–2004: a population-based study. *Osteoporosis International,* 19**,** 1139-1145.

INDERJEETH, C. A., GLENNAN, D. A., POLAND, K. E., INGRAM, K. V., PRINCE, R. L., VAN, V. R. & HOLMAN, C. D. J. 2010. A multimodal intervention to imrpove fragility fracture management in patietns presenting to emergency departments. *Med J Aust,* 193**,** 149-153.

INSTITUTE FOR GOVERNEMENT 2010. MINDSPACE: Influencing behaviour through public policy. *In:* OFFICE, T. C. (ed.).

INTERNATIONAL OSTEOPOROSIS FOUNDATION 2006. Preventing osteoporosis. *Women's Health Medicine,* 3**,** 155-156.

INTERNATIONAL OSTEOPOROSIS FOUNDATION 2009. The Asian Audit: Epidemiology, cost and burden of osteoporosis in Asia 2009.

INTERNATIONAL OSTEOPOROSIS FOUNDATION. 2012a. *Capture the Fracture: A global campaign to break the fragility fracture cycle* [Online]. Available: http://www.worldosteoporosisday.org/ [Accessed 26 February 2015].

INTERNATIONAL OSTEOPOROSIS FOUNDATION. 2012b. *Capture the Fracture: break the worlwide fragility fracture cycle* [Online]. Available: http://www.osteofound.org/capture-fracture [Accessed 27 December 2015].

JACKSON, R. D., LACROIX, A. L., GASS, M., WALLACE, R. B., ROBBINS, J., LEWIS, C. E., BASSFORD, T., BERESFORD, S. A. A., BLACK, H. R., BLANCHETTE, P., BONDS, D. E., BRUNNER, R. L., BRZYSKI, R. G., CAAN, B., CAULEY, J. A., CHLEBOWSKI, R. T., CUMMINGS, S. R., GRANEK, I., HAYS, J., HEISS, G., HENDRIX, S. L., HOWARD, B. V., HSIA, J., HUBBELL, F. A., JOHNSON, K. C., JUDD, H., KOTCHEN, J. M., KULLER, L. H., LANGER, R. D., LASSER, N. L., LIMACHER, M. C., LUDLAM, S., MANSON, E. M., MARGOLIS, K. L., MCGOWAN, J., OCKENE, J. K., O'SULLIVAN, M. J., PHILLIPS, L., PRENTICE, R. L., SARTO, G. E., STEFANICK, M. L., VAN HORN, L., WACTAWSKI-WENDE, J., WHITLOCK, E., ANDERSON, G. L., ASSAF, A. R. & WOMEN'S HEALTH INITIATIVE INVESTIGATORS 2006. Calcium plus Vitamin D Supplementation and the Risk of Fractures. *The New England Journal of Medicine,* 354**,** 669-683.

JAGLAL, S. B., CAROLL, J., HAWKER, G., MCISAAC, W. J., JAAKKIMAINEN, L., CADARETTE, S. M., CAMERON, C. & DAVIS, D. 2003. How are family physicians managing osteoporosis? Qualitative study of thier experiences and educational neeeds. *Canadian Fam Physician,* 49**,** 462-468.

JAGLAL, S. B., DONESCU, O. S., BANSOD, V., LAPRADE, J., THORPE, K., HAWKER, G., MAJUMDAR, S. R., MEADOWS, L., CADARETTE, S. M., PAPAIOANNOU, A., KLOSECK, M., BEATON, D., BOGOCH, E. & ZWARENSTEIN, M. 2012. Impact of a centralized osteoporosis coordinator on post-fracture osteoporosis management: a cluster randomized trial. *Osteoporosis International,* 23**,** 87-95.

JALILI, Z., NAKHAEE, N., ASKURI, R. & SHARIFI, V. 2007. Knowledge, attitude and preventive practice of women concerning osteoporosis. *Iranian J Public Health,* 36**,** 19-24.

JENSEN, A. L., LOMBORG, K., WIND, G. & LANGDAHL, B. L. 2013. Effectiveness and characteristics of multifaceted

osteoporosis group education—a systematic review. *Osteoporosis International,* 25**,** 1209-1224.

JITAPUNKUL, S., THAMARPIRAT, J., CHAIWANICHSIRI, D. & BOONHONG, J. 2008. Incidence of vertebral fractures in Thai women and men: a prospective population-based study. *Geriatr Gerontol Int,* 8**,** 251-8.

JOHNELL, O. 1997. The socioeconomic burden of fractures:today and in the 21st century. *AM J Med,* 103**,** 20s-25s.

JOHNELL, O. & KANIS, J. A. 2006. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporosis International,* 17**,** 1726-1733.

JOHNELL, O., KANIS, J. A., ODEN, A., JOHANSSON, H., DE LAET, C., DELMAS, P., EISMAN, J. A., FUJIWARA, S., KROGER, H., MELLSTROM, D., MEUNIER, P. J., MELTON, L. J., O'NEILL, T., POLS, H., REEVE, J., SILMAN, A. & TENENHOUSE, A. 2005. Predictive Value of BMD for Hip and Other Fractures. *Journal of Bone and Mineral Research,* 20**,** 1185-1194.

JOHNELL, O., KANIS, J. A., ODÉN, A., SERNBO, I., REDLUND-JOHNELL, I., PETTERSON, C., DE LAET, C. & JÖNSSON, B. 2004. Mortality after osteoporotic fractures. *Osteoporosis International,* 15**,** 38-42.

JOHNSON, J. A., COONS, S. J., HAYS, R. D., SABERS, D., JONES, P. & LANGLEY, P. C. 1997. A comparison of satisfaction with mail versus traditional pharmacy services. *Journal of managed care pharmacy,* 3**,** 327-337.

JORGENSON, D., LAMB, D. & MACKINNON, N. J. 2011. Practice change challenges and priorities: a national survey of practising pharmacists. *Can Pharm J,* 144**,** 125-131.

KAISER, H. F. 1960. The application of electronic computers to factor analysis. *Educational and Psychological Measurement,* 20**,** 141-151.

KANIS, J. A. 2007. WHO Scientific Group Technical Report. 66.

KANIS, J. A. 2014. *FRAX WHO Fracture Risk Assessment Tool* [Online]. World Health Organization Collaborating Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available: http://www.shef.ac.uk/FRAX/ [Accessed 22 December 2014].

KANIS, J. A., JOHANSSON, H., JOHNELL, O., ODEN, A., DE LAET, C., EISMAN, J. A., POLS, H. & TENENHOUSE, A. 2004a. Alcohol intake as a risk factor for fracture. *Osteoporosis International,* 16**,** 737-742.

KANIS, J. A., JOHNELL, O., DE LAET, C., JOHANSSON, H., ODEN, A., DELMAS, P., EISMAN, J., FUJIWARA, S., GARNERO, P., KROGER, H., MCCLOSKEY, E. V., MELLSTROM, D., MELTON, L. J., POLS, H., REEVE, J., SILMAN, A. & TENENHOUSE, A. 2004b. A meta-analysis of previous fracture and subsequent fracture risk. *Bone,* 35**,** 375-382.

KARKKAINEN, M. U. M., LAMBERG-ALLARDT, C. J. E., AHONEN, S. & VALIMAKI, M. 2001. Does it make a difference how and when you take your calcium? The acute effects of calcium on calcium and bone metabolism. *Am J Clin Nutr,* 74**,** 335-342.

KASPER, M. J., PETERSON, M. G. & ALLEGRANTE, J. P. 1994. Knowledge, beliefs, and behaviours among college women concerning the prevention of osteoporosis. *Arch Fam Med,* 3**,** 696-702.

KAUFFMAN, T. L., BARR, J. O. & MORAN, M. L. 2007. *Geriatric rehabilitation manual,* Philadelphia, USA, Elsevier Ltd.

KHAN, Y. H., SARRIFF, A., KHAN, A. M. & MALLHI, T. H. 2014. Knowledge, attitude and practice (KAP) survey of osteoporosis among students of a tertiary institution in Malaysia. *Tropical Journal of Pharmaceutical Research,* 13**,** 155-162.

KIM, J. O. & MUELLER, C. W. 1978. *Factor analysis: statistical methods and practical issues,* California, USA, Sage.

KIM, K., HORAN, M. & GENDLER, P. 1991. *Osteoporosis knowledge tests, osteoporosis health belief scale, and osteoporosis self- efficacy scale,* Allendale, MI: Grand Valley State University.

KIM, S.-R., HA, Y.-C., PARK, Y.-G., LEE, S.-R. & KOO, K.-H. 2011. Orthopedic Surgeon's Awareness Can Improve Osteoporosis Treatment Following Hip Fracture: A Prospective Cohort Study. *Journal of Korean Medical Science,* 26**,** 1501.

KITAZAWA, A., KUSHIDA, K., YAMAZAKI, K. & T., I. 2001. Prevalence of vertebral fractures in a population-based sample in Japan. *J Bone Miner Metab,* 19**,** 115-118.

KODA-KIMBLE, M. A., YOUNG, L. E., ALLDREDGE, B. K., CORELLI, R. L., KRADJAN, W. A. & WILLIAMS, B. R. 2009. *Applied therapeutics: The clinical use of drugs,* Baltimore, Lippincott Williams and Wilkins.

KOH, L. K. H. 2007. Osteoporosis in Asian populations. *Menopause Medicine,* 15**,** S10-S14.

KOH, L. K. H., SAW, S.-M., LEE, J. J. M., LEONG, K.-H. & LEE, J. 2001a. Hip fracture incidence rates in Singapore 1991-1998. *Osteoporos Int,* 12**,** 311-318.

KOH, L. K. H., SEDRINE, W. B., TORRALBA, T. P., KUNG, A. W., FUJIWARA, S., CHAN, S. P., HUANG, Q. R., RAJATANAVIN, R., TSAI, K. S., PARK, H. M. & REGINSTER, J. Y. 2001b. A simple tool to identify Asian women at increased risk of osteoporosis. *Osteoporos Int,* 12**,** 699-705.

KRASS, I., DELANEY, C., GLAUBITZ, S. & KANJANARACH, T. 2009. Measuring patient satisfaction with diabetes disease state management services in community pharmacy. *Res Social Adm Pharm,* 5**,** 31-9.

KUNG, A. W., HO, A. Y., SEDRINE, W. B., REGINSTER, J. Y. & ROSS, P. D. 2003. Comparison of a simple clinical risk index and quantitative bone ultrasound for identifying women at increased risk of osteoporosis. *Osteoporos Int,* 14**,** 716-21.

LAI, P. S., CHUA, S. S., CHAN, S. P. & LOW, W. Y. 2008. The validity and reliability of the Malaysian Osteoporosis Knowledge Tool in postmenopausal women. *Maturitas,* 60**,** 122-30.

LAI, P. S., CHUA, S. S., CHAN, S. P., LOW, W. Y. & WONG, I. C. 2010. Development and validation of the osteoporosis patient satisfaction questionnaire (OPSQ). *Maturitas,* 65**,** 55-63.

LAI, P. S. M. 2013. Validating instruments of measure-is it really necessary? *Malaysian Family Physicians,* 8**,** 2-4.

LAI, P. S. M., CHUA, S. S. & CHAN, S. P. 2013. Impact of pharmaceutical care on knowledge, quality of life and satisfaction of postmenopausal women with osteoporosis. *International Journal of Clinical Pharmacy,* 35**,** 629-637.

LAKSHMAN, R., GRIFFIN, S., HARDEMAN, W., SCHIFF, A., KINMONTH, A. L. & ONG, K. K. 2014. Using the Medical Research Council Framework for the Development and Evaluation of Complex Interventions in a Theory-Based Infant Feeding Intervention to Prevent Childhood Obesity: The Baby Milk Intervention and Trial. *Journal of Obesity,* 2014**,** 1-10.

LALIBERTÉ, M.-C., PERREAULT, S., DAMESTOY, N. & LALONDE, L. 2012. Ideal and actual involvement of community pharmacists in health promotion and prevention: a cross-sectional study in Quebec, Canada. *BMC Public Health,* 12**,** 192.

LALIBERTÉ, M. C., PERREAULT, S., DAMESTOY, N. & LALONDE, L. 2013. The role of community pharmacists in the prevention and management of osteoporosis and the risk of falls: results of a cross-sectional study and

qualitative interviews. *Osteoporosis International,* 24**,** 1803-1815.

LALIBERTÉ, M. C., PERREAULT, S., JOUINI, G., SHEA, B. J. & LALONDE, L. 2011. Effectiveness of interventions to improve the detection and treatment of osteoporosis in primary care settings: a systematic review and meta-analysis. *Osteoporosis International,* 22**,** 2743-2768.

LANCASTER, G. A., DODD, S. & WILLIAMSON, P. R. 2004. Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation in Clinical Practice,* 10**,** 307-312.

LAU, E., PAPAIOANNOU, A., DOLOVICH, L., ADACHI, J., SAWKA, A. M., BURNS, S., NAIR, K. & PATHAK, A. 2008. Patients' adherence to osteoporosis therapy: Exploring the perceptions of postmenopausal women. *Can Fam Physician,* 54**,** 394-402.

LAW, A. V. & SHAPIRO, K. 2004. Impact of a community pharmacist-directed clinic in improving screening and awareness of osteoporosis. *Journal of Evaluation in Clinical Practice,* 11**,** 247-255.

LESLIE, W. D., GIANGREGORIO, L. M., YOGENDRAN, M., AZIMAEE, M., MORIN, S., METGE, C., CAETANO, P. & LIX, L. M. 2011. A population-based analysis of the post-fracture care gap 1996–2008: the situation is not improving. *Osteoporosis International,* 23**,** 1623-1629.

LESLIE, W. D., O'DONNELL, S., LAGACÉ, C., WALSH, P., BANCEJ, C., JEAN, S., SIMINOSKI, K., KAISER, S., KENDLER, D. L. & JAGLAL, S. 2010. Population-based Canadian hip fracture rates with international comparisons. *Osteoporosis International,* 21**,** 1317-1322.

LI-YU, J. T., LLAMADO, L. J. & TORRALBA, T. P. 2005. Validation of OSTA among Filipinos. *Osteoporos Int,* 16**,** 1789-93.

LI, Y.-M. 2008. Concordance of a Self Assessment Tool and Measurement of Bone Mineral Density in Identifying the Risk of Osteoporosis in Elderly Taiwanese Women. *Tzu Chi Medical Journal,* 20**,** 206-212.

LIH, A., NANDAPALAN, H., KIM, M., YAP, C., LEE, P., GANDA, K. & SEIBEL, M. J. 2011. Targeted intervention reduces refracture rates in patients with incident non-vertebral osteoporotic fractures: a 4-year prospective controlled study. *Osteoporosis International,* 22**,** 849-858.

LIM, P. C. & LIM, K. 2010. Evaluation of pharmacist-managed diabetes medication therapy adherence clinic. *Pharmacy Practice,* 8**,** 250-254.

LIM, P. S., ONG, F. B., ADEEB, N., SERI, S. S., NOOR-AINI, M. Y., SHAMSUDDIN, K., HAPIZAH, N., MOHAMED, A. L., MOKHTAR, A. & WAN, H. W. 2005. Bone health in urban midlife Malaysian women: risk factors and prevention. *Osteoporos Int,* 16**,** 2069-79.

LIM, P. S., ONG, F. B., SUNIZA, S. S. & ADEEB, N. 2011. Developing a Malaysian Osteoporosis Screening Tool (MOST) for early osteoporosis detection in Malaysian women. *Sexual & Reproductive Healthcare,* 2**,** 77-82.

LIM, S., KOO, B. K., LEE, E. J., PARK, J. H., KIM, M. H., SHIN, K. H., HA, Y. C., CHO, N. H. & SHIN, C. S. 2008. Incidence of hip fractures in Korea. *J Bone Miner Metab,* 26**,** 400-5.

LIN, Y.-C. & PAN, W.-H. 2011. Bone mineral density in adults in Taiwan: results of the Nutrition and Health Survey in Taiwan 2005-2008 (NAHSIT-2005-2008). *Asia Pac J Clin Nur,* 20**,** 283-291.

LITTLE, E. A. & ECCLES, M. P. 2010. A systematic review of the effectiveness of interventions to improve post-fracture investigation and management of patients at risk of osteoporosis. *Implement Sci,* 5**,** 80.

LIU, Y., NEVINS, J. C., CARRUTHERS, K. M., DOUCETTE, W. R., MCDONOUGH, R. P. & PAN, X. 2007. Osteoporosis risk screening for women in a community pharmacy. *J Am Pharm Assoc (2003),* 47**,** 521-6.

LIZA, H., DARAT, H. N. & PANDE, K. C. 2009. Knowledge about osteoporosis in Bruneian women attending an orthopaedic clinic. *Malaysian Orthopaedic Journal,* 3**,** 28-30.

LOCKER, D. & DUNT, D. 1978. Theoratical and methodological issues in sociological studies of consumer satisfaction with medical care. *Soc Sci Med,* 12**,** 283-292.

LORISH, C. D., PARKER, J. & BROWN, S. 1985. Effective patient education. *Arthritis Rheum,* 28**,** 1289-1297.

LUNDY, K. S. & JANES, S. 2009. *Community health nursing: Caring for the public's health,* Sudbury, USA, Jones and Bartless Publisher.

LUO, L. & XU, L. 2005. Analysis of direct economic burden of osteoporotic hip fracture and its influence factors. *Chinese Journal of Epidemiology,* 9.

LYDICK, E., COOK, K., TURPIN, J., MELTON, M., STINE, R. & BYRNES, C. 1998. Development and validation of simple questionnaire to facilitate identification of women likely to have low bone density. *The American Journal of Managed Care,* 4**,** 37-48.

MACHADO, M., BAJCAR, J., GUZZO, G. C. & EINARSON, T. R. 2007a. Sensitivity of Patient Outcomes to Pharmacist

Interventions. Part I: Systematic Review and Meta-Analysis in Diabetes Management. *Annals of Pharmacotherapy,* 41**,** 1569-1582.

MACHADO, M., BAJCAR, J., GUZZO, G. C. & EINARSON, T. R. 2007b. Sensitivity of Patient Outcomes to Pharmacist Interventions. Part II: Systematic Review and Meta-Analysis in Hypertension Management. *Annals of Pharmacotherapy,* 41**,** 1770-1781.

MACLAUGHLIN, E. J., MACLAUGHLIN, A. A., SNELLA, K. A., WINSTON, T. S., FIKE, D. S. & RAEHL, C. R. 2005. Osteoporosis screening and education in community pharmacies using a team approach. *Pharmacotherapy,* 25**,** 379-386.

MAFAUZY, M. 2000. The problems and challenges of the aging population of malaysia. *Malaysian Journal of Medical Sciences,* 7**,** 1-3.

MAGNUS, J. H., JOAKIMSEN, R. M., BERNTSEN, G. K., TOLLAN, A. & SOOGAARD, A. J. 1996. What do Norwegian women and men know about osteoporosis? *Osteoporos Int,* 6**,** 32-36.

MAJUMDAR, S. R., BEAUPRE, L. A., HARLEY, C. H., HANLEY, D. A., LIER, D. A., JUBY, A. G., MAKSYMOWYCH, W. P., CINATS, J. G., BELL, N. R. & MORRISH, D. W. 2007. Use of a case manager to improve osteoporosis treatment after hip fracture. *Arch Intern Med,* 167**,** 2110-2115.

MAJUMDAR, S. R., JOHNSON, J. A., MCALISTER, F. A., BELLEROSE, D., RUSSELL, A. S., HANLEY, D. A., MORRISH, D. W., MAKSYMOWYCH, W. P. & ROWE, B. H. 2008. Multifaceted intervention to improve diagnosis and treatment of osteoporosis in patients with recent wrist fracture: a randomized controlled trial. *CMAJ,* 178**,** 569-75.

MARSHALL, D., JOHNELL, O. & WEDEL, H. 1997. Meta-analysis of how well measures of bone mineral density predict occurence of osteoporotic fractures. *BMJ,* 312**,** 1254-1259.

MAYS, N. & POPE, C. 2000. Qualitative research in health care: Assessing quality in qualitative research. *BMJ,* 320**,** 50-52.

MCCLOSKEY, E. 2009. FRAX Identifying people at high risk of fracture. Nyon, Switzerland: International Osteoporosis Foundation.

MCCLUNG, M. R., WASNICH, R. D., RECKER, R., CAULEY, J. A., CHESNUT, C. H., ENSRUD, K. E., BURDESKA, A. & MILLS, T. 2003. Oral Daily Ibandronate Prevents Bone Loss in Early Postmenopausal Women Without

Osteoporosis. *Journal of Bone and Mineral Research,* 19**,** 11-18.

MCCONAHA, J. L., BERDINE, H. J., SKOMO, M. L., LAUX, R. V., HIGGINBOTHAM, S. K. & O'NEIL, C. K. 2014. Impact of the Fracture Risk Assessment on Patient and Physician Behavior in Osteoporosis Prevention. *Journal of Pharmacy Practice,* 27**,** 25-30.

MCDONOUGH, R. P., DOUCETTE, W. R., KUMBERA, P. & KLEPSER, D. G. 2005. An evaluation of managing and educating patients on the risk of glucocorticoid-induced osteoporosis. *Value Health,* 8**,** 24-31.

MCDOWELL, I. 2006. *Measuring health: A guide to rating scales and questionnaires,* New York, USA, Oxford University Press.

MCGIVNEY, M. S., MEYER, S. M., DUNCAN-HEWITT, W., HALL, D. L., GOODE, J. V. K. & SMITH, R. B. 2007. Medication therapy management: Its relationship to patient counseling, disease management, and pharmaceutical care. *Journal of the American Pharmacists Association,* 47**,** 620-628.

MCLELLAN, A. R., GALLACHER, S. J., FRASER, M. & MCQUILLIAN, C. 2003. The fracture liaison service: success of a program for the evaluation and management of patients with osteoporotic fracture. *Osteoporosis International,* 14**,** 1028-1034.

MCLELLAN, A. R., WOLOWAVZ, S. E., ZIMOVETZ, E. A., BEARD, M. K., LOCK, S., MCCRINK, L., ADEKUNIE, F. & ROBERTS, D. 2011. Fracture liaison services for the evaluation and management of patients with osteoporotic fracture: a cost-effective evaluation based on data collected over 8 years of service provision. *Osteoporos Int,* 22**,** 2083-2098.

MEADOWS, L. M., MRKONJIC, L. A., O'BRIEN, M. D. & TINK, W. 2007. The importance of communication in secondary fragility fracture treatment and prevention. *Osteoporos Int,* 18**,** 159-166.

MEDICAL RESEARCH COUNCIL 2000. A Framework for development and evaluation of RCTs for complex interventions to improve health.

MEDICAL RESEARCH COUNCIL 2008. Developing and evaluating complex interventions- New guidance.

MEETA 2013. *Postmenopausal osteoporosis: Basic and clinical concepts,* Haryana, India, Jaypee Brother Medical Publisher.

MELTON, L. J. R., THERNEAU, T. M. & LARSON, D. R. 1998. Long-term trends in hip fracture prevalence: The

influence of hip fracture incidence and survival. *Osteoporos Int,* 8**,** 68-74.

MEUNIER, P. J., ROUX, C., SEEMAN, E., ORTOLANI, S., BADURSKI, J. E., SPECTOR, T. D., CANNATA, J., BALOGH, A., LEMMEL, E.-M., PORS-NIELSEN, S., RIZZOLI, R., GENANT, H. K. & REGINSTER, J.-Y. 2004. The Effects of Strontium Ranelate on the Risk of Vertebral Fracture in Women with Postmenopausal Osteoporosis. *New England Journal of Medicine,* 350**,** 459-468.

MICHAËLSSON, K., BERGSTRÖM, R., MALLMIN, H., HOLMBERG, L., WOLK, A. & LJUNGHALL, S. 1996. Screening for osteopenia and osteoporosis: Selection by body composition. *Osteoporos Int,* 6**,** 120-126.

MICHIE, S., FIXSEN, D., GRIMSHAW, J. M. & ECCLES, M. P. 2009. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implementation Science,* 4**,** 40.

MICHIE, S., RICHARDSON, M., JOHNSTON, M., ABRAHAM, C., FRANCIS, J., HARDEMAN, W., ECCLES, M. P., CANE, J. & WOOD, C. E. 2013. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. *Annals of Behavioral Medicine,* 46**,** 81-95.

MICHIE, S., VAN STRALEN, M. M. & WEST, R. 2011. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science,* 6**,** 42.

MIKI, R. A., OETGEN, M. E., KIRK, J., INSOGNA, K. L. & LINDSKOG, D. M. 2008. Orthopaedic management improves the rate of early osteoporosis treatment after hip fracture. A randomized clinical trial. *J Bone Joint Surg Am,* 90**,** 2346-53.

MILES, M. B. & HUBERMAN, A. M. 1994. *Qualitative data: An expanded sourcebook,* Thousang Oaks, California, Sage Publications.

MILSOM, S., LEUNG, W., TWIGDEN, V., MITCHELL, P., NOWITZ, M. & CORNISH, J. 2013. Does insufficient access to dual-energy X-ray absorptiometry (DXA) stifle the provision of quality osteoporosis care in New Zealand? *Archives of Osteoporosis,* 8.

MINISTRY OF HEALTH MALAYSIA 2012. Clinical Guideline on Management of Osteoporosis 2012. *In:* HEALTH, M. O. (ed.). Putrajaya: Malaysian Osteoporosis Society.

MITRA, A. K., LOW, C. K., CHAO, A. K. & TAN, S. K. 1994. Social aspects in patients following proximal femoral fractures. *Ann Acad Med Singapore,* 23**,** 876-878.

MOAYYERI, A., ADAMS, J. E., ADLER, R. A., KRIEG, M. A., HANS, D., COMPSTON, J. & LEWIECKI, E. M. 2012. Quantitative ultrasound of the heel and fracture risk assessment: an updated meta-analysis. *Osteoporosis International,* 23**,** 143-153.

MOHY TAHA, M. D. 2011. *Prevalence of osteoporosis in Middle East systemic literature review* [Online]. 10th ECOO. Available: http://www.scribd.com/doc/53103901/Osteopoorosis-Cairo-April-2011-v1 [Accessed 20 February 2015].

MONIZ, C. 1994. Alcohol and bone. *British Medical Bulletin,* 50**,** 67-75.

MORRISON, N. A., QI, J. C., TOKITA, A., KELLY, P. J., CROFTS, L., NGUYEN, T. V., SAMBROOK, P. N. & EISMAN, J. A. 1994. Prediction of bone density from vitamin D receptor alleles. *Nature,* 367**,** 284-287.

MORTENSEN, L., CHARLES, P., BEKKER, P. J., DIGENNARO, J. & JOHNSTON, C. C. 1998. Risendronate increases bone mass in an early postmenopausal population: Two years of treatment plus one year of follow up. *Journal of Clinical Endocrinology and Metabolism,* 83**,** 396-402.

MUDANO, A. S., LISA, C. G., OLIVEIRA, A., MARY, M., WRIGHT, N. C., CURTIS, J., DELZELL, E., HARRINGTON, T. M., MEREDITH, L. K., CORA ELIZABETH, L., JASVINDER, A. S., WARRINER, WILSON, P. & SAAG, K. 2013. Using tablet computers compared to interactive voice response to improve subject recruitment in osteoporosis pragmatic clinical trials: feasibility, satisfaction, and sample size. *Patient Preference and Adherence,* 7**,** 517-523.

MUNDFORM, D. J., SHAW, D. G. & K., T. L. 2005. Minimum sample size recommendations for conductiong factor analysis. *International Journal of Testing,* 5**,** 159.

MURPHY, E., DINGWALL, R., GREATBATCH, D., PARKER, S. & WATSON, P. 1998. Qualitative research methods in health technology assessment: a review of the literature. *Health Technology Assessment,* 2.

MUSLIM, D. A. J., MOHD, E. F., SALLEHUDIN, A. Y., TENGKU MUZAFFAR, T. M. S. & EZANE, A. M. 2012. Performance of osteoporosis self-assessment tool for Asian (OSTA) for primary osteoporosis in post-menopausal Malay women. *Malaysian Orthopaedic Journal,* 6**,** 35-39.

NATIONAL COMMITTEE FOR QUALITY ASSURANCE. 2014. *HEDIS & Performance Measurement. Proposed Changes to Existing Measure for HEDIS®1 2015: Osteoporosis Management in Women Who Had a Fracture (OMW)* [Online]. Washington, USA. Available: www.ncqa.org/HEDISQualityMeasurement.aspx [Accessed 25 February 2015].

NATIONAL COMMITTEE FOR QUALITY ASSURANCE (NCQA). 2004. *HEDIS* [Online]. Available: http://www.ncqa.org/Portals/0/HEDISQM/Archives/2004/ [Accessed 14 March 2015].

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE 2012. Osteoporosis: assessing the risk of fragility fracture. . *In:* 146, N. C. G. (ed.). London, UK: NICE.

NATIONAL INSTITUTE FOR HEALTH RESEARCH. 2012. *NIHR Evaluation, trials and studies coordination centre: Glossry* [Online]. Available: www.netscc.ac.uk/glossary/#glos6/ [Accessed 28 December 2014].

NATIONAL OSTEOPOROSIS FOUNDATION. *Having a bone density test* [Online]. Washington, USA: National Osteoporosis Foundation,. Available: http://nof.org/articles/743 [Accessed 25 February 2015].

NATIONAL OSTEOPOROSIS FOUNDATION 2010. Clinician's Guide to Treatment and Prevention of Osteoporosis. Washington, USA.

NATIONAL OSTEOPOROSIS FOUNDATION. 2014. *54 million Americans affected by osteoporosis and low bone mass* [Online]. Washington, USA: The National Osteoporosis Foundation. Available: http://nof.org/news/2948 [Accessed 20 February 2015].

NATIONAL OSTEOPOROSIS SOCIETY 2001. Position statement on the use of quantitative ultrasound in the management os osteoporosis.

NEELEMAAT, F., LIPS, P., BOSMANS, J. E., THIJS, A., SEIDELL, J. C. & VAN BOKHORST-DE VAN DER SCHUEREN, M. A. E. 2012. Short-Term Oral Nutritional Intervention with Protein and Vitamin D Decreases Falls in Malnourished Older Adults. *J Am Geriatr Soc,* 60**,** 691-699.

NEER, R. M., ARNAUD, C. D., ZANCHETTA, J. R., PRINCE, R., GAICH, G. A., REGINSTER, J. Y., HODSMAN, A. B., ERIKSEN, E. F., ISH-SHALOM, S., GENANT, H. K., WANG, O. & MITLAK, B. H. 2001. Effects of parathyroid hormone (1-34) on fractures and bone mineral density

in postmenopausal women with osteoporosis. *New England Journal of Medicine,* 344**,** 1434-1441.

NGUYEN, T. V., SAMBROOK, P. N. & EISMAN, J. 1998. Bone loss, physical activity and weight change in elderly women: the Dubbo osteoporosis epidemiology study. *J Bone Miner Res,* 13**,** 1458-1467.

NIELSEN, D., RYG, J., NISSEN, N., NIELSEN, W., KNOLD, B. & BRIXEN, K. 2008. Multidisciplinary patient education in groups increases knowledge on osteoporosis: a randomized controlled trial. *Scand J Public Health,* 36**,** 346-52.

NIH CONSENSUS DEVELOPMENT PANEL ON OSTEOPOROSIS PREVENTION, D., AND THERAPY 2001. Osteoporosis prevention, diagnosis, and therapy. *The journal of the American Medical Association,* 285**,** 785-795.

NKANSAH, N., MOSTOVETSKY, O., YU, C., CHHENG, T., BENEY, J., BOND, C. M. & BERO, L. 2010. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. *Cochrane Database Systematic Review,* 7.

NORDYKE, R. J., CHANG, C.-H., CHIOU, C.-F., WALLACE, J. F., YAO, B. & SCHWARTZBERG, L. S. 2006. Validation of a patient satisfaction questionnaire for anemia treatment, the PSQ-An. *Health Qual Life Outcomes,* 4**,** 28.

NUTRITION., N. C. C. O. F. A. 2005. Recommended nutrient intakes for Malaysia. Malaysia: Ministry of Health.

O' LOUGHLIN, J., MASSON, P., DERY, V. & FAGNAN, D. 1999. The role of community pharmacists in health education and disease prevention: A survey of thier intersts and needs in relation to cardiovascular disease. *Preventinve Medicine,* 28**,** 324-331.

ORIMO, H., SHIRAKI, M., HAYASHI, Y., HOSHINO, T., ONAYA, T., MIYAZAKI, S., KUROSAWA, H., NAKAMURA, T. & OGAWA, N. 1994. Effects of 1 alpha-hydroxyvitamin D3 on lumbar bone mineral density and vertebral fractures in patients with postmenopausal osteoporosis. *Calcif Tissue Int,* 54**,** 370-376.

OTMAR, R., REVENTLOW, S. D., NICHOLSON, G. C., KOTOWICZ, M. A. & PASCO, J. A. 2012. General medical practitioners' knowledge and beliefs about osteoporosis and its investigation and management. *Archives of Osteoporosis,* 7**,** 107-114.

PADDOCK, L. E., VELOSKI, J., CHATTERTON, M. L., GEVIRTZ, F. O. & NASH, D. B. 2000. Development and validation of a questionnaire to evaluate patient satisfaction with diabetes disease management. *Diabetes Care,* 23**,** 951-956.

PALLANT, J. 2011. *SPSS survival manual: A step by step guide to data analysis using SPSS,* New South Wales, Australia, Allen and Unwin.

PANDE, K. C., TAKATS, D., KANIS, J. A., EDWARDS, V., SLADE, P. & MCCLOSKEY, E. V. 2000. Development of a questionnaire (OPQ) to assess patient's knowledge about osteoporosis. *Maturitas,* 237**,** 75-81.

PAPA, L. J. & WEBER, B. E. 1997. Physician characteristics associated with the use of bone densitometry. *J Gen Intern Med,* 12**,** 781-783.

PAPAIOANNOU, A., MORIN, S., CHEUNG, A. M., ATKINSON, S., BROWN, J. P., FELDMAN, S., HANLEY, D. A., HODSMAN, A., JAMAL, S. A., KAISER, S. M., KVERN, B., SIMINOSKI, K. & LESLIE, W. D. 2010. 2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada: summary. *Canadian Medical Association Journal,* 182**,** 1864-1873.

PARK, H. J., PARK, K. H., PARK, G. M., PAEK, Y. J. & CHO, J. J. 2003. Evaluation of simple tool as a screening test for osteoporosis and osteopenia in Korean postmenopausal women. *J Korean Acad Fam Med,* 24**,** 702-708.

PASCOE, G. C. 1983. Patient satisfaction in primary health care: A literature review and analysis. *Evaluation and Program Planning,* 6**,** 185-210.

PEAT, J. 2001. *Health science research: A handbook of quantitative methods,* Sydney, Allen and Unwin.

PELLEGRINO, A. N., MARTIN, M. T., TILTON, J. J. & TOUCHETTE, D. R. 2009. Medication therapy management services: definitions and outcomes. *Drugs,* 69**,** 393-406.

PENCILLE, L. J., CAMPBELL, M. E., VAN HOUTEN, H. K., SHAH, N. D., MULLAN, R. J., SWIGLO, B. A., BRESLIN, M., KESMAN, R. L., TULLEDGE-SCHEITEL, S. M., JAEGER, T. M., JOHNSON, R. E., BARTEL, G. A., WERMERS, R. A., MELTON, L. J. & MONTORI, V. M. 2009. Protocol for the Osteoporosis Choice trial. A pilot randomized trial of a decision aid in primary care practice. *Trials,* 10**,** 113.

POUWER, F. & SNOEK, F. J. 2002. Patients evaluation of the quality of diactes care (PEQD): development and validation of a new instrument. *Qual Saf Health Care,* 11**,** 131-136.

PREMAOR, M. O., PILBROW, L., TONKIN, C., ADAMS, M., PARKER, R. A. & COMPSTON, J. 2009. Low rates of treatment in postmenopausal women with a history of low trauma fractures: results of audit in a Fracture Liaison Service. *Qjm,* 103**,** 33-40.

READER, T. W. & GILLESPIE, A. 2013. Patient neglect in healthcare institutions: a systematic review and conceptual model. *BMC Health Services Research,* 13**,** 156.

REID, D. M. 2011. *Osteoporosis,* London, UK, Springer Healthcare.

RICHY, F., ETHGEN, O., BRUYERE, O., MAWET, A. & REGINSTER, J.-Y. 2004a. Primary Prevention of Osteoporosis: Mass Screening Scenario or Prescreening With Questionnaires? An Economic Perspective. *Journal of Bone and Mineral Research,* 19**,** 1955-1960.

RICHY, F., ETHGEN, O., BRUYERE, O. & REGINSTER, J.-Y. 2004b. Efficacy of alphacalcidol and calcitriol in primary and corticosteroid-induced osteoporosis: a meta-analysis of their effects on bone mineral density and fracture rate. *Osteoporosis International,* 15**,** 301-310.

RICHY, F., GOURLAY, M., ROSS, P. D., SEN, S. S., RADICAN, L., DE CEULAER, F., BEN SEDRINE, W., ETHGEN, O., BRUYERE, O. & REGINSTER, J. Y. 2003. Validation and comparative evaluation of the osteoporosis self-assessment tool (OST) in a Caucasian population from Belgium. *Qjm,* 97**,** 39-46.

RIGGS, L. B., O'FALLON, W. M., MUHS, J., O'CONNOR, K. M., KUMAR, R. & MELTON, L. J. 1998. Long-term effects of calcium supplementation on serum parathyroid hormone level, bone turnover, and bone loss in elderly women. *Journal of Bone and Mineral Research,* 13**,** 168-174.

ROBBINS, J. A., ARAGAKI, A., CRANDALL, C. J., MANSON, J. E., CARBONE, L., JACKSON, R., LEWIS, C. E., JOHNSON, K. C., SARTO, G., STEFANICK, M. L. & WACTAWSKI-WENDE, J. 2014. Women's Health Initiative clinical trials:interaction of calcium and vitamin D with hormone therapy. *Menopause,* 21**,** 116-123.

ROCKWOOD, P. R., HORNE, J. G. & CRYER, C. 1990. Hip fractures: A future epidemic? *J Orthop Trauma,* 4**,** 388-393.

ROSENSTOACK, I. M., STRECHER, V. J. & BECKER, M. H. 1988. Social learning theory and the health belief model. *Health Education Quarterly,* 15**,** 175-183.

ROSS, A. C., TAYLOR, C. L., YAKTINE, A. L. & DEL VALLE, H. B. 2011. *To Review Dietary Reference Intakes for Vitamin D and Calcium: Institute of Medicine (US) Committee,,* Wahington, USA, National Academies Press (US).

ROSSOUW, J. E., MANSON, J. E., KAUNITZ, A. M. & ANDERSON, G. L. 2013. Lessons learnt from the

women's health initiative trials of menopausal hormone therapy. *Obstet gynecol,* 121**,** 172-176.

ROZENTAL, T. D., MAKHNI, E. C., DAY, C. S. & BOUXSEIN, M. L. 2008. Improving evaluation and treatment for osteoporosis following distal radial fractures. A prospective randomized intervention. *J Bone Joint Surg Am,* 90**,** 953-61.

RYDER, K. M., KESSLER, L. A., JONES, C. B. & SHORR, R. I. 2007. A Captive Audience: A Pilot Study of Screening and Counseling Hospitalized Women for Fracture Risk. *J Gen Intern Med,* 22**,** 830-834.

SAETUNG, S., ONGPHIPHADHANAKUL, B. & RAJATANAVIN, R. 2008. The relationship of an Asian-specific screening tool for osteoporosis to vertebral deformity and osteoporosis. *J Bone Miner Metab,* 26**,** 47-52.

SALE, J. E. M., BEATON, D., POSEN, J., ELLIOT-GIBSON, V. & BOGOCH, E. R. 2011. Systematic review on intervention to improve osteoporosis intervestigation and treatment in fragility fracture patients. *Osteoporos Int,* 22**,** 2067-2082.

SALE, J. E. M., BOGOCH, E., HAWKER, G., GIGNAC, M., BEATON, D., JAGLAL, S. & FRANKEL, L. 2014. Patient perceptions of provider barriers to post-fracture secondary prevention. *Osteoporosis International,* 25**,** 2581-2589.

SAMBROOK, P. N., GEUSENS, P., RIBOT, C., SOLIMANO, J. A., FERRER-BARRIENDOS, J., GAINES, K., VERBRUGGEN, N. & MELTON, M. E. 2004. Alendronate produces greater effects than ralozifene on bone density and bone turnover in postmenopausal women with low bone density: results of EFFECT (EFficacy of FOSAMAX versus EVISTA comparison trial) International. *Journal of Internal Medicine,* 255**,** 503-511.

SAMBROOK, P. N., SEEMAN, E., PHILLIPS, S. R. & EBELING, P. R. 2002. Preventing osteoporosis: outcomes of the Australian fracture prevention summit. *Med J Aust,* 176**,** 1-16.

SARKER, H. N. 2014. *An aid to electrocardiogram,* New Delphi, India, Jaypee Brothers Medical Publishers (P) Ltd.

SAW, S. M., HONG, C. Y., LEE, J., WONG, M. L., CHAN, M. F., CHENG, A. & LEONG, K. H. 2003. Awareness and health beliefs of women towards osteoporosis. *Osteoporos Int,* 14**,** 595-601.

SCHAIRER, C., LUBIN, J., TROISI, R., STURGEON, S., BRINTON, L. & HOOVER, R. 2000. Menopausal estrogen and estrogen-progestin replacement therapy and breast

cancer risk. *The Journal of the American Medical Association,* 283**,** 485-491.

SEDLAK, C. A., DOHENY, M. O. & JONES, S. L. 2000. Osteoporosis education programs: Changing knowledge and behaviors. *Public Health Nursing,* 17**,** 398-402.

SEDRINE, W. B., DEVOGELAER, J. P., KAUFMAN, J. M., GOEMARE, S., DEPRESSEUX, G., ZEGELS, B., DEROISY, R. & REGINSTER, J. Y. 2001. Evaluation of the simple calculate osteoporosis risk estimation (SCORE) in a sample of white women from Belgium. *Bone,* 29**,** 374-380.

SIMONELLI, C., KILLEEN, K., MEHLE, S. & SWANSON, L. 2002. Barriers to osteoporosis identification and treatment among primary care physicians and orthopedic surgeons. *Mayo Clin Proc,* 77**,** 334-338.

SIQUEIRA, F. V., FACCHINI, L. A. & HALLAL, P. C. 2005. The burden of fractures in Brazil: A population-based study. *Bone,* 37**,** 261-266.

SMITH, F. 2002. *Research methods in pharmacy practice,* London, Pharmaceutical Press.

SMITH, F. 2010. *Conducting your pharmacy practice research project,* London, Pharmaceutical Press.

SOLOMON, D. H., POLINSKI, J. M., STEDMAN, M., TRUPPO, C., BREINER, L., EGAN, C., JAN, S., PATEL, M., WEISS, T. W., CHEN, Y. T. & BROOKHART, M. A. 2007. Improving care of patients at-risk for osteoporosis: a randomized controlled trial. *J Gen Intern Med,* 22**,** 362-7.

SQUIRES, A. 2008. Language barriers and qualitative nursing research: Methodological considerations. *International Nursing Review,* 55**,** 265-273.

STRAUS, S. E., TETROE, J. M. & GRAHAM, I. D. 2011. Knowledge translation is the use of knowledge in health care decision making. *Journal of Clinical Epidemiology,* 64**,** 6-10.

STREINER, D. L. & NORMAN, G. R. 2008. *Health measurement scales: A Practical guide to their development and use,* Oxford, Oxford University Press.

STRÖM, O., BORGSTRÖM, F., KANIS, J. A., COMPSTON, J., COOPER, C., MCCLOSKEY, E. V. & JÖNSSON, B. 2011. Osteoporosis: burden, health care provision and opportunities in the EU. *Archives of Osteoporosis,* 6**,** 59-155.

STUURMAN-BIEZE, A. G. G., HIDDINK, E. G., VAN BOVEN, J. F. M. & VEGTER, S. 2014. Proactive pharmaceutical care interventions decrease patients' nonadherence to osteoporosis medication. *Osteoporosis International,* 25**,** 1807-1812.

SUNYECZ, J. A. 2008. The use of calcium and vitamin D in the management of ostoeporosis. *Therapeutics and clinical risk management 2008,* 4**,** 827-836.

SVEDBOM, A., HERNLUND, E., IVERGÅRD, M., COMPSTON, J., COOPER, C., STENMARK, J., MCCLOSKEY, E. V., JÖNSSON, B. & KANIS, J. A. 2013. Osteoporosis in the European Union: a compendium of country-specific reports. *Archives of Osteoporosis,* 8**,** 137.

TAYLOR, J. C., STERKEL, B., UTLEY, M., SHIPLEY, M., NEWMAN, S., HORTON, M. & FITZ-CLARENCE, H. 2001. Opinions and experiences in general practice on osteoporosis prevention, diagnosis and management. *Osteoporos Int,* 12**,** 844-848.

TERRIO, K. & AULD, G. W. 2002. Osteoporosis knowledge, calcium intake, and weight-bearing physical activity in three age groups os women. *Journal of Community Health,* 27**,** 307-320.

THABANE, L., MA, J., CHU, R., CHENG, J., ISMAILA, A., RIOS, L. P., ROBSON, R., THABANE, M., GIANGREGORIO, L. & GOLDSMITH, C. H. 2010. A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology,* 10**,** 1.

THE NORTH AMERICAN MENOPAUSE SOCIETY (NAMS) 2010. Management of osteoporosis in postmenopausal women: 2010 position statement of the The North American Menopause Society. *The Journal of the North American Menopause Society,* 17**,** 25-54.

THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS 2010. Clinical guideline for prevention and treatment of osteoporosis in postmenopausal women and older men. *In:* AUSTRALIAN GOVERNMENT, N. H. A. M. R. C. (ed.). Melbourne, Australia: The Royal Australian College of General Practitioners.

THE WOMEN'S HEALTH INITIATIVE STEERING COMMITTEE 2004. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy. The women's health initiative randomized controlled trial. *The journal of the American Medical Association,* 291**,** 1701-1712.

TICKLE-DEGNEN, L. 2013. Nuts and bolts of conducting feasibility studies. *The American Journal of Occupational Therapy***,** 171-176.

TOH, L. S., LAI, P. S. M., WONG, K. T., LOW, B. Y. & ANDERSON, C. 2012. What are the barriers encountered while screening for osteoporosis in a government university hospital primary care setting? Preliminary

results of a qualitative study on Malaysian nurses views. *Osteoporos Int,* 23**,** S777.

TOH, L. S., LAI, P. S. M., WONG, K. T., TAN, A. T. B., LOW, B. Y., ANDERSON, C. & BIN-CHIA, D. W. 2014. The development and validation of the Satisfaction Questionnaire for Osteoporosis Prevention in Malaysia. *Patient Preference and Adherence,* 8**,** 1365-1381.

TRIVEDI, D. P., DOLL, R. & KHAW, K. T. 2003. Effect of four monthly oral vitamin D3 (cholecalciferol) supplementation on fractures and mortality in men and women living in the community: randomised double blind controlled trial. *British Medical Journal,* 326**,** 469-472.

TULIP, S. & CAMPBELL, D. 2001. Evaluating pharmaceutical care in hospitals. *Hospital Pharmacists,* 8**,** 275-279.

TULLY, M. P. & BUCHAN, I. E. 2009. Prescribing errors during hospital inpatient care: factors influencing identification by pharmacists. *Pharmacy World & Science,* 31**,** 682-688.

TWINN, S. 1997. An exploratory study examining the influence of the translation on the validity and reliability of qualitatice data in nursing research. *Journal of Advanced Nursing,* 28**,** 418-423.

UNGAN, M. & TUMER, M. 2001. Turkish women's knowledge of osteoporosis. *Family Practice,* 18**,** 199-203.

UNITED NATIONS 2011. World Population Prospects The 2010 Revision Volume I: Comprehensive Tables. *In:* DIVISION, D. O. E. A. S. A. P. (ed.).

VAN BOVEN, J. F. M., STUURMAN0BIEZE, A. G. G., HIDDINK, E. G., POSTMA, M. J. & VEGTER, S. 2014. Medication monitoring and optimization: A targeted pharmacist program for effective and cost-effective improvement of chronic therapy adherence. *Journal of Managed Care & Specialty Pharmacy* 20**,** 786-792.

VAUS, D. D. 2002. *Survey in social research,* New South Wales, Australia, Allen & Unwin.

VINCENT, C., TAYLOR-ADAMS, S., CHAPMAN, E. J., HEWETT, D., PRIOR, S., STRANGE, P. & TIZZARD, A. 1999. *A protocol for investigation and analysis of clinical incidents,* London, University College London/Assocation of Litigation and Risk Management.

VINCENT, C., TAYLOR-ADAMS, S., CHAPMAN, E. J., HEWETT, D., PRIOR, S., STRANGE, P. & TIZZARD, A. 2000. How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management protocol. *BMJ,* 320**,** 777-781.

WALLACE, I., CALLACHAND, F., ELLIOTT, J. & GARDINER, P. 2011. An evaluation of an enhanced fracture liaison service as the optimal model for secondary prevention of osteoporosis. *JRSM Short Reports,* 2**,** 8-8.

WARE, J. E., SNYDER, M. K., WRIGHT, R. & DAVIES, A. R. 1983. Defining and measuring patient satisfaction with medical care. *Evaluation and Program Planning,* 6**,** 247-263.

WEINSTEIN, L. & ULLERY, B. 2000. Identification of at-risk women for osteoporosis screening. *Am J Obstet Gynecol,* 183**,** 547-9.

WERNER, P. 2005. Knowledge about osteoporosis: assessment, correlates and outcomes. *Osteoporosis International,* 16**,** 115-127.

WEST, R., WALIA, A., HYDER, N., SHAHAB, L. & MICHIE, S. 2010. Behavior change techniques used by the English Stop Smoking Services and their associations with short-term quit outcomes. *Nicotine & Tobacco Research,* 12**,** 742-747.

WHO TECHNICAL REPORT SERIES 843 1994. Assessment of fracture risk and its application to screening for postmenopausal oteoporosis. Geneva: World Health Organisation.

WHYTE, M. P. 2006. The Long and the Short of Bone Therapy. *New England Journal of Medicine,* 354**,** 860-863.

WILD, D., GROVE, A., MARTIN, M., EREMENCO, S., MCELROY, S., VERJEE-LORENZ, A. & ERIKSON, P. 2005. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. *Value Health,* 8**,** 94-104.

WINZENBERG, T. M., OLDENBURG, B., FRENDIN, S. & JONES, G. 2003. The design of a valid and reliable questionnaire to measure osteoporosis knowledge in women: The osteoporosis knowledge assessment tool (OKAT). *BMC Musculoskeletal Disorders,* 4**,** 17.

WONG, I. C. K. 2004. Randomised controlled trials (RCTs) to evaluate complex healthcare interventions- a case study. *Pharm World Sci,* 26**,** 247-252.

WORLD HEALTH ORGANIZATION GENEVA 1998. Guidelines for preclinical evaluation and clinical trial in osteoporosis. Switzerland.

WORLD HEALTH ORGANIZATION GENEVA 1999. Both health organizations and individuals must act now to avoid an impending epidemic. Press Release WHO/58.

WRIGHT, N. C., LOOKER, A. C., SAAG, K. G., CURTIS, J. R., DELZELL, E. S., RANDALL, S. & DAWSON-HUGHES, B.

2014. The Recent Prevalence of Osteoporosis and Low Bone Mass in the United States Based on Bone Mineral Density at the Femoral Neck or Lumbar Spine. *Journal of Bone and Mineral Research,* 29**,** 2520-2526.

WRIGHT, S. A., MCNALLY, C., BERINGER, T., MARSH, D. & FINCH, M. B. 2005. Osteoporosis fracture liaison experience: the Belfast experience. *Rheumatology International,* 25**,** 489-490.

WRITING GROUP FOR THE WOMEN'S HEALTH INITIATIVE 2002. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative Randomized Controlled Trial. *Journal of the American Medical Association,* 288**,** 321-333.

XIA, W. B., HE, S. L., XU, L., LIU, A. M., JIANG, Y., LI, M., WANG, O., XING, X. P., SUN, Y. & CUMMINGS, S. R. 2012. Rapidly increasing rates of hip fracture in Beijing, China. *J Bone Miner Res,* 27**,** 125-9.

YEAP, S. S., GOH, E. M. L. & GUPTA, E. D. 2010. Knowledge about osteoporosis in a Malaysian population. *Asia-Pacific Journal of Public Health,* 22**,** 233-241.

YU, S. & HUANG, Y. C. 2003. Knowledge of, attitude toward, and activity to prevenet osteoporosis among middel-aged and elderly women. *Journal of Nursing Research,* 11**,** 65-72.

YUKSEL, N., MAJUMDAR, S. R., BIGGS, C. & TSUYUKI, R. T. 2010. Community pharmacist-initiated screening program for osteoporosis: randomized controlled trial. *Osteoporos Int,* 21**,** 391-8.

ZHANG, Y.-P., LI, X.-M., WANG, D.-L., GUO, X.-Y. & GUO, X. 2012. Evaluation of educational program on osteoporosis awareness and prevention among nurse students in China. *Nursing & Health Sciences,* 14**,** 74-80.

ZIEBLAND, S. & MCPHERSON, A. 2006. Making sense of qualitatative data analysis: An introduction with illustrations from DIPEx (personal experiences of health and illness). *Medical Education,* 40**,** 405-414.

APPENDICES

5.11   Appendix 1- Baseline demographic form for patients

Please circle or fill up the related sections.

Appendix 1: Baseline Demographic Sheet (Phase 1, 2, 3) | Serial no | | | |

Paste HIS label here:

Patient Name*: _____

IC/RN: _____

Address: _____

_____

Tel no: (H) _____ (HP) _____ (O) _____

Next of kin

Name:_____

Relationship: _____

Tel no: (H) _____ (HP) _____ (O) _____

Date of 1st visit: (recruitment) _____

Date of 1st follow up: _____ Time: _____ No of days since last visit: _____

Date of 2nd follow up: _____ Time: _____ No of days since last visit: _____

Baseline demographics (Phase 1, 2, 3)

Serial no			

Section A: Patient demographics

1) What language do you prefer me to use?
- ❑ $_1$Bahasa Malaysia
- ❑ $_2$English
- ❑ $_3$Chinese Specify _____

2) Year of birth _____
- ❑ _____ years

3) Race
- ❑ $_1$Malay
- ❑ $_2$Chinese
- ❑ $_3$Indian
- ❑ $_4$Others _____

4) Marital status
- ❑ $_1$Single
- ❑ $_2$Married
- ❑ $_3$Divorced
- ❑ $_4$Widow/widower

5) Weight
- ❑ _____ kg

6) Height
- ❑ _____ cm

7) Hip circumference_____ cm/inch
- ❑ $_1$-<90cm
- ❑ $_2$->90cm

8) Are you still working?
- ❑ $_1$-Yes, specify _____
- ❑ $_2$-No

9) If no, have you worked before?
- ❑ $_1$-Yes, specify _____
- ❑ $_2$-No

10) Household income per month
- ❑ $_1$<RM1000
- ❑ $_2$RM1000-1999
- ❑ $_3$RM2000-2999
- ❑ $_4$RM3000-3999
- ❑ $_5$RM4000-4999
- ❑ $_6$ >RM5000

11) What is the highest level of education you have obtained?
- ❑ $_1$Primary
- ❑ $_2$Secondary
- ❑ $_3$Diploma / technical school training
- ❑ $_4$Tertiary (basic degree)
- ❑ $_5$Post graduate degree

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12) At what age did you start menstruating?
❑ _____ years of age

13) At what age did you reach menopause?
❑ _____ years of age

❑ _____ years menopausal

14) How did you reach menopause?
❑ $_1$-Naturally
❑ $_2$-Surgical removal of the uterus & ovaries
❑ $_3$-chemotherapy / radiation
❑ $_4$-others _____

15) Do you think you are at risk for osteoporosis?
❑ $_1$-Yes
❑ $_2$-No
❑ $_3$-Maybe

16) Do you have any current medical condition?
❑ $_1$-Yes
❑ $_2$-No

17) If yes, specify: _____
❑ $_1$-Gastrointestinal disease
❑ $_2$-Heart Disease (hypertension, stroke, IHD)
❑ $_3$-Respiratory disease (asthma)
❑ $_4$-CNS (depression/migraine)
❑ $_5$-Infections (pneumonia)
❑ $_6$-Endocrine (Diabetes, Cushings)
❑ $_7$-Obstetrics & Gyn/UTI
❑ $_8$-Cancer
❑ $_9$-Nutrition & blood (anaemia)
❑ $_{10}$-Musculoskeletal and joint disease
❑ $_{11}$-Eye
❑ $_{12}$-ENT
❑ $_{13}$-Skin

18) Are there any of your family members who have or had osteoporosis?
❑ $_1$-Yes specify_____
❑ $_2$-No
❑ $_3$-Don't know

19) Have you had a fracture before?
❑ $_1$-Yes, please specify and circle below:

No of times	1	2	3	>3
Which part	Hip/ Ribs/ Wrist/ Others	Hip/ Ribs/ Wrist/ Others	Hip/ Ribs/ Wrist/ Others	Hip/ Ribs/ Wrist/ Others
Age 45	Before /after	Before /after	Before /after	Before/ after

❑ $_2$-No
❑ $_3$-Don't know

20) Do you have rheumatoid arthritis?
❑ $_1$-Yes
❑ $_2$-No

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21) Do you currently have any back pain or bone pain?

❑ ₁-Yes
❑ ₂-No
❑ ₃-Don't know

22) How often do you have a drink containing alcohol (a glass of beer, wine, a mixed drink, or any kind of alcoholic beverage) in the last 30 days?

❑ ₁Everyday
❑ ₂Nearly everyday
❑ ₃Two to three times a week
❑ ₄Occasionally
❑ ₅Never

23) How often do you have coffee or tea in the last 30 days?

❑ ₁Everyday
❑ ₂Nearly everyday
❑ ₃Two to three times a week
❑ ₄Occasionally
❑ ₅Never

24) Are you a _____?

❑ ₁current smoker
❑ ₂ex smoker
❑ ₃never smoked

25) How much cheese, milk or yoghurt do you take in a week?

❑ ₐ-cheese _____ slices
❑ ᵦ-milk _____ glasses. What type of milk do you take?
   i) normal or skim milk
   ii) high calcium milk
   iii) both
❑ ᵤ-yoghurt _____ servings

26) Are taking any thing else in your diet that is high in calcium

❑ ₁-Yes specify

_____
_____
_____
_____

❑ ₂-No

27) Are you currently taking any calcium supplements?

❑ ₁-Yes specify

_____mg _____times a day

Type/Brand_____
_____
_____

❑ ₂-No

28) Are you currently taking any Vitamin D supplements?

❑ $_1$-Yes specify

_____units _____times a day

Type/Brand_____

_____

_____

❑ $_2$-No

29) How often do you exercise in a week? Exercises include mopping, sweeping, brisk walking, jogging, dancing or taichi for at least 30 minutes.

❑ $_1$-Everyday
❑ $_2$-Every other day
❑ $_3$-Twice a week
❑ $_4$-Once a week
❑ $_5$-Less than once a week
❑ $_6$-Never

30) Are you doing any other kind of exercise aside from those mentioned above?

❑ $_1$-Yes specify

_____

_____

_____

_____

❑ $_2$-No

31) Are you taking hormonal replacement therapy?

❑ $_1$Currently taking for _____ months
❑ $_2$Previously taken. _____ months ago
❑ $_3$never tried

32) Are you taking any other medications? This includes any medications obtained from outside this hospital, health supplements and traditional medicines

❑ $_1$-Yes specify

_____

_____

_____

_____

❑ $_2$-No

33) Total no. of medications taken

_____

34) Do you do anything to prevent falls at home? For example, putting anti slip mats in the toilet and lighting up the stair case well?

❑ $_1$-Yes specify

_____

_____

_____

_____

❑ $_2$-No

Thank you for your time

5.12   Appendix 2- Baseline demographic form for healthcare professionals (nurses, pharmacists, doctors) and policy makers

Please circle or fill up the related sections.

Baseline Demographic Sheet (Phase 1, 2) | Serial no | | | |

Name*: _____*

Position: _____
Department_____

Address: _____

Tel no: (H) _____ (HP) _____ (O) _____

Date of recruitment _____

Date of 2nd visit: _____ Time: _____   No of days since last visit:

Section A: Background information

1) Year of birth _____   ❑   _____ years

2) Race   ❑ $_1$Malay
                        ❑ $_2$Chinese
                        ❑ $_3$Indian
                        ❑ $_4$Others _____

3) Marital status   ❑ $_1$Single
                        ❑ $_2$Married
                        ❑ $_3$Divorced
                        ❑ $_4$Widow/widower

4) What is the highest level of education you have obtained*?*
                        ❑ $_{1-}$ Diploma
                           Name of College_____
                        ❑ $_{2-}$Tertiary (basic degree)
                           Name of University_____
                        ❑ $_{3-}$Post graduate degree
                            Name of University_____

5) How many years have you worked?
                        ❑ $_1$-< 1 year
                        ❑ $_2$- 1- 4 years
                        ❑ $_3$- 5-10 years
                        ❑ $_4$- >10 years

6) Have you worked overseas?
                        ❑ $_1$-Yes, specify -hospital/community / clinic/ industrial sector
                        ❑ $_2$-No

7) Have you worked in the private sector?
                        ❑ $_1$-Yes, specify -hospital/community / clinic/ industrial
                        ❑ $_2$-No

8) Have you worked in a government health clinic?
                        ❑ $_1$-Yes
                        ❑ $_2$-No

9) Have you locum before?
                        ❑ $_1$-Yes
                        ❑ $_2$-No

10)   Have you worked with out patient osteoporosis patients?
                        ❑ $_1$-Yes
                        ❑ $_2$-No

11)   Have you worked with in patient osteoporosis patients?
                        ❑ $_1$-Yes
                        ❑ $_2$-No

12)   Do you know any friends/family that has osteoporosis?
                        ❑ $_1$-Yes
                        ❑ $_2$-No

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5.13 Appendix 3- Topic guide for patients

Topic Guide- Patients

1. Understanding of osteoporosis
2. Feelings and attitudes towards osteoporosis
3. Knowledge about preventive measure
4. Feelings and attitudes towards preventive measure
5. Knowledge of bone scans
6. Feelings and attitudes towards bone scans
7. Knowledge of roles of health care professionals
8. Feelings and attitudes towards the roles of health care professionals in osteoporosis

Topic Guide sample questions

1. Understanding of osteoporosis
   a. Definition
      i. What are some of the health problems that you think post menopausal women may experience?
      ii. Have you heard of osteoporosis/brittle bones?
      iii. What do you think osteoporosis is?
         Probes:

         ➢ Easily broken bone
         ➢ Thinning bones
         ➢ Weak bones
   b. Causes
      i. Why do you think osteoporosis happens? OR Why do you think the bones become

      weak?

         Probes: Some people think it's:

         ➢ calcium
         ➢ old age
   c. Risk factors
      i. Who do you think is more susceptible to osteoporosis?
      ii. What makes you think so?
      iii. What other reasons/risk factors do you think that causes someone to get osteoporosis?
         Probes:

         ➢ Old age
         ➢ Calcium
         ➢ Exercise
         ➢ Smoking

      d. Symptoms/Effects
          i. How do you think someone knows they have osteoporosis?
             Probes

- Pain
- Height
- Doctor's diagnosis

2. Feelings and attitudes towards osteoporosis

    a. Feelings about osteoporosis
        ii. Do you think that you may have osteoporosis?
        iii. How do you think it will affect your life if you had osteoporosis?
    b. Family/Friends history of osteoporosis
        i. Does anyone in your family/friends have osteoporosis?
        ii. What did you think of their osteoporosis?
    c. Perceptions of osteoporosis treatment
        i. Do you know what kind of treatment is available for osteoporosis? For example?
        ii. What do you think of the current treatment available?
        iii. Would you like more information on it?
    d. Sources of knowledge about osteoporosis
        i. How did you find out about osteoporosis?
        ii. How do you find this information? Did it help?
        iii. Would you like more information on osteoporosis? What?
        iv. Where would you go to find more information about this?
        v. Where do you think should provide this kind of information?
- Probes: Pharmacist, hospitals.

3. Knowledge about preventive measure

    a. Types of preventive measure
        i. What are the possible ways to prevent osteoporosis?
           Probes:

- Lifestyle changes
  - Calcium Intake/ Diet/ Supplements

- From where do you think you get your calcium?
- How much supplements/calcium rich food do you take?
- When did you begin changing your diet/taking supplements?
- Was there a particular reason? How did you begin?
- So this is included in your daily routine?
- Do you find it inconvenient or is it no trouble at all?

▪ Exercise, Types
- What type of exercise do you do?
- How often? Once a week? For how many minutes?
- Do you find it inconvenient or is it no trouble at all?

▪ Quit Smoking and Alcohol
- How often?
- When did you start?
- When did you stop? What made you stop?

➢ Medication
▪ Did you know that there are also medications for osteoporosis prevention?
▪ What do you think of taking medication to prevent osteoporosis?

➢ Fall prevention/ Well lit stairs/ No clutter/ Anti slipping mats
▪ How did you fall prove your house?
▪ Do you think it has an effect?

b. Sources of osteoporosis preventive knowledge
  i. How did you find out about osteoporosis prevention?
  ii. How did you find the information? Did it help?

        iii. Would you like more information on osteoporosis prevention? What?

        iv. Where would you go to find more information about this?

        v. Where do you think should provide this kind of information?

           ➢ Probes: Pharmacist, hospitals.

4. Feelings and attitudes towards preventive measure

  a. Experiences and Capability of taking preventive measure

      i. Do you take any preventive measures? What kind?

      ii. What influence you to take these measures?

      iii. How do you think these preventive measures have affected your life so far? (barriers/benefits) Has it caused any change in your life?

      iv. What are the reasons for taking/not taking these measures?

      v. What do you think you can do to prevent osteoporosis at this point? (What else do you think you can try?)

        Probe:

           ➢ Calcium
           ➢ Exercise
           ➢ Weight
           ➢ Get a check up (screening)

      vi. Do you know anyone else who have taken these measures? What did he/she do?

      vii. Would you ask your friends/family to take osteoporosis preventive measures? Which type and why?

5. Knowledge of bone scans

  a. Do you know how osteoporosis is diagnosed?

  b. Bone scan Procedure

      i. What do you think having a bone scan involves?

      ii. What do you think about the radiation involved in the bone scan?

  c. Usefulness of Bone Scan

      i. How do you think it identifies someone as being osteoporosis?

6. Feelings and attitudes towards bone scans
   a. Feeling about undergoing a bone scan
      i. What is the first thing that comes to your mind if I told you that you had to go for a bone scan tomorrow?
      ii. How do you feel about knowing your risk status (including comparison with other illnesses)
      iii. Why would you want to know/ not know?
      iv. How do you think it will affect you after knowing your osteoporosis risk status? (feelings/actions)
         Probes:

         ➢ See a doctor
         ➢ Take preventive methods
         ➢ Scared

7. Knowledge of roles of health care professionals
   a. Programmes available
      i. Has your doctor/ pharmacist ever mentioned anything about osteoporosis? What was discussed?
      ii. Have you heard about any kind of osteoporosis seminar, risk assessment (screening) programme about osteoporosis?
         ➢ Yes- Did you attend? Were they helpful? How?
         ➢ No- Would you like them to be available? What sort?
      iii. Would you attend an osteoporosis screening programme if there was one? What makes you say that?
      iv. What do you think the screening programme should be like?
      v. Where do you think this programme should be available?

8. Feelings and attitudes towards the roles of health care professionals in osteoporosis
   a. Expectations
      i. What do you think you need from the healthcare providers (pharmacist, nurses, doctor) for prevention of osteoporosis?
         Probe:

         ➢ More consultation time

> ➢ Counseling sessions
> ➢ Empathy

ii.   Who would you go to for more information? Why?

iii. What do you think of the current services available with regards to osteoporosis prevention?
> ➢ Attitude/Caring
> ➢ Enough information

iv. Is there anything you would like to change/improve with regards to the current osteoporosis prevention healthcare services?

5.14   Appendix 4- Topic guide for healthcare professionals (nurses, pharmacists, doctors)

Topic Guide- Pharmacist, Doctor, Nurses.

1. Understanding of osteoporosis
2. Feelings and attitudes towards osteoporosis
3. Knowledge and experience towards preventive measure
4. Knowledge of bone scans
5. Feelings and attitudes towards bone scans
6. Knowledge of roles of health care professionals
7. Feelings and attitudes towards the roles of health care professionals in osteoporosis

Topic Guide sample questions

1. **Understanding of osteoporosis**
   a. Definition
      i. What are some of the health problems that you think post menopausal women may experience?
      ii. What do you think of osteoporosis impact to society??
         ➢ Serious or small impact
      iii. What do you think osteoporosis is?
         Probes:

         ➢ Easily broken bone
         ➢ Thinning bones
         ➢ Weak bones

2. **Feelings and attitudes towards osteoporosis**
   a. Feelings about osteoporosis
      i. Do you think that you may have patients who have undetected osteoporosis?
      iv. Do you think this should be addressed?
         ➢ Priority
      v. How do you think this should be tackled? What do you think you can do to detect osteoporosis?
      vi. What do you think is the role of the doctors/nurses/pharmacists in osteoporosis prevention?
   b. Experience with osteoporosis
      i. Have you had any experience with osteoporosis patients here? What did you have to do?
         Probes

> - Osteoporosis treatment
> - Osteoporosis prevention
> - Counseling

    ii. How do you find your involvement in their treatment/prevention?
Probes

> - Helpful
> - Sufficient
> - Could have done more?

    iii. What do you think patients think of osteoporosis?

c. Perceptions of osteoporosis treatment?
    i. Do you know what kind of treatment is available for osteoporosis? For example?
    ii. What do you think of the current treatment available?
    iii. Would you like more types of medication to be available?
    iv. What do the patients think about the medications available?

3. Knowledge and Experience towards preventive measure

a. Types of preventive measure
    i. What are the possible ways to prevent osteoporosis?

Probes → What do you think of…… and

osteoporosis?

> - Lifestyle changes
>   - Calcium Intake/ Diet/ Supplements
>   - From where do you think patients can get their calcium intake?
>   - Have you met any patients taking calcium supplements? (Was it for osteoporosis?)
>   - How much/type do they normally take?
>   - What do you think normally causes them to change their diet/taking supplements?

- Is this included in their daily routine?
- How do you think it is like for them to include them in their daily routine?
- Is it inconvenient for the patients or is it no trouble at all?
- How do you find the effect of the calcium supplements?
- How do you think the patients feel about taking calcium supplements?
  - Convenient? Effective?

- Exercise, Types
  - What type of exercise do you think can help?
  - How often? Once a week? For how many minutes?
  - Have you known any patients who did any of these exercises? How did they find it?
  - How do you find the effect of the exercises?
- Quit Smoking and Alcohol
  - Do you think smoking and alcohol has a role in osteoporosis? What makes you say so?
  - Is this a common scenario here?
  - Do you think that most people are aware that these may increase their risk of osteoporosis? What makes you think that?
- Medication
  - Did you know that there are also medications for osteoporosis prevention?
  - What do you think of taking medication to prevent osteoporosis?

- How do you think patient's perceived taking medications for osteoporosis
  - Fall prevention/ Well lit stairs/ No clutter/ Anti slipping mats
    - Have you heard of fall prevention to prevent fractures due to osteoporosis? What do you think of it?
    - How would you advice someone to fall proof their house?
    - Do you think it has an effect?
  - ii. Do you think patients are aware of these available measures?
b. Sources of osteoporosis preventive knowledge
  - i. How did you find out about osteoporosis prevention?
  - ii. How did you find the information? Did it help?
  - iii. Would you like more information on osteoporosis prevention? What?
  - iv. How much information do you think patients should receive? What kind? What form?
  - v. Where would you go to find more information about this?
  - vi. Where do you think should provide this kind of information?
    - ➢ Probes: Pharmacist, hospitals.

4. **Knowledge of bone scans**
   a. How do you think osteoporosis is diagnosed?
   b. Bone scan Procedure
     - i. What does a bone scan involve?
     - ii. What do you think about the radiation involved in the bone scan?
     - iii. What do you think of the current referral system?
       Probes

       - ➢ Smooth, target population
       - ➢ Criteria for referral
       - ➢ Clear guideline
   c. Usefulness of Bone Scan

    i. What do you think of the current bone scan facility and its availability?
       Probes

- ➢ Waiting time
- ➢ Cost
- ➢ Number of machines (Availability)

    ii. Do you think there should be a prior risk assessment for osteoporosis using a simpler and cheaper tool before actually conducting the bone scan? What makes you say that?

    iii. Do you think the patient's are willing to pay and wait for a bone scan?
       Probes

- ➢ Long waiting time
- ➢ Accessibility and affordability
- ➢ Acceptability

5. Feelings and attitudes towards bone scans

a. Feeling about bone scan referral

    i. Have you ever referred patients for a bone scan? What would make you do so?

    ii. Do you think pharmacist/nurses should be able to make a BMD referral or prescribe osteoporosis medications?

b. Osteoporosis Risk status (including comparison with other illnesses)

    i. What are your thoughts on knowing the patient's osteoporosis risk factors as compared to other diseases like diabetes? What makes you say that? (HCP and patients)

    ii. What do you think are the opinions of patients to knowing their risk status

6. Knowledge of roles of health care professionals

a. Programmes available

    i. Have you heard of any kind of osteoporosis screening/risk assessment programme?
       Probes

- ➢ How was it like? What did you think of it?
- ➢ Who organized it (By doctors? Pharmacist? Nurses?)
- ➢ Where: Location: pharmacy? Hospitals?

    ii. Have you heard about any kind of osteoporosis seminar?
        Probes

- ➢ Yes- Did you attend? Were they helpful? How?
- ➢ No- Would you like them to be available? What sort?

    iii. Would you assist in an osteoporosis screening programme if there was one? What makes you say that?

    iv. How do you think the screening programme should be like?
        Probes

- ➢ By whom
- ➢ How much (Cost)
- ➢ How should it be done?
- ➢ What should be done?
- ➢ Where

    v. What benefits do you see from a screening programme?

    vi. What barriers do you see from a screening programme?

    vii. How do you think patients will response to this programme?

    viii. How do you think healthcare professionals will response to this programme

7. Feelings and attitudes towards the roles of health care professionals in osteoporosis

    a. Expectations

        i. What do you think healthcare providers (pharmacist, nurses, doctor) can do for osteoporosis prevention care (treatment)?
            Probes:

- ➢ More consultation time
- ➢ Counseling sessions, Empathy

        ii. What do you think of the current services available with regards to osteoporosis prevention? How about treatment?
            Probes

- ➢ Attitude, Information

        iii. Is there anything you would like to change/improve with regards to the current osteoporosis prevention healthcare services? (or treatment)

5.15 Appendix 5- Topic guide for policy makers

Topic Guide- Policy makers
1. Osteoporosis in general
2. Feelings and attitudes towards osteoporosis
3. Perception of Bone Scans and Medication usage system.
4. Perception of Osteoporosis prevention and screening programmes
5. Pharmacist role in osteoporosis prevention and screening

Topic Guide sample questions

1.Osteoporosis in general

What is the impact of osteoporosis on society?
   Probes:
   - QOL
   - Cost

2.Feelings and attitudes towards osteoporosis

Feelings about osteoporosis
What is the first thing that comes to your mind when I mention osteoporosis?

3. Perception of Bone Scans and Medication usage system.

a.   Usefulness of Bone Scan
   i. What is the role of the BMD in osteoporosis?
      Probes:
      - Diagnosis, gold standard
   ii. What do you think of having a prior risk assessment tool? What makes you say that?

b.   Bone scan and Medication procedure
   What do you think of the current process for the patient to get a referral for the BMD?
   Probes:
   - Smooth
   - Target a wide enough population
   - Criteria for referral
   - Clear guideline
   What do you think of the accessibility of the current bone scan facility?
      Probes:
      - Any idea, how often does the machine break down?

- What are the alternatives for patients when the machine is down?
- Waiting time

What do you think of the affordability of the current bone scan?

Probes:
- Cost
- Number of machines

How do you think patients perceive the bone scan facility?

Probes:
- Long waiting time
- Accessibility and affordability
- Acceptability

Medication

- What do you think about the usage of osteoporosis medication in this hospital?

Probes: Under or over used?

-What do you think of the Prescribing restriction enforced on the osteoporosis medication?

Probes: Previous interviews with doctors, some suggested to make the prescribing restrictions more flexible to may be lighten workload or for patients convenience. What do you think of this?

-Why was it enforced to begin with?

4.Perception of Osteoporosis prevention and screening programmes

a. Future of an osteoporosis prevention programme

What do you think of the current services available with regards to osteoporosis prevention and screening?

What do you think about the detection of osteoporosis in this hospital?

Probes:
- Priority?

What do you think are the reasons for this to occur?

Do you think this need to be changed?

How do you think this should be tackled?
- What would be the solutions?

-Are you aware of the National Osteoporosis Foundation (NOF) guideline/recommendation for the screening of osteoporosis?

Probes:

- >60 age women all need screening

What do you think the hospital can do to increase osteoporosis prevention and screening awareness?

Probes:

- Provide Lifestyle education
- Screening programmes

-Would you support conducting an osteoporosis screening and prevention programme if there was one? What makes you say that? Why?

- Is it a necessity?

How do you think the programme should be like?

- By whom
- How much
- What should be done
- Where

-How do you think patients will response to this programme?

-How do you think healthcare professionals will response to this programme?

-What benefits do you see from a screening programme?

Probes:

- More undetected patients identifies
- Better patient outcome
- Less fractures

b. Resources

Do you think it is sustainable?

What barriers do you see in conducting this programme?

Probes:

- Enthusiasm will fade
- Lack of space and time

How do you think the budget will affect this programme?

Probes:

- Management of fund
- Staff commitment

Normally what is the priority when allocating money from the budget?

Do you see the possibility of allocating more money for osteoporosis

screening/prevention/ medication purchase/ BMD subsidy?

-Are there enough staff to implement a new screening programme? Reasons

-Is the Ministry of Higher Education (MOHE) supportive of such programmes? What makes you say that?

-What else do you think is needed to be able to conduct an osteoporosis screening programme?

c. Programmes available

Have you heard of any kind of osteoporosis screening and prevention programme conducted outside of this hospital? How was it like? What did you think of it?

Probes:
- By doctors? Pharmacist? Nurses?
- Location: pharmacy? Hospitals?

Where do you think should the disease focus of the health care be?

Diseases

Prevention/ Treatment

5.Pharmacist role in osteoporosis prevention and screening

How do you perceive the pharmacist role in the osteoporosis care?

Probe:
- Is there a role for the pharmacist in screening and prevention of osteoporosis?

Is there anything else you would like to change/improve with regards to the current osteoporosis healthcare services?

5.16   Appendix 6- Topic guide for patients, Malay version

<u>**Panduan topik - Pesakit**</u>

1. Pemahaman tentang osteoporosis
2. Perasaan dan sikap terhadap osteoporosis
3. Pengetahuan mengenai langkah pencegahan
4. Perasaan dan sikap terhadap langkah pencegahan
5. Pengetahuan tentang imbasan tulang
6. Perasaan dan sikap terhadap imbasan tulang
7. Pengetahuan mengenai peranan pegawai kesihatan
8. Perasaan dan sikap terhadap peranan pegawai kesihatan tentang osteoporosis

<u>**Contoh-contoh soalan untuk panduan topik**</u>

1. Pemahaman tentang osteoporosis
   a. Definisi
      i. Pada pendapat anda, apakah masalah kesihatan yang mungkin dialami wanita selepas menopaus?
      ii. Pernahkah anda dengar tentang osteoporosis / tulang rapuh?
      iii. Pada pendapat anda, apakah itu osteoporosis? Probe:
         ➢ Tulang rapuh
         ➢ Penipisan tulang
         ➢ Tulang lemah
   b. Punca-punca
      i. Pada pendapat anda mengapakah osteoporosis berlaku?
      ATAU Mengapa tulang menjadi lemah?
      Probe: Sesetengah orang berpendapat bahawa ia disebabkan oleh:
         ➢ Kalsium
         ➢ Usia tua
   c. Faktor-faktor risiko
      i. Siapakah yang lebih terdedah kepada osteoporosis?
      ii. Apakah sebab anda berpendapat sedemikian?
      iii. Pada pendapat anda, apakah sebab lain/ faktor risiko yang boleh menyebabkan seseorang itu mendapat osteoporosis?
      probe:
         ➢ Usia tua
         ➢ Kalsium
         ➢ Senaman

> ➤ Merokok

d. Gejala / Kesan

    i. Pada pendapat anda, bagaimanakah seseorang akan tahu bahawa mereka mengalami osteoporosis?

    Probe:
> ➤ Sakit
> ➤ Ketinggian
> ➤ Diagnosis Doktor

2. Perasaan dan sikap terhadap osteoporosis

a. Perasaan mengenai osteoporosis

    i. Pernahkan anda berfikir bahawa anda mungkin mengalami osteoporosis?

    ii. Pada pendapat anda, bagaimanakah kesan terhadap gaya hidup anda jika anda menghidap osteoporosis?

b. Keluarga / Kawan sejarah osteoporosis

    i. Adakah ada di antara ahli keluarga / rakan-rakan anda yang menghidap osteoporosis?

    ii. Apakah pendapat anda tentang osteoporosis mereka?

c. Persepsi rawatan osteoporosis

    i. Adakah anda tahu jenis rawatan yang disediakan untuk osteoporosis? Contohnya?

    ii. Apakah pendapat anda tentang rawatan yang sedia ada?

    iii. Adakah anda ingin maklumat lanjut mengenainya?

d. Sumber pengetahuan mengenai osteoporosis

    i. Bagaimanakah anda mendapat tahu tentang osteoporosis?

    ii. Apakah pendapat anda tentang maklumat ini? Adakah ia membantu?

    iii. Adakah anda inginkan maklumat lanjut tentang osteoporosis? Maklumat apa yang diperlukan?

    iv. Dimanakah anda akan pergi untuk mendapatkan maklumat lebih lanjut mengenai perkara ini?

    v. Dimanakah tempat yang sepatutnya menyediakan maklumat tentang penyakit ini?
> ➤ probe: Pegawai Farmasi, hospital.

3. Pengetahuan mengenai langkah pencegahan

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a. Jenis-jenis langkah pencegahan
   i. Pada pendapat anda, apakah cara-cara untuk mencegah osteoporosis?
      Probe:
      ➤ Perubahan Gaya Hidup
        ▪ Pengambilan Kalsium / Pemakanan / Vitamin
          - Pada pendapat anda, dari manakah anda mendapatkan kalsium anda?
          - Berapa banyak vitamin/makanan berkalsium yang anda ambil?
          - Bilakah anda mula mengubah cara pemakanan anda / mengambil vitamin?
          - Adakah terdapatnya sebab tertentu? Bagaimana anda bermula?
          - Oleh itu, ini dimasukkan dalam rutin harian anda?
          - Adakah ia susah atau ia tidak langsung menimbulkan masalah bagi anda?
        ▪ Senaman, Jenis
          - Apakah jenis senaman yang anda lakukan?
          - Berapa kerap? Sekali seminggu? Berapa minit?
          - Adakah is susah atau senang untuk dilakukan?
        ▪ Berhenti Merokok dan Alkohol
          - Berapa kerap?
          - Bilakah anda bermula?
          - Bilakah anda berhenti? Apa yang menyebabkan anda berhenti?
        ▪ Ubat
          - Adakah anda tahu bahawa terdapatnya ubat untuk pencegahan osteoporosis?
          - Apakah pendapat anda mengenai pengambilan ubat untuk mencegah osteoporosis?

- Mencegah jatuh / tangga yang terang / Tiada kekacauan / tikar anti gelincir
  - Bagaimana anda mencegah kejatuhan dalam rumah anda?
  - Adakah ia berkesan?

b. Sumber pengetahuan cara pencegahan osteoporosis

  i. Bagaimana anda mendapat tahu tentang cara pencegahan osteoporosis?
  ii. Apakah pendapat anda terhadap maklumat ini? Adakah ia membantu?
  iii. Adakah anda inginkan maklumat lanjut mengenai pencegahan osteoporosis? Apakah jenis maklumat yang diperlukan?
  iv. Dimanakah anda akan pergi untuk mendapatkan maklumat lebih lanjut mengenai perkara ini?
  v. Dimanakah tempat yang sepatutnya menyediakan maklumat perkara ini?
      probes: pengawai farmasi, hospital

4. **Perasaan dan sikap terhadap langkah pencegahan**
    a. Pengalaman dan Keupayaan mengambil langkah pencegahan
      i. Adakah anda mengambil mana-mana langkah-langkah pencegahan? Jenis apa?
      ii. Apakah yang mempengaruhi anda untuk mengambil langkah-langkah ini?
      iii. Bagaimanakah langkah-langkah pencegahan ini telah memberi kesan dalam kehidupan anda setakat ini? (Halangan / faedah) Adakah ia menyebabkan apa-apa perubahan dalam hidup anda?
      iv. Apakah sebab-sebab untuk mengambil / tidak mengambil langkah-langkah ini?
      v. Pada pendapat anda, apakah yang anda boleh lakukan untuk mencegah osteoporosis pada ketika ini? (Apakah perkara lain yang anda rasa anda boleh cuba?)
          Probe:
          ➢ Kalsium
          ➢ Senaman
          ➢ Berat badan
          ➢ Dapatkan Pemeriksaan (Penyaringan)

<div style="margin-left:2em;">

vi. Adakah anda tahu sesiapa yang telah mengambil langkah-langkah pencegahan ini? Apakah yang beliau lakukan?

vii. Adakah anda akan meminta rakan/keluarga anda untuk mengambil langkah-langkah pencegahan osteoporosis? Jenis apa dan mengapa?

</div>

5. **Pengetahuan tentang imbasan tulang**
   a. Adakah anda tahu bagaimanakah seseorang disahkan mengalami osteoporosis?
   b. Prosedur Tulang imbasan
      i. Pada pendapat anda, apa yang terlibat dalam imbasan tulang ?
      ii. Apakah pendapat anda tentang radiasi yang terlibat dalam imbasan tulang?
   c. Kegunaan/Imbasan Tulang
      i. Pada pendapat anda, bagaimanakah imbasan tulang mengenal pasti seseorang sebagai mangalami osteoporosis?

6. **Perasaan dan sikap terhadap imbasan tulang**
   a. Perasaan tentang menjalani imbasan tulang
      i. Apakah perkara pertama yang berada di fikiran anda jika saya memberitahu bahawa anda perlu menjalani imbasan tulang esok?
      ii. Bagaimanakah perasaan anda untuk mengetahui tentang status risiko anda (termasuk perbandingan dengan penyakit-penyakit lain)
      iii. Mengapa anda ingin tahu / tidak ingin mengetahui?
      iv. Bagaimanakah anda fikir ia memberi kesan kepada anda selepas mengetahui status risiko osteoporosis anda? (Perasaan/tindakan) Probe:
         ➢ Berjumpa Doktor
         ➢ Mengambil kaedah pencegahan
         ➢ Takut

7. **Pengetahuan mengenai peranan pegawai kesihatan**
   a. Programme yang disediakan
      i. Adakah doktor / ahli farmasi anda pernah menyebut tentang osteoporosis? Apa yang dibincangkan?

ii. Adakah anda pernah mendengar tentang apa-apa jenis osteoporosis seminar, programme penilaian risiko (penyaringan) osteoporosis?
  - Ya-Adakah anda menyertainya? Adakah ia membantu? Bagaimana?
  - Tiada-Adakah anda ingin mereka mengadakan seminar atau programme penilaian tersebut? Jenis manakah?

iii. Adakah anda akan menghadiri programme penyaringanosteoporosis jika terdapat satu? Apakah yang membuat anda mengatakan sedemikian?

iv. Pada pendapat anda, bagaimanakah programme penyaringan itu harus dijalankan?

v. Pada pendapat anda, dimanakah programme tersebut harus disediakan?

8. Perasaan dan sikap terhadap peranan pegawai kesihatan tentang osteoporosis

a. Jangkaan

  i. Pada pendapat anda, apakah yang anda perlu daripada pegawai-pegawai kesihatan (pengawai farmasi, jururawat dan doktor) untuk mencegah osteoporosis?
  Probe:

  - Masa perundingan yang lebih lama
  - Sesi Kaunseling
  - Belas Kasihan

  ii. Siapakah yang anda akan cari untuk mendapatkan maklumat lanjut? Mengapa?

  iii. Apakah pendapat anda tentang perkhidmatan pencegahan osteoporosis kini? Dari segi
  - Sikap
  - Maklumat

  iv. Adakah terdapat perkara yang ingin anda ubah / perbaiki berhubung dengan perkhidmatan pencegahan osteoporosis yang dijalankan sekarang?

5.17 Appendix 7- Topic guide for healthcare professionals (nurses, pharmacists, doctors), Malay version

Topik Panduan- Doktor, Pegawai Farmasi, Jururawat

1. Pemahaman tentang osteoporosis
2. Perasaan dan sikap terhadap osteoporosis
3. Pengetahuan dan pengalaman mengenai langkah pencegahan
4. Pengetahuan tentang imbasan tulang
5. Perasaan dan sikap terhadap imbasan tulang
6. Pengetahuan mengenai peranan pegawai kesihatan
7. Perasaan dan sikap terhadap peranan pegawai kesihatan tentang osteoporosis

Soalan sampel Panduan topik

1. Pemahaman tentang osteoporosis
   a. Definisi
      i. Pada pendapat anda, apakah masalah kesihatan yang mungkin dialami oleh wanita menopaus?
      ii. Pada pendapat anda apakah kesan osteoporosis kepada masyarakat?
         ➢ Impak yang serius atau kecil
      iii. Pada pendapat anda apakah itu osteoporosis? Probe:
         Probes

         ➢ Tulang rapuh
         ➢ Penipisan tulang
         ➢ Tulang lemah

2. Perasaan dan sikap terhadap osteoporosis
   a. Perasaan mengenai osteoporosis
      i. Pernahkan anda terfikir bahawa anda mungkin mempunyai pesakit yang mengalami osteoporosis tetapi tidak dapat dikesan?
      ii. Adakah anda berfikir ini perlu ditangani?
         ➢ Keutamaan
      iii. Bagaimanakah perkara ini boleh ditangani? Pada pendapat anda apakah yang anda boleh lakukan untuk mengesan osteoporosis?
      iv. Pada pendapat anda, apakah peranan doktor/ pegawai farmasi/ jururawat dalam pencegahan osteoporosis?

  b. Pengalaman dengan osteoporosis
    i. Adakah anda mempunyai sebarang pengalaman dengan pesakit osteoporosis di sini? Apa yang anda perlu lakukan?
    probe
     Probes

- ➤ Rawatan Osteoporosis
- ➤ Pencegahan osteoporosis
- ➤ Kaunseling

    ii. Pada pendapat anda, bagaimanakah penglibatan anda dalam rawatan / pencegahan mereka?
    Probe

     Probes

- ➤ Membantu
- ➤ Mencukupi
- ➤ Boleh melakukannya dengan lebih?

    iii. Pada pendapat anda apkah pendapat pesakit terhadap osteoporosis?
  c. Persepsi rawatan osteoporosis
    i. Adakah anda tahu jenis rawatan yang disediakan untuk osteoporosis? Contohnya?
    ii. Apakah pendapat anda tentang rawatan yang sedia ada?
    iii. Adakah anda ingin menambahkan jenis ubat yang kini ada?
    iv. Pada pendapat anda apakah pendapat pesakit tentang jenis ubat yang sedia ada?

3. Pengetahuan dan pengalaman mengenai langkah pencegahan
  a. Jenis-jenis langkah pencegahan
    i. Pada pendapat anda, apakah cara-cara untuk mencegah osteoporosis?
    Probes: Apakah pendapat anda tentang..... .. dan osteoporosis?

- ➤ Perubahan Gaya Hidup
    - ▪ Pengambilan Kalsium / Pemakanan / Vitamin
        - - Pada pendapat anda, dari manakah pesakit mendapatkan kalsium mereka?
        - - Pernahkan anda berjumpa dengan pesakit yang

mengambil vitamin kalsium? (Adakah untuk osteoporosis?)
- Berapa banyak/jenis kalsium yang mereka ambil?
- Pada pendapat anda apakah yang menyebabkan mereka mengubah cara pemakanan / mengambil vitamin?
- Adakah, ini dimasukkan dalam rutin harian mereka?
- Adakah ia sukar ataupun normal untuk menambah ini di dalam rutin harian mereka?
- Adakah mereka berasa kurang selesa atau ia tidak langsung menimbulkan masalah?
- Pada pendapat anda, adakah pengambilan kalsium ini berkesan?
- Pada pendapat anda, apakah perasaan pesakit tentang pengambilan kalsium
    - Senang? Berkesan ke?
- Senaman, Jenis
  - Apakah jenis senaman yang boleh membantu?
  - Seberapa kerap? Sekali seminggu? Berapa minit?
  - Adakah anda berjumpa dengan pesakit yang bersenam seperti yang dinyatakan? Apakah perasaan mereka?
  - Pada pendapat anda, apakah kesan yang diperolehi dari bersenam?
- Berhenti Merokok dan Alkohol
  - Pada pendapat anda adakah merokok dan alkohol memainkan peranan dalam osteoporosis? Mengapa anda berpendapat demikian?
  - Adakah merokok dan minum alkohol adalah perkara biasa di sini?

- Adakah pesakit tahu bahawa merokok dan meminum arak boleh meningkatkan risiko osteoporosis? Mengapakah anda berpendapat sedemikian?

- Ubat
  - Adakah anda tahu bahawa terdapatnya ubat untuk pencegahan osteoporosis?
  - Apakah pendapat anda mengenai pengambilan ubat untuk mencegah osteoporosis?
  - Pada pendapat anda apakah persepsi pesakit tentang pengambilan ubat untuk pencegahan osteoporosis?

- Mencegah jatuh / tangga yang terang / Tiada kekacauan / tikar anti gelincir
  - Penahkan anda mendengar tentang pencegahan jatuh untuk mengelakkan tulang patah kerana ostoporosis? Apakah pendapat anda tentang cara ini?
  - Bagaimanakah anda akan menasihati pesakit untuk mencegah kejatuhan?
  - Adakah ia berkesan?

ii. Pada pendapat anda adakah pesakit tahu tentang cara- cara pencegahan osteoporosis?

b. Sumber pengetahuan cara pencegahan osteoporosis

i. Bagaimana anda mendapat tahu tentang cara pencegahan osteoporosis?

ii. Apakah pendapat anda tentang maklumat ini? Adakah ia membantu?

iii. Adakah anda inginkan maklumat lanjut mengenai pencegahan osteoporosis? Apakah jenis maklumat yang diperlukan?

iv. Pada pendapat anda berapa banyak maklumat yang diperlukan oleh pesakit? Jenis apakah?

v. Dimanakah anda mendapatkan maklumat lebih lanjut mengenai perkara ini?

vi. Dimanakah tempat yang sepatutnya mempunyai maklumat tentang penyakit ini?
  - ➢ Probes: Pegawai farmasi, hospital

4. Pengetahuan imbasan tulang
  a. Pada pendapat anda bagaimanakah osteoporosis dikenal pastikan?
  b. Prosedur Tulang imbasan
    i. Pada pendapat anda, apakah yang terlibat dalam imbasan tulang ?
    ii. Apa pendapat anda tentang radiasi yang terlibat dalam imbasan tulang?
    iii. Apakah pendapat anda terhadap sistem rujukan untuk imbasan tulang di hospital ini?
       Probes

       - ➢ Lancar, populasi yang di tuju
       - ➢ Kriteria rujukan
       - ➢ Garis panduan yang senang difahami
  c. Kepentingan/Kegunaan imbasan Tulang
    i. Bagaimanakah imbasan tulang mengenal pasti seseorang sebagai mangalami osteoporosis?
    ii. Bagaimanakah imbasan tulang dapat meramalkan risiko osteoporosis?
    iii. Apa yang anda fikir tentang kemudahan imbasan tulang kini dan keberadaannya?
       Probes

       - ➢ Masa menunggu
       - ➢ Kos
       - ➢ Bilangan mesin (Keberadaan)
    iv. Adakah perlunya untuk mengunakan alat yang lebih mudah dan murah untuk mengenalpasti risiko osteoporosis terlebih dahulu sebelum menggunakan imbasan tulang? Mengapa anda berpendapat sedemikian?
    v. Pada pendapat anda, adakah pesakit sanggup membayar dan menunggu untuk imbasan tulang?
       probe
         Probes

       - ➢ Waktu masa menunggu
       - ➢ Kebolehcapaian (kemudahan untuk pergi) dan kemampuan (harga)

➢ Penerimaan untuk menjalankan imbasan

5. Perasaan dan sikap terhadap imbasan tulang
    a. Perasaan tentang menjalani imbasan tulang
        i. Adakah anda pernah merujuk pesakit untuk menjalankan imbasan tulang? Apakah yang akan menyebabkan anda berbuat demikian?
        ii. Pada pendapat anda adakah jururawat/pegawai farmasi harus di beri peluang untuk merujuk pesakit untuk menjalankan imbasan tulang?
    b. Status risiko osteoporosis (berbanding dengan penyakit lain)
        i. Apakah pendapat anda tentang mengetahui risiko osteoporosis pesakit berbanding dengan risiko lain seperti kencing manis? Mengapakah anda berpendapat sedemikian? (Anda dan pesakit)
        ii. Pada pendapat anda, apakah persepsi pesakit untuk mengetahui status risiko osteoporosis mereka?

6. Pengetahuan mengenai peranan profesional penjagaan kesihatan
    a. Programme yang disediakan
        i. Adakah anda pernah mendengar tentang bentuk-bentuk programme berkenaan dengan penyaringan/penialain risiko osteoporosis?
           Probes

               ➢ Bagaimanakah ia didakan? Apakah pendapat anda terhadapnya?
               ➢ Dianjurkan oleh siapa? (oleh doktor, pegawai farmasi, jururawat)
               ➢ Di mana? Lokasi: farmasi? Hospital?
        ii. Adakah anda pernah mendengar tentang seminar osteoporosis
           Probes

               ➢ Ya- adakah anda pernah menyertai? Adakah ia berguna? Bagaimana?
               ➢ Tidak- Adakah anda ingin seminar ini dianjurkan? Bagaimana?
        iii. Jika terdapatnya programme saringan osteoporosis, adakah anda akan

menyertai/membantu untuk menjalankannya? Mengapakah anda berkata demikian?

iv. Pada pendapat anda, bagaimanakah program saringan itu harus dijalankan?

Probes

➢ Siapa
➢ Berapa harga/Kos
➢ Bagaimakah ia harus diadakan
➢ Apakah yang perlu dilakukan
➢ Di mana

v. Apakah kebaikan program ini?
vi. Apakah halangan untuk mengadakan program ini?
vii. Pada pendapat anda, adakah pesakit akan menghadiri program ini?
viii. Pada pendapat anda, adakah pegawai kesihatan akan menyertai/menolong program ini?

7. Perasaan dan sikap terhadap peranan pegawai-pegawai kesihatan terhadap osteoporosis

a. Jangkaan

i. Pada pendapat anda, apakah yang boleh dilakukan oleh pegawai-pegawai kesihatan untuk mencegah osteoporosis (rawatan)?

Probes

➢ masa perundingan yang lebih lama
➢ Sesi Kaunseling
➢ Belas Kasihan

ii. Apakah pendapat anda tentang perkhidmatan pencegahan osteoporosis masa kini? Dari segi rawatan?

Probes

➢ Sikap
➢ Maklumat

Adakah terdapat perkara yang ingin anda ubah / perbaiki berhubung dengan perkhidmatan pencegahan osteoporosis yang dijalankan sekarang? (ataupun rawat

5.18

5.19 **Appendix 8- Patients information sheet for Phase one**

Study Title: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study *(patients)*

 Version: V1-PT-08/03/12

> **Part 1** tells you the purpose of this study and what will happen to you if you take part.
>
> **Part 2** gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. **What is the purpose of the study?**

   In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is usually a "silent disease' which means that a woman with

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osteoporosis may experience no symptoms. Consequently, there may be a proportion of women who may have osteoporosis but who are not identified, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk. This would empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to identify the needs of postmenopausal women in osteoporosis screening, prevention and awareness. We would like to better understand some of the barriers and potential solutions so that we are able develop and to further improve the upcoming osteoporosis screening programme.

2. Why have I been invited?

Since you are currently seeing a doctor from the Department of Primary Care Medicine for your medical condition, we would like to explore your experience and perceptions of osteoporosis regarding its screening, prevention and awareness. This information will be used to guide the development of the new osteoporosis screening programme in UMMC. Your care will be more wholesome as you will be seen by both the doctor and the pharmacist.

A total of 20 patients who are attending the Primary Care Family Clinic will be invited to participate in the study.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you attend the interview. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect your treatment or the standard of care you receive*.*

4. What type of study is this?

This is a qualitative study using the method of a one-to-one interview. It is a challenging task to identify the needs and barriers of postmenopausal women attending the clinic. For example, postmenopausal may not consider themselves at risk for osteoporosis and may not know the availability of preventive measures. To find out, we need to conduct one-to-one interviews with postmenopausal women who may be at risk for osteoporosis. By recording and analysing these interviews, we are able to obtain useful information from them and find out the problems they have experienced with regards to osteoporosis.

5. What will happen to me if I take part?

1. Your doctor will ask you if you would like to take part in this study. If you agree, you will be referred to the researcher.

2. Before the one-to-one interview, the researcher will go through the Patient Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

3. The researcher will ask questions related to your experience in osteoporosis screening, awareness and prevention. He/she will record the conversation using an audio tape recorder. The purpose of the recording is to allow the researcher to capture the information discussed during the interview, which is important for them to analyze later.

4. The interview will be conducted in the Primary Care Clinic and will take about 60 minutes.

6. Expenses and payment

You will be given RM 20 as a reimbursement for your travel expenses.

7. What will I have to do?

You are required to answer the questions based on your personal experience during the interview. However, you can refuse to answer any questions which you feel uncomfortable and you can stop the interview at any time.

8. What are the possible disadvantages and risks of taking part?

You will have to spend more time in the hospital as you will be participating in the one-to-one interview after your consultation with the doctor.

During the interview, you might be asked questions about certain topics which are sensitive and may upset you. You can refuse to answer any questions which you feel uncomfortable with, or you can stop the interview anytime. Even if you agree to be taped, you may choose to have the recorder turned off at any time and withdraw from the interview without any negative outcome or prejudice.

9. What happens when the research study stops?

Your doctor will continue to provide medical care for you.

10. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

11. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

12. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

> **This completes Part 1.**
> **If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.**

Part 2

13. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving a reason and without affecting your care.

14. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

15. Will my taking part in this study be kept confidential?

The recorded conversation will be transcribed by the researcher. Only the interviewer and the field supervisor will have access to the audiotape. All information will be coded and anonymised (no name mentioned). Once the transcript has been completed and checked by the interviewer for accuracy, the audiotape will be destroyed professionally.

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic will have your name, telephone and address removed so that you cannot be recognized.

16. Involvement of the General Practitioner/Family doctor (GP)

Your doctor will be informed about your participation in this study.

17. What will happen to the results of the research study?

The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. Direct quotes from the interviews may be used in reports and publications; however, the quotes will be anonymised to

ensure that you cannot be identified. You will also be able to request a summary for the research.

18. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

19. Who has reviewed the study?

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

20. Further information and contact details.

Specific information about this research project:

Toh Li Shean

Tel: 012-2846-849

Email: rinoa8387@yahoo.com

Advice as to whether you should participate:

As above.

Who you should approach if unhappy withthe study:

As above.

6.1   Appendix 9- Patients information sheet for Phase one, Malay version

Maklumat Lembaran pesakit

Tajuk Projek: Menangani keperluan pencegahan osteoporosis di kalangan wanita menopaus di hospital pengajian tinggi di Malaysia: Satu kajian penerokaan kualitatif (pesakit)

Versi: V1-PT-BM-08/03/12

> **Bahagian 1** menerangkan tentang tujuan kajian ini dan apa yang akan berlaku kepada anda jika anda mengambil bahagian.
>
> **Bahagian 2** memberi anda maklumat yang lebih terperinci tentang cara kajian ini dijalankan.

Bahagian 1

Kami ingin menjemput anda untuk mengambil bahagian dalam kajian penyelidikan

Sebelum anda membuat keputusan sama ada untuk menyertai kajian ini, anda perlu memahami mengapa penyelidikan ini dilakukan serta perkara-perkara yang berkaitan dengannya. Sila luangkan masa untuk membaca maklumat berikut dengan teliti, atau berbincang dengan orang lain mengenai kajian ini jika anda berminat.

Hubungi kami jika terdapat sebarang keraguan atau inginkan maklumat lanjut. Luangkan masa untuk memutuskan sama ada anda ingin mengambil bahagian atau sebaliknya

1. **Apakah tujuan kajian ini?**

   Di Pusat Perubatan Universiti Malaya (PPUM), doktor dari Jabatan Perubatan Rawatan Utama merawat banyak wanita menopause untuk pelbagai keadaan seperti

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kencing manis and tekanan darah tinggi. Pada kebiasaanya, osteoporosis merupakan 'penyakit yang senyap' di mana wanita yang menghidap osteoporosis berkemungkinan tidak akan mengalami sebarang gejala osteoporosis. Kesannya, terdapat sebahagian daripada wanita yang tidak sedar bahawa mereka menghidap osteoporosis yang akhirnya mengakibatkan keretakan pada tulang.

Ahli farmasi bersama-sama dengan doktor memainkan peranan yang penting dalam rawatan pesakit. Ahli farmasi boleh menambah perkhidmatan kesihatan dengan menjalankan programme saringan osteoporosis dan mendidik pesakit tentang risiko osteoporosis. Ini dapat menambah ilmu pengetahuan mereka supaya langkah-langkah pencegahan osteoporosis dapat diambil. Sehingga kini, perkhidmatan ini masih belum diwujudkan di PPUM.

Oleh itu, tujuan kajian ini adalah untuk mengenal pasti keperluan wanita menopaus dalam saringan osteoporosis, pencegahan dan kesedarannya. Kami ingin untuk lebih memahami halangan dan penyelesaiannya supaya kita dapat membangun dan meningkatkan lagi program saringan osteoporosis yang akan datang.

2. Mengapa saya dijemput?

Oleh kerana anda sedang berjumpa doktor dari Jabatan Perubatan Rawatan Utama untuk keadaan kesihatan anda, kami ingin mengenalpasti pendapat dan pandangan anda tentang saringan osteoporosis, pencegahan dan

kesedaran. Maklumat ini akan digunakan untuk memperbaiki pelaksanaan program saringan osteoporosis yang akan datang.

Sejumlah 20 pesakit yang menghadiri Jabatan Perubatan Rawatan Utama akan dijemput untuk mengambil bahagian dalam kajian ini.

3. Adakah saya perlu mengambil bahagian?

Penyertaan anda adalah secara sukarela dan bergantung kepada anda untuk membuat keputusan. Kami akan menerangkan tentang kajian dan lembaran maklumat ini kepada anda sebelum anda mengisi soal selidik. Kami akan meminta anda menandatangani borang persetujuan untuk menunjukkan bahawa anda telah bersetuju untuk mengambil bahagian. Anda bebas untuk menarik diri pada bila-bila masa, tanpa memberi sebab. Ini tidak akan menjejaskan rawatan anda atau tahap penjagaan yang akan anda terima*.*

4. Apakah jenis kajian ini?

Kajian ini merupakan kajian kualitatif yang menggunakan kaedah temubual secara individu. Ini merupakan satu tugas yang mencabar untuk mengenal pasti keperluan dan halangan wanita menopaus yang menghadiri klinik. Sebagai contoh, wanita menopaus mungkin tidak tahu adanya langkah-langkah pencegahan osteoporosis dan bahawa mereka mungkin berisiko untuk menghidap osteoporosis. Untuk mengetahui, kami perlu untuk menjalankan temu bual ini dengan wanita menopaus yang mungkin berisiko menghidap osteoporosis. Dengan mengumpul dan menganalisis temubual ini, kami

berpeluang untuk mendapatkan maklumat yang berguna dan mengetahui masalah mengenai osteoporosis yang mungkin dialami.

5. **Apakah yang akan berlaku jika saya mengambil bahagian?**

Penyelidik akan bertanya jika anda berminat untuk mengambil bahagian dalam kajian ini. Sebelum menjalankan temubual ini, penyelidik akan menerangkan tentang Maklumat Lembaran Pesakit kepada anda. Jika anda bersetuju untuk menyertai, penyelidik akan meminta anda menandatangani borang persetujuan, diikuti dengan menjawab soal selidik ringkas mengenai latar belakang anda (10 minit).

Penyelidik akan bertanya soalan yang berkaitan dengan pengalaman anda dalam saringan, kesedaran dan pencegahan osteoporosis. Perbualan audio anda akan dirakam dengan menggunakan pita rakaman audio. Tujuan rakaman adalah untuk membolehkan penyelidik untuk mendapatkan maklumat yang dibincangkan semasa temu duga supaya analisis dapat dikemudian.

Temu bual itu akan dijalankan di Klinik Rawatan Utama dan akan mengambil masa kira-kira 60 minit.

6. **Perbelanjaan dan bayaran**

Sebagai bayaran balik untuk perbelanjaan perjalanan anda.

7. **Apa yang perlu saya lakukan?**

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Anda dikehendaki menjawab soalan-soalan temuduga berdasarkan pengalaman peribadi. Anda boleh menolak untuk menjawab apa-apa soalan yang anda rasa kurang selesa dan anda boleh memberhentikan temuduga pada bila-bila masa.

8. Apakah kelemahan dan risiko yang mungkin terjadi jika saya mengambil bahagian?

Anda dikehendaki meluangkan lebih banyak masa di hospital kerana anda perlu menghadiri temuduga ini sebelum berjumpa dengan doktor anda.

Semasa temu bual tersebut, anda mungkin ditanya mengenai topik yang sensitif dan boleh menyebabkan anda kurang selesa. Anda boleh menolak untuk menjawab apa-apa soalan yang anda rasa kurang selesa atau anda boleh berhenti temuduga pada bila-bila masa. Walaupun anda bersetuju untuk dirakamkan secara audio, anda boleh memilih untuk menghentikan perakaman pada bila-bila masa dan menarik diri daripada temu bual itu tanpa apa-apa hasil negatif atau penjelasan.

9. Apa yang akan berlaku jika kajian penyelidikan ini terhenti?

Doktor anda akan meneruskan rawatan anda seperti biasa.

10. Bagaimana jika berlakunya masalah?

Sebarang aduan mengenai cara anda dilayan semasa kajian atau sebarang bahaya yang mungkin anda alami

akan diberi perhatian. Maklumat terperinci mengenai perkara ini akan dijelaskan di Bahagian 2.

11. Adakah pengambilan bahagian saya dalam kajian ini sulit?

Ya. Kami akan mematuhi amalan etika dan undang-undang serta semua maklumat mengenai anda akan dikendalikan secara sulit. Butirannya terdapat di Bahagian 2.

12. Adakah tujuan kajian ini untuk pendidikan?

Ya. Sebahagian daripada data dari kajian ini akan digunakan untuk kajian PhD.

Ini adalah akhir Bahagian 1.
Jika anda berminat dan sedang mempertimbangkan penyertaan selapas membaca maklumat di Bahagian 1, sila teliti maklumat tambahan di Bahagian 2 sebelum membuat keputusan

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Bahagian 2

13. Apakah yang akan berlaku jika saya tidak mahu meneruskan kajian?

Anda boleh menarik diri dari kajian tanpa memberi sebab dan tanpa menjejaskan rawatan anda.

14. Bagaimana jika terdapat masalah?

Jika anda mempunyai sebarang keraguan mengenai mana-mana aspek kajian ini, anda boleh berbincang dengan penyelidik yang akan berusaha menjawab soalan anda dengan baik.

15. Adakah penglibatan saya dalam kajian ini sulit?

Perbualan yang direkodkan akan disalin oleh penyelidik. Hanya penemuduga dan penyelia bidang akan mempunyai akses kepada rakaman anda. Semua maklumat akan dikodkan dan nama anda tidak akan didedahkan. Sebaik sahaja traskrip itu telah diperiksa oleh penumuduga untuk ketepatak, rakaman audio itu akan dimusnahkan secara profesional. Hanya penyelidik terlibat akan mempunyai akses kepada nota perubatan anda dan data yang dikumpul. Semua maklumat tidak akan didedahkan.

Maklumat yang kami kumpulkan sebagai salinan kertas akan disimpan secara sulit, manakala data elektronik hanya boleh diakses menggunakan kata laluan yang selamat. Hanya penyelidik akan mempunyai akses kepada data.

Data yang dikumpul hanya akan digunakan untuk tujuan kajian ini. Jika data ini perlu digunakan untuk kajian lain, kelulusan baru dari Jawatankuasa Etika akan dipohon.

Semua maklumat yang dikumpul semasa kajian adalah sulit, dan sebarang maklumat yang dibawa keluar dari klinik tidak akan mempunyai nama, nombor telefon serta alamat supaya tidak dapat dikenalpasti.

16. Penglibatan doktor

Doktor anda akan dimaklumkan mengenai penyertaan anda dalam kajian ini.

17. Apakah yang akan berlaku kepada hasil kajian ini?

Keputusan kajian ini akan diterbitkan di dalam jurnal perubatan.

Anda tidak akan dikenal pasti dalam sebarang laporan, penerbitan atau persembahan tanpa persetujuan penuh daripada anda. Petikan langsung daripada rakaman audio mungkin akan digunakan dalam laporan dan penerbitan tanpa mendedahkan identiti anda. Anda juga boleh meminta untuk mendapatkan naskah ringkasan penyelidikan.

18. Siapa yang akan menganjurkan dan membiayai penyelidikan?

Kajian ini dianjurkan oleh Cik Toh Li Shean dan Dr Pauline Lai dari Universiti Malaya, serta Prof Claire Anderson, Prof Madya Encik Wong Kok Thong dan Dr Low Bee Yean dari University of Nottingham. Pembiayaan penyelidikan ini akan diperolehi sama ada daripada University of Nottingham atau Kementerian Pengajian Tinggi.

19. Siapakah yang telah mengkaji/memeriksa kajian ini?

Semua penyelidikan di PPUM diperiksa oleh sekumpulan orang bebas, yang dipanggil Jawatankuasa Etika

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Penyelidikan untuk melindungi keselamatan anda, hak, kesejahteraan dan maruah.

20. **Maklumat lanjut serta butiran lain.**

Maklumat khusus mengenai projek penyelidikan:

Toh Li Shean

Tel: 012-2846-849

Emel: rinoa8387@yahoo.com

Nasihat untuk penglibatan:

Seperti diatas.

Siapa yang perlu anda hubungi jika tidak berpuas hati dengan kajian:

Seperti diatas.

7.1 Appendix 10- Patients consent form for Phase one

Participant identification number for this trial:

CONSENT FORM

Title of Project: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study (Patients)

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 08/03/12 (Version 1-PT) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University Malaya Medical Center, the University of Malaya and the University of Nottingham, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to have the interview audio-taped as described in the informatic sheetet dated 08/03/12 (Version 1-PT)

5. I give my consent for anonymised direct quotes to be used in reports and publications.

6. I agree to take part in the above study.

_____   _____

Name of Participant   Date   Signature

_____   _____

Name of Person taking consent   Date   Signature

Appendix 11- Patients consent form for Phase one,

7.3 Malay version

Nombor pengenalan perserta untuk kajian ini:

BORANG PERSETUJUAN

Tajuk Projek: **Menangani keperluan pencegahan osteoporosis di kalangan wanita menopaus di hospital pengajian tinggi di Malaysia: Satu kajian penerokaan kaulitatif (pesakit)**

Nama Penyelidik: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Sila tandatangan di kotak berkenaan

1. Saya mengesahkan bahawa saya telah membaca dan memahami Iembaran maklumat yang bertarikh 08/03/12 (Version 1-PT-BM) untuk kajian di atas. Saya juga telah diberi peluang untuk mempertimbangkan maklumat, bertanya soalan dan mendapatkan jawapan yang memuaskan.

2. Saya memahami bahawa penyertaan saya adalah secara sukarela dan saya bebas untuk menarik diri pada bila-bila masa, tanpa memberi apa-apa sebab, tanpa menjejaskan hak undang-undang saya.

3. Saya faham bahawa data yang berkaitan dan data yang dikumpulkan semasa kajian, boleh dilihat oleh individu yang bertanggungjawab dari Universiti Malaya, Pusat Perubatan Universiti Malaya dan University of Nottingham. Saya memberi kebenaran kepada individu-individu ini untuk mendapatkan maklumat daripada data ini.

4. Saya bersetuju supaya wawancara audio akan dirakamkan seperti yang dinyatakan dalam lembaran maklumat yang bertarikh 08/03/12 (Version 1-PT-BM).

5. Saya memberi kebenaran supaya petikan langsung daripada wawancara dapat digunakan dalam laporan dan penerbitan tanpa mendedahkan identiti saya.

6. Saya bersetuju untuk menyertai kajian di atas.

_____   _____

Nama Peserta   Tarikh   Tandatangan

_____   _____

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7.4   Appendix 12- Nurses information sheet for Phase one

Participant Information Sheet

Study Title: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study *(nurses)*

Version: V1-NUR-08/03/12

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is usually

a "silent disease' which means that a woman with osteoporosis may experience no symptoms. Consequently, there may be a proportion of women who may have osteoporosis but who are not identified, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk and empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to identify the needs of postmenopausal community dwelling women in osteoporosis screening, prevention and awareness. We would like to better understand some of the barriers and potential solutions so that we are able develop and to further improve the upcoming osteoporosis screening program.

2. Why have I been invited?

You have been invited because of your experience and expertise in working in the Department of Primary Care medicine. Your views and opinions will help us to identify the problems and needs to be addressed in the screening, prevention and awareness of osteoporosis. This information is then used to guide the set up of the osteoporosis screening program.

A total of five nurses will be invited to participate in the study. We will also be interviewing twenty postmenopausal women, ten pharmacists, ten physicians and five policymakers.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you attend the interview. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

4. What type of study is this?

This is a qualitative study using the method of a one-to-one interview. It is a challenging task to identify the needs and barriers of the nurses in managing postmenopausal women who may be at risk for osteoporosis. To find out, we need to conduct one-to-one interviews. By recording and analysing these interviews, we are able to obtain useful information from you.

5. What will happen to me if I take part?

Before the one-to-one interview, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

The researcher will ask questions related to your experience in osteoporosis screening, awareness and prevention. He/she will record the conversation using an

audio tape recorder. The purpose of the recording is to allow the researcher to capture the information discussed during the interview, which is important for them to analyze later.

The interview will take about 60 minutes.

6. Expenses and payment

You will be given RM 50 to compensate for the time you have taken to participate in this research.

7. What will I have to do?

You are required to answer the questions based on your personal experience during the interview. However, you can refuse to answer any questions which you feel uncomfortable and you can stop the interview at any time.

8. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

9. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

10. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

the study?

You can withdraw from the study without giving any reason.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

13. Will my taking part in this study be kept confidential?

The recorded conversation will be transcribed by the researcher. Only the interviewer and the field supervisor will have access to the audiotape. All information will be coded and anonymised (no name mentioned). Once the transcript has been completed and checked by the interviewer for accuracy, the audiotape will be destroyed professionally.

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic will have your name, telephone and address removed so that you cannot be recognized.

14. What will happen to the results of the research study?

The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. Direct quotes from the interviews may be used in reports and publications; however, the quotes will be anonymised to ensure that you cannot be identified. You will also be able to request a summary for the research.

15. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai Siew Mei from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

16. Who has reviewed the study?

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

17. **Further information and contact details.**

Specific information about this research project:

Toh Li Shean

Tel: 012-2846-849

Email: rinoa8387@yahoo.com

Advice as to whether you should participate:

As above.

Who you should approach if unhappy with the study:

As above.

8.1 Appendix 13- Nurses information sheet for Phase one, Malay version

Maklumat Lembaran pesakit

Tajuk Projek: Menangani keperluan pencegahan osteoporosis di kalangan wanita menopaus di hospital pengajian tinggi di Malaysia: Satu kajian penerokaan kualitatif (Jururawat)

Versi: V1-NUR-BM-08/03/12

> **Bahagian 1** menerangkan tentang tujuan kajian ini dan apa yang akan berlaku kepada anda jika anda mengambil bahagian.
>
> **Bahagian 2** memberi anda maklumat yang lebih terperinci tentang cara kajian ini dijalankan.

Bahagian 1

Kami ingin menjemput anda untuk mengambil bahagian dalam kajian penyelidikan.

Sebelum anda membuat keputusan sama ada untuk menyertai kajian ini, anda perlu memahami mengapa penyelidikan ini dilakukan serta perkara-perkara yang berkaitan dengannya. Sila luangkan masa untuk membaca maklumat berikut dengan teliti, atau berbincang dengan orang lain mengenai kajian ini jika anda berminat.

Hubungi kami jika terdapat sebarang keraguan atau sebarang maklumat lanjut. Luangkan masa untuk memutuskan sama ada anda ingin mengambil bahagian atau sebaliknya.

1. Apakah tujuan kajian ini?

Di Pusat Perubatan Universiti Malaya (PPUM), doktor dari Jabatan Perubatan Rawatan Utama merawat banyak

wanita menopause untuk pelbagai keadaan seperti kencing manis and tekanan darah tinggi. Pada kebiasaanya, osteoporosis merupakan 'penyakit yang senyap' di mana wanita yang menghidap osteoporosis berkemungkinan tidak akan mengalami sebarang gejala osteoporosis. Kesannya, terdapat sebahagian daripada wanita yang tidak sedar bahawa mereka menghidap osteoporosis yang akhirnya mengakibatkan keretakan pada tulang.

Ahli farmasi bersama-sama dengan doktor memainkan peranan yang penting dalam rawatan pesakit. Ahli farmasi boleh menambah perkhidmatan kesihatan dengan menjalankan program saringan osteoporosis dan mendidik pesakit tentang risiko osteoporosis. Ini dapat menambah ilmu pengetahuan mereka supaya langkah-langkah pencegahan osteoporosis dapat diambil. Sehingga kini, perkhidmatan ini masih belum diwujudkan di PPUM.

Oleh itu, tujuan kajian ini adalah untuk mengenal pasti keperluan wanita menopaus dalam saringan osteoporosis, pencegahan dan kesedarannya. Kami ingin untuk lebih memahami halangan dan penyelesaiannya supaya kami dapat membangun dan meningkatkan lagi program saringan osteoporosis yang akan datang.

2. Mengapa saya dijemput?

Oleh kerana anda mempunyai pengalaman dan kepakaran semasa bekerja di Jabatan Perubatan Rawatan Utama. Pandangan dan pendapat anda akan membantu kami

untuk mengenal pasti masalah dan keperluan yang perlu ditangani dalam pemeriksaan, pencegahan dan kesedaran osteoporosis. Maklumat ini akan digunakan untuk memperbaiki pelaksanaan program saringan osteoporosis yang akan datang.

Sejumlah 5 orang jururawat akan dijemput untuk mengambil bahagian dalam kajian ini.

3. Adakah saya perlu mengambil bahagian?

Penyertaan anda adalah secara sukarela dan bergantung kepada anda untuk membuat keputusan. Kami akan menerangkan tentang kajian dan lembaran maklumat ini kepada anda sebelum anda mengisi soal selidik. Kami akan meminta anda menandatangani borang persetujuan untuk menunjukkan bahawa anda telah bersetuju untuk mengambil bahagian. Anda bebas untuk menarik diri pada bila-bila masa, tanpa memberi sebab. Ini tidak akan menjejaskan rawatan anda atau tahap penjagaan yang akan anda terima.

4. Apakah jenis kajian ini?

Kajian ini merupakan kajian kualitatif yang menggunakan kaedah temubual secara individu. Ini merupakan satu tugas yang mencabar untuk mengenal pasti keperluan dan halangan wanita menopaus yang menghadiri klinik. Sebagai contoh, wanita menopaus mungkin tidak tahu adanya langkah-langkah pencegahan osteoporosis dan bahawa mereka mungkin berisiko untuk menghidap osteoporosis. Untuk mengetahui, kita perlu untuk menjalankan temu bual ini. Dengan mengumpul dan menganalisis temubual ini, kita berpeluang untuk

mendapatkan maklumat yang berguna dan mengetahui masalah mengenai osteoporosis yang mungkin dialami.

5. **Apakah yang akan berlaku jika saya mengambil bahagian?**

   1. Sebelum menjalankan temubual ini, penyelidik akan menerangkan tentang Maklumat Lembaran Pesakit kepada anda. Jika anda bersetuju untuk menyertai, penyelidik akan meminta anda menandatangani borang persetujuan, diikuti dengan menjawab soal selidik ringkas mengenai latar belakang anda (10 minit).

   2. Penyelidik akan bertanya soalan yang berkaitan dengan pengalaman anda dalam saringan, kesedaran dan pencegahan osteoporosis. Perbualan audio anda akan dirakam dengan menggunakan pita rakaman audio. Tujuan rakaman adalah untuk membolehkan penyelidik menangkap maklumat yang dibincangkan semasa temu duga supaya analisis dapat dilakukan.

   3. Temu bual itu akan dijalankan di Klinik Rawatan Utama dan akan mengambil masa kira-kira 60 minit.

6. **Perbelanjaan dan bayaran**

   Anda akan diberi RM 50 sebagai pampasan bagi masa yang anda telah ambil untuk mengambil bahagian dalam kajian ini.

7. Apa yang saya perlu lakukan?

Anda dikehendaki menjawab soalan-soalan temuduga berdasarkan pengalaman peribadi. Anda boleh menolak untuk menjawab mana-mana soalan yang anda rasa kurang selesa dan anda boleh memberhentikan temuduga pada bila-bila masa.

8. Bagaimana jika berlakunya masalah?

Sebarang aduan mengenai cara anda dilayan semasa kajian atau sebarang bahaya yang mungkin anda alami akan diberi perhatian. Maklumat terperinci mengenai perkara ini akan dijelaskan di Bahagian 2.

9. Adakah pengambilan bahagian saya dalam kajian ini sulit?

Ya. Kami akan mematuhi amalan etika dan undang-undang serta semua maklumat mengenai anda akan dikendalikan secara sulit. Butirannya terdapat di Bahagian 2.

10. Adakah tujuan kajian ini untuk pendidikan?

Ya. Sebahagian daripada data dari kajian ini akan digunakan untuk kajian PhD.

Ini adalah akhir Bahagian 1.
Jika anda berminat dan sedang mempertimbangkan penyertaan selapas membaca maklumat di Bahagian 1, sila teliti maklumat tambahan di Bahagian 2 sebelum membuat keputusan

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Bahagian 2

11. Apakah yang akan berlaku jika saya tidak mahu meneruskan kajian?

Anda boleh menarik diri dari kajian tanpa memberi sebab dan tanpa menjejaskan rawatan anda.

12. Bagaimana jika terdapat masalah?

Jika anda mempunyai sebarang keraguan mengenai mana-mana aspek kajian ini, anda boleh berbincang dengan penyelidik yang akan berusaha menjawab soalan anda dengan baik.

13. Adakah penglibatan saya dalam kajian ini sulit?

Perbualan yang direkodkan akan disalin oleh penyelidik. Hanya penemuduga dan penyelia bidang akan mempunyai akses kepada rakaman anda. Semua maklumat akan dikodkan dan nama anda tidak akan didedahkan. Sebaik sahaja traskrip itu telah diperiksa oleh penumuduga untuk ketepatak, rakaman audio itu akan dimusnahkan secara profesional. Hanya penyelidik terlibat akan mempunyai akses kepada nota perubatan anda dan data yang dikumpul. Semua maklumat tidak akan didedahkan.

Maklumat yang kami kumpulkan sebagai salinan kertas akan disimpan secara sulit, manakala data elektronik hanya boleh diakses menggunakan kata laluan yang selamat. Hanya penyelidik akan mempunyai akses kepada data.

Data yang dikumpul hanya akan digunakan untuk tujuan kajian ini. Jika data ini perlu digunakan untuk kajian lain, kelulusan baru dari Jawatankuasa Etika akan dipohon.

Semua maklumat yang dikumpul semasa kajian adalah sulit, dan sebarang maklumat yang dibawa keluar dari klinik tidak akan mempunyai nama, nombor telefon serta alamat supaya tidak dapat dikenalpasti.

14. **Apakah yang akan berlaku kepada hasil kajian ini?**

Keputusan kajian ini akan diterbitkan di dalam jurnal perubatan.

Anda tidak akan dikenal pasti dalam sebarang laporan, penerbitan atau persembahan tanpa persetujuan penuh daripada anda. Petikan langsung daripada rakaman audio mungkin akan digunakan dalam laporan dan penerbitan tanpa mendedahkan identiti anda. Anda juga boleh meminta untuk mendapatkan naskah ringkasan penyelidikan.

15. **Siapa yang akan menganjurkan dan membiayai penyelidikan?**

Kajian ini dianjurkan oleh Cik Toh Li Shean dan Dr Pauline Lai dari Universiti Malaya, serta Prof Claire Anderson, Prof Madya Encik Wong Kok Thong dan Dr Low Bee Yean dari University of Nottingham. Pembiayaan penyelidikan ini akan diperolehi sama ada daripada University of Nottingham atau Kementerian Pengajian Tinggi.

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16. Siapakah yang telah mengkaji/memeriksa kajian ini?

Semua penyelidikan di PPUM diperiksa oleh sekumpulan orang bebas, yang dipanggil Jawatankuasa Etika Penyelidikan untuk melindungi keselamatan anda, hak, kesejahteraan dan maruah.

17. Maklumat lanjut serta butiran lain.

Maklumat khusus mengenai projek penyelidikan:

Toh Li Shean

Tel: 012-2846-849

Emel: rinoa8387@yahoo.com

Nasihat untuk penglibatan:

Seperti diatas

Siapa yang perlu anda hubungi jika tidak berpuas hati dengan kajian:

Seperti diatas

9.1 Appendix 14- Pharmacists information sheet for Phase one

Participant Information Sheet

Study Title: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study *(pharmacist)*
 Version: V1-PHARM-08/03/12

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is usually a "silent disease' which means that a woman with osteoporosis may experience no symptoms. Consequently,

there may be a proportion of women who may have osteoporosis but who are not identified, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk and empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to identify the needs of postmenopausal community dwelling women in osteoporosis screening, prevention and awareness. We would like to better understand some of the barriers and potential solutions so that we are able develop and to further improve the upcoming osteoporosis screening program.

2. Why have I been invited?

You have been invited because of your experience as an outpatient pharmacist in managing postmenopausal women. Your views and opinions will help us to identify the problems and needs to be addressed in the screening, prevention and awareness of osteoporosis. This information is then used to guide the set up of the osteoporosis screening program.

A total of ten pharmacists will be invited to participate in the study. We will also be interviewing twenty

postmenopausal women, ten physicians, five nurses and five policymakers.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you attend the interview. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

4. What type of study is this?

This is a qualitative study using the method of a one-to-one interview. It is a challenging task to identify the needs and barriers of the outpatient pharmacist in managing postmenopausal women who may be at risk for osteoporosis. To find out, we need to conduct one-to-one interviews. By recording and analysing these interviews, we are able to obtain useful information from you.

5. What will happen to me if I take part?

1. Before the one-to-one interview, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

2. The researcher will ask questions related to your experience in osteoporosis screening, awareness and prevention. He/she will record the conversation using an audio tape recorder. The purpose of the recording

is to allow the researcher to capture the information discussed during the interview, which is important for them to analyze later.

3. The interview will take about 60 minutes.

6. Expenses and payment

You will be given RM 50 to compensate for the time you have taken to participate in this research.

7. What will I have to do?

You are required to answer the questions based on your personal experience during the interview. However, you can refuse to answer any questions which you feel uncomfortable and you can stop the interview at any time.

8. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

9. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

10. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

> **This completes Part 1.**
> **If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.**

Part 2

11. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving any reason.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

13. Will my taking part in this study be kept confidential?

The recorded conversation will be transcribed by the researcher. Only the interviewer and the field supervisor will have access to the audiotape. All information will be coded and anonymised (no name mentioned). Once the transcript has been completed and checked by the interviewer for accuracy, the audiotape will be destroyed professionally.

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic will have your name, telephone and address removed so that you cannot be recognized.

14. What will happen to the results of the research study?

The results of this study will be published in medical journals.
You will not be identified in any report, publications or presentation without seeking your full consent. Direct quotes from the interviews may be used in reports and publications; however, the quotes will be anonymised to ensure that you cannot be identified. You will also be able to request a summary for the research.

15. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

16. **Who has reviewed the study?**

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

17. **Further information and contact details.**

Specific information about this research project:

Toh Li Shean

Tel: 012-2846-849

Email: rinoa8387@yahoo.com

Advice as to whether you should participate:

As above.

Who you should approach if unhappy with the study:

As above.

11.1 Appendix 15- Doctors information sheet for Phase one

Participant Information Sheet

Study Title: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study *(physicians)*
 Version: V1-DR-08/03/12

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is usually a "silent disease' which means that a woman with osteoporosis may experience no symptoms. Consequently, there may be a proportion of women who may have

osteoporosis but who are not identified, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk and empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to identify the needs of postmenopausal community dwelling women in osteoporosis screening, prevention and awareness. We would like to better understand some of the barriers and potential solutions so that we are able develop and to further improve the upcoming osteoporosis screening program.

2. Why have I been invited?

You have been invited because of your experience and expertise in managing postmenopausal women in the Department of Primary Care Medicine. Your views and opinions will help us to identify the problems and needs to be addressed in the screening, prevention and awareness of osteoporosis. This information is then used to guide the set up of the osteoporosis screening programme.

A total of ten physicians will be invited to participate in the study. We will also be interviewing twenty postmenopausal women, ten pharmacists, five nurses and five policymakers.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you attend the interview. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

4. What type of study is this?

This is a qualitative study using the method of a one-to-one interview. It is a challenging task to identify the needs and barriers of the physicians in managing postmenopausal women who may be at risk for osteoporosis. To find out, we need to conduct one-to-one interviews. By recording and analysing these interviews, we are able to obtain useful information from you.

5. What will happen to me if I take part?

1. Before the one-to-one interview, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

2. The researcher will ask questions related to your experience in osteoporosis screening, awareness and prevention. He/she will record the conversation using an audio tape recorder. The purpose of the recording is to allow the researcher to capture the information

discussed during the interview, which is important for them to analyze later.

3. The interview will take about 60 minutes.

6. Expenses and payment

You will be given RM 50 to compensate for the time you have taken to participate in this research.

7. What will I have to do?

You are required to answer the questions based on your personal experience during the interview. However, you can refuse to answer any questions which you feel uncomfortable and you can stop the interview at any time.

8. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

9. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

10. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

11. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving any reason.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions

13. Will my taking part in this study be kept confidential?

The recorded conversation will be transcribed by the researcher. Only the interviewer and the field supervisor will have access to the audiotape. All information will be coded and anonymised (no name mentioned). Once the transcript has been completed and checked by the interviewer for accuracy, the audiotape will be destroyed professionally.

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic will have your name, telephone and address removed so that you cannot be recognized.

14. What will happen to the results of the research study?

The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. Direct quotes from the interviews may be used in reports and publications; however, the quotes will be anonymised to ensure that you cannot be identified. You will also be able to request a summary for the research.

15. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai Siew Mei from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

16. Who has reviewed the study?

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

17. Further information and contact details.

Specific information about this research project

Toh Li Shean

Tel: 012-2846-849

Email: rinoa8387@yahoo.com

Advice as to whether you should participate

As above

Who you should approach if unhappy with the study

As above

12.1   Appendix 16- Policy makers information sheet for Phase one

Participant Information Sheet

Study Title: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study *(policy makers)*
 Version: V1-POL-08/03/12

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is usually a "silent disease' which means that a woman with osteoporosis may experience no symptoms. Consequently, there may be a proportion of women who may have

osteoporosis but who are not identified, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk and empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to identify the needs of postmenopausal community dwelling women in osteoporosis screening, prevention and awareness. We would like to better understand some of the barriers and potential solutions so that we are able develop and to further improve the upcoming osteoporosis screening programme.

2. Why have I been invited?

You have been invited because of your position as a policy maker in UMMC. Your views and opinions will help us to identify the problems and needs to be addressed in the screening, prevention and awareness of osteoporosis. This information is then used to guide the set up of the osteoporosis screening programme.

A total of five policy makers will be invited to participate in the study. We will also be interviewing twenty postmenopausal women, ten pharmacists, ten physicians and five nurses.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you attend the interview. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

4. What type of study is this?

This is a qualitative study using the method of a one-to-one interview. It is a challenging task to identify the needs and barriers of policy makers in running a tertiary, referral centre. To find out, we need to conduct one-to-one interviews. By recording and analysing these interviews, we are able to obtain useful information from you.

5. What will happen to me if I take part?

1. Before the one-to-one interview, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

2. The researcher will record the conversation using an audio tape recorder. The purpose of the recording is to allow the researcher to capture the information discussed during the interview, which is important for them to analyse later.

3. The interview will take about 60 minutes.

6. Expenses and payment

You will be given RM 50 to compensate for the time you have taken to participate in this research.

7. What will I have to do?

You are required to answer the questions based on your personal experience during the interview. However, you can refuse to answer any questions which you feel uncomfortable and you can stop the interview at any time.

8. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

9. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

10. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

11. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving any reason.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

13. Will my taking part in this study be kept confidential?

The recorded conversation will be transcribed by the researcher. Only the interviewer and the field supervisor will have access to the audiotape. All information will be coded and anonymised (no name mentioned). Once the transcript has been completed and checked by the interviewer for accuracy, the audiotape will be destroyed professionally.

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic will have your name, telephone and address removed so that you cannot be recognized.

14. What will happen to the results of the research study?

The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. Direct quotes from the interviews may be used in reports and publications; however, the quotes will be anonymised to ensure that you cannot be identified. You will also be able to request a summary for the research.

15. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr. Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

16. Who has reviewed the study?

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

17. Further information and contact details.

Specific information about this research project:

Toh Li Shean

Tel: 012-2846-849

Email: rinoa8387@yahoo.com

Advice as to whether you should participate:

As above.

Who you should approach if unhappy with the study:

As above.

13.1   Appendix 17- Nurses consent form for Phase one

Participant identification number for this trial:

CONSENT FORM

Title of Project: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study (Nurses)

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 08/03/12 (Version 1-NUR) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I agree to have the interview audio-taped as described the information sheet d dated 08/03/12 (Version 1-NUR).

4. I give my consent for anonymised direct quotes to be used in reports and publications.

5. I agree to take part in the above study.

_____   _____

Name of Participant   Date   Signature

_____   _____

Name of Person taking consent   Date Signature

13.2 Appendix 18- Nurses consent form for Phase one, Malay version

Nombor pengenalan perserta untuk kajian ini:

BORANG PERSETUJUAN

Tajuk Projek: **Menangani keperluan pencegahan osteoporosis di kalangan wanita menopaus di hospital pengajian tinggi di Malaysia: Satu kajian penerokaan kualitatif (pesakit)**

Nama Penyelidik: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Sila tandatangan di kotak berkenaan

1. Saya mengesahkan bahawa saya telah membaca dan memahami Iembaran maklumat yang bertarikh 08/03/12 (Version 1-NUR-BM) untuk kajian di atas. Saya juga telah diberi peluang untuk mempertimbangkan maklumat, bertanya soalan dan mendapatkan jawapan yang memuaskan.

2. Saya memahami bahawa penyertaan saya adalah secara sukarela dan saya bebas untuk menarik diri pada bila-bila masa, tanpa memberi apa-apa sebab, tanpa menjejaskan hak undang-undang saya.

4. Saya bersetuju supaya wawancara audio akan dirakamkan seperti yang dinyatakan dalam lembaran maklumat yang bertarikh 08/03/12 (Version 1- NUR-BM).

5. Saya memberi kebenaran supaya petikan langsung daripada wawancara dapat digunakan dalam laporan dan penerbitan tanpa mendedahkan identiti saya.

6. Saya bersetuju untuk menyertai kajian di atas.

_____ _____

Nama Peserta Tarikh Tandatangan

_____ _____

Pihak Yang Mengambil Persetujuan Tarikh Tandatangan

13.3   Appendix 19- Pharmacists consent form for Phase one

Participant identification number for this trial:

CONSENT FORM

Title of Project: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study (Pharmacist)

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 08/03/12 (Version 1-PHARM) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I agree to have the interview audio-taped as described in the information sheet dated 08/03/12 (Version 1-PHARM).

4. I give my consent for anonymised direct quotes to be used in reports and publications.

5. I agree to take part in the above study.

_____   _____

Name of Participant   Date   Signature

_____   _____

Name of Person taking consent   Date   Signature

504

13.4 Appendix 20- Doctors consent form for Phase one

Participant identification number for this trial:

CONSENT FORM

Title of Project: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study (Doctor*)*

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 08/03/12 (Version 1-DR) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I agree to have the interview audio-taped described in the information sheet dated 08/03/12 (Version 1-DR).

4. I give my consent for anonymised direct quotes to be used in reports and publications.

5. I agree to take part in the above study.

_____   _____

Name of Participant   Date   Signature

_____   _____

Name of Person taking consent   Date   Signature

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13.5 Appendix 21- Policy makers consent form for Phase one

13.6 Participant identification number for this trial:

CONSENT FORM

Title of Project: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: An exploratory qualitative study (Policy maker*)*

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 08/03/12 (Version 1-POL) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I agree to have the interview audio-taped as described the information sheet d dated 08/03/12 (Version 1-POL).

4. I give my consent for anonymised direct quotes to be used in reports and publications.

5. I agree to take part in the above study.

_____   _____
Name of Participant   Date   Signature

_____   _____
Name of Person taking consent   Date   Signature

13.7   Appendix 22- Ethical approval for Phase one

UNIVERSITI MALAYA
PUSAT PERUBATAN UM

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE
ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 FAXIMILE: 03-79494638

NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre	ETHICS COMMITTEE/IRB REFERENCE NUMBER:
ADDRESS: LEMBAH PANTAI 59100 KUALA LUMPUR	914.14
PROTOCOL NO: TITLE: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysian: An exploratory qualitative study	
PRINCIPAL INVESTIGATOR: Mrs. Toh Li Shean TELEPHONE: KOMTEL:	SPONSOR:

The following item [✓] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[✓] Application Form   Ver date: 20 Mar 12
[✓] Study Protocol   Ver date:
[ ] Investigator Brochure   Ver date:
[✓] Patient Information Sheet
[✓] Consent Form
[ ] Questionnaire
[✓] Investigator(s) CV's (Mrs. Toh Li Shean)

and have been [✓]

[✓] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Investigator are required to:
1) follow instructions, guidelines and requirements of the Medical Ethics Committee.
2) report any protocol deviations/violations to Medical Ethics Committee.
3) provide annual and closure report to the Medical Ethics Committee.
4) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.
5) note that Medical Ethics Committee may audit the approved study.

Date of approval: 18th APRIL 2012

c.c   Head
        Department of Primary Care Medicine

        Deputy Dean (Research)
        Faculty of Medicine

        Secretary   PROF. DATUK LOOI LAI MENG
        Medical Ethics Committee   Chairman
        University Malaya Medical Centre   Medical Ethics Committee

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13.8 Appendix 23- Finalized version of the Satisfaction questionnaire for osteoporosis Prevention (SQOP)

self/assisted

This questionnaire is to assess your satisfaction about a pharmacist conducted osteoporosis prevention programme. Filling out this questionnaire will provide information for us to further improve our services.
Please tick the answer that best suits your opinion.

A. Clinical Services

Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)

1. The service was conducted at a time that _____ (fill in the blank) for you.

- ☐ 5 Was definitely suitable
- ☐ 4 Was probably suitable
- ☐ 3 Made no difference
- ☐ 2 Was probably unsuitable
- ☐ 1 Was definitely unsuitable

2. During the session, what did you think about the time given to discuss your problems with the pharmacist?

- ☐ 5 Definitely enough time
- ☐ 4 Probably enough time
- ☐ 3 No difference
- ☐ 2 Probably insufficient time
- ☐ 1 Definitely insufficient time

3. How would you rate the location of this service?

- ☐ 5 Very convenient
- ☐ 4 Somewhat convenient
- ☐ 3 No difference
- ☐ 2 Somewhat inconvenient
- ☐ 1 Very inconvenient

4. How would you rate the comfort of the location?

- ☐ 5 Very comfortable
- ☐ **4** Somewhat comfortable
- ☐ 3 No difference
- ☐ 2 Somewhat uncomfortable
- ☐ 1 Very uncomfortable

5. If you have questions about osteoporosis, would you ask the pharmacist?

- ☐ 5 Yes, I would definitely trust the answer given by the pharmacist.
- ☐ 4 Yes, I would probably trust the answer given by the pharmacist.
- ☐ 3 No comment.
- ☐ 2 No, I probably would not trust the answer given by the pharmacist.
- ☐ 1 No, I definitely would not trust the answer given by the pharmacist.

6. Was the pharmacist easy to talk to?

- ☐ 5 Definitely approachable
- ☐ 4 Probably approachable
- ☐ 3 No difference
- ☐ 2 Probably unapproachable
- ☐ 1 Definitely unapproachable

7. How would you rate the service provided by the pharmacist?

- ☐ 5 Definitely useful
- ☐ 4 Useful
- ☐ 3 No difference
- ☐ 2 Not useful
- ☐ 1 Definitely not useful

8. How would you rate the advice given by the pharmacist?

- ☐ 5 Definitely helpful
- ☐ 4 Probably helpful
- ☐ 3 No difference
- ☐ 2 Probably not helpful
- ☐ 1 Definitely not helpful at all

9. How would you rate the overall quality of service that was given by the pharmacist to you?

- ☐ 5 Excellent
- ☐ 4 Good
- ☐ 3 Satisfactory
- ☐ 2 Fair
- ☐ 1 Poor

10. This pharmacist service should _____ (fill in the blank)

- ☐ 5 Definitely be continued
- ☐ 4 Probably be continued
- ☐ 3 No comment

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		☐	₂ Probably be discontinued
		☐	₁ Definitely be discontinued

11	What do you think about having the same pharmacist to see you for subsequent osteoporosis care?	☐	₅ Yes, I would definitely like that
		☐	₄ Yes, I would probably like that
		☐	₃ No difference
		☐	₂ No, I probably would not like that
		☐	₁ No, I definitely would not like that

12	Pharmacist in other hospitals should _____ (fill in the blank) this service	☐	₅ Definitely provide
		☐	₄ Probably provide
		☐	₃ No comment
		☐	₂ Probably not provide
		☐	₁ Definitely not provide

13	How would you rate the amount of information provided to prevent falls?	☐	₅ Definitely enough
		☐	₄ Probably enough
		☐	₃ No difference
		☐	₂ Probably not enough
		☐	₁ Definitely not enough

14	How would you rate the amount of information provided to change your diet to prevent bone loss?	☐	₅ Definitely enough
		☐	₄ Probably enough
		☐	₃ No difference
		☐	₂ Probably not enough
		☐	₁ Definitely not enough

15	How would you rate the amount of information provided on the exercises to help strengthen bones?	☐	₅ Definitely enough
		☐	₄ Probably enough
		☐	₃ No difference
		☐	₂ Probably not enough
		☐	₁ Definitely not enough

16	Would you pay for a pharmacist counselling service?	☐	₅ Yes, definitely
		☐	₄ Yes, probably
		☐	₃ No difference
		☐	₂ No, probably not
		☐	₁ No, definitely not

17	If yes, how much are you willing to pay for each visit to the pharmacist? If you are not willing to pay anything for the service, please proceed to question 18.	☐	₅RM1-5
		☐	₄RM6-10
		☐	₃RM11-15
		☐	₂RM16-20
		☐	₁More than RM20

18	How would you rate your understanding of osteoporosis now?	☐	₅Much better than before
		☐	₄Slightly better than before
		☐	₃Same as before
		☐	₂Slightly worse than before
		☐	₁Much worse than before

B. Types of counselling

Please indicate how you found the following information which the pharmacist may have provided. If you were not provided with any counselling, please omit this section.

19	Explanation of osteoporosis	❑	$_0$Not Applicable
		❑	$_1$Definitely not useful
		❑	$_2$Not useful
		❑	$_3$No difference
		❑	$_4$Useful
		❑	$_5$Extremely useful

20	Explanation of consequences of untreated osteoporosis	❑	$_0$Not Applicable
		❑	$_1$Definitely not useful
		❑	$_2$Not useful
		❑	$_3$No difference
		❑	$_4$Useful
		❑	$_5$Extremely useful

21	Explanation on how osteoporosis can be prevented via lifestyle change(s)	❑	$_0$Not Applicable
		❑	$_1$Definitely not useful
		❑	$_2$Not useful
		❑	$_3$No difference
		❑	$_4$Useful
		❑	$_5$Extremely useful

22	Explanation on the available methods to screen for osteoporosis	❑	$_0$Not Applicable
		❑	$_1$Definitely not useful
		❑	$_2$Not useful
		❑	$_3$No difference
		❑	$_4$Useful
		❑	$_5$Extremely useful

23	Osteoporosis booklet provided	❑	$_0$Not Applicable
		❑	$_1$Definitely not useful
		❑	$_2$Not useful
		❑	$_3$No difference
		❑	$_4$Useful
		❑	$_5$Extremely useful

13.9   Appendix 24- Osteoporosis booklet

You can prevent osteoporosis!

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1.0 What is osteoporosis?

- Osteoporosis is a disease that weakens bones, resulting in an increased loss of bone and bone strength.

- This makes bones more at risk to sudden and unexpected fractures.

- Often the disease progresses **without** any symptoms or pain and is not discovered until weakened bones cause painful fractures.

Osteoporosis may also be known as:
- *Thinning of bones*
- *Brittle bones*
- *Narrowing of bones*
- *Easily fractured bones*

Signs and symptoms of osteoporosis:
- *Hunched back (Dowager's hump)*
- *Loss of height*
- *Back pain*
- *Impaired motility*
- *Fractures associated with minor events*

13.10

2.0 Consequences of untreated osteoporosis

The long term effects of osteoporosis vary between patients.

However, the most common effect is a bone fracture after a minor fall such as tripping on a wire.

Further complications can arise from the healing process, as well as from the loss of movement (walking) that often occurs after a spine or hip fracture.

2.1 Wrist fractures

- Broken wrists may be the first indication that you have osteoporosis.

- Usually occurs when arms are used to break a fall.

- Healthy bones should be able to withstand a fall from standing height.

- A broken bone in this situation is known as a fragility fracture.

2.2 Hip fractures

- Hips broken as a result of osteoporosis occur most commonly in the those age 75 years and over.

- Happens as a result of a fall.

- Has a major impact on independence such as being able to walk normally.

- It can also create a real fear of falling among older people and can make them cautious of daily activities.

2.3 Spinal fractures

- A fracture of the spine can occur as the result of an awkward movement such as:

  ◊ Coughing or sneezing.
  ◊ Reaching up to get something high from a kitchen cupboard.
  ◊ Lifting heavy shopping bags.

If someone has many bad fractures:

- Significant height loss and curving of the spine causing shortness of breath.
- Protruding (A sticking out) stomach.
- Indigestion problems.
- Frequent urination

Due to a reduction in available space for internal organs.

- Posture and shape changes may affect **body image**. This may cause distress and difficulties when buying suitable clothes.

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2.4 Spinal compression

- Even if a fracture does not occur, spinal bones may get crushed. This may result in:

    ◊ Back pain
    ◊ Height loss
    ◊ Difficulty in breathing since there is less space under the ribs.

3.0 What are the risk factors for osteoporosis?

Table 1: Osteoporosis risk factors

Potentially modifiable	Non modifiable
Inadequate intake of calcium or vitamin D	Advanced age over 75 years
Use of some medications (steroids, anticancer)	Early menopause (<45 years old)
Small body build or low body weight	First degree relative with fracture
Lack of female hormones	Race (Caucasian or Asian)
Current cigarette smoking	
Excessive alcohol intake	Personal history of fractures as an adult
Lack of exercise	
Falling often	Female

13.12

4.0 How can I find out if I have osteoporosis?

4.1 Bone mineral density (BMD) scan

- According to the World Health Organization, the gold standard in diagnosing osteoporosis is to have a BMD scan.

- BMD scans are painless.

- It uses very small amounts of radiation (one tenth of the dosage of a chest x-ray) to determine the BMD of the spine and hip which are the main areas for osteoporosis fractures.

- A BMD scan will take between 10-20 minutes.

- It involves lying on a firm couch whilst a scanning arm passes over the body taking an image of the spine and hips.

- It does not involve being enclosed in a mechanical tunnel or having an injection.

- Generally, clothing does not have to be removed but clothes with metal at the hips or along the spine should be avoided (trouser zips are not a problem).
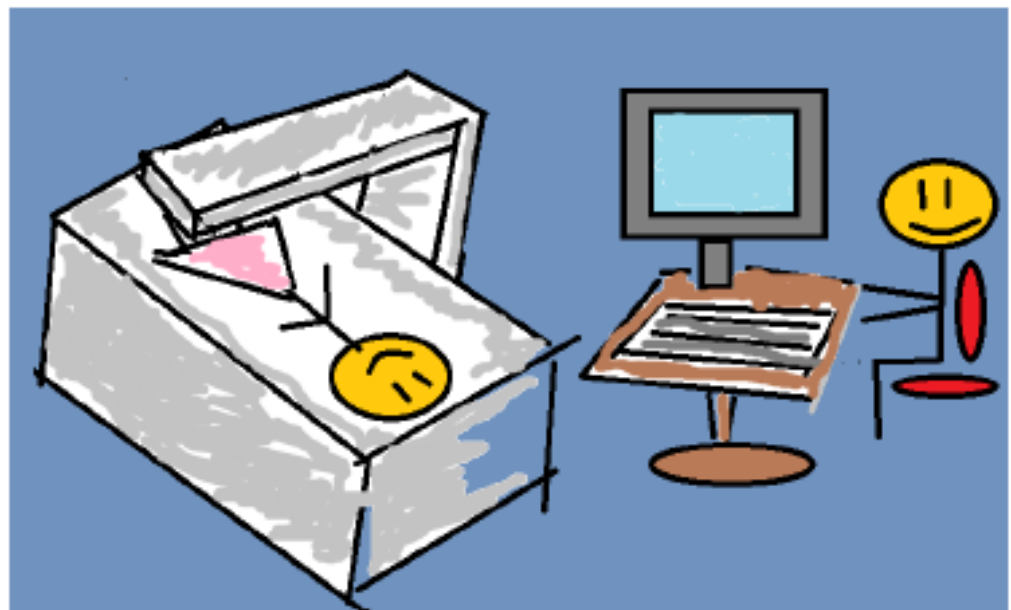
13.13

4.1(a) What will the results tell me?

- The results of your BMD scan will be compared to a reference range of young healthy adults with average bone density.

- The difference between this average and your bone density is then calculated and expressed in terms of standard deviations (SD). This is called the T-score.

Table 2: BMD results

BMD T-score (SD)	Definition
≥ -1	Normal
< -1 to > -2.5	Osteopenia (low bone mass)
≤ -2.5	Osteoporosis
≤ -2.5 + fragility fracture	Severe / established osteoporosis

- **OSTEOPOROSIS** is having a T-score ≤ -2.5. You will need to be started on medications to treat osteoporosis.

- **OSTEOPENIA** is a state between having osteoporotic and normal bones. You will not be given any medications to treat osteopenia, as it has not been found to be cost effective. However, you will be monitored more closely by your doctor and be asked to go for a repeat BMD scan 2 years later.

- **NORMAL** is having a T-score of ≥ -1. You will still need to adopt a well-balanced, calcium-rich diet and regular weight-bearing exercise to prevent further bone loss.

4.1(b) Where can I obtain a BMD scan?

- BMD scans are available in most major hospitals in Malaysia, including the University Malaya Medical Centre.

13.14

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4.1(c) How often should I have a BMD scan?

Table 3: Recommended duration to repeat a BMD scan

	Recommended duration to repeat a BMD scan
Osteoporosis	2 years later
Osteopenia	2 years later
Normal	5 years later

- Bones take a long time to change. Performing a BMD more frequently will not show any changes.

4.2 What about quantitative ultrasound scanning (QUS)?

- A heel ultrasound is a simple and painless procedure.

- In some machines, the heel is placed into a small water bath machine.

- In others, gel is applied to the heel, finger or wrist area and a dry machine is used.

- QUS cannot be used to confirm the diagnosis of osteoporosis.

- QUS may sometimes be used as a tool to identify women who are at risk of osteoporosis.

- Eventually, a BMD scan will still have to be performed for the diagnosis of osteoporosis.

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4.3 Can X-rays be used to diagnose osteoporosis?

- X-rays are used to see if a fracture has occurred.

- It cannot be used to diagnose osteoporosis

4.4 Other blood tests

- Full blood count, thyroid function tests, bone profile, liver profile and renal profile, are other blood tests usually performed.

- These test are used to rule out other causes of osteoporosis.

4.5 Osteoporosis screening tool for Asians (OSTA)

- A simpler method to assess if a person is at risk of osteoporosis is to use the OSTA.

- OSTA is a questionnaire which asks information about how heavy and tall you are. In addition, it will also ask if you have any risk factors for osteoporosis.

- A score will then be calculated. You will then be informed if you are at high, medium or low risk of osteoporosis.

- If you are at high or medium risk for osteoporosis, you will be sent for a BMD scan.

5.0 What life style changes can I do to prevent further bone loss?

5.1 Consume sufficient calcium

- Calcium is essential for skeletal health and bone strength.

- Increasing age and menopause increases the daily requirements of calcium.

- Increasing calcium intake can reduce the incidence of fracture in both men and women with a low calcium intake.

- Calcium can be obtained from calcium supplements or from diet.

5.1(a) Calcium daily requirements

Table 4: Calcium daily recommended intake

	Age	Recommended Intake
Infants	0 - 6 months	300 mg (breast-fed) 400 mg (non-breast-fed)
	6 - 12 months	400 mg
Children	1 – 3	500mg
	4-6	600mg
	7-9	700mg
Adolescents (boys & girls)	10 - 18	1000mg
Men	19 – 49	800 mg
	> 50 years	1000 mg
Women	19 – 49	800 mg
	> 50 years	1000 mg
Pregnant	Third trimester	1000 mg
Lactating		1000 mg

5.1(b) Calcium from diet

200g of ikan bilis

1600g of mussels

750g of yoghurt

750g of steamed tofu

200g of cheese

2400g of baked beans

1000 mg of Calcium
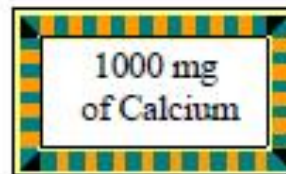
350g of raw spinach

400ml (2 glasses) of high calcium milk

500g of green leafy vegetables

500g of almond or nuts

400g sardines

5.1(c) Calcium supplements

What are calcium supplements?

- When the diet is lacking in calcium, calcium may be given in the form of supplements.

- The absorption of calcium supplements can vary from 20-40% depending on the formulation.

When and how to take it
Calcium is best absorbed by the body when it is taken several times a day.
Calcium carbonate is absorbed best when taken with food.
Calcium lactate or calcium citrate can be taken any time.
The daily amount of calcium taken includes the food that you take that contains calcium.

If you forget to take your calcium
Do not take an extra dose. Wait until the next dose and take your normal dose then. Do not try to make up for the dose that you missed by taking more than one dose at a time.

Side effects
You will experience side effects if you take too much calcium. The common side effects are constipation and stomach bloating.

Product Description

What calcium looks like
Calcium tablets supplied by the UMMC are:

Calcium lactate 300mg tablet: Each tablet is round and white in colour, with a white line across the tablet on one side and "Kotra" written on the other. Each tablet contains 200mg elemental calcium.

Calcium carbonate 500mg tablet: Each tablet is round and pale orange in colour, with "MPT" written on one side of the tablet. Each tablet contains 200mg elemental calcium.
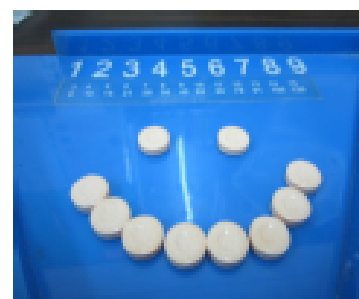
5.1(d) I am a vegan, will this cause problems for my bones?

- If you don't eat dairy products, you will need to include lots of other calcium rich foods such as:

    - Green leafy vegetables.
    - Almonds.
    - Sesame seeds.
    - Dried fruit.
    - Fortified (enriched)soya drinks .
    - Soya protein tofu in your diet.

5.1(e) Can I have too much calcium?

- Having more than the upper safe limit of 2,000 to 2,500mg of calcium a day on a regular basis could lead to medical problems including a high level of calcium in the blood.

- It may also interfere with the absorption of other minerals such as iron and magnesium.

5.1(f) I am lactose intolerant, how can I get more calcium into my diet?

- Some people cannot tolerate lactose, the natural sugar found in milk. If you are lactose intolerant, make sure you enjoy plenty of non-dairy calcium rich foods like:

    - Sardines.
    - Curly kale.
    - Watercress.
    - Sesame seeds.
    - Fortified foods such as soya milk.

5.1(g) Can eating fortified foods help?

- These are supplemented foods that are fortified with vitamins and minerals. They may be a convenient way of improving the nutritional value of your diet.

5.2 Consume sufficient vitamin D

- Vitamin D is necessary for effective calcium absorption from the gut.

- There are 2 types of vitamin D: vitamin D2 and vitamin D3.

- Vitamin D3 is formed in the skin through the action of ultraviolet B radiation and **usually** is **included as** the main ingredient in supplements.

- Vitamin D2 is produced in plants.

5.2(a) Vitamin D3 daily requirements

Table 5: Vitamin D3 daily recommended intake

Age	Vitamin D3 requirements (IU)/day
0–12 months	400 IU
1–70 years	600 IU
>70 years	800 IU
Pregnancy and lactation	600 IU

5.2(b) Vitamin D from sunlight exposure

- Exposure of the hands, face and arms to sunlight for about 15 minutes a day should be adequate.

- Achieved by performing some outdoor activities such as gardening or walking.

- Fairer persons will only need 5 minutes of exposure to the sun.

- Darker persons will probably need about 30 minutes of exposure.

- Prolonged exposure to the sun should be avoided.

5.2(c) The effect of sunscreens and glass

- Glass prevents the transmission of ultraviolet B radiation (which is necessary for the skin to produce vitamin D).

- Sunscreens also reduce the amount of ultraviolet B that gets to the skin.

- Sunscreens should only be applied if exposure to the sun will be over a longer period of time (like a trip to the beach).

5.2(d) Vitamin D from diet

- A smaller amount is obtained from the diet e.g. margarine, butter, milk, salmon, tuna, oily fish, eggs, breakfast cereals.

- Most adults are unlikely to obtain more than 5%–10% of their vitamin D requirement from dietary sources.

5.2(e) Vitamin D supplements

What are vitamin D supplements?

Vitamin D is a fat-soluble vitamin.

Deficiency in Vitamin D can also cause muscle weakness.

There are many different types of vitamin D preparations available. Some examples are Metocal ™ and Oscal D™ .

When and how to take it
Vitamin D can be taken any time of the day with or without food. Vitamin D is more effective when taken in divided doses with fat-containing, low fiber meals.

If you forget to take it
Do not take an extra dose. Wait until the next dose and take your normal dose then. Do not try to make up for the dose that you missed by taking more than one dose at a time.

Side effects
* Loss of appetite
* Feeling sick
* Headache
* Fever
* Vomiting or stomach ache
* Constipation
* Weakness or muscle weakness
* Dry mouth or thirst
* Irregular and/or rapid heart beat
* Urinary tract infection

5.3 Perform weight bearing exercises

5.3(a) Types of exercise

- Leading an active lifestyle can halve your risk of breaking a bone, particularly in your hip.

- The term 'active lifestyle' means enjoying a variety of physical activities throughout the day that keep you on the move.

- Weight bearing exercises may include:

  ◊ **Brisk walking 30 minutes every day**
  ◊ **Dancing of all varieties**
  ◊ **Tai Chi**
  ◊ **Gardening**

- Simple exercises from the comfort of your own home:

  ◊ **Lifting tins of food** while you watch TV can help strengthen your wrists.
  ◊ **Arm press** (refer next page) which helps in strengthening bone and balance.
  ◊ **Climbing the stairs regularly.**

- Swimming and cycling is **not** a weight-bearing exercise. It therefore has no impact on bone density.

Table 6: Benefits of exercise

How does the bone benefit from weight bearing exercise?	
• Minimise bone loss and possibly reduce the risk of broken bones	• Enables you to carry out daily tasks and activities better
• Increase muscle and bone strength	• Maintain or improve posture
• Improve balance	• Relieve or decrease pain associated with other conditions such as osteoarthritis
• Improve your sense of well being	• Reduce the risk of falls
• Improve cognitive (brain) function	• Reduce the risk of many medical conditions

5.3(b) Exercising safety

Do not rush
Begin with activities you are comfortably with. Gradually increase the amount until you have reached your target. This will take time.

Exercise regularly to obtain its benefit.
Exercise for 30 minutes, five days per week.

A little muscle stiffness for a day or two after exercise indicates that you have done more than usual; this will stimulate improvements. However, persistent pain for a few days may be a sign of injury . Please see your doctor.

Warm up and cool down
Always warm up gradually before physical activity and exercise. Take the time to cool down afterwards to prevent injury.

Clothes, footwear and environment
Wear comfortable flat shoes or trainers and comfortable clothes. Make sure you have enough space to move.

5.3(c) Arm press

- Stand facing a wall, about 50cm away from it, with your feet slightly apart, arms bent at the elbows and hands at shoulder height.

- Lean your body forward towards the wall by bending your elbows in a controlled movement.

- Push your body back to the starting position.

- Performed three times a week and repeated 10–15 times on each occasion.

- Keep breathing easily and try not to hold your breath while doing this.

5.4 Fall prevention

Many older people fall in the home, so it is important to try to reduce hazards that could cause you to trip and fall.

- **Floors:** Remove all loose wires and cords. Throw loose rugs or carpets. Minimize clutter. Make sure rugs are anchored and smooth. Keep furniture in its usual places.

- **Bathrooms:** Install grab bars and non skid tape in the tub or shower.

- **Stairs:** Make sure treads, rails and rugs are secure.
- Take your time when using the stairs. Hold on to the rail.

- **Lighting:** Make sure halls, stairways and entrances are lit well.

- **Shoes:** Wear sturdy, rubber-soled shoes.

- **Avoid lifting** heavy objects.

- **Have your eyesight and hearing checked.** Poor eyesight can increase your risk of falling. Deafness can also affect your balance.

- **Other health problems** such as Parkinson's disease, arthritis or stroke are common causes of falls.

- **Medications** can sometimes cause one to be dizzy or drowsy.

- Ask your pharmacist to review all the medications you are currently taking. Some medications that may increase your risk of falls are:

  ◊ Antidepressants
  ◊ Sleeping pills
  ◊ Antihypertensives
  ◊ Antiepileptics
  ◊ Pain killers
  ◊ Antiparkinson medications
  ◊ Anti histamines
  ◊ Antidiabetics

6.0 What can I do to treat osteoporosis?

- Medications currently available for osteoporosis include:
    - ◊ Bisphosphonates: Alendronate, risedronate, ibandronate
    - ◊ Estrogen or hormone replacement therapy : Conjugated estrogens
    - ◊ Selective estrogen receptor modulators: Raloxifene
    - ◊ Strontium ranelate
    - ◊ Anabolic therapy: Teriparatide
    - ◊ Calcitonin

- These medications will either help rebuild your bones or prevent further bone loss.

- Your doctor will help you select the medication which is suitable for you.

Remember— Osteoporosis can be prevented and treated

References:

1. National Osteoporosis Society– Healthy Living for Strong Bones Leaflet
2. National Osteoporosis Society– Healthy Bones– Fact about Food Leaflet
3. National Osteoporosis Society– Exercise and Osteoporosis Leaflet
4. National Osteoporosis Society– Scans and Test and Osteoporosis Leaflet
5. NHS– Calcium + Vitamin D and Osteoporosis Leaflet
6. Nowson C.A. et al Vitamin D and health in adults in Australiaand New Zealand: a position statement 2012
7. Smith M. on behalf of WAM Falls in Elderly Steering Group, Medications and the Risk of Falls in the Older Person 2004
8. Clinical Guidance on Management of Osteoporosis 2012– Malaysia
9. Institute of Medicine, Food and Nutrition Board, Dietary calcium intake of calcium and vitamin D. 2011
10. The World Health Organisation (WHO) definitions based on BMD

If you any queries or would like more information
Please contact Ms Toh Li Shean (pharmacist) at

012 2846 849

TREASURE
YOUR
BONES!!

13.16   Appendix 25- Patients information sheet for Phase two- Satisfaction questionnaire for osteoporosis Prevention (SQOP)

Patient Information Sheet

Study Title: The development and validation of tools for the screening and prevention of osteoporosis in community dwelling postmenopausal women in a tertiary hospital in Malaysia. *(Patients):* The validation of the satisfaction tool.
 Version: V1-SATISFT-VLD-PT-17/03/12

> **Part 1** tells you the purpose of this study and what will happen to you if you take part.
>
> **Part 2** gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is

usually a "silent disease' where women with osteoporosis may experience no symptoms. Consequently, there may be a proportion of women who may have osteoporosis but who are not aware, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk. This would empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to develop and validate a tool on evaluating patient's satisfaction towards an osteoporosis screening programme. This tool will be used as a quality indicator for the upcoming osteoporosis screening programme.

2. Why have I been invited?

Since you are currently seeing a doctor from the Department of Primary Care Medicine for your medical condition, we would like to explore your satisfaction with the current osteoporosis healthcare practices and your preferences for future improvements using this tool. This information will be used to guide the development and validation of a patient satisfaction evaluation tool for the new osteoporosis screening programme in UMMC. Your care will be more wholesome as you will be seen by both the doctor and the pharmacist.

A total of 96 patients who are attending the Primary Care Family Clinic will be invited to participate in this study.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you before you fill up the questionnaire. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect your treatment or the standard of care you receive.

4. What type of study is this?

This is a quantitative study using questionnaires. It is a challenging task to determine whether patients are satisfied with the current osteoporosis health treatment and services received. To find out, we need to develop and validate a tool on evaluating patients' satisfaction towards an osteoporosis screening programme. By collecting and analysing these data, we are able to obtain useful information from them and find out the effectiveness of this tool in evaluating patient satisfaction with regards to an osteoporosis screening programme.

5. What will happen to me if I take part?

The researcher will ask you if you would like to take part in this study. Before filling up the questionnaire, the researcher will go through the Patient Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

You will then need to fill up the patient satisfaction questionnaire for the first time. This will take about 15 minutes.

After filling up the questionnaire, you will be randomly allocated to the control or intervention group. Participants in the intervention group will receive a 30 minute counseling session and a follow up phone counseling session two weeks later; whilst the control group will receive the standard care with no counseling intervention.

All participants will be scheduled a second appointment for a month later.

During your second appointment (a month later) you will need to fill up the patients' satisfaction questionnaire for the second time.

However, the control group will not be at a disadvantage as they will receive the counseling session at the end of the study and a follow up phone counseling 6 weeks later.

6. Expenses and payment

You will be given RM 20 per visit as a reimbursement for your travel expenses.

7. What will I have to do?

You are required to attend one counseling session and answer all the questions in the questionnaire during two separate occasions based on your experience.

8. What are the possible disadvantages and risks of taking part?

You will have to spend more time in the hospital as you will need to come back for your second appointment one month later.

9. What happens when the research study stops?

Your doctor will continue to provide medical care for you.

10. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

11. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

12. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

13. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving a reason and without affecting your care.

14. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

15. Will my taking part in this study be kept confidential?

Only the researchers involved will have access to your medical notes and data collected. All information will be anonymised (no name mentioned).

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic will have your name, telephone and address removed so that you cannot be recognized.

16. Involvement of the General Practitioner/Family doctor (GP)

Your doctor will be informed about your participation in this study.

17. **What will happen to the results of the research study?**

The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. You will also be able to request a summary for the research.

18. **Who is organizing and funding the research?**

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai Siew Mei from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

19. **Who has reviewed the study?**

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

20. **Further information and contact details.**

Specific information about this research project:

Toh Li Shean

Tel: 012-2846-849

Email: rinoa8387@yahoo.com.

Advice as to whether you should participate:

As above.

Who you should approach if unhappy with the study:

As above.

14.1 Appendix 26- Patients consent form for Phase two- Satisfaction questionnaire for osteoporosis Prevention (SQOP)

Participant identification number for this trial:

CONSENT FORM

Title of Project: The development and validation of tools for the screening and prevention of osteoporosis in community dwelling postmenopausal women in a tertiary hospital in Malaysia. (Patients) The validation of the satisfaction tool.

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 17/03/12 (Version 1- SATISFT-VLD-PT) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University Malaya Medical Center, the University of Malaya and the University of Nottingham, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study.

_____   _____
Name of Participant   Date   Signature

_____   _____
Name of Person taking consent   Date   Signature

14.2 Appendix 27- Ethical approval for Phase two

UNIVERSITI MALAYA

PUSAT PERUBATAN UM

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE
ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 FAXIMILE: 03-79494638

NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre	ETHICS COMMITTEE/IRB REFERENCE NUMBER:
ADDRESS: LEMBAH PANTAI 59100 KUALA LUMPUR	920.27
PROTOCOL NO:	
TITLE: The development and validation of tools for the screening and prevention of osteoporosis in community dwelling postmenopausal women in a tertiary hospital in Malaysia	
PRINCIPAL INVESTIGATOR: Mrs. Toh Li Shean	SPONSOR:
TELEPHONE: KOMTEL:	

The following item [✓] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[✓] Application Form   Ver date: 24 Apr 12
[✓] Study Protocol   Ver date:
[ ] Investigator Brochure   Ver date:
[✓] Patient Information Sheet
[✓] Consent Form
[ ] Questionnaire
[✓] Investigator(s) CV's (Mrs. Toh Li Shean)

and have been [✓]

[✓] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Investigator are required to:
1) *follow instructions, guidelines and requirements of the Medical Ethics Committee.*
2) *report any protocol deviations/violations to Medical Ethics Committee.*
3) *provide annual and closure report to the Medical Ethics Committee.*
4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
5) *note that Medical Ethics Committee may audit the approved study.*

Date of approval: 16th MAY 2012

c.c   Head
Department of Primary Care Medicine

Deputy Dean (Research)
Faculty of Medicine

Secretary
Medical Ethics Committee
University Malaya Medical Centre

....
PROF. KULENTHRAN ARUMUGAM
Deputy Chairman
Medical Ethics Committee

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14.3 Appendix 28- The finalized Osteoporosis Prevention and Awareness Tool (OPAAT)

21. **Osteoporosis Prevention And Awareness Tool (OPAAT)**

Serial no			

Total score_____

Please tick at the appropriate box:

1. A. What can you tell me about osteoporosis?

	$True_1$	$False_2$	Don't $know_3$
1. Makes bones weaker, more brittle and more likely to break (fracture)	❑	❑	❑
2. Everybody will get osteoporosis as it is part of aging	❑	❑	❑
3. Osteoporosis occurs because bone is removed faster than it is formed	❑	❑	❑
4. Osteoporosis and osteoarthritis are different names we can use to describe the same disease	❑	❑	❑
5. Osteoporosis usually has no symptoms	❑	❑	❑
6. Postmenopausal women are not at risk for osteoporosis	❑	❑	❑
7. Osteoporosis is an untreatable disease.	❑	❑	❑
8. A bone mineral density test is used to diagnose osteoporosis	❑	❑	❑
9. I do not need a bone mineral density test unless I fracture my bones.	❑	❑	❑
10. A bone mineral density test is high in radiation	❑	❑	❑

	True[1]	False[2]	Don't know[3]
11. A bone mineral density test should be performed monthly to monitor bone loss	❑	❑	❑

B. What will happen if your osteoporosis is left untreated?

	True[1]	False[2]	Don't know[3]
12. Results in back pain	❑	❑	❑
13. Loss of height or hunchback	❑	❑	❑
14. Loss of mobility (unable to move around myself)	❑	❑	❑
15. Results in tooth loss	❑	❑	❑
16. Results in joint pain or swelling of fingers	❑	❑	❑

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C. What can you tell me about osteoporosis prevention?

	True₁	False₂	Don't know₃
17. The recommended daily intake for calcium in women above 50 years of age is 1000mg	❑	❑	❑
18. It is too late to increase calcium intake after the age 50	❑	❑	❑
19. Glucosamine can help prevent osteoporosis	❑	❑	❑
20. Calcium supplements can help prevent osteoporosis	❑	❑	❑
21. The regular dose of calcium supplements can cause kidney stones.	❑	❑	❑
22. Foods such as milk, tofu, anchovies (*ikan bilis*), yellow dhal and spinach are rich in calcium	❑	❑	❑
23. You can obtain your recommended daily intake of vitamin D via exposing your skin to sunlight for about 15 minutes a day	❑	❑	❑
24. Increasing coffee and tea intake can help in osteoporosis prevention	❑	❑	❑
25. Weight bearing exercise (such as brisk walking and line dancing) can decrease bone loss.	❑	❑	❑
26. Exercise will wear out bones	❑	❑	❑
27. Certain medications (such as sleeping tablets or high blood pressure medications) may reduce the risk of falling	❑	❑	❑

28. To prevent falls, comfortable shoes with a good grip should be used.	❑	❑	❑
29. Poor vision may lead to falls	❑	❑	❑
30. Being under weight helps prevent osteoporosis	❑	❑	❑

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14.4   Appendix 29- Patients information sheet for Phase two- Osteoporosis Prevention and Awareness Tool (OPAAT) and risk assessment too

Patient Information Sheet

Study Title: The validation of tools for the screening and prevention of osteoporosis in community dwelling postmenopausal women in a tertiary hospital in Malaysia. *(patients):* The validation of the knowledge tool and the validation of the osteoporosis risk assessment tools.

Version: V1-KNOWL/SCREEN-VLD-PT-17/03/12

Part 1 tells you the purpose of this study and what will happen to you if you take part.   **Part 2** gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat

many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is usually a "silent disease' where women with osteoporosis may experience no symptoms. Consequently, there would a proportion of women who have osteoporosis but who are not aware, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk. This would empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to develop and validate two tools. The first is a tool to assess the knowledge of osteoporosis screening, prevention and awareness among patients in Malaysia. The second is to validate several osteoporosis risk assessment tools for use in Malaysia. These tools will be used to assist the upcoming osteoporosis screening programme.

2. Why have I been invited?

Since you are currently seeing a doctor from the Department of Primary Care Medicine for your medical condition, we would like to explore your knowledge and understanding of osteoporosis regarding its screening, prevention and awareness using OPAAT knowledge tool. This information will be used to validate the knowledge tool for the new osteoporosis screening programme in UMMC.

Secondly, we would like to ask you some questions about your past medical history and diet to calculate your risk of getting osteoporosis using some osteoporosis risk assessment tools. We will also require you to go for a bone mineral density (BMD) to confirm the results obtained from these risk assessment tools. This process is to validate the use of the osteoporosis risk assessment tools among Malaysian patients. Your care will be more wholesome as you will be seen by both the doctor and the pharmacist.

A total of 150 patients who are attending the Primary Care Family Clinic will be invited to participate in the study.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you before you fill up the questionnaire. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect your treatment or the standard of care you receive.

4. What type of study is this?

This is a quantitative study using questionnaires. It is a challenging task to determine whether patients are getting sufficient information about osteoporosis and whether patients at risk for osteoporosis are being identified adequately. For example, postmenopausal women may not know the availability of osteoporosis

preventive measures and that they may be at risk for osteoporosis. To find out, we need to develop and validate a knowledge assessment questionnaire.

Aside from that, based on the results of your BMD scans we will compare the results obtained from the osteoporosis risk assessment tool. By collecting and analysing these data, we are able to obtain useful information from them and find out the effectiveness of these tools in identifying the knowledge gaps of the current practices and its effectiveness in assessing the risk of osteoporosis.

5. What will happen to me if I take part?

The researcher will ask you if you would like to take part in this study. Before filling up the questionnaire, the researcher will go through the Patient Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

You will then need to fill up the knowledge assessment questionnaire for the first time. This will take about 10 minutes.

Subsequently, there will be a short interview of about 5 minutes to assess your osteoporosis risk factors.

The researcher will schedule a date for your BMD scan appointment. A BMD request form will be given to you which you **MUST BRING to the ANOC Neuroscience and Orthopedic centre.You will then need to call**

up ANOC to confirm the time and date that you are available for the BMD scan.

Lastly, a phone follow up will be scheduled two weeks later where the pharmacist will review your BMD results. You will be asked questions from the knowledge assessment questionnaire for the second time.

The copy of your BMD scan results will be sent to you via registered mail.

6. What is a Bone Mineral Density (BMD) Scan?

A BMD scan uses a Dual Energy X-ray Absortiometry (DEXA) machine to measure how strong, or dense your bones are. The results show how much risk there is of the bones fracturing. The scan will take about 10 to 20 minutes and is not unpleasant or painful in any way. You will be asked to lie on a firm couch, fully clothed, whilst the machine takes the pictures. You will NOT go into a tunnel or have an injection. In addition, the scan is very safe and the dose of radiation is tiny. The dose of radiation is similar to spending a day out in the sun.

7. Expenses and payment

You will be given RM 20 per visit as a reimbursement for your travel expenses and another RM20 will be given for your time during the phone follow up. This research project will cover the RM180 fee of your BMD scan at ANOC.

8. What will I have to do?

You are required to answer all the questions in the questionnaire during two separate occasions based on your current knowledge. You will also need to stop taking any calcium supplements 3 days before your BMD scan.

9. What are the possible disadvantages and risks of taking part?

You will have to spend more time in the hospital.

10. What happens when the research study stops?

Your doctor will continue to provide medical care for you.

11. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

12. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

13. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

> **This completes Part 1.**
> **If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.**

Part 2

14. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving a reason and without affecting your care.

15. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

16. Will my taking part in this study be kept confidential?

Only the researchers involved will have access to your medical notes and data collected. All information will be anonymised (no name mentioned).

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic

will have your name, telephone and address removed so that you cannot be recognized.

17. Involvement of the General Practitioner/Family doctor (GP)

Your doctor will be informed about your participation in this study.

18. What will happen to the results of the research study?

The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. You will also be able to request a summary for the research.

19. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai Siew Mei from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research is from the Ministry of Higher Education.

20. Who has reviewed the study?

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

21. Further information and contact details.

Specific information about this research project:

Toh Li Shean

Tel: 012-2846-849

Email: rinoa8387@yahoo.com

Advice as to whether you should participate:

As above.

Who you should approach if unhappy with the study:
As above.

14.5 Appendix 30- Patients consent form for Phase two- Osteoporosis Prevention and Awareness Tool (OPAAT) and risk assessment tools

Participant identification number for this trial:

CONSENT FORM

Title of Project: The validation of tools for the screening and prevention of osteoporosis in community dwelling postmenopausal women in a tertiary hospital in Malaysia. (Patients): The validation of the knowledge tool and the validation of the osteoporosis risk assessment tools.

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 17/03/12 (Version 1-KNOWL/SCREEN-VLD-PT) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University Malaya Medical Center, the University of Malaya and the University of Nottingham, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study.

_____   _____
Name of Participant   Date   Signature

_____   _____
Name of Person taking consent   Date   Signature

14.6   Appendix 31- Pharmacists information sheet for Phase two - Osteoporosis Prevention and Awareness Tool (OPAAT)

Participant Information Sheet

Study Title: The development and validation of tools for the screening and prevention of osteoporosis in community dwelling postmenopausal women in a tertiary hospital in Malaysia. *(Healthcare professionals- doctors and pharmacists):* The validation of the knowledge tool.
 Version: V1-KNOWL-VLD-HCP-18/03/12

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. **What is the purpose of the study?**

   In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as

diabetes or hypertension. However, osteoporosis is usually a "silent disease' which means that a woman with osteoporosis may experience no symptoms. Consequently, there may be a proportion of women who may have osteoporosis but who are not identified, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients on their osteoporosis risk and empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to develop and validate an instrument to assess the knowledge of osteoporosis screening, prevention and awareness. This tool will be used to assist the upcoming osteoporosis screening programme.

2. Why have I been invited?

You have been invited because of your experience as an outpatient healthcare professional in managing postmenopausal women. Your views and knowledge assessment will help us to develop and validate a tool to identify the knowledge gaps in the screening, prevention and awareness of osteoporosis. This information is then used to guide the development and validation of a knowledge assessment tool for the new osteoporosis screening programme in UMMC.

A total of 30 healthcare professionals will be invited to participate in the study.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you before you fill up the questionnaire. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

4. What type of study is this?

This is a quantitative study using questionnaires. It is a challenging task to determine whether there is sufficient information and awareness about osteoporosis in the current practices. For example, postmenopausal women may not know the availability of osteoporosis preventive measures and that they may be at risk for osteoporosis. To find out, we need to develop and validate a knowledge assessment questionnaire. By collecting and analysing these data, we are able to obtain useful information from them and find out the effectiveness of this tool in identify the knowledge gaps in osteoporosis.

5. What will happen to me if I take part?

1. An appointment will be made at a time convenient to you. The researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

2. You will then need to fill up the knowledge assessment questionnaire for the first time. This will take about 15 minutes. A second appointment will be made for a month later.

3. During the second appointment (one month later), you would need to fill up the knowledge questionnaire for the second time.

6. What will I have to do?

You are required to answer all the questions in the questionnaire during two separate occasions based on your current knowledge.

7. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

8. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

9. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

> **This completes Part 1.**
> **If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.**

Part 2

10. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving any reason.

11. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

12. Will my taking part in this study be kept confidential?

Only the researchers involved will have access to the data collected. All information will be anonymised (no name mentioned).

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic

will have your name, telephone and address removed so that you cannot be recognized.

13. What will happen to the results of the research study?

The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. You will also be able to request a summary for the research.

14. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai Siew Mei from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

15. Who has reviewed the study?

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

16. Further information and contact details.

Specific information about this research project:
Toh Li Shean Tel: 012-2846-849
Email: rinoa8387@yahoo.com

Advice as to whether you should participate:

As above.

Who you should approach if unhappy with the study:

As above.

14.7 Appendix 32- Pharmacists consent form for Phase two- - Osteoporosis Prevention and Awareness Tool (OPAAT)

Participant identification number for this trial:

CONSENT FORM

Title of Project: The development and validation of tools for the screening and prevention of osteoporosis in community dwelling postmenopausal women in a tertiary hospital in Malaysia. (Healthcare professionals- pharmacist and doctors): The validation of the knowledge tool.

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 18/03/12 (Version 1- KNOWL-VLD-HCP) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

4. I agree to take part in the above study.

_____   _____
Name of Participant   Date   Signature

_____   _____
Name of Person taking consent   Date Signature

14.8 Appendix 33- WHO Fracture Risk Assessment tool

14.9 Appendix 34- Pharmacist recommendation form

Pharmacist referral form for the Pharmacist Initiated Osteoporosis Screening Program (PIOS) using the Osteoporosis Screening Tool for Asians (OSTA)

Paste HIS label here

Weight: _____ kg   **Height:** _____meter

Risk factors (*Major risk factor):

- ≥50 years old
- Female
- Asian
- Menopause
- Early menopause (<45 years old)
- Fractured as an adult * (____ years old)

- Long term use of steroids * (___mg _____ duration_____)
- Family history of osteoporosis * (Grandparents/parents/sibling)

- Inadequate intake of calcium and Vitamin D
- Small body built
- Lack of exercise
- Current smoker
- Excessive alcohol intake

OSTA score: _____

| | -5 | -4 | -3 | -2 | -1 | 0 | 1 |

High risk   Moderate risk   Low risk
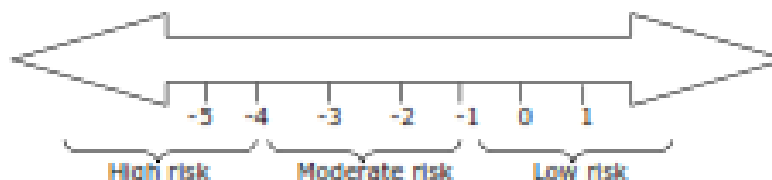
Pharmacist's recommendation BMD is:

- Not required   ☐ Required
                                          ↓
Schedule an appointment within a month later to review the BMD results
                                          ↓
Diagnosis (one month later): osteoporosis/osteopenia/normal
                                          ↓
Refer to osteoporosis clinic when necessary

Please do not hesitate to call Toh Li Shean at 012-2846 849 if you have any queries. Your cooperation is very much appreciated.

14.10 Appendix 35- Patients information sheet for Phase three

Patient Information Sheet

Study Title: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: A feasibility study of an osteoporosis screening programme *(patients)*

Version: V1-OP-SCREEN-PT-24/03/12

> **Part 1** tells you the purpose of this study and what will happen to you if you take part.
>
> **Part 2** gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

In the University Malaya Medical Centre (UMMC), doctors from the Department of Primary Care Medicine treat many postmenopausal women for other conditions such as diabetes or hypertension. However, osteoporosis is

usually a "silent disease' where women with osteoporosis may experience no symptoms. Consequently, there would be a proportion of women who have osteoporosis but who are not aware, resulting in unwanted fractures.

Pharmacists together with doctors play an important role in patient care. Pharmacists can supplement the doctor's role by screening for osteoporosis and educating patients about their risk of osteoporosis. This would empower patients to take osteoporosis preventive measures. To date, no such service exists in the UMMC.

Therefore, the purpose of this study is to evaluate the effectiveness of a pharmacist screening programme of community dwelling postmenopausal women in a tertiary hospital in Malaysia using the Osteoporosis Screening Tool for Asians (OSTA).

2. Why have I been invited?

Since you are currently seeing a doctor from the Department of Primary Care Medicine for your medical condition, we would like you to participate in this osteoporosis screening programme. The information obtained from your participation will be used to improve future wide scale implementations of an osteoporosis screening programme. Your care will be more holistic as you will be seen by both the doctor and the pharmacist.

A total of 50 patients who are attending the Primary Care Family Clinic will be invited to participate in the study.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you before your participation. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect your treatment or the standard of care you receive.

4. What type of study is this?

This is a prospective. It is a challenging task to identify patients who are at risk of osteoporosis using the gold standard Bone Mineral Density (BMD) scan due to its cost. At this point there are many postmenopausal women who are unaware of their osteoporosis risk and that they are able to take steps to prevent osteoporosis. Therefore, this study would like to establish a cost effective osteoporosis screening programme whereby we would include a section on patient education and an osteoporosis risk assessment using a simple and cheap tool called OSTA. To find out if this programme is effective, we need to conduct a feasibility study to be able to identify barriers of conducting an osteoporosis screening programme. This will also help us to establish an effective workflow for future implementation.

5. What will happen to me if I take part?

1. The nurse will recommend the pharmacist if you are potential participant. The researcher/pharmacist will then ask you if you would like to take part in this study. Before beginning the study, the

pharmacist will go through the Patient Information Sheet with you. If you agree to participate, the pharmacist will ask you to sign a consent form, followed by answering a simple questionnaire about your background (10 minutes).

2. You will then need to fill up 1 questionnaire which will assess your knowledge on osteoporosis. You will then be measured for your weight and height and interviewed for other risk factors for osteoporosis.

3. You will be provided an "intervention package" which consists of:

   i. A counseling session at baseline (1st visit).

      1. In addition, depending on your osteoporosis risk assessment the pharmacist may recommend to the GP to schedule a Bone Mineral Density (BMD) scan.

   ii. An appointment for the BMD scan.

      1. If both you and your GP agrees for a BMD scan, your BMD scan will be scheduled on the same day or three days later depending on whether you have been taking calcium supplements. (You will have to go for a BMD scan within two weeks)

      2. Subsequently, an appointment for 1 month later with the GP will be made to review your BMD.

3. The pharmacist will also call you the next day. You will need to fill up two questionnaires which will assess your satisfaction of the services received and your knowledge of osteoporosis before the counseling session. There will also be a short interview to ask if there were any changes in your lifestyle. The interview will take about 5 minutes.

4. For participants that do not require a BMD scan or decline to go for a BMD scan or where the GP does not order a BMD scan, an appointment will be given to the patient 1 month later to fill up the two questionnaires.

5. A phone call will be placed to all participants the day before, to remind them about their appointment with the pharmacist.

4. Finally, after two months all participants will receive a phone interview to find out if you attended the osteoporosis clinic or have started on any osteoporosis medications.

6. What is a Bone Mineral Density (BMD) Scan?

A BMD scan uses a Dual Energy X-ray Absortiometry (DEXA) machine to measure how strong, or dense your bones are. The results show how much risk there is of the bones fracturing. The scan will take about 10 to 20 minutes and is not unpleasant or painful in any way. You will be asked to lie on a firm couch, fully clothed, whilst

the machine takes the pictures. You will NOT go into a tunnel or have an injection. In addition, the scan is very safe and the dose of radiation is tiny. The dose of radiation is similar to spending a day out in the sun.

7. Expenses and payment

You will be given RM 20 per visit as a reimbursement for your travel expenses.

8. What will I have to do?

You are required to attend two GP appointments and answer all the questions in each questionnaire during three separate occasions based on your current knowledge and experiences. You may need to stop taking any calcium supplements for 3 days if you are involved with the BMD scan. Lastly, you will need to participate in a phone interview.

9. What are the possible disadvantages and risks of taking part?

You will have to spend more time in the hospital as you may need to undergo a BMD scan. Also, you need to come back for one extra appointment after one month.

10. What happens when the research study stops?

Your doctor will continue to provide medical care for you.

11. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

12. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

13. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

1. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving a reason and without affecting your care.

2. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions .

3. **Will my taking part in this study be kept confidential?**

   Only the researchers involved will have access to your medical notes and data collected. All information will be anonymised (no name mentioned).

   The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers will have access to the data.

   The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought.

   All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the clinic will have your name, telephone and address removed so that you cannot be recognized.

4. **Involvement of the General Practitioner/Family doctor (GP)**

   Your doctor will be informed about your participation in this study.

5. **What will happen to the results of the research study?**

   The results of this study will be published in medical journals.

You will not be identified in any report, publications or presentation without seeking your full consent. You will also be able to request a summary for the research.

6. Who is organizing and funding the research?

This research is organized by Ms. Toh Li Shean and Dr Pauline Lai Siew Mei from the University of Malaya, as well as Prof Claire Anderson, Associate Prof Mr Wong Kok Thong and Dr Low Bee Yean from the University of Nottingham. Funding of this research will be obtained from either University of Nottingham or the Ministry of Higher Education.

7. Who has reviewed the study?

All research in the UMMC is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity.

8. Further information and contact details.

Specific information about this research project:
Toh Li Shean
Tel: 012-2846-849
Email: rinoa8387@yahoo.com
Advice as to whether you should participate:
As above.
Who you should approach if unhappy with the study:
As above.

14.11   Appendix 36- Patients consent form for Phase three

Participant identification number for this trial:

CONSENT FORM

Title of Project: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: A feasibility study of an osteoporosis screening programme (Patients)

Name of Researchers: Prof Claire Anderson / Assoc Prof Mr Wong Kok Thong/ Dr Lai Siew Mei Pauline/ Dr Low Bee Yean/ Toh Li Shean

Please initial box

1. I confirm that I have read and understand the information sheet dated 24/03/12 (Version 1-OP-SCREEN-PT) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University Malaya Medical Center, the University of Malaya and the University of Nottingham, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study.

_____   _____
Name of Participant   Date Signature

_____   _____
Name of Person taking consent   Date   Signature

14.12   Appendix 37- Ethical approval for Phase three

UNIVERSITI MALAYA

PUSAT PERUBATAN UM

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE
ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 FAXIMILE: 03-79494638

NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre	ETHICS COMMITTEE/IRB REFERENCE NUMBER:
ADDRESS: LEMBAH PANTAI 59100 KUALA LUMPUR	920.26

PROTOCOL NO:	
TITLE: Addressing the needs of osteoporosis prevention in community dwelling postmenopausal women in a tertiary hospital in Malaysia: A feasibility study of an osteoporosis screening program	

PRINCIPAL INVESTIGATOR: Mrs. Toh Li Shean	SPONSOR:
TELEPHONE: KOMTEL:	

The following item [✓] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[✓] Application Form   Ver date: 24 Apr 12
[✓] Study Protocol   Ver date:
[ ] Investigator Brochure   Ver date:
[✓] Patient Information Sheet
[✓] Consent Form
[ ] Questionnaire
[✓] Investigator(s) CV's (Mrs. Toh Li Shean)

and have been [✓]

[✓] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Investigator are required to:
1) *follow instructions, guidelines and requirements of the Medical Ethics Committee.*
2) *report any protocol deviations/violations to Medical Ethics Committee.*
3) *provide annual and closure report to the Medical Ethics Committee.*
4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
5) *note that Medical Ethics Committee may audit the approved study.*

Date of approval: 16th MAY 2012

c.c   Head
         Department of Primary Care Medicine

         Deputy Dean (Research)
         Faculty of Medicine

         Secretary
         Medical Ethics Committee
         University Malaya Medical Centre

....
PROF. KULENTHRAN ARUMUGAM
Deputy Chairman
Medical Ethics Committee

14.13   Appendix 38- Journal publication for the Osteoporosis Prevention and Awareness Tool (OPAAT)

The development and validation of the Osteoporosis Prevention and Awareness Tool (OPAAT) in Malaysia

Li Shean Toh[1][¶], Pauline Siew Mei Lai [2][¶]*, David Bin-Chia, Wu[3][¶], Kok Thong Wong[1][&], Bee Yean Low[1][&], Claire Anderson[4][¶]*

[1] Faculty of Science, School of Pharmacy, University of Nottingham, Jalan Broga, Semenyih, 43500, Selangor, Malaysia; [2] Department of Primary Care Medicine, University of Malaya Primary Care Research Group (UMPCRG), Faculty of Medicine, University of Malaya, Lembah Pantai, 59100, Kuala Lumpur, Malaysia; [3] School of Pharmacy, Monash University Malaysia, Jalan Lagoon Selatan, 47500 Bandar Sunway, Selangor, Malaysia; [4] Division of Social Research in Medicine and Health, School of Pharmacy, University of Nottingham, University Park, NG7 2RD, Nottingham, United Kingdom

*Corresponding author: Prof Claire Anderson, Tel: 01159515389, Fax: 01158466249, E-mail: claire.anderson@nottingham.ac.uk

[¶]These authors contributed equally to this work
[&]These authors also contributed equally to this work

Abstract

Objectives: To develop and validate Osteoporosis Prevention and Awareness Toole (OPAAT) in Malaysia.

Methods: The OPAAT was modified from the Malaysian Osteoporosis Knowledge Tool and developed from an exploratory study on patients. Face and content validity was established by an expert panel. The OPAAT consists of 30 items, categorized into three domains. A higher score indicates higher knowledge level. English speaking non-osteoporotic postmenopausal women ≥50 years of age and pharmacists were included in the study.

Results: A total of 203 patients and 31 pharmacists were recruited. Factor analysis extracted three domains. Flesch reading ease was 59.2. The mean±SD accuracy rate was 0.60±0.22 (range:0.26-0.94). The Cronbach's α for each domain ranged from 0.286-0.748. All items were highly correlated (Spearman's rho:0.761-0.990, p<0.05), with no significant change in the overall test-retest scores, indicating that OPAAT has achieved stable reliability. Pharmacists had higher knowledge score than patients (80.9±8.7vs63.6±17.4, p<0.001), indicating that the OPAAT was able to discriminate between the knowledge levels of pharmacists and patients.

Conclusion: The OPAAT was found to be a valid and reliable instrument for assessing patient's knowledge about osteoporosis and its prevention in Malaysia. The OPAAT can be used to identify individuals in need of osteoporosis educational intervention.

Keywords: osteoporosis; knowledge; validation; prevention; education; postmenopausal

Introduction

The validation of an instrument is necessary to ensure that the cultural differences and language used are suitable for a population, and that the instrument measures what it was designed to measure (Smith, 2002, Lai, 2013). Seven knowledge tools for osteoporosis have been developed and validated: the Facts on Osteoporosis (Ailinger et al., 2003, Ailinger et al., 1998, Ailinger and Emerson, 1998), the Osteoporosis Knowledge Assessment Tool (OKAT) (Winzenberg et al., 2003), the Osteoporosis Questionnaire (OPQ) (Pande et al., 2000), the Osteoporosis Knowledge Test (OKT) (Kim et al., 1991), the Osteoporosis and You (Cadarette et al., 2007), the Osteoporosis Knowledge Questionnaire (OKQ) (Curry and Hogstel, 2001), and the Malaysian Osteoporosis Knowledge Tool (MOKT) (Lai et al., 2008). All these tools were developed and validated in English (Ailinger et al., 2003, Ailinger et al., 1998, Ailinger and Emerson, 1998, Winzenberg et al., 2003, Pande et al., 2000, Kim et al., 1991, Cadarette et al., 2007, Lai et al., 2008). These studies were mainly conducted in Australia (Winzenberg et al., 2003), United Kingdom (Pande et al., 2000), United States of America (Ailinger et al., 2003, Ailinger et al., 1998, Ailinger and Emerson, 1998, Kim et al., 1991, Curry and Hogstel, 2001) and Canada (Cadarette et al., 2007). None of these tools were validated in an Asian population except for the MOKT, which was developed and validated in Malaysia (Lai et al., 2008). These tools focused mainly on assessing knowledge of osteoporosis and its treatment (Lai et al., 2008, Kim et al., 1991, Ailinger et al., 2003, Ailinger et al., 1998, Ailinger and Emerson, 1998, Winzenberg et al., 2003, Pande et al., 2000, Cadarette et al., 2007, Curry and Hogstel, 2001).

In Malaysia, the English version of the OKT was translated to Malay and validated in men and women aged 38-90 years with diabetes mellitus (Abdulameer et al., 2013, Kim et al., 1991). However, the Malay version of the OKT was unsuitable for our study, as the OKT assessed prevention knowledge by rating the likelihood of getting osteoporosis based on the type of preventive measure taken. The items in the OKT were also based on the American population and lifestyle, making it unsuitable for the current study (Kim et al., 1991).

Knowledge of osteoporosis plays an important role in developing attitudes towards the disease which in turn impacts health care behaviors (Andersen, 1995). Patients' health beliefs are defined by attitudes, values and knowledge about health and health services. Although knowledge is not the only component to cause behavioural changes in patients, it is one of the essential components. Therefore patients should be equipped with the knowledge of the various prevention measures available to increase the likelihood of osteoporosis prevention and its fractures.This includes knowledge on physical activity, adequate calcium intake, adequate vitamin D intake, fall prevention and screening of osteoporosis (Ministry of Health Malaysia, 2012).

Primary prevention of osteoporosis is directed at identifying high risk non-osteoporotic individuals, while secondary prevention of osteoporosis refers to the early detection of the disease and prevention of subsequent fragility fracture. Both primary and secondary prevention involve osteoporosis preventing behaviours (Lundy and Janes, 2009). Therefore, it is important to educate patients on the importance of screening and prevention, as studies have found that early

detection of osteoporosis are the most cost-effective ways to reduce the number of hospital admittance due to osteoporotic fractures (Hajcsar et al., 2000, Cranney et al., 2008, Davis et al., 2007, Richy et al., 2004a).

Although there are many methods to increase osteoporosis preventive behaviour such as physician reminders (Cranney et al., 2008) and screening programs (Yuksel et al., 2010), patient education has been found to be an effective component in increasing knowledge and frequency of osteoporosis preventive behavior (Nielsen et al., 2008, Gaines and Marx, 2011)Studies have found a positive relationship between osteoporosis knowledge and preventive behaviour (Burke-Doe et al., 2008, Terrio and Auld, 2002). Additionally, a systematic review found that educational programs may have a positive impact on the patients' ability to engage in preventing and managing osteoporosis (Jensen et al., 2013)However, some studies suggest otherwise (Etemadifar, 2013, Kasper et al., 1994). The differences in their methodologies makes it difficult to generalize results, as some studies used qualitative methods (Terrio and Auld, 2002) whilst others used quantitative methods (Etemadifar, 2013, Burke-Doe et al., 2008, Kasper et al., 1994). Additionally, these variation in results may also suggest that knowledge is not the only component that affects behavioural change, Beliefs, attitudes and values are other components that may be a barrier to implementing osteoporosis preventive efforts (Andersen, 1995). Nonetheless, knowledge is one of the components in behavioral change and should be addressed when implementing osteoporosis prevention efforts.
Previous studies have found that the knowledge of osteoporosis in adult women aged 21-90 years in Europe

(Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Ungan and Tumer, 2001), Canada (Cadarette et al., 2007), United States (Ailinger and Emerson, 1998, Burke-Doe et al., 2008), Middle East (Baheiraei et al., 2005b), and Australia (Winzenberg et al., 2003) was low. In Asia, the knowledge of osteoporosis ranged fromlow to moderate for women aged 19-90 in Brunei (Liza et al., 2009), Singapore (Saw et al., 2003) and Malaysia (Abdulameer et al., 2013, Yeap et al., 2010, Khan et al., 2014). However, another study in Malaysia found that the knowledge of osteoporosis was moderate in women aged 49-84 (Lai et al., 2008). Additionally, we would like to highlight the lack of knowledge on osteoporosis occurs in women who have not experienced a fracture, as well as those who had a previous fracture (Beaton et al., 2012). Conversely, women and men aged 16-79 years in Norway were knowledgeable about osteoporosis (Magnus et al., 1996). The different tools used to assess knowledge and the different cohorts in which the tool was administered to (Lai et al., 2008, Abdulameer et al., 2013, Khan et al., 2014, Yeap et al., 2010) made comparison between studies difficult. In addition, most studies did not report the use of validated tools to assess knowledge levels (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Ungan and Tumer, 2001, Burke-Doe et al., 2008, Liza et al., 2009, Yeap et al., 2010, Khan et al., 2014, Kasper et al., 1994, Etemadifar, 2013, Magnus et al., 1996).

In Malaysia, there is currently no available tool to assess the knowledge of osteoporosis and its prevention in Asia. Hence, we aimed to develop and validate the English version of the Osteoporosis Prevention and Awareness Tool (OPAAT) in Malaysia.

Method:

Design:

This study was divided into 2 phases: development and validation of the OPAAT. The development of the OPAAT involved modifications of the MOKT and qualitative findings. The validation of the OPAAT was a prospective study conducted at a primary care clinic of a tertiary hospital, from October 2013 to January 2014.

14.14

14.15   The development of the Osteoporosis Prevention

14.16   and Awareness Tool (OPAAT)

Despite Malay being the national language of Malaysia, postmenopausal women aged 50 years and above are more fluent in English as schooling was only conducted in the English language then. Hence, the OPAAT was developed in English, based on modifications from the MOKT (Lai et al., 2008) and findings from a qualitative study which examined the barriers and needs towards an osteoporosis screening and prevention service in Malaysia (Toh et al., 2012).

We took 10 out of the 50 items from the MOKT, as the other items were related to assessing knowledge on risk factors of osteoporosis, osteoporosis medication or misconceptions about osteoporosis. Six items were rephrased. For item 1, we added the word "fracture" in parenthesis to emphasize that the word "broken bones" means fracture (Refer to supplementary document 1). For item 5, "early on" was removed as patients were unaware that osteoporosis was asymptomatic and the phrase "early on" may confuse them (Toh et al., 2012). As for item 13 and 16, we combined the original four questions to develop two questions; as "a loss of

height" and "hunchback" were essentially assessing the same thing, and "joint pain" and "swelling of the fingers" were both referring to symptoms of osteoarthritis. Four items from the MOKT were used in its original format.

Results from the qualitative study found that patients, nurses, general practitioners, pharmacists and policy makers lacked knowledge in the following areas: screening and prevention of osteoporosis, and misconceptions of osteoporosis (Toh et al., 2012). Therefore 22 new items were added. The final OPAAT consist of 30 items, and was divided into three domains: osteoporosis in general (Domain A), consequences of untreated osteoporosis (Domain B) and osteoporosis prevention (Domain C).

Face and content validity of the OPAAT was established via consultation with an expert panel consisting of four pharmacists with many years of research and clinical experience. Comprehension of the questionnaire was tested on 10 postmenopausal women who understood English. This involved asking the patients for their opinions about the phrasing, format and content of the tool. The patients encountered no difficulty in answering the questionnaire. Hence, no further changes were made.

14.17

14.18   Participants

Patient group

English speaking postmenopausal women aged 50 years and above, who had not been diagnosed with osteoporosis/osteopenia was included. The patients' clinical information on the diagnosis of osteoporosis/osteopenia were obtained from medical records prior to the provision of

service. Participants who were feeling too unwell to participate in the study were excluded. The OPAAT was administered to the patient group at baseline and 2 weeks later to assess reliability.

Professional group

To assess discriminant validity, pharmacists were recruited from the same tertiary hospital as the healthcare professionals. Pharmacists were expected to have higher knowledge of osteoporosis than patients. The OPAAT was administered to the pharmacists only once, as we wanted to assess the instrument's ability to discriminate between the knowledge scores of patients and healthcare professionals at baseline.

Sample size

Patient group

Sample size was calculated based on a 5:1 participant ratio for factor analysis (Gorsuch, 1983). Since the OPAAT had 30 items, the total number of participants needed was 150. Allowing for a 20% loss to follow up, the final number of participants required was 180.

Professional group

The sample size of the professional group was 31 as that was the total number of pharmacists in the setting. Nonetheless, we recruited the pharmacist to assess the discriminant validity using the Mann-Whitney U test and chi-square test. Both these test were able to assess the discriminant validity using unequal sample sizes (Mann and Whitney, 1947, McHugh, 2013). The pharmacists were excluded from factor analysis.

14.19 Validation of the Osteoporosis Prevention and Awareness Tool (OPAAT)

14.20 Instruments used

Baseline demographics

Baseline demographic information such as patients' medical history, lifestyle and medication history was collected. Pharmacists' baseline information, work experience and education level were also collected.

Osteoporosis Prevention and Assessment tool (OPAAT)

The OPAAT consist of 30 items with three domains: osteoporosis in general, consequence of untreated osteoporosis and osteoporosis preventive measure.

Procedure

Patients were recruited at two waiting rooms as the waiting time for the general practitioner's appointment is normally one to two hours. This makes it an ideal time to recruit the patients without increasing the frequency of the patients' visit to the hospital. Additionally, we recruited patients at the waiting room as not all patients who attended the primary care clinic had a scheduled appointment. Primary care patients

include both walk-in and appointment patients. We wanted to include both these groups of patients in our study to reflect the actual clinic scenario. Additionally, not all patients' contact number was updated as the primary care clinic uses both paper and electronic records. Therefore it was not possible to randomly contact the participants.

A 1:2 systematic random sampling method was used by the researcher to recruit participants as it was not possible for one researcher to recruit all the potentially eligible participants at the clinic. The medical folders of eligible participants were labelled from 1-40, and a number was randomly drawn from a bag to determine the starting number at the start of each day that the researcher recruited participants. This was performed to ensure that sampling was random. Subsequently every 2nd medical folder was selected for recruitment.

Additionally, some participants (11 participants) were also recruited using the "snowballing" method as the validation of the OPAAT was conducted concurrently with the validation of several osteoporosis risk assessment tools. As the awareness of the project spread the participants began to refer their friends and family. Although this is a non-randomized method or recruiting the patients, it only comprise of 7.3% of the participants in our study and should not affect the outcome as 20% of the sample size was allocate for drop-outs..

The patient's baseline demographic information was collected. Patients answered the questionnaire themselves. For those who experienced some difficulty in reading the questions, the researcher assisted them. The researcher then checked the questionnaire to ensure that questions were answered. Most

patients took approximately 10 minutes to complete the questionnaire. The OPAAT was administered again to the same group of patients after two weeks to assess reliability. A duration of two weeks was used as this time interval is generally accepted to be long enough that the participants do not remember their original responses but not long enough for their knowledge of the material to have change (DeVon et al., 2007). atients were questioned about significant changes or events occurring within two weeks and all changes were documented. Pharmacist baseline information was collected. The OPAAT was administered to the pharmacists only once at baseline.

14.21   Ethics approval

Written consent was obtained from all participants. This study was approved by the Medical Ethics Committee of the hospital (University Malaya Medical Centre) under study (ref no 920.27).

14.22   Data analysis

All data was entered into the IBM® SPSS® version 20 (IBM Corporation, Armonk, NY, USA). For the OPAAT, a score of one was given for a correct response and zero for an incorrect or do not know response. The total score was converted into percentage ranging from 0-100. Each domain score was also analyzed. Flesch reading ease was calculated using Microsoft Office® Word® 2007 (Microsoft Corporation, Redmond, WA, USA). Non-parametric tests were used since data obtained were not normally distributed. A p-value <0.05 was considered as statistically significant.

Factor analysis

The construct validity of OPAAT was examined by using exploratory factor analysis (EFA). Traditionally, factor analysis such as EFA and confirmatory factor analysis (CFA) can only be performed when data are of continuous scale (Harrington, 2009, Kim and Mueller, 1978). However, Bruin (2006) developed a new algorithm of EFA to account for categorical data. In this study, EFA was performed on three separate domains to explore the appropriateness of factor structure of the current questionnaire (Bruin, 2006). Factors with eigenvalues greater than one were considered as having significant contribution in explaining the overall model variation and were retained (Kaiser, 1960, Harman, 1976).

Flesch reading ease

Flesch reading index is a tool used for estimating the reading comprehension level necessary to understand a written document based on the average number of syllables per word and the average number of words per sentence. The Flesch reading ease was calculated using the formula below:

Flesch reading ease= 206.835- (1.015x average sentence length) - (84.6 x average number of syllables per word)

The Flesch reading score (which range from 0 to 100) indicates the level of difficulty in understanding the document. The lower the score, the greater the difficulty. An average document should have a score of 60-70 (Flesch, 1948).

Accuracy rate

The accuracy rate is used to measure the difficulty of a question. It is calculated by the number of correct responses

divided by the total number of responses. The higher the accuracy rate, the easier the question is. The optimal level should be 0.5 as a value of higher than 0.75 is deemed to be poor as the question may be too easy. Items with difficulty values between 0.3 and 0.7 are most effective. (University Testing Services).

Cronbach's α

Cronbach's α coefficient is a tool used to assess internal consistency. Cronbach's α value: >0.9- Excellent, >0.8- Good, >0.70- Acceptable, >0.6- Questionable, >0.5 – Poor and <0.5- Unacceptable (George and Mallery, 2003). If omitting an item increases Cronbach's α significantly, then excluding the item will increase the homogeneity of the scale (Cronbach, 1951).

Corrected inter-item correlations are the correlations between each item and the total score from the questionnaire. All items should correlate with the total to be considered a reliable scale. A value of less than 0.3 shows a poor correlation and these items should be considered to be excluded. (Field, 2005).

Test-retest for reliability

For test- retest, categorical data were analysed using the kappa measure of agreement and the Mc Nemar's test. In order to define inter-rater reliability, a kappa measure of agreement was calculated for each item. A kappa value of 0.5 represents moderate agreement, above 0.7 represents good agreement and above 0.8 represents very good agreement (Peat, 2001). Mc Nemar's test was used to examine the test-retest reliability on the individual items. Continuous data of

the individual items and total domain scores were analyzed using the Wilcoxon signed-rank test and Spearman's rho correlation coefficient. According to Cohen 1988, a value of 0.10-0.29 showed a low correlation, 0.30-0.49 moderate correlation and 0.50-1.00 high correlation (Cohen, 1988).

Discriminative validity

To assess discriminative validity, the chi square test was used on categorical data of the individual items to detect the difference between the patient group and professional group. The Mann-Whitney U test was used for continuous data of the individual items and total domains score to compare if there was any significant difference between the patient and professional group.

Factors associated with knowledge score

Linear multiple regression was used to identify factors associated with knowledge. It used to estimate the linear relationship between a dependent variable (knowledge score) and one or more independent variables (demographic variables).

Results

A total of 253 patients were approached, 19 declined. 234 participants were recruited (patients=203, hospital pharmacists=31), [patient response rate=91.4%, pharmacists response rate= 100.0%]. Patients' demographic data are shown in Table 1. Pharmacists recruited worked in different areas of the pharmacy, with working experience ranging from 1-10 years.

14.23   Factor analysis

As shown in Table 2(a), for domain A, EFA yielded one factor with eigenvalue of 4.04 which contributed to 81.0% of total variation. Ten items within this domain have factor loadings greater than 0.3 in Table 3(a), suggesting substantial contribution in explaining overall variation. In Table 2(b),for domain B, EFA also produced only one factor with eigenvalue greater than one, i.e. 1.9 which explained 87.3% of total variation. All five questions within this domain had factor loadings greater than 0.3 as shown in Table 3(b). In Table 2(c), for domain C, EFA generated the only one factor with eigenvalue greater than one (4.4). This factor contributed to 69.4% of total variation. Table 3(c) showed that factor loadings of all 12 items within this domain were above 0.3. Overall, the data from the three EFAs suggested the adequacy of one factor for each of the domain [Table 2 and 3].

14.24   Psychometric properties of the Osteoporosis Prevention And Awareness Tool (OPAAT)

Flesh reading ease was 59.2. The mean ± SD accuracy rate was 0.60±0.22 (range:0.26-0.94). Four out of 30(13.3%) items had values <0.3 and 11/30(36.7%) items had values of >0.75. The remaining 15/30(50.0%) items had values between 0.3-0.75.

Cronbach's α was analyzed for the three domains. All domains had a Cronbach's α of ≥0.6 except for the domain B (0.286).. All 30 items met the requirement of >0.3 for the corrected item –total correlations except for items 13/30(43.3%) [Table 4]. However all items were retained

14.25   Test-retest reliability

At retest, 9(4.4%) patients could not be contacted. Hence, 194 questionnaires from patients (response rate = 95.6%) were included in test-retest [See table 5]. The Kappa measurement of agreement showed that 29/30 items (96.7%) were in very good agreement, and 1/30 items (3.3%) was in good agreement. The McNemar's test showed no significant differences for all test-retest items. The Wilcoxon signed-rank test showed no significant difference for all domain scores except for the domain score on 'consequences of untreated osteoporosis.' Nonetheless, the total score showed no significant difference. All domains and items were significantly correlated using the Spearman's rho correlation coefficient (0.760-0.990, $p < 0.05$) [Table 5].

The overall total knowledge score for the pharmacist group was significantly higher than the patient group (80.9 ± 8.7 vs 63.6 ± 17.4, $p < 0.001$) [Table 6]. The chi square test showed no significant difference for 16/30(53.3%) items between the patient and pharmacist group. There were significant differences in all domains based on the Mann-Whitney U-test.

14.26   Factors associated with knowledge

Knowledge was higher in patients who completed their high school education, and patients who conducted fall prevention activities ($R^2=0.208$, F=3.949, df=18, $p < 0.001$). These two factors explained 27.9% of the variances.

14.27   Comparison of the Osteoporosis Prevention And Awareness Tool (OPAAT) with other validated instruments

The OPAAT had a similar Flesch reading ease as the MOKT 59.2 and 57 respectively. The Cronbach's α if the OPAAT ranged from 0.27-0.75 which was similar to the MOKT, Osteoporosis and you, OKAT and FOOQ which ranged from 0.60-0.82. This shows that the psychometric properties of the OPAAT were similar to that of other validated instruments for measuring patients' knowledge [Table 7].

14.28   Discussion

The OPAAT performed satisfactorily in its psychometric properties and was able to discriminate between knowledge level of patients and pharmacists. This indicates that the English version of OPAAT is suitable to assess knowledge of postmenopausal women about osteoporosis prevention in Malaysia.

EFA confirmed that there were three domains (osteoporosis in general, consequences of untreated osteoporosis and osteoporosis prevention) in the OPAAT to assess patient's knowledge on osteoporosis and its prevention. This provides support for the construct validity of our tool. To the best of our knowledge no other osteoporosis knowledge assessment tool has validated the construct of their tool via this method.

Flesch reading ease was at 59.2. This indicates the OPAAT can be understood by patients who have completed primary education. Since all of our participants have completed primary education, they were able to complete the OPAAT

without any problems. The OPAAT had a satisfactory accuracy rate of 0.60±0.22 (range: 0.26-0.94). Out of the 30 items, four items were considered difficult (accuracy rates <0.3) and five considered easy (accuracy rates >0.7). The optimum difficulty level would be 0.5. This indicates that the OPAAT was moderately easy for the participants to answer.

The construct of the tool was considered to be multi-dimensional and an overall Cronbach's α was unsuitable. We then analyzed the Cronbach's α by domain. All domains demonstrated good and acceptable internal reliability except the domain on the 'consequences of untreated osteoporosis' with a Cronbach α value of 0.286. This could be because there were only 5 items in this domain, and knowing the correct answer for one item may not necessarily mean that they knew the correct answer for the next item. However, increasing the number of items within the domain would have made the questionnaire too lengthy reducing the likelihood of completion. Corrected item-total correlations showed that all items measured the same main component which is satisfaction except items 13/30(43.3%). However all items were retained as removing any of the items did not improve the overall Cronbach's α significantly.

All 30 items performed satisfactorily at test-retest except for the domain on "consequences of untreated osteoporosis." Patients may have forgotten the answer they selected at test (as they were just guessing) as opposed to knowing the right answer. This led to a significant difference in this domain score as it had a small number of items. Although this limits how well this domain can measure the knowledge on the consequences of untreated osteoporosis, the guessing of

answer reflects actual practice. Nonetheless, there was no significant difference in the overall scores.This indicates the OPAAT has achieved stable reliability. The domains and items had a high Spearman's rho correlation coefficient ranging from 0.760-0.990. They were all significantly correlated at $p<0.05$. Therefore, all items were retained.

Although pharmacists were expected to have a higher score than patients for all items, there were three items (items no. 13, 17 and 23) where no significant difference was found. This may be because more than 80.0% of both patients and pharmacists correctly answered items no. 13 and 23, indicating that their knowledge level for these items were high. As for item no. 17 which was pertaining to calcium intake, less than 60.6% of patients and pharmacists answered this item correctly. This concurs with our previous qualitative findings that found that both patients and pharmacists lacked knowledge in this area. (Toh et al., 2012). Nonetheless, the overall score and all domain scores of the OPAAT showed a significant difference between the patient and pharmacist group. This indicates that the OPAAT has achieved discriminative validity.

Patients' overall knowledge score was 63.6±17.4, which indicate that their knowledge level was moderate. Our results were similar to a previous study conducted in Malaysia which assessed knowledge on osteoporosis and its prevention (Lai et al., 2008). This may be because both studies were conducted in the same setting. In addition, participants in both studies were mainly health seeking urban patients.

However, we would like to highlight that the cohort of patients used in the Lai et al study was on patients who had

osteoporosis. Our study evaluated non-osteoporotic patients, this shows that there was no difference in knowledge in osteoporotic patients and undiagnosed patients. Another tool, the Osteoporosis Knowledge Questionnaire (OKQ) assessed on osteoporosis risk factors, diagnosis, prevention and treatment in female population aged 60 and above scored 57.4% (Curry and Hogstel, 2001). OKQ score was similar to OPAAT as they assessed non-osteoporotic postmenopausal population of a similar age group.

Other studies using the Osteoporosis Knowledge Assessment Tool (OKAT) assessed osteoporosis knowledge and risk factors in females aged 25-44 years scored only 44% (Winzenberg et al., 2003). Osteoporosis and You assessed knowledge of osteoporosis, risk factors, consequences of untreated osteoporosis and prevention in females aged 65-90 years scored even lower at 37.7% (Cadarette et al., 2007). Both the OPAAT and OKAT had a similar number of items with low difficulty level of 17.9% and 15% respectively. Hence, the difference of OPAAT and OKAT's score may be because OKAT examined the younger generation who may not have reached menopause leading to a lack of awareness of osteoporosis. Similarly, Osteoporosis and You examined more elderly population and they may not have been as educated as the younger generation. People have become more aware of osteoporosis in the recent years but this may not have reached older people. Osteoporosis and you had 60% of its items in the low difficulty level which was more than the OPAAT.

Patients' knowledge was lowest on the domain on the 'consequences of untreated osteoporosis.' This concurs with

findings from our qualitative research which indicates that there is a need to educate patients in this area (Toh et al., 2012). Correspondingly, Osteoporosis and You noted a deficit in knowledge in the area of consequences of untreated osteoporosis (Cadarette et al., 2007). These tools were developed mainly to assess the knowledge of domains of osteoporosis in general and treatment, the OPAAT was developed specifically to evaluate osteoporosis prevention.

In our study, factors with a positive correlation to the knowledge score includes patients with a secondary or higher education level, and patients who conducted fall prevention activities. Similarly, a Greek and Turkish study noted an association with knowledge and level of education (Alexandraki et al., 2008, Gemalmaz and Oge, 2007, Khan et al., 2014). Additionally, Khan et al's findings concurred with our study as they noted a significant association between knowledge and ethnicity (Khan et al., 2014). Conversely, Ailinger et al stated neither education level, age nor the menopause status increase osteoporosis knowledge (Ailinger and Emerson, 1998). Patients who conduct fall preventive measure had more knowledge of osteoporosis. This further justifies the importance of a higher knowledge level about osteoporosis prevention to ensure its implementation.

One of the limitations was that convergent validity could not be performed as a gold standard tool to measure knowledge of osteoporosis prevention and screening was unavailable during the period of study. Additionally, the patients in our study were mainly Chinese (62.1%), Malay (14.8%) and Indians (21.7%). This does not represent the ethnic distribution of Malaysia, but it represents the patients who sought treatment

in our study site. Future validation studies of our tool to Malay and Mandarin, and enrolment of patients from multi-sites would be more representative of the Malaysian population. Nonetheless, a large proportion of our patients had a monthly household income above $1553 (81/203) which was representative of the married Malaysian household population income. Seventy six percent (155/203) of our participants were married. The average individual monthly income in Malaysia ranges from RM1445-3137 ($451.6-980.3) depending on the location (rural or urban) (Department of statistics Malaysia, 2013)

Another limitation is that our research used mixed methods when administering the OPAAT. At baseline we used self-administration and interviewed participants who had difficulty answering the OPAAT (2.5% patients required assistance). Subsequently, the OPAAT was administered using telephones interviews during the two week follow up. We used this approach to optimize response rate and cost. However, mixing the administration method increases the probability that the participants will give different answers due to the difference in administrations mode rather than in opinion (Check and Schutt, 2012). Nonetheless, we have carefully designed the survey to ensure that the survey was equivalent across modes (De Leeuw, 2005). The researcher was also trained to reduce interviewer bias (Check and Schutt, 2012).

14.29   Conclusion:

The English version of the OPAAT was found to be a reliable and valid instrument for assessing patient knowledge on osteoporosis and its prevention in Malaysia. Future studies, using Bahasa Malaysia and Mandarin versions of the questionnaire are required to assess patient knowledge for

Malaysians that are not fluent in English. The OPAAT can assists in identifying patients who need more information on osteoporosis and its prevention. These patients can then be enrolled in an osteoporosis prevention and screening program with an education intervention component. OPAAT can subsequently be used to evaluate the effectiveness of the education efforts provided.

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References

ABDULAMEER, S. A., SULAIMAN, S. A. S., HASSALI, M. A. A., SUBRAMANIAM, K. & SAHIB, M. N. 2013. Psychometric properties of osteoporosis knowledge tool and self-management behaviours among Malaysian type 2 diabetic patients. *J Community Health,* 38**,** 95-105.

ADAY, L. A. & CORNELIUS, L. J. 2006. *Designing and conducting health surveys: A comprehensive guide,* San Francisco, USA, Jossey-Bass A Wiley Imprint.

AILINGER, R. L. & EMERSON, J. 1998. Women's knowledge of osteoporosis.pdf>. *Applied Nursing Research,* 11**,** 111-114.

AILINGER, R. L., HARPER, D. C. & LASUS, H. A. 1998. Bone up on osteoporosis development of the facts on osteoporosis quiz. *Orthop Nurs,* 17**,** 66-73.

AILINGER, R. L., LASUS, H. A. & BRAUN, M. A. 2003. Brief report: revision of the factors on Osteoporosis Quiz. *Nurs Res,* 52**,** 198-201.

AJZEN, I. 1991. The theory of planned behavior. *Organizational behaviour and human decision processes,* 50**,** 179-211.

ALEXANDRAKI, K. I., SYRIOU, V., ZIAKAS, P. D., APOSTOLOPOULOS, N. V., ALEXANDRAKIS, A. I., PIPERI, C., KAVOULAKI, E., MYRIOKEFALITAKIS, I., KORRES, G. & DIAMANTI-KANDARAKIS, E. 2008. The

knowledge of osteoporosis risk factors in a Greek female population. *Maturitas,* 59**,** 38-45.

ANDERSEN, R. M. 1995. Revisiting the behavioral model and access to medical care: Does it matter? *Journal of Health and Social Behavior,* 36.

ANDERSON, C. 2010. Presenting and evaluating qualitative research. *American Journal of Pharmaceutical Education,* 74**,** 1-7.

ANDERSON, C., BLENKINSOPP, A. & ARMSTRONG, M. 2009. *The contribution of community pharmacy' to improving the public's health: summry report of the literature review 1990-2007* [Online]. Available: www.pharmacyhealthlink.org.uk [Accessed 12 December 2014].

AUSTRALIAN GOVERNMENT 2006. PBS extended listing of alendronate for treating osteoporosis and Medicare extended listing for bone mineral density testing. . *In:* AGEING, D. O. H. A. (ed.). Canberra, Australia: Australian government,.

AZMI, M. Y., JUNIDAH, R., SITI MARIAM, A., SAFIAH, M. Y., FATIMAH, S., NORIMAH, A. K., POH, B. K., KANDIAH, M., ZALILAH, M. S., WAN ABDUL MANAN, W. M., SITI HASLINDA, M. D. & TAHIR, A. 2009. Body mass index (BMI) of adults: Findings ofthe Malaysian adult nutrition survey (MANS). *Mal J Nutr,* 15**,** 97-119.

BACKETT-MILBURN, K., PARRY, O. & MAUTHNER, N. 2000. 'I'll worry about that when it comes along': osteoporosis, a meaningful issue for women at mid life. *Health Education Research,* 15**,** 153-162.

BAGGER, Y. Z., TANKÓ, L. B., ALEXANDERSEN, P., HANSEN, H. B., MØLLGAARD, A., RAVN, P., QVIST, P., KANIS, J. A. & CHRISTIANSEN, C. 2004. Two to three years of hormone replacement treatment in healthy women have long-term preventive effects on bone mass and osteoporotic fractures: the PERF study. *Bone,* 34**,** 728-735.

BAHEIRAEI, A., POCOCK, N. A., EISMAN, J. A., NGUYEN, N. D. & NGUYEN, T. V. 2005a. Bone mineral density, body mass index and cigarette smoking among Iranian women: implications for prevention. *BMC Musculoskeletal Disorders,* 6**,** 34.

BAHEIRAEI, A., RITCHIE, J. E., EISMAN, J. A. & NGUYEN, T. V. 2005b. Psychometric properties of the Persian version of the osteoporosis knowledge and health belief questionnaires. *Maturitas,* 50**,** 134-139.

BALASEGARAM, S., MAJEED, A. & FITZ-CLARENCE, H. 2001. Trends in hospital admissions for fractures of the hip and

femur in England, 1989-1990 to 1997-1998. *J Public Health Med,* 23**,** 11-17.

BARBER, N. 2001. Pharmaceutical care and medicines management- is tere a difference? *Pharm World Sci,* 23**,** 210-211.

BARON, J. A., FARAHMAND, B. Y., E., W., MICHAËLSSON, K., ALBERTS, A., PERSSON, I. & LJUNGHALL, S. 2001. Cigarette smoking, alcohol consumption, and risk of hip fracture in women. *Arch Intern Med,* 161**,** 983-988.

BARRIS BLUNDELL, D., RODRIGUEZ ZARZUELO, C., SABIO SANCHEZ, B., GUTIERREZ ALVAREZ, J. L., NAVARRO VISA, E., VALDES MUNOZ, O., GARRIDO JIMENEZ, B. & SANCHEZ GOMEZ, R. 2006. Screening for osteoporosis among post-menopausal women in community pharmacy. *Pharmacy Practice,* 4**,** 95-101.

BARTHOLOMEW, L. K., PARCEL, G. S., KOK, G. & GOTTLIEB, N. H. 2001. *Intervention mapping: Designing theory- and evidence-based health promotion programs,* Mountain view, CA, Mayfield.

BARTHOLOMEW, L. K., PARCEL, G. S., KOK, G. & GOTTLIEB, N. H. 2011. *Planning health promotion programs: Intervention mapping,* San Francisco, USA, Jossey-Bass.

BARTL, R. & FRISCH, B. 2004. *Osteoporosis: Diagnosis, prevention, therapy: A practical guide for all physicians- from pediatrics to geriatrics,* Heidelberg, Germany, Springer.

BAZELEY, P. 2007. *Qualitative data analysis with Nvivo,* London, Sage publications.

BAZELEY, P. 2009. Analysing qualitative data: More than 'identifying themes'. *Malaysian Journal of Qualitative Research,* 2**,** 6-22.

BEATON, D. E., SUJIC, R., MCILROY BEATON, K., SALE, J., ELLIOT-GIBSON, V. & BOGOCH, E. R. 2012. Patient Perceptions of the Path to Osteoporosis Care Following a Fragility Fracture. *Qualitative Health Research,* 22**,** 1647-1658.

BESSER, S. J., ANDERSON, J. E. & WEINMAN, J. 2012. How do osteoporosis patients perceive their illness and treatment? Implications for clinical practice. *Arch Osteoporosis,* 7**,** 115-124.

BILEZIKIAN, J. P., KHAN, A., POTTS, J. T., BRANDI, M. L., CLARKE, B. L., SHOBACK, D., JÜPPNER, H., D'AMOUR, P., FOX, J., REJNMARK, L., MOSEKILDE, L., RUBIN, M. R., DEMPSTER, D., GAFNI, R., COLLINS, M. T., SLINEY, J. & SANDERS, J. 2011. Hypoparathyroidism in the adult: Epidemiology, diagnosis, pathophysiology, target- organ involvement, treatment, and challenges for future

research. *Journal of Bone and Mineral Research,* 26**,** 2317-2337.

BLACK, D. M., ARDEN, N. K., PALERMO, L., PEARSON, J. & CUMMINGS, S. R. 1999. Prevalent vertebral deformities predict hip fractures and new vertebral deformities but not wrist fractures. Study of Osteoporotic Fractures Research Group. . *J Bone Miner Res,* 14**,** 821-828.

BOGOCH, E. R., ELLIOT-GIBSON, V., BEATON, D., JAMAL, S. A., JOSSE, R. G. & MURRAY, T. M. 2006. Effective initiation of osteoporosis diagnosis and treatment for patients with fragility fracture in orthopaedic environment. *J Bone Joint Surg Am,* 88**,** 25-34.

BOUDOU, L., GERBAY, B., CHOPIN, F., OLLAGNIER, E., COLLET, P. & THOMAS, T. 2011. Management of osteoporosis in fracture liaison service associated with long-term adherence to treatment. *Osteoporosis International,* 22**,** 2099-2106.

BOWEN, G. A. 2008. Naturalistic inquiry and the saturation concept: a research note. *Qualitative Research,* 8**,** 137-152.

BOWLING, A. 2009. *Research methods in health: Investigating health and health services,* Glasgow, McGraw Hill.

BOYATZIS, R. E. 1998. *Transforming qualitative information: Thematic analysis and code development,* Thousang Oaks, California, Sage publications.

BRAUER, C. A., COCA-PERRAILLON, M., CUTLER, D. M. & ROSEN, A. B. 2009. Incidence and mortality of hip fractures in the United States. *JAMA,* 302**,** 1573-1579.

BRAUN, V. & CLARKE, V. 2008. Using thematic analysis in psychology. *Qualitative research in psychology,* 3**,** 77-101.

BRUIN, J. 2006. *Newtest: command to compute new test* [Online]. UCLA: Statistical Consulting Group. Available: http://www.ats.ucla.edu/stat/stata/ado/analysis/ [Accessed 5th May 2014].

BRYMAN, A. 2004. *Social Research Methods,* Hampshire, UK, Ashford Colour Press.

BURGE, R., DAWSON-HUGHES, B., SOLOMON, D. H., WONG, J. B., KING, A. & TOSTESON, A. 2007. Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025. *Journal of Bone and Mineral Research,* 22**,** 465-475.

BURKE-DOE, A., HUDSON, A., WERTH, H. & D.G., R. 2008. Knowledge of osteoporosis risk factors and prevalence of risk factors for osteoporosis, falls and fracture in functionally independent older adults. *Journal of Geriatric Physical Therapy,* 31**,** 11-17.

BYRE, M., CUPPLES, M. E., SMITH, S. M., LEATHAM, C., CORRIGAN, M., BYRE, M. C. & MURPHY, A. 2006. Development of a complex intervention for secondary prevention of coronary heath disease in praimry care using the UK Medical Reseach Council framework. *American Journal of Managed Care,* 12**,** 261-266.

CADARETTE, S. M., GIGNAC, M. A. M., BEATON, D. E., JAGLAL, S. B. & HAWKER, G. A. 2007. Psychometric properties of the "Osteoporosis and You" questionnaire: osteoporosis knowledge deficits among older community-dwelling women. *Osteoporos Int,* 18**,** 981-989.

CADARETTE, S. M., JAGLAL, S. B., KREIGER, N., MCISAAC, W. J., DARLINGTON, G. A. & TU, J. V. 2000. Development and validation of the osteoporosis risk assessment instrument to facilitate selection of women for bone densitometry. *CMAJ,* 162**,** 1289-1294.

CADARETTE, S. M., MCISAAC, W. J., HAWKER, G. A., JAAKKIMAINEN, L., CULBERT, A., ZARIFA, G., OLA, E. & JAGLAL, S. B. 2004. The validity of decision rules for selecting women with primary osteoporosis for bone mineral density testing. *Osteoporos Int,* 15**,** 361-6.

CAMPBELL, O., CLELAND, J., COLLUMBIEN, M. & SOUTHWICK, K. 1999. Social science methods for research in reproductive health. *World Health Organization: Geneva*.

CAULEY, J. A., ROBBINS, J., CHEN, Z., CUMMINGS, S. R., JACKSON, R. D., LACROIX, A. Z., LEBOFF, M., LEWIS, C. E., MCGOWAN, J., NEUNER, J., PETTINGER, M., STEFANICK, M. L., WACTAWSKI-WENDE, J. & B., W. N. 2003. Women's Health Initiative investigators. Effects of estrogen plus progestin on risk of fractures and bone mineral density; the Women's Health Initiative randomised trial. *the journal of the American Medical Association,* 290**,** 1729-1738.

CENTER, J. R., BLIUE, D., NGUYEN, T. V. & EISMAN, J. 2007. Risk of subsequent fracture after low-trauma fracture in men and women. *The journal of the American Medical Association,* 297**,** 387-394.

CERULLI, J. & ZEOLLA, M. M. 2004. Impact and feasibility of a community pharmacy bone mineral density screening and education program. *J Am Pharm Assoc,* 44**,** 161-167.

CHAN, S. P., TEO, C. C., NG, S. A., GOH, N., TAN, C. & DEURENBERG-YAP, M. 2006. Validation of various osteoporosis risk indices in elderly Chinese females in Singapore. *Osteoporos Int,* 17**,** 1182-8.

CHANDRA, A., MALCOLM, N. & FETTERS, M. 2003. Practicing Health Promotion Through Pharmacy Counseling Activities. *Health Promotion Practice,* 4**,** 64-71.

CHANG, K. P., CENTER, J. R., NGUYEN, T. V. & EISMAN, J. A. 2004. Incidence of Hip and Other Osteoporotic Fractures in Elderly Men and Women: Dubbo Osteoporosis Epidemiology Study. *Journal of Bone and Mineral Research,* 19**,** 532-536.

CHAPUY, M. C., ARLOT, M. E., DELMAS, P. D. & MEUNIER, P. J. 1994. Effect of calcium and cholecalciferol treatment for three years on hip fractures in elderly women. *British Medical Journal,* 308**,** 1081-1082.

CHARMAZ, K. 2006. *Constructing grounded theory,* London, Sage.

CHECK, J. & SCHUTT, R. K. 2012. *Research methods in education,* California, USA, Sage.

CHEE, S. S., ISMAIL, M. N., NG, K. K. & ZAWIAH, H. 1997. Food intake assessment of adults in rural and urban areas from four selected regions in Malaysia. *Mal J Nutr,* 3**,** 91-102.

CHEN, H. Y. & BOORE, J. R. P. 2009. Translation and back-translation in qualitative nursing research: Methodological review. *Journal of Clinical Nursing,* 19**,** 234-239.

CHEN, I. J., YU, S., WANG, T. F., CHENG, S. P. & HUANG, L. H. 2005. Knowledge about osteoporosis and its related factors among public health nurses in Taiwan. *Osteoporos Int,* 16**,** 2142-2148.

CIPOLLE, R. J., STRAND, L. M. & MORLEY, P. C. 2004. *Pharmaceutical Care Practice,* New York, USA, McGraw-Hill.

CLAESSON, A., TOTH-PAL, E., PIISPANEN, P. & SALMINEN, H. 2015. District nurses' perceptions of osteoporosis management: a qualitative study. *Osteoporosis International*.

CLUNIE, G. & STEPHENSON, S. 2008. Implementing and running a fracture liaison service: An integrated clinical service providing a comprehensive bone health assessment at the point of fracture management. *Journal of Orthopaedic Nursing,* 12**,** 159-165.

COHEN, J. W. 1988. *Statistical power analysis for the behavioral sciences,* Hillsdale, NJ, Lawrence Erlbaum Associates.

COMPSTON, J., COOPER, A., COOPER, C., FRANCIS, R., KANIS, J. A., MARSH, D., MCCLOSKEY, E., REID, D. M., SELBY, P., DAVIES, C. & BOWRING, C. 2014. Guideline for the diagnosis and management of osteoporosis in

postmenopausal women and men from the age of 50 years in the UK. *In:* GROUP, N. O. G. (ed.). Sheffield, UK.

CONRAD, K. J., RANDOLPH, F. L., KIRBY, M. W. & BEBOUT, R. R. 1999. Creating and Using Logic Models. *Alcoholism Treatment Quarterly,* 17**,** 17-31.

COOPER, C. 1993. Epidemiology and public health impact of osteoporosis. *Bailliere Clin Rheumatol Osteoporosis,* 7**,** 459-477.

COOPER, C., CAMPION, G. & J, M. L. 1992. Hip fracture in the elderly: A world-wide projection. *Osteoporos Int,* 2**,** 285-289.

COOPER, M. S., PALMER, A. J. & SEIBEL, M. J. 2011. Cost-effectiveness of the Concord Minimal Trauma Fracture Liaison service, a prospective, controlled fracture prevention study. *Osteoporosis International,* 23**,** 97-107.

COSMAN, F., LINDSAY, R., LEBOFF, M. S., JAN DE BEUR, S. & TANNER, B. 2014. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation.

CRAIG, P., DIEPPE, P., MACINTYRE, S., MICHIE, S., NAZARETH, I. & PETTICREW, M. 2008. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ,* 337**,** a1655.

CRANNEY, A., LAM, M., RUHLAND, L., BRISON, R., GODWIN, M., HARRISON, M. M., HARRISON, M. B., ANASTASSIADES, T., GRIMSHAW, J. M. & GRAHAM, I. D. 2008. A multifaceted intervention to improve treatment of osteoporosis in postmenopausal women with wrist fractures: a cluster randomized trial. *Osteoporos Int,* 19**,** 1733-40.

CRESWELL, J. W. 2009. *Research design: Qualitative, quatitative, and mixed methods approaches,* London, Sage.

CROCKETT, J. A., TAYLOR, S. J. & MCLEOD, L. J. 2008. Patient responses to an integrated service, initiated by community pharmacists, for the prevention of osteoporosis. *International Journal of Pharmacy Practice,* 16**,** 65-72.

CRONBACH, L. J. 1951. Coefficient alpha and the internal structure of tests. *Psychometrika,* 16**,** 297-334.

CUMMINGS, R. G. & NEVITT, M. C. 1997. Calcium for prevention of osteoporotic fractures in postmenopausal women. *Journal of Bone and Mineral Research,* 12**,** 1321-1329.

CUMMINGS, S. R. & MELTON, L. J. 2002. Epidemiology and outcomes of osteoporotic fractures. *The Lancet,* 359**,** 1761-1767.

CURRY, L. C. & HOGSTEL, M. O. 2001. Risk status related to knowledge of osteoporosis in older women. *J Women Aging,* 13.

D'AMOUR, D., GOULET, L., LABADIE, J.-F., MARTÍN-RODRIGUEZ, L. & PINEAULT, R. 2008. A model and typology of collaboration between professionals in healthcare organizations. *BMC Health Services Research,* 8**,** 188.

DAROSZEWSKA, A. 2012. Prevention and treatment of osteoporosis in women: an update. *Obstetrics, Gynaecology & Reproductive Medicine,* 22**,** 162-169.

DAVIS, J. C., GUY, P., ASHE, M. C., LIU-AMBROSE, T. & KHAN, K. 2007. Hip watch: Osteoporosis investigation and treatment after a hip fracture: A 6-month randomized controlled trial. *Journal of Gerontology,* 62A**,** 888-891.

DE LEEUW, E. D. 2005. To mix or not to mix data collection modes in survey. *Journal of Official Statistics,* 21**,** 223-255.

DELL, R., GREENE, D., SCHELKUN, S. R. & WILLIAMS, K. 2008. Osteoporosis Disease Management: The Role of the Orthopaedic Surgeon. *The Journal of Bone and Joint Surgery (American),* 90**,** 188-194.

DEPARTMENT OF STATISTICS MALAYSIA 2013. Salaries and wages survey report. *In:* MALAYSIA, D. O. S. (ed.). Putrajaya, Malaysia: Department of statistics Malaysia.

DEVON, H. A., BLOCK, M. E., MOYLE-WRIGHT, P., ERNST, D. M., HAYDEN, S. J., LAZZARA, D. J., SAVOY, S. M. & KOSTAS-POLSTON, E. 2007. A psychometric toolbox for validity n reliability. *Journal of Nursing Scholarship,* 39**,** 155-164.

DHANWAL, D. K., DENNISON, E. M., HARVEY, N. C. & COOPER, C. 2011. Epidemiology of hip fracture: Worldwide geographic variation. *Indian J Orthop,* 45**,** 15-22.

DOLOVICH, L., POTTIE, K., KACZOROWSKI, J., FARRELL, B., AUSTIN, Z., RODRIGUEZ, C., GAEBEL, K. & SELLORS, C. 2008. Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics. *Clinical Pharmacology and Therapeutics,* 83**,** 913-917.

DUYVENDAK, M., NAUNTON, M., VAN ROON, E. N. & BROUWERS, J. R. B. J. 2011. Doctors' beliefs and knowledge on corticosteroid-induced osteoporosis: identifying barriers to improve prevention. *Journal of Clinical Pharmacy and Therapeutics,* 36**,** 356-366.

EADES, C. E., FERGUSON, J. S. & O'CARROLL, R. E. 2011. Public health in community pharmacy: A systematic review of pharmacist and consumer views. *BMC Public Health,* 11**,** 582.

ELIAS, M. N., BURDEN, A. M. & CADARETTE, S. M. 2011. The impact of pharmacist interventions on osteoporosis management: a systematic review. *Osteoporos Int,* 22**,** 2587-96.

ELLIOT-GIBSON, V., BOGOCH, E. R., JAMAL, S. A. & BEATON, D. E. 2004. Practice patterns in the diagnosis and treatment of osteoporosis after a fragility fracture: a systematic review. *Osteoporosis International,* 15**,** 767-778.

ELLIOT, M. E., MEEK, P. D., KANOUS, N. L., SCHILL, G. R., WEINSWIG, P. A., BOHLMAN, J. P., ZIMPEL, C. L., JENSEN, B. C., WALTERS, D. R., SUTTER, S. L., PETERSON, A. N., PETERSON, R. M. & BINKLEY, N. C. 2002. Osteoporosis screening by community pharmacists: Use of National Osteoporosis Foundation resources. *J Am Pharm Assoc,* 42**,** 101-10.

ESCOTT, S. & WALLEY, S. 2005. Listening to those on the frontline: Lessons for community-based tuberculosis programmes from a qualitative study in Swaziland. *Soc Sci Med,* 61**,** 1701-1710.

ESPOSITO, N. 2001. From meaning to meaning: The influence of translation techniques on non-English focus group research. *Qualitative Health Research,* 11**,** 568-579.

ETEMADIFAR, M. R. 2013. Relationship of knowledge about osteoporosis with education level and life habits. *World Journal of Orthopedics,* 4**,** 139-143.

FAWCETT, T. 2006. An introduction to ROC analysis. *Pattern Recognition Letters,* 27**,** 861-874.

FELDSTEIN, A., ELMER, P. J., SMITH, D. H., HERSON, M., ORWOLL, E., CHEN, C., AICKIN, M. & SWAIN, M. C. 2006. Electronic medical record reminder improves osteoporosis management after a fracture: a randomized, controlled trial. *J Am Geriatr Soc,* 54**,** 450-7.

FELDSTEIN, A. C., SCHNEIDER, J., SMITH, D. H., VOLLMER, W. M., RIX, M., GLAUBER, H., BOARDMAN, D. L. & HERSON, M. 2008. Harnessing stakeholder perspectives to improve the care of osteoporosis after a fracture. *Osteoporosis International,* 19**,** 1527-1540.

FESKANICH, D., WILLETT, W. & COLDITZ, G. 2002. Walking and leisure-time activity and risk of hip fracture in postmenopausal women. *The journal of the American Medical Association,* 288**,** 2300-2306.

FIELD, A. P. 2005. *Discovering statistics using SPSS,* London, Sage.

FIELDEN, J., PURDIE, G., HORNE, G. & DEVANE, P. 2001. Hip fracture incidence in New Zealand, revisited. *N Z Med J,* 114**,** 154-156.

FLESCH, R. 1948. A new readability yardstick. *Journal of Applied Psychology,* 32**,** 221-233.

FLOOD, E. M., BEUSTERIEN, K. M., GREEN, H., SHIKIAR, R., BARAN, R. W., AMONKAR, M. M. & CELLA, D. 2006. Psychometric evaluation of the Osteoporosis Patient Treatment Satisfaction Questionnaire (OPSAT-Q), a novel measure to assess satisfaction with bisphosphonate treatment in postmenopausal women. *Health Qual Life Outcomes,* 4**,** 42.

FOPPE VAN MILL, J. W. 2004. Proving the benefits of pharmaceutical care. *Pharm World Sci,* 26**,** 123.

FOPPE VAN MILL, J. W., SCHULZ, M. & TROMP, T. F. 2004. Pharmaceutical care, European developments in concepts, implementation, teaching, and research: a review. *Pharm World Sci,* 26**,** 303-311.

FORD, R. C., BACH, S. A. & FOTTLER, M. D. 1997. Methods of measuring patient satisfaction in health care organizations. *Health care management review,* 22**,** 74-89.

FUJIWARA, S., MASUNARI, N., SUZUKI, G. & ROSS, P. D. 2001. Performance of Osteoporosis Risk Indices in a Japanese Population. *Curr Ther Res Clin Exp,* 62**,** 586-594.

GAINES, J. M. & MARX, K. A. 2011. Older men's knowledge about osteoporosis and educational interventions to increase osteoporosis knowledge in older men: A systematic review. *Maturitas,* 68**,** 5-12.

GALLAGHER, J. C. 1990. Metabolic effects of synthetic calcitriol (Rocaltrol) in the treatment of postmenopausal osteoporosis. *Metabolism,* 39**,** 27-29.

GANDA, K., PUECH, M., CHEN, J. S., SPEERIN, R., BLEASEL, J., CENTER, J. R., EISMAN, J. A., MARCH, L. & SEIBEL, M. J. 2012. Models of care for the secondary prevention of osteoporotic fractures: a systematic review and meta-analysis. *Osteoporosis International,* 24**,** 393-406.

GARDNER, M. J., BROPHY, R. H., DEMETRAKOPOULOS, D., KOOB, J., HONG, R., RANA, A., LIN, J. T. & LANE, J. M. 2005. Interventions to improve osteoporosis treatment following hip fracture. A prospective, randomized trial. *J Bone Joint Surg Am,* 87**,** 3-7.

GEATER, S., LEELAWATTANA, R. & GEATER, A. 2004. Validation of the OSTA index for discriminating between

high and low probability of femoral neck and lumbar spine osteoporosis among Thai postmenopausal women. *J Med Assoc Thai,* 87**,** 1286-1292.

GEMALMAZ, A. & OGE, A. 2007. Knowledge and awareness about osteoporosis and its related factors among rural Turkish women. *Clinical Rheumatology,* 27**,** 723-728.

GEORGE, D. & MALLERY, P. 2003. *SPSS for Windows step by step: A simple guide and reference,* Boston, USA, Allyn and Bacon.

GEORGE, P. P., MOLINA, J. A. D., CHEAH, J., CHAN, S. C. & LIM, B. P. 2010. The evolving role of the community pharmacist in chronic disease management- A literature review. *Ann Acad Med Singapore,* 39**,** 861-867.

GEUSENS, P., HOCHBERG, M. C., VAN DER VOORT, D. J. M., POLS, H., VAN DER KLIFT, M., SIRIS, E., MELTON, M. E., TURPIN, J., BYRNES, C. & ROSS, P. D. 2002. Performance of Risk Indices for Identifying Low Bone Density in Postmenopausal Women. *Mayo Clin Proc,* 77**,** 629-637.

GIANGREGORIO, L., PAPAIOANNOU, A., CRANNEY, A., ZYTARUK, N. & ADACHI, J. D. 2006. Fragility Fractures and the Osteoporosis Care Gap: An International Phenomenon. *Seminars in Arthritis and Rheumatism,* 35**,** 293-305.

GLASGOW, R. E., VOGT, T. M. & BOLES, S. M. 1999. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Publich Health,* 88**,** 1322-1327.

GOLD, D. T., HORNE, R., COON, C. D., PRICE, M. A., BORENSTEIN, J., VARON, S. F., SATRAM-HOANG, S. & MACARIOS, D. 2011. Development, reliability, and validity of a new Preference and Satisfaction Questionnaire. *Value Health,* 14**,** 1109-16.

GOODE, J. V. K., SWIGER, K. & BLUML, B. M. 2004. Regional osteoporosis screening, referral and monitoring program in community pharmacies: Findings from project imPACT: Osteoporosis. *Journal of the American Pharmacists Association,* 44**,** 152-160.

GORSUCH, R. L. 1983. *Factor analysis,* Hillsdale, NJ, Lawarence Erlbaum Associates.

GOURLAY, M. L., MILLER, W. C., RICHY, F., GARRETT, J. M., HANSON, L. C. & REGINSTER, J. Y. 2005. Performance of osteoporosis risk assessment tools in postmenopausal women aged 45-64 years. *Osteoporos Int,* 16**,** 921-7.

GOURLEY, G. A. & DUNCAN, D. V. 1998. Patient satisfaction and quality of life: Humanistic outcomes. *The American Journal of Managed Care,* 4**,** 746-755.

GREEN, L. W. & KREUTER, M. W. 1999. *Healt promotion planning: An educational and ecological apptroach,* Mountain View, CA, Mayfield.

GREENSPAN, S. L., WYMAN, A., HOOVEN, F. H., ADAMI, S., GEHLBACH, S., ANDERSON JR, F. A., BOONE, S., LACROIX, A. Z., LINDSAY, R., COEN NETELENBOS, J., PFEILSCHIFTER, J., SILVERMAN, S., SIRIS, E. S. & WATTS, N. B. 2012. Predictors of Treatment with Osteoporosis Medications After Recent Fragility Fractures in a Multinational Cohort of Postmenopausal Women. *J Am Geriatr Soc,* 60**,** 455-461.

GRIMES, D. A. & SCHULZ, K. F. 2002. Descriptive studies: what they can and cannot do. *The Lancet,* 359**,** 145-149.

GRODSTEIN, F., MANSON, J. E., STAMPFER, M. J. & REXRODE, K. 2008. Postmenopausal Hormone Therapy and Stroke. *Archives of Internal Medicine,* 168**,** 861-866.

GUTIN, B. & KASPER, M. J. 1992. Can vigorous exercise play a role in osteoporosis prevention? A review. *Osteoporos Int,* 2**,** 55-69.

GUZMAN-CLARK, J. R., FANG, M. A., SEHL, M. E., TRAYLOR, L. & HAHN, T. J. 2007. Barriers in the management of glucocorticoid-induced osteoporosis. *Arthritis Rheum,* 57**,** 140-146.

HA, Y.-C., LEE, Y.-K., LIM, Y.-T., JANG, S.-M. & SHIN, C. S. 2014. Physicians' Attitudes to Contemporary Issues on Osteoporosis Management in Korea. *Journal of Bone Metabolism,* 21**,** 143.

HAGINO, H., KATAGIRI, H., OKANO, T., YAMAMOTO, K. & TESHIMA, R. 2005. Increasing incidence of hip fracture in Tottori Prefecture, Japan: trend from 1986 to 2001. *Osteoporos Int,* 16**,** 1963-8.

HAJCSAR, E. E., HAWKER, G. & BOGOCH, E. R. 2000. Investigation and treatment of osteoporosis in patients with fragility fractures. *CMAJ,* 16**,** 819-822.

HARDEMAN, W., SUTTON, S., GRIFFIN, S., JOHNSTON, M., WHITE, A., WAREHAM, N. J. & KINMONTH, A. L. 2005. A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. *Health Education Research,* 20**,** 676-687.

HARDY, G. E., WEST, M. A. & HILL, F. 1996. Components and predictors of patient satisfaction. *British Journal of Health Psychology,* 1**,** 65-85.

HARMAN, H. 1976. *Modern factor analysis,* Chicago, University of Chicago Press.

HARRINGTON, D. 2009. *Confirmatory factor analysis,* New York, USA, Oxford University Press, Inc.

HASKARD ZOLNIEREK, K. B. & DIMATTEO, M. R. 2009. Physician Communication and Patient Adherence to Treatment: A meta analysis. *Medical Care,* 47**,** 826-834.

HEILMANN, R. M. F., FRIESLEBEN, C. R. & BILLUPS, S. J. 2012. Impact of a pharmacist-directed intervention in postmenopausal women after fracture. *American Journal of Health-System Pharmacy,* 69**,** 504-509.

HEINONEN, A., KANNUS, P., SIEVÄNEN, H., OJA, P., PASANEN, M., RINNE, M., UUSI-RASI, K. & VUORI, I. 1996. Randomised controlled trial of effect of high-impact exercise on selected risk factors for osteoporotic fractures. *The Lancet,* 348**,** 1343-1347.

HENDERSON, V. W. & LOBO, R. A. 2012. Hormone therapy and the risk of stroke: perspectives 10 years after the Women's Health Initiative trials. *Climacteric,* 15**,** 229-234.

HEPLER, C. D. & STRAND, L. M. 1990. Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy,* 47**,** 533-542.

HERNLUND, E., SVEDBOM, A., IVERGÅRD, M., COMPSTON, J., COOPER, C., STENMARK, J., MCCLOSKEY, E. V., JÖNSSON, B. & KANIS, J. A. 2013. Osteoporosis in the European Union: medical management, epidemiology and economic burden. *Archives of Osteoporosis,* 8**,** 136.

HEYWORTH, L., KLEINMAN, K., ODDLEIFSON, S., BERNSTEIN, L., FRAMPTON, J., LEHRER, M., SALVATO, K., WEISS, T. W., SIMON, S. R. & CONNELLY, M. 2014. Comparison of interactive voice response, patient mailing, and mailed registry to encourage screening for osteoporosis: a randomized controlled trial. *Osteoporosis International,* 25**,** 1519-1526.

HINTON, P. S., NIGH, P. & THYFAULT, J. 2015. Effectiveness of resistance training or jumping-exercise to increase bone mineral density in men with low bone mass: A 12-month randomized, clinical trial. *Bone,* 79**,** 203-212.

HJALMARSON, H. V., AHGREN, B. & KJÖLSRUD, M. S. 2013. Developing interprofessional collaboration: A longitudinal case of secondary prevention for patients with osteoporosis. *Journal of Interprofessional Care,* 27**,** 161-170.

HOLICK, M. F. 2004. Sunlight and vitamin D for bone health and prevention of autoimmune diseases, cancers, and cardiovascular disease. *Am J Clin Nutr,* 80**,** Suppl 1, 1678-1688S.

HOSKING, D., CHILVERS, C., CHRISTIANSEN, C., RAVN, P., WASNICH, R., ROSS, P., MCCLUNG, M., BALSKE, A., THOMPSON, D., DALEY, M. & YATES, J. 1994. Prevention

of bone loss with alendronate in postmenopausal women under 60 years of age. *The New England Journal of Medicine,* 338**,** 485-492.

HOUILLIER, P., FROISSART, M., MARUANI, G. & BLANCHARD, A. 2006. What serum calcium can tell us and what it can't. *Nephrology Dialysis Transplantation,* 21**,** 29-32.

HOWE, T. E., SHEA, B., DAWSON, L. J., DOWNIE, F., MURRAY, A., ROSS, C., HARBOUR, R. T., CALDWELL, L. M. & CREED, G. 2011. Exercise for preventing and treating osteoporosis in postmenopausal women (Review). *Cochrane Database Systematic Review***,** CD000333.

HUNTJENS, K. M. B., VAN GEEL, T. A. C. M., BLONK, M. C., HEGEMAN, J. H., VAN DER ELST, M., WILLEMS, P., GEUSENS, P. P., WINKENS, B., BRINK, P. & VAN HELDEN, S. H. 2010. Implementation of osteoporosis guidelines: a survey of five large fracture liaison services in the Netherlands. *Osteoporosis International,* 22**,** 2129-2135.

ICKS, A., HAASTERT, B., WILDNER, M., BECKER, C. & MEYER, G. 2008. Trend of hip fracture incidence in Germany 1995–2004: a population-based study. *Osteoporosis International,* 19**,** 1139-1145.

INDERJEETH, C. A., GLENNAN, D. A., POLAND, K. E., INGRAM, K. V., PRINCE, R. L., VAN, V. R. & HOLMAN, C. D. J. 2010. A multimodal intervention to imrpove fragility fracture management in patietns presenting to emergency departments. *Med J Aust,* 193**,** 149-153.

INSTITUTE FOR GOVERNEMENT 2010. MINDSPACE: Influencing behaviour through public policy. *In:* OFFICE, T. C. (ed.).

INTERNATIONAL OSTEOPOROSIS FOUNDATION 2006. Preventing osteoporosis. *Women's Health Medicine,* 3**,** 155-156.

INTERNATIONAL OSTEOPOROSIS FOUNDATION 2009. The Asian Audit: Epidemiology, cost and burden of osteoporosis in Asia 2009.

INTERNATIONAL OSTEOPOROSIS FOUNDATION. 2012a. *Capture the Fracture: A global campaign to break the fragility fracture cycle* [Online]. Available: http://www.worldosteoporosisday.org/ [Accessed 26 February 2015].

INTERNATIONAL OSTEOPOROSIS FOUNDATION. 2012b. *Capture the Fracture: break the worlwide fragility fracture cycle* [Online]. Available: http://www.osteofound.org/capture-fracture [Accessed 27 December 2015].

JACKSON, R. D., LACROIX, A. L., GASS, M., WALLACE, R. B., ROBBINS, J., LEWIS, C. E., BASSFORD, T., BERESFORD, S. A. A., BLACK, H. R., BLANCHETTE, P., BONDS, D. E., BRUNNER, R. L., BRZYSKI, R. G., CAAN, B., CAULEY, J. A., CHLEBOWSKI, R. T., CUMMINGS, S. R., GRANEK, I., HAYS, J., HEISS, G., HENDRIX, S. L., HOWARD, B. V., HSIA, J., HUBBELL, F. A., JOHNSON, K. C., JUDD, H., KOTCHEN, J. M., KULLER, L. H., LANGER, R. D., LASSER, N. L., LIMACHER, M. C., LUDLAM, S., MANSON, E. M., MARGOLIS, K. L., MCGOWAN, J., OCKENE, J. K., O'SULLIVAN, M. J., PHILLIPS, L., PRENTICE, R. L., SARTO, G. E., STEFANICK, M. L., VAN HORN, L., WACTAWSKI-WENDE, J., WHITLOCK, E., ANDERSON, G. L., ASSAF, A. R. & WOMEN'S HEALTH INITIATIVE INVESTIGATORS 2006. Calcium plus Vitamin D Supplementation and the Risk of Fractures. *The New England Journal of Medicine,* 354**,** 669-683.

JAGLAL, S. B., CAROLL, J., HAWKER, G., MCISAAC, W. J., JAAKKIMAINEN, L., CADARETTE, S. M., CAMERON, C. & DAVIS, D. 2003. How are family physicians managing osteoporosis? Qualitative study of thier experiences and educational neeeds. *Canadian Fam Physician,* 49**,** 462-468.

JAGLAL, S. B., DONESCU, O. S., BANSOD, V., LAPRADE, J., THORPE, K., HAWKER, G., MAJUMDAR, S. R., MEADOWS, L., CADARETTE, S. M., PAPAIOANNOU, A., KLOSECK, M., BEATON, D., BOGOCH, E. & ZWARENSTEIN, M. 2012. Impact of a centralized osteoporosis coordinator on post-fracture osteoporosis management: a cluster randomized trial. *Osteoporosis International,* 23**,** 87-95.

JALILI, Z., NAKHAEE, N., ASKURI, R. & SHARIFI, V. 2007. Knowledge, attitude and preventive practice of women concerning osteoporosis. *Iranian J Public Health,* 36**,** 19-24.

JENSEN, A. L., LOMBORG, K., WIND, G. & LANGDAHL, B. L. 2013. Effectiveness and characteristics of multifaceted osteoporosis group education—a systematic review. *Osteoporosis International,* 25**,** 1209-1224.

JITAPUNKUL, S., THAMARPIRAT, J., CHAIWANICHSIRI, D. & BOONHONG, J. 2008. Incidence of vertebral fractures in Thai women and men: a prospective population-based study. *Geriatr Gerontol Int,* 8**,** 251-8.

JOHNELL, O. 1997. The socioeconomic burden of fractures:today and in the 21st century. *AM J Med,* 103**,** 20s-25s.

JOHNELL, O. & KANIS, J. A. 2006. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporosis International,* 17**,** 1726-1733.

JOHNELL, O., KANIS, J. A., ODEN, A., JOHANSSON, H., DE LAET, C., DELMAS, P., EISMAN, J. A., FUJIWARA, S., KROGER, H., MELLSTROM, D., MEUNIER, P. J., MELTON, L. J., O'NEILL, T., POLS, H., REEVE, J., SILMAN, A. & TENENHOUSE, A. 2005. Predictive Value of BMD for Hip and Other Fractures. *Journal of Bone and Mineral Research,* 20**,** 1185-1194.

JOHNELL, O., KANIS, J. A., ODÉN, A., SERNBO, I., REDLUND-JOHNELL, I., PETTERSON, C., DE LAET, C. & JÖNSSON, B. 2004. Mortality after osteoporotic fractures. *Osteoporosis International,* 15**,** 38-42.

JOHNSON, J. A., COONS, S. J., HAYS, R. D., SABERS, D., JONES, P. & LANGLEY, P. C. 1997. A comparison of satisfaction with mail versus traditional pharmacy services. *Journal of managed care pharmacy,* 3**,** 327-337.

JORGENSON, D., LAMB, D. & MACKINNON, N. J. 2011. Practice change challenges and priorities: a national survey of practising pharmacists. *Can Pharm J,* 144**,** 125-131.

KAISER, H. F. 1960. The application of electronic computers to factor analysis. *Educational and Psychological Measurement,* 20**,** 141-151.

KANIS, J. A. 2007. WHO Scientific Group Technical Report. 66.

KANIS, J. A. 2014. *FRAX WHO Fracture Risk Assessment Tool* [Online]. World Health Organization Collaborating Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available: http://www.shef.ac.uk/FRAX/ [Accessed 22 December 2014].

KANIS, J. A., JOHANSSON, H., JOHNELL, O., ODEN, A., DE LAET, C., EISMAN, J. A., POLS, H. & TENENHOUSE, A. 2004a. Alcohol intake as a risk factor for fracture. *Osteoporosis International,* 16**,** 737-742.

KANIS, J. A., JOHNELL, O., DE LAET, C., JOHANSSON, H., ODEN, A., DELMAS, P., EISMAN, J., FUJIWARA, S., GARNERO, P., KROGER, H., MCCLOSKEY, E. V., MELLSTROM, D., MELTON, L. J., POLS, H., REEVE, J., SILMAN, A. & TENENHOUSE, A. 2004b. A meta-analysis of previous fracture and subsequent fracture risk. *Bone,* 35**,** 375-382.

KARKKAINEN, M. U. M., LAMBERG-ALLARDT, C. J. E., AHONEN, S. & VALIMAKI, M. 2001. Does it make a difference how and when you take your calcium? The

acute effects of calcium on calcium and bone metabolism. *Am J Clin Nutr,* 74**,** 335-342.

KASPER, M. J., PETERSON, M. G. & ALLEGRANTE, J. P. 1994. Knowledge, beliefs, and behaviours among college women concerning the prevention of osteoporosis. *Arch Fam Med,* 3**,** 696-702.

KAUFFMAN, T. L., BARR, J. O. & MORAN, M. L. 2007. *Geriatric rehabilitation manual,* Philadelphia, USA, Elsevier Ltd.

KHAN, Y. H., SARRIFF, A., KHAN, A. M. & MALLHI, T. H. 2014. Knowledge, attitude and practice (KAP) survey of osteoporosis among students of a tertiary institution in Malaysia. *Tropical Journal of Pharmaceutical Research,* 13**,** 155-162.

KIM, J. O. & MUELLER, C. W. 1978. *Factor analysis: statistical methods and practical issues,* California, USA, Sage.

KIM, K., HORAN, M. & GENDLER, P. 1991. *Osteoporosis knowledge tests, osteoporosis health belief scale, and osteoporosis self- efficacy scale,* Allendale, MI: Grand Valley State University.

KIM, S.-R., HA, Y.-C., PARK, Y.-G., LEE, S.-R. & KOO, K.-H. 2011. Orthopedic Surgeon's Awareness Can Improve Osteoporosis Treatment Following Hip Fracture: A Prospective Cohort Study. *Journal of Korean Medical Science,* 26**,** 1501.

KITAZAWA, A., KUSHIDA, K., YAMAZAKI, K. & T., I. 2001. Prevalence of vertebral fractures in a population-based sample in Japan. *J Bone Miner Metab,* 19**,** 115-118.

KODA-KIMBLE, M. A., YOUNG, L. E., ALLDREDGE, B. K., CORELLI, R. L., KRADJAN, W. A. & WILLIAMS, B. R. 2009. *Applied therapeutics: The clinical use of drugs,* Baltimore, Lippincott Williams and Wilkins.

KOH, L. K. H. 2007. Osteoporosis in Asian populations. *Menopause Medicine,* 15**,** S10-S14.

KOH, L. K. H., SAW, S.-M., LEE, J. J. M., LEONG, K.-H. & LEE, J. 2001a. Hip fracture incidence rates in Singapore 1991-1998. *Osteoporos Int,* 12**,** 311-318.

KOH, L. K. H., SEDRINE, W. B., TORRALBA, T. P., KUNG, A. W., FUJIWARA, S., CHAN, S. P., HUANG, Q. R., RAJATANAVIN, R., TSAI, K. S., PARK, H. M. & REGINSTER, J. Y. 2001b. A simple tool to identify Asian women at increased risk of osteoporosis. *Osteoporos Int,* 12**,** 699-705.

KRASS, I., DELANEY, C., GLAUBITZ, S. & KANJANARACH, T. 2009. Measuring patient satisfaction with diabetes disease state management services in community pharmacy. *Res Social Adm Pharm,* 5**,** 31-9.

KUNG, A. W., HO, A. Y., SEDRINE, W. B., REGINSTER, J. Y. & ROSS, P. D. 2003. Comparison of a simple clinical risk index and quantitative bone ultrasound for identifying women at increased risk of osteoporosis. *Osteoporos Int,* 14**,** 716-21.

LAI, P. S., CHUA, S. S., CHAN, S. P. & LOW, W. Y. 2008. The validity and reliability of the Malaysian Osteoporosis Knowledge Tool in postmenopausal women. *Maturitas,* 60**,** 122-30.

LAI, P. S., CHUA, S. S., CHAN, S. P., LOW, W. Y. & WONG, I. C. 2010. Development and validation of the osteoporosis patient satisfaction questionnaire (OPSQ). *Maturitas,* 65**,** 55-63.

LAI, P. S. M. 2013. Validating instruments of measure-is it really necessary? *Malaysian Family Physicians,* 8**,** 2-4.

LAI, P. S. M., CHUA, S. S. & CHAN, S. P. 2013. Impact of pharmaceutical care on knowledge, quality of life and satisfaction of postmenopausal women with osteoporosis. *International Journal of Clinical Pharmacy,* 35**,** 629-637.

LAKSHMAN, R., GRIFFIN, S., HARDEMAN, W., SCHIFF, A., KINMONTH, A. L. & ONG, K. K. 2014. Using the Medical Research Council Framework for the Development and Evaluation of Complex Interventions in a Theory-Based Infant Feeding Intervention to Prevent Childhood Obesity: The Baby Milk Intervention and Trial. *Journal of Obesity,* 2014**,** 1-10.

LALIBERTÉ, M.-C., PERREAULT, S., DAMESTOY, N. & LALONDE, L. 2012. Ideal and actual involvement of community pharmacists in health promotion and prevention: a cross-sectional study in Quebec, Canada. *BMC Public Health,* 12**,** 192.

LALIBERTÉ, M. C., PERREAULT, S., DAMESTOY, N. & LALONDE, L. 2013. The role of community pharmacists in the prevention and management of osteoporosis and the risk of falls: results of a cross-sectional study and qualitative interviews. *Osteoporosis International,* 24**,** 1803-1815.

LALIBERTÉ, M. C., PERREAULT, S., JOUINI, G., SHEA, B. J. & LALONDE, L. 2011. Effectiveness of interventions to improve the detection and treatment of osteoporosis in primary care settings: a systematic review and meta-analysis. *Osteoporosis International,* 22**,** 2743-2768.

LANCASTER, G. A., DODD, S. & WILLIAMSON, P. R. 2004. Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation in Clinical Practice,* 10**,** 307-312.

LAU, E., PAPAIOANNOU, A., DOLOVICH, L., ADACHI, J., SAWKA, A. M., BURNS, S., NAIR, K. & PATHAK, A. 2008. Patients' adherence to osteoporosis therapy: Exploring the perceptions of postmenopausal women. *Can Fam Physician,* 54**,** 394-402.

LAW, A. V. & SHAPIRO, K. 2004. Impact of a community pharmacist-directed clinic in improving screening and awareness of osteoporosis. *Journal of Evaluation in Clinical Practice,* 11**,** 247-255.

LESLIE, W. D., GIANGREGORIO, L. M., YOGENDRAN, M., AZIMAEE, M., MORIN, S., METGE, C., CAETANO, P. & LIX, L. M. 2011. A population-based analysis of the post-fracture care gap 1996–2008: the situation is not improving. *Osteoporosis International,* 23**,** 1623-1629.

LESLIE, W. D., O'DONNELL, S., LAGACÉ, C., WALSH, P., BANCEJ, C., JEAN, S., SIMINOSKI, K., KAISER, S., KENDLER, D. L. & JAGLAL, S. 2010. Population-based Canadian hip fracture rates with international comparisons. *Osteoporosis International,* 21**,** 1317-1322.

LI-YU, J. T., LLAMADO, L. J. & TORRALBA, T. P. 2005. Validation of OSTA among Filipinos. *Osteoporos Int,* 16**,** 1789-93.

LI, Y.-M. 2008. Concordance of a Self Assessment Tool and Measurement of Bone Mineral Density in Identifying the Risk of Osteoporosis in Elderly Taiwanese Women. *Tzu Chi Medical Journal,* 20**,** 206-212.

LIH, A., NANDAPALAN, H., KIM, M., YAP, C., LEE, P., GANDA, K. & SEIBEL, M. J. 2011. Targeted intervention reduces refracture rates in patients with incident non-vertebral osteoporotic fractures: a 4-year prospective controlled study. *Osteoporosis International,* 22**,** 849-858.

LIM, P. C. & LIM, K. 2010. Evaluation of pharmacist-managed diabetes medication therapy adherence clinic. *Pharmacy Practice,* 8**,** 250-254.

LIM, P. S., ONG, F. B., ADEEB, N., SERI, S. S., NOOR-AINI, M. Y., SHAMSUDDIN, K., HAPIZAH, N., MOHAMED, A. L., MOKHTAR, A. & WAN, H. W. 2005. Bone health in urban midlife Malaysian women: risk factors and prevention. *Osteoporos Int,* 16**,** 2069-79.

LIM, P. S., ONG, F. B., SUNIZA, S. S. & ADEEB, N. 2011. Developing a Malaysian Osteoporosis Screening Tool (MOST) for early osteoporosis detection in Malaysian women. *Sexual & Reproductive Healthcare,* 2**,** 77-82.

LIM, S., KOO, B. K., LEE, E. J., PARK, J. H., KIM, M. H., SHIN, K. H., HA, Y. C., CHO, N. H. & SHIN, C. S. 2008.

Incidence of hip fractures in Korea. *J Bone Miner Metab,* 26**,** 400-5.

LIN, Y.-C. & PAN, W.-H. 2011. Bone mineral density in adults in Taiwan: results of the Nutrition and Health Survey in Taiwan 2005-2008 (NAHSIT-2005-2008). *Asia Pac J Clin Nur,* 20**,** 283-291.

LITTLE, E. A. & ECCLES, M. P. 2010. A systematic review of the effectiveness of interventions to improve post-fracture investigation and management of patients at risk of osteoporosis. *Implement Sci,* 5**,** 80.

LIU, Y., NEVINS, J. C., CARRUTHERS, K. M., DOUCETTE, W. R., MCDONOUGH, R. P. & PAN, X. 2007. Osteoporosis risk screening for women in a community pharmacy. *J Am Pharm Assoc (2003),* 47**,** 521-6.

LIZA, H., DARAT, H. N. & PANDE, K. C. 2009. Knowledge about osteoporosis in Bruneian women attending an orthopaedic clinic. *Malaysian Orthopaedic Journal,* 3**,** 28-30.

LOCKER, D. & DUNT, D. 1978. Theoratical and methodological issues in sociological studies of consumer satisfaction with medical care. *Soc Sci Med,* 12**,** 283-292.

LORISH, C. D., PARKER, J. & BROWN, S. 1985. Effective patient education. *Arthritis Rheum,* 28**,** 1289-1297.

LUNDY, K. S. & JANES, S. 2009. *Community health nursing: Caring for the public's health,* Sudbury, USA, Jones and Bartless Publisher.

LUO, L. & XU, L. 2005. Analysis of direct economic burden of osteoporotic hip fracture and its influence factors. *Chinese Journal of Epidemiology,* 9.

LYDICK, E., COOK, K., TURPIN, J., MELTON, M., STINE, R. & BYRNES, C. 1998. Development and validation of simple questionnaire to facilitate identification of women likely to have low bone density. *The American Journal of Managed Care,* 4**,** 37-48.

MACHADO, M., BAJCAR, J., GUZZO, G. C. & EINARSON, T. R. 2007a. Sensitivity of Patient Outcomes to Pharmacist Interventions. Part I: Systematic Review and Meta-Analysis in Diabetes Management. *Annals of Pharmacotherapy,* 41**,** 1569-1582.

MACHADO, M., BAJCAR, J., GUZZO, G. C. & EINARSON, T. R. 2007b. Sensitivity of Patient Outcomes to Pharmacist Interventions. Part II: Systematic Review and Meta-Analysis in Hypertension Management. *Annals of Pharmacotherapy,* 41**,** 1770-1781.

MACLAUGHLIN, E. J., MACLAUGHLIN, A. A., SNELLA, K. A., WINSTON, T. S., FIKE, D. S. & RAEHL, C. R. 2005. Osteoporosis screening and education in community

pharmacies using a team approach. *Pharmacotherapy,* 25**,** 379-386.

MAFAUZY, M. 2000. The problems and challenges of the aging population of malaysia. *Malaysian Journal of Medical Sciences,* 7**,** 1-3.

MAGNUS, J. H., JOAKIMSEN, R. M., BERNTSEN, G. K., TOLLAN, A. & SOOGAARD, A. J. 1996. What do Norwegian women and men know about osteoporosis? *Osteoporos Int,* 6**,** 32-36.

MAJUMDAR, S. R., BEAUPRE, L. A., HARLEY, C. H., HANLEY, D. A., LIER, D. A., JUBY, A. G., MAKSYMOWYCH, W. P., CINATS, J. G., BELL, N. R. & MORRISH, D. W. 2007. Use of a case manager to improve osteoporosis treatment after hip fracture. *Arch Intern Med,* 167**,** 2110-2115.

MAJUMDAR, S. R., JOHNSON, J. A., MCALISTER, F. A., BELLEROSE, D., RUSSELL, A. S., HANLEY, D. A., MORRISH, D. W., MAKSYMOWYCH, W. P. & ROWE, B. H. 2008. Multifaceted intervention to improve diagnosis and treatment of osteoporosis in patients with recent wrist fracture: a randomized controlled trial. *CMAJ,* 178**,** 569-75.

MANN, H. B. & WHITNEY, D. R. 1947. On a test of whether one of two random variables is stochastically larger than the other. *Annals of Mathematical Sciences,* 18**,** 50-60.

MARSHALL, D., JOHNELL, O. & WEDEL, H. 1997. Meta-analysis of how well measures of bone mineral density predict occurence of osteoporotic fractures. *BMJ,* 312**,** 1254-1259.

MAYS, N. & POPE, C. 2000. Qualitative research in health care: Assessing quality in qualitative research. *BMJ,* 320**,** 50-52.

MCCLOSKEY, E. 2009. FRAX Identifying people at high risk of fracture. Nyon, Switzerland: International Osteoporosis Foundation.

MCCLUNG, M. R., WASNICH, R. D., RECKER, R., CAULEY, J. A., CHESNUT, C. H., ENSRUD, K. E., BURDESKA, A. & MILLS, T. 2003. Oral Daily Ibandronate Prevents Bone Loss in Early Postmenopausal Women Without Osteoporosis. *Journal of Bone and Mineral Research,* 19**,** 11-18.

MCCONAHA, J. L., BERDINE, H. J., SKOMO, M. L., LAUX, R. V., HIGGINBOTHAM, S. K. & O'NEIL, C. K. 2014. Impact of the Fracture Risk Assessment on Patient and Physician Behavior in Osteoporosis Prevention. *Journal of Pharmacy Practice,* 27**,** 25-30.

MCDONOUGH, R. P., DOUCETTE, W. R., KUMBERA, P. & KLEPSER, D. G. 2005. An evaluation of managing and

educating patients on the risk of glucocorticoid-induced osteoporosis. *Value Health,* 8**,** 24-31.

MCDOWELL, I. 2006. *Measuring health: A guide to rating scales and questionnaires,* New York, USA, Oxford University Press.

MCGIVNEY, M. S., MEYER, S. M., DUNCAN-HEWITT, W., HALL, D. L., GOODE, J. V. K. & SMITH, R. B. 2007. Medication therapy management: Its relationship to patient counseling, disease management, and pharmaceutical care. *Journal of the American Pharmacists Association,* 47**,** 620-628.

MCHUGH, M. L. 2013. The Chi-square test of independence. *Biochemia Medica,* 23**,** 143-149.

MCLELLAN, A. R., GALLACHER, S. J., FRASER, M. & MCQUILLIAN, C. 2003. The fracture liaison service: success of a program for the evaluation and management of patients with osteoporotic fracture. *Osteoporosis International,* 14**,** 1028-1034.

MCLELLAN, A. R., WOLOWAVZ, S. E., ZIMOVETZ, E. A., BEARD, M. K., LOCK, S., MCCRINK, L., ADEKUNIE, F. & ROBERTS, D. 2011. Fracture liaison services for the evaluation and management of patients with osteoporotic fracture: a cost-effective evaluation based on data collected over 8 years of service provision. *Osteoporos Int,* 22**,** 2083-2098.

MEADOWS, L. M., MRKONJIC, L. A., O'BRIEN, M. D. & TINK, W. 2007. The importance of communication in secondary fragility fracture treatment and prevention. *Osteoporos Int,* 18**,** 159-166.

MEDICAL RESEARCH COUNCIL 2000. A Framework for development and evaluation of RCTs for complex interventions to improve health.

MEDICAL RESEARCH COUNCIL 2008. Developing and evaluating complex interventions- New guidance.

MEETA 2013. *Postmenopausal osteoporosis: Basic and clinical concepts,* Haryana, India, Jaypee Brother Medical Publisher.

MELTON, L. J. R., THERNEAU, T. M. & LARSON, D. R. 1998. Long-term trends in hip fracture prevalence: The influence of hip fracture incidence and survival. *Osteoporos Int,* 8**,** 68-74.

MEUNIER, P. J., ROUX, C., SEEMAN, E., ORTOLANI, S., BADURSKI, J. E., SPECTOR, T. D., CANNATA, J., BALOGH, A., LEMMEL, E.-M., PORS-NIELSEN, S., RIZZOLI, R., GENANT, H. K. & REGINSTER, J.-Y. 2004. The Effects of Strontium Ranelate on the Risk of Vertebral Fracture in Women with Postmenopausal

Osteoporosis. *New England Journal of Medicine,* 350**,** 459-468.

MICHAËLSSON, K., BERGSTRÖM, R., MALLMIN, H., HOLMBERG, L., WOLK, A. & LJUNGHALL, S. 1996. Screening for osteopenia and osteoporosis: Selection by body composition. *Osteoporos Int,* 6**,** 120-126.

MICHIE, S., FIXSEN, D., GRIMSHAW, J. M. & ECCLES, M. P. 2009. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implementation Science,* 4**,** 40.

MICHIE, S., RICHARDSON, M., JOHNSTON, M., ABRAHAM, C., FRANCIS, J., HARDEMAN, W., ECCLES, M. P., CANE, J. & WOOD, C. E. 2013. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. *Annals of Behavioral Medicine,* 46**,** 81-95.

MICHIE, S., VAN STRALEN, M. M. & WEST, R. 2011. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science,* 6**,** 42.

MIKI, R. A., OETGEN, M. E., KIRK, J., INSOGNA, K. L. & LINDSKOG, D. M. 2008. Orthopaedic management improves the rate of early osteoporosis treatment after hip fracture. A randomized clinical trial. *J Bone Joint Surg Am,* 90**,** 2346-53.

MILES, M. B. & HUBERMAN, A. M. 1994. *Qualitative data: An expanded sourcebook,* Thousang Oaks, California, Sage Publications.

MILSOM, S., LEUNG, W., TWIGDEN, V., MITCHELL, P., NOWITZ, M. & CORNISH, J. 2013. Does insufficient access to dual-energy X-ray absorptiometry (DXA) stifle the provision of quality osteoporosis care in New Zealand? *Archives of Osteoporosis,* 8.

MINISTRY OF HEALTH MALAYSIA 2012. Clinical Guideline on Management of Osteoporosis 2012. *In:* HEALTH, M. O. (ed.). Putrajaya: Malaysian Osteoporosis Society.

MITRA, A. K., LOW, C. K., CHAO, A. K. & TAN, S. K. 1994. Social aspects in patients following proximal femoral fractures. *Ann Acad Med Singapore,* 23**,** 876-878.

MOAYYERI, A., ADAMS, J. E., ADLER, R. A., KRIEG, M. A., HANS, D., COMPSTON, J. & LEWIECKI, E. M. 2012. Quantitative ultrasound of the heel and fracture risk assessment: an updated meta-analysis. *Osteoporosis International,* 23**,** 143-153.

MOHY TAHA, M. D. 2011. *Prevalence of osteoporosis in Middle East systemic literature review* [Online]. 10th ECOO.

Available: http://www.scribd.com/doc/53103901/Osteopoorosis-Cairo-April-2011-v1 [Accessed 20 February 2015].

MONIZ, C. 1994. Alcohol and bone. *British Medical Bulletin,* 50**,** 67-75.

MORRISON, N. A., QI, J. C., TOKITA, A., KELLY, P. J., CROFTS, L., NGUYEN, T. V., SAMBROOK, P. N. & EISMAN, J. A. 1994. Prediction of bone density from vitamin D receptor alleles. *Nature,* 367**,** 284-287.

MORTENSEN, L., CHARLES, P., BEKKER, P. J., DIGENNARO, J. & JOHNSTON, C. C. 1998. Risendronate increases bone mass in an early postmenopausal population: Two years of treatment plus one year of follow up. *Journal of Clinical Endocrinology and Metabolism,* 83**,** 396-402.

MUDANO, A. S., LISA, C. G., OLIVEIRA, A., MARY, M., WRIGHT, N. C., CURTIS, J., DELZELL, E., HARRINGTON, T. M., MEREDITH, L. K., CORA ELIZABETH, L., JASVINDER, A. S., WARRINER, WILSON, P. & SAAG, K. 2013. Using tablet computers compared to interactive voice response to improve subject recruitment in osteoporosis pragmatic clinical trials: feasibility, satisfaction, and sample size. *Patient Preference and Adherence,* 7**,** 517-523.

MUNDFORM, D. J., SHAW, D. G. & K., T. L. 2005. Minimum sample size recommendations for conductiong factor analysis. *International Journal of Testing,* 5**,** 159.

MURPHY, E., DINGWALL, R., GREATBATCH, D., PARKER, S. & WATSON, P. 1998. Qualitative research methods in health technology assessment: a review of the literature. *Health Technology Assessment,* 2.

MUSLIM, D. A. J., MOHD, E. F., SALLEHUDIN, A. Y., TENGKU MUZAFFAR, T. M. S. & EZANE, A. M. 2012. Performance of osteoporosis self-assessment tool for Asian (OSTA) for primary osteoporosis in post-menopausal Malay women. *Malaysian Orthopaedic Journal,* 6**,** 35-39.

NATIONAL COMMITTEE FOR QUALITY ASSURANCE. 2014. *HEDIS & Performance Measurement. Proposed Changes to*
Existing Measure for HEDIS®1 2015: Osteoporosis Management in Women Who Had a Fracture (OMW) [Online]. Washington, USA. Available: www.ncqa.org/HEDISQualityMeasurement.aspx [Accessed 25 February 2015].

NATIONAL COMMITTEE FOR QUALITY ASSURANCE (NCQA). 2004. *HEDIS* [Online]. Available: http://www.ncqa.org/Portals/0/HEDISQM/Archives/2004/ [Accessed 14 March 2015].

NATIONAL COORDINATING COMMITEE ON FOOD AND NUTRITION 2005. Recommended nutrient intakes for Malaysia. Malaysia: Ministry of Health.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE 2012. Osteoporosis: assessing the risk of fragility fracture. . *In:* 146, N. C. G. (ed.). London, UK: NICE.

NATIONAL INSTITUTE FOR HEALTH RESEARCH. 2012. *NIHR Evaluation, trials and studies coordination centre: Glossry* [Online]. Available: www.netscc.ac.uk/glossary/#glos6/ [Accessed 28 December 2014].

NATIONAL OSTEOPOROSIS FOUNDATION. *Having a bone density test* [Online]. Washington, USA: National Osteoporosis Foundation,. Available: http://nof.org/articles/743 [Accessed 25 February 2015].

NATIONAL OSTEOPOROSIS FOUNDATION 2010. Clinician's Guide to Treatment and Prevention of Osteoporosis. Washington, USA.

NATIONAL OSTEOPOROSIS FOUNDATION. 2014. *54 million Americans affected by osteoporosis and low bone mass* [Online]. Washington, USA: The National Osteoporosis Foundation. Available: http://nof.org/news/2948 [Accessed 20 February 2015].

NATIONAL OSTEOPOROSIS SOCIETY 2001. Position statement on the use of quantitative ultrasound in the management os osteoporosis.

NEELEMAAT, F., LIPS, P., BOSMANS, J. E., THIJS, A., SEIDELL, J. C. & VAN BOKHORST-DE VAN DER SCHUEREN, M. A. E. 2012. Short-Term Oral Nutritional Intervention with Protein and Vitamin D Decreases Falls in Malnourished Older Adults. *J Am Geriatr Soc,* 60**,** 691-699.

NEER, R. M., ARNAUD, C. D., ZANCHETTA, J. R., PRINCE, R., GAICH, G. A., REGINSTER, J. Y., HODSMAN, A. B., ERIKSEN, E. F., ISH-SHALOM, S., GENANT, H. K., WANG, O. & MITLAK, B. H. 2001. Effects of parathyroid hormone (1-34) on fractures and bone mineral density in postmenopausal women with osteoporosis. *New England Journal of Medicine,* 344**,** 1434-1441.

NELSON, M. E., FIATARONE, M. A., MORGANTI, C. M., TRICE, I., GREENBERG, R. A. & EVANS, W. J. 1994. Effects of high-intensity strength training on multiple risk factors for osteoporotic fractures. A randomized controlled trial. *The journal of the American Medical Association,* 272**,** 1909-14.

NGUYEN, T. V., SAMBROOK, P. N. & EISMAN, J. 1998. Bone loss, physical activity and weight change in elderly women: the Dubbo osteoporosis epidemiology study. *J Bone Miner Res,* 13**,** 1458-1467.

NHS FOUNDATION TRUST. 2006. *Involving patients and the public in medical research* [Online]. London. Available: http://www.acprc.org.uk/Data/Resource_Downloads/brc_userinvolvement_staff_guide.pdf [Accessed 8 October 2015].

NIELSEN, D., RYG, J., NISSEN, N., NIELSEN, W., KNOLD, B. & BRIXEN, K. 2008. Multidisciplinary patient education in groups increases knowledge on osteoporosis: a randomized controlled trial. *Scand J Public Health,* 36**,** 346-52.

NIH CONSENSUS DEVELOPMENT PANEL ON OSTEOPOROSIS PREVENTION, D., AND THERAPY 2001. Osteoporosis prevention, diagnosis, and therapy. *The journal of the American Medical Association,* 285**,** 785-795.

NKANSAH, N., MOSTOVETSKY, O., YU, C., CHHENG, T., BENEY, J., BOND, C. M. & BERO, L. 2010. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. *Cochrane Database Systematic Review,* 7.

NORDYKE, R. J., CHANG, C.-H., CHIOU, C.-F., WALLACE, J. F., YAO, B. & SCHWARTZBERG, L. S. 2006. Validation of a patient satisfaction questionnaire for anemia treatment, the PSQ-An. *Health Qual Life Outcomes,* 4**,** 28.

O' LOUGHLIN, J., MASSON, P., DERY, V. & FAGNAN, D. 1999. The role of community pharmacists in health education and disease prevention: A survey of thier intersts and needs in relation to cardiovascular disease. *Preventinve Medicine,* 28**,** 324-331.

ORIMO, H., SHIRAKI, M., HAYASHI, Y., HOSHINO, T., ONAYA, T., MIYAZAKI, S., KUROSAWA, H., NAKAMURA, T. & OGAWA, N. 1994. Effects of 1 alpha-hydroxyvitamin D3 on lumbar bone mineral density and vertebral fractures in patients with postmenopausal osteoporosis. *Calcif Tissue Int,* 54**,** 370-376.

OTMAR, R., REVENTLOW, S. D., NICHOLSON, G. C., KOTOWICZ, M. A. & PASCO, J. A. 2012. General medical practitioners' knowledge and beliefs about osteoporosis and its investigation and management. *Archives of Osteoporosis,* 7**,** 107-114.

PADDOCK, L. E., VELOSKI, J., CHATTERTON, M. L., GEVIRTZ, F. O. & NASH, D. B. 2000. Development and validation of a questionnaire to evaluate patient satisfaction with

diabetes disease management. *Diabetes Care,* 23**,** 951-956.

PALLANT, J. 2011. *SPSS survival manual: A step by step guide to data analysis using SPSS,* New South Wales, Australia, Allen and Unwin.

PANDE, K. C., TAKATS, D., KANIS, J. A., EDWARDS, V., SLADE, P. & MCCLOSKEY, E. V. 2000. Development of a questionnaire (OPQ) to assess patient's knowledge about osteoporosis. *Maturitas,* 237**,** 75-81.

PAPA, L. J. & WEBER, B. E. 1997. Physician characteristics associated with the use of bone densitometry. *J Gen Intern Med,* 12**,** 781-783.

PAPAIOANNOU, A., MORIN, S., CHEUNG, A. M., ATKINSON, S., BROWN, J. P., FELDMAN, S., HANLEY, D. A., HODSMAN, A., JAMAL, S. A., KAISER, S. M., KVERN, B., SIMINOSKI, K. & LESLIE, W. D. 2010. 2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada: summary. *Canadian Medical Association Journal,* 182**,** 1864-1873.

PARK, H. J., PARK, K. H., PARK, G. M., PAEK, Y. J. & CHO, J. J. 2003. Evaluation of simple tool as a screening test for osteoporosis and osteopenia in Korean postmenopausal women. *J Korean Acad Fam Med,* 24**,** 702-708.

PASCOE, G. C. 1983. Patient satisfaction in primary health care: A literature review and analysis. *Evaluation and Program Planning,* 6**,** 185-210.

PEAT, J. 2001. *Health science research: A handbook of quantitative methods,* Sydney, Allen and Unwin.

PELLEGRINO, A. N., MARTIN, M. T., TILTON, J. J. & TOUCHETTE, D. R. 2009. Medication therapy management services: definitions and outcomes. *Drugs,* 69**,** 393-406.

PENCILLE, L. J., CAMPBELL, M. E., VAN HOUTEN, H. K., SHAH, N. D., MULLAN, R. J., SWIGLO, B. A., BRESLIN, M., KESMAN, R. L., TULLEDGE-SCHEITEL, S. M., JAEGER, T. M., JOHNSON, R. E., BARTEL, G. A., WERMERS, R. A., MELTON, L. J. & MONTORI, V. M. 2009. Protocol for the Osteoporosis Choice trial. A pilot randomized trial of a decision aid in primary care practice. *Trials,* 10**,** 113.

POUWER, F. & SNOEK, F. J. 2002. Patients evaluation of the quality of diactes care (PEQD): development and validation of a new instrument. *Qual Saf Health Care,* 11**,** 131-136.

PREMAOR, M. O., PILBROW, L., TONKIN, C., ADAMS, M., PARKER, R. A. & COMPSTON, J. 2009. Low rates of treatment in postmenopausal women with a history of

low trauma fractures: results of audit in a Fracture Liaison Service. *Qjm,* 103**,** 33-40.

READER, T. W. & GILLESPIE, A. 2013. Patient neglect in healthcare institutions: a systematic review and conceptual model. *BMC Health Services Research,* 13**,** 156.

REID, D. M. 2011. *Osteoporosis,* London, UK, Springer Healthcare.

RICHY, F., ETHGEN, O., BRUYERE, O., MAWET, A. & REGINSTER, J.-Y. 2004a. Primary Prevention of Osteoporosis: Mass Screening Scenario or Prescreening With Questionnaires? An Economic Perspective. *Journal of Bone and Mineral Research,* 19**,** 1955-1960.

RICHY, F., ETHGEN, O., BRUYERE, O. & REGINSTER, J.-Y. 2004b. Efficacy of alphacalcidol and calcitriol in primary and corticosteroid-induced osteoporosis: a meta-analysis of their effects on bone mineral density and fracture rate. *Osteoporosis International,* 15**,** 301-310.

RICHY, F., GOURLAY, M., ROSS, P. D., SEN, S. S., RADICAN, L., DE CEULAER, F., BEN SEDRINE, W., ETHGEN, O., BRUYERE, O. & REGINSTER, J. Y. 2003. Validation and comparative evaluation of the osteoporosis self-assessment tool (OST) in a Caucasian population from Belgium. *Qjm,* 97**,** 39-46.

RIGGS, L. B., O'FALLON, W. M., MUHS, J., O'CONNOR, K. M., KUMAR, R. & MELTON, L. J. 1998. Long-term effects of calcium supplementation on serum parathyroid hormone level, bone turnover, and bone loss in elderly women. *Journal of Bone and Mineral Research,* 13**,** 168-174.

ROBBINS, J. A., ARAGAKI, A., CRANDALL, C. J., MANSON, J. E., CARBONE, L., JACKSON, R., LEWIS, C. E., JOHNSON, K. C., SARTO, G., STEFANICK, M. L. & WACTAWSKI-WENDE, J. 2014. Women's Health Initiative clinical trials:interaction of calcium and vitamin D with hormone therapy. *Menopause,* 21**,** 116-123.

ROCKWOOD, P. R., HORNE, J. G. & CRYER, C. 1990. Hip fractures: A future epidemic? *J Orthop Trauma,* 4**,** 388-393.

ROSENSTOACK, I. M., STRECHER, V. J. & BECKER, M. H. 1988. Social learning theory and the health belief model. *Health Education Quarterly,* 15**,** 175-183.

ROSS, A. C., TAYLOR, C. L., YAKTINE, A. L. & DEL VALLE, H. B. 2011. *To Review Dietary Reference Intakes for Vitamin D and Calcium: Institute of Medicine (US) Committee,,* Wahington, USA, National Academies Press (US).

ROSSOUW, J. E., MANSON, J. E., KAUNITZ, A. M. & ANDERSON, G. L. 2013. Lessons learnt from the women's health initiative trials of menopausal hormone therapy. *Obstet gynecol,* 121**,** 172-176.

ROUGHEAD, E. E., SEMPLE, S. J. & VITRY, A. I. 2005. Pharmaceutical care services: a systematic review of published studies, 1990 to 2003, examining effectiveness in improving patient outcomes. *International Journal of Pharmacy Practice,* 13**,** 53-70.

ROZENTAL, T. D., MAKHNI, E. C., DAY, C. S. & BOUXSEIN, M. L. 2008. Improving evaluation and treatment for osteoporosis following distal radial fractures. A prospective randomized intervention. *J Bone Joint Surg Am,* 90**,** 953-61.

RYDER, K. M., KESSLER, L. A., JONES, C. B. & SHORR, R. I. 2007. A Captive Audience: A Pilot Study of Screening and Counseling Hospitalized Women for Fracture Risk. *J Gen Intern Med,* 22**,** 830-834.

SAETUNG, S., ONGPHIPHADHANAKUL, B. & RAJATANAVIN, R. 2008. The relationship of an Asian-specific screening tool for osteoporosis to vertebral deformity and osteoporosis. *J Bone Miner Metab,* 26**,** 47-52.

SALE, J. E. M., BEATON, D., POSEN, J., ELLIOT-GIBSON, V. & BOGOCH, E. R. 2011. Systematic review on intervention to improve osteoporosis intervestigation and treatment in fragility fracture patients. *Osteoporos Int,* 22**,** 2067-2082.

SALE, J. E. M., BOGOCH, E., HAWKER, G., GIGNAC, M., BEATON, D., JAGLAL, S. & FRANKEL, L. 2014. Patient perceptions of provider barriers to post-fracture secondary prevention. *Osteoporosis International,* 25**,** 2581-2589.

SAMBROOK, P. N., GEUSENS, P., RIBOT, C., SOLIMANO, J. A., FERRER-BARRIENDOS, J., GAINES, K., VERBRUGGEN, N. & MELTON, M. E. 2004. Alendronate produces greater effects than ralozifene on bone density and bone turnover in postmenopausal women with low bone density: results of EFFECT (EFficacy of FOSAMAX versus EVISTA comparison trial) International. *Journal of Internal Medicine,* 255**,** 503-511.

SAMBROOK, P. N., SEEMAN, E., PHILLIPS, S. R. & EBELING, P. R. 2002. Preventing osteoporosis: outcomes of the Australian fracture prevention summit. *Med J Aust,* 176**,** 1-16.

SARKER, H. N. 2014. *An aid to electrocardiogram,* New Delphi, India, Jaypee Brothers Medical Publishers (P) Ltd.

SAW, S. M., HONG, C. Y., LEE, J., WONG, M. L., CHAN, M. F., CHENG, A. & LEONG, K. H. 2003. Awareness and health beliefs of women towards osteoporosis. *Osteoporos Int,* 14**,** 595-601.

SCHAIRER, C., LUBIN, J., TROISI, R., STURGEON, S., BRINTON, L. & HOOVER, R. 2000. Menopausal estrogen and estrogen-progestin replacement therapy and breast cancer risk. *The Journal of the American Medical Association,* 283**,** 485-491.

SEDLAK, C. A., DOHENY, M. O. & JONES, S. L. 2000. Osteoporosis education programs: Changing knowledge and behaviors. *Public Health Nursing,* 17**,** 398-402.

SEDRINE, W. B., DEVOGELAER, J. P., KAUFMAN, J. M., GOEMARE, S., DEPRESSEUX, G., ZEGELS, B., DEROISY, R. & REGINSTER, J. Y. 2001. Evaluation of the simple calculate osteoporosis risk estimation (SCORE) in a sample of white women from Belgium. *Bone,* 29**,** 374-380.

SHEA, B., WELLS, G., CRANNEY, A., ZYTARUK, N., ROBINSON, V., GRIFFITH, L., HAMEL, C., ORTIZ, Z., PETERSON, J., ADACHI, J., TUGWELL, P., GUYATT, G., OSTEOPOROSIS METHODOLOGY GROUP & OSTEOPOROSIS RESEARCH ADVISORY GROUP 2004. Calcium supplementation on bone loss in postmenopausal women. *Cochrane Database Systematic Review,* 1**,** CD004526.

SIMONELLI, C., KILLEEN, K., MEHLE, S. & SWANSON, L. 2002. Barriers to osteoporosis identification and treatment among primary care physicians and orthopedic surgeons. *Mayo Clin Proc,* 77**,** 334-338.

SIQUEIRA, F. V., FACCHINI, L. A. & HALLAL, P. C. 2005. The burden of fractures in Brazil: A population-based study. *Bone,* 37**,** 261-266.

SMITH, F. 2002. *Research methods in pharmacy practice,* London, Pharmaceutical Press.

SMITH, F. 2010. *Conducting your pharmacy practice research project,* London, Pharmaceutical Press.

SOLOMON, D. H., POLINSKI, J. M., STEDMAN, M., TRUPPO, C., BREINER, L., EGAN, C., JAN, S., PATEL, M., WEISS, T. W., CHEN, Y. T. & BROOKHART, M. A. 2007. Improving care of patients at-risk for osteoporosis: a randomized controlled trial. *J Gen Intern Med,* 22**,** 362-7.

SQUIRES, A. 2008. Language barriers and qualitative nursing research: Methodological considerations. *International Nursing Review,* 55**,** 265-273.

STRAUS, S. E., TETROE, J. M. & GRAHAM, I. D. 2011. Knowledge translation is the use of knowledge in health

care decision making. *Journal of Clinical Epidemiology,* 64**,** 6-10.

STREINER, D. L. & NORMAN, G. R. 2008. *Health measurement scales: A Practical guide to their development and use,* Oxford, Oxford University Press.

STRÖM, O., BORGSTRÖM, F., KANIS, J. A., COMPSTON, J., COOPER, C., MCCLOSKEY, E. V. & JÖNSSON, B. 2011. Osteoporosis: burden, health care provision and opportunities in the EU. *Archives of Osteoporosis,* 6**,** 59-155.

STUURMAN-BIEZE, A. G. G., HIDDINK, E. G., VAN BOVEN, J. F. M. & VEGTER, S. 2014. Proactive pharmaceutical care interventions decrease patients' nonadherence to osteoporosis medication. *Osteoporosis International,* 25**,** 1807-1812.

SUNYECZ, J. A. 2008. The use of calcium and vitamin D in the management of ostoeporosis. *Therapeutics and clinical risk management 2008,* 4**,** 827-836.

SVEDBOM, A., HERNLUND, E., IVERGÅRD, M., COMPSTON, J., COOPER, C., STENMARK, J., MCCLOSKEY, E. V., JÖNSSON, B. & KANIS, J. A. 2013. Osteoporosis in the European Union: a compendium of country-specific reports. *Archives of Osteoporosis,* 8**,** 137.

TAYLOR, J. C., STERKEL, B., UTLEY, M., SHIPLEY, M., NEWMAN, S., HORTON, M. & FITZ-CLARENCE, H. 2001. Opinions and experiences in general practice on osteoporosis prevention, diagnosis and management. *Osteoporos Int,* 12**,** 844-848.

TERRIO, K. & AULD, G. W. 2002. Osteoporosis knowledge, calcium intake, and weight-bearing physical activity in three age groups os women. *Journal of Community Health,* 27**,** 307-320.

THABANE, L., MA, J., CHU, R., CHENG, J., ISMAILA, A., RIOS, L. P., ROBSON, R., THABANE, M., GIANGREGORIO, L. & GOLDSMITH, C. H. 2010. A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology,* 10**,** 1.

THE NORTH AMERICAN MENOPAUSE SOCIETY (NAMS) 2010. Management of osteoporosis in postmenopausal women: 2010 position statement of the The North American Menopause Society. *The Journal of the North American Menopause Society,* 17**,** 25-54.

THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS 2010. Clinical guideline for prevention and treatment of osteoporosis in postmenopausal women and older men. *In:* AUSTRALIAN GOVERNMENT,

N. H. A. M. R. C. (ed.). Melbourne, Australia: The Royal Australian College of General Practitioners.

THE WOMEN'S HEALTH INITIATIVE STEERING COMMITTEE 2004. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy. The women's health initiative randomized controlled trial. *The journal of the American Medical Association,* 291**,** 1701-1712.

TICKLE-DEGNEN, L. 2013. Nuts and bolts of conducting feasibility studies. *The American Journal of Occupational Therapy***,** 171-176.

TOH, L. S., LAI, P. S. M., WONG, K. T., LOW, B. Y. & ANDERSON, C. 2012. What are the barriers encountered while screening for osteoporosis in a government university hospital primary care setting? Preliminary results of a qualitative study on Malaysian nurses views. *Osteoporos Int,* 23**,** S777.

TOH, L. S., LAI, P. S. M., WONG, K. T., TAN, A. T. B., LOW, B. Y., ANDERSON, C. & BIN-CHIA, D. W. 2014. The development and validation of the Satisfaction Questionnaire for Osteoporosis Prevention in Malaysia. *Patient Preference and Adherence,* 8**,** 1365-1381.

TRIVEDI, D. P., DOLL, R. & KHAW, K. T. 2003. Effect of four monthly oral vitamin D3 (cholecalciferol) supplementation on fractures and mortality in men and women living in the community: randomised double blind controlled trial. *British Medical Journal,* 326**,** 469-472.

TULIP, S. & CAMPBELL, D. 2001. Evaluating pharmaceutical care in hospitals. *Hospital Pharmacists,* 8**,** 275-279.

TULLY, M. P. & BUCHAN, I. E. 2009. Prescribing errors during hospital inpatient care: factors influencing identification by pharmacists. *Pharmacy World & Science,* 31**,** 682-688.

TWINN, S. 1997. An exploratory study examining the influence of the translation on the validity and reliability of qualitatice data in nursing research. *Journal of Advanced Nursing,* 28**,** 418-423.

U.S. PREVENTIVE SERVICE TASK FORCE. 2014. *Final Recommendation Statement: Osteoporosis: Screening. U.S. Preventive Services Task Force.* [Online]. Available: http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/osteoporosis-screening [Accessed 17 September 2015].

UNGAN, M. & TUMER, M. 2001. Turkish women's knowledge of osteoporosis. *Family Practice,* 18**,** 199-203.

UNITED NATIONS 2011. World Population Prospects The 2010 Revision Volume I: Comprehensive Tables. *In:* DIVISION, D. O. E. A. S. A. P. (ed.).

UNIVERSITY TESTING SERVICES, A. S. U. *A guide to interpreting the item analysis report* [Online]. Available: http://www.asu.edu/uts/pdf/InternpIAS.pdf [Accessed 5th May 2014].

VAN BOVEN, J. F. M., STUURMAN0BIEZE, A. G. G., HIDDINK, E. G., POSTMA, M. J. & VEGTER, S. 2014. Medication monitoring and optimization: A targeted pharmacist program for effective and cost-effective improvement of chronic therapy adherence. *Journal of Managed Care & Specialty Pharmacy* 20**,** 786-792.

VAUS, D. D. 2002. *Survey in social research,* New South Wales, Australia, Allen & Unwin.

VINCENT, C., TAYLOR-ADAMS, S., CHAPMAN, E. J., HEWETT, D., PRIOR, S., STRANGE, P. & TIZZARD, A. 1999. *A protocol for investigation and analysis of clinical incidents,* London, University College London/Assocation of Litigation and Risk Management.

VINCENT, C., TAYLOR-ADAMS, S., CHAPMAN, E. J., HEWETT, D., PRIOR, S., STRANGE, P. & TIZZARD, A. 2000. How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management protocol. *BMJ,* 320**,** 777-781.

WALLACE, I., CALLACHAND, F., ELLIOTT, J. & GARDINER, P. 2011. An evaluation of an enhanced fracture liaison service as the optimal model for secondary prevention of osteoporosis. *JRSM Short Reports,* 2**,** 8-8.

WARE, J. E., SNYDER, M. K., WRIGHT, R. & DAVIES, A. R. 1983. Defining and measuring patient satisfaction with medical care. *Evaluation and Program Planning,* 6**,** 247-263.

WEINSTEIN, L. & ULLERY, B. 2000. Identification of at-risk women for osteoporosis screening. *Am J Obstet Gynecol,* 183**,** 547-9.

WERNER, P. 2005. Knowledge about osteoporosis: assessment, correlates and outcomes. *Osteoporosis International,* 16**,** 115-127.

WEST, R., WALIA, A., HYDER, N., SHAHAB, L. & MICHIE, S. 2010. Behavior change techniques used by the English Stop Smoking Services and their associations with short-term quit outcomes. *Nicotine & Tobacco Research,* 12**,** 742-747.

WHO TECHNICAL REPORT SERIES 843 1994. Assessment of fracture risk and its application to screening for

postmenopausal oteoporosis. Geneva: World Health Organisation.

WHYTE, M. P. 2006. The Long and the Short of Bone Therapy. *New England Journal of Medicine,* 354**,** 860-863.

WILD, D., GROVE, A., MARTIN, M., EREMENCO, S., MCELROY, S., VERJEE-LORENZ, A. & ERIKSON, P. 2005. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. *Value Health,* 8**,** 94-104.

WINZENBERG, T. M., OLDENBURG, B., FRENDIN, S. & JONES, G. 2003. The design of a valid and reliable questionnaire to measure osteoporosis knowledge in women: The osteoporosis knowledge assessment tool (OKAT). *BMC Musculoskeletal Disorders,* 4**,** 17.

WONG, I. C. K. 2004. Randomised controlled trials (RCTs) to evaluate complex healthcare interventions- a case study. *Pharm World Sci,* 26**,** 247-252.

WORLD HEALTH ORGANIZATION 2004. WHO Scientific group on the assessment of osteoporosis at primary health care level. Brussels, Belgium: WHO Press.

WORLD HEALTH ORGANIZATION GENEVA 1998. Guidelines for preclinical evaluation and clinical trial in osteoporosis. Switzerland.

WORLD HEALTH ORGANIZATION GENEVA 1999. Both health organizations and individuals must act now to avoid an impending epidemic. Press Release WHO/58.

WRIGHT, N. C., LOOKER, A. C., SAAG, K. G., CURTIS, J. R., DELZELL, E. S., RANDALL, S. & DAWSON-HUGHES, B. 2014. The Recent Prevalence of Osteoporosis and Low Bone Mass in the United States Based on Bone Mineral Density at the Femoral Neck or Lumbar Spine. *Journal of Bone and Mineral Research,* 29**,** 2520-2526.

WRIGHT, S. A., MCNALLY, C., BERINGER, T., MARSH, D. & FINCH, M. B. 2005. Osteoporosis fracture liaison experience: the Belfast experience. *Rheumatology International,* 25**,** 489-490.

WRITING GROUP FOR THE WOMEN'S HEALTH INITIATIVE 2002. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative Randomized Controlled Trial. *Journal of the American Medical Association,* 288**,** 321-333.

XIA, W. B., HE, S. L., XU, L., LIU, A. M., JIANG, Y., LI, M., WANG, O., XING, X. P., SUN, Y. & CUMMINGS, S. R. 2012. Rapidly increasing rates of hip fracture in Beijing, China. *J Bone Miner Res,* 27**,** 125-9.

YEAP, S. S., GOH, E. M. L. & GUPTA, E. D. 2010. Knowledge about osteoporosis in a Malaysian population. *Asia-Pacific Journal of Public Health,* 22**,** 233-241.

YU, S. & HUANG, Y. C. 2003. Knowledge of, attitude toward, and activity to prevenet osteoporosis among middel-aged and elderly women. *Journal of Nursing Research,* 11**,** 65-72.

YUKSEL, N., MAJUMDAR, S. R., BIGGS, C. & TSUYUKI, R. T. 2010. Community pharmacist-initiated screening program for osteoporosis: randomized controlled trial. *Osteoporos Int,* 21**,** 391-8.

ZHANG, Y.-P., LI, X.-M., WANG, D.-L., GUO, X.-Y. & GUO, X. 2012. Evaluation of educational program on osteoporosis awareness and prevention among nurse students in China. *Nursing & Health Sciences,* 14**,** 74-80.

ZIEBLAND, S. & MCPHERSON, A. 2006. Making sense of qualitatative data analysis: An introduction with illustrations from DIPEx (personal experiences of health and illness). *Medical Education,* 40**,** 405-414.

Tables

Table 1: Baseline demographic characteristics of patients

Characteristics	Patients (n=203)
Mean age ± S. D. (years) [range] (Median)	62.1±7.2 [50-79] (61.0)
Age range (years) [n (%)]	
<65	120 (59.1)
≥ 65	83 (40.9)
Ethnicity [n (%)]	
Malay	30 (14.8)
Chinese	126 (62.1)
Indian	44 (21.7)
Eurasian	3 (1.5)
Mean BMI (kg/m^2) ± S.D. (Median)	24.2±4.6 (23.3)
BM I (kg/m^2) [n (%)]	
<18.5 (underweight)	10 (4.9)
18.5-24.9 (normal)	118 (58.1)
25.0-29.9 (overweight)	55 (27.1)
≥30.0 (obese)	20 (9.9)
Level of education [n (%)]	
Primary (6 years of education)	10 (4.9)
Secondary (11-13 years of education)	78 (38.4)
Diploma/Technical school training (12-14 years of education)	39 (19.2)
Tertiary/Postgraduate (15-21 years of education)	
	76 (37.4)
Income per month [n (%)]	
<RM1000 (<$ 310.7)	36 (17.7)
RM1000-1999 ($ 310.7-621.0)	25 (12.3)
RM2000-2999 ($ 621.3- 931.7)	23 (11.3)
RM3000-3999 ($ 932.0- 1242.3)	21 (10.3)
RM4000-4999 ($ 1242.6-1553)	17 (8.4)
>RM5000 (>$1553.3)	81 (39.9)

S.D. = standard deviation; BMI=body mass index; $= US dollar

Table 2: Eigenvalues of the domains in the Osteoporosis Prevention and Awareness Tool (OPAAT) using exploratory factor analysis (EFA)

(d) Eigenvalues of domain A

Domain A	Eigenvalue
Factor1	4.04065
Factor2	0.80586
Factor3	0.50583
Factor4	0.22203
Factor5	0.11458
Factor6	0.01873
Factor7	-0.02871
Factor8	-0.10657
Factor9	-0.16125
Factor10	-0.19727
Factor11	-0.22522

(a) Eigenvalues of domain B

Domain B	Eigenvalue
Factor1	1.8924
Factor2	0.74467
Factor3	-0.04495
Factor4	-0.19105
Factor5	-0.23417

(a) Eigenvalues of domain C

Domain C	Eigenvalue
Factor1	4.36008
Factor2	0.84406
Factor3	0.56791
Factor4	0.44087
Factor5	0.31589
Factor6	0.26055
Factor7	0.17115
Factor8	0.01055
Factor9	-0.04459
Factor10	-0.15964
Factor11	-0.21151
Factor12	-0.27104

Table 3: Factor loadings of the Osteoporosis Prevention and Awareness Tool (OPAAT) using exploratory factor analysis (EFA)

(d) Factor loadings of domain A

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8
ITEM1	0.3207	0.2394	-0.1778	0.1858	0.2448	0.2203	-0.0682	0.0334
ITEM2	0.3641	-0.2981	0.389	0.1759	0.1214	-0.05	-0.177	-0.0281
ITEM3	0.6867	0.4137	-0.0234	-0.2121	-0.1167	0.0259	-0.1924	0.0187
ITEM4	0.5165	-0.277	0.1993	0.0702	-0.2318	0.104	-0.0083	0.0588
ITEM5	0.7448	0.2325	0.057	0.3106	-0.1576	-0.1444	-0.0722	-0.0153
ITEM6	0.4156	0.4079	0.0697	0.27	0.0308	-0.0044	0.2128	-0.012
ITEM7	0.6944	-0.1801	0.1375	-0.04	0.1071	0.2178	0.0844	-0.0266
ITEM8	0.3345	0.1019	0.359	-0.1986	0.0684	0.0893	0.1261	0.019
ITEM9	0.6472	0.0113	-0.1588	-0.1892	-0.1781	0.172	-0.0105	-0.0556
ITEM10	0.6949	-0.3275	-0.3495	0.0851	0.1654	0.0115	-0.04	0.0059
ITEM11	0.7208	0.0986	0.0598	-0.2682	0.2446	-0.256	0.0009	0.0059
ITEM12	0.8021	-0.264	-0.1945	-0.0087	-0.1141	-0.1628	0.1512	0.0155

Only the factor loadings (represented as eigenvalue) greater than 1 were selected (Harman, 1976)

(e) Factor loadings of domain B

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8
ITEM12	0.3207	0.2394	-0.1778	0.1858	0.2448	0.2203	-0.0682	0.0334
ITEM13	0.3641	-0.2981	0.389	0.1759	0.1214	-0.05	-0.177	-0.0281
ITEM14	0.6867	0.4137	-0.0234	-0.2121	-0.1167	0.0259	-0.1924	0.0187
ITEM15	0.5165	-0.277	0.1993	0.0702	-0.2318	0.104	-0.0083	0.0588
ITEM16	0.7448	0.2325	0.057	0.3106	-0.1576	-0.1444	-0.0722	-0.0153

Only the factor loadings (represented as eigenvalue) greater than 1 were selected (Harman, 1976

(f) Factor loadings of domain C

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8
ITEM17	0.3207	0.2394	-0.1778	0.1858	0.2448	0.2203	-0.0682	0.0334
ITEM19	0.3641	-0.2981	0.389	0.1759	0.1214	-0.05	-0.177	-0.0281
ITEM20	0.6867	0.4137	-0.0234	-0.2121	-0.1167	0.0259	-0.1924	0.0187
ITEM21	0.5165	-0.277	0.1993	0.0702	-0.2318	0.104	-0.0083	0.0588
ITEM22	0.7448	0.2325	0.057	0.3106	-0.1576	-0.1444	-0.0722	-0.0153
ITEM23	0.4156	0.4079	0.0697	0.27	0.0308	-0.0044	0.2128	-0.012
ITEM24	0.6944	-0.1801	0.1375	-0.04	0.1071	0.2178	0.0844	-0.0266
ITEM25	0.3345	0.1019	0.359	-0.1986	0.0684	0.0893	0.1261	0.019
ITEM26	0.6472	0.0113	-0.1588	-0.1892	-0.1781	0.172	-0.0105	-0.0556
ITEM27	0.6949	-0.3275	-0.3495	0.0851	0.1654	0.0115	-0.04	0.0059
ITEM29	0.7208	0.0986	0.0598	-0.2682	0.2446	-0.256	0.0009	0.0059
ITEM30	0.8021	-0.264	-0.1945	-0.0087	-0.1141	-0.1628	0.1512	0.0155

Only the factor loadings (represented as eigenvalue) greater than 1 were selected (Harman, 1976)

Table 4: Psychometric properties of the Osteoporosis Prevention And Awareness Tool (OPAAT)

Domains	Item Number		Accuracy rate	Cronbach's α	Corrected Item correlation	Cronbach's α if item deleted
	1	Makes bones weaker, more brittle and more likely to break (fracture)	0.91		0.421	0.639
	2	Everybody will get osteoporosis as it is part of aging	0.32		0.173	0.672
Osteoporosis in general (A)	3	Osteoporosis occurs because bone is removed faster than it is formed	0.52	0.668	0.176	0.673
	4	Osteoporosis and osteoarthritis are different names we can use to describe the same disease	0.58		0.455	0.619
	5	Osteoporosis usually has no symptoms	0.48		0.065	0.693
	6	Postmenopausal women are not at risk for osteoporosis	0.72		0.416	0.629
	7	Osteoporosis is an untreatable disease.	0.56		0.232	0.663
	8	A bone mineral density test is used to diagnose osteoporosis	0.76		0.428	0.628
	9	I do not need a bone mineral density test unless I fracture my bones.	0.79		0.555	0.608
	10	A bone mineral density test is high in radiation	0.45		0.321	0.646
	11	A bone mineral density test should be performed monthly to monitor bone loss	0.60		0.407	0.629
	12	Results in back pain	0.72		0.272	0.095
Consequences of untreated osteoporosis (B)	13	Loss of height or hunchback	0.88		0.235	0.173
	14	Loss of mobility (unable to move around myself)	0.78	0.286	0.164	0.215
	15	Results in tooth loss	0.26		0.006	0.373
	16	Results in joint pain or swelling of fingers	0.27		0.056	0.319
	17	The recommended daily intake for calcium in women above 50 years of age is 1000mg	0.61		0.274	0.744
	18	It is too late to increase calcium intake after the age 50	0.55		0.417	0.727
	19	Glucosamine can help prevent osteoporosis	0.29		0.181	0.753
	20	Calcium supplements can help prevent osteoporosis	0.85		0.397	0.731
	21	The regular dose of calcium supplements can cause kidney stones.	0.26		0.264	0.744

Osteoporosis prevention (C)	22	Foods such as milk, tofu, anchovies (*ikan bilis*), yellow dhal and spinach are rich in calcium	0.90		0.398	0.73
				0.748		
	23	You can obtain your recommended daily intake of vitamin D via exposing your skin to sunlight for about 15 minutes a day	0.87		0.300	0.739
	24	Increasing coffee and tea intake can help in osteoporosis prevention	0.67		0.479	0.719
	25	Weight bearing exercise (such as brisk walking and line dancing) can decrease bone loss.	0.68		0.248	0.747
	26	Exercise will wear out bones	0.78		0.459	0.723
	27	Certain medications (such as sleeping tablets or high blood pressure medications) may reduce the risk of falling	0.57		0.421	0.726
	28	To prevent falls, comfortable shoes with a good grip should be used.	0.94		0.524	0.728
	29	Poor vision may lead to falls	0.92		0.380	0.734
	30	Being under weight helps prevent osteoporosis	0.60		0.490	0.718
Total Cronbach's α				0.820		

Table 5: Test and retest reliability of the individual items for the Osteoporosis Prevention And Awareness Tool (OPAAT)

Domain	Item number	Test (n=203)			Retest (n=194)			McNemar's test p-value	Kappa measurement of agreement* P-value	Spearman's rho correlation coefficient*	Wilcoxon signed-rank test		
		Mean±SD	Median	No. of correct responses [n (%)]	Mean±SD	Median	No. of correct responses [n (%)]				Mean/rank	z-value	P-value
Osteoporosis in general (A)	1	0.91±0.28	1.00	185 (91.1)	0.89±0.32	1.00	172 (88.7)	0.219	0.833	0.838			
	2	0.32±0.47	0.00	64 (31.5)	0.30±0.46	0.00	58 (29.9)	0.250	0.964	0.964			
	3	0.52±0.50	1.00	105(51.7)	0.52±0.50	1.00	101 (52.1)	1.000	0.979	0.979			
	4	0.58±0.50	1.00	117 (57.6)	0.57±0.50	1.00	110 (56.7)	1.000	0.958	0.958			
	5	0.48±0.50	0.00	97 (47.8)	0.48±0.50	0.00	94 (48.5)	1.000	0.990	0.990			
	6	0.72±0.45	1.00	147 (72.4)	0.71±0.46	1.00	137 70.6)	0.508	0.886	0.887			
	7	0.56±0.50	1.00	113 (55.7)	0.54±0.50	1.00	105 (54.1)	0.453	0.927	0.928			
	8	0.76±0.43	1.00	155 (76.4)	0.74±0.44	1.00	144 (74.2)	0.219	0.917	0.918			
	9	0.79±0.41	1.00	160 (78.8)	0.78±0.42	1.00	152 (78.4)	1.000	0.970	0.970			
	10	0.45±0.50	0.00	92 (45.3)	0.46±0.50	0.00	90 (46.4)	0.219	0.938	0.938			
	11	0.60±0.49	1.00	121 (59.6)	0.60±0.49	1.00	118 (60.8)	0.754	0.892	0.893			
	Domain score (%)	60.7±22.2	63.64		60.0±23.8	63.63				0.953	14.54/11.33	-0.724	0.469
Consequences of untreated osteoporosis (B)	12	0.72±0.45	1.00	147 (72.4)	0.72±0.45	1.00	140 (72.2)	1.000	0.923	0.923			
	13	0.88±0.33	1.00	178 (87.7)	0.89±0.31	1.00	173 (89.2)	0.250	0.925	0.927			
	14	0.78±0.42	1.00	158 (77.8)	0.78±0.41	1.00	152 (78.4)	0.500	0.970	0.971			
	15	0.26±0.44	0.00	52 (25.6)	0.27±0.45	0.00	53 (27.3)	0.453	0.908	0.908			
	16	0.27±0.44	0.00	54 (26.6)	0.29±0.45	0.00	56 (28.9)	0.219	0.923	0.924			
	Domain score (%)	58.0±21.3	60.00		59.2±21.7	60.00				0.909	7.50/10.27	-2.216	0.027*
Prevention of osteoporosis	17	0.61±0.49	1.00	123 (60.6)	0.60±0.49	1.00	116 (59.8)	0.687	0.935	0.936			
	18	0.55±0.50	1.00	112 (55.2)	0.55±0.50	1.00	106 (54.6)	1.000	0.948	0.948			
	19	0.29±0.46	0.00	59 (29.1)	0.28±0.45	0.00	55 (28.4)	1.000	0.962	0.962			

(C)	20	0.85±0.36	1.00	173 (85.2)	0.83±0.38	1.00	161 (83.0)	0.250	0.943	0.945			
	21	0.26±0.44	0.00	52 (25.6)	0.26±0.44	0.00	51 (26.3)	0.375	0.932	0.933			
	22	0.90±0.30	1.00	183 (90.1)	0.88±0.32	1.00	171 (88.1)	0.375	0.869	0.872			
	23	0.87±0.34	1.00	176 (86.7)	0.85±0.36	1.00	165 (85.1)	0.453	0.852	0.854			
	24	0.67±0.47	1.00	137 (67.5)	0.68±0.47	1.00	131 (67.5)	0.727	0.905	0.905			
	25	0.68±0.47	1.00	138 (68.0)	0.65±0.48	1.00	126 (64.9)	0.070	0.908	0.910			
	26	0.78±0.41	1.00	159 (78.3)	0.76±0.43	1.00	148 (76.3)	0.289	0.882	0.884			
	27	0.57±0.50	1.00	116 (57.1)	0.55±0.50	1.00	106 (54.6)	0.405	0.760	0.761			
	28	0.94±0.24	1.00	191 (94.1)	0.92±0.28	1.00	178 (91.8)	0.125	0.846	0.856			
	29	0.92±0.28	1.00	186 (91.6)	0.90±0.30	1.00	174 (89.7)	0.250	0.910	0.914			
	30	0.60±0.49	1.00	122 (60.1)	0.59±0.49	1.00	115 (59.3)	1.000	0.947	0.947			
	Domain score (%)	67.8±20.2	71.42		66.4±22.6	71.43				0.937	21.17/19.50	-1.339	0.171
Total OPAAT score (%)		63.6±17.4	66.67		62.9±19.1	66.67				0.950	28.98/27.05	-0.107	0.914

*Statistically significant at p<0.05. Wilcoxon signed-rank test and Spearman's rho correlation coefficient was used for continuous variables. McNemar's test and Kappa measurement of agreement was conducted for categorical variables

Table 6: Knowledge scores of the patient and pharmacist group at test and retest

Domains	Item Number	Patients(n=203)			Pharmacist(n=31)			Mann-Whitney U-test			p-value [a]
		Mean±SD	Median	Participants that answered correctly [n (%)]	Mean±SD	Median	Participants that answered correctly [n (%)]	Mean/rank	Z-value	p-value	
Osteoporosis in general (A)	1	0.91±0.28	1.00	185 (91.1)	0.97±1.80	1.00	30 (96.8)				0.482 [b]
	2	0.32±0.47	0.00	64 (31.5)	0.58±0.50	1.00	18 (58.1)				0.007*
	3	0.52±0.50	1.00	105(51.7)	0.90±0.30	1.00	28 (90.3)				0.000*
	4	0.58±0.50	1.00	117 (57.6)	0.94±0.25	1.00	29 (93.5)				0.000*
	5	0.48±0.50	0.00	97 (47.8)	0.55±0.51	1.00	17 (54.8)				0.590
	6	0.72±0.45	1.00	147 (72.4)	1.00±0.00	1.00	31 (100.0)				0.002*
	7	0.56±0.50	1.00	113 (55.7)	0.68±0.48	1.00	21 (67.7)				0.284
	8	0.76±0.43	1.00	155 (76.4)	0.94±0.25	1.00	29 (93.5)				0.052
	9	0.79±0.41	1.00	160 (78.8)	0.97±0.18	1.00	30 (96.8)				0.033*
	10	0.45±0.50	0.00	92 (45.3)	0.48±0.51	0.00	15 (48.4)				0.900
	11	0.60±0.49	1.00	121 (59.6)	0.77±0.43	1.00	24 (77.4)				0.088

	Item	Mean±SD	Median	n (%)	Mean±SD	Median	n (%)	Ratio	Z	p	p
	Domain score (%)	60.7±22.2	63.64		79.8±12.6	81.82		109.23/171.68	-4.834	0.000*	
Consequences of untreated osteoporosis (B)	12	0.72±0.45	1.00	147 (72.4)	0.77±0.43	1.00	24 (77.4)				0.713
	13	0.88±0.33	1.00	178 (87.7)	0.84±0.37	1.00	26 (83.9)				0.565 [b]
	14	0.78±0.42	1.00	158 (77.8)	0.81±0.40	1.00	25 (80.6)				0.905
	15	0.26±0.44	0.00	52 (25.6)	0.51±0.51	1.00	16 (51.6)				0.006*
	16	0.27±0.44	0.00	54 (26.6)	0.74±0.44	1.00	23 (74.2)				0.000*
	Domain score (%)	58.0±21.3	60.00		73.6±17.4	80.00		110.98/160.21	-4.086	0.000*	
Prevention of osteoporosis (C)	17	0.61±0.49	1.00	123 (60.6)	0.58±0.50	1.00	18 (58.1)				0.944
	18	0.55±0.50	1.00	112 (55.2)	0.84±0.37	1.00	26 (83.9)				0.005*
	19	0.29±0.46	0.00	59 (29.1)	0.78±0.43	1.00	24 (77.4)				0.000*
	20	0.85±0.36	1.00	173 (85.2)	0.94±0.25	1.00	29 (93.5)				0.271 [b]
	21	0.26±0.44	0.00	52 (25.6)	0.61±0.50	1.00	19 (61.3)				0.000*
	22	0.90±0.30	1.00	183 (90.1)	1.00±0.00	1.00	31 (100.0)				0.084 [b]
	23	0.87±0.34	1.00	176 (86.7)	0.81±0.40	1.00	25 (80.6)				0.405 [b]
	24	0.67±0.47	1.00	137 (67.5)	0.94±0.25	1.00	29 (93.5)				0.006*
	25	0.68±0.47	1.00	138 (68.0)	0.71±0.4	1.00	22 (71.0)				0.900

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26	0.78±0.41	1.00	159 (78.3)	0.84±0.37	1.00	26 (83.9)			0.638
27	0.57±0.50	1.00	116 (57.1)	0.94±0.25	1.00	29 (93.5)			0.000*
28	0.94±0.24	1.00	191 (94.1)	0.97±0.18	1.00	30 (96.8)			1.000 [b]
29	0.92±0.28	1.00	186 (91.6)	1.00±0.00	1.00	31 (100.0)			0.138 [b]
30	0.60±0.49	1.00	122 (60.1)	0.87±0.34	1.00	27 (87.1)			0.007*
Domain score (%)	67.8±20.2	71.42		84.3±10.5	85.71		109.14/172.26	-4.876	0.000*
Total (%)	63.6±17.4	66.67		80.9±8.7	83.33		107.67/181.84	-5.694	0.000*

* Statistically significant at p<0.05, The Mann-Whitney U-test was conducted for continuous variables and the chi square was conducted for categorical variables.

[a] Chi-square test

[b] Fisher's exact test was used as the number of cells with expected count less that 5 is more than 20% of the total number of cells

Table 7: Comparison of psychometric properties of the Osteoporosis Prevention And Awareness Tool (OPAAT)

	OPAAT	MOKT	Osteoporosis and You	OKAT	FOOQ	OKQ	OPQ
Age (years)	50-79	49-84	65-90	25-44	-	≥ 60	≥ 50
Number of subjects	203	88	871	467	256	188	50
Number of items with low difficulty level (%)	4(13.3)	19 (47.5)	6 (60)	3(15)	-	-	(44)
Flesch reading ease	59.2	57	-	45	81-90	-	74.3
Cronbach's α or Kuder Richardson (KR)	0.27-0.75	0.82	0.60	0.70	0.76	0.80 (KR)	0.84 (KR)
Mean score (%)	63.6	69.0	37.7	44.0	-	57.4	-

OPAAT: Osteoporosis Prevention And Awareness Tool; MOKT: Malaysian Osteoporosis Knowledge Test (Lai et al., 2008), Osteoporosis and You (Cadarette et al., 2007); OKAT: Osteoporosis Knowledge Assessment Tool (Winzenberg et al., 2003); FOOQ: facts on Osteoporosis Quiz (Ailinger et al., 1998, Ailinger et al., 2003); OKQ: Osteoporosis Knowledge Questionnaire (Curry and Hogstel, 2001); OPQ: Osteoporosis Questionnaire (Pande et al., 2000)

14.30 **Appendix 39- Journal publication for the Satisfaction Questionnaire for Osteoporosis Prevention (SQOP)**