

**USER CENTRED APPROACH TO THE DESIGN,  
DEVELOPMENT AND IMPLEMENTATION OF  
PATIENT INFORMATION**

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# Abstract

Clinical pathways define patient journeys with medical devices often utilised to diagnose and treat patients. In the contexts of screening and diagnosis, devices are utilised in the form of investigations and tests. They are utilised to detect preventable medical conditions in otherwise healthy individuals and to determine the cause of symptoms in patients presenting symptoms. Patient experiences of investigations and tests vary depending on the healthcare situation, investigation or test, and requirements, expectations and physical experiences of patients before, during and after investigations and tests. Information can be a valuable resource to inform, support and guide patients, and to contribute to quality patient experiences. However, this can only be achieved if information meets patient needs and preferences. This was the basis of the thesis, which took a user centred approach to the design, development and implementation of patient information.

Two studies were conducted focussing on understanding attitudes towards investigations and tests, and informational needs and preferences. The first study examined attitudes towards different types of diagnostic procedure and the second examined attitudes towards screening for a vascular condition. Information was valuable in the former to inform about diagnostic procedures and patients' physical involvement with them, and in the latter to inform about the medical condition, screening for the condition, the screening procedure, the benefits of being screened, and the risks of being or not being screened. Both studies also established factors affecting attitudes, providing a constructive understanding of attitudes. Ten factors were established that affected attitudes towards diagnostic procedures of which physical involvement, trust, familiarity and purpose were the most influential factors. Fifteen factors were established that affected attitudes towards screening of which benefits and risks, referring to personal benefits and risks, were the most influential factors. The established factors inspired a user centred design concept for patient information – a 'factors based approach' to the design of patient information.

The factors based approach to the design of patient information is theoretical and consists of including and organising information based on factors. This approach

was examined in two studies, which involved re-designing a patient information resource for an invasive investigation by applying appropriate factors established in the first two studies to it and examining and comparing it with the original information resource. The original resource was based on a standardised presentation of information for the investigation. The factors based resource was quantitatively no better nor worse than the standard resource; however, qualitative data found it had features that were important for its usability, which seemed to make it easier to understand compared to the standard resource. These findings demonstrated the potential of the factors based approach to the design of patient information, which led to the development of patient information guidelines.

Patient information guidelines are provided for diagnostic procedures and screening. The guidelines represent the essence of the thesis and its work, and the contribution it has made to knowledge. They combine substantial data from four studies and it is hoped the guidelines assist information designers and others involved in patient information. The guidelines also aim to contribute to quality patient experiences through better meeting patient informational needs and preferences. Since the factors based approach to the design of patient information is a novel concept and the patient information guidelines are a draft, further research is recommended to better understand the potential of the factors based approach and to further develop and refine the guidelines. The guidelines have been made publicly available to use as a separate document and for further dissemination, and can be accessed and downloaded from the following link: <https://db.tt/e6BQeJuu>

## **Publications**

KEANE, D., CRAVEN, M.P. and SHARPLES, S. (2011) Information provision and decision aids for diagnosis in clinical pathways. In: ALBOLINO, S., BAGNARA, S., BELLANDI, T., LLANEZA, J., ROSAL, G. and TARTAGLIA, R., eds. *Healthcare Systems Ergonomics and Patient Safety 2011: an alliance between professionals and citizens for patient safety and quality of life*. Proceedings of the 3<sup>rd</sup> International Conference on Healthcare Systems Ergonomics and Patient Safety (HEPS 2011), Oviedo, Spain, 22<sup>nd</sup>-24<sup>th</sup> June 2011. Boca Raton: CRC Press, p. 36 (abstract – full paper in accompanying CD-ROM), ISBN 978-0-415-68413-2.

KEANE, D., CRAVEN, M.P. and SHARPLES, S. (2012) A vignette study examining the effects of different types of diagnostic procedure and information provision preferences. In: ANDERSON, M., ed. *Contemporary Ergonomics and Human Factors 2012*. Proceedings of the International Conference on Contemporary Ergonomics and Human Factors 2012 (EHF 2012), Blackpool, United Kingdom, 16<sup>th</sup>-19<sup>th</sup> April 2012. Boca Raton: CRC Press, pp. 161-168, ISBN 978-0-415-62152-6.

KEANE, D., LANG, A.R., CRAVEN, M.P. and SHARPLES, S. (2012) The use of vignettes for conducting healthcare research. In: DUFFY, V.G., ed. *Advances in human aspects of healthcare*. Proceedings of the 4<sup>th</sup> International Conference on Applied Human Factors and Ergonomics (AHFE 2012), San Francisco, United States of America, 21<sup>st</sup>-25<sup>th</sup> July 2012. Boca Raton: CRC Press, pp. 451-460, ISBN 978-1-4398-7021-1.



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# CHAPTER 1

## Introduction

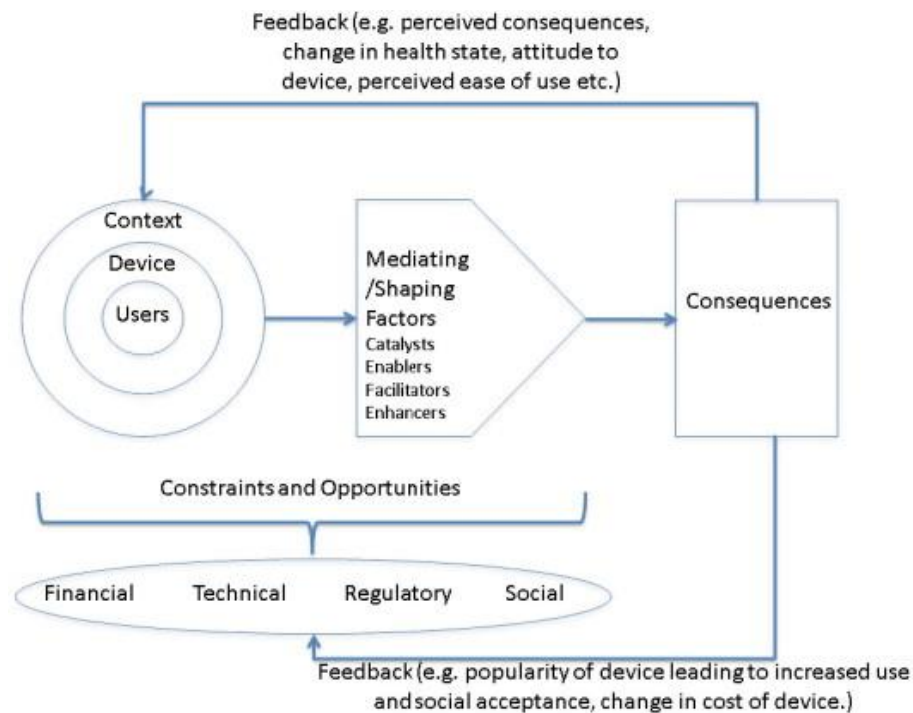
### 1.1 Background

Technological innovations have evolved the nature of healthcare via medical devices utilised across clinical pathways to detect and treat disease and injury. Devices are employed in screening programmes to detect medical conditions with the aim of preventing their advancement to untreatable states in otherwise healthy individuals, during diagnosis to determine the cause of symptoms when a patient presents to a GP in a primary care setting or is referred to secondary healthcare, during emergency situations when a rapid response is needed to understand a patient's medical condition, and during treatment to absolve the threat of or to alleviate a patient's medical condition.

Medical devices used in these various situations vary in terms of technological complexity (i.e. sophistication of components and processes), cost, demands on operator (e.g. level of technical knowledge), demands on patient (e.g. level of physical invasiveness) and informational output (e.g. image from an X-ray). Understanding the effects devices have on their users will provide valuable data to improve the utilisation of current medical devices; a guideline for the design, development and implementation of future devices; and a framework to assess and meet user needs and preferences.

Sharples *et al.* (2012) developed a model (Figure 1.1) that takes into consideration users, medical device, interaction of users and the device, and resultant consequences of the interaction. This describes a human factors approach that aims to understand the relationship between users and a medical device in a particular context of utilisation, and the effects this has on user behaviour. Such an approach provides insight into what facilitates the utilisation of a medical device and what hinders it.



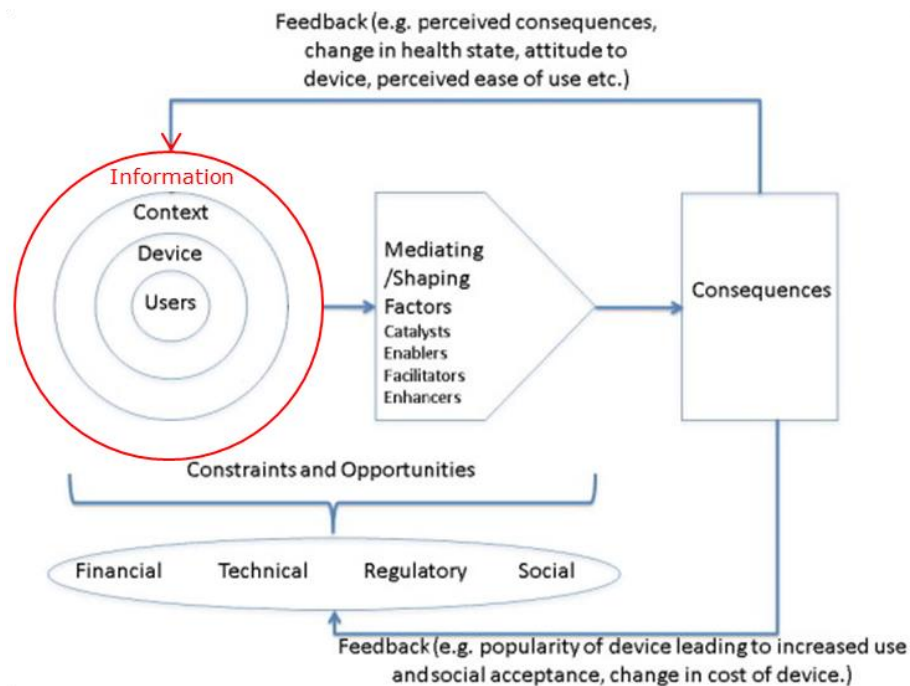


**Figure 1.1** Model of relationship between user-device interaction and consequences (Sharples *et al.*, 2012)

A central component of the model are mediating/shaping factors, which are described as catalysts, enablers, facilitators and enhancers. They are depicted as outputs of the interaction between users and a medical device within a context, but feedback into this relationship through understanding consequences of the interaction. Through assessing this relationship, its outputs and consequences, an understanding of user needs and preferences can be achieved. Such an understanding can provide a foundation upon which improvements can be made to promote the utilisation of a medical device.

*What improvements can be made?* Given that users and context are intrinsically defined by a healthcare situation (i.e. prevention, diagnosis and treatment of a medical condition), as is a medical device to a degree, and that a device is also defined by the encapsulation of its technology to enable desired functionality, a malleable and influential resource could be in the form of information. The Patient Information Forum (2013a, p. 5) describes information as ‘an intervention that impacts health and wellbeing and [that] it contributes to...clinical effectiveness, safety and patient experience’. From this perspective, information has the potential to positively affect the utilisation of medical devices and more. To emphasise this potential, information has been incorporated into the model by Sharples *et al.*

(Figure 1.2) to demonstrate the relationship it could have between users and a medical device within a context.



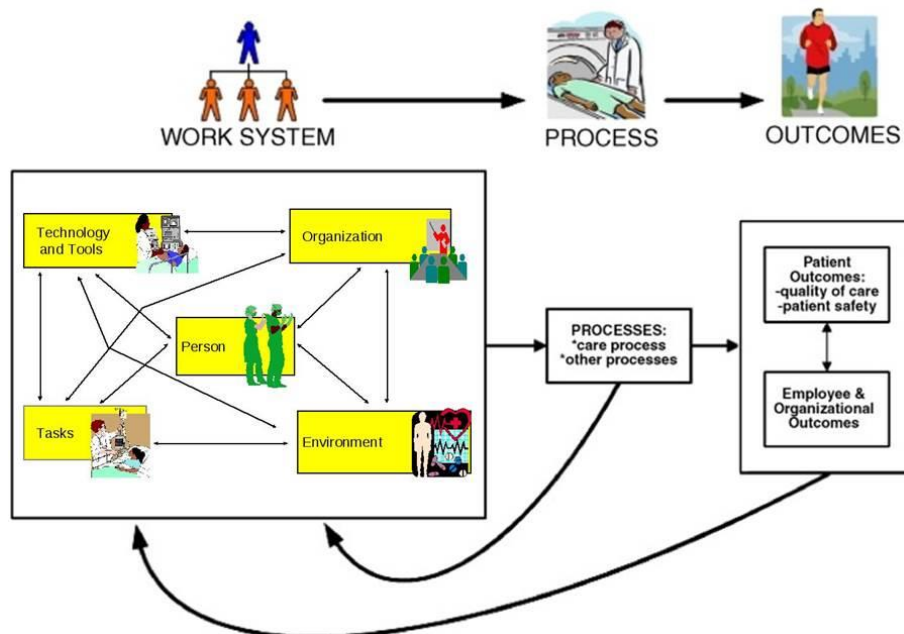
**Figure 1.2** Model of relationship between user-device interaction and consequences (Sharples *et al.*, 2012) with information incorporated

This potential, however, can only be achieved through the appropriate design, development and implementation of information. To achieve this requires assessing information, its interaction between users and a medical device within a context, and its effects on outputs (mediating/shaping factors) and consequences of the interaction. Through such an assessment the value of information and the contributions it can make to healthcare situations will be better understood.

*What contributions can be made?* Healthcare situations vary and so will the contributions of information, but its general principle should be to meet user needs and preferences so that user experiences can be at as high a standard as possible. However, users themselves vary and so tailoring information to specific user needs and preferences is essential if the information is going to contribute to quality experiences. This requires an assessment of the needs and preferences of users individually, and considering these within the realm of healthcare situations and other users, as well as possible constraints and opportunities, which as described in the Sharples *et al.* model (Figures 1.1 and 1.2) could be financial, technical,

regulatory and social. Such an approach would lead to a systems approach in the design, development and implementation of information.

Carayon *et al.* (2006) developed a model, Systems Engineering Initiative for Patient Safety (Figure 1.3), which consists of system components that interact and how these interactions can contribute to different processes and outcomes. The model is of work system design for patient safety and provides a framework for understanding interactions between components. This enables the system design to facilitate and enhance performance of a person at the centre of the work system, and to alleviate conditions that infringe upon performance, which could have negative consequences on an organisation.



**Figure 1.3** Systems Engineering Initiative for Patient Safety model of work system and patient safety (Carayon *et al.*, 2006)

The person at the centre of a work system could be a healthcare professional performing a healthcare related task or a patient receiving healthcare. However, for the design of the system to be effective, the needs of all persons must be met. In the design, development and implementation of information the persons or users could be individuals considering screening, patients, primary care clinicians, secondary care clinicians, other healthcare professionals and carers. With such an array of possible users and for information to be truly effective, it must meet all their needs

and preferences whilst fitting within the remit of a system and its constraints and opportunities.

*How to meet user needs and preferences?* Through applying human factors user needs and preferences can be derived. These can then inform the design, development and implementation of information. This will include applying methodologies to extract data from users and theories to interpret the meaning of the data. However, the extraction of data has to be meaningful in the first instance, and methodologies applied have to be done with respect to aims and objectives. Aims and objectives themselves have to be a reflection of real life or appropriately realistic scenarios, which will benefit from analytical assessments.

Information is fundamental in modern healthcare and has become part of healthcare legal requirements. In the United Kingdom, Regulations 2010 of The Health and Social Care Act 2008 (UK Legislation, 2010, Part 4 (17), p. 9) requires information and support to be provided to service users in relation to their care or treatment, whilst in the United States, the Patient Protection and Affordable Care Act (U.S. Congress, 2010, Title III, Part III, Subtitle F, Section 3506, pp. 409-412) requires information to be provided to patients, caregivers or authorised representatives in relation to treatment trade-offs, and to incorporate patient preferences and values. Providing patients and carers with appropriate information that meets their needs and preferences is essential for supporting patients and incorporating their preferences and values. This is the basis of the thesis and its work, which aims to develop a user centred approach to the design, development and implementation of patient information that contributes to quality patient experiences. Furthermore, the thesis aims to assist information designers and others involved in patient information by providing a ‘practical guide’. This was considered a useful tool by the majority of healthcare information producers who took part in a recent survey by the Patient Information Forum about producing information for people with low literacy (2013b, p. 10).

The thesis takes a user centred approach to the patient journey. The focus will be on individuals considering screening and patients requiring diagnosis, where most patient journeys begin. Informational needs and preferences will be assessed in the context of healthcare situations where medical devices are utilised for investigation

and testing. Subsequent findings, as well as knowledge gained from secondary research, will inform the design, development and implementation of patient information.

Studies will be designed based on and to represent the modified onion component of the model by Sharples *et al.* (2012) (Figure 1.2) whilst still taking account of the other components. They will elicit patient informational needs and preferences, with the aim of producing and providing information that meet these and contribute to quality patient experiences. Although studies conducted and thus elicitation processes will be based on specific healthcare situations in the context of screening and diagnosis, it is expected that the findings will have value for other situations in these contexts and other stages of patient journeys, such as the diagnosis and subsequent treatment of a medical condition.

The research questions are systematic with respect to investigations and tests utilised in screening and diagnostic healthcare situations, and the value of patient information in these situations. Although ‘patient’ is used in the context of screening, patients in this context are asymptomatic (i.e. no symptoms present) whilst in the context of diagnosis they are symptomatic (i.e. symptoms present). The user centred approach will elicit differences and similarities of informational needs and preferences between patients in these contexts.

## 1.2 Research questions

The user centred approach to the design, development and implementation of patient information will be constructed from and in response to the following three research questions:

- 1) What factors affect patient attitudes towards diagnostic and screening procedures?
- 2) What are patient informational needs and preferences when encountering diagnostic and screening procedures?
- 3) How does patient information based on factors affecting patients’ attitudes towards diagnostic and screening procedures affect the value of the information?

The original conceptualisation of the research questions was focussed on examining the effects of diagnostic procedures and information provision on patient attitudes and behaviours, and the relationship between diagnostic procedures and information provision. However, following findings from the first study and the forming of a relationship with an NHS screening programme the questions became ‘factors’ focussed and incorporated screening. Changing circumstances with the screening programme due to an alteration in the programme’s schedule also resulted in focussing on patient attitudes alone rather than patient attitudes and behaviours. The third research question combines the original concept of examining the relationship between diagnostic procedures and information provision, and the changes that ensued. The research questions are outlined below.

### **1.2.1 What factors affect patient attitudes towards diagnostic and screening procedures?**

Factors that patients consider in screening and diagnostic healthcare situations when encountering investigations and tests are to be identified. Their meanings and effects on patients are to be understood, including their influence upon patient decision-making. Differences and similarities of factors in screening and diagnostic healthcare situations are to be reflected on.

### **1.2.2 What are patient informational needs and preferences when encountering diagnostic and screening procedures?**

The value of information and the contributions it makes to patients in diagnostic and screening healthcare situations when encountering investigations and tests are to be understood. This includes eliciting patient informational needs and preferences, considering how these are currently met, and proposing improvements to the design, development and implementation of information. Differences and similarities of patient informational needs and preferences in screening and diagnostic healthcare situations are to be reflected on.

### **1.2.3 How does patient information based on factors affecting patients' attitudes towards diagnostic and screening procedures affect the value of the information?**

Patient information is to be designed based on factors identified in diagnostic and screening healthcare situations when patients encounter investigations and tests, and compared with information that is currently produced and provided to patients. The comparison will examine the value of patient information, and whether it meets patient informational needs and preferences and would contribute to quality patient experiences. The effectiveness and application of the factors based approach to the design of patient information is to be assessed also.

## **1.3 Studies in response to research questions**

Two studies were conducted in response to the first two research questions, and two further studies were conducted in response to the third research question. The studies are outlined below.

### **1.3.1 Studies to examine attitudes and informational needs and preferences**

The first two studies were in response to the first two research questions. They examined attitudes towards different types of diagnostic procedure and screening for a vascular condition, and informational needs and preferences. Both studies established factors affecting attitudes and the characterisation of the factors in the healthcare situations. This established whether factors positively or negatively contributed to the situations or whether they were neutral. Both studies also assessed information provided and whether the information met needs and preferences for the healthcare situations in which they were provided.

### **1.3.2 Studies to examine patient information based on factors**

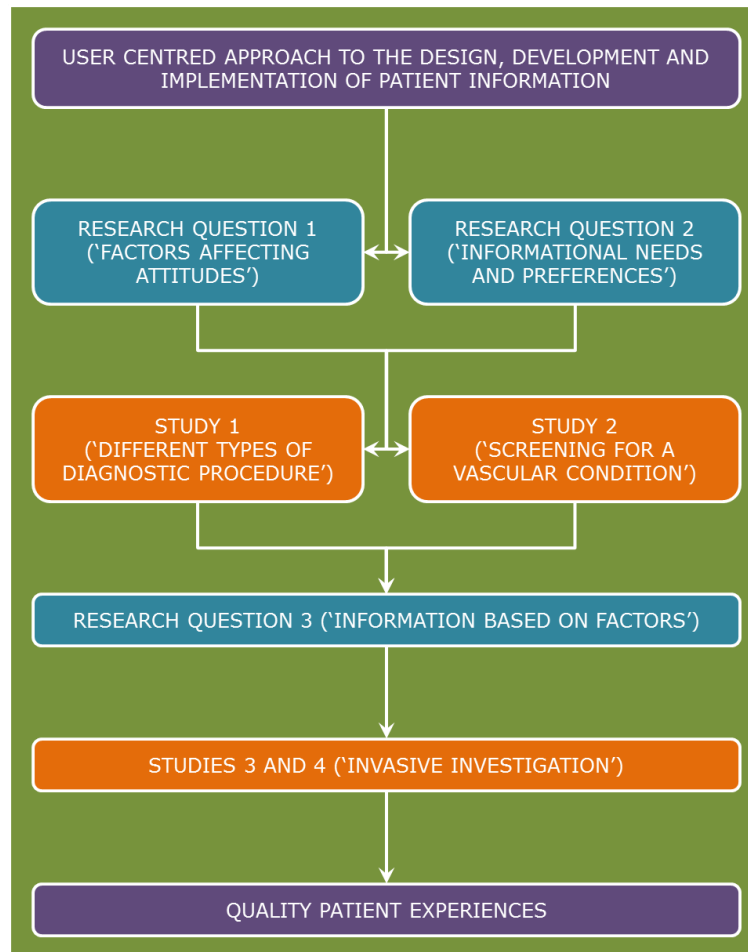
The last two studies were in response to the third research question. They examined the content, design and structure of patient information for an invasive

investigation. This involved examining and comparing two patient information resources that had almost the same content and design, but which varied in the structure of information. One of the information resources presented information based on factors established in the first two studies and the other presented information based on a standardised presentation of information for the investigation. This involved researching patient information resources that were currently available for the investigation and synthesising the way information was structured within these into a homogeneous version.

## **1.4 Organisation of thesis**

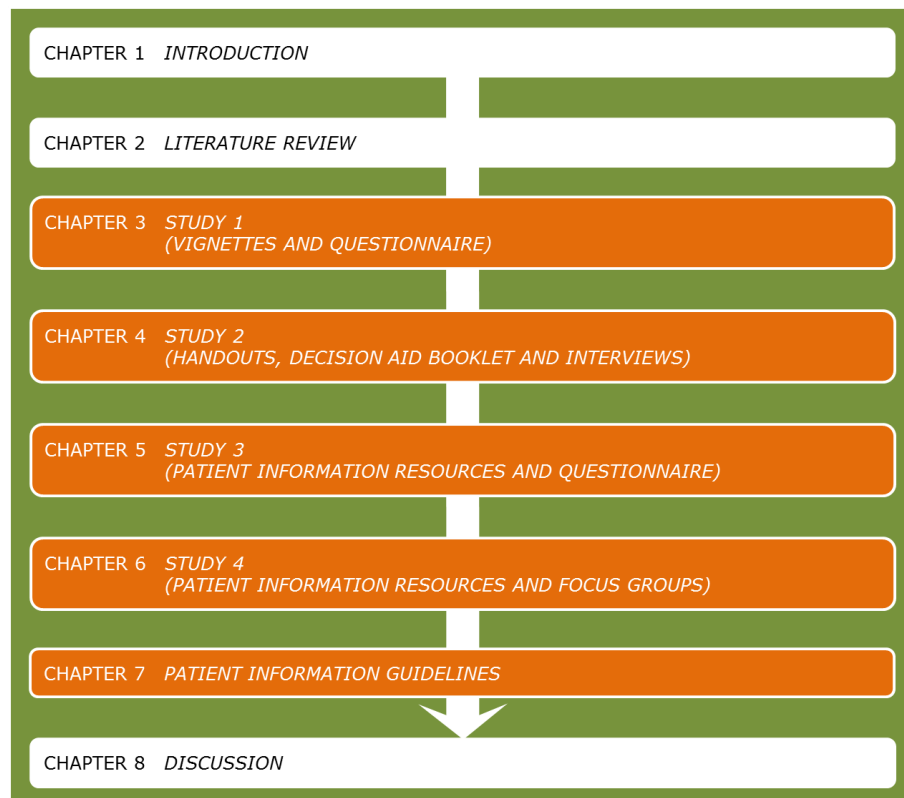
The four studies were progressive in response to the research questions and to the user centred approach to the design, development and implementation of patient information. Figure 1.4 graphically represents this process and provides a structure of the research questions and studies within the user centred approach.





**Figure 1.4** Structure of the research questions and studies within the user centred approach to the design, development and implementation of patient information

The thesis itself is progressive in response to the four studies and their findings. This includes establishing the basis of the studies in this introduction (Chapter 1) and a literature review (Chapter 2), reporting findings (Chapters 3-6) and developing patient information guidelines (Chapter 7) from them, and discussing the findings in response to the research questions, including the contribution made to knowledge and recommendations for further research (Chapter 8). Figure 1.5 graphically represents the structure of the thesis, which also includes details of the materials and methodologies used within the studies.



**Figure 1.5** Structure of thesis

# CHAPTER 2

## Literature review

### 2.1 Introduction

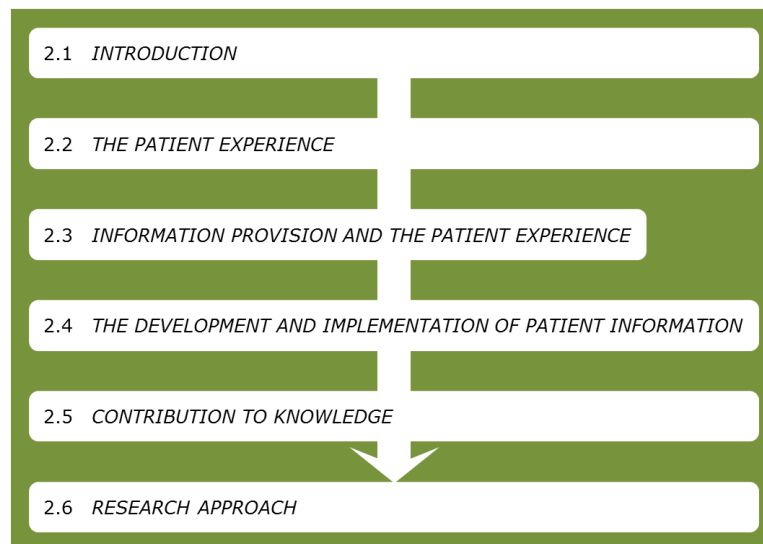
The thesis takes a user centred approach to the patient journey with the focus being on asymptomatic patients (i.e. patients presenting no symptoms) considering screening and symptomatic patients (i.e. patients presenting symptoms) requiring diagnosis. The literature review will begin with the contextualisation of the patient experience with the utilisation of medical devices in the context of screening and diagnosis, leading to patient experiences of devices in these contexts.

From this, literature of information provision is reviewed to understand how information affects patient experiences. This includes understanding the pivotal roles patients have in their own healthcare with respect to consumeristic clinician-patient relationships and the value of information in the patient experience.

A review of current methods and guidelines used in the design, development and evaluation of patient information will provide an appreciation of patient involvement in and establish principles of these processes. The implementation of patient information is also reviewed, focussing on new media and the personalisation of patient information.

The chapter concludes with the contribution to knowledge that can be made from research, followed by the research approach. These will take account of what has been learned from the literature review, what is to be gained from the thesis and its work, and the approach to undertaking the work.

Figure 2.1 graphically represents the structure of the literature review.



**Figure 2.1** Structure of literature review

Sections 2.2 to 2.4 conclude with summaries within which there are boxes to summarise important aspects of research from the sections. Their purpose is to build the scope and develop the story of the thesis, leading to the contribution to knowledge and research approach sections where gaps in the research that would benefit from the application of human factors are discussed.

## 2.2 The patient experience

### 2.2.1 Contextualising the patient experience

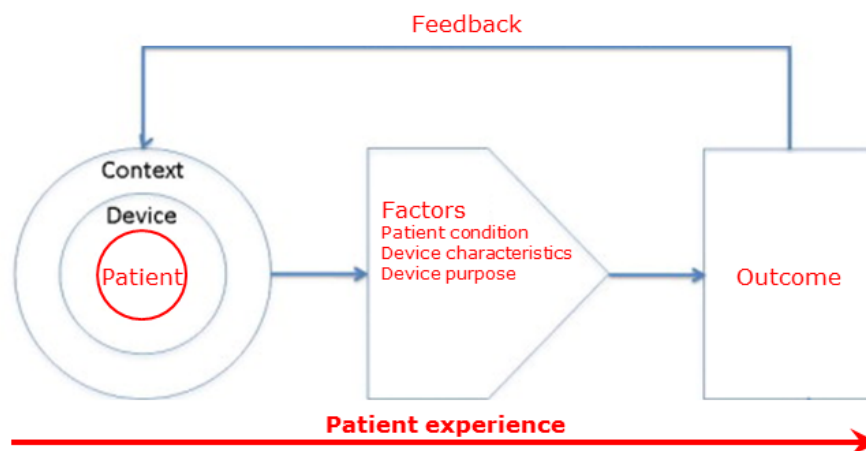
In the contexts of screening and diagnosis, medical devices are utilised in the form of investigations and tests to collect information that can be used to diagnose or rule out medical conditions (Sense About Science, 2008, p. 10). This is more prominent in diagnostic clinical pathways because information is used after the patient has provided a clinical history and undergone examination, and investigations and tests will aim to confirm a suspected or rule out a possible diagnosis (Coulter and Collins, 2011, p. 22).

For diagnostic decision-making processes when choosing investigations and tests, factors that are important to clinicians, as discussed by the National Imaging Board (2010, p. 29) from the United Kingdom and which have been generalised, are:

- deciding on the information to be collected;

- availability of an investigation or test to collect the information;
- strengths and weaknesses of available investigations and tests;
- availability, cost and convenience; and
- risk to the patient.

There are a number of factors that clinicians consider, and although some may prove constraining, they are considered with the aim of optimising outcomes for patients. However, in addition to clinical outcomes, the manner in which patients experience investigations and tests is important. The factors discussed above, as well as the characteristics of a medical device and other relevant factors, will vary patient experiences. To demonstrate this, the model by Sharples *et al.* (2012) (Figure 1.1) has been adapted to make it patient focussed and to graphically represent the patient experience (Figure 2.2). The model was first introduced in Chapter 1 and describes a human factors approach that aims to understand the relationship between users and a medical device in a particular context of utilisation, and the effects this has on user behaviour (see pages 1-2 for recap).



**Figure 2.2** Model of relationship between user-device interaction and consequences (Sharples *et al.*, 2012) adapted to represent the patient experience

The adapted model is in effect a stage in a screening or diagnostic clinical pathway where a patient has the option of or requires an investigation or test, respectively. The patient's condition (i.e. health state), medical device characteristics (e.g. level of invasiveness) and purpose (i.e. what information is to be collected), as well as the clinical outcome (e.g. patient is diagnosed with a medical condition), will have

varying effects on the patient experience<sup>1</sup>. For example, in an ill health state requiring an invasive investigation or test to collect information that will confirm a suspected or rule out a possible diagnosis of serious magnitude, it can be assumed that the combination of these factors, as well as the eventual clinical outcome, will have a significant effect on the patient experience. The patient may experience anxiety, fear, and discomfort or pain.

Emotional support and physical comfort are included in the NHS National Quality Board criteria for measuring patient experiences across the NHS (Department of Health, 2012a). The criteria provide a framework for a working definition of the patient experience and are deemed crucial to achieving quality patient experiences. They are based on criteria set by The Picker Institute for defining patient centred care (The Institute for Alternative Futures, 2004, pp. 9-10) and are as follows:

- Patient centred values, preferences and expressed needs respected.
- Care coordinated and integrated.
- Autonomy, self-care and health promotion facilitated through information, communication and education.
- Physical comfort achieved through appropriate management and assistance.
- Emotional support provided and fears and anxieties alleviated.
- Involvement of family and friends welcomed to support patients.
- Information to support patients and ease care transition and continuity.
- Care accessed within a suitable timeframe.

Patient experiences of investigations and tests are explored in the next part of this section. This will involve exploring the effects of physical comfort, fears and anxieties, in addition to other factors that affect patients. This will then lead into the next section, which explores information provision and the patient experience. The value of information is represented in the criteria with respect to the facilitation of autonomy, self-care and health promotion, and supporting patient care transition and continuity.

---

<sup>1</sup> The factors included are for demonstration and do not represent a comprehensive set of factors that affect the patient experience.

## 2.2.2 Patient experiences of investigations and tests

As already explained, investigations and tests are utilised to collect information for the diagnoses or ruling out of medical conditions. In the context of diagnosis, this will be to confirm a suspected or rule out a possible diagnosis, and understanding the cause of symptoms can relieve patient uncertainty (Lapsley, 2013; Marton *et al.*, 1982; O'Connor *et al.*, 1994). In the context of screening, patients are not affected by symptoms and this can deter or act as a barrier for patients to be screened (Hoffman *et al.*, 2011; Marcus *et al.*, 1993; Montaña *et al.*, 2004; Ogedegbe *et al.*, 2005). Family history of a medical condition (Montaña *et al.*, 2004; Nekhlyudov *et al.*, 2003; Shah *et al.*, 2007; Wallner *et al.*, 2008) and advancing age (Livingston *et al.*, 2002; Nekhlyudov *et al.*, 2003; Underwood, 1999; Weinberg *et al.*, 2004) can, however, have the opposite effect and facilitate screening.

Some investigations and tests require patients to prepare (i.e. follow pre-investigation or test requirements). An example of a common preparation is bowel preparation for barium enema, colonoscopy and virtual colonoscopy (also known as computed tomography (CT) colonography or magnetic resonance (MR) colonography; dependent on the imaging technique used). In a study conducted by Gluecker *et al.* (2003) where patient perceptions and preferences were compared between the three investigations, most patients experienced discomfort associated with preparing for the investigations and preparation was considered inconvenient. The investigations were compared in the context of screening and all investigations were deemed more acceptable for repeat screening at shorter intervals if bowel preparation could be avoided.

In a similar study comparing colonoscopy and virtual colonoscopy conducted by van Gelder *et al.* (2004), bowel preparation was indicated as the most burdensome aspect of the investigations by patients both immediately and five weeks after they had been performed. At five weeks, there was an actual increase in the number of patients who indicated that preparation was the most burdensome aspect. Bowel preparation in this study was the same for each investigation since patients underwent colonoscopy approximately one hour after virtual colonoscopy.

However, in a study conducted by Jensch *et al.* (2010) where bowel preparation for

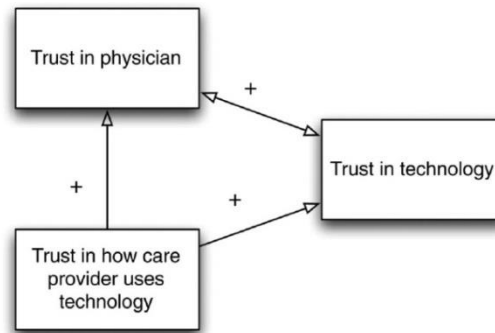
colonoscopy was full and for virtual colonoscopy was limited, the total burden experienced by patients for preparation was significantly lower for the virtual colonoscopy. This contributed to virtual colonoscopy being the preferred investigation but it is worth noting that patients were informed that diagnostic accuracies of the two investigations were comparable, which may otherwise have affected preferences.

Virtual colonoscopy uses CT or MR scans to create two dimensional and three dimensional images of the bowel, with bowel preparation improving the quality of the images for inspection. When given the option of avoiding bowel preparation for virtual colonoscopy, participants in a study conducted by von Wagner *et al.* (2009a) considered this to impede diagnostic accuracy, which came as an unexpected critical response to the authors. The participants also deemed the investigation to be technologically superior and therefore more sensitive (i.e. more likely to correctly identify patients with disease) compared to colonoscopy, which it was being compared with. This may have influenced participants' critical responses and participants expressed disappointment that virtual colonoscopy was not as sensitive as colonoscopy. A similar confidence in virtual colonoscopy technology was mentioned by a small number of patients (3 out of 124) in a study conducted by Thomeer *et al.* (2002), and in a study conducted by Friedemann-Sánchez *et al.* (2007) where colonoscopy and sigmoidoscopy were being compared, most participants considered colonoscopy to be a 'complete test' and sigmoidoscopy a 'partial test'.

The very existence of an investigation or test may be deemed trustworthy by patients on the grounds that they would not be offered one if it was not worth having (Marteau and Richards, 1996, p. 152). However, Montague and Asan's (2012) patient trust in medical technology model (Figure 2.3) depicts patients' trust in medical technology as being dependent on trustworthy characteristics of the technology, trust in clinician (physician) or other healthcare professional (care provider), and trust in how the technology is used by the healthcare professional. This was observed in a study conducted by Montague *et al.* (2010) where patients' trust in medical technology used in obstetric work systems was developed from combining trust in the technology and those who use it into a system, and then



determining whether the technology was trustworthy or not by evaluating the system. Similarly, in a study conducted by Merchant *et al.* (2009), participants believed a rapid HIV test and a standard HIV test to be equally accurate since both were approved tests and were being used by the hospital where the testing took place.



**Figure 2.3** Model of patient trust in medical technology (Montague and Asan, 2012)

Trust can have positive effects on the patient experience. In a study conducted by Zener and Bernstein (2011), which examined gender and patient comfort in the neurological operating room, a theme that emerged was patients' trust in their surgeon. Notwithstanding fears and concerns expressed by both female and male patients, confidence in the surgeon was most important in alleviating anxiety. Patients also extended that same trust to other healthcare professionals involved in their care.

Anxiety is commonly experienced by patients. It can occur prior to an investigation or test, for example, prior to arthrography, colonoscopy, MRI, myelography and virtual colonoscopy (Albeck and Danneskiold-Samsøe, 1995; Blanchard *et al.*, 1997; Ylinen *et al.*, 2009); it can be provoked by the environment of an investigation or test, for example, claustrophobia during chest X-ray (also known as chest radiograph), positron emission tomography (PET) and MRI, or from exposure during virtual colonoscopy (Bastiaannet *et al.*, 2009; Jung *et al.*, 2009; Zakaria *et al.*, 2009); it can be caused by potential side-effects, such as incontinence during Pap smear testing and virtual colonoscopy (Armstrong *et al.*, 2012; Hafeez *et al.*, 2012); or it can be experienced after an investigation or test, waiting for an outcome or result, respectively (Bastiaannet *et al.*, 2009; Karnieli-Miller *et al.*, 2009; von Wagner *et al.*, 2009b). Anxiety can affect patient experiences of, preferences for

and adherence to investigations and tests (Early *et al.*, 1999; Jung *et al.*, 2009; Pivot *et al.*, 2008; U-King-Im *et al.*, 2004).

Other factors that can affect patients include discomfort or pain, embarrassment and fear. Discomfort or pain can be caused from having an instrument inserted (e.g. colonoscope for colonoscopy and speculum for Pap smear testing), and air or a solution injected (e.g. insufflation of bowel for barium enema, colonoscopy and virtual colonoscopy, or a contrast medium injected for arthrography, barium enema and virtual colonoscopy) (Armstrong *et al.*, 2012; Blanchard *et al.*, 1997; Svensson *et al.*, 2002; von Wagner *et al.*, 2009b). Feeling cold, difficulty lying still and holding one's breath during an investigation or test, as experienced during chest X-ray, PET and virtual colonoscopy, can also be causes of discomfort or pain (Albeck and Danneskiold-Samsøe, 1995; Bastiaannet *et al.*, 2009; Hafeez *et al.*, 2012).

Embarrassment can be caused from partial nudity, as experienced during chest X-ray (Bastiaannet *et al.*, 2009); exposure of an intimate body part, as experienced during Pap smear testing (Armstrong *et al.*, 2012); exposure of one's private life, as experienced during routine gynaecological cancer screening for obese women (Amy *et al.*, 2006); disconcerting posture, as experienced during barium enema (von Wagner *et al.*, 2009b); and not knowing what to do, as experienced during chest X-ray, PET and virtual colonoscopy (Bastiaannet *et al.*, 2009). Fear can be caused from a potential medical condition, as experienced by patients requiring single photon emission computed tomography-computed tomography (SPECT-CT) (Nightingale *et al.*, 2012); complexity of an investigation or test, such as the complexity of a diabetes risk screening test (Nijhof *et al.*, 2008); harm from an investigation or test, such as the harm of radiation from mammography and SPECT-CT (Marcus *et al.*, 1993; Nightingale *et al.*, 2012); and an unexpected sensation during an investigation or test, as experienced from a contrast medium injection during virtual colonoscopy, which was warm (von Wagner *et al.*, 2009b).

Many factors can affect patients, with different factors having different effects. For example, danger, embarrassment, inconvenience and physical discomfort were used as criteria in a study conducted by Nelson *et al.* (2001) where preferences of an experienced group (patients) and a naïve group (convenience sample) were examined between barium enema, colonoscopy and white blood cell scanning. The

investigations were to be used as a diagnostic procedure for intestinal inflammation and both groups were to assume that they gave roughly equivalent diagnostic information. Both groups indicated significantly greater preference for white blood scanning, and embarrassment and physical discomfort ranks essentially duplicated preference ranks.

Discomfort or pain can be controlled in some investigations and tests with the use of analgesics and sedatives. For example, sedation is often used in colonoscopy and can have positive effects on patient experiences by minimising discomfort or pain (Akerkar *et al.*, 2001; von Wagner *et al.*, 2009b; Ristvedt *et al.*, 2003; Westerterp *et al.*, 2008). However, there are risks and side-effects to patients who are sedated during investigations or tests, including not being able to clearly remember information, being unable to drive and needing accompanying home afterwards (Hafeez *et al.*, 2012; Pooler *et al.*, 2012).

Experiences of patients can vary immensely and improving these is difficult since the process of investigating and testing is to collect information to diagnose or rule out medical conditions. However, as already discussed with respect to the NHS National Quality Board criteria for measuring patient experiences across the NHS (Department of Health, 2012a), information is essential to achieving quality patient experiences. The next section explores information provision and the patient experience.

### **2.2.3 Summary**

In the contexts of screening and diagnosis, medical devices are utilised in the form of investigations and tests to collect information that can be used to diagnose or rule out medical conditions. They have varying effects on patient experiences and can be a cause of anxiety, discomfort or pain, embarrassment and fear. Emotional support and physical comfort are included in criteria that provide a framework for a working definition of the patient experience, which are deemed crucial to achieving quality patient experiences. Information is a valuable resource included in the criteria to facilitate autonomy, self-care and health promotion, and support patient care transition and continuity. The next section explores information provision and the patient experience.

The box below summarises important aspects of research from this section to begin building the scope and developing the story of the thesis. Two further boxes are included at the end of the next two sections, leading to the contribution to knowledge and research approach sections where gaps in the research that would benefit from the application of human factors are discussed.

### **Summary of important aspects of research**

#### ***Contextualising the patient experience***

In the contexts of screening and diagnosis, medical devices are utilised in the form of investigations and tests to collect information that can be used to diagnose or rule out medical conditions (Sense About Science, 2008, p. 10). This is more prominent in diagnostic clinical pathways and there are a number of factors that clinicians consider when choosing investigations and tests (National Imaging Board, 2010, p. 29), which are chosen to optimise outcomes for patients. However, in addition to clinical outcomes, patient experiences of investigations and tests, which vary, are important. The NHS National Quality Board has developed criteria that are deemed crucial to achieving quality patient experiences (Department of Health, 2012a), including achieving physical comfort and alleviating fears and anxieties.

#### ***Patient experiences of investigations and tests***

Anxiety, discomfort or pain and fear, as well as embarrassment, are often experienced by patients when they encounter medical devices in the form of investigations and tests. For example, anxiety can be provoked by the environment of an investigation or test (Bastiaannet *et al.*, 2009; Jung *et al.*, 2009; Zakaria *et al.*, 2009), discomfort or pain from having an instrument inserted and air or a solution injected (Armstrong *et al.*, 2012; Blanchard *et al.*, 1997; Svensson *et al.*, 2002; von Wagner *et al.*, 2009b), fear from the harm of an investigation or test (Marcus *et al.*, 1993; Nightingale *et al.*, 2012), and embarrassment from exposure of an intimate body part (Armstrong *et al.*, 2012). Improving patient experiences is difficult since the process of investigating and testing is to optimise patient outcomes, although avoiding pre-investigation or test requirements (Gluecker *et al.*, 2003) and trust in

clinician and other healthcare professionals (Zener and Bernstein, 2011) can have positive effects. In the criteria developed by the NHS National Quality Board (Department of Health, 2012a) information is essential to quality patient experiences through facilitating autonomy, self-care and health promotion, and supporting patient care transition and continuity. The next section explores information provision and the patient experience.

## **2.3 Information provision and the patient experience**

### **2.3.1 Consumeristic clinician-patient relationships**

Healthcare has transcended the traditional biomedical model, which emphasises diagnosis and treatment, and moved to an outcomes model, which focuses on the extension of or improvement in quality of life (Kaplan, 1999; Sieber and Kaplan, 2000). In both of these models the role of the patient differs: the first model has a paternalistic view of the patient and the second a consumeristic. Beisecker and Beisecker (1993) discuss these two views with respect to the clinician-patient relationship. Patients in paternalistic clinician-patient relationships take lead from the clinician and put trust in the decisions they make on their behalf, believing that such decisions are done in their best interest. Patients in consumeristic clinician-patient relationships take a more active role, with their input valued and decisions that are made done so following appropriate discussion with the clinician. Wright *et al.* (2008, p. 30) comment that patients who favour consumeristic clinician-patient relationships see the relationship as an exchange of information between the two, and that this has similarities with business transactions that are made between providers and consumers in other types of services.

Information is essential to patients who favour consumeristic clinician-patient relationships. In 2011 one survey found that 71% of Internet users in Britain searched for health information online (Dutton and Blank, 2011, p. 23) and another found that 80% of Internet users in the United States searched for health information online (Fox, 2011, p. 2). E-health, the delivery or enhancement of

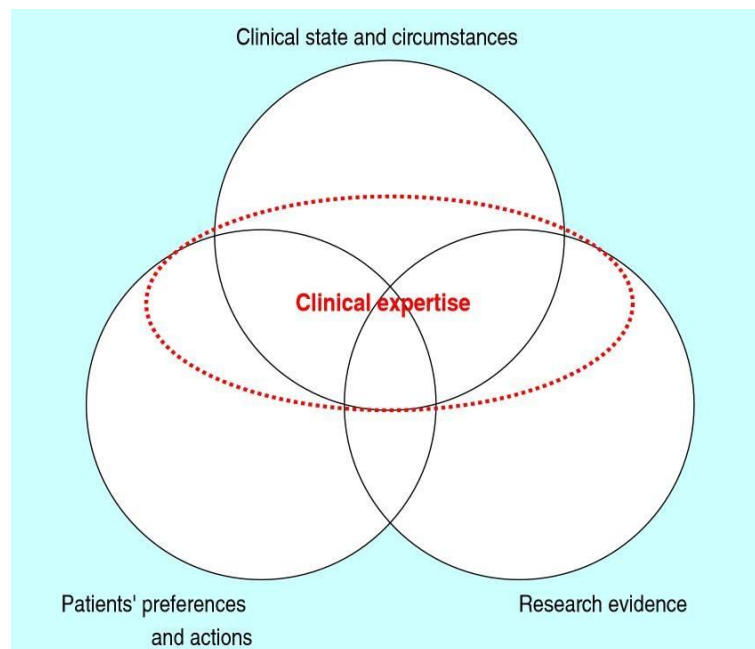
health services and information through the Internet and other related technologies (Eysenbach, 2001), is transforming the clinician-patient relationship and empowering patients. Ball and Lillis (2001) discuss three factors that characterise e-health consumers: 1) convenience; 2) control; and 3) choice. They expect the highest level of convenience with services they transact with; they take control of their own health and have active roles in their healthcare; and they demand a variety of services and products to choose from that they require.

Such high expectations and demands may be intimidating and challenging for clinicians. Perhaps this has added to the rise in defensive medicine where clinicians act primarily but not solely to reduce malpractice liability (Catino, 2011; U.S. Congress, Office of Technology Assessment, 1994, p. 3). Defensive medicine can be either positive defensive medicine where clinicians order extra investigations, tests or visits; or it can be negative defensive medicine where high risk patients, investigations or tests are avoided. Summerton (1995) conducted a study with GPs and found that defensive medicine was practised as a possible consequence of concerns about being sued and the risks of this, or the lodging of complaints. Negative defensive medicine was in particular strongly associated with this. However, Summerton did comment about the benefits of positive defensive medicine with respect to increased patient explanations and more detailed note taking.

Patients may perceive the ordering of investigations and tests as an indication of clinician quality. This was found in a study conducted by Marton *et al.* (1982) where patients felt that a good clinician requires the aid of laboratory tests most of the time and that extensive test ordering correlates with clinician quality. In a more recent study conducted by Schleifer and Rothman (2012) participants placed enormous value on testing and screening, and reacted with hostility to guidelines recommending less of either, which the authors commented conflicted with their active and engaged information seeking roles. However, the participants were suspicious of overmedication and the authors commented that this was due to a wariness of pharmaceuticals. Both of these studies were conducted in the United States where healthcare is predominantly private and insurance based (this is changing somewhat with the Affordable Care Act signed by President Obama (U.S.

Department of Health and Human Services, 2010)). Attitudes may differ in the United Kingdom where healthcare is predominantly provided by the state and based on clinical need and achieving best value for public money (Department of Health, 2013, p. 3-4).

The role of patients in consumeristic clinician-patient relationships is never more evident than in their desired role in decision-making when they have healthcare options to choose from, such as screening, diagnostic or treatment options. They prefer to make decisions independently or to share decisions with their clinicians (Frosch *et al.*, 2003; Hawley *et al.*, 2012; Mazur *et al.*, 2005; Sheridan *et al.*, 2012), and they may exercise their control by actually limiting it or relinquishing their decision-making role (Beisecker and Beisecker, 1993; Nekhlyudov *et al.* 2003). Kaplan (1999) and Sieber and Kaplan (2000) discuss shared decision-making as a product of the outcomes model, and Gupta (2011) takes a similar stance and recognises the ethics of shared decision-making in evidence based medicine. Gupta explains that shared decision-making reflects the dynamics of real clinical practice where both evidence and patient values are represented in clinical encounters. This is depicted in Haynes' *et al.* (2002) model for evidence based clinical decisions (Figure 2.4).



**Figure 2.4** Model for evidence based clinical decisions (Haynes *et al.*, 2002)

Respecting patient centred values, preferences and expressed needs is included in the criteria that are deemed crucial to achieving quality patient experiences (Department of Health, 2012a, see page 15 for recap). Information is a valuable resource that is included in the criteria to facilitate autonomy, self-care and health promotion, and support patient care transition and continuity. In addition to this, information can be especially valuable for respecting patient centred values, preferences and expressed needs when patients have healthcare options and choices since information is the pivot upon which all decisions are made, whether they are good, bad or neutral. Understanding the value of information and the effects it has on the patient experience is explored in the next part of this section.

### **2.3.2 The value of information**

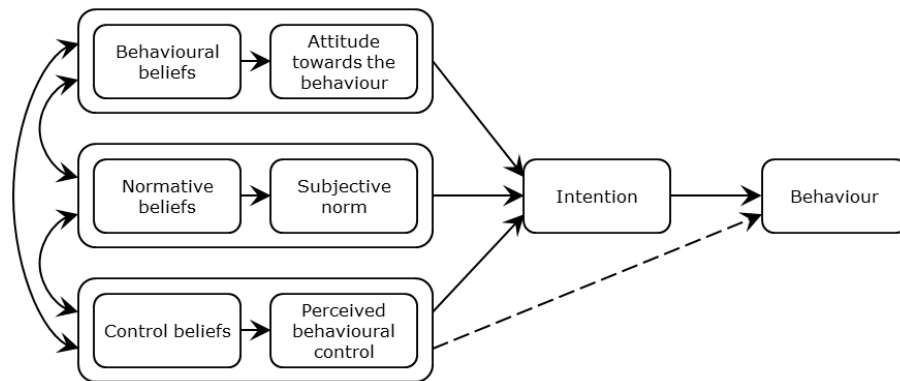
The Patient Information Forum (2013a, p. 6) defines information as ‘consumer health information’ that is provided to support patients and carers in understanding, managing and/or making decisions about their health, condition or treatment. A similar definition is provided by the Department of Health (2012b, p. 13) in which information is an ‘essential service’ to enable patients to understand their own health, choose healthier lifestyles, and choose treatment and support that is right for them. Both of these provide quite a tangible and resourceful perspective of information, which covers the main paradigm of information provision. However, information provision can also be personal, situational and reformative. In order to achieve a comprehensive understanding of the value of information and the effects it has on the patient experience, information provision will be explored directly and indirectly to cover both of these perspectives.

#### ***2.3.2.1 Behavioural theories***

As mentioned in reference to respecting patient centred values, preferences and expressed needs when patients have healthcare options and choices, information is the pivot upon which all decisions are made. Ajzen’s theory of planned behaviour depicts this phenomenon with beliefs as the informational foundation upon which intentions to perform behaviour are determined (2005, p. 126) (Figure 2.5). There are three determinants: 1) attitudes towards the behaviour, which is a personal determinant; 2) subjective norm, which is a social determinant; and 3) perceived



behavioural control, which is an individual's sense of ability to perform the behaviour of interest. There is a direct link between perceived behavioural control and behaviour as perceived behavioural control corresponds reasonably well to actual control and so can influence behaviour directly.

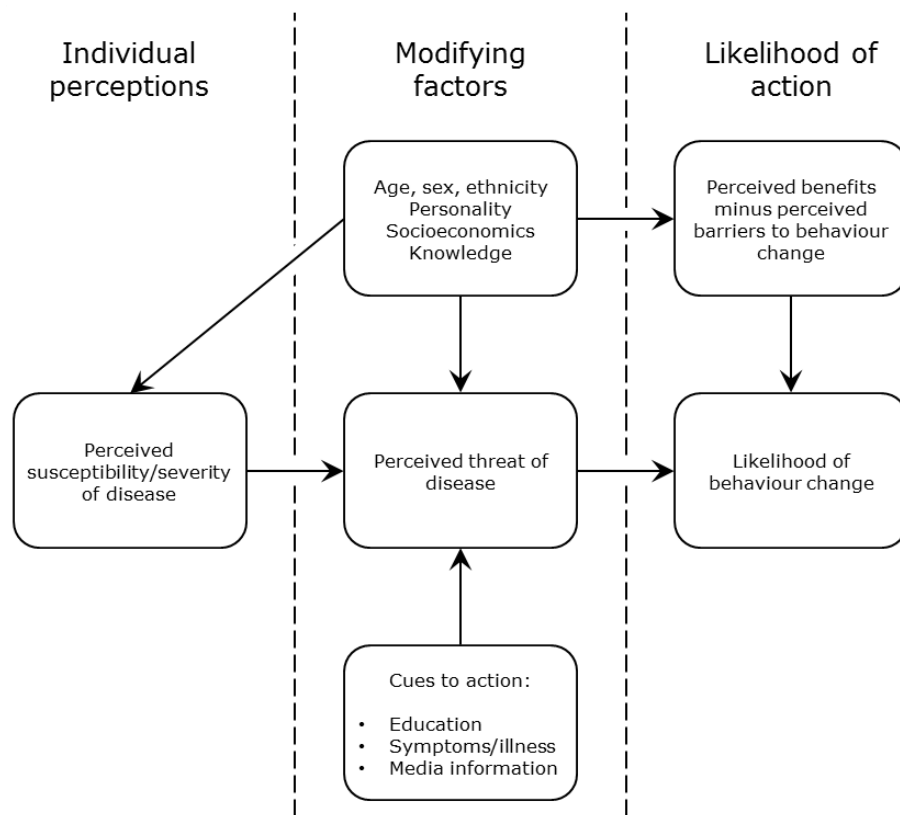


**Figure 2.5** Theory of planned behaviour with beliefs as the informational foundation of intentions and behaviour (Ajzen, 2005, p. 126)

The theory determines that an individual's behaviour follows reasonably from the information or beliefs that the individual has about the behaviour under consideration, and that beliefs originate from a variety of sources (e.g. personal experiences, education, media, family and friends, etc.) (Ajzen and Albarracín, 2007). This has been observed in many studies examining attitudes towards screening. For example, the belief that an investigation or test will be painful can act as a barrier for patients to be screened (Abdullah *et al.*, 2011; Griffith *et al.*, 2012; Pivot *et al.*, 2008; Weinberg *et al.*, 2004). However, the belief that screening will reduce the likelihood of becoming ill with a treatable medical condition can act as a facilitator (Griffith *et al.*, 2012; Montañaño *et al.*, 2004; Weinberg *et al.*, 2004; Yim *et al.*, 2012).

The theory of planned behaviour is a value expectancy theory, which is determined by an individual's subjective values (or evaluations) of the outcomes associated with behaviour and the strength of these associations. Another value expectancy theory is the health belief model (Strecher *et al.*, 1997) (Figure 2.6), which is determined by an individual's subjective value (or evaluation) of personal susceptibility to and severity of disease, and the likelihood of reducing that threat through personal action (i.e. behaviour change). Modifying factors affect the

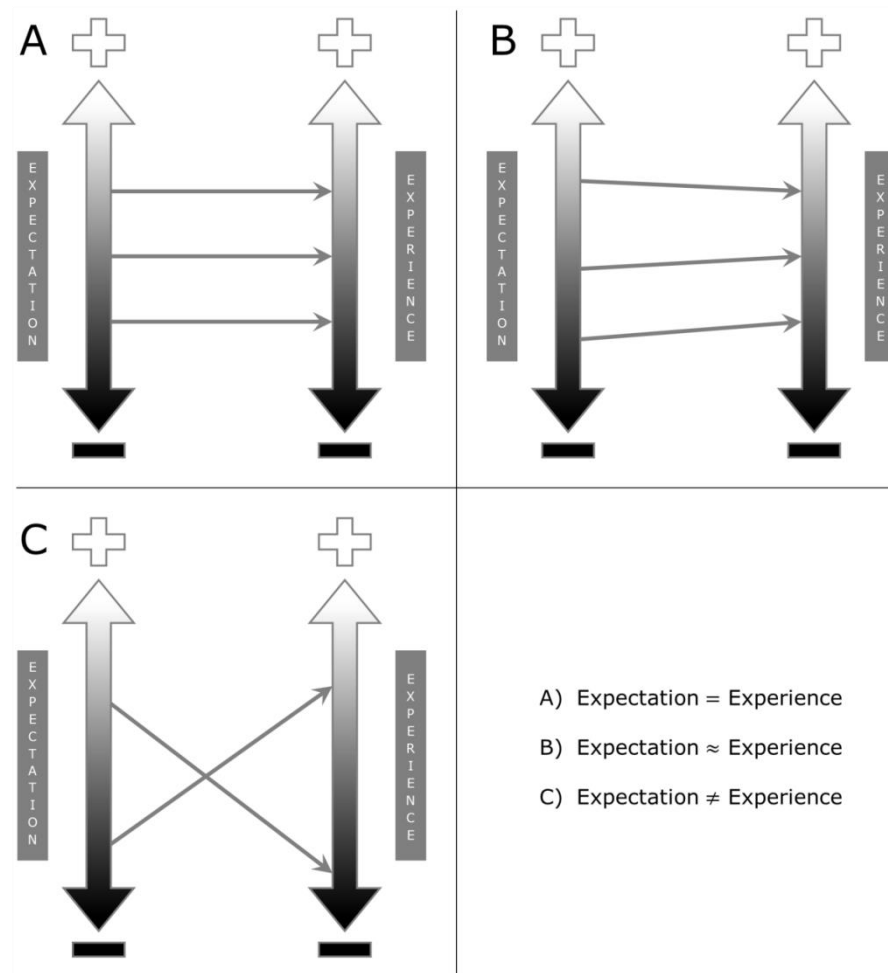
perceived threat of disease and the likelihood of action, which includes demographic and personal dispositional factors, and information or cues to action.



**Figure 2.6** The health belief model (Strecher *et al.*, 1997)

In both theories, information can have a significant effect on beliefs and perceived threat of disease, which may be inaccurate, biased or irrational (Ajzen, 2005, p. 126). Information enables patients to generate realistic expectations and to make informed decisions. Kendall *et al.* (1979) talk of patient education as a ‘dry run’ and a desensitising experience for patients who were to undergo cardiac catheterisation, and Ridgeway and Mathews (1982) talk of cognitive coping methods as effective ways of managing specific worries about hysterectomy. Information can minimise expectation mismatch with experience, which can be detrimental to the patient experience if experiences are not consistent with or worse than expected. Figure 2.7 graphically represents three expectation versus experience scenarios. In expectation versus experience scenarios A and B, experiences are either equal or almost equal to expectations, and so expectation mismatch with experience will not occur. Contrary to these, scenario C depicts expectation versus experience mismatches where the experience is worse than or

better than expected. In the former patients will most probably be unprepared for the experience, and in the latter patients will most probably experience anxiety and other avoidable emotions.

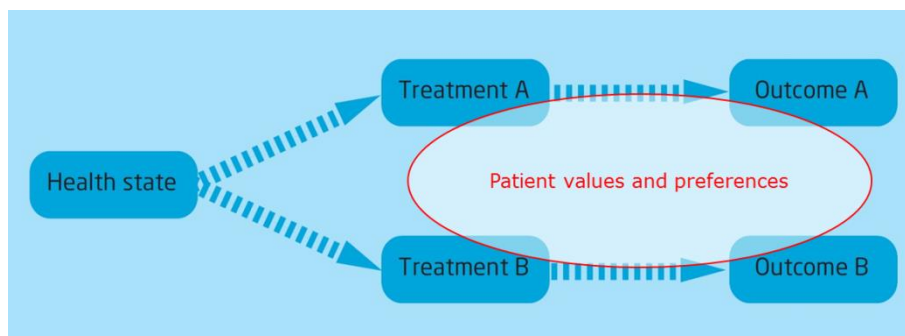


**Figure 2.7** Expectation versus experience scenarios

Expectation mismatch with experience was observed in studies conducted by Nightingale *et al.* (2012) and von Wagner *et al.* (2009b). In the former there was an apparent ‘expectation-reality divide’ of patient experiences of SPECT-CT with patients’ actual experiences being in some cases a pleasant surprise and in others a shock. In the latter a similar pleasure was experienced by patients who had negative expectations of barium enema but their experiences were much better. Expectation mismatch was also observed in studies conducted by de Jonge *et al.* (2010) (colonoscopy mismatch), and Gluecker *et al.* (2003) and Ristvedt *et al.* (2003) (colonoscopy and virtual colonoscopy mismatches).

### 2.3.2.2 Decision aids and decision-making

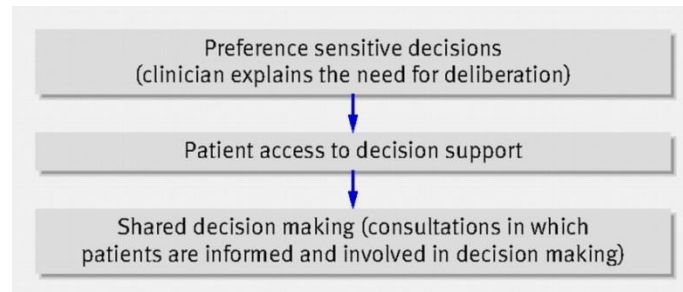
The effects of information in decision-making can be the difference between patients making informed decisions and partially- or non-informed decisions. That is assuming that information provided to patients is representative of evidence based medicine and that patients correctly understand the information. This is the basis for decision aids (also known as decision support technologies), which are tools often used by patients when they have healthcare options and choices. They are used to encourage and facilitate informed shared decision-making in which the patient is informed of their options, the options are discussed with the relevant clinician or other healthcare professional, and the decision that is made is one that is satisfactory to the patient's values and preferences (O'Connor *et al.*, 1999a; O'Connor *et al.*, 2004; O'Connor *et al.*, 2009; Wennberg *et al.*, 2002). This is depicted in a diagram by Mulley *et al.* (2012, p. 17), which has been adapted to graphically represent how patient values and preferences may lead one patient to choose Treatment A with Outcome A and another patient to choose Treatment B with Outcome B (Figure 2.8). The authors comment that 'outcome' typically refers to benefits and side-effects, and 'treatment' may actually involve an option to not treat at all.



**Figure 2.8** Patient choice between two hypothetical treatment options (Mulley *et al.*, 2012, p. 7) adapted to include patient values and preferences

Elwyn *et al.* (2010a) describes shared decision-making as a process that respects patient autonomy and promotes patient engagement when preference sensitive decisions have to be made (i.e. the best decision for the patient depending on their values and preferences). An important consideration for shared decision-making is access to decision support. Elwyn *et al.* discuss this with respect to decision support being part of a referral pathway in the NHS. Figure 2.9 depicts the link decision

support has between preference sensitive decisions and shared decision-making as part of a referral pathway in the NHS. Wirrmann and Askham (2006, p. 53) advocate decision support programmes as methods to ensure that patients are optimally placed to reach decisions when they have complex treatment options.



**Figure 2.9** Decision support as part of a referral pathway in the NHS (Elwyn *et al.*, 2010a)

The most commonly reported effect of decision aids is an increase in knowledge. Significant increases in knowledge were observed in studies conducted by Frosch *et al.* (2003) where an Internet and a video based decision aid educated men about issues relevant to prostate cancer screening with the prostate specific antigen test; by Gimeno-García *et al.* (2009) where a colorectal cancer educational video educated members of the public about the condition and available screening for it; by McCormack *et al.* (2011) where a multimodal community based intervention informed patients about prostate cancer screening with the prostate specific antigen test and the early treatment of the condition; and by Wilt *et al.* (2001) where a mailed education pamphlet aimed to educate men about the early detection of prostate cancer.

Other effects of decision aids include effects on anxiety, as observed in a study conducted by Humphris *et al.* (2001) where a patient information leaflet about oral cancer screening significantly reduced anxiety in primary care patients; intentions, as observed in the previously mentioned study by Humphris *et al.* where the leaflet significantly increased patients' screening intentions, and in a study conducted by Flood *et al.* (1996) where participants, having viewed an educational video, significantly preferred not to be screened for prostate cancer with the prostate specific antigen test and to receive no active treatment if cancer was found; and even willingness to pay, as observed in a study conducted by Yasunaga *et al.* (2011) where an information sheet with additional information about prostate

cancer screening with the prostate specific antigen test, including the possibility of false positives (i.e. incorrect diagnosis of medical conditions) and false negatives (i.e. incorrect ruling out of medical conditions), significantly reduced participants' willingness to pay compared with those who received an information sheet that did not include the additional information.

Further effects of 'additional information' or information content can be found in a study conducted by von Wagner *et al.* (2009a) where participant preferences were examined between colonoscopy and virtual colonoscopy in a diagnostic context. On the basis of minimum information the majority of participants preferred virtual colonoscopy but following provision of information about outcomes, practicalities, risks and sensitivity, the majority of participants preferred colonoscopy. In a similar study conducted by Angtuaco *et al.* (2001) but in a screening context, participants preferred virtual colonoscopy whilst clinicians would prefer patients to have colonoscopy. However, information about outcomes, practicalities, risks and sensitivity was not provided, although participants and clinicians were informed that colonoscopy would be required if virtual colonoscopy detected a polyp. Controversially, although clinicians preferred patients to have colonoscopy, they would, however, prefer virtual colonoscopy for themselves.

#### *2.3.2.3 Format and framing of information*

In addition to the effects of information content, there are also the effects of information format. Edwards (2004) suggests that there is support for a range of different formats, including descriptive, numerical and graphical, to meet the individual needs and preferences of patients. Edwards also suggests that patient narratives of their experiences may be used to convey the pros and cons of decisions in certain situations. Ahmed *et al.* (2012) make a similar suggestion with respect to communicating risk and the degree to which perceived risk will affect behaviour change, and Zikmund-Fisher (2013) argues for 'taxonomy' of formats of risk communication to meet specific informational needs. Thorne *et al.* (2006) discuss how numerical information became a focus for cancer patients to make sense of uncertainties with respect to prognosis and healthcare options. However, Nagle *et al.* (2006) discuss the difficulty women had with numerical information, which led to the incorporation of graphs and diagrams in the development of a draft

decision aid to be used in a prenatal clinic during early pregnancy. Sheard and Garrud (2006) report that the experimental group in a study they conducted gave positive feedback on the use of drawings and diagrams, and Garcia-Retamero and Cokely (2013) and Paling (2003) advocate the use of visual aids; the former to improve decision-making, change attitudes and reduce risky behaviour, and the latter to support better understanding for patients from all types of backgrounds. Visual aids were used in a study conducted by Hofman *et al.* (2012) where they reported that most patients and healthy participants in their study were able to make immediate decisions based on this information, which depicted multimodal treatment options for colorectal cancer in different scenarios. Interestingly, most patients chose the intensive treatment option in the scenario with a clear survival benefit. However, in scenarios without survival benefit both patients and healthy participants preferred the milder treatment option. When patients do have options, they may benefit from the use of Option Grids (Decision Laboratory, 2013; Elwyn *et al.*, 2013) to summarise information in table format for direct comparison.

As well as considering information format, the manner in which information is conveyed to patients must be done so as to avoid framing (Edwards, 2004; Paling, 2003). Raffle and Gray (2007, p. 223) explain framing as the elicitation of different responses and conclusions from the same data when presented or framed differently, which can even happen in the same person. For example, an investigation or test can be positively framed by stating the chance of no side-effects is '95 out of 100', or negatively framed by stating the chance of side-effects is '5 out of 100'. Bekker (2010) proposes rather than information promote informed decision-making for colorectal cancer screening, information should be framed as to promote screening uptake to reduce mortality. This would fit the biomedical model but not the outcomes model and has been criticised on ethical grounds. What would seem to have an 'uptake' effect on screening, however, is clinician recommendation. A number of studies have found clinician recommendation to facilitate screening (DeFrank *et al.*, 2012; Ling *et al.*, 2001; Hemsing Cruz *et al.*, 2008; Ogedegbe *et al.*, 2005) whilst the lack of one can have the opposite effect and is commonly predictive of screening non-attendance (DeFrank *et al.*, 2012; Ogedegbe *et al.*, 2005; Salimzadeh *et al.*, 2011; Taylor *et al.*, 2002).

#### *2.3.2.4 Information to support patient experiences*

In a study conducted by Ylinen *et al.* (2009), patients' pain experiences of colonoscopy were eased by non-drug interventions, including nurses' peaceful talk, explanations of the causes of pain and guidance. In a study conducted by von Wagner *et al.* (2009b), social interactions with clinicians and other healthcare professionals in the care of patients experiencing barium enema, colonoscopy and virtual colonoscopy improved the patients' experiences and helped patients control feelings of embarrassment. And in a study conducted by Miller *et al.* (2013), patients' perceptions of better communication with radiologists were associated with lower levels of anxiety before and after imaging guided breast biopsies. Wording of information can also affect the patient experience. In a study conducted by Ott *et al.* (2012), wording of warnings before venous blood sampling was varied. Two participant groups were randomised to either be warned directly before insertion of a needle with the word 'sting' or 'beware'. Participants experienced significantly more pain having been warned with the word 'sting'.

#### *2.3.2.5 Investigation outcomes and test results*

For some investigations, such as transrectal ultrasonography when prostate cancer is suspected, patients may receive a diagnosis during the investigation (Kelly, 2009). Whilst there is little research on the effects of receiving a diagnosis during an investigation, Miles *et al.* (2003) report that one of the central features of patients who received a screen detected diagnosis of colorectal cancer during a flexible sigmoidoscopy trial in the United Kingdom was the fast transition from being healthy to becoming a patient, and their consequential lack of preparation for this. Letterstål (2010) discusses the transition process of patients who had gone from having a suspected abdominal aortic aneurysm to being diagnosed with the condition, and them being unprepared for the transition both physically and emotionally. There could be the case for patients being delayed notification of a diagnosis due to the effects it will have on their emotional state and other negative consequences, which was reported in a study conducted by O'Connor *et al.* (1994) with respect to perceptions among some clinicians for the diagnosis of patients with multiple sclerosis.



Meza and Webster (2000) conducted a study to examine patient preferences for notification of laboratory test results for cholesterol, and found that patients were satisfied whether they were informed of normal or abnormal test results. However, there was a significant difference in satisfaction between patients who were notified and those who were not. Meza and Webster state that if patients receive no notification they will not be able to take action or change behaviour, and may assume nothing is wrong with them, which could have dangerous implications. In a study conducted by Watson *et al.* (2001) where patient perceptions and experiences of gastroscopy were compared with patients who were sedated and those who were not, there were no significant differences. However, an important consideration for patients who were not sedated was their ability to speak with the endoscopist immediately after the investigation. The effect on patients receiving preliminary outcomes of colonoscopies before leaving the endoscopy unit in a study conducted by de Jonge *et al.* (2010) was that they were more willing to return for colonoscopy in comparison to patients who had not received preliminary outcomes before leaving.

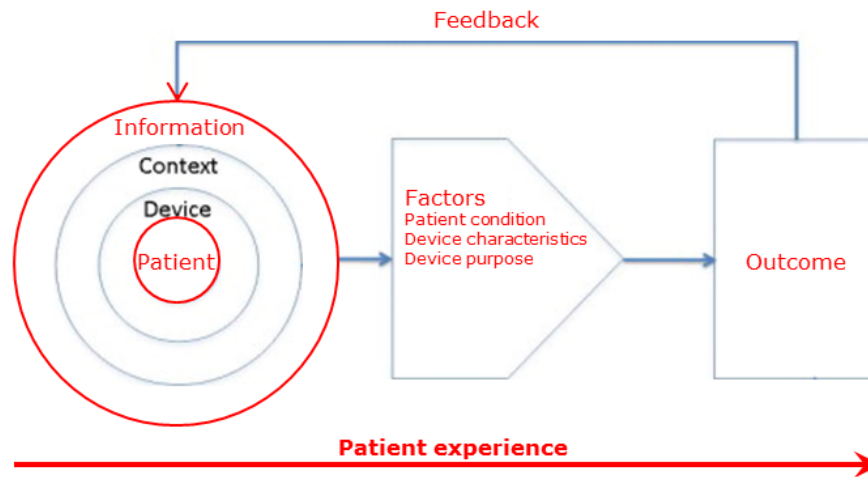
The time in between an investigation or test and receiving an outcome or result, respectively, can be a difficult time for patients. A variety of negative emotions were expressed by patients in a study conducted by Karnieli-Miller *et al.* (2009) whilst waiting for histopathology test results, which included anxiety, anger and a feeling of disrespect. An investigation outcome or test result can give patients a sense of relief (Püschel *et al.*, 2010), disclosure (Sapir *et al.*, 2000) and enable them to understand their own health (Elder and Barney, 2012; O'Connor *et al.*, 1994). Inadequate understanding can contribute to an unsatisfactory patient experience. This was observed in a study conducted by McDonald *et al.* (1996) where patients who received a normal echocardiography outcome, having had the investigation because of symptoms or a heart murmur, experienced residual anxiety. The patients lacked adequate understanding that symptoms and a murmur could persist regardless of whether or not the heart was normal. Almost half of the patients in the study by Karnieli-Miller *et al.* did not understand their results, which were delivered via mailed letters, and more than one-third did not understand recommendations for health behaviour change. Information format of outcomes and results can also affect their comprehensibility, which was observed in a study

conducted by Elder and Barney (2012). They found patients were more satisfied and better understood lipid profile results when notified with the actual results and a low-literacy paragraph describing the purpose of cholesterol testing, in comparison to actual results with a description of desired lipid profiles and actual results with a coloured bar chart. Patients felt that all methods lacked guidance on health behaviour change or what to do next.

The effects of investigation outcomes or test results were clearly observed in a study conducted by Sandwell *et al.* (2006) where participants were screened for heart risk factors with electron beam CT. There was a difference in high risk participants compared to low risk as they were significantly more likely to discuss outcomes with a clinician, undergo further cardiac investigations, have a cholesterol test, and begin taking cholesterol lowering medication, aspirin and multivitamins. A similar change in behaviour was reported in the study by Meza and Webster (2000) for patients who had their lipid profile tested. McNaughton-Collins *et al.* (2004) found that men who had a suspicious prostate specific antigen test result but a benign prostate biopsy result from a transrectal ultrasonography reported significantly greater thinking and more worrying about prostate cancer in comparison to men who had a normal prostate specific antigen test result.

#### *2.3.2.6 The role of information in the patient experience*

Information is vital for patients to make informed decisions when they have healthcare options and choices, to generate realistic expectations and improve their experiences of investigations and tests, and to understand their own health and act accordingly in response to investigation outcomes and test results. Information that consists of quality content and is well presented and easy for patients to understand will contribute to quality patient experiences. To demonstrate the value of information in the patient experience, the model by Sharples *et al.* (2012) (Figure 1.1), which was adapted to make it patient focussed and to graphically represent the patient experience (Figure 2.2), has been further adapted to incorporate information in order to demonstrate the relationship this has between the patient and the investigation or test (device) in the context of a screening or diagnostic healthcare situation (Figure 2.10).



**Figure 2.10** Model of relationship between user-device interaction and consequences (Sharples *et al.*, 2012) adapted to represent the patient experience with information incorporated

The relationship need not be one-way (information → patient), but it can be two-way (patient ↔ information) where patients are involved in the design, development and evaluation of patient information, and are consulted about the possible media for the implementation of information. Through such a process patient information may better meet the needs and preferences of patients, and be embedded within healthcare systems to be easily accessed both by patients and by clinicians and other healthcare professionals for distribution. This may also lead to a protocol or standardisation for information provision that can be adopted across healthcare providers. The next section explores the development and implementation of patient information, with a particular interest in patient involvement in and the use of guidelines for these processes, and the personalisation of healthcare.

### 2.3.3 Summary

Healthcare has transcended the traditional biomedical model to the outcomes model where patients in consumeristic clinician-patient relationships take an active role in their healthcare. Information is essential to patients who favour consumeristic clinician-patient relationships and is a valuable resource throughout the patient journey. Information is vital for patients to make informed decisions when they have healthcare options and choices; to generate realistic expectations and improve their experiences of investigations and tests; and to understand their own health and

act accordingly in response to investigation outcomes and test results. Involving patients in the design, development and evaluation of patient information, as well as consulting them about the possible media for the implementation of information, may better enable information to meet their needs and preferences, and be embedded within healthcare systems to be easily accessed both by patients and by clinicians and other healthcare professionals for distribution. The next section explores the development and implementation of patient information, with a particular interest in patient involvement in and the use of guidelines for these processes, and the personalisation of healthcare.

The box below summarises important aspects of research from this section to continue building the scope and developing the story of the thesis. The previous box summarised important aspects of research about the patient experience (see pages 21-22 for recap).

### **Summary of important aspects of research**

#### ***Consumeristic clinician-patient relationships***

The clinician-patient relationship has changed with patients who favour consumeristic relationships taking a more active role in their healthcare in comparison to patients who favour paternalistic relationships (Beisecker and Beisecker, 1993). They prefer to make decisions independently or to share decisions with their clinicians (Frosch *et al.*, 2003; Hawley *et al.*, 2012; Mazur *et al.*, 2005; Sheridan *et al.*, 2012), and they may exercise their control by actually limiting it or relinquishing their decision-making role (Beisecker and Beisecker; Nekhlyudov *et al.* 2003). Information and in particular e-health (Eysenbach, 2001) is essential to patients who favour consumeristic relationships, and three factors characterise e-health consumers: 1) convenience; 2) control; and 3) choice (Ball and Lillis, 2001). Information is a valuable resource and is included in the criteria developed by the NHS National Quality Board, which are deemed crucial to achieving quality patient experiences (Department of Health, 2012a). Information is essential to quality patient experiences through facilitating autonomy, self-care and health promotion, and supporting patient care transition and continuity. Respecting

patient centred values, preferences and expressed needs is also included in the criteria, and information can be especially valuable for this when patients have healthcare options and choices since information is the pivot upon which all decisions are made, whether they are good, bad or neutral.

### ***The value of information***

The theory of planned behaviour (Ajzen, 2005, p. 126) and the health belief model (Strecher *et al.*, 1997) are value expectancy theories, and information can have a significant effect in both. Information can affect beliefs and perceived threat of disease, which may be inaccurate, biased or irrational (Ajzen), and information can also minimise expectation mismatch with experience, which has been observed in a number of studies (Gluecker *et al.*, 2003; Nightingale *et al.*, 2012; Ristvedt *et al.*, 2003; von Wagner *et al.*, 2009b). The effects of information in decision-making can be the difference between patients making informed decisions and partially- or non-informed decisions. This is the basis for decision aids (also known as decision support technologies) that are used to encourage and facilitate informed shared decision-making so patients can make decisions that are satisfactory to their values and preferences (O'Connor *et al.*, 1999a; O'Connor *et al.*, 2004; O'Connor *et al.*, 2009; Wennberg *et al.*, 2002). Decision aids often increase user knowledge (Frosch *et al.*, 2003; Gimeno-García *et al.*, 2009; McCormack *et al.*, 2011; Wilt *et al.*, 2001) but consideration should be given to the effects of information content (Angtuaco *et al.*, 2001; von Wagner *et al.*, 2009a), as well as the format (Ahmed *et al.*, 2012; Edwards, 2004; Zikmund-Fisher, 2013) and framing (Edwards; Paling, 2003; Raffle and Gray, 2007, p. 223) of information. Information provided by clinicians and other healthcare professionals to patients during investigations and tests has been found to support patient experiences (Miller *et al.*, 2013; von Wagner *et al.*, 2009b; Ylinen *et al.*, 2009), and the notification of investigation outcomes and test results has been found to give patients a sense of relief (Püschel *et al.*, 2010), disclosure (Sapir *et al.*, 2000) and enable them to understand their own health (Elder and Barney, 2012; O'Connor *et al.*, 1994), as well as make behavioural changes (Meza and Webster, 2000; Sandwell *et al.*, 2006). Information is a

valuable resource throughout the patient journey but this relationship need not be one-way (information → patient). A two-way (patient ↔ information) relationship where patients are involved in the design, development and evaluation of patient information, as well as being consulted about the possible media for the implementation of information, may better enable information to meet their needs and preferences, and be embedded within healthcare systems to be easily accessed both by patients and by clinicians and other healthcare professionals for distribution. The next section explores the development and implementation of patient information, with a particular interest in patient involvement in and the use of guidelines for these processes, and the personalisation of healthcare.

## **2.4 The development and implementation of patient information**

### **2.4.1 Current methods used in the design, development and evaluation of patient information**

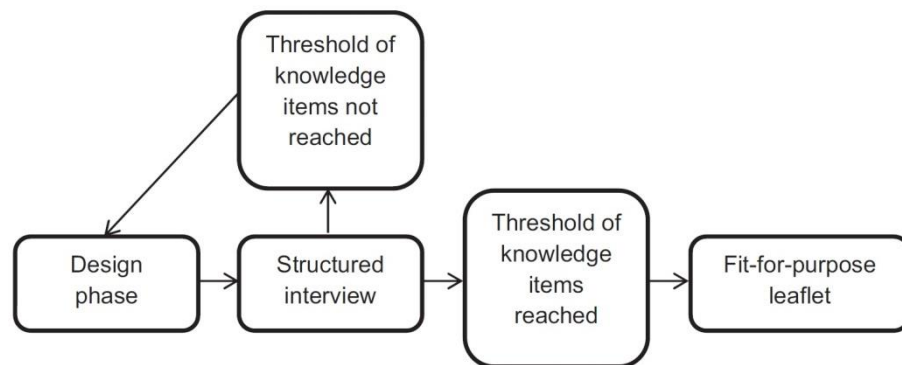
Understanding patients' needs and preferences before the design and development of patient information will better equip information designers to meet these. The U.S. Department of Health and Human Services (2006, p. 4) comment for web design and usability guidelines that early and continual focus on users is one of the basic principles of user centred design. Duman (2003, pp. 33-38) advocates patient involvement right from the start of patient information development and states that this is an important criterion for quality patient information resources. Duman suggests the following methods for collecting the views of patients (and carers):

- Focus groups.
- Surveys.
- In-depth interviews.
- The Delphi technique.
- Group panels.
- Observation of relevant, specified processes.

Jenkinson *et al.* (1998) report the positive effects and outcomes from a user centred approach for the development of a decision support technology (also known as decision aid) to assist patients facing prostate cancer treatment decisions. One hour interviews with 10 patients were used to determine patients understanding of their diagnoses, information seeking behaviour and level of comfort with computers. Patients also completed a form to enquire about subject areas for which they wanted additional information, and reviewed and discussed three sample screen designs. The screen designs encouraged conversations about other relevant topics, including the tailoring of information to meet patient specific informational needs (i.e. information to reflect prognosis of patient – from healthy to poor). Data collected contributed to the development of a prototype of the decision support technology.

Glenton (2002) comments that qualitative methods are particularly appropriate in the development of patient centred healthcare information because it enables informational needs to be elicited as sufferers themselves experience them. Glenton was referring to illness narratives and the needs of back pain sufferers, but also comments about the importance of channelling evidence based healthcare information within a patient centred approach. A similar approach has been applied by Smith *et al.* (2013b). They developed a ‘gist’ (i.e. brief) leaflet from a booklet that informs about colorectal cancer screening in the United Kingdom. The booklet was developed by Cancer Research UK, in association with the NHS Bowel Cancer Screening Programme and with advice from the English Bowel Cancer Screening Pilot (NHS Bowel Cancer Screening Programme, 2011). Having developed the leaflet, which involved consultation with experts on cancer control to ascertain what should be considered essential information about the English colorectal cancer screening programme and to have this information presented first, they conducted user testing. The primary outcome of the testing was for participants to correctly respond to eight true or false statements about colorectal cancer and colorectal cancer screening. In order for the leaflet to be deemed legible, clear and easy to read each statement had to be answered correctly by at least 80% of participants. Three rounds of user testing were conducted before the leaflet reached the required standard. This process is depicted in Figure 2.11 where ‘structured interview’ is the

user testing phase, which also involved participants providing feedback about which particular areas in the leaflet caused difficulties with comprehension.



**Figure 2.11** Procedure for user testing a comprehensible leaflet (Smith *et al.*, 2013b)

Although the Jenkinson *et al.* (1998) and Smith *et al.* (2013b) studies have had patients or proxy patients, respectively, involved in the development of their patient information resources, this is after one or more design iterations. These iterations are top-down (i.e. from a clinician, other healthcare professional and researcher perspective) and may not truly reflect user centred design. This is not to say that they do not incorporate user centred design but rather the user is consulted following a design phase, as depicted in Figure 2.11. Therefore the user's input is constrained and limited by an information resource presented to them, although they can evaluate the resource and offer suggestions for improvements. This occurred in a study conducted by Evans *et al.* (2007) where semistructured interviews were used in the field testing of a decision support technology to assist men considering prostate cancer screening with the prostate specific antigen test. Much of the information included in the decision support technology came from a paper based decision aid, which was developed by researchers from the Cancer Research UK Primary Care Education Research Group (Watson *et al.*, 2006). The decision aid was reviewed and approved by the Prostate Cancer Risk Management Programme Scientific Reference Group, which included a number of clinicians and other healthcare professionals, as well as patient representatives. Evans *et al.* comment that of particular importance in the decision aid were statistical/epidemiological data, which allowed them to present in the decision support technology some of the more controversial issues surrounding prostate cancer screening. The field testing of the support technology found navigation of



information to be important but a decision-making scale, which was to enable users of the technology to weigh the impact of specific information in their decision-making, was not particularly used. The scale was, however, kept in case it would be of use. Following the study Evans *et al.* proposed a model for field testing, which composed of two distinct processes. The first process was defined as exploratory field testing and would involve users to assess specific components of a decision support technology early in its development, before construction of a first prototype. The second process was defined as prototype field testing and users would assess successive prototypes, with particular reference to changes made during the development process.

The model proposed by Evans *et al.* (2007) seems to be another top-down one where users would be involved to evaluate, in the first stage, specific components of a decision support technology, and in the second stage, an interactive prototype but with a focus on changes made to the prototype from the first stage (and second stage if another iteration of the prototype was developed). What is not known from the top-down model proposed by Evans *et al.* and the methods used by Jenkinson *et al.* (1998) and Smith *et al.* (2013b) is whether the first iteration of a patient information resource is fitting of the information required by patients and that the presentation of this information is fitting within the cognitive processes of patients. Elwyn *et al.* (2010b) considered a similar premise with respect to the design of decision support interventions and the theory-practice gap. They proposed that there are an increasing number of decision support interventions for patients, including decision aids, but that few make explicit use of theory. They argue about the importance of using theory to guide design and reviewed eight decision-making theories and models to examine this. In conclusion of the review they see a role for existing theories and models in the design of decision support components that address cognitive tasks. These components are to contain information about a patient's options (i.e. relevant attributes and outcomes) and to aid the patient deliberate about their choice.

Currently the design and development of patient information is often top-down, and patients are normally involved to evaluate patient information resources and offer suggestions for improvements. Patients are constrained and limited by the

information resources presented to them, and the resources may have already had one or more design iterations. This approach does not fit within the basic principles of user centred design as put forward by the U.S. Department of Health and Human Services (2006, p. 4), which is to have early and continual focus on users. Duman (2003, pp. 33-38) also advocates patient involvement right from the start of patient information development. The design and development of patient information may therefore need a new approach, one that incorporates the needs and preferences of patients before any patient information resources or components of information resources are developed. This approach may benefit from being theory led. Elwyn *et al.* (2010b) see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance.

Incorporating such guidance within guidelines for the design, development and evaluation of patient information may assist information designers in producing information resources that meet the needs and preferences of patients. Current guidelines for patient information are not explicitly theory led, although provide valuable principles for the design, development and evaluation of patient information. Patient information guidelines are explored in the next part of this section, and to fully appreciate and comprehend the range, purpose and application of guidelines, all varieties are explored.

#### **2.4.2 Current guidelines for the design, development and evaluation of patient information**

Current guidelines for the design and development of patient information exist in the form of guidelines for medicinal product packaging (i.e. labelling) and package leaflets. This is in accordance with European Medicinal Products for Human Use Directive 2001/83/EC (European Union, 2001, Title V, pp. 85-88). Articles 59 and 62 of Title V of the Directive detail the information to be included on packaging and in package leaflets. A summary of the six main information sections to be included in Article 59 are provided by the Medicines and Healthcare products Regulatory Agency (MHRA, 2012, p. 4) and are as follows:

- Medicinal product identification.
- Therapeutic indications.
- Necessary information prior to medicinal product consumption.

- Dosage.
- Side-effects.
- Additional information, including medicinal product description and storage conditions.

The Medicines and Healthcare products Regulatory Agency also provide a guideline for the design and layout of patient information leaflets (pp. 6-10). The guideline covers:

- information design, which includes:
  - information architecture,
  - typography,
  - clear language, and
  - how to meet the needs of the intended audience, including those of children or young adults, healthcare professionals who will use medicinal products in clinics, hospitals and other healthcare settings, and for those whose sight might be affected by medicinal products;
- important patient information;
- information navigation; and
- other factors to consider, including the use of colour, symbols and pictograms to aid understanding.

Guidelines have also been produced by the European Commission (2009, p.6) for the legibility of particulars on packaging and in package leaflets. Their main purpose is to ensure accessibility of and for packaging and package leaflets to be understood by those who receive them so that medicinal products are used safely and appropriately. An amendment that has been made to Directive 2001/83/EC is for consultations with target patient groups to occur to ensure medicinal product package leaflets are legible, clear and easy to use (European Union, 2004, amendment 44, Article 59 (3), p. 49). The Medicines and Healthcare products Regulatory Agency reports this legislation as ‘user testing’ (MHRA, 2012, p. 10) but the Committee on Safety of Medicines Working Group on Patient Information comment in their *Always read the leaflet* report (MHRA, 2005, p. 26) that the legislation does not actually describe what user testing methods to use. They further comment that the legislation requires evidence of consultations with target patient

groups to demonstrate that information in package leaflets can be found and appropriately used. The European Commission describe user testing as testing readability of leaflets with target patient groups (2009, p. 20).

A method that is commonly used for user testing package leaflets is the ‘Australian’ method (CMDh, 2011). The method is described as to optimise content and design elements of leaflets, and that important messages for safe and effective use of medicinal products can be found in them. The method involves face to face interviews with participants in groups of 10 (preceded by three pilot interviews) in which a questionnaire is used. The questionnaire contains open questions with respect to important messages and general questions about overall perceptions of leaflets. Following interviews, revisions to leaflets and retesting may occur. Testing of final versions will involve two rounds of 10 participants. Successful testing is measured by 90% of participants being able to find information required, and of these, 90% being able to understand the information.

None of the guidelines described so far include guidelines for risk communication and the Committee on Safety of Medicines Working Group on Patient Information discuss the little guidance there is (MHRA, 2005, p. 34). They also provide variations and consider the suitability of statistical expressions for risk communication (pp. 46-47). Criteria for the content and presentation of information for the public about NHS Cancer Screening Programmes developed by Informed Choice about Cancer Screening include guidance for risk communication (Ramirez and Forbes, 2012, pp. i-iv). This includes the use of:

- natural frequencies (e.g. 3 in 10) to express benefits and harms,
- timeframes for the benefits and harms,
- absolute reduction in risk of dying to express mortality benefits (e.g. out of 1,000 people 5 fewer will die),
- constant denominators (e.g. out of 1,000), and
- both positive and negative points of view (i.e. positively and negatively frame benefits and harms – see page 32 for recap about the framing of information).

Following the assembly of evidence and the development of an evidence resource, the criteria are to be used to develop a first draft of a leaflet. The draft is then

reviewed by experts, including clinicians, other healthcare professionals and researchers, and representatives of users. A second draft is then developed, followed by user testing and the development of a third draft. The leaflet is to be used in conjunction with a letter offering the invitation of screening and to provide information about the benefits and harms of the screening. Online information is to be provided to those who require more detail, which may include the use of online decision aids.

Guidelines for decision aids exist in the form of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009). The instrument is a checklist produced by the International Patient Decision Aid Standards Collaboration (2012) and measures quality of decision support technologies using 10 dimensions, which include a total of 47 items. The 10 dimensions are described in Table 2.1.

<b>Dimension</b>	<b>Description</b>
Information	Eight items included to ensure that information about healthcare options are provided in sufficient detail to enable patients to make specific decisions.
Probabilities	Eight items to ensure the appropriate presentation of outcome probabilities of healthcare options.
Values	Four items to ensure patients are able to consider physical, psychological and social effects of healthcare options, and their positive and negative features.
Decision guidance	Two items to ensure structured guidance when patients are considering healthcare options and to aid patient communication with healthcare professionals.
Development	Six items to ensure systematic development processes of decision support technologies, and that patients and healthcare professionals are involved in these processes when finding out what information needs to be included in support technologies for specific decisions to be made, and to review and field test the technologies.
Evidence	Five items to ensure appropriate selection of evidence based medicine, and that details about included evidence (e.g. citations) and its quality are described.
Disclosure	Two items to ensure transparency of funding used for development and qualifications of developers or authors.
Plain language	One item to ensure readability level reported.
Decision support technology evaluation	Two items to ensure there is evidence that decision support technologies match healthcare options chosen by informed patients with the features that matter most to them and that patients' knowledge about options improve.

Test	Nine items to ensure that investigations or tests for screening inform patients of their true positives (i.e. correct diagnosis of medical conditions), true negatives (i.e. correct ruling out of medical conditions), false positives (i.e. incorrect diagnosis of medical conditions), false negatives (i.e. incorrect ruling out of medical conditions), the patient's journey if a medical condition is diagnosed or ruled out, the chances of diagnosing the condition with or without the investigations or tests, and the consequences of medical conditions being diagnosed that would never have been problematic in the event of the patient had never been screened.
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**Table 2.1** Descriptions of the dimensions of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009)

Patient involvement is advocated in the development dimension of the instrument, which includes finding out what patients need to prepare them to discuss a specific decision. Patient involvement is also advocated in a toolkit produced by the Department of Health (2003) for producing patient information. Involvement is advocated at the planning stage to identify specific informational needs of patients (and carers or clinicians), at the writing stage to provide editorial assistance and at the consultation stage to assess patient information (p. 7). The toolkit also provides checklists with a number of subheadings that can be considered when designing patient information. One of the checklists is for patient leaflets or booklets for operations, treatments and investigations, and includes the following subheadings:

- *What is the leaflet about and who is it for?*
- *What is the procedure?*
- *Why are they having it? Give the benefits and alternatives where appropriate.*
- *What preparation do they need or not need?*
- *Do they need a general anaesthetic, sedation or local anaesthetic?*
- *What happens when they arrive at the hospital or the clinic, and who will they meet?*
- *Will they be asked to sign a consent form or is verbal consent needed?*
- *What does the procedure involve? How long does it last? What does it feel like?*
- *What happens after the procedure – pain control, nursing checks, stitches.*

- *How long will they stay in hospital?*
- *Do they need someone with them or any special equipment when they go home?*
- *What care do they need at home?*
- *What follow-up care is needed? Do they need to visit their doctor?*
- *What can go wrong, what signs to look out for and what to do if something goes wrong.*
- *When can they start their normal activities again, for example, driving, sport, sex or work?*
- *Who can they contact if they have any more questions?*
- *Tell people where they can find more information, for example, support groups and websites.*

(Department of Health, 2003, p. 12)

The checklists provided in the International Patient Decision Aid Standards instrument (2009) and the Department of Health toolkit (2003) are more fitting for the evaluation of patient information resources. They would, however, be suitable as design specifications and be beneficial to refer to before developing information resources. Other guidelines that would be beneficial in the initial stages of information design and to be included in design specifications would be assessment protocols for kitemarks or trustmarks. Duman (2003, p. 84) discusses the value of kitemarks or trustmarks and the trustworthiness of health information. This was in relation to information that is available and accessible via the Internet. This is also discussed by the Committee on Safety of Medicines Working Group on Patient Information (MHRA, 2005, p. 39) with respect to the possibility of a Medicines and Healthcare products Regulatory Agency logo or quality mark. One mark that represents high quality health information is The Information Standard (2013a) (Figure 2.12).



**Figure 2.12** The Information Standard (2013a)

The Information Standard represents evidence based health and care information for the public that has undergone an assessment protocol to ensure its comprehensibility, accuracy, balance, and that it is evidence based and up to date. Six principles guide the protocol and are as follows:

- Process for producing high quality information is defined and documented.
- Evidence sources used are current, relevant, balanced and trustworthy.
- Information users are understood and information is user tested.
- Checklist used to check final productions of information.
- Comments, complaints and incidents are managed appropriately.
- Information and process is reviewed on a planned and regular basis.

(The Information Standard, 2013b)

Other marks that are relevant to health information include the Crystal Mark (Figure 2.13) and the Health On the Net Foundation Code of Conduct (Figure 2.14).



**Figure 2.13** Crystal Mark (Plain English Campaign, 2013)



**Figure 2.14** Health On the Net Foundation Code of Conduct (Health On the Net Foundation, 2013)

The Crystal Mark is given by the Plain English Campaign (2013) when information is clearly written and comprehensible, although it does not ensure content accuracy. The Health On the Net Foundation Code of Conduct (Health On the Net Foundation, 2013) holds website developers to ethical standards for information presentation and to ensure readers know the source and purpose of the data they are reading.

Current guidelines for the design, development and evaluation of patient information exist in the form of guidelines for medicinal product packaging and package leaflets, leaflets about cancer screening, decision support technologies, and leaflets or booklets for operations, treatments and investigations. The guidelines for



medicinal product packaging and package leaflets provide specific instructions for information designers to follow in the design and development of patient information. The guidelines for leaflets about cancer screening provide criteria for the content and presentation of information, which are to be applied to an evidence resource. The guidelines for decision support technologies, and leaflets or booklets for operations, treatments and investigations, are in the form of checklists and would be more fitting for the evaluation of patient information resources. They would, however, be suitable as design specifications and be beneficial to refer to before developing information resources. Other guidelines that would be beneficial in the initial stages of information design and to be included in design specifications would be assessment protocols for kitemarks or trustmarks. The value of kitemarks or trustmarks may be of more significance given the amount of health information that is available and accessible via the Internet. The Internet is one medium that can be used for information provision and may also provide a means to tailor and personalise patient information. New media and the personalisation of patient information are explored in the next part of this section.

### **2.4.3 New media and the personalisation of patient information**

The Royal College of General Practitioners (2013, p. 15) envision that general practice in 2022 will be personalised and the expectation is that healthcare will be increasingly delivered online, with e-health supporting this deliverance. This is in accordance with a 'Digital first' initiative set by the Department of Health, which aims to reduce unnecessary face to face contact between healthcare professionals and patients by incorporating technology (Innovation Health & Wealth, 2012). The Royal College of General Practitioners also see a role for m-health, which is the provision of healthcare or healthcare information via mobile technologies, including mobile phones and specialist mobile medical devices (PWC, 2012, p. 6). This is an emerging field within healthcare and healthcare research but may be of particular benefit to developing countries, which Kaplan (2006) discusses. Patients in the PWC report (p. 7) believe that m-health will improve convenience, quality and cost of healthcare in the next three years. However, this is only believed by around half of patients questioned. Convenience is one of three factors that

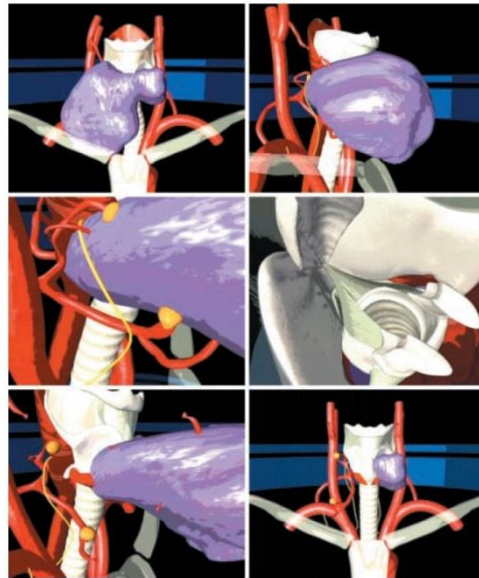
characterise e-health consumers (Ball and Lillis, 2001, see page 23 for recap) and m-health may be another system for improving patient convenience, as well as control and choice, which are the other two factors.

As mentioned in the first part of the previous section, 71% and 80% of Internet users in Britain and the United States, respectively, searched for health information online in 2011 (Dutton and Blank, 2011, p. 23; Fox, 2011, p. 2). This is a clear indication of the role of new media for information provision in healthcare.

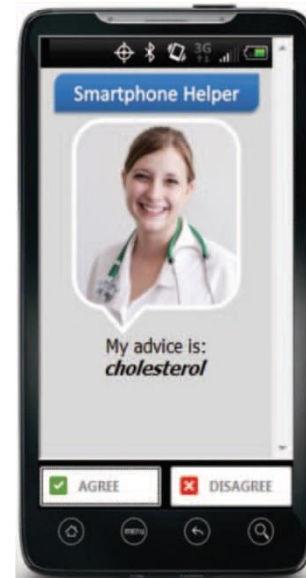
However, the inaccuracy of online information is an issue, which was referred to in the previous part of this section with respect to the value of kitemarks or trustmarks and the trustworthiness of health information. The potential of researching inaccurate information was a known issue of patients in a study conducted by Nightingale *et al.* (2012) who researched the Internet before SPECT-CT to provide them with information and reassurance. Patients in a study conducted by Davison and Breckon (2012), whose treatment decision-making and information preferences for active surveillance of prostate cancer were being examined, identified general information about prostate cancer and access to reliable Internet sites as additional information resources they wanted to access. ‘Internet based information banks’, as proposed by Nyrrhinen *et al.* (2009) to signpost patients who were attending care units for genetic testing, could be used to ensure patients access accurate and reliable information. There are already such banks in existence for decision aids (BMJ Group, 2012a; Informed Medical Decisions Foundation, 2013; NPC, 2012; Ottawa Hospital Research Institute, 2013).

Having a multitude and a variety of online resources with interactive features may prevail in information provision meeting the needs and preferences of the masses, but which is also tailored for the individual. This is seen as potentially beneficial for risk communication; Ahmed *et al.* (2012) discuss personalised risk information and Edwards *et al.* (2013) found from a systematic review that participants who received personalised risk information made more informed decisions compared to participants who received general risk information. Tariman *et al.* (2010) believe there is a lack of ‘innovative interventions’ to match patients’ preferred and actual decision-making role, but having a ‘toolbox’ of aids, as described by Edwards (2004), will help in achieving this. New media can also improve trust in healthcare,

as reported by Hermann (2002) with the use of a three dimensional computer animation of a thyroid operation (Figure 2.15) and Pak *et al.* (2012) with the use of a decision support aid with anthropomorphic characteristics for diabetes management (Figure 2.16).



**Figure 2.15** Three dimensional computer animation of a thyroid operation (Hermann, 2002)



**Figure 2.16** Decision support aid with anthropomorphic characteristics for diabetes management (Pak *et al.*, 2012)

A toolbox of aids may help clinicians who find it difficult to provide patients with the necessary information. A toolbox of aids in the form of a library of evidence based decision aids were used in a study conducted by Hirsch *et al.* (2012). They found that the majority of patients were very satisfied or satisfied with the counselling, a large proportion would want to be counselled again with the decision aids, and only a small proportion of clinicians believed that the duration of consultations was unacceptably extended by the decision aids. The library of evidence based decision aids facilitated clinician uptake of decision aids. This corresponds with Graham *et al.* (2003) who advise if clinicians had opportunities to examine and try decision aids, which were easily accessible and distributional, clinician uptake of decision aids would be facilitated. A benefit of a library of evidenced based decision aids that were accessed and distributed via the Internet would be the possibility to update decision aids with the latest clinical evidence, which was a concern discussed at the International Patient Decision Aid Standards Symposium (Holmes-Rovner *et al.*, 2007).

Another possibility with patient information accessed and distributed via the Internet is the notification of investigation outcomes and test results. An aim of NHS England (2013, p. 6) is for all patients to be able to access their GP records online by 2015, which may ease patient anxiety and improve satisfaction by reducing the outcome and result notification period. A reduction in anxiety was observed in a study conducted by Wiljer *et al.* (2010) when breast cancer patients were able to review laboratory test results and diagnostic imaging reports via their online patient health record, and Palen *et al.* (2012) report that patients who were able to access their online records, including secure communications with clinicians via email, had a subsequent increase in clinician visits and accessing clinic telephone services. Privacy and security may be of concern to patients when using online resources, which was evident in a study conducted by Baldwin *et al.* (2005) where email and web based systems were two of six media used to notify patients of normal laboratory test results. Although this may be more of a concern for the older patient as research suggests that the younger the patient, the more comfortable they are with and the more likely they are to find new media acceptable (Couper *et al.*, 2010; Grimes *et al.*, 2009; Leekha *et al.*, 2009). Another limitation of new media is that there is no clinician-patient interaction. This is mentioned by Meza and Webster (2000) with respect to mailed letters but which also applies to most new media, and a desire for interpersonal connection with clinicians was important to primary care patients in a study conducted by Elder and Barney (2012), which examined communication preferences for the notification of test results.

New media present many opportunities, as well as challenges, for information provision in healthcare. Patients are becoming more comfortable with new media, such as the Internet, to access information, but problems or perceived problems of accuracy, limited clinician-patient interaction, privacy, reliability and security exist. However, information banks and toolboxes of aids can help patients access or be signposted to trustworthy information, and online resources can reduce the notification period of investigation outcomes and test results. The Royal College of General Practitioners (2013, p. 15) envision new media to play an increasing role in the personalisation of healthcare by 2022, the Department of Health have set the Digital first initiative (Innovation Health & Wealth, 2012) and NHS England (2013, p. 6) aim for all patients to be able to access their GP records online by 2015. With

the transition to e-health begun and set to increase in the coming years, it is increasingly important to engage patients in the design, development and evaluation of patient information, as well as consider their preferred media for the implementation of information. Buchan *et al.* (2010) believe that patients need to be empowered to coproduce healthcare with healthcare professionals in the digital challenge for health economies. Whilst the thesis is not focussed on the 'digital challenge for health economies', it does see a benefit in and an opportunity to take a user centred approach to patient information, and to make a contribution to knowledge. The next section explores the contribution to knowledge that can be made from research, which will then lead into the research approach section.

#### **2.4.4 Summary**

Current methods used in the design and development of patient information are often top-down. Patient involvement is typically to evaluate and suggest improvements to patient information resources or components of information resources that have already be developed (with perhaps more than one design iteration) by clinicians, other healthcare professionals and researchers. Although this form of input by patients is beneficial to the development of resources, it may not truly reflect user centred design. And what is not known from the top-down approach is whether information presented to patients is fitting of what they require and that the presentation of this information fits within their cognitive processes. The design and development of patient information may therefore need a new approach, one that incorporates the needs and preferences of patients before any patient information resources or components of information resources are developed. This approach may be more theoretical and could be incorporated within guidelines for the design, development and evaluation of patient information. Current guidelines exist in the form of guidelines for medicinal product packaging and package leaflets, criteria for leaflets about cancer screening, and checklists for the evaluation of patient information resources, which would be suitable as design specifications and be beneficial to refer to before developing information resources. Other guidelines that would be beneficial in the initial stages of information design and to be included in design specifications would be assessment protocols for kitemarks or trustmarks. The value of kitemarks or

trustmarks may be of more significance given the amount of health information that is available and accessible via the Internet. The Internet and other new media present many opportunities, as well as challenges, for information provision in healthcare. This includes the personalisation of patient information, but issues surrounding reliability, privacy and security. Engaging with patients in the design, development and evaluation of patient information, as well as considering their preferred media for the implementation of information, may better meet their needs and preferences. Such an approach to patient information, a user centred one, can also make a contribution to knowledge. The next section will explore the contribution to knowledge that can be made from research, which will then lead into the research approach section.

The box below summarises important aspects of research from this section to finalise the scope and the basis of the thesis. Previous boxes summarised important aspects of research about the patient experience (see pages 21-22 for recap), and information provision and the patient experience (see pages 37-39 for recap).

### **Summary of important aspects of research**

#### ***Current methods used in the design, development and evaluation of patient information***

Early and continual focus on users is one of the basic principles of user centred design as commented by the U.S. Department of Health and Human Services (2006, p. 4) about web design and usability guidelines, and Duman (2003, pp. 33-38) advocates patient involvement right from the start of patient information development and that this is an important criterion for quality patient information resources. Duman suggests focus groups, surveys, in-depth interviews, the Delphi technique, group panels and observation of relevant, specified processes for collecting the views of patients (and carers). Current methods used in the design and development of patient information, including the development of a decision support technology (also known as decision aid) (Jenkinson *et al.*, 1998) and a ‘gist’ (i.e. brief) leaflet from a booklet (Smith *et al.*, 2013b), are often top-down (i.e. from a clinician, other healthcare professional and researcher perspective). Patients are involved to evaluate

patient information resources and offer suggestions for improvements, which occurred in a study conducted by Evans *et al.* (2007) where semistructured interviews were used in the field testing of a decision support technology. The design and development of patient information may need a new approach, one that incorporates the needs and preferences of patients before any patient information resources or components of information resources are developed. This approach may benefit from being theory led. Elwyn *et al.* (2010b) see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. Incorporating such guidance within guidelines for the design, development and evaluation of patient information may assist information designers in producing information resources that meet the needs and preferences of patients.

### ***Current guidelines for the design, development and evaluation of patient information***

Guidelines for the design and development of patient information exist in the form of guidelines for medicinal product packaging (i.e. labelling) and package leaflets. There are six main information sections to be included on packaging and in package leaflets (European Union, 2001, Title V, pp. 85-88; MHRA, 2012, p. 4), and other guidelines are available for the design and layout of patient information leaflets (MHRA, 2012, pp. 6-10) and the legibility of particulars on packaging and in package leaflets (European Commission, 2009, pp. 7-15). Guidelines for the design and development of patient information also exist in the form of criteria for the content and presentation of information in leaflets about cancer screening. The criteria have been developed by Informed Choice about Cancer Screening (Ramirez and Forbes, 2012, pp. i-iv) and are to be applied to an evidence resource to produce a first draft of a leaflet. Guidelines for the evaluation of patient information exist in the form of checklists. The International Patient Decision Aid Standards Collaboration (2012) has produced a checklist, the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009), which measures quality of decision support technologies. Checklists are also included in a toolkit produced by the Department of Health (2003) for

producing patient information. The checklists would be suitable as design specifications and be beneficial to refer to before developing patient information resources. Assessment protocols for kitemarks or trustmarks, such as The Information Standard (2013a), the Crystal Mark (Plain English Campaign, 2013) and the Health On the Net Foundation Code of Conduct (Health On the Net Foundation, 2013), would also be beneficial in the initial stages of information design and to be included in design specifications. The value of kitemarks or trustmarks may be of more significance given the amount of health information that is available and accessible via the Internet. The Internet is one medium that can be used for information provision and may also provide a means to tailor and personalise patient information.

### ***New media and the personalisation of patient information***

The Royal College of General Practitioners (2013, p. 15) envision that general practice in 2022 will be personalised and the expectation is that healthcare will be increasingly delivered online, with e-health supporting this deliverance. A ‘toolbox’ of aids, as described by Edwards (2004) and demonstrated in a study conducted by Hirsch *et al.* (2012) in the form of a library of evidence based decision aids, may contribute to this vision. If accessed and distributed via the Internet, decision aids can be updated with the latest clinical evidence, which was a concern discussed at the International Patient Decision Aid Standards Symposium (Holmes-Rovner *et al.*, 2007). Online resources may enable the tailoring of patient information to meet individual needs and preferences. This was demonstrated in a systematic review, which found participants who received personalised risk information made more informed decisions compared to participants who received general risk information (Edwards *et al.*, 2013). Online resources may also be used for the notification of investigation outcomes and test results. An aim of NHS England (2013, p. 6) is for all patients to be able to access their GP records online by 2015. However, privacy and security (Baldwin *et al.*, 2005) and no clinician-patient interaction (Meza and Webster, 2000; Elder and Barney, 2012) might be issues. The Department of Health have set a ‘Digital first’ initiative (Innovation Health & Wealth, 2012) and Buchan *et al.* (2010) believe that



patients need to be empowered to coproduce healthcare with healthcare professionals in the digital challenge for health economies. Whilst the thesis is not focussed on the ‘digital challenge for health economies’, it does see a benefit in and an opportunity to take a user centred approach to patient information, and to make a contribution to knowledge.

## 2.5 Contribution to knowledge

Information is incorporated in Figure 2.10, the adapted model by Sharples *et al.* (2012), to demonstrate its value in the patient experience. Information is vital for patients to make informed decisions when they have healthcare options and choices, to generate realistic expectations and improve their experiences of investigations and tests, and to understand their own health and act accordingly in response to investigation outcomes and test results. This description is akin to descriptions by the Patient Information Forum (2013a, p. 6) and the Department of Health (2012b, p. 13) who define information as ‘consumer health information’ and an ‘essential service’, respectively.

The relationship between information and the patient need not be one-way, and information may better meet the needs and preferences of patients through a two-way process. This would entail patient involvement in the design, development and evaluation of patient information, and their consultation about the possible media for the implementation of information. Current methods used in the design and development of patient information are often top-down, with clinicians, other healthcare professionals and researchers dictating information to be included in patient information resources and the presentation of this information (Evans *et al.*, 2007; Jenkinson *et al.*, 1998; Smith *et al.*, 2013b). Perhaps their involvement should be to ensure information resources are evidence based, which Informed Choice about Cancer Screening advise in the development of leaflets about cancer screening with the development of an evidence resource to occur first (Ramirez and Forbes, 2012, pp. 9-11). Perhaps the actual information to be included in resources and the presentation of this information should be user centred.

Information is the pivot upon which all decisions are made and a user centred approach to patient information may be of particular benefit to information for when patients have healthcare options and choices, and to assist them in making decisions representative of their values and preferences. The value of information is depicted in two value expectancy theories: 1) the theory of planned behaviour (Ajzen, 2005, p. 126) (Figure 2.5); and 2) the health belief model (Strecher *et al.*, 1997) (Figure 2.6). The theory of planned behaviour determines that an individual's behaviour follows reasonably from the information or beliefs that the individual has about the behaviour under consideration; and the health belief model determines that personal action is affected by an individual's subjective value (or evaluation) of personal subjectivity to and severity of disease, and the likelihood of reducing this threat. A user centred approach to patient information led by theory might be a better method to meet the informational needs and preferences of patients, which is a concept shared by Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance.

Incorporating such guidance within guidelines for the design, development and evaluation of patient information may assist information designers in producing information resources that meet the needs and preferences of patients. Guidelines for medicinal product packaging and package leaflets (European Union, 2001, Title V, pp. 85-88; MHRA, 2012, p. 4) are currently the only guidelines that provide specific instructions for information designers to follow, whilst Informed Choice about Cancer Screening have developed criteria for the content and presentation of information in leaflets about cancer screening (Ramirez and Forbes, 2012, pp. i-iv). There are currently no specific guidelines for information designers to follow when designing patient information for when patients have options of or require investigations or tests. This is a significant discovery since most patient journeys begin with patients having options of or requiring investigations or tests, and information is valuable to inform patients of what to expect and to aid decision-making. The majority of healthcare information producers who took part in a recent survey by the Patient Information Forum about producing information for people with low literacy reported a limited understanding of how to develop resources (and services) and a practical guide was considered a useful tool (2013b, p. 10).

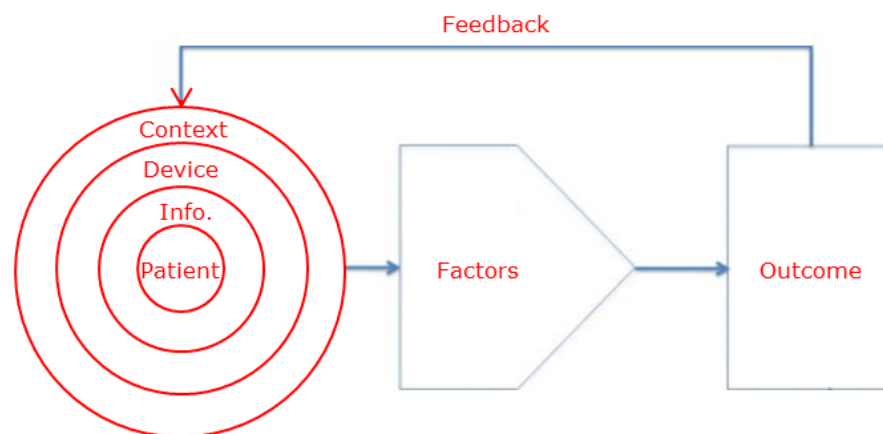
A practical guide to the implementation of patient information may also be a useful tool. The Royal College of General Practitioners (2013, p. 15), the Digital first initiative by the Department of Health (Innovation Health & Wealth, 2012) and NHS England (2013, p. 6) all have an agenda for patient information accessed and distributed via new media, especially online information via the Internet. New media present many opportunities, including the personalisation of patient information (Ahmed *et al.*, 2012; Edwards *et al.*, 2013), but there are issues surrounding reliability of information (Davison and Breckon, 2012; Nightingale *et al.*, 2012) and privacy and security (Baldwin *et al.*, 2005). Patient involvement in this ‘digital challenge’, as put forward by Buchan *et al.* (2010), will be of particular importance in the push for new media (as well as pull considering the amount of health information searched online in 2011 (Dutton and Blank, 2011, p. 23; Fox, 2011, p. 2)).

The value of information is evident in the criteria that are deemed crucial to achieving quality patient experiences (Department of Health, 2012a, see page 15 for recap), and the thesis aims to develop a user centred approach to the design, development and implementation of patient information that contributes to quality patient experiences. This includes developing patient information guidelines for investigations and tests to assist information designers and others involved in patient information for when patients have options of or require investigations or tests. Insights into what promotes or prohibits the use of new media will also be of interest since they provide many opportunities and challenges for information provision. The basis of the user centred approach and study designs are outlined in the next section.

## 2.6 Research approach

Four studies will be designed and conducted to reflect a user centred approach to the design, development and implementation of patient information. The first two studies (Chapters 3 and 4) will evoke emotional, psychological and social responses from participants to investigations and tests in the context of screening and diagnostic healthcare situations, and examine the value and contributions of information in these situations. The last two studies (Chapters 5 and 6) will

incorporate findings from the first two studies into the design of patient information, and examine the value of the information and whether it better meets participants' needs and preferences. The user centred approach is graphically represented in Figure 2.17, which is similar to the adapted Sharples *et al.* (2012) model that represents the patient experience with information incorporated (Figure 2.10). Information has moved from the outside of the onion model in Figure 2.10 to the inside between the patient and device in Figure 2.17. This is to appropriately demonstrate its relationship between context and device, and the patient.



**Figure 2.17** Model of relationship between user-device interaction and consequences (Sharples *et al.*, 2012) adapted to represent a user centred approach to the design, development and implementation of patient information

For the first two studies *context* defines the type of healthcare situation, which will be either a screening context or diagnostic context. *Device* defines the investigation or test to be used in the healthcare situation, which will be utilised to either screen the *patient* for a medical condition in the context of screening or to further investigate the patient's symptoms in the context of diagnosis. *Info.* (information) informs the patient about the healthcare situation, providing details about context and device. Human factors methodologies will be applied to extract data and will aim to: 1) establish *factors* affecting attitudes towards the healthcare situations; and 2) understand informational needs and preferences in the healthcare situations. Understanding informational needs and preferences includes understanding needs and preferences following the patient *outcome*. Findings from the first two studies will then be incorporated into the last two studies and specifically into the design of patient information. The information will inform about a device solely rather than

about a device within a context. This means the information could be used in either a screening or diagnostic context to inform about an investigation or test, but with no reference to a specific healthcare situation. The patient information will be evaluated and compared with information that is already available to examine whether it better meets the needs and preferences of patients.

Qualitative and quantitative data will be collected in both the first and last two studies, and methods used will include focus groups, interviews and questionnaires. Theories will be used to interpret the meaning of data and the process of incorporating findings from the first two studies into the design of patient information used in the last two studies is fitting of ISO 9241-201:2010 (ISO, 2010). This is an international standard that provides requirements and recommendations for human centred design. Key principles of the standard are that design is based upon an explicit understanding of users, tasks and environments, and that users involvements are active (i.e. users are involved in all design phases, from early conceptualisations to final user testing). The following chapter begins this process and examines potential patients' attitudes towards diagnostic procedures and their informational needs and preferences.

## CHAPTER 3

# Potential patients' attitudes towards diagnostic procedures and their informational needs and preferences

### 3.1 Introduction

Chapter 3 reports the findings from a study that takes a human factors approach to medical devices from the perspective of potential patients in the context of diagnosis. The study aimed to understand:

- attitudes towards diagnostic procedures, and
- informational needs and preferences.

The effects of technological complexity, physical demands on the patient and informational output, as well as patient symptoms, were also examined to explore the interacting dimensions of these on attitudes and informational needs and preferences. The study is in response to the first two research questions, which are as follows:

- 1) What factors affect patient attitudes towards diagnostic and screening procedures?
- 2) What are patient informational needs and preferences when encountering diagnostic and screening procedures?

The study is one of two that will contribute to a user centred approach to the design, development and implementation of patient information. This is outlined in the research approach (see pages 60-62 for recap), and will involve findings from this and the second study (Chapter 4) being incorporated into the design of patient information used in the last two studies (Chapters 5 and 6). The last two studies are in response to the third research question, which is as follows:

- 3) How does patient information based on factors affecting patients' attitudes towards diagnostic and screening procedures affect the value of the information?

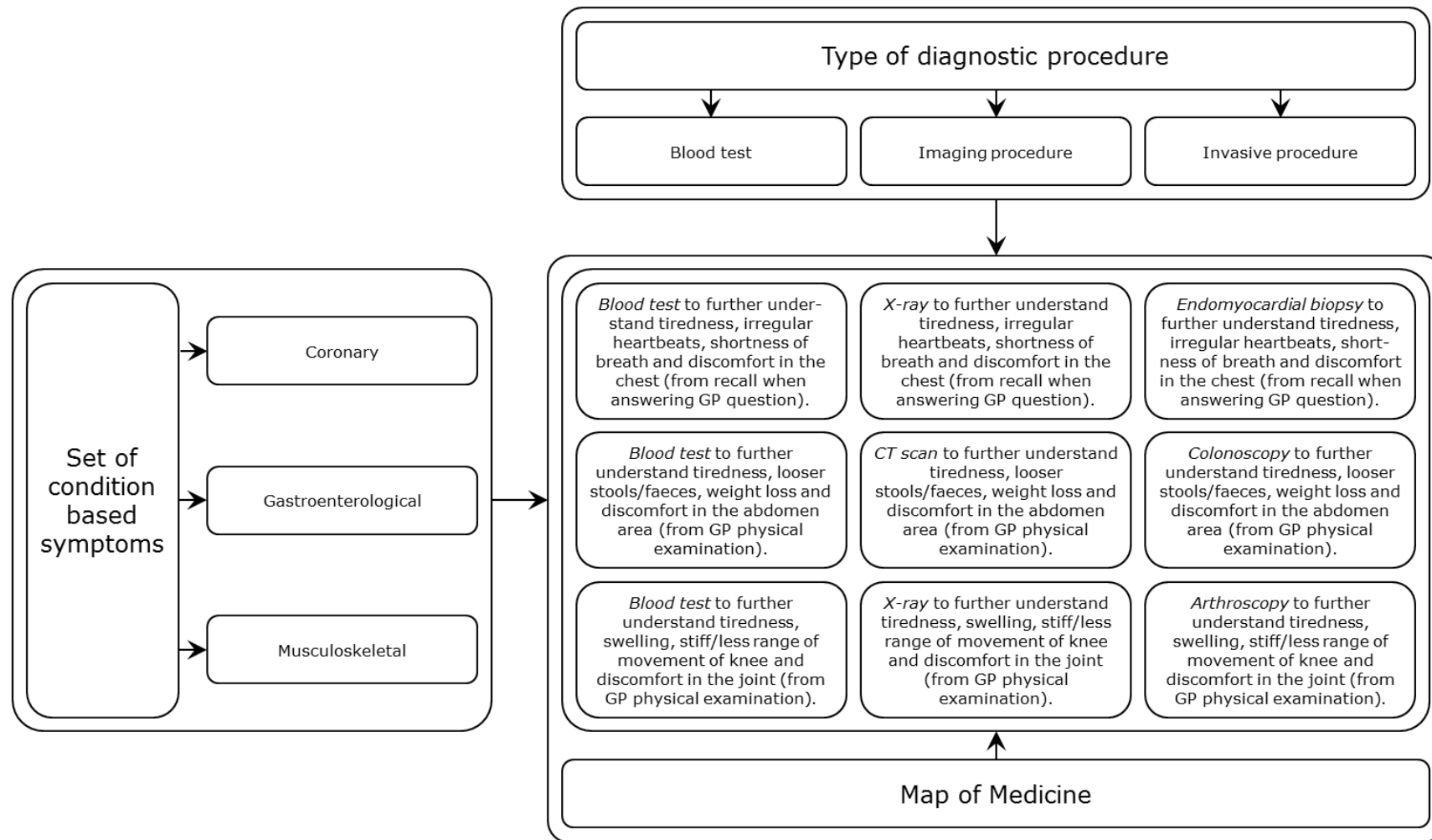
## 3.2 Methodology

### 3.2.1 Study design

The study was conceptualised as an exploratory and prospective one to provide broad, yet profuse data in response to the first two research questions. This was done to enable a detailed examination of potential patients' attitudes towards medical devices in the context of diagnosis and their informational needs and preferences, and provide a worthy foundation for the user centred approach to the design, development and implementation of patient information. The study was designed to include variables that would facilitate the collection of an assortment of valuable data and support the direction of the user centred approach. Hypothetical situations called vignettes were used and proved essential to these objectives. Alexander and Becker (1978) define vignettes as 'short descriptions of a person or social situation which contain precise references to what are thought to be the most important factors in the decision-making or judgement-making process of respondents'.

Vignettes were used to create diagnostic medical scenarios that portrayed diagnostic procedures with varying degrees of technological complexity, physical demands on the patient and informational output, and which were to be used to further investigate a selection of relevant and various patient symptoms. Scenarios were based around three sets of condition based symptoms (coronary, gastroenterological and musculoskeletal) and three types of diagnostic procedure (blood test, imaging procedure and invasive procedure). Using a three by three factorial design, nine vignettes were produced.

The Map of Medicine (2013), an online proprietary resource providing clinicians and other healthcare professionals in the United Kingdom with evidence based clinical pathways, was referred to in the design and development of the vignettes. The vignettes were cross referenced against each other to ensure their only variances were the systematic variance of the sets of condition based symptoms and types of diagnostic procedure, the two independent variables. Figure 3.1 graphically represents this process and describes the actual symptoms and the specific diagnostic procedures used in the vignettes.



**Figure 3.1** Design and development of vignettes with the Map of Medicine (2013)



Information about pre-procedural requirements, such as bowel preparation for colonoscopy; alleviating substances, such as sedation for colonoscopy and endomyocardial biopsy (also known as heart biopsy); and post-procedural effects, such as the effects of sedation, were excluded to avoid the implications this would have on the study design. Although these are important aspects of patient experiences, the study was focused on perceptions rather than experiences, and on the medical devices used in the diagnostic procedures rather than what happens before or after the procedures.

The vignettes for the imaging type of diagnostic procedure stated that there would be exposure to radiation but that there would be no harmful side-effects. Generic information was provided about the accuracies of the diagnostic procedures stating 'no test is 100% accurate' and that they are part of a 'process of elimination'.

The blood test can be referred to as an invasive procedure because it requires a needle to be inserted into a patient's arm. However, it is relatively minimal compared to the procedures for the invasive type of diagnostic procedure. Since the blood test is well-known and unchanged for each set of condition based symptoms it also provided a basis for establishing findings in the other two types of diagnostic procedure.

Vignettes were in hard copy (i.e. distributed handouts) and participants were requested to imagine that they were a patient who had symptoms and that a diagnostic procedure was being used to further understand the reason for their symptoms, having presented their symptoms to GP and been referred to a specialist clinician. A brief explanation of the diagnostic procedure was provided, which included details about what the procedure was and what it required in terms of patient involvement (i.e. what happens to the patient during the procedure). An image was included of each diagnostic procedure.

Appendix 1 provides screenshots of the clinical pathways from the Map of Medicine that were used to design and develop the vignettes for the gastroenterological symptoms. Appendices 2-4 provide three vignettes in their entirety demonstrating each set of condition based symptoms and each type of diagnostic procedure.

### **3.2.2 Data collection**

To measure the effects of the sets of condition based symptoms and types of diagnostic procedure a combination of closed and open-ended questions were used in a questionnaire to collect quantitative and qualitative data, respectively. Seven-point interval scales (minimum rating = 1.00; maximum rating = 7.00) with verbal anchors were used to answer the majority of the closed questions and a number of these were followed by the open-ended questions for participants to explain their selected ratings. One closed question was answered using categories. The questionnaire was designed in three sections: 1) preferences for information in the pre-diagnosis stage; 2) attitudes towards diagnostic procedures; and 3) preferences for information in the post-diagnosis stage. Appendix 5 provides details about stages of information provision in the patient journey.

The first section was designed to elicit participants' responses about their satisfaction levels with the information provided for them about the diagnostic procedures in the vignettes; whether they would like information about what suspected medical condition(s) were being investigated or tested; and whether they would like information about possible clinical pathways in the event of a positive (i.e. medical condition is diagnosed), negative (i.e. medical condition is ruled out) or inconclusive (i.e. uncertain – neither positive nor negative) diagnostic procedure outcome or result.

The second section involved querying participants' perceived levels of accuracies of the diagnostic procedures and their confidence in them to further understand the reason for the symptoms described in the vignettes; perceived levels of apprehension and embarrassment, if actually encountering the procedures; perceived likelihood of talking to a family member or friend about the symptoms described in the vignettes, as well as talking about the procedures; and perceived likelihood in proceeding to have the procedures.

The third section was designed to elicit participants' responses on whether they would like to receive a diagnostic procedure outcome or result during or immediately after a procedure in the event of it being positive, negative or inconclusive, presuming that this was possible; the amount of information they

would like to receive in a procedure outcome or result, which was devised using three levels of information provision (Table 3.1); and levels of acceptance of different media for the notifying of an outcome or result (Table 3.2).

Level	Description
1	Receive diagnostic procedure outcome or result and information on what happens next.
2	Receive diagnostic procedure outcome or result with an explanation about it and what it means, and information on what happens next.
3	Receive diagnostic procedure outcome or result with an explanation about it and what it means, including images and/or numerical data that might be produced from a procedure, and information on what happens next.

**Table 3.1** Levels of information provision for a diagnostic procedure outcome or result

Medium
Call GP practice automated notification phone service
Collect from GP practice reception
Email
Face to face with GP
Face to face with specialist clinician
Interactive kiosk/touchscreen monitor at GP practice (in privacy)
Letter through the post
Mobile phone application to notify and allow access to outcome or result
Mobile phone text message
Online access to personal healthcare record
Phone call from GP
Phone call from GP practice reception
Phone call from specialist clinician

**Table 3.2** Different media for the notification of a diagnostic procedure outcome or result

Participants were presented with three of the nine vignettes but only one at a time and they encountered each set of condition based symptoms (coronary, gastroenterological and musculoskeletal) and type of diagnostic procedure (blood test, imaging procedure and invasive procedure) only once. This resulted in six possible combinations for the vignettes to be distributed in. And for each combination to be received once every six participants but in a different sequence, 36 sequences were required. Appendix 6 provides details of the combinations and the sequences for the distribution of the vignettes. Participants were advised to read each vignette first before proceeding to the questionnaire, although they could refer back to the vignette when completing it. The study was conducted under

supervision to avoid satisficing (Krosnick, 1991) and to be of assistance if required. The questionnaire is provided in its entirety in Appendix 7.

### **3.2.3 Data analysis**

Quantitative data from the closed questions were analysed using IBM SPSS Statistics 19 (IBM Corp., 2010) and involved two phases of statistical analysis: 1) examine the effects of the types of diagnostic procedure; and 2) examine the effects of the types of diagnostic procedure for each set of condition based symptoms. Before commencing with the first phase the three variables (blood test, imaging procedure and invasive procedure) were tested to examine whether they met the assumptions of parametric data or not. This was not required for the question answered using categories, which used both forms of chi-square test: the goodness of fit and the multi-dimensional. Variables that met the assumptions of parametric data used the one-way analysis of variance (ANOVA) and if statistical significance was found Tukey's honestly significant difference test was to be used post hoc. Variables that did not meet the assumptions of parametric data used the Kruskal Wallis test (two-tailed) and if statistical significance was found the Mann-Whitney test was to be used post hoc.

In the second phase of statistical analysis, variables that did not meet the assumptions of parametric data in the first phase of analysis used the same non-parametric tests. Variables that met the assumptions of parametric data used the two-way ( $3 \times 3$ ) ANOVA (between subjects), if the assumption of homogeneity of variance was met. If statistical significance was found the independent *t*-test was to be used to analyse the interaction effect between the types of diagnostic procedure for each set of condition based symptoms. One-way repeated measures ANOVA was used to compare the different media for the notifying of a diagnostic procedure outcome or result.

Statistical significance for each test was valued at  $p < 0.05$  apart from the Mann-Whitney test and the independent *t*-test where a Bonferroni correction was applied to ensure that the Type I errors did not build up to more than 0.05 (Field, 2009, pp. 372-375, pp. 565-568). The Bonferroni correction meant that the level of statistical significance for the Mann-Whitney test and the independent *t*-test was valued at  $p <$

0.0167 ( $0.05 \div 3$  (three types of diagnostic procedure)). Means ( $\bar{x}$ ) and standard deviations ( $SD$ ) are reported to summarise scores instead of medians for consistency and to accurately show differences in participant ratings, and because medians will likely be identical even when there are statistically significant differences.

Qualitative data from the open-ended questions were transcribed verbatim and analysed using NVivo 9 (QSR International Pty Ltd., 2010) using a thematic data led approach (Howitt, 2010, p. 175). This involved reading through the data and coding relevant data together, generating a coding scheme. Depending on the coding scheme, some data existed in more than one code. Data in the different codes were then re-read and the coding scheme revised, which included data being moved between codes, data being removed or added to codes, and restructuring and renaming of codes. This process was repeated until the codes that were established developed into themes that represented a systematic structuring and understanding of the data. Peer debriefing (Creswell and Miller, 2000) with colleagues at supervision meetings and project meetings was used to validate the data and the data analysis. This was often in the manner of an interrogation so that the data were and the data analysis was rationalised, and the coding scheme and the eventual themes were ascertained for their basis and reasoning. Appendix 8 provides a screenshot of the coding of the qualitative data, demonstrating coding for different open-ended questions.

### **3.2.4 Sample**

The sample used in the study was students from The University of Nottingham. They were less likely to have encountered the diagnostic procedures used in the vignettes compared to an older population, with the exception of a blood test, and therefore bias from past experiences could be avoided. This reflects the focus of the study, which was on perceptions rather than experiences. Although they are not real patients they will be at some time in their lives and the use of vignettes was appropriate to compensate for the lack of healthcare experiences of students, and to enable a young demographic to contribute to research where they may otherwise be unable to. However, a trade-off in using students, who would be less likely to encounter the diagnostic procedures used in the vignettes compared to an older

population, is that their responses may not be the same if they were to actually encounter the procedures in the future. This will remain unknown in this study and in the thesis in general, but the use of proxy patients in healthcare research is not uncommon.

Proxy patients were used a study conducted by Angtuaco *et al.* (2001) who recruited participants from a local video rental store to examine attitudes towards colonoscopy and virtual colonoscopy for colorectal cancer screening using a questionnaire; by Berry and Hochhauser (2006) who recruited participants from a London coach station to examine the effects of verbal labels on perceptions of risk in clinical trials using a hypothetical scenario; by Elder and Barney (2012) who recruited a convenience sample of primary care patients from a number of healthcare settings to examine communication preferences for the notification of test results using vignettes; by Nelson *et al.* (2001) who recruited participants visiting a general paediatrician's office and personnel working in that office to examine attitudes towards diagnostic procedures for intestinal inflammation using a questionnaire; by Smith *et al.* (2013a) who recruited participants from two community organisations to examine a booklet that informs about colorectal cancer screening in the United Kingdom; and by Smith *et al.* (2013b) who recruited participants from two community organisations to user test a leaflet that informs about colorectal cancer screening in the United Kingdom. The participants in the Nelson *et al.* study had their responses compared with those of patients, and the authors comment how remarkably similar they were.

Healthcare research where students have been used as proxy patients is limited but Al-Naggar and Isa (2010) used medical students (female and male) to examine perceptions of and opinions to Pap smear testing. Focus groups were used and the authors comment that this enabled an in-depth meaning of the perceptions of medical students towards Pap smear testing. Although this may be a reasonable justification for the use of students with respect to the aims and objectives of Al-Naggar and Isa's study, caution is raised by Peterson (2001) about the use of students in social science research. Peterson found from a meta-analysis that responses of college students tend to be more homogenous than the adult nonstudent population. This would indicate that there should be less confounding

variables in student populations in comparison to nonstudent populations, which supports the argument of using university students in this study with respect to avoiding bias from past experiences. But to repeat and to clarify this is also a trade-off, and what will not be known is whether the responses of the participants would be the same if they were to actually encounter the diagnostic procedures used in the vignettes in the future.

### **3.2.5 Recruitment**

The study gained ethical approval from the Faculty of Engineering Research Ethics Committee at The University of Nottingham. Participants were recruited through posters promoting the study in the main campus of the university and targeted emailing of students. Participants provided written consent to participate and were remunerated with £5 in high street vouchers for their participation. To collect participant information about investigation and test history, as well as demographic information, participants completed a participant profile form.

## **3.3 Results**

Seventy-two participants took part in the study of which 39 (54.2%) were female and 33 (45.8%) male, and of which 47 (65.3%) were aged 18-23 years, 19 (26.4%) 24-29 years and 6 (8.3%) 30 years or older. Sixty-two (86.1%) of the participants reported that they had experienced at least one diagnostic procedure, and 51 (82.3%) of these reported that they had experienced a blood test, 37 (59.7%) an imaging procedure and 5 (8.1%) an invasive procedure. A total of 211 questionnaires were completed from a possible maximum of 216 (72 participants × 3 vignettes) with one participant completing 1 questionnaire and three completing 2. The results are discussed in four parts: 1) preferences for information in the pre-diagnosis stage; 2) attitudes towards diagnostic procedures; 3) preferences for information in the post-diagnosis stage; and 4) factors affecting attitudes towards diagnostic procedures.

### 3.3.1 Preferences for information in the pre-diagnosis stage

#### 3.3.1.1 Satisfaction with information

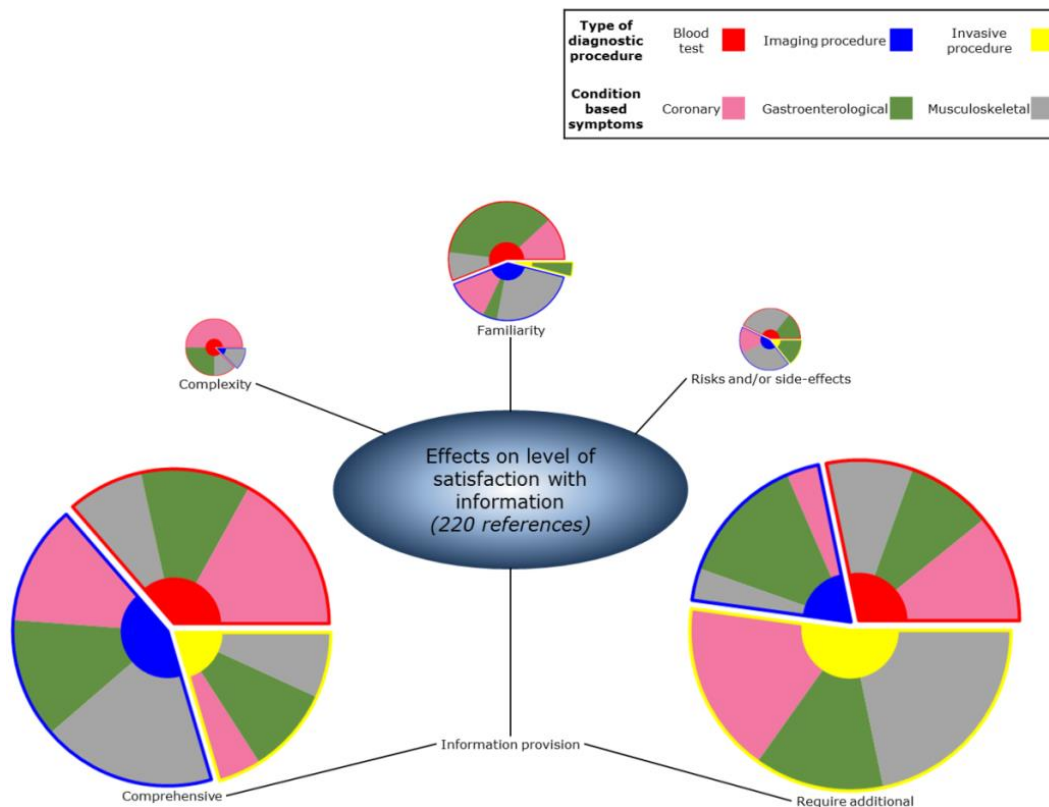
There was a statistically significant effect of the type of diagnostic procedure on participants' satisfaction with information provided for them about the diagnostic procedures in the vignettes,  $H(2) = 49.26, p < 0.001$ . Post hoc tests revealed that participants were significantly less satisfied with information provided about an invasive type of diagnostic procedure ( $\bar{x} = 4.14, SD = 1.49$ ) compared to a blood test ( $\bar{x} = 5.65, SD = 1.41$ ),  $U = 1162.00, p < 0.001, r = -0.47$  and an imaging type of diagnostic procedure ( $\bar{x} = 5.78, SD = 1.03$ ),  $U = 946.50, p < 0.001, r = -0.54$ . Analysis of the type of diagnostic procedure for each set of condition based symptoms yielded similar results apart from there being no significant difference between the imaging procedure ( $\bar{x} = 5.50, SD = 0.96$ ) and the invasive procedure ( $\bar{x} = 4.75, SD = 1.36$ ) for the gastroenterological based symptoms,  $U = 179.50, p = 0.054, r = -0.28$ .

Figure 3.2 graphically represents the themes that affected participants' levels of satisfaction with the information provided for them about the diagnostic procedures in the vignettes<sup>2</sup>. The most influential theme was *information provision* and the two sub-themes that formed this are *comprehensive* and *require additional*. This refers to whether the explanation about a diagnostic procedure and the patient's physical involvement with it (i.e. what is expected and what would happen to the patient during the procedure) was comprehensive or whether additional information was required. The two sub-themes clearly depict the statistically significant findings. Other themes that emerged were *familiarity* (experience/knowledge/perceived knowledge of diagnostic procedure), *complexity* (perceived level of complexity of diagnostic procedure) and *risks and/or side-effects* (perceived level of risks and/or side-effects, if any, of diagnostic procedure). The number of references in the graphical representation refers to the total number of sentences, comments and phrases included in the thematic analysis.

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<sup>2</sup> The themes are graphically represented using pie charts, which depict the types of diagnostic procedure and the sets of condition based symptoms using a colour coding scheme. The bigger the pie chart the more influential the theme, and the colour coding enables the influence of the variables to be independently appreciated within the themes.





**Figure 3.2** Effects on level of satisfaction with information

### 3.3.1.2 Preferences for receiving information about suspected medical condition(s) being investigated or tested

There was a statistically significant effect of the type of diagnostic procedure in the musculoskeletal based symptoms on participants' preference for receiving information about what suspected medical condition(s) were being investigated or tested,  $H(2) = 7.05, p < 0.05$ . Post hoc tests revealed that participants significantly preferred more information about what suspected condition(s) were being investigated or tested for the invasive procedure ( $\bar{x} = 6.71, SD = 0.86$ ) compared to the imaging procedure ( $\bar{x} = 5.87, SD = 1.54$ ),  $U = 191.50, p < 0.167, r = -0.36$ . There was a very high preference for this information for the three types of diagnostic procedure (Table 3.3).

Type of diagnostic procedure	$\bar{x}$	$SD$
Blood test	6.24	1.13
Imaging procedure	6.19	1.22
Invasive procedure	6.46	1.08

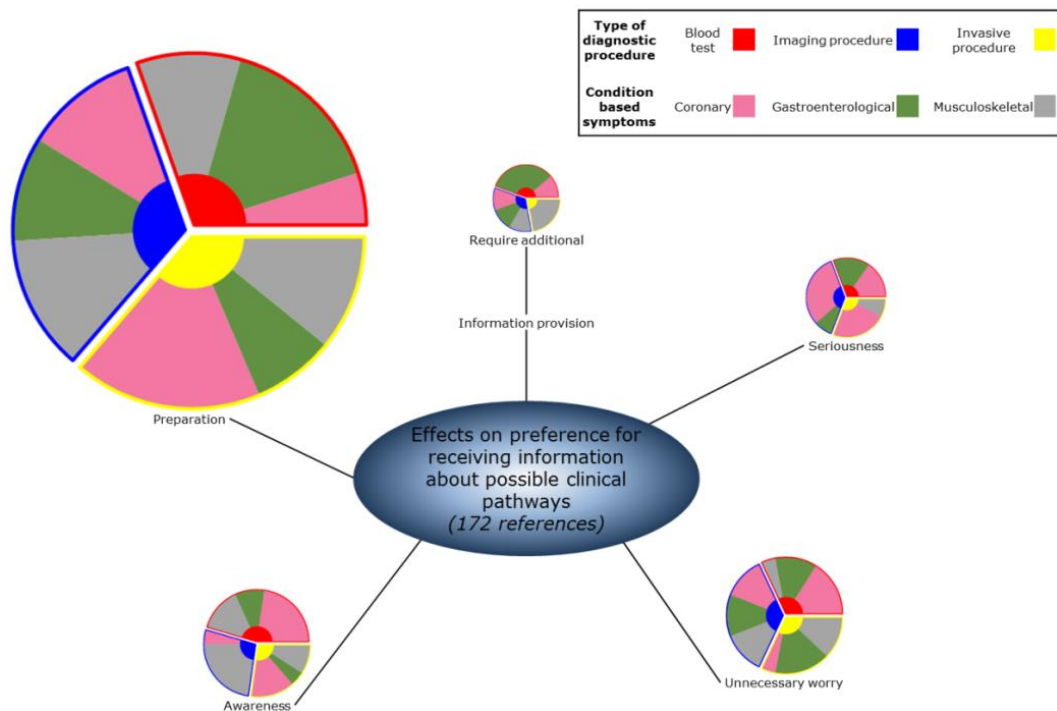
**Table 3.3** Preference for receiving information about what suspected medical condition(s) were being investigated or tested (minimum rating = 1.00; maximum rating = 7.00)

### 3.3.1.3 Preferences for receiving information about possible clinical pathways

There were no statistically significant effects on participants' preference for receiving information about possible clinical pathways in the event of a positive, negative or inconclusive outcome or result. There was, however, a very high preference for this information for the three types of diagnostic procedure (Table 3.4). The most influential theme that seemed to contribute to this preference was *preparation* (Figure 3.3), which refers to information that would aid preparation for possible diagnosis, prognosis and clinical pathway. Other themes that emerged were *unnecessary worry* (information deemed to cause unnecessary worry and/or the participant would rather wait until diagnostic procedure result was available), *awareness* (awareness of anything that should be avoided and/or adjustments to current lifestyle that should be made, and/or any other symptoms to look out for) and *seriousness* (perceived level of seriousness of symptoms and/or diagnostic procedure). There was also the re-emergence of *information provision* and *require additional*.

Type of diagnostic procedure	$\bar{x}$	<i>SD</i>
Blood test	6.28	1.21
Imaging procedure	6.29	1.11
Invasive procedure	6.30	1.20

**Table 3.4** Preference for receiving information about possible clinical pathways in the event of a positive, negative or inconclusive outcome or result (minimum rating = 1.00; maximum rating = 7.00)



**Figure 3.3** Effects on preference for receiving information about possible clinical pathways (in the event of a positive, negative or inconclusive outcome or result)

### 3.3.2 Attitudes towards diagnostic procedures

#### 3.3.2.1 Perceptions of accuracies of and confidence in diagnostic procedures

There were no statistically significant effects on participants' perceptions of how accurate a diagnostic procedure was and their confidence in a procedure to further understand the reason for the symptoms described in the vignettes. However, perceptions and levels of confidence were high (Tables 3.5 and 3.6). The most influential theme that seemed to contribute to the high perceptions and confidence levels was *trust* (Figures 3.4 and 3.5), which refers to trust in clinicians and/or clinical practice. *Require additional* information was also influential in both thematic analyses and *accuracy* was a new sub-theme to emerge of *information provision* in the analysis for perceived levels of accuracies, which refers to the influence of the generic information provided in the vignettes about the accuracies of the diagnostic procedures and that they are part of a 'process of elimination'. Other themes that emerged were *familiarity*, *physical involvement* (physical involvement with diagnostic procedure), *technology* (perceived level of quality of

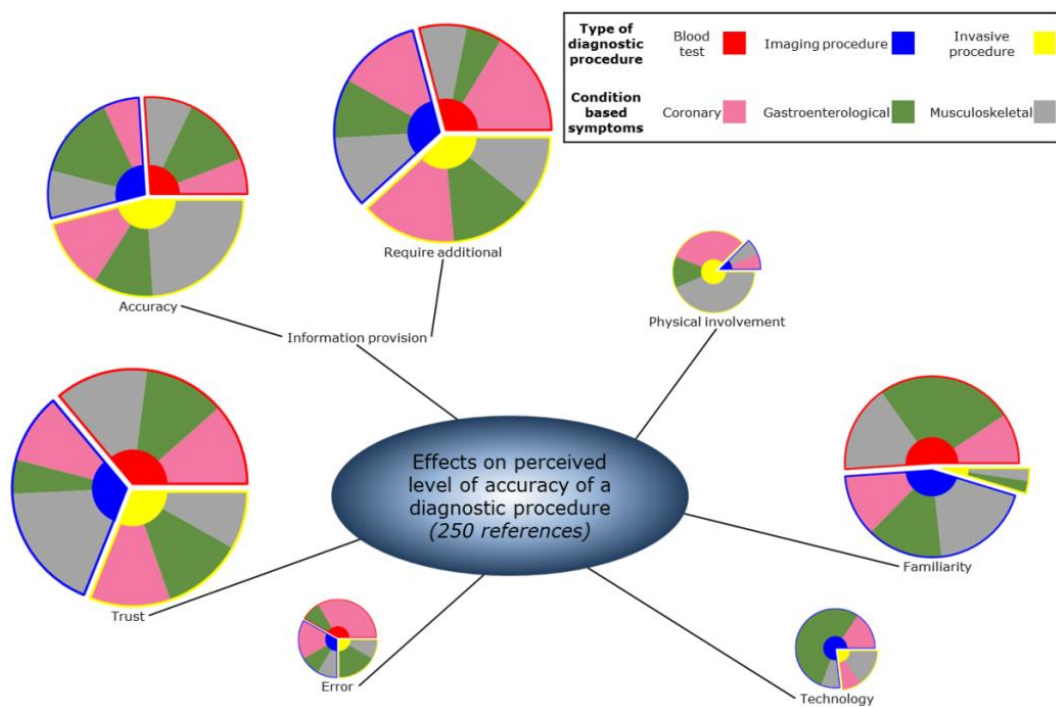
technology used in diagnostic procedure), *error* (perceived level of error due to human error and/or false diagnostic procedure outcome or result) and *complexity*.

Type of diagnostic procedure	$\bar{x}$	<i>SD</i>
Blood test	5.16	1.06
Imaging procedure	5.33	0.98
Invasive procedure	5.14	1.17

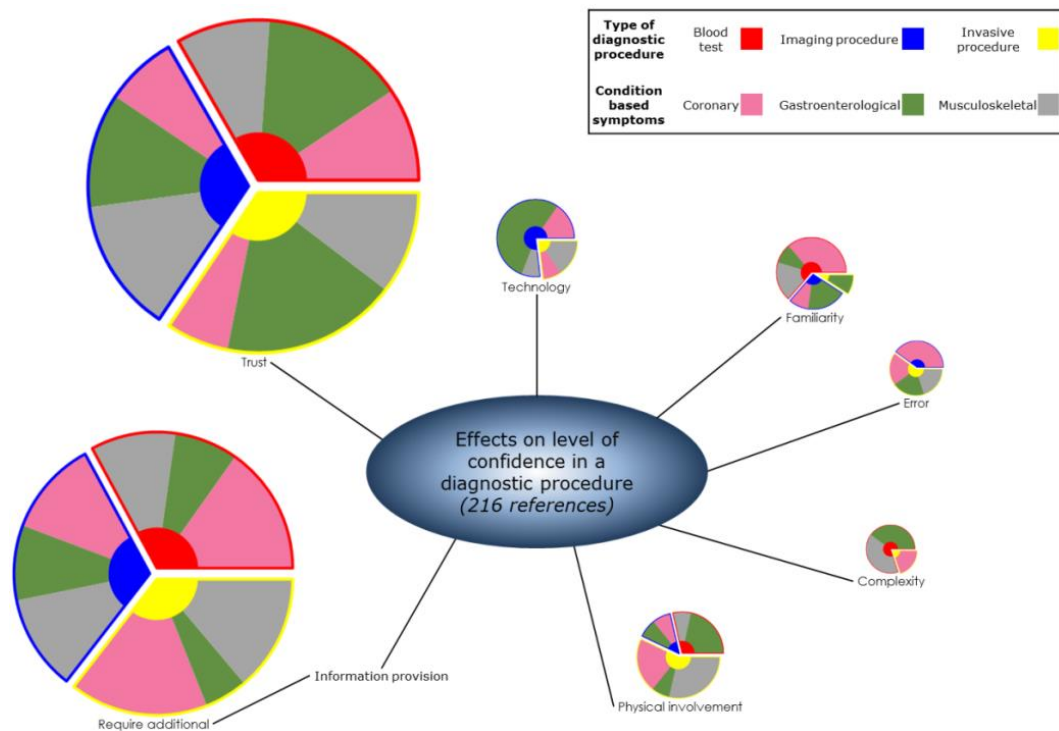
**Table 3.5** Perceptions of how accurate a diagnostic procedure was (minimum rating = 1.00; maximum rating = 7.00)

Type of diagnostic procedure	$\bar{x}$	<i>SD</i>
Blood test	5.24	1.31
Imaging procedure	5.45	1.18
Invasive procedure	5.20	1.37

**Table 3.6** Confidence in diagnostic procedure to further understand the reason for the symptoms described in the vignettes (minimum rating = 1.00; maximum rating = 7.00)



**Figure 3.4** Effects on perceived level of accuracy of a diagnostic procedure



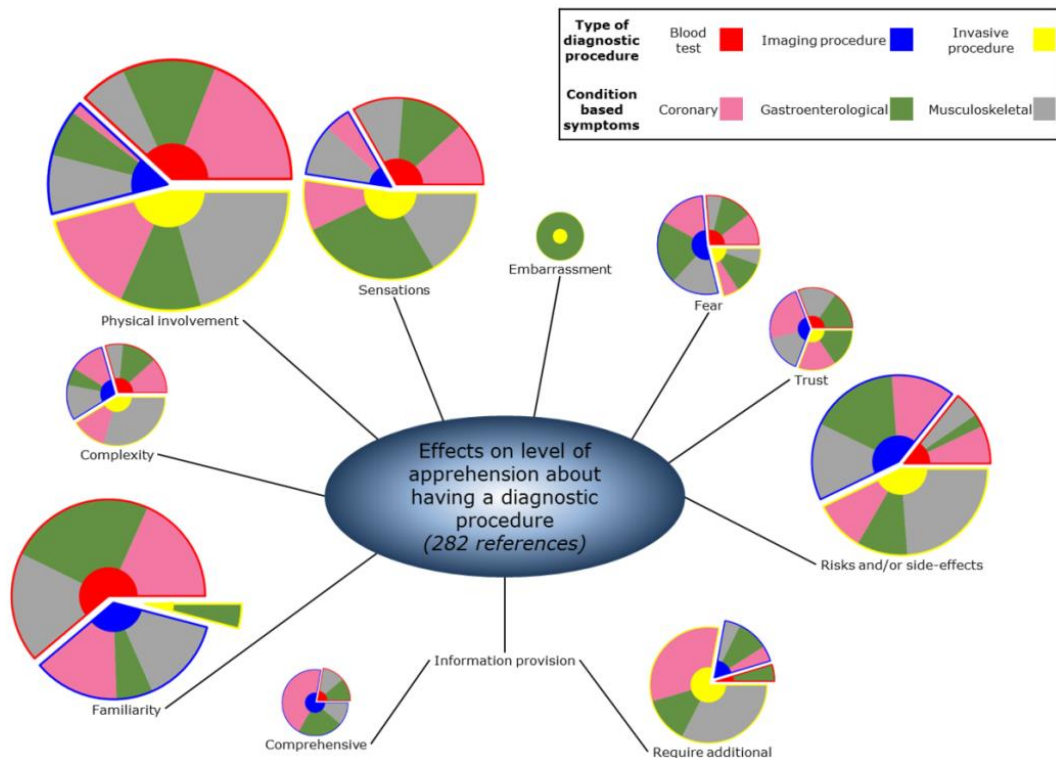
**Figure 3.5** Effects on level of confidence in a diagnostic procedure

### 3.3.2.2 Apprehension about having diagnostic procedures

There was a statistically significant effect of the type of diagnostic procedure on participants' levels of apprehension about having a diagnostic procedure,  $H(2) = 52.32$ ,  $p < 0.001$ . Post hoc tests revealed that participants were significantly more apprehensive about having an invasive type of diagnostic procedure ( $\bar{x} = 5.14$ ,  $SD = 1.62$ ) compared to a blood test ( $\bar{x} = 3.07$ ,  $SD = 2.07$ ),  $U = 1129.50$ ,  $p < 0.001$ ,  $r = -0.48$  and an imaging type of diagnostic procedure ( $\bar{x} = 2.80$ ,  $SD = 1.76$ ),  $U = 859.00$ ,  $p < 0.001$ ,  $r = -0.57$ . Analysis of the type of diagnostic procedure for each set of condition based symptoms yielded similar results apart from there being no significant difference between the imaging procedure ( $\bar{x} = 3.23$ ,  $SD = 1.74$ ) and the invasive procedure ( $\bar{x} = 4.54$ ,  $SD = 1.77$ ) for the gastroenterological based symptoms,  $U = 159.00$ ,  $p = 0.019$ ,  $r = -0.35$ .

*Physical involvement* (Figure 3.6) was an influential theme that seemed to contribute to the statistical significance. Other influential themes were *familiarity*, *sensations* (perceived level of pain and/or discomfort, if any, during diagnostic procedure and/or use of an alleviating substance) and *risks and/or side-effects*. There were a number of other themes and *fear* (fear of diagnostic procedure

outcome or result) and *embarrassment* (level of embarrassment, if any, due to symptoms and/or diagnostic procedure) were two new themes that emerged.

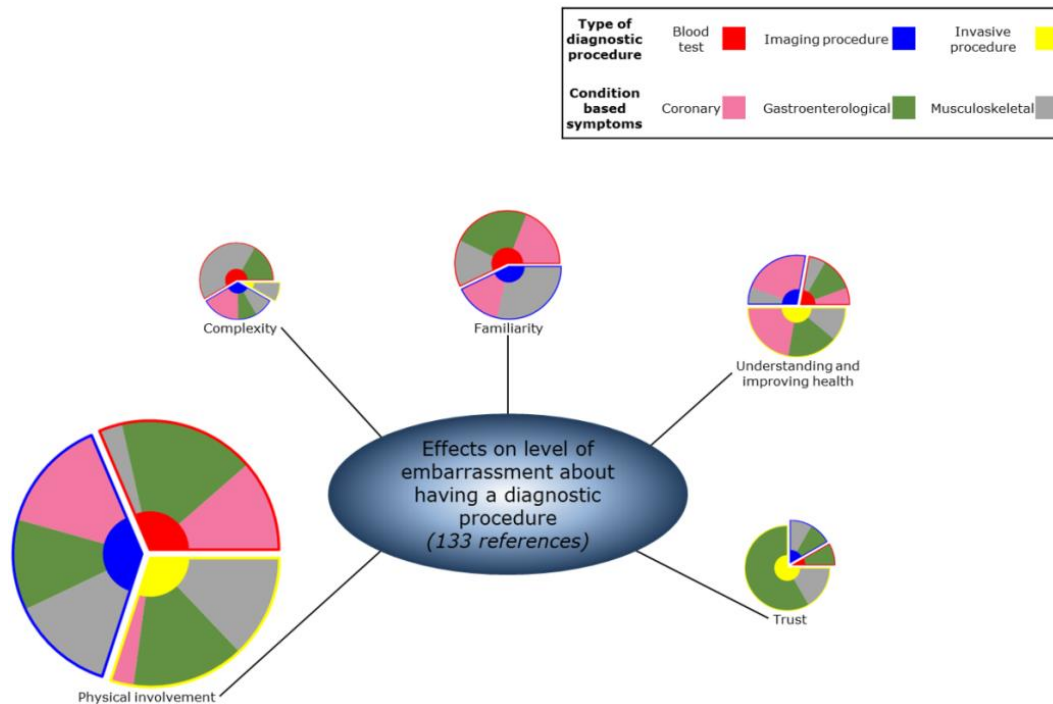


**Figure 3.6** Effects on level of apprehension about having a diagnostic procedure

### 3.3.2.3 Embarrassment about having diagnostic procedures

There was a statistically significant effect of the type of diagnostic procedure on participants' levels of embarrassment about having a diagnostic procedure,  $H(2) = 30.87, p < 0.001$ . Post hoc tests revealed that participants were significantly more embarrassed about having an invasive type of diagnostic procedure ( $\bar{x} = 2.58, SD = 1.78$ ) compared to a blood test ( $\bar{x} = 1.39, SD = 2.07$ ),  $U = 1451.50, p < 0.001, r = -0.41$  and an imaging type of diagnostic procedure ( $\bar{x} = 1.54, SD = 1.16$ ),  $U = 1546.50, p < 0.001, r = -0.35$ . Analysis of the type of diagnostic procedure for each set of condition based symptoms found only one set of similar results, which was for the gastroenterological based symptoms,  $H = 30.38, p < 0.001$ . Post hoc tests revealed that participants were significantly more embarrassed about having the invasive procedure ( $\bar{x} = 4.04, SD = 1.81$ ) compared to a blood test ( $\bar{x} = 1.35, SD = 1.07$ ),  $U = 49.50, p < 0.001, r = -0.74$  and the imaging procedure ( $\bar{x} = 1.91, SD = 1.66$ ),  $U = 93.50, p < 0.001, r = -0.57$ .

*Physical involvement* (Figure 3.7) was yet again an influential theme and seemed to contribute to the statistical significance. Other themes that emerged were *familiarity, understanding and improving health* (understanding what is causing symptoms so appropriate measures can be taken to improve health), *complexity* and *trust*.



**Figure 3.7** Effects on level of embarrassment about having a diagnostic procedure

#### 3.3.2.4 Likelihood of talking to family or friends about symptoms and diagnostic procedures

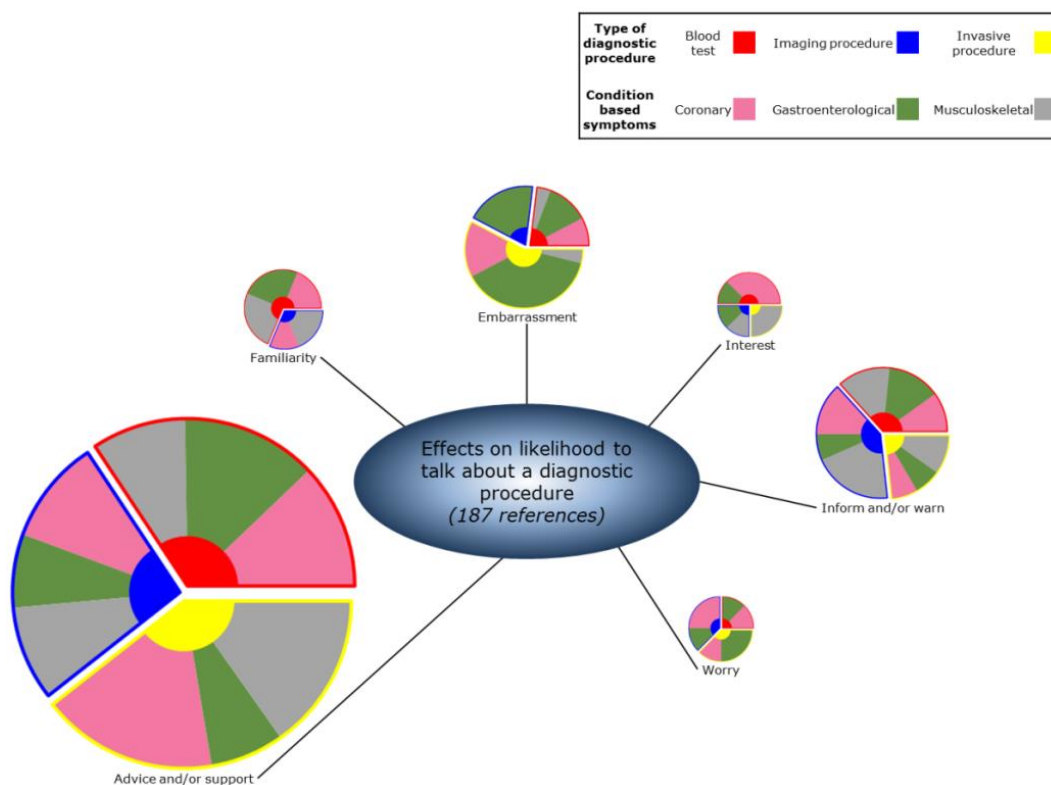
There was a statistically significant effect of the condition based symptoms on participants' likelihood of talking to a family member or friend about the symptoms described in the vignettes,  $H(2) = 6.74, p < 0.05$ . Post hoc tests revealed that participants were significantly less likely to talk about the gastroenterological based symptoms ( $\bar{x} = 5.68, SD = 1.60$ ) compared to the musculoskeletal based symptoms ( $\bar{x} = 6.37, SD = 0.90$ ),  $U = 1879.50, p < 0.0167, r = -0.22$ . There were no statistically significant effects on participants' likelihood of talking to a family member or friend about having a diagnostic procedure, although the likelihood was high for the three types of diagnostic procedure (Table 3.7). The most influential theme that seemed to contribute to this likelihood was *advice and/or support* (Figure 3.8), which refers to receiving advice and/or support from a family member



or friend. Other themes that emerged were *inform and/or warn* (inform family member and/or friend about situation and/or warn them about potential possibilities), *embarrassment*, *familiarity*, *interest* (perceived level of interest of symptoms and/or diagnostic procedure) and *worry* (do not want to worry family member and/or friend about symptoms, diagnostic procedure and/or potential medical condition(s), and/or will wait until diagnostic procedure outcome or result is received).

Type of diagnostic procedure	$\bar{x}$	$SD$
Blood test	5.79	1.52
Imaging procedure	5.77	1.64
Invasive procedure	5.79	1.66

**Table 3.7** Likelihood of talking to a family member or friend about having a diagnostic procedure (minimum rating = 1.00; maximum rating = 7.00)



**Figure 3.8** Effects on likelihood to talk about a diagnostic procedure

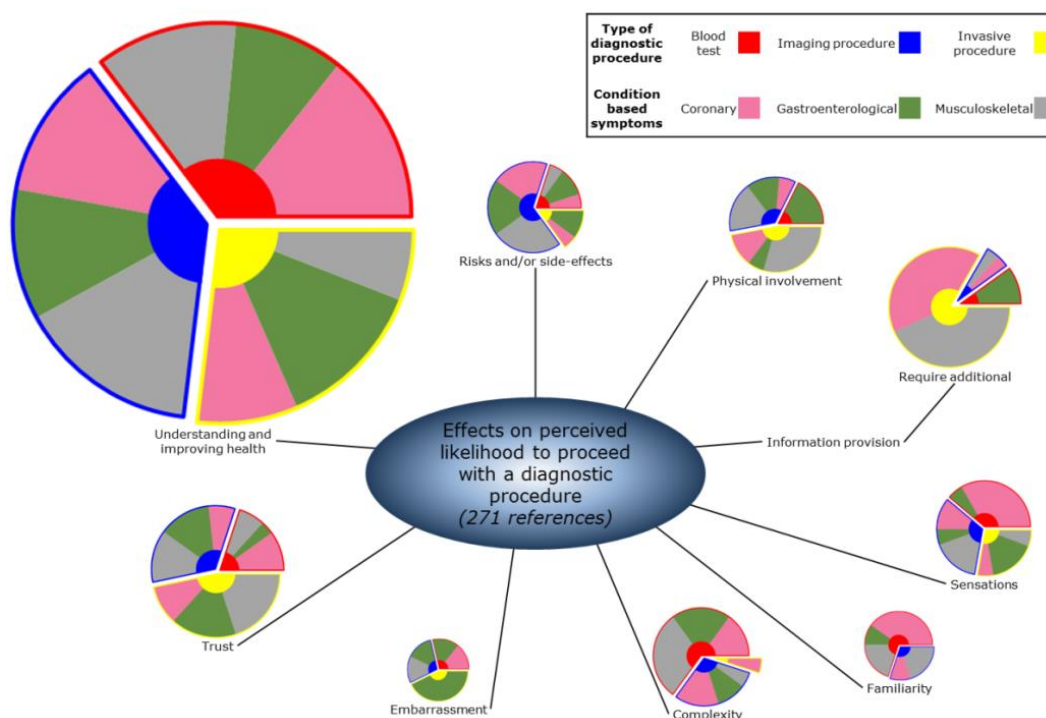
### 3.3.2.5 Likelihood of proceeding with diagnostic procedures

There was a statistically significant effect of the type of diagnostic procedure on participants' perceived likelihood of proceeding with a diagnostic procedure,  $H(2) = 44.81, p < 0.001$ . Post hoc tests revealed that participants were significantly less



likely to proceed with an invasive type of diagnostic procedure ( $\bar{x} = 5.46$ ,  $SD = 1.44$ ) compared to a blood test ( $\bar{x} = 6.56$ ,  $SD = 0.87$ ),  $U = 1245.00$ ,  $p < 0.001$ ,  $r = -0.46$  and an imaging type of diagnostic procedure ( $\bar{x} = 6.62$ ,  $SD = 0.71$ ),  $U = 1166.50$ ,  $p < 0.001$ ,  $r = -0.48$ . Analysis of the type of diagnostic procedure for each set of condition based symptoms yielded similar results for the coronary based symptoms but not for the gastroenterological and the musculoskeletal based symptoms. There was a statistically significant effect of the type of diagnostic procedure for the gastroenterological based symptoms,  $H(2) = 6.79$ ,  $p < 0.05$ , however, post hoc tests revealed that there was no significant difference between a blood test ( $\bar{x} = 6.57$ ,  $SD = 0.79$ ) and the imaging procedure ( $\bar{x} = 6.50$ ,  $SD = 0.96$ ),  $U = 249.00$ ,  $p = 0.911$ ,  $r = -0.02$ , a blood test and the invasive procedure ( $\bar{x} = 5.79$ ,  $SD = 1.56$ ),  $U = 180.50$ ,  $p = 0.025$ ,  $r = -0.3$  and the imaging procedure and the invasive procedure,  $U = 176.50$ ,  $p = 0.035$ ,  $r = -0.31$ . There was also a statistically significant effect of the type of diagnostic procedure for the musculoskeletal based symptoms,  $H(2) = 8.36$ ,  $p < 0.05$ , however, post hoc tests revealed only one significant difference, which was between a blood test ( $\bar{x} = 6.46$ ,  $SD = 1.06$ ) and the invasive procedure ( $\bar{x} = 5.52$ ,  $SD = 1.53$ ),  $U = 167.00$ ,  $p < 0.0167$ ,  $r = -0.37$ .

*Understanding and improving health* was the most influential theme that seemed to contribute to the statistical significance for participants' perceived likelihood of proceeding with a diagnostic procedure (Figure 3.9). There were also a number of other re-emerging themes.



**Figure 3.9** Effects on perceived likelihood to proceed with a diagnostic procedure

### 3.3.3 Preferences for information in the post-diagnosis stage

#### 3.3.3.1 Preferences for receiving diagnostic procedure outcomes or results during or immediately after diagnostic procedures

There were no statistically significant effects on participants' preferences for receiving a diagnostic procedure outcome or result if positive, negative or inconclusive during or immediately after a diagnostic procedure. There was, however, a very high preference for this, if possible (Table 3.8).

Type of diagnostic procedure	Positive		Negative		Inconclusive	
	$\bar{x}$	$SD$	$\bar{x}$	$SD$	$\bar{x}$	$SD$
Blood test	6.73	0.53	6.58	1.19	6.35	1.53
Imaging procedure	6.70	0.60	6.83	0.57	6.33	1.43
Invasive procedure	6.62	0.96	6.55	1.22	6.32	1.54

**Table 3.8** Preference for receiving a diagnostic procedure outcome or result if positive, negative or inconclusive during or immediately after a diagnostic procedure (minimum rating = 1.00; maximum rating = 7.00)

#### 3.3.3.2 Preferences for amount of information to receive when receiving diagnostic procedure outcomes or results

A statistically significant association was not found between the types of diagnostic procedure, as well as the types of diagnostic procedure for each set of condition

based symptoms, and participants' preference for the amount of information they would like to receive when receiving a diagnostic procedure outcome or result. However, there was a statistically significant difference between the three levels of information provision (Table 3.9),  $\chi^2 (2) = 110.88, p < 0.001, \phi = 0.73$ . Participants significantly preferred the third level of information provision compared to the first level,  $\chi^2 (1) = 117.28, p < 0.001, \phi = 0.95$  and the second level,  $\chi^2 (1) = 117.28, p < 0.001, \phi = 0.95$ . There was also a significant difference between the second and first levels,  $\chi^2 (1) = 71.43, p < 0.001, \phi = 0.93$ .

Level	Description	No. (%)
3	Receive diagnostic procedure outcome or result with an explanation about it and what it means, including images and/or numerical data that might be produced from a procedure, and information on what happens next.	126 (60.3)
2	Receive diagnostic procedure outcome or result with an explanation about it and what it means, and information on what happens next.	80 (38.3)
1	Receive diagnostic procedure outcome or result and information on what happens next.	3 (1.4)

**Table 3.9** Preferences for levels of information provision for a diagnostic procedure outcome or result

### 3.3.3.3 Acceptance of different media for the notification of diagnostic procedure outcomes or results

There was a statistically significant effect of the type of diagnostic procedure in the gastroenterological based symptoms on participants' levels of acceptance of a face to face visit with a GP,  $H (2) = 7.26, p < 0.05$ . Post hoc tests revealed that a face to face visit with a GP was significantly more acceptable after a blood test ( $\bar{x} = 6.83, SD = 0.49$ ) compared to the imaging procedure ( $\bar{x} = 6.41, SD = .059$ ),  $U = 152.50, p < 0.01, r = -0.41$ . This was the only statistically significant effect in both phases of statistical analysis for all the different media for the notification of a diagnostic procedure outcome or result. For comparison of the different media to examine which were more acceptable multivariate tests are reported ( $\varepsilon = 0.56$ ) because Mauchly's test indicated that the assumption of sphericity had been violated,  $\chi^2 (77) = 1014.87, p < 0.001$  between the levels of acceptance of the different media.

There was a statistically significant effect of the medium to be used for the notification of a diagnostic procedure outcome or result on participants' levels of

acceptance of the different media,  $V = 0.89$ ,  $F(12, 191) = 134.03$ ,  $p < 0.001$ ,  $\omega^2 = 0.43$ . Face to face with GP ( $\bar{x} = 6.58$ ,  $SD = 0.69$ ) or face to face with specialist clinician ( $\bar{x} = 6.76$ ,  $SD = 0.52$ ) were significantly more acceptable compared to all the other media. With respect to these two, face to face with specialist clinician was significantly more acceptable than face to face with GP,  $p < 0.01$ ,  $r = 0.31$ . The next two acceptable media were phone call from GP ( $\bar{x} = 5.57$ ,  $SD = 1.58$ ) and phone call from specialist clinician ( $\bar{x} = 5.92$ ,  $SD = 1.43$ ). With respect to these two, phone call from specialist clinician was significantly more acceptable than phone call from GP,  $p < 0.001$ ,  $r = 0.72$ . The only new medium to have a mean score above 3.5 was online access to personal healthcare record ( $\bar{x} = 4.38$ ,  $SD = 1.88$ ). This was significantly more acceptable compared to all the other media apart from the four already mentioned and collecting from GP practice reception ( $\bar{x} = 3.98$ ,  $SD = 1.97$ ) and phoning GP practice reception ( $\bar{x} = 3.92$ ,  $SD = 1.97$ ). The levels of acceptance of all the media are provided in Table 3.10.

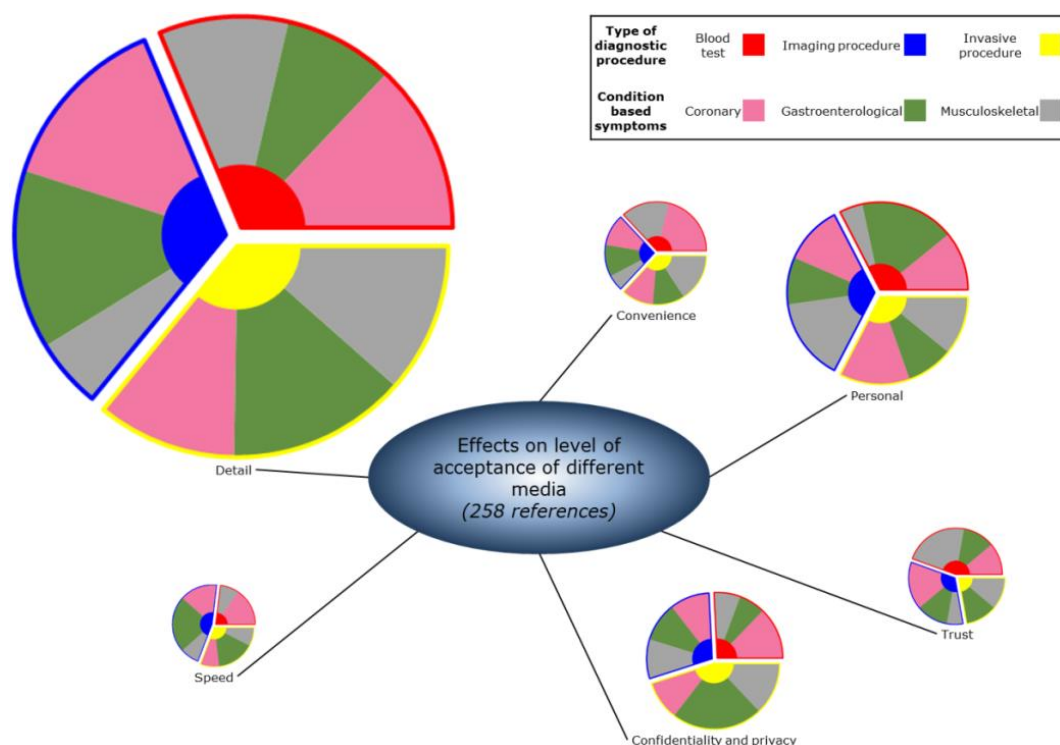
Medium	$\bar{x}$	$SD$
Face to face with specialist clinician	6.76	0.52
Face to face with GP	6.58	0.69
Phone call from specialist clinician	5.92	1.43
Phone call from GP	5.57	1.58
Online access to personal healthcare record	4.38	1.88
Collect from GP practice reception	3.98	1.97
Phone call from GP practice reception	3.92	1.97
Letter through the post	3.63	1.80
Email	3.20	1.82
Interactive kiosk/touchscreen monitor at GP practice (in privacy)	3.00	1.78
Mobile phone application to notify and allow access to outcome or result	2.71	1.78
Call GP practice automated notification phone service	2.62	1.63
Mobile phone text message	2.48	1.69

**Table 3.10** Levels of acceptance of the different media for the notification of a diagnostic procedure outcome or result (minimum rating = 1.00; maximum rating = 7.00)

*Detail* (Figure 3.10) was the most influential theme that affected participants' levels of acceptance of the different media, which refers to level of importance, if any, of detail when a receiving a diagnostic procedure outcome or result, including receiving quality explanations and the ability to ask questions. The seriousness of symptoms and/or diagnostic procedures was factored into some responses and

perhaps the statistical analysis of the quantitative data for the levels of acceptance of the different media may have produced different findings if the type of diagnostic procedure outcomes or results (i.e. positive, negative or inconclusive outcomes or results) were also variables.

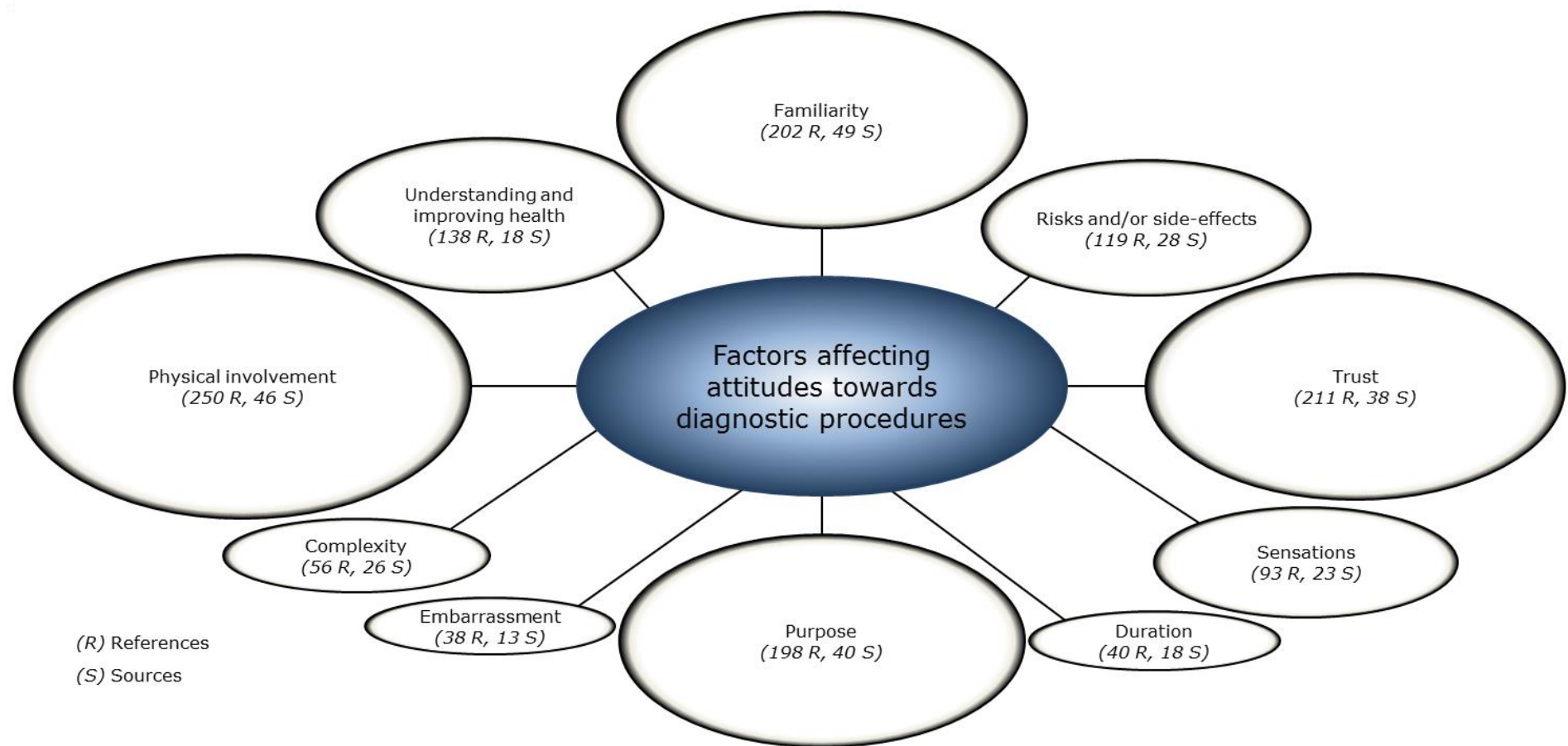
*Personal* was a moderately influential theme to emerge, which refers to the personal nature of a medium and the fact that technology was impersonal. However, there was awareness that in some situations a less personal approach may be acceptable and therefore the use of technology may be satisfactory. Other themes that emerged were *confidentiality and privacy* (level of importance, if any, of confidentiality and privacy when receiving diagnostic procedure outcome or result), *convenience* (level of importance, if any, of convenience of medium for receiving diagnostic procedure outcome or result), *trust* (level of importance, if any, of trust in medium for receiving diagnostic procedure outcome or result) and *speed* (level of importance, if any, of speed of medium to access diagnostic procedure outcome or result).



**Figure 3.10** Effects on level of acceptance of different media

### **3.3.4 Factors affecting attitudes towards diagnostic procedures**

An overall thematic analysis of all the qualitative data, apart from the data from the open responses about levels of acceptance of different media for the notifying of a diagnostic procedure outcome or result, was conducted to establish factors affecting attitudes towards diagnostic procedures. Ten factors were established and are graphically represented in Figure 3.11 and described in Table 3.11. References are accounted for in each factor, which are either positive or negative characterisations of the factors, or impartial remarks. ‘Sources’ are also accounted for in each factor, which are the number of open responses given in the first two sections of the questionnaire for the nine vignettes (possible maximum of 72 sources from 8 open-ended questions and 9 vignettes).



**Figure 3.11** Factors affecting attitudes towards diagnostic procedure

<b>Factor</b>	<b>Description</b>	<b>References</b>	<b>Sources</b>
Physical involvement	Physical involvement with diagnostic procedure (i.e. what is expected and what will happen during diagnostic procedure).	250	46
Trust	Trust in clinicians and/or clinical practice.	211	38
Familiarity	Experience/knowledge/perceived knowledge of diagnostic procedure.	202	49
Purpose	Understanding purpose of diagnostic procedure in response to symptoms.	198	40
Understanding and improving health	Understanding what is causing symptoms so appropriate measures can be taken to improve health.	138	18
Risks and/or side-effects	Perceived level of risks and/or side-effects, if any, of diagnostic procedure.	119	28
Sensations	Perceived level of pain and/or discomfort, if any, during diagnostic procedure and/or use of an alleviating substance.	93	23
Complexity	Perceived level of complexity of diagnostic procedure.	56	26
Duration	Perceived time it will take to complete diagnostic procedure or the requirement for such information.	40	18
Embarrassment	Level of embarrassment, if any, due to symptoms and/or diagnostic procedure.	38	13

**Table 3.11** Descriptions of the factors affecting attitudes towards diagnostic procedures

#### 3.3.4.1 *Physical involvement*

*Physical involvement* (250 references, 46 sources) was the most influential factor and was considered with respect to the information provided about the diagnostic procedures and whether information was considered sufficient or more was required about physical demands:

‘The specialist clinician explained all steps of the procedure for a blood test, although they did not specify how much or how little blood, or whether it would need to be a fasting blood test.’ (Response to blood test for gastroenterological symptoms)

‘Details exactly what I will have to do in an easy to understand manner.’  
(Response to imaging procedure for musculoskeletal symptoms)



‘No real explanation of what would happen to you.’ (Response to invasive procedure for coronary symptoms)

Participants reflected on the body part that was the focus of a diagnostic procedure and its subsequent interaction with an artefact of a procedure:

‘It’s taken from your arm, so not a ‘personal’ area.’ (Response to blood test for gastroenterological symptoms)

‘It’s only my legs being scanned.’ (Response to imaging procedure for musculoskeletal symptoms)

‘Embarrassing having someone inserting objects into you especially in a notoriously unclean area.’ (Response to invasive procedure for gastroenterological symptoms)

Invasive diagnostic procedures were reflected on their ability to permit close inspection of diseased areas:

‘The process seems like the doctor tries to have a direct contact with my heart. It means the result should be accurate enough.’ (Response to invasive procedure for coronary symptoms)

‘Is taking parts of the body affected by the disease and getting pictures of affected parts.’ (Response to invasive procedure for gastroenterological symptoms)

‘It involves examining inner part of my knee and seeing what is going on directly.’ (Response to invasive procedure for musculoskeletal symptoms)

A blood test received a mixture of responses, which included responses about finding veins and apprehension associated with the test:

‘Depend how good they are at drawing blood. I don’t mind needles as long as they get the vein.’ (Response to blood test for coronary symptoms)

‘I always get worried I will faint when have blood taken as other members of my family do.’ (Response to blood test for coronary symptoms)

### 3.3.4.2 *Trust*

Another influential factor was *trust* (211 references, 38 sources). Participants trusted decisions made by GPs, specialist clinicians' recommendations and other healthcare professionals involved in patient care:

‘Although I know little about the test, I trust my GP and the specialist clinician.’ (Response to blood test for musculoskeletal symptoms)

‘Full confidence in the experience of the GP, the clinical experts and staff that operate the X-ray. They know better than anyone the serious nature of their work and the potential dangers that come with it.’ (Response to imaging procedure for coronary symptoms)

‘I would trust the specialist clinicians in their decision that this would be the best course of action to take.’ (Response to invasive procedure for gastroenterological symptoms)

Participants presumed that diagnostic procedures would only be used if safe and of benefit, and that they would not be a waste of time and money:

‘[T]here must be a reasonable level of accuracy or they wouldn't waste time/money doing the test.’ (Response to blood test for musculoskeletal symptoms)

‘Confidence and trust in the medical profession. They wouldn't waste time, money and resources if they did not deem it necessary.’ (Response to imaging procedure for gastroenterological symptoms)

‘I imagine if there was a less painful way they'd do it but this one's pretty effective.’ (Response to invasive procedure for gastroenterological symptoms)

Participants also presumed appropriateness of diagnostic procedures in relation to symptoms and they were either deemed appropriate or a good starting point to better understand the cause of symptoms:

‘Clinical tests examine the blood; confident that a result (positive or negative) will provide some comfort or understanding of underlying illness.’ (Response to blood test for musculoskeletal symptoms)

‘The test has been specifically chosen to help understand the stated symptoms, whether it allows for complete diagnosis of condition or elimination of conditions the test results help to further understand the reason for the symptoms.’ (Response to imaging procedure for coronary symptoms)

‘The problems I’m having are with my bowel movements so it makes sense to check my bowel.’ (Response to invasive procedure for gastroenterological symptoms)

#### 3.3.4.3 *Familiarity*

Participants expressed *familiarity* (202 references, 49 sources) of diagnostic procedures and most expressions were of procedures being regarded as common or standard:

‘Taking blood from the arm is common place and blood testing is frequent.’ (Response to blood test for gastroenterological symptoms)

‘Ubiquity of X-rays – everyone knows the X-ray procedure and how they are done.’ (Response to imaging procedure for coronary symptoms)

‘Fairly common.’ (Response to invasive procedure for gastroenterological symptoms)

Some participants had first-hand experiences of diagnostic procedures whilst others were not aware of some:

‘You know what to expect – most people already know what a blood test is so it’s nothing new.’ (Response to blood test for gastroenterological symptoms)

‘The experience I had helps me a lot about the procedure.’ (Response to imaging procedure for musculoskeletal symptoms)

‘I do not know since know no experience or knowledge of biopsy.’  
(Response to invasive procedure for coronary symptoms)

#### *3.3.4.4 Purpose*

*Purpose* (198 references, 40 sources) was an influential factor and participants were concerned with the purpose of diagnostic procedures, including why they were being used, why they were being used in response to specific symptoms and what they were investigating:

‘I am not clear about the relationship between my knee symptoms and blood tests.’ (Response to blood test for musculoskeletal symptoms)

‘Test is clearly related to the symptoms, but it has not been explained how it will help.’ (Response to imaging procedure for coronary symptoms)

‘Would want to know what they were hoping to find/not find so seems worthwhile, not random.’ (Response to invasive procedure for gastroenterological symptoms)

Diagnostic procedures were, however, considered in an eliminating framework as the first course of action in enabling a better understanding of symptoms:

‘Would like to know what it is testing for but seems good first course of action as easy.’ (Response to blood test for musculoskeletal symptoms)

‘This X-ray gives just 2D images of an area. Maybe a CT scan would give a better understanding. It might, however, be able to identify areas which should be further examined.’ (Response to imaging procedure for coronary symptoms)

‘They will eliminate things as they do more tests.’ (Response to invasive procedure for gastroenterological symptoms)

#### *3.3.4.5 Understanding and improving health*

*Understanding and improving health* (138 references, 18 sources) was a moderately influential factor and a major motivation for the diagnostic procedures. They were

deemed necessary to understand causes of symptoms so diagnoses could be made and treatments begun:

‘I would want my condition to be diagnosed so that I could proceed with the best course of treatment.’ (Response to blood test for gastroenterological symptoms)

‘Would want to get to bottom of what could be a life-threatening problem.’ (Response to imaging procedure for coronary symptoms)

‘If the specialist feels this is the correct test and it is necessary in the pathway to diagnosis and treatment then it would need to be done.’ (Response to invasive procedure for musculoskeletal symptoms)

Participants were also willing to endure uncomfortable diagnostic procedures if they were to be of benefit:

‘If I want to know the underlying illness of these symptoms, I would be prepared to have potentially uncomfortable tests to find out.’ (Response to blood test for musculoskeletal symptoms)

‘If it was necessary, I would grin and bare it! Want to know what the clinical diagnosis is.’ (Response to invasive procedure for coronary symptoms)

#### **3.3.4.6 Risks and/or side-effects**

Another moderately influential factor was *risks and/or side-effects* (119 references, 28 sources) and participants estimated levels of risks and/or side-effects of diagnostic procedures, which ranged from very safe to fatal:

‘An X-ray seems very safe.’ (Response to imaging procedure for coronary symptoms)

‘It’s my heart! If anything goes wrong then I could die!’ (Response to invasive procedure for coronary symptoms)

Information included in vignettes about side-effects was regarded positively and did not cause any worry. Although information about radiation from imaging procedures received a mixed response:

‘Slight apprehension as the X-ray clinician stepping out while the procedure was taking place but reassured by the ubiquity of X-ray investigations and the assurances of no side effects.’ (Response to imaging procedure for coronary symptoms)

‘A simple step-by-step guide has been provided, my fears at having the clinician leave the room are discounted by the information that there is only a low level of radiation.’ (Response to imaging procedure for musculoskeletal symptoms)

#### 3.3.4.7 *Sensations*

Participants perceived *sensations* (93 references, 23 sources) that patients would experience during diagnostic procedures but if they did not they have any perceptions they would prefer to be informed of any pain and/or discomfort that may be experienced:

‘There appears to be no explanation regarding whether to expect any pain in the test.’ (Response to blood test for musculoskeletal symptoms)

‘Not enough information – as the test involves internal probing I would have thought information about the effect on the patient would be there rather than what the procedure does.’ (Response to invasive procedure for gastroenterological symptoms)

Information about the use of anaesthetics or sedatives was also required:

‘I don’t know what state I would be in i.e. anaesthetic given, lying down or sitting up. Afraid of potential pain and un-comfortableness.’ (Response to invasive procedure for coronary symptoms)

‘Information on any anaesthetic to be given during the test would have been helpful.’ (Response to invasive procedure for musculoskeletal symptoms)

#### 3.3.4.8 Complexity and duration

*Complexity* (56 references, 26 sources) and *duration* (40 references, 18 sources) were two of the three least influential factors. Participants categorised the level of complexity of diagnostic procedures from simple to complex, and estimated the duration of procedures and the time they would take to complete:

‘Blood tests are not complicated procedures.’ (Response to blood test for coronary symptoms)

‘Takes 20 minutes at most.’ (Response to imaging procedure for coronary symptoms)

Some diagnostic procedures were jointly categorised and estimated, and others required further information about the time they would take to complete:

‘Test seems simple and quick.’ (Response to blood test for musculoskeletal symptoms)

‘The only information lacking which I would want to know is how long the scan would take.’ (Response to imaging procedure for gastroenterological symptoms)

#### 3.3.4.9 Embarrassment

The least influential factor was *embarrassment* (38 references, 13 sources) and participants felt embarrassment towards some diagnostic procedures and to others, none. Symptoms were associated with levels of embarrassment, which tended to infer embarrassment of procedures. Embarrassment was also considered socially:

‘The embarrassment of the situation and symptoms would put me off talking about the test.’ (Response to imaging procedure for gastroenterological symptoms)

‘They may not wish to know about rectum examinations.’ (Response to invasive procedure for gastroenterological symptoms)

## 3.4 Discussion

The study took a human factors approach to medical devices from the perspective of potential patients in the context of diagnosis. Vignettes were used to create diagnostic medical scenarios and 10 factors were established that affected attitudes towards diagnostic procedures (Figure 3.11). They represent the themes that emerged from a thematic analysis of qualitative data from open responses that followed a number of closed questions in a questionnaire. Physical involvement, trust, familiarity and purpose were the most influential factors that affected attitudes, whilst embarrassment, duration and complexity were the least influential. Understanding and improving health, risks and/or side-effects and sensations were the other three factors that were moderately influential.

The factors were consistently present as themes in the thematic analyses in the first and second sections of the questionnaire. Their presence was also derivative, which was the case in the thematic analysis for effects on level of satisfaction with information (Figure 3.2). In this analysis, physical involvement is derived from the two sub-themes of information provision and whether information was comprehensive or additional information was required about physical involvement with diagnostic procedures. The theme also correlates with the significant findings because participants were significantly less satisfied with information provided about the invasive procedures in comparison to a blood test and the imaging procedures. There was a slight variation in the findings for the gastroenterological symptoms since there was not a significant difference between the imaging procedure (computed tomography (CT) scan) and the invasive procedure (colonoscopy). Familiarity may have contributed to this because colonoscopy is a well-documented investigation due to the media attention it receives about its use in colorectal cancer screening programmes (Schroy *et al.*, 2008); an uptake in colorectal cancer screening was observed in England following media coverage of the Flexible Sigmoidoscopy Trial (Lo *et al.*, 2012). Of the 62 participants who reported that they had experienced at least one diagnostic procedure only 8.1% of these had experienced an invasive procedure, which corresponds with the familiarity factor and their satisfaction levels. It is commented in a cancer patient survey that young patients need to receive information that is given in a fashion that



recognises their lack of hospital experiences (Department of Health, 2010, p. 11); findings suggest that information would be of particular benefit to patients who are experiencing a diagnostic procedure for the first time, especially invasive procedures.

There was a slight variation in the significant findings for preferences when receiving information about what suspected medical condition(s) were being investigated or tested. There were no significant differences between a blood test, the imaging procedures and the invasive procedures, but for the musculoskeletal symptoms there was a significant difference between the imaging procedure (X-ray) and the invasive procedure (arthroscopy). The purpose factor provides some rationale for this because this factor is about understanding the purpose of a diagnostic procedure in response to symptoms and perhaps participants had a better comprehension of what an X-ray could be investigating compared to an arthroscopy, which had the lowest and highest mean scores, respectively, of all the diagnostic procedures.

There was a very high preference for receiving information about what suspected medical conditions(s) were being investigated or tested in the case of a blood test, the imaging procedures and the invasive procedures (Table 3.3), with a similar preference for information about possible clinical pathways in the event of a positive, negative or inconclusive outcome or result (Table 3.4). Preparation was the major theme to affect preference for information about possible clinical pathways (Figure 3.3) and there are a near equal proportion of references between a blood test, the imaging procedures and the invasive procedures in the theme.

References are proportional between a blood test, the imaging procedures and the invasive procedures for the trust theme that emerged in the thematic analyses for effects on perceived level of accuracy of a diagnostic procedure (Figure 3.4) and effects on level of confidence in a diagnostic procedure (Figure 3.5). Trust was an influential theme, as well as an influential factor, and this was unexpected since the trust was in clinicians and/or clinical practice. What makes this unexpected is the fact that participants had no interaction with clinicians or other healthcare professionals, nor any experiences of being within a healthcare setting with the requirement or expectation of a diagnostic procedure. There was also no specific

trust in diagnostic procedure or medical technology, although technology itself was a minor theme. This does not fit with Montague and Asan's (2012) patient trust in medical technology model (Figure 2.3), which depicts patients' trust in medical technology as being dependent on trustworthy characteristics of the technology, trust in clinician (physician) or other healthcare professional (care provider), and trust in how the technology is used by the healthcare professional. Participants' trust is typical of patients in paternalistic clinician-patient relationships (see page 22 for recap) and is similar to that shown by patients in a study conducted by Zener and Bernstein (2011). Patients in Zener and Bernstein's study had trust in their surgeon in the neurological operating room, which extended to other healthcare professionals involved in their care and was important in alleviating anxiety.

There were no significant differences between the three diagnostic procedures for accuracy and confidence levels, although perceptions were high (Tables 3.5 and 3.6). Familiarity was a factor that was present as a theme in the thematic analysis for effects on perceived level of accuracy, whilst information provision was a theme that was present in both analyses. For effects on perceived level of accuracy, generic information provided in the vignettes about the accuracies of the procedures and that they are part of a 'process of elimination' was influential, especially for the invasive procedures and specifically the invasive procedure for the musculoskeletal symptoms. A similar requirement for information was required between a blood test, the imaging procedures and invasive procedures for effects on perceived level of accuracy and effects on level of confidence. This was because there was uncertainty about accuracies of and confidence in the procedures.

Technology, as already mentioned, was a minor theme that emerged in the thematic analyses for effects on perceived level of accuracy and effects on level of confidence, and refers to the perceived level of quality of technology used in the diagnostic procedures. The majority of references were for the imaging procedures and specifically the imaging procedure for the gastroenterological symptoms; there were no references for a blood test. Perhaps the ability to view the inside of the body was regarded as more advantageous for the imaging procedure for the gastroenterological symptoms compared to the other imaging procedures for the coronary and musculoskeletal symptoms. Vignettes were designed to portray

diagnostic procedures with varying degrees of technological complexity, physical demands on the patient and informational output. Although physical demands on the patient had significant effects with the invasive procedures and physical involvement was the most influential factor, technological complexity and informational output had little impression. Trust, familiarity and purpose, as well as the three other moderately influential factors, were more meaningful to participants. However, complexity had some meaning, although minimal and not specific to technological complexity (i.e. sophistication of components and processes) but rather to complexity range (i.e. from simple to complex).

Seven of the 10 factors emerged as themes in the thematic analysis for effects on level of apprehension about having a diagnostic procedure (Figure 3.6). Physical involvement was the most influential theme in this analysis, followed by familiarity, risks and/or side-effects and sensations. Participants were significantly more apprehensive about having the invasive procedures in comparison to a blood test and the imaging procedures, and the four themes mentioned replicate this difference quite well for the three procedures with respect to the proportion of references. There was no significant difference between the invasive procedure and the imaging procedure for the gastroenterological symptoms, and familiarity may have contributed to this as it did for effects on level of satisfaction with information. Both of these analyses demonstrate that familiarity for the invasive procedures is only present for the gastroenterological symptoms.

Participants were significantly more embarrassed about having the invasive procedures compared to a blood test and the imaging procedures. Physical involvement was present again as the most influential theme in the thematic analysis (Figure 3.7) and there are a near equal proportion of references between the three procedures in the theme. Significance was only repeated for the gastroenterological symptoms and the embarrassment factor reflects the importance of symptoms because symptoms were associated with levels of embarrassment, which tended to infer embarrassment of diagnostic procedures. Perhaps this is another reason why the majority of references in the technology theme that emerged in the thematic analyses for effects on perceived level of accuracy and effects on level of confidence were for the imaging procedure for the

gastroenterological symptoms. Participants were also significantly less likely to talk about the gastroenterological symptoms to a family member or friend in comparison to the coronary symptoms and musculoskeletal symptoms. However, there were no significant differences for talking about a diagnostic procedure in which the likelihood of talking was high (Table 3.7), and of particular importance was receiving advice and/or support (Figure 3.8).

Participants were significantly less likely to proceed with the invasive procedures in comparison to a blood test and imaging procedures, and a similar significance was only repeated for the coronary symptoms. The most influential theme that seemed to contribute to this significance was understanding and improving health (Figure 3.9), and the proportion of references for the invasive procedures are fewer compared to a blood test and the imaging procedures in this theme. However, the likelihood of proceeding with a diagnostic procedure was high to very high for all procedures, demonstrating the influence of understanding and improving health. This may contribute to relieving patient uncertainty, which has been reported in studies where diagnostic procedures have been utilised to diagnose or rule out medical conditions (Lapsley, 2013; Marton *et al.*, 1982; O'Connor *et al.*, 1994).

Relieving uncertainty may have contributed to the very high preferences for receiving a diagnostic procedure outcome or result if positive, negative or inconclusive during or immediately after a diagnostic procedure (Table 3.8). There were no significant differences between a blood test, the imaging procedures and the invasive procedures, but the very high preferences are consistent with the very high preferences participants had for receiving information about suspected medical condition(s) being investigated or tested, and information about possible clinical pathways. Participants also significantly preferred the most detailed level of information when receiving a diagnostic procedure outcome or result (Table 3.9); there were no significant differences between a blood test, the imaging procedures and the invasive procedures for the amount of information participants preferred. The very high preference for receiving a diagnostic procedure outcome or result during or immediately after a procedure, as well as the preference for detailed information, fits the three characteristics Elder and Barney (2012) described that were important to patients for the notification of a hypothetical test result for a

mildly elevated lipid profile. These were: 1) timeliness; 2) desire for clinician interpersonal connection (which would occur during or immediately after a procedure); and 3) desire for a hard copy (i.e. written result).

There was only one significant difference from all the media for acceptance of a medium for the notification of a diagnostic procedure outcome or result. For the gastroenterological symptoms a face to face visit with a GP was significantly more acceptable following a blood test in comparison to the imaging procedure. This medium was the second significantly acceptable medium overall, following a face to face visit with a specialist clinician. These two healthcare professionals were also included in the third and fourth significantly preferred media, with a phone call from a specialist clinician third and a phone call from a GP fourth. Detail was the most influential theme affecting acceptance of the different media (Figure 3.10), and in which there is a near equal proportion of references between a blood test, the imaging procedures and the invasive procedures in the theme. Another theme, personal, which was moderately influential and refers to the personal nature of a medium, had proportional references between the three procedures.

Participants' current use of new media, including use of smart phones and social media, was not examined in this study, although one might assume with such a young and educated sample that usage of new media would be high. This is why the low preference participants had for new media (Table 3.10) was quite unexpected, which was also mentioned by Jo Harcombe from the UK National Screening Committee (UK Screening Portal, 2013) who found this quite an interesting and surprising finding. Research has suggested that younger patients tend to be more comfortable with and more likely to find new media acceptable in comparison to older patients (Couper *et al.*, 2010; Grimes *et al.*, 2009; Leekha *et al.*, 2009), but as mentioned in the results section, perhaps if diagnostic procedure outcomes or results were variables then acceptance levels may have varied also. This was observed in a study conducted by Grimes *et al.* (2009) who examined patient preferences for normal and abnormal laboratory test result notifications. For normal results patients preferred a mailed letter (31.7%), phone call from clinic staff (23.7%) and clinician phone call (22.8%); however, for abnormal results patients preferred a clinician phone call (64.3%), phone call from clinic staff

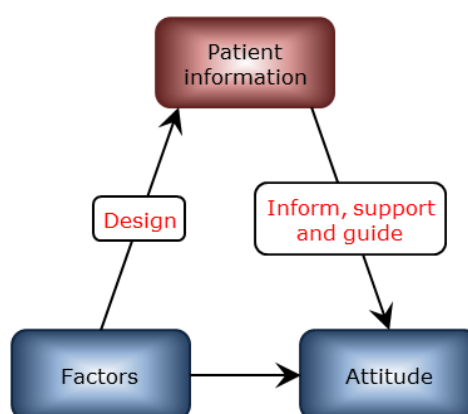
(16.4%) and a clinician visit (9.9%). Given NHS England's (2013, p. 6) aim for all patients to be able to access their GP records online by 2015 and the Department of Health's Digital first initiative (Innovation Health & Wealth, 2012), an effective strategy for these to be successful could be ensuring detail as described in the detail theme, including patients receiving quality explanations and having the ability to ask questions.

The study aimed to understand attitudes towards diagnostic procedures and informational needs and preferences, as well as to explore interacting dimensions. Participants had high to very high informational needs and preferences for information in the pre- and post-diagnosis stages, with higher needs and preferences in the pre-diagnosis stage when symptoms required an invasive procedure to further investigate them. Trust was influential on perceived accuracy of and confidence in diagnostic procedures, although information about procedure accuracies would be appreciated by patients. Since physical involvement was influential on apprehension and embarrassment levels; it could be suggested when patients require an invasive procedure that information at the investigating-diagnosis stage would be of particular benefit. In a study conducted by Davison and Breckon (2012) where decision-making and information preferences of prostate cancer patients on active surveillance were examined, they found anxiety was associated with an increased requirement for information provision. The factors established provide a constructive understanding of attitudes towards diagnostic procedures and they have the potential to guide the design of patient information. This concept is explored in the next section.

### **3.5 User centred design concept for patient information**

The factors affecting attitudes towards diagnostic procedures (Figure 3.11) inspired a concept to design information based on factors. For diagnostic procedures the factors established would provide guidance for information to include in a patient information resource (i.e. content) and for the organisation of the information (i.e. content structure). The logic behind the concept is that the factors represent the themes that were most important to participants, and if information is representative

of these then patient engagement with and retention of information could be facilitated and decision-making aided, which would be important for patients to make decisions that are satisfactory to their values and preferences when they have healthcare options and choices. The factors could also contribute to patient information guidelines. Figure 3.12 graphically represents the ‘factors based approach’ to the design of patient information, which aims to inform, support and guide patients.



**Figure 3.12** Factors based approach to the design of patient information

The factors based approach to the design of patient information has taken inspiration from Ajzen’s theory of planned behaviour, which depicts beliefs as the informational foundation upon which intentions to perform behaviour are determined and behavioural beliefs determine attitudes towards behaviours (2005, p. 126, see pages 25-26 for recap). The factors, which contain positive and negative characterisations of diagnostic procedures as well as impartial remarks, represent behavioural beliefs, which determine behaviour through affecting attitude towards and intention to perform behaviour. This is graphically represented in Figure 3.13 to demonstrate how characteristics, whether positive, negative or neutral, determine behaviour through affecting attitude.



**Figure 3.13** Characteristics as the informational foundation of behaviour

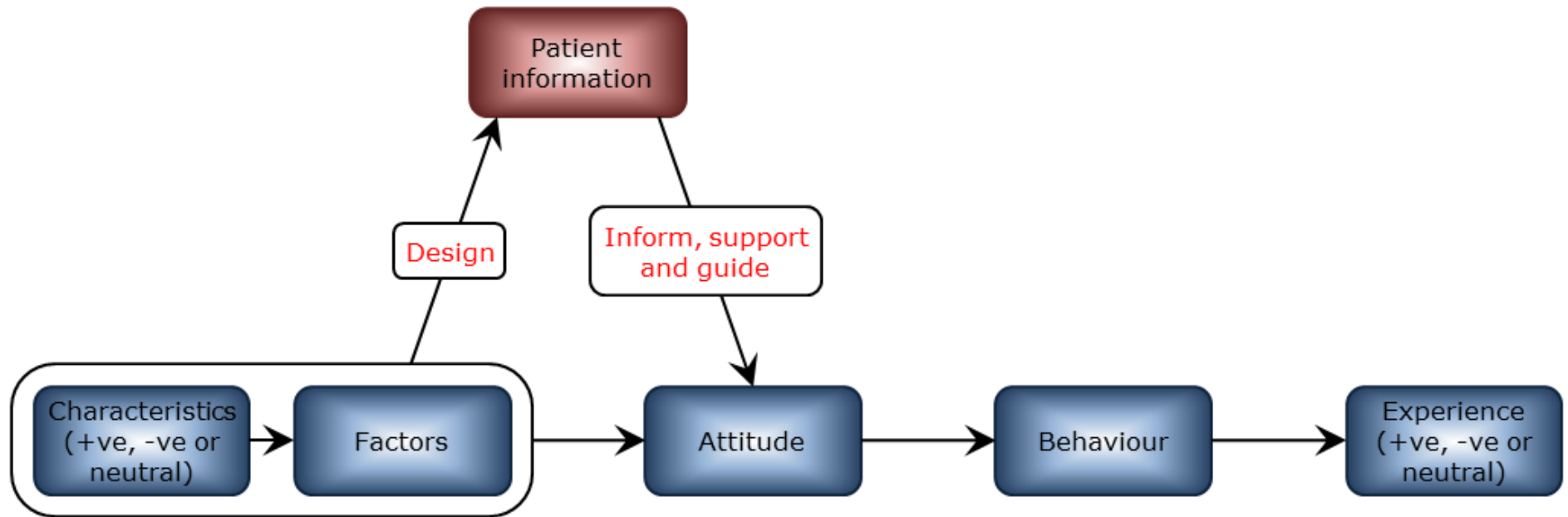
Behaviour itself can affect experience since it will have emotional, physical, psychological and sociological effects, which could be positive, negative or neutral. Experience is included in Figure 3.14.



**Figure 3.14** Characteristics as the informational foundation of behaviour with behaviour affecting experience

Therefore designing patient information based on factors affecting attitudes could contribute to quality patient experiences through appropriately informing, supporting and guiding patients. This is graphically represented in Figure 3.15, which could also minimise expectation mismatch with experience. This was discussed in the literature review (Chapter 2) following the theory of planned behaviour (and the health belief model) (see pages 27-28 for recap).





**Figure 3.15** Factors based approach to the design of patient information with characteristics as the informational foundation of behaviour and behaviour affecting experience

As already mentioned, the factors based approach to the design of patient information has taken inspiration from Ajzen's (2005, p. 126) theory of planned behaviour, with the concept of the approach to provide guidance for information to include in a patient information resource and the organisation of the information. This theory led approach could be one that satisfies Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. And as already mentioned, the factors could contribute to patient information guidelines, which there are currently no specific guidelines for information designers to follow when designing patient information for when patients have options of or require investigations or tests. A practical guide was considered a useful tool by the majority of healthcare information producers who took part in a recent survey by the Patient Information Forum (2013b, p. 10).

The factors have been established using qualitative methodology, which conforms to Glenton's (2002) comments about the use of qualitative methods with respect to the development of patient centred healthcare information. They have been established in the context of diagnosis so the factors are limited to investigations and tests in this context. The next chapter will therefore examine attitudes towards investigations and tests in the context of screening. This may result in some of the factors established in the diagnostic context re-emerging, although it is expected that others will emerge due to the context of screening. This may include factors that have a direct effect on behaviour since patients in a screening context are asymptomatic (i.e. no symptoms present), and attitudes may affect whether patients decide to be or not to be screened. Qualitative methodology will be used once again to establish factors and, following this, factors from both contexts will be considered to guide the design of a patient information resource, with the aim of examining the factors based approach to the design of patient information.

## **3.6 Methodology considerations**

The use of vignettes was appropriate with respect to the young demographics of the majority of participants, to compensate for their lack of healthcare experiences. This is one of the strengths of vignettes (Barter and Renold, 2000), although they

are limited by their hypothetical nature, which can limit the generalisation of responses to them (Ogden *et al.*, 2009), as can the likelihood of the participants being less likely to encounter the diagnostic procedures used in the vignettes compared to an older population. Since responses may be limited what has not been examined in this study is the extent to which participant responses would be the same if they were to actually encounter the procedures in the future. This was a trade-off as well as a limit because it avoided bias from past experiences, and enabled research where practical and ethical issues would have made it a difficult study to conduct. Another trade-off, which was in the design of the vignettes to ensure they were balanced, was the exclusion of information about pre-procedural requirements, alleviating substances and post-procedural effects. Although these are important aspects of patient experiences, the study was focussed on perceptions rather than experiences, and on the medical devices used in the diagnostic procedures rather than what happens before or after the procedures.

The vignettes were designed using the Map of Medicine (2013) and facilitated the collection of an assortment of valuable data, and supported the user centred approach to the design, development and implementation of patient information. They enabled participants of a mostly young demographic to contribute to research where they may otherwise be unable to, and to do so with comfort expressing their opinions and without conforming to impression management biases (Alexander and Becker, 1978; Torres, 2009). Vignettes that have been used in recent healthcare research include vignettes describing symptoms in a study conducted by Herndon *et al.* (2008) and vignettes representing two alternative approaches to patient notification of test results in a study conducted by Elder and Barney (2012).

In the statistical analysis the Bonferroni correction was applied to the Mann-Whitney test (the independent *t*-test was not required) to ensure that the Type I errors did not build up to more than 0.05. Statistical significance was therefore valued at  $p < 0.0167$ , which limited statistical power and consequently quantitative findings. Also for the second phase of statistical analysis, the maximum number of participants for this analysis was 24, compared to 72 for the first phase. A bigger sample may have provided more conclusive results in the second phase of analysis

since Cohen *et al.* (2007, p. 101) recommend an ideal minimum sample size of 30 per variable.

The qualitative data were collected in response to open-ended questions in the questionnaire, which were enquiring about selected ratings in response to closed questions about the diagnostic procedures used in the vignettes. Therefore it could be suggested that the qualitative data are limited to the procedures in the vignettes and the selected ratings that were enquired about. However, the questionnaire, as well as the vignettes, was developed following sufficient piloting to ensure valid data were collected for a range of questions, and themes in the thematic analyses differentiate between the three types of diagnostic procedure and the three sets of condition based symptoms so they can be appreciated for their influence as a whole but also specifically with respect to the variables.

Finally, the analysis of the qualitative data was from the perspective of the researchers involved in this study. If researchers with different perspectives analysed the data, the interpretation, coding and theming of the data may vary. Respondent validation or ‘member checking’ (Creswell and Miller, 2000; Mays and Pope, 2000) could have been used to examine the credibility of the themes and the factors, which might have involved a focus group, resulting in further data collection and analysis. And Cohen’s Kappa coefficient (Cohen, 1960) could have been used to provide a statistical measure for inter-rater reliability for qualitative coding, which has been used by Roebuck *et al.* (2001) and Hruschka *et al.* (2004) in healthcare research, and would ideally have required a researcher not connected with the study design to analyse a selection of the open responses. However, the thematic analyses were rigorously conducted and peer debriefing (Creswell and Miller, 2000) was used, so the themes that emerged and the factors that were established were discussed and rationalised to ascertain their basis and reasoning.

### 3.7 Conclusion

Ten factors were established that affected attitudes towards diagnostic procedures (Figure 3.11). Physical involvement, trust, familiarity and purpose were particularly influential on participants’ preferences for information at the pre-diagnosis stage,

attitudes towards the procedures and preferences for information at the post-diagnosis stage. Participants had high to very high informational needs and preferences in the pre- and post-diagnosis stages, and meeting these will contribute to quality patient experiences. Information will be of particular importance in the pre-diagnosis stage when patients require an invasive procedure, as will ensuring sufficient detail in the diagnostic procedure outcome or result in the post-diagnosis stage. Additionally, information will most probably be beneficial in the investigating-diagnosis stage when patients require an invasive procedure.

Other factors that were established include understanding and improving health, risks and/or side-effects and sensations, which were moderately influential, and embarrassment, duration and complexity, which were minor. Overall the factors provide a constructive understanding of attitudes towards diagnostic procedures, which has inspired the potential to guide the design of patient information using a 'factors based approach' (Figure 3.12). This potential will be developed further in the next chapter, which examines men's attitudes towards abdominal aortic aneurysm screening and their informational needs and preferences.

## CHAPTER 4

# Men's attitudes towards abdominal aortic aneurysm screening and their informational needs and preferences

### 4.1 Introduction

Chapter 4 reports the findings from a study that takes a human factors approach to medical devices from the perspective of men in the context of screening. The study aimed to understand:

- attitudes towards abdominal aortic aneurysm (AAA) screening, and
- informational needs and preferences.

The study is in response to the first two research questions, which are as follows:

- 1) What factors affect patient attitudes towards diagnostic and screening procedures?
- 2) What are patient informational needs and preferences when encountering diagnostic and screening procedures?

The study is one of two that will contribute to a user centred approach to the design, development and implementation of patient information. This is outlined in the research approach (see pages 60-62 for recap), and will involve findings from this and the first study (Chapter 3) being incorporated into the design of patient information used in the last two studies (Chapters 5 and 6). The last two studies are in response to the third research question, which is as follows:

- 3) How does patient information based on factors affecting patients' attitudes towards diagnostic and screening procedures affect the value of the information?

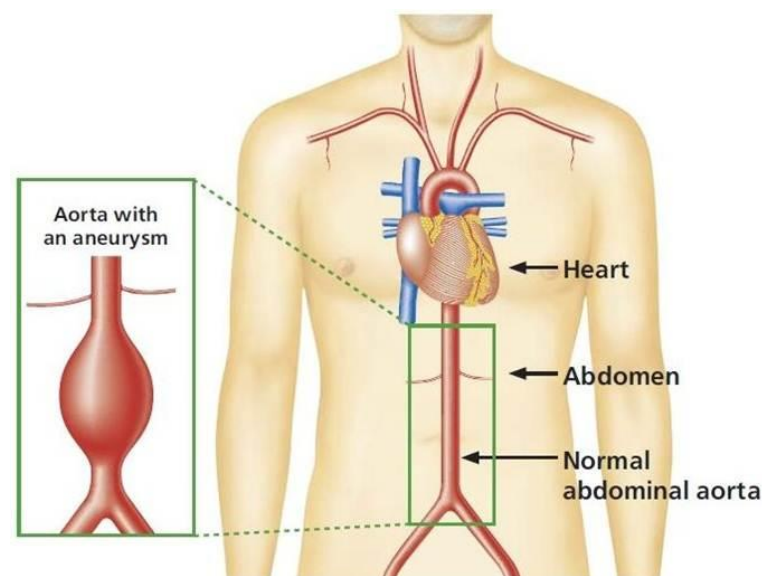
Ten factors affecting attitudes towards diagnostic procedures were established in the first study (see pages 87-96 for recap), inspiring a user centred design concept for patient information – a 'factors based approach' to the design of patient

information (see pages 103-107 for recap). This study will develop further the potential of the factors based approach by establishing factors affecting attitudes towards AAA screening. This may result in some of the factors that were established in the diagnostic context re-emerging. However, it is expected others will emerge due to the context of screening.

## 4.2 Methodology

### 4.2.1 An introduction to abdominal aortic aneurysm screening

The aorta is the largest artery in the body and the abdominal aorta is a section of the aorta that runs straight down through the abdomen area. An AAA is a degenerative condition where the wall of the abdominal aorta becomes weak and swells, causing an aneurysm (Figure 4.1). If the aneurysm gets too large it could rupture, which will more than likely result in death (Ashton *et al.*, 2002; Thompson *et al.*, 2009).



**Figure 4.1** An abdominal aortic aneurysm (Source: NHS Abdominal Aortic Aneurysm Screening Programme)

The condition particularly affects elderly men and screening programmes have been established to screen men (women in some programmes also) as a cost effective method of reducing AAA related mortality (Stather *et al.*, 2013). In the United Kingdom, screening for AAA is the latest screening programme to be funded by the

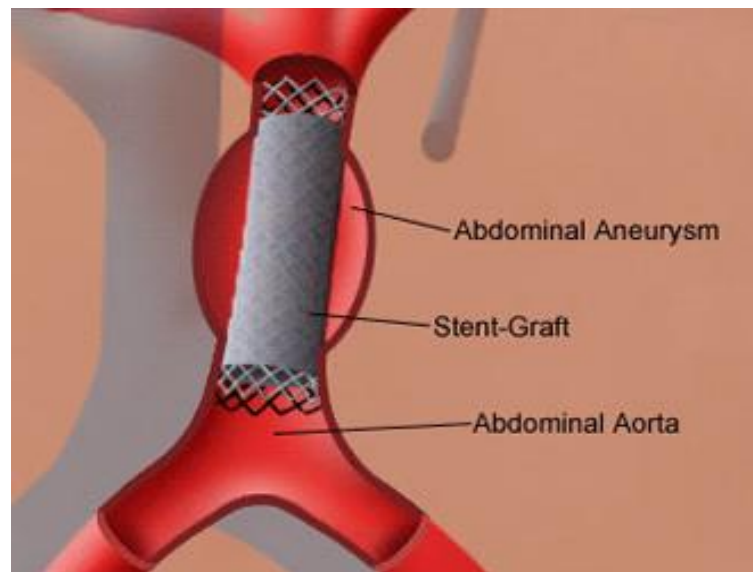
NHS where men aged 65 years are invited to be screened using an ultrasound scan (Figure 4.2). The screening programme is not risk-free, however, and Brownsword and Earnshaw (2010) mention that it is the first funded programme where there is certain potential of mortality of an otherwise healthy individual. This could occur if a man is screened, diagnosed with a large AAA and has a surgical intervention to prevent its rupture, but dies during or soon after the intervention.



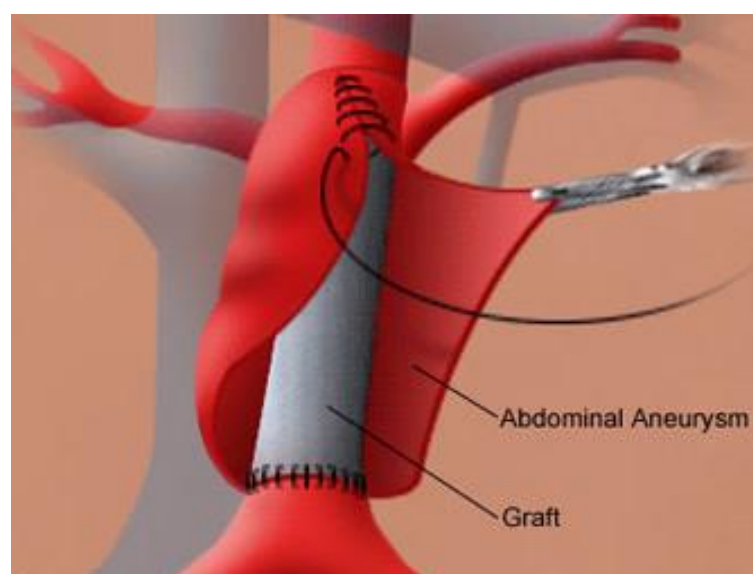


**Figure 4.2** Screening for an abdominal aortic aneurysm using an ultrasound scan (Source: BBC East Midlands Today)

There are two types of surgical intervention: 1) endovascular surgery (also known as endovascular repair) (Figure 4.3); or 2) open surgery (also known as open repair) (Figure 4.4). The former is a keyhole surgery where an AAA is strengthened with a stent graft, and the latter is a surgical procedure through the abdomen where an AAA is replaced with a graft. The NHS Abdominal Aortic Aneurysm Screening Programme for the year 2011-2012 reports that out of 86 men who had endovascular surgery there were two deaths within 30 days of the surgery, and out of 101 men for open surgery there was one death within 30 days (2012).



**Figure 4.3** Endovascular surgery to treat an abdominal aortic aneurysm (Source: The University of Chicago Medical Center)



**Figure 4.4** Open surgery to treat an abdominal aortic aneurysm (Source: The University of Chicago Medical Center)

As well as the risk of death during or soon after surgery, there is the consideration of emotional and psychological distress. There is distress of living with a large AAA and knowing the risk of mortality if it were to burst, as may be experienced by men diagnosed with a small AAA. There is also further distress for men who have a large AAA, are healthy enough to have one of the two surgical interventions (some men might not be) and elect to do so knowing the risk of mortality associated with the surgeries. It is therefore important that men invited for AAA screening are informed of the negative as well as the positive features of being screened, which is discussed in the ‘information’ dimension of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009, see pages 46-47 for recap).

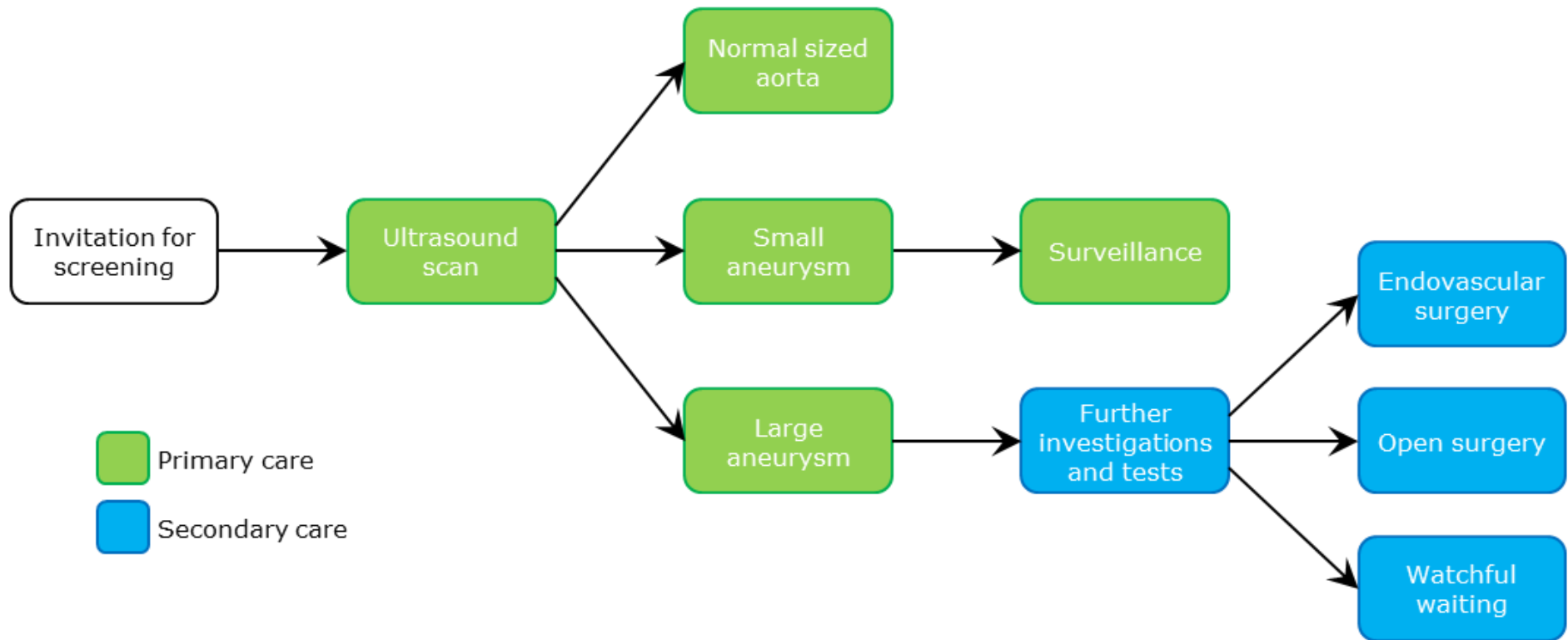
The NHS Abdominal Aortic Aneurysm Screening Programme has developed a decision aid (DA) (also known as decision support technology) to encourage and facilitate decision-making for men invited to AAA screening. However, rather than encourage and facilitate informed shared decision-making, the emphasis is on informed independent decision-making. This is not to suggest that men cannot discuss their decision with a relevant clinician or other healthcare professional, rather that the process of being informed and deciding whether to be or not to be screened is a very independent one, which is supported by the chosen medium of the DA, an online medium (BMJ Group, 2012b).

A relationship was formed with the NHS Abdominal Aortic Aneurysm Screening Programme. They provided a number of materials in relation to AAA screening and the DA, including a draft version of the core text of the DA. Initial ideas about the content and design of the DA were developed at a two-day workshop organised by the NHS Abdominal Aortic Aneurysm Screening Programme, which included advice about DAs provided by Paul Hewitson, who was then Research Fellow at the Department of Primary Health Care, University of Oxford. There was no information provided about additional time it took to develop the draft version of the core text or other materials, but their development was top-down since they were produced following one or more design iterations from a clinician, other healthcare professional and researcher perspective. This may not truly reflect user centred design, which is discussed in the literature review (see pages 39-43 for

recap). The content of the draft version was used in this study to examine men's attitudes and their informational needs and preferences.

#### **4.2.2 Study design**

In order to design a study that portrayed AAA screening and its stages, from the screening procedure to the stages that patients may journey depending on procedure outcome, the Map of Medicine (2013) was referred to. The Map of Medicine, as explained in the first study, is an online proprietary resource providing clinicians and other healthcare professionals in the United Kingdom with evidence based clinical pathways. This enabled an objective appreciation of the AAA screening clinical pathway, which is provided in Appendix 9 as a screenshot, and a simplified version of this is graphically represented in Figure 4.5. The study design was developed from this with interviews being used as the method for data collection and two information resources supplementing the interview process: 1) handouts to inform about the stages of AAA screening; and 2) a booklet with the proposed content of the DA.



**Figure 4.5** Simplified version of the abdominal aortic aneurysm screening clinical pathway provided by the Map of Medicine (2013)

Table 4.1 describe the stages the handouts were divided into and the sections of the DA booklet. Information in the handouts was concise and very much matter of fact; however, information in the booklet was considerably more informative and comprehensive. Numerical information was included in the booklet to communicate risks, which were in the form of natural frequencies, although these were not supported by pictograms. Images were included in the handouts of an AAA, screening for an AAA using an ultrasound scan, further investigations and tests that may be encountered if a large aneurysm is diagnosed, and of the two surgical interventions. Images were not included in the booklet to avoid repetition and to focus on its content. The content in the sections of the booklet were framed within a graphical representation of a computer monitor to remind participants that the DA was intended to be used online via the Internet. The handouts and the DA booklet are provided in their entirety in Appendix 10 and Appendix 11, respectively.

<b>Handouts</b>	<b>DA booklet</b>
An introduction to abdominal aortic aneurysm screening	What is an abdominal aortic aneurysm?
Screening procedure	Should I be screened?
Normal sized aorta	What if my result is normal?
Small aneurysm	What if my result shows I have a small aneurysm?
Large aneurysm	What if my result shows I have a large aneurysm?

**Table 4.1** Stages of handouts and sections of decision aid booklet for abdominal aortic aneurysm screening

### 4.2.3 Interviews

Interviews were semistructured and included questions that were generally based on and sequential to the stages in the handouts and sections of the DA booklet.

Handouts were distributed to participants one stage at a time. Following each stage participants were asked questions, including how that stage made them feel towards AAA screening, after which participants would then read through the section of the DA booklet for that stage, and highlight information that they deemed important and influential. This involved underlining information that would make them more likely to be screened and putting a plus sign next to it, and underlining information that would make them less likely to be screened and putting a minus sign next to it.

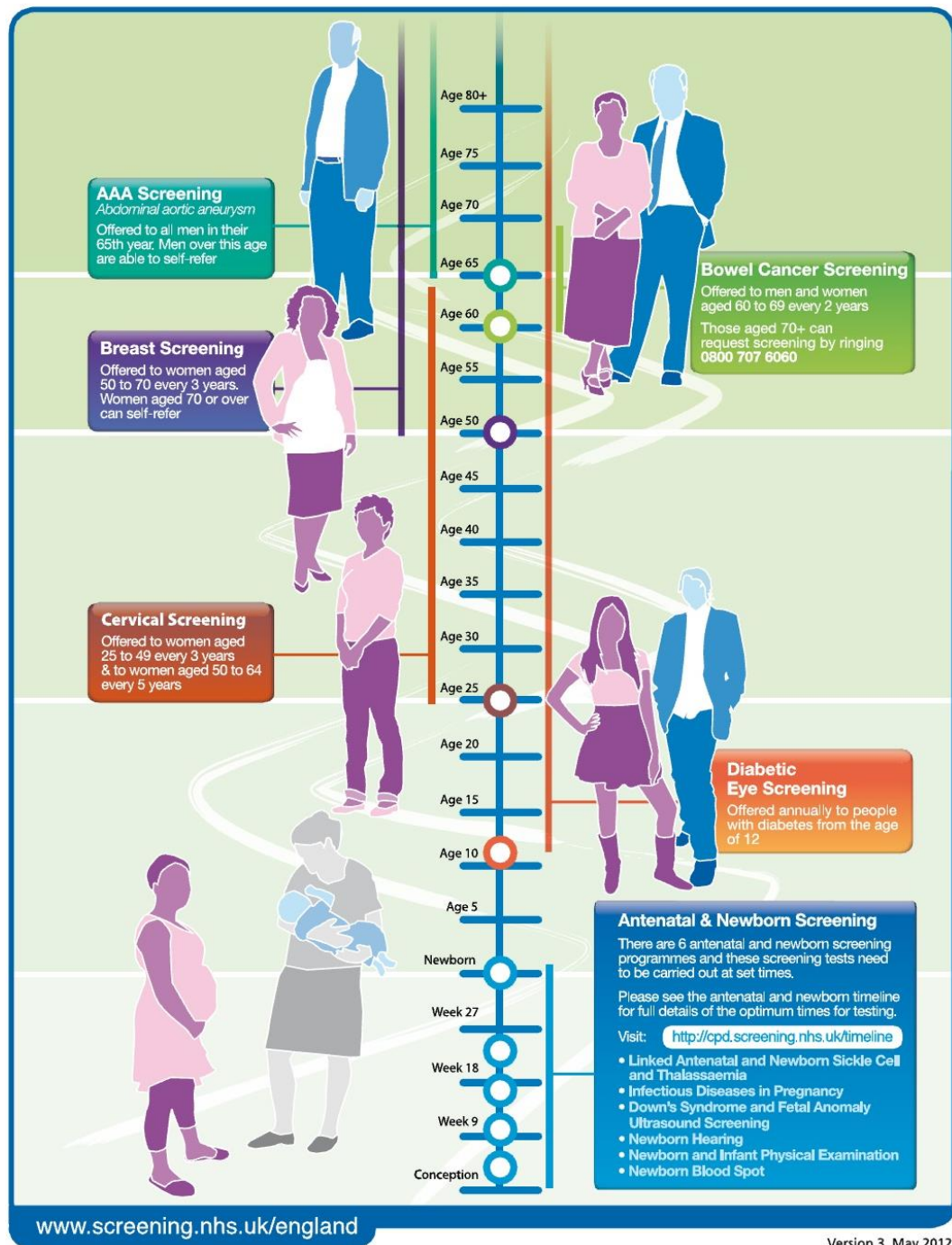
Information that did not make sense or was misleading was also underlined and a question mark was put next to this. A handout was provided to participants of these instructions for them to refer to when reading and highlighting information in the DA booklet. Participants were then asked to comment on the section of the DA booklet, with particular reference to the highlighted information. Interviews were audio recorded and the interview schedule is provided in its entirety in Appendix 12. An advantage of semistructured interviews is their ability to better understand responses through the use of further questions to ‘probe’ for further information.

#### **4.2.4 Thematic analysis**

Qualitative data from the interviews were transcribed verbatim and, as for the first study, analysed using NVivo 9 (QSR International Pty Ltd., 2010) using a thematic data led approach (Howitt, 2010, p. 175). And as for the first study, peer debriefing (Creswell and Miller, 2000) with colleagues at supervision meetings and project meetings was used to validate the data and the data analysis. Appendix 13 provides a screenshot of the coding of the qualitative data, demonstrating preliminary coding. (See page 70 for a recap on a thematic data led approach and peer debriefing).

#### **4.2.5 Sample**

Men in England aged 65 years or older are eligible for AAA screening, which is why the sample used in the study were men in their 50s (aged 50-59 years). This was to prevent ethical implications of including participants who would soon be invited for AAA screening and also because participants will most probably not have had any other screening experiences, as depicted in the NHS Screening Timeline (Figure 4.6). Therefore bias from past experiences could be avoided, which was reasoned in a study conducted by Smith *et al.* (2013a) who recruited participants approaching colorectal cancer screening age to examine a booklet that informs about colorectal cancer screening in the United Kingdom. And similarly to the first study, what will not be known in this study is whether the responses of the participants would be the same if they were to actually encounter AAA screening in the future.



**Figure 4.6** NHS Screening Timeline (Source: UK National Screening Committee)

#### 4.2.6 Recruitment

The study gained ethical approval from the Faculty of Engineering Research Ethics Committee at The University of Nottingham. Participants were recruited through advertising in a local newspaper, posters promoting the study in the local community, and through targeted emailing of non-academic staff at the university (e.g. estates and security) as there was a number of such staff at the university.



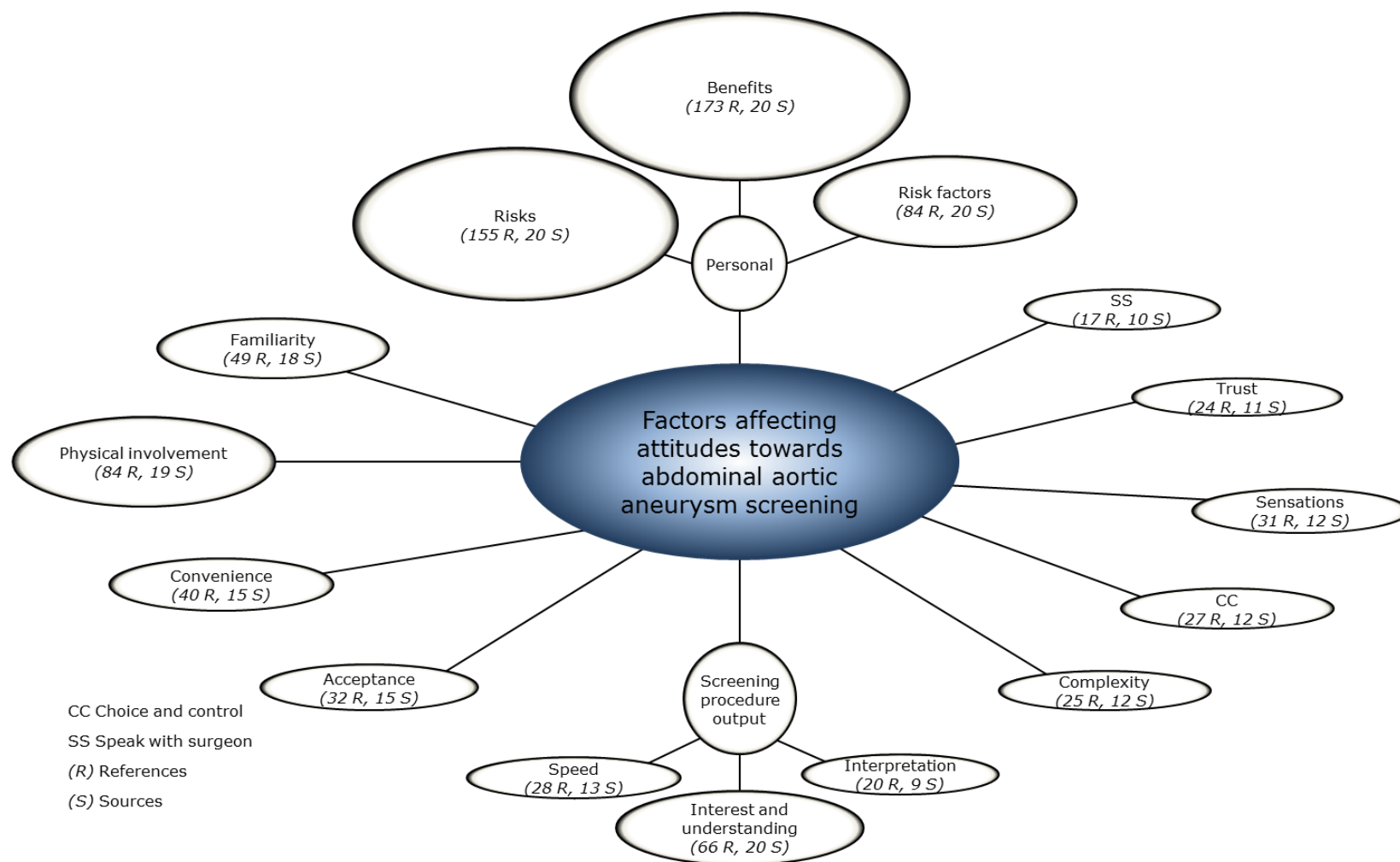
Participants provided written consent to participate and were remunerated with £20 in high street vouchers for their participation. Following interviews participants were provided with a debriefing document to advise them that information included in the study did not constitute medical advice. Details were also included of organisations where more information about AAAs and screening for the condition could be found.

## 4.3 Results

Twenty participants took part in the study and none of them were aware of what an AAA was and of the screening programme for the condition. A total of 17 hours 32 minutes of interviews were conducted, which ranged from 40 minutes to 1 hour 23 minutes; mean interview duration was 53 minutes. The results are discussed in two parts: 1) factors affecting attitudes towards AAA screening; and 2) feedback about information provision for AAA screening. All information participants highlighted in the DA booklet have been consolidated into one to demonstrate which information was most influential. The consolidated highlighted DA booklet is provided in Appendix 14, which also includes participants' written remarks.

### 4.3.1 Factors affecting attitudes towards abdominal aortic aneurysm screening

Factors affecting attitudes towards abdominal aortic aneurysm screening are graphically represented in Figure 4.7 and described in Table 4.2. Fifteen factors were established and as for the factors affecting attitudes towards diagnostic procedures, references and sources are accounted for in each factor. References are the total number of sentences, comments and phrases included in the factors, which are either positive or negative characterisations of the factors, or impartial remarks. Sources are the number of participants from whom the references were obtained.



**Figure 4.7** Factors affecting attitudes towards abdominal aortic aneurysm screening

<b>Factor</b>	<b>Description</b>	<b>References</b>	<b>Sources</b>
Personal			
Benefits	Personal benefits of being screened, including being made aware that you do or do not have an aneurysm, and receiving appropriate health advice and/or healthcare if screened and an aneurysm was diagnosed.	173	20
Personal			
Risks	Personal risks of being or not being screened, including risks of screening procedure and/or treatments.	155	20
Personal			
Risk factors	Risk factors associated with medical condition being screened and personal value of being screened for the condition.	84	20
Physical involvement	Level of physical involvement with screening procedure and/or further investigations and tests.	84	19
Screening procedure output			
Interest and understanding	Level of interest in screening procedure output and understanding of it.	66	20
Familiarity	Experience/knowledge/perceived knowledge of screening procedure and/or further investigations and tests.	49	18
Convenience	Convenience to arrange and/or attend screening, including duration of screening procedure.	40	15
Acceptance	Acceptance of further investigations and tests and/or surgery if screened and a large aneurysm was diagnosed.	32	15
Sensations	Perceived level of pain and/or discomfort, if any, during screening procedure and/or use of an alleviating substance.	31	12
Screening procedure output			
Speed	Speed at which screening procedure output is interpreted to screening outcome.	28	13
Choice and control	Control in deciding whether to	27	12

	be or not to be screened, and if screened and a large aneurysm was diagnosed, control in deciding on which treatment.		
Complexity	Perceived level of complexity of screening procedure.	25	12
Trust	Trust in clinicians and/or clinical practice.	24	10
Screening procedure output			
Interpretation	Awareness that screening outcome is dependent on quality of interpretation of screening procedure output.	20	9
Speak with surgeon	Speak with surgeon to discuss and/or gain advice about treatment if screened and a large aneurysm was diagnosed.	17	10

**Table 4.2** Descriptions of the factors affecting attitudes towards abdominal aortic aneurysm screening

#### 4.3.1.1 Personal: benefits, risks and risk factors

The most influential factors were *benefits* and *risks*, which are *personal* sub-factors, as is *risk factors*, which was moderately influential. *Benefits* (173 references, 20 sources) of being screened included participants being made aware that they did or did not have an aneurysm in which there would be no symptoms to indicate the presence of an AAA:

“The fact that I wouldn’t be aware if anything was wrong, there wouldn’t be any indicators.” (Interview 04)

“[T]he fact that you cannot tell you’ve got this condition in any way, shape or form so that’s a good reason to be screened for it.” (Interview 08)

“[Y]ou got ‘not usually tell’ is important, is persuasive; you don’t know if it’s going on so that makes it more likely that it’s useful for someone else to do it.” (Interview 16)

Another benefit of AAA screening was participants would not need to be screened for the condition again if a normal sized aorta was found because the likelihood of an aneurysm developing later on in life would be small:

“[W]ell what I like about that is that it tells you if it’s a normal result it’s unlikely that you’re going to have one later on so you can pretty much relax then and that you won’t get that.” (Interview 07)

“Most men have a normal result so you like to think you’re most men, and if you have a normal result it’s very unlikely you’ll come to harm from a large aneurysm later in life. So you have this screening and you’ve been told ‘everything is normal’, and then you can be hopefully worry free for this condition.” (Interview 08)

“I suppose it answers probably the most important question that you would want to; if you don’t have one you’re very unlikely to get a large one later on.” (Interview 19)

Although being diagnosed with an aneurysm, small or large, is not good news, it was perceived positively by participants since they would receive appropriate health advice and/or healthcare, and make appropriate lifestyle changes:

“I think it’s sort of building up a picture that screening is a good thing. If it’s a small one then there’s a good treatment plan: health, lifestyle choice; advice; monitoring. If it’s a larger one, you would see a specialist surgeon. The fact for all the various diagnoses there’s a clear treatment plan; I think that’s encouraging.” (Interview 02)

“[T]hat information would be important for me, having advice for the healthy eating, exercise and whatever; pills and that, well that will be part of the course any way; and the blood pressure, well you get your blood pressure checked on your annual check-up.” (Interview 06)

“You’ve got a large one and it could be serious and you could die so that’s quite positive isn’t it? In the sense if you’ve got one, you need to get it looked at. And most of them can be repaired successfully if operated on.” (Interview 07)

Participants deliberated over the *risks* (155 references, 20 sources) of being or not being screened. For example, the screening procedure itself was not considered risky but the notion of not being screened in the first instance was:

“I think you’ve got death in this in two ways. You got death because you’re not screened, they don’t find it and it happens to you, and you’ve got death because you are screened, you’re found to be at risk and you’re on the slab being operated so you’ve got death in two areas. I think you need to stress the death risk through not being screened; if through not being screened and your body does have the aneurysm. So I think you should stress that is a risk to you but I don’t think at this stage you go into great detail over the surgery.” (Interview 01)

“[W]ell how much risk is there to me if I don’t get screened; how likely is it that it’s going to affect me if something does happen and it’s not picked up earlier. ...I’m thinking about whether I want to enter a screening programme; I’d want to know if I don’t enter that screening programme then what risk am I putting myself at.” (Interview 09)

“[I]t says here if it’s a large aneurysm it could be very weak and it could burst, and you could probably die; well nobody wants to die when they can do something about it.” (Interview 12)

Although risks were associated with the treatments, both surgical interventions and watchful waiting, these were not actually associated with the risks of being screened for an AAA:

“It’s not the risk of screening. What that should be entitled; ‘risks of operating if you’re found to have an aneurysm’; that’s what that should be entitled.” (Interview 03)

“The fact there is a risk in the operation, I’m distancing that from the screening because if I was told there was a large aneurysm then that would be another hurdle to cross but certainly the benefits of knowing would outweigh that.” (Interview 04)

“They’re important to me but not at the start of the process. I wouldn’t want to know that when I’m deciding whether to be screened or not. Really, all I’d really want to know if I was asked if I wanted to be screened or not is

what percentage does this apply to, okay; and if I had got it, what are the risks and the treatment for that in high level terms.” (Interview 05)

One participant was concerned with false outcomes or results and in particular the consequences of false positives (‘false negatives’ is used by the participant but their explanation refers to false positives):

“People don’t think of screening as having risks, it’s just a way, just seeing whether you’ve got a condition or not but there can be risks; false negatives where you may have procedures that are unnecessary or obviously worry if it’s unnecessary.” (Interview 02)

Participants constructed personal valuations of being screened for a medical condition with respect to *risk factors* (84 references, 20 sources). If they were or felt that they were at risk of a condition then screening was seen as a necessity; however, if they were not or felt they were not at risk then there was less necessity. As AAA screening is for men and specifically for men aged 65 years, this gave the screening value as participants reflected on the importance of screening as they get older:

“[W]hen you get to a certain age the more checks you can have on your body the better.” (Interview 06)

“[Y]ou’ll have to consider yourself; are you pretty fit anyway; what your age is; what relevant dangers would be associated with that sort of age.” (Interview 15)

“[W]hen you get older; not necessary because I suppose you could screen this from a younger age, or is that not permitted, I don’t know; but I think everything is important as you get older to get screened for things.” (Interview 18)

The screening was also valued with respect to the three risk factors associated with having an aneurysm: 1) being a smoker; 2) having high blood pressure; and 3) having a first-degree relative who has or has had an aneurysm. If participants associated with any of these risk factors then the screening became more of a

necessity; however, if they did not associate with them the screening became less so:

“Based on reading that I am less likely because I don’t fall into the added risk. ...I don’t smoke, never have done; my blood pressure is very rarely high; and brother, sister, parents have never had these issues, to date!”  
(Interview 01)

“[G]etting older; I’m obviously conscious of my age; what can be going on inside my body; if it’s actually serious I could even die. These here; some of these are applicable; I don’t, I’ve never smoked but I have had problems with high blood pressure in the past; I’ve had an uncle who died, now I come to think of it, of an aortic aneurysm.” (Interview 13)

“I think having been made aware of how potentially deadly this condition could be, particularly as I fall in the category as a smoker as well; I suppose that asks the question, as a smoker, should I be pushing to have that done before I reach the age of sixty-five or not?” (Interview 19)

#### *4.3.1.2 Physical involvement*

*Physical involvement* (84 references, 19 sources) was a factor as influential as risk factors. The screening procedure was of no concern due to its minimal level of physical involvement and since there was no exposure of body parts, apart from the abdomen, there was no infringement of dignity. To demonstrate its non-invasiveness participants compared the procedure with other procedures where incisions into the body, endoscopes entering bodily orifices and needles into blood vessels are used:

“If it was more invasive, something like a needle being inserted, I think that would put a lot of people off. Then you’d have to weigh it up more seriously with risks.” (Interview 02)

“[I]t’s not intrusive, is it? You’re not having an endoscope put in you or anything like that so it’s just like a little jelly on your belly.” (Interview 06)



“Nobody’s asking you to stick needles into you and make incisions etcetera to have a look round inside with a camera; anything like that.” (Interview 18)

The further investigations and tests were remarked for their non-invasiveness and were also compared with other procedures:

“[A]n endoscopy is far worse than that. Force yourself to lie still for a few minutes is nothing; having something rammed down your throat is not fun.” (Interview 01)

Although a number of participants were not particularly keen on a blood test, which was one of the further investigations and tests:

“Well the most invasive one here is a blood test and if I was to say which of those ones was the negative one it would be the blood test.” (Interview 03)

“I can’t stand giving blood; I just hate needles.” (Interview 14)

“The only one I don’t like is blood test, I must admit; I’m covered in tattoos but that’s a different type of needle.” (Interview 18)

One participant was also not particularly keen on a computed tomography (CT) scan, another further investigation and test, because he suffered from claustrophobia:

“[T]his CT thing, I was hoping not to have any of those in my life because I’m a bit claustrophobic.” (Interview 16)

#### ***4.3.1.3 Screening procedure output: interest and understanding, speed and interpretation***

The *screening procedure output*, the informational output (image) from an ultrasound scan, was constituted by three sub-factors: 1) *interest and understanding*; 2) *speed*; and 3) *interpretation*. The most influential of these was *interest and understanding* (66 references, 20 sources), which was moderately influential overall. Participants would generally want to view the screening procedure output on a display monitor due to interest and curiosity. This would

involve viewing the procedure output during and after the procedure to observe what was happening and what had been found, respectively:

“I’d probably actually quite like to turn my head and see it or if I couldn’t see at the time, if it was distracting, I would like her, her or him, to tell me what it was about afterwards.” (Interview 05)

“[I]f I had the screening and if I could see the screen and I had this information beforehand then I’d look at the screen and think ‘oh yeah, I’ve got one of them, yeah’.” (Interview 06)

“[I]t’s just natural curiosity to see; it’s you and you can see inside you, and don’t often get to see that so I suppose, yeah, I suppose if it was possible then probably you would.” (Interview 19)

The impact of an aneurysm being diagnosed was perceived to be greater by one participant if he were able to view it:

“I would actually prefer to see even if it might scare the living daylights out of me if I see a great big bulge; I would rather see. ...I think that hammers home the message that you’ve got a problem and something has got to be done about it; so I would rather see.” (Interview 01)

This relates to understanding the screening procedure output, which a number of participants reflected on, and where reflections also took into consideration nurses who would be performing the screening procedure. This was perceived to improve understanding because there would be someone to talk to and answer questions:

“I personally would be interested to see it but I mean, if technically it was difficult for them, which meant that I couldn’t see it; well that’s okay, it’s not a problem. For me personally, I would be interested to see what’s going on there and maybe have someone explain to me oh ‘that’s X and that’s Y and etcetera’; I personally find that interesting.” (Interview 03)

“So obviously you can see what’s going on and understand, a better understanding of someone just going up and down your stomach with a little machine like she is. You can have a look for yourself and you’d also

know if this lady was explaining to you what was happening on the screen, you'll be able to see and understand it better by being able to see what she's talking about as opposed to just listening." (Interview 18)

"I suppose two questions spring to mind: one – would it mean anything to me anyway? And if it didn't then I wouldn't see any benefit of me seeing it. On the other hand if there was something there, maybe I would rather that it was explained to me by somebody who actually understood what it was; than me perhaps reaching for the wrong conclusion." (Interview 19)

One participant would potentially be squeamish but thought curiosity would get the better of him, and another wanted to but was concerned with potentially misinterpreting the diagnostic procedure output:

"[G]iving my squeamish nature, look away but I don't know; curiosity could potentially get the better of me." (Interview 08)

"It's not that I don't want to view it's just that it probably wouldn't make sense to me. I might be seeing some other organ, something that looks to be bigger than seven centimetres and I would be saying 'what's that, what's that, what's that?' and she will saying 'that's your spleen and something, don't worry about it'. It's not I don't want to; it's just that I probably wouldn't be interpreting it right. I would rely on the nurse to interpret it for me. There's no point in seeing it if you don't know what you're looking at and you're not trained to." (Interview 02)

This leads to the *interpretation* factor (20 references, 9 sources), which was the least influential of the three screening procedure output sub-factors and second to least overall. There was a general awareness from some participants that the screening outcome would be dependent on the screening procedure output, which would be dependent on the training and experience of the nurse performing the screening procedure:

"[W]ell it's not the machine is it, it's the person looking at the results from the machine; that's the problem isn't it? If they're good at their job then

they should be accurate so I'm assuming the people who are using them know what they're doing." (Interview 07)

"I understand the operator must be experienced to get a decent result and to get the decent measurements, and I suppose there's a certain amount of interpretation. But I know it's not just a case of learning the procedure and away you go; you have to be well practiced to actually identify the measurements that you want. If you go a proper trained person I would expect a high standard." (Interview 09)

There was concern expressed about the speed of interpretation of the screening procedure output and that there was not any deliberation or consultation with another healthcare professional, such as a doctor:

"Perhaps the nurse would go and review it and discuss it with another nurse or even with a doctor and say 'we'll inform the patient that'; both ways they could inform there's nothing there but if they have a longer review of it and reassess it with a colleague they might see some small early ones or they may see a pattern if they were discussing with other colleagues that indicates something serious. It's not the fact that, it's the fact that it's immediate and I think it implies that there's less thought and consideration gone into interpreting the results, which may be complex sometimes." (Interview 02)

"Being told on the day is great but there's always the worry that they miss something. That maybe, I'm not sort of doubting their training but a doctor might pick-up; I don't know if that would be relevant." (Interview 14)

This leads to the *speed* factor (28 references, 13 sources), the last of the three screening procedure output sub-factors. There was surprise that the screening procedure outcome would be notified immediately but this was perceived as a positive characteristic of the screening procedure because it would avoid any anxiety that would otherwise be experienced if there was a waiting period:

"It just means that I'm not; if you have a screen I think it introduces; you then start to think is it good or is it bad. Before the screening you don't

think about these things but once it's underway you then think I just had a test, the test could be good or bad; and so immediately there's some level of apprehension because you start to think about what if it's bad. So if there's a delay between having the screening and then maybe two weeks later getting a letter; you do carry some degree of apprehension for that period of time, probably not much but it's there, psychologically. Getting the results straightaway removes that and so that's why I think that's quite good.” (Interview 03)

“[F]rom experience they do a scan don't they and they say 'I can't tell you because I'm not allowed to tell you' so you have to wait to three or four days before you see someone; and that could be the worrying part. ...[Y]ou want screeners to tell you the result straightaway.” (Interview 07)

Another positive of being notified the screening procedure outcome immediately was that action could be taken sooner if an aneurysm was diagnosed:

“I just suppose I'm an optimist, I think well 'I'll be told' and I think the other side of that, if it was there, I'll be keener to know earlier rather than later, particularly going back to the first sheet being told 'if it is there the chances are it can be successfully dealt with' so it's not like you're going to be told you've got something terminal, it's unlikely to be terminal.” (Interview 04)

“I'll walk out there knowing one way or the other, and if there's a way forward if it's a bad outcome.” (Interview 13)

#### *4.3.1.4 Familiarity*

*Familiarity* (49 references, 18 sources) was a somewhat influential factor and there was familiarity of the screening procedure and/or the further investigations and tests. Participants predominantly knew about the procedure and the investigations and tests, and possibly had first-hand experiences of them:

“Obviously I've had the blood test for diabetes; every year for my diabetes. I've had an electrocardiogram; they did one when I was first diagnosed with

diabetes; they gave me a full health check so I've had that as well. I'm familiar with the other ones." (Interview 01)

"I've certainly had X-rays; I've probably had one of those at some point; I've certainly had blood taken; I've probably done some max VO2 type test, something like that. I've never been in a CT scanner; people tell me it can get claustrophobic but I don't believe I'm claustrophobic." (Interview 05)

The screening procedure was referred to for its use during pregnancy and some participants recalled observing pregnant wives who had an ultrasound scan:

"[I]t's a tried and tested technique. I've known other people who've had ultrasounds; my wife when she was pregnant and stuff like that; and the results were frighteningly accurate; positively accurate." (Interview 13)

"I've seen ultrasound probes on my wife when she was pregnant." (Interview 17)

One participant had no knowledge of the screening procedure and another was not familiar with an echocardiogram, one of the further investigations and tests:

"I know nothing about ultrasound. ...I don't really because I've got no knowledge about it." (Interview 04)

"I'm not sure about an echocardiogram because I'm not totally familiar with that." (Interview 09)

#### *4.3.1.5 Convenience*

*Convenience* (40 references, 15 sources) was a somewhat influential factor also and because the screening procedure was perceived as quick this was positively associated with the convenience of attending AAA screening:

"[F]or any screening for anything like that; if it doesn't take up much time; if it doesn't disrupt your normal life; I'll say go for it." (Interview 06)

"I think it's not much of my time that is being used for screening." (Interview 10)

Although arranging a screening and being able and having the time to attend might influence whether participants would be or would not be screened:

“[T]he screening needs to be efficient and local, an appointment made and easy access really; easy access, if it’s difficult to do and going to cause problems trying to arrange the screening then that might make me think twice.” (Interview 09)

“I suppose the obvious practical one is actually, it’s a bit like going to the dentist or optician; it’s being able to book easily. So if there was an online booking system I could go and choose my own slot; for a very, very simple level, that would probably help because it means I’d probably go and book it straightaway rather than saying I would do that and then six months later you still haven’t done it.” (Interview 20)

#### *4.3.1.6 Acceptance*

In the instance that participants are screened and a large aneurysm was diagnosed there was *acceptance* (32 references, 15 sources) of the further investigations and tests and/or surgery. The investigations and tests were seen as good clinical practice and a necessity for assessing and preparing for surgery whilst both surgical interventions were accepted as a necessity in treating a large aneurysm:

“So I accept that all these other tests combined help them sort out exactly what’s wrong, where the weakness really is and how they’re going to go about putting it right. I mean don’t get me wrong, two of those will scare the hell out of me but once I have them done. Sorry one of them will scare the hell out of me.” (Interview 01)

“I mean obviously in terms of there being something wrong they’ve got to repair it haven’t they so it’s nice to know there is a couple of procedures they can do.” (Interview 12)

#### *4.3.1.7 Sensations*

Although there was acceptance of the further investigations and tests and/or surgery ‘as a means to an end’ this did not necessarily correlate with the screening

procedure and *sensations* (31 references, 12 sources), a minor factor but an important aspect of AAA screening. Participants gave the impression that in deciding whether to be or not to be screened (for any medical condition) that pain and/or discomfort would be a factor that would be considered, but the fact that the screening procedure was painless and that it caused no discomfort was a positive characteristic of the procedure:

“If it was particularly unpleasant but the screening process, i.e. painful, embarrassing or something like that; that would put me off.” (Interview 13)

““The test does not hurt”; well that’s very important.” (Interview 16)

Another positive characteristic of the screening procedure was that alleviating substances such as anaesthetics would not be used and sedation would not be required:

“[I]t’s not painful; you don’t have to take any drugs or anything like that.” (Interview 03)

“[Y]ou’re not going to be put to sleep so it’s pain free; it’s a pain free procedure.” (Interview 18)

#### *4.3.1.8 Choice and control*

Given that sensations may influence decision-making, decision-making itself was valued with respect to *choice and control* (27 references, 12 sources), another minor factor but important aspect of AAA screening. Participants valued control in deciding whether to be or not to be screened, and if screened and a large aneurysm was diagnosed participants would have control in deciding on which treatment to proceed with:

“I think I would definitely have the screening done; there are no doubts about that. Until you know the results of your screening; yeah, it puts it in a nutshell for you, doesn’t it; it gives you all the information; you know exactly where you stand and it’s up to you to make a decision on it.” (Interview 12)



“Well the fact that I have a choice in whether I have the operation, and the fact that if I choose not to have the operation that’s not the end of it; they’ll give me other methods so I can overcome this problem.” (Interview 13)

#### *4.3.1.9 Complexity*

*Complexity* (25 references, 12 sources) of the screening procedure would be a factor participants would consider when deciding whether to be or not to be screened and similar to the painlessness of and no discomfort to be experienced from the procedure with respect to sensations, the procedure was regarded positively with respect to its simplicity and ease:

“[T]he fact that it’s an uncomplicated, effortless one would make me feel even more comfortable,” (Interview 04)

“[I]t’s a bit of a no brainer given the simplicity and the friendliness of the test.” (Interview 20)

#### *4.3.1.10 Trust*

Participants had *trust* (24 references, 11 sources) in the screening programme and the research supporting it, and trust in clinicians and other healthcare professionals involved in the screening, as well as a doctor’s recommendation. There was the notion of relying on and having confidence in experts and accepting information that would be given:

“[S]ay a doctor said to you ‘you’ve got a condition and you need a screening to find out the best way forward’; well that’s the decision really taken out of your hands then; you’ve got to go for it under your doctor’s orders.” (Interview 08)

“I mean obviously I’m not in the medical field; I leave that with the experts; if they say this is the way they find something then I leave it with them because that is the way they do it.” (Interview 12)

It was also mentioned that the NHS would not waste people’s time and that screening would not be available if it was not of benefit due to the litigious nature of society:

“I just presume that they wouldn’t be going to this trouble to go to screening if there wasn’t a reasonable degree of accuracy. ...[B]ecause of the sort of litigious sort of nature of society now.” (Interview 04)

#### *4.3.1.11 Speak with surgeon*

Trust can also be considered with respect to *speak with surgeon* (17 references, 10 sources), the final and least influencing factor but still another important aspect of AAA screening. Participants would be reassured if they were screened and a large aneurysm was diagnosed because they would meet with a vascular surgeon to receive explanations, discuss treatment options, ask questions and gain advice. This generated a positive perspective that there was well-defined treatment in place:

“The fact it has a clear treatment plan that seems to be effective and they’re saying the plan is ‘you get an appointment with the surgeon and it’s usually successful’.” (Interview 02)

“[T]he fact if things did develop into larger I would get the appointment with the surgeon; so I suppose the fact that I’m in a system where things are being checked out.” (Interview 04)

### **4.3.2 Feedback about information provision for abdominal aortic aneurysm screening**

Feedback about information provision for AAA screening includes themes that relate specifically to the handouts and the DA booklet. They represent aspects of information provision for the two information resources and for AAA screening in general, and provide an understanding of participants’ informational needs and preferences. This will be of particular benefit to the NHS Abdominal Aortic Aneurysm Screening Programme in the development of their DA. Themes are described and references and sources are accounted for in Table 4.3. They are discussed in a logical manner with respect to accessing and using information online via the Internet, considerations and recommendations for information content about AAA screening, leading to quantifying the benefits and risks of the screening, and the use of images and videos to support information provision.

Theme	Description	References	Sources
Considerations and recommendations			
Large aneurysm	Considerations and recommendations for information provision about a large aneurysm.	141	20
Quantitative evidence	Use of quantitative evidence to quantify benefits and risks of screening.	82	15
Images and videos	Use of images and videos to support information provision.	55	19
Internet	Use of Internet as medium for information provision.	52	20
Considerations and recommendations			
Screening	Considerations and recommendations for information provision about purpose of screening and screening procedure.	26	13
Considerations and recommendations			
Small aneurysm	Considerations and recommendations for information provision about a small aneurysm.	24	7

**Table 4.3** Descriptions of the themes for feedback about information provision for abdominal aortic aneurysm screening

#### 4.3.2.1 *The use of the Internet*

Participants were positive overall about the use of the *Internet* (52 references, 20 sources) as the medium for information provision about AAA screening because they were comfortable and experienced with it. There was concern, however, of some men not being comfortable:

“For me personally, I wouldn’t have a problem with it being on the Internet but I know people who are a bit older and who aren’t so good on the Internet; whether it’s good for them or not. I think the more personal touch is better for older people.” (Interview 12)

“I’m okay with it. I know there’s a lot of people who are maybe more scared about it. I mean it’s like when NHS Direct came out; people were very sceptical about it. However, having used it a couple of times; not for myself but for my dad; yeah, it’s fine.” (Interview 14)

The ability to access additional information such as videos via hyperlinks was regarded as a beneficial feature of the Internet, but limitations were answers to specific questions might not be covered and there was no personal communication. Additionally, the Internet was perceived to work to the ‘lowest common denominator’:

“An issue with the Internet is that they have to, sometimes they have to work to the lowest common denominator so therefore if you have some knowledge – you know the old saying – ‘some knowledge is dangerous’; and it just raises questions and if you can’t have those questions answered you are either going to guess at the answer that you give or you’re not going to want to complete it at all.” (Interview 01)

The reputability of online information was discussed and as long as information came from a trusting source the information would be accepted:

“[I]t’s okay if it’s a proper database that is probably linked to something like the NHS or some proper body; I suppose doing it on Wikipedia where everybody can put what they like in so you need to trust it.” (Interview 15)

“I’ve no problems with that at all. I mean, I suppose like a lot of people nowadays, I use the Internet a lot for information so no that wouldn’t present a problem; I think providing it was coming from; the big problem with the Internet obviously is that there is an awful lot of guff so I would only want to access something from a reputable; NHS site something like that.” (Interview 19)

The Internet was also considered for its accessibility, design and interactivity:

“No as long as it’s easily accessible and you can just click on and go through it. A sheet and just click yes and no and go through it like that.” (Interview 07)

“It depends on what form it is on online so if it’s purely just documents then; well it depends on what it looks like and how interactive it is. So I’m not sure; stuff’s okay on the Internet if it’s in an appropriate form, if it’s not it could be terrible so it depends.” (Interview 20)

#### 4.3.2.2 *Considerations and recommendations for information about screening, small aneurysms and large aneurysms*

Participants had a number of *considerations and recommendations* for screening information, *small aneurysm* information and *large aneurysm* information. For screening information (26 references, 13 sources) this included information about the purpose of AAA screening and the screening procedure, and most considerations and recommendations were because information was either regarded irrelevant or needed clarifying. The table in the DA booklet describing the benefits and risks of AAA screening was regarded as irrelevant because the risk of an operation to repair a large aneurysm was not associated with the risk of the screening itself:

“I think you should come to that at the point in time when it’s relevant. I don’t know, there’s a chance it could turn people off; they could misinterpret that and think that’s sort of a risk of screening when it’s not.” (Interview 08)

“It just needs better writing I think; better ways of expressing what it’s trying to say. There’s nothing wrong with what it’s trying to say but it just doesn’t hit me properly. Okay, ‘this is a major operation’, ‘there is a small risk you may die’; okay why do you need to say that? This is risks of screening and then you start talking about the operation, sorry, it starts talking about the operation, which I don’t think is necessary. I think that’s something you’ve; I don’t think you want to let people know; well no, I suppose is that trying to scare them into having the screening?” (Interview 17)

Information that needed clarifying included information about why an aorta might not been seen during the screening procedure and what would be different at a second attempt at a later date compared to a first if it was not seen:

“[T]here’s a question mark I should have put about it somewhere and that is ‘sometimes the screener will not be able to see your aorta clearly and you’ll then be offered another scan’; well if they can’t see it clearly then why would they see it clearly later on?” (Interview 03)

“I guess I would like a bit more information as to why they may not be able to see the aorta clearly. ... [I]f my aorta can't be seen, when lots of other peoples can; why might that be?” (Interview 16)

Clarification was also required about why men's information would be kept on a national computer system if they were screened:

“I can see why it would go on your medical record but I'm not clear why it would go on a national database. Obviously a lot of people have their records on the [Summary Care Record], but a lot of people have opted out of that I think.” (Interview 02)

Some terms such as ‘should reduce’ in ‘[t]he NHS introduced AAA screening after research showed it should reduce the number of deaths from burst aneurysms among men aged 65 and older’ and words such as ‘die’ in ‘[t]his is a major operation and there is a small risk that you may die during or soon after the operation’ were regarded as inappropriate and that better wording could be used. Some participants even gave suggestions on how better to convey information:

“[T]he words like ‘should reduce’; they could choose different words that are more; ‘there's a strong possibility of death’ rather than ‘should’; it just seems a bit; sorry it's me.” (Interview 11)

“I don't know whether you should put that ‘operations to repair aneurysms are usually successful’; I think you should just don't say a word. ... I think what you need to specify there is that ‘the screening finds aneurysms so they can be treated’; just a simple statement like that.” (Interview 14)

Considerations and recommendations for *small aneurysm* information (24 references, 7 sources) included confusion over the use of ‘[i]f you have an operation for a small aneurysm you might get other health problems’ when men would not have any surgical interventions if they were screened and a small aneurysm was diagnosed. One participant felt that it needed clarifying at the start of the DA booklet that the screening procedure outcome could be one of three because he was not expecting information about a small aneurysm. The same participant also questioned if a small aneurysm was diagnosed why it would not grow any

bigger if the all clear was given after several check-ups and what happens if a small aneurysm does grow into a large aneurysm:

“[W]hen there are several tests saying that it’s not getting bigger meaning it’s unlikely to have any problems; I guess what that’s saying here, but it’s my interpretation, ‘this is how you are, you are a bit wider than normal, it’s not changing; we’ve ascertained you’re that you’re that side of the spectrum, it’s not a problem, don’t worry about it’. That’s not telling me that. That’s saying to me you’ve got this small aneurysm but it’s not getting bigger so don’t worry about it. I’m thinking I’ve got this small aneurysm, they told me it’s not getting bigger but hang on, after the tests it could suddenly start to get bigger. Whereas I think what they’re trying to say here ‘on a normal curve you’re that side of it and we’ve worked that out so don’t worry about it anymore, it’s just the way you are’.” (Interview 03)

“I guess what they haven’t quite said here, I suppose if it is getting bigger; so you’ve got a small aneurysm and it’s getting bigger, is that the same as finding a big aneurysm at the beginning. Suppose I did this and it’s getting bigger, I would be thinking what now? I’m assuming there would be an operation but that doesn’t make; it just talks about if you haven’t got it, it doesn’t say if you have got it growing.” (Interview 03)

The table in the DA booklet with aorta sizes and risks of aneurysms bursting per year was considered ambiguous with respect to the risk of a small aneurysm, and the risk of a small aneurysm growing and not growing. The table was also considered too technical by one participant and that this information should be given at the actual screening:

“I think there’s too much technical information being given; you’re saying three centimetres or less, three to five point five centimetres; myself I understand that but I suppose it’s just a number; it’s the sort of information that would be best given to you at the actual screening.” (Interview 10)

One participant would have liked more information on staying healthy and another wanted to know how staying healthy affected the size of a small aneurysm:

“What do you mean by healthy food? I guess what that means but I would probably like that spelt out to me. Again, the regular exercise, does that mean I’m running a marathon every week or walking round the block or something? So yeah, probably a few pointers that explain what that means.” (Interview 13)

“I’m interested to know quite whether it’s going to change the size of your aneurysm because I would have thought the only thing that could do anything that was useful would be to get your blood pressure down because it’s not going to heal itself.” (Interview 20)

Considerations and recommendations for *large aneurysm* information (141 references, 20 sources) was that it was too much, too detailed and not relevant with the decision to be or not be screened. There were a number of suggestions that formed a general consensus that information provision about a large aneurysm needed to be simple and succinct, if it was needed:

“[A]ll I would want to be told is, if it’s an aneurysm, you’ll get all of that and all it would say here is ‘surgery’. You can say there are different types of surgery depending on your situation but because at this stage you don’t know what your situation is; why worry people more than they need to be worried.” (Interview 01)

“If it said ‘the large aneurysm needed surgery and then before that you would have a few tests’; I don’t think that would influence the decision at all. I think the fact that the seriousness of the large aneurysm is emphasised and surgery is required; these kinds of things are expected so I don’t think it would be needed at that early stage, not the initial screening stage.” (Interview 02)

The use of the word ‘stomach’ in ‘[o]pen surgery involves accessing the aneurysm through cutting the stomach and replacing it with a graft’ was described as confusing and dramatic. The use of the word ‘die’ in ‘[i]f the wall of your aorta gets very weak it could burst...[and] you would probably die’ was also described as dramatic, and similar to the screening information, the word was considered inappropriate:



“I’m still worried about the use of ‘you’. People don’t like to think they’re going to die so I’m going to put a negative next to those. If this is, this is where the passive actually is very useful; I hate the passive normally but it can be useful; ‘if this happens death would result’; and then it’s not saying ‘you are going to die tomorrow’.” (Interview 03)

“[T]he fact that it keeps mentioning the word ‘die’, which makes me a bit uneasy although I know it’s only putting the facts forward.” (Interview 08)

Some participants did not completely comprehend what watchful waiting was and so clarification about this would be beneficial:

“I’m not sure; basically you realise that you’ve got a large one; what does this actually mean ‘watchful waiting’? Are you going to say ‘my risk is ten per cent of dying from it now but if you come back in three months and if it’s twenty per cent’; we’ll think that the risk of twenty per cent outweighs the risks of having these done.” (Interview 05)

“That needs more information; that’s too stark. I can’t remember what it specifically said for watchful waiting; I think what it says is true but I don’t think it has been put in the right way because if there was a significant risk that you were going to have a burst aneurysm then you have surgery so I don’t think that risk is applicable, as stark as that to watchful waiting, if that makes sense.” (Interview 17)

There was a suggestion for a ‘what if’ scenario to obtain more information if preferred by clicking for it, if online, and a similar suggestion that there could be a hyperlink to another web page for additional information about further investigations and tests. One participant termed this like ‘peeling an onion’, the more information you wanted because you were interested in and/or preferred to be further informed, the more layers you could peel to access the information:

“I think it’s like peeling an onion; at one level you’re saying you need tests and then you put more and more detail underneath so people can stop reading when they want to.” (Interview 17)

#### 4.3.2.3 *The use of quantitative evidence*

The majority of participants were keen on the use of *quantitative evidence* (82 references, 15 sources) to quantify the benefits and risks of AAA screening. Quantifying why AAA screening was only for men of 65 years of age would have better justified it for some participants, and ambiguous terms such as ‘should reduce’, which is mentioned in the screening information and ‘most men’ in ‘[m]ost men have a normal result’ were particularly referred to with respect to quantification to make them relevant and comprehensible:

“The fact, just the phrase ‘it should reduce’; it sounds very vague as if there’s no evidence there and they’re saying ‘perhaps, there’s a possibility’; it’s just the phrasing. ...If there was evidence, it says ‘the evidence shows that screening will reduce, should reduce’, that implies that it’s not clear evidence.” (Interview 02)

“[W]hat is most, ‘most men’?; I mean is that ninety-five per cent? Are we talking ninety-nine per cent?” (Interview 14)

There was a suggestion for the term ‘small chance’ in ‘there is a small chance you will die after an operation to repair a large aneurysm’ that the term could be clicked, if online, and a new window could open that provides statistical information. Consideration of appropriately matching wording with statistical information should be taken to avoid misrepresentation of benefits and risks. Misrepresentation occurred with the word ‘unlikely’ in ‘[t]his means it is unlikely [a small aneurysm] will give you any problems’ and the reported risk of a small aneurysm bursting per year from the table in the DA booklet:

“Unlikely and one in a hundred are not compatible to me so that is confusing and it’s starting to make me get confused by that information and what’s the point of this table like this. I think you have to say, and maybe you don’t have the statistics, you have to differentiate between small aneurysm and not growing and small aneurysm and growing.” (Interview 03)

There was the suggestion of having the table in a sliding scale because in its current format there was no smooth transition between the sizes of an aorta and the risks of an aneurysm bursting per year:

“I might question why it’s one in a hundred there and fifteen in a hundred there; that’s quite a big change isn’t it. ... This has got to be on a sliding scale of some sort. It’s a bit pause.” (Interview 05)

The risk of an aneurysm bursting per year for a normal sized aorta was regarded as irrelevant because there was no actual aneurysm:

“I don’t quite understand that one because if you haven’t got a risk of aneurysm, I don’t see why there’s a risk; if you haven’t got an aneurysm then surely you can’t have a risk of it bursting so it’s probably being a little pedantic. You might have problems with the aorta but if you haven’t got an aneurysm it can’t be an aneurysm that bursts.” (Interview 20)

One participant was not keen on the use of quantitative evidence, and another was suspicious and cautious:

“The only thing I would say about any screening is what I just said. Sometimes it’s overplayed and the statistics are manipulated so it makes it look worse than it really is. I don’t want to be told there’s an extra twenty per cent in me dying when in fact it’s not just that simple. It’s twenty per cent, one in a hundred extra at risk. Keep it simple and don’t try and bullshit us.” (Interview 01)

If there was a method to refine quantitative evidence so it could be specific to individuals or demographic groups then this would have made the evidence more relevant for some participants, and one participant suggested that the benefits and risks of AAA screening should be updated annually to give a ‘true representation’:

“I think every year they have assessments and they give figures like charts, etcetera; it would be good to have a true representation of this per year.” (Interview 11)

#### 4.3.2.4 *The use of images and videos*

Participants were positive overall about the use of *images and videos* (55 references, 19 sources) for supporting information provision about AAAs and the screening procedure. They were regarded as valuable in improving knowledge and understanding, and with respect to the screening procedure image in the handouts, there was one remark that the image was a way for people to become familiar with the procedure who were not already:

“[F]or ultrasound, a lot of people will be familiar with that but if you’re not images of someone passing something over you; that’s helpful I think. So images of what the testing is and what the condition are, are helpful.”

(Interview 02)

The use of videos was regarded as beneficial for its audio attributes and that there could be narration and having a video like ‘Casualty’ would make it easier to comprehend:

“I think it’s better, especially because some people like me might misread the medical information. To have it as a Casualty type television programmes is easier for you to comprehend.” (Interview 14)

The use of images and videos to visualise an aorta grow into an aneurysm, which could differentiate between risks of an aneurysm bursting was deemed a potential benefit:

“[T]hat explains, if you have some sort of graphic thing saying ‘here’s it growing and look what can happen’ and then explaining the worst case situation that it can serious.” (Interview 03)

“Like this is what one looks like and this is healthy man and something you know. With that table where you had all the sizes then corresponding; just needs to be a picture or something like that. ...[I]f there’s some kind of thing like a time-lapse aneurysm showing an aneurysm getting bigger that would be good to see that.” (Interview 06)

One participant, however, remarked videos could be time consuming and it's easier to skip forward with text:

“[W]hen you’ve got it on the screen and you can move your page where you want it and you can read a bit and think ‘oh yeah, I’ve seen that’, and move on, move on and move on. But with a video you’re stuck watching it aren’t you until it finishes.” (Interview 09)

One participant suggested that videos should be accessed via an ‘optional click’, if online:

“[I]f I want to see a video I can click on the video but I think it should be an optional click, to see videos.” (Interview 17)

With respect to the images of the further investigations and tests in the handouts, it was suggested that it should include men relevant to the screening age since some of the men look younger than 65 years of age:

“[I]t’s such a minor point it’s almost irrelevant but given that this is aimed at men over sixty-five, the images of having young men seems to be a little bit; but it doesn’t matter; maybe it would have been, perhaps, better if it was people of the same sort of age appearance of those who are going to be under the procedure.” (Interview 19)

## 4.4 Discussion

The study took a human factors approach to medical devices from the perspective of men in the context of screening. Two information resources were used in interviews to understand attitudes towards AAA screening and informational needs and preferences. One of the information resources (handouts) provided brief details about AAA screening and its stages whilst the other (DA booklet) was based on a draft version of the core text of a DA developed by the NHS Abdominal Aortic Aneurysm Screening Programme and was considerably more detailed. Fifteen factors were established that affected attitudes towards AAA screening (Figure 4.7) and benefits and risks were the most influential factors, which are personal sub-

factors. Although the other twelve factors were smaller and less influential, they were still important aspects of AAA screening.

When deciding whether to be or not to be screened it can be concluded that personal benefits and risks would be pivotal in men's decision-making. Men would assess benefits and risks of being screened, including being made aware that they do or do not have an aneurysm, receiving appropriate health advice and/or healthcare if screened and an aneurysm was diagnosed, and the risks of the screening procedure and/or treatments. Men would also assess the risks of not being screened. As mentioned in the introduction of this chapter it is important that men invited for AAA screening are informed of the negative as well as the positive features of being screened, and the benefits and risks would contribute considerably to this. The effects of benefits and risks can be theorised using the theory of planned behaviour (Ajzen, 2005, p. 126, see pages 25-26 for recap) and the health belief model (Strecher *et al.*, 1997, see pages 26-27 for recap), where information or beliefs about benefits and risks contribute to screening intentions. This was observed in studies conducted by Griffith *et al.* (2012), Montaña *et al.* (2004), Weinberg *et al.* (2004) and Yim *et al.* (2012) who found the belief that screening will reduce the likelihood of becoming ill with a treatable medical condition facilitated screening attendance.

With respect to the risks of the treatments, which include endovascular surgery, open surgery and watchful waiting, these were not associated with the risks of being screened for an AAA. Feedback about information provision for AAA screening correlates with this since considerations and recommendations for large aneurysm information was that it was too much, too detailed and not relevant with the decision to be or not be screened. A similar observation was found in a study conducted by Smith *et al.* (2013a) where participants who examined a booklet that informs about colorectal cancer screening in the United Kingdom found the booklet too long and complex. It should also be noted that information participants highlighted in the DA booklet consisted of more from the first three sections than the last two (about what happens if a small aneurysm or a large aneurysm is diagnosed). Therefore in deciding on whether to be or not to be screened it can be assumed that information about the condition, the screening procedure and what

happens if a normal aorta is found, which is very much about the benefits of being screened, would suffice for most men. Although there were suggestions that more information could be obtained if the information was online for those who were interested and/or preferred to be further informed. This was termed by one participant as a ‘what if’ scenario and by another like ‘peeling an onion’. This is somewhat similar to tailoring information, which patients in a study conducted by Jenkinson *et al.* (1998) reported would be beneficial with respect to a decision support technology (also known as DA) that assists patients facing prostate cancer treatment decisions and the tailoring of information in the support technology to meet specific informational needs (i.e. information to reflect prognosis of patient – from healthy to poor).

Risk factors, another personal sub-factor, and physical involvement would also be pivotal in men’s decision-making about whether to be or not be screened, although to a lesser degree than personal benefits and risks. Men would consider the risk factors associated with the condition being screened, which for AAA screening are being a smoker, having high blood pressure and having a first-degree relative who has or has had an aneurysm, and their personal value of being screened for the condition, which would influence the level of necessity of being screened. This is referred to in the health belief model (Strecher *et al.*, 1997) with respect to an individual’s subjective value (or evaluation) of personal susceptibility to and severity of disease, and the likelihood of reducing that threat through personal action (i.e. behaviour change). This has been observed in studies where family history of a medical condition (Montaño *et al.*, 2004; Nekhlyudov *et al.*, 2003; Shah *et al.*, 2007; Wallner *et al.*, 2008) and advancing age (Livingston *et al.*, 2002; Nekhlyudov *et al.*, 2003; Underwood, 1999; Weinberg *et al.*, 2004) have facilitated screening attendance. Participants reflected on the importance of screening as they get older and AAA screening was valued for screening men aged 65 years. However, quantification of this with quantitative evidence would have better justified why the screening was only for men of 65 years of age. Similar feedback was provided by participants who user tested a leaflet that informs about colorectal cancer screening in the United Kingdom (Smith *et al.*, 2013b). They found information in the leaflet about the eligibility age for the screening confusing and that it was not ‘backed up’.

Quantification of ambiguous terms such as ‘most men’ and ‘should reduce’ would make them relevant and comprehensible, and if quantitative evidence could be specific to individuals or demographic groups and updated annually then this would give a ‘true representation’ as termed by one participant. Berry and Hochhauser (2006) recommend verbal labels linked with indicative frequency ranges to communicate risk (e.g. ‘rare’ linked with ‘between 0.01% and 0.01% at risk’), and Zikmund-Fisher (2013) argues for ‘taxonomy’ of formats of risk communication to meet specific informational needs. In attempting to meet such informational needs, patient information resources can be checked against the requirements of the ‘probabilities’ dimension of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009, see pages 46-47 for recap), and the Confidence to Decide about Treatment Scale (Kryworuchko *et al.*, 2008; McBride *et al.*, 2002) and the Realistic Expectations tool (O’Connor, 2002b; O’Connor *et al.*, 1998a; O’Connor *et al.*, 1998b) can be used to evaluate the effectiveness of risk communication. A benefit of the Internet is the ease of updating information to provide up to date evidence, which would allay concerns discussed at the International Patient Decision Aid Standards Symposium (Holmes-Rovner *et al.*, 2007) and contribute to quality DAs through meeting the requirements of the ‘evidence’ dimension of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009). Although there were limitations to the use of the Internet, including no personal communication and ‘working to the lowest denominator’, these can also apply to other media such as leaflets. It is worth noting that the online DA (BMJ Group, 2012b) developed by the NHS Abdominal Aortic Aneurysm Screening Programme does have contact details for decision support at the end for men who require assistance.

Physical involvement with the screening procedure and/or the further investigations and tests were of no concern due to their minimal level of physical involvement, and to demonstrate their non-invasiveness participants compared them with other procedures. Although information about the further investigations and tests would most probably not be of interest to men deciding whether to be or not to be screened, a minor but important point made by one participant with respect to images of these in the handouts was that they should include men relevant to the screening age since some of the men look younger than 65 years of age.



Participants were positive overall about the use of images and videos for supporting information provision, and were regarded as valuable in improving knowledge and understanding. Videos were regarded as beneficial for their audio attributes and potential visualisations, but their duration might be an issue. However, another benefit of the Internet is that information can be given in more than one format, and if appropriately presented, can give users more options. The screening procedure image in the handouts was remarked as a way for people to become familiar with the procedure who were not already.

Most participants were familiar with the screening procedure and the further investigations and tests. Knowledge came from first-hand experiences and for the screening procedure some experiences came from observing pregnant wives who had had an ultrasound scan. The image from an ultrasound scan was regarded with respect to the screening procedure output factor. Participants generally would want to view the procedure output because of interest and understanding, a screening procedure output sub-factor, and having a nurse perform the screening procedure was perceived to improve understanding because there would be someone to talk to and answer questions. Clarification about why an aorta might not be seen during the screening procedure would be beneficial information, as would information about why a small aneurysm would not grow any bigger after several check-ups, and that if a small aneurysm grows into a large one it would be treated as if a large aneurysm was diagnosed from the initial screening.

There was awareness that the interpretation of the screening procedure output, another screening procedure output sub-factor, would be dependent on the training and experience of the nurse performing the screening procedure, which in turn could affect screening outcome. There was also concern expressed about the speed of interpretation of the screening procedure output, but speed itself, the final screening procedure output sub-factor, was perceived as a positive characteristic of the screening procedure because it would avoid any anxiety that would otherwise be experienced if there was a waiting period and action could be taken sooner if an aneurysm was diagnosed. Avoiding anxiety was probably the reason why some women in a study conducted by Hulka *et al.* (1997) commented that the ideal notification of screening mammography outcomes would be an immediate

notification at the screening and a delayed notification after the mammography output had been viewed twice (i.e. more thoroughly). Incidentally, there was a significant preference for delayed outcomes, and ‘reducing odds’ and ‘better odds’ of beating cancer were mentioned as reasons why.

The screening procedure was perceived as quick, which was positively associated with the convenience of attending AAA screening, although arranging a screening and being able and having the time to attend might influence whether participants would be screened. The procedure was also considered to have a low level of complexity and was perceived as simple and easy. This positive characteristic is similar to sensations from the procedure because it would be painless and cause no discomfort, and alleviating substances would not be used or required. This may facilitate screening attendance since Abdullah *et al.* (2011), Griffith *et al.* (2012), Pivot *et al.* (2008) and Weinberg *et al.* (2004) found the belief that an investigation or test will be painful acted as a barrier. The theory of planned behaviour (Ajzen, 2005, p. 126) and the health belief model (Strecher *et al.*, 1997) can be used to theorise this, as they have with respect to personal benefits and risks.

Deciding whether to be or not to be screened is a preference sensitive decision where values and preferences would influence decision-making. Participants valued choice and control of the initial screening decision, as well as when deciding on which treatment to proceed with if screened and a large aneurysm was diagnosed. If a large aneurysm was diagnosed participants had a positive perspective that there was well-defined treatment in place, because they would ‘speak with surgeon’ or more specifically meet with a vascular surgeon to receive explanations, discuss treatment options, ask questions and gain advice. Trust is elemental to this and the trust factor consists of trust in clinicians and/or clinical practice. Participants had trust in the screening programme and the research supporting it, and trust in clinicians and other healthcare professionals involved in the screening. There was no specific trust with the screening procedure or medical technology, which, like trust in the diagnostic context from the first study, does not fit with Montague and Asan’s (2012, see pages 17-18 for recap) patient trust in medical technology model. There was, however, trust in a doctor’s recommendation and a number of studies have found clinician recommendation to facilitate screening (DeFrank *et al.*, 2012;

Ling *et al.*, 2001; Hemsing Cruz *et al.*, 2008; Ogedegbe *et al.*, 2005) whilst the lack of one can have the opposite effect and is commonly predictive of screening non-attendance (DeFrank *et al.*, 2012; Ogedegbe *et al.*, 2005; Salimzadeh *et al.*, 2011; Taylor *et al.*; 2002). Trust could also be considered with respect to the acceptance of the further investigations and tests and/or surgery if screened and a large aneurysm was diagnosed. The investigations and tests were seen as good clinical practice and a necessity for assessing and preparing for surgery, whilst both surgical interventions were accepted as a necessity in treating a large aneurysm.

The study aimed to understand attitudes towards AAA screening and informational needs and preferences. In deciding whether to be or not to be screened participants' informational needs and preferences were on the basis of information to inform them about AAAs, screening for the condition, the screening procedure, the benefits of being screened, and the risks of being or not being screened. Information about what to expect if diagnosed with a small or large aneurysm was not required, although media permitting, it was suggested that this information could be obtained for men who were interested and/or preferred to be further informed. Participants valued the decision to be or not to be screened as a preference sensitive one, and that another and separate preference sensitive decision would be required if a large aneurysm was diagnosed, which Stiggelbout and Kievit (2009) discuss with respect to decision support in the treatment of AAAs. The factors established provide a constructive understanding of attitudes towards AAA screening and similarly to factors affecting attitudes towards diagnostic procedures, they have the potential to guide the design of patient information. This concept, the user centred design concept for patient information, which was conceptualised in the previous chapter (see pages 103-107 for recap), is developed in the next section.

## **4.5 Development of the user centred design concept for patient information**

The factors affecting attitudes towards diagnostic procedures inspired a concept to design information based on factors. The factors based approach (Figure 3.12) consists of including and organising information based on factors, which could also contribute to patient information guidelines (i.e. provide guidance for content and

content structure of patient information). The factors based approach is theory led and has taken inspiration from Ajzen's (2005, p. 126, see pages 25-26 for recap) theory of planned behaviour. This theory led approach could be one that satisfies Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. There are currently no specific guidelines for information designers to follow when designing patient information for when patients have options of or require investigations or tests, and therefore guidance in the form of patient information guidelines may be a useful tool. A practical guide was considered a useful tool by the majority of healthcare information producers who took part in a recent survey by the Patient Information Forum (2013b, p. 10).

Using the factors based approach to the design of patient information the 10 factors affecting attitudes towards diagnostic procedures (Figure 3.11) could guide the design of patient information for investigations and tests in the context of diagnosis, and the 15 factors affecting attitudes towards AAA screening (Figure 4.7) could guide the design of patient information for investigations and tests in the context of screening. Both sets of factors, which have factors that are identical (e.g. physical involvement) or similar (e.g. understanding and improving health from the diagnostic context and benefits from the screening context), could also be combined to guide the design of patient information. This could include guiding the design of patient information for both diagnostic and screening contexts, or guiding the design of information without context orientation (i.e. with no reference to symptoms and/or medical conditions). Without context orientation means information could be used in either diagnostic or screening contexts to inform about an investigation or test, but with no reference to a specific healthcare situation.

The next two chapters will consider all factors, as well as other relevant findings from the first two studies, to guide the design of patient information for an investigation or test without context orientation. This is because the factors based approach to the design of patient information is a novel concept and the next two chapters are focussed on examining the factors based approach. Depending on findings, the factors based approach could be further examined using diagnostic and screening contexts, and factors will be considered for these contexts for future

reference. However, it is envisaged to adapt patient information without context orientation to patient information for diagnostic and screening contexts should be a relatively simple exercise since only a small number of factors will be context specific (i.e. only for diagnostic and screening contexts).

## 4.6 Methodology considerations

The participants were proxies and what has not been examined in this study is the extent to which participant responses would be the same if they were actually invited for AAA screening. However, they were approaching an age that was representative of the age when men are invited for the screening and participants did reflect on the importance of screening as they get older. The Map of Medicine (2013) was valuable in designing a study that portrayed AAA screening and its stages, and the interview schedule was developed following sufficient piloting to ensure valid data were collected with respect to these and the proposed content of the DA developed by the NHS Abdominal Aortic Aneurysm Screening Programme. The data cannot be assumed to be random due to the purposive convenience sampling technique used and therefore cannot be generalised to a population of all men invited for AAA screening.

No pictograms were included to communicate risks, which could have affected how participants interpreted risk information, although the semistructured interviews enabled the interviewer to probe for further information and for participants to explain responses so that any misinterpretation would have been noted.

Additionally, the use of semistructured interviews enabled participants to suggest ideas that may improve risk communication for AAA screening and specifically the quantification of the benefits and risks of the screening.

Some participants might have highlighted information in the DA booklet as to what they perceived to be good or bad about AAA screening for men in general rather than what would make them, personally, more likely or less likely to be screened. However, participants were informed of this throughout interviews and were provided with a handout of these instructions for reference. The exercise of highlighting information in the DA booklet and then commenting on this was a

successful facilitator between interviewer and participant, and as a user testing technique for developing patient information resources and specifically DAs, it generated quality feedback with respect to legibility and understanding, which would be important in ensuring readability and meeting the requirements of the ‘plain language’ dimension of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009, see pages 46-47 for recap). The DA booklet and the handouts also generated suggestions about accessing and using information online via the Internet, and the use of images and videos to support information provision.

Finally, as for the first study, the analysis of the qualitative data was from the perspective of the researchers involved in this study. If researchers with different perspectives analysed the data, the interpretation, coding and theming of the data may vary. Respondent validation or ‘member checking’ (Creswell and Miller, 2000; Mays and Pope, 2000) could have been used to examine the credibility of the factors and the themes, and Cohen’s Kappa coefficient (Cohen, 1960) could have been used to provide a statistical measure for inter-rater reliability for qualitative coding. However, the thematic analyses were rigorously conducted and peer debriefing (Creswell and Miller, 2000) was used, so the factors that were established and the themes that emerged were discussed and rationalised to ascertain their basis and reasoning. (See page 109 for a recap on respondent validation and Cohen’s Kappa coefficient).

## 4.7 Conclusion

Fifteen factors were established that affected attitudes towards AAA screening (Figure 4.7) and benefits and risks, personal sub-factors, were the most influential factors and would be pivotal for men deciding whether to be or not to be screened. Information about risk factors, another personal sub-factor, and physical involvement would also be pivotal but to a lesser degree. Other factors that were established include screening procedure output sub-factors interest and understanding, interpretation, and speed; and familiarity, convenience, acceptance, sensations, choice and control, complexity, trust and speak with surgeon. Although the other factors were smaller and less influential, they were still important aspects of AAA screening.

Participants valued the decision to be or not to be screened as a preference sensitive one, and that another and separate preference sensitive decision would be required if a large aneurysm was diagnosed. Information provision preferences reflected this and information about what to expect if diagnosed with a small or large aneurysm was not required. It was suggested, media permitting, that this information could be obtained for men who were interested and/or preferred to be further informed.

Overall the factors provide a constructive understanding of attitudes towards AAA screening and have continued the development of the potential to guide the design of patient information using a 'factors based approach' (Figure 3.12). This potential will be examined in the next two chapters using an online study and focus groups.

## CHAPTER 5

# Online study to examine the factors based approach to the design of patient information

### 5.1 Introduction

Chapter 5 reports the findings from an online study examining the factors based approach to the design of patient information, which was conceptualised in Chapter 3 as a user centred design concept (see pages 103-107 for recap) and developed in Chapter 4 (see pages 156-158 for recap). The study is in response to the third research question, which is as follows:

- 3) How does patient information based on factors affecting patients' attitudes towards diagnostic and screening procedures affect the value of the information?

The factors based approach to the design of patient information consists of including and organising information based on factors, which could also contribute to patient information guidelines (i.e. provide guidance for content and content structure of patient information). The factors based approach is theory led and has taken inspiration from Ajzen's (2005, p. 126, see pages 25-26 for recap) theory of planned behaviour. This theory led approach could be one that satisfies Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. Factors established include 10 factors affecting attitudes towards diagnostic procedures (see pages 87-96 for recap) and 15 factors affecting attitudes towards abdominal aortic aneurysm (AAA) screening (see pages 122-139 for recap). These factors arose from taking a human factors approach to medical devices from the perspective of potential patients and men in the contexts of diagnosis and screening, respectively. They are qualitatively sourced and developed, and provide a constructive understanding of attitudes.



## 5.2 Methodology

### 5.2.1 Study design

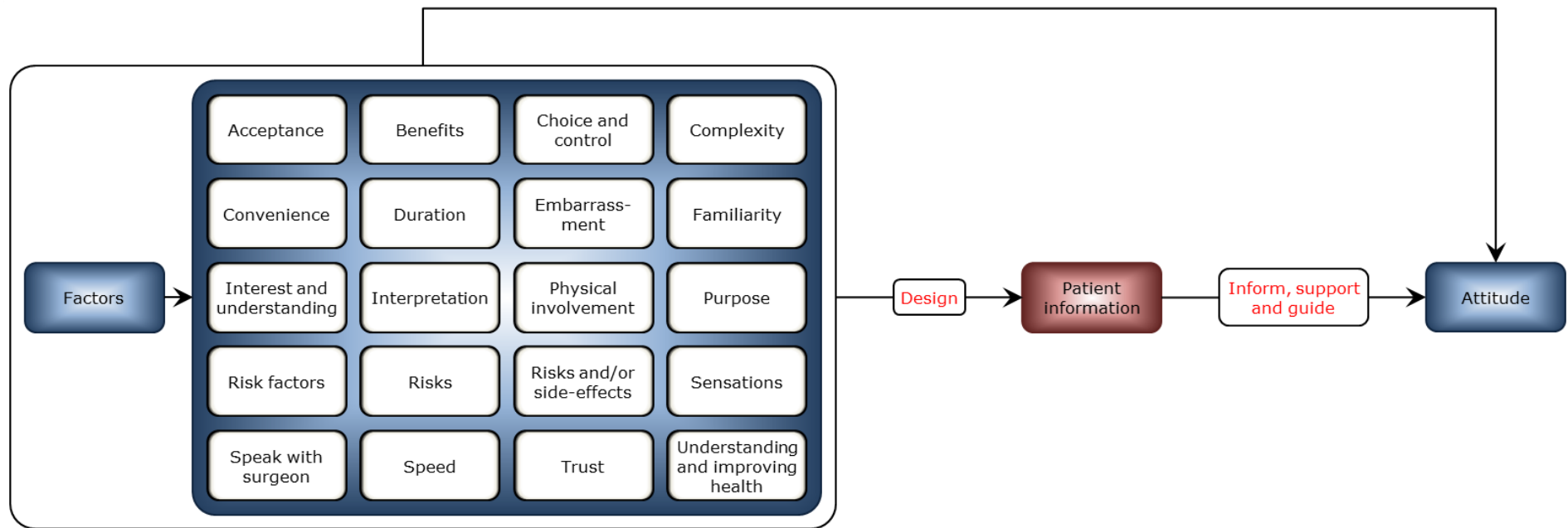
#### *5.2.1.1 Consideration of factors to guide the design of patient information using the factors based approach*

All 20 established factors (5 identical factors were merged) affecting attitudes towards diagnostic procedures (Figure 3.11) and AAA screening (Figure 4.7) were considered to guide the design of patient information using the factors based approach. There were three aspects to this process: 1) consider factors appropriate to guide the design of patient information for an investigation or test without context orientation (i.e. with no reference to symptoms and/or medical conditions); 2) consider factors appropriate for diagnostic contexts; and 3) consider factors appropriate for screening contexts. The first aspect, without context orientation, relates to information that could be used in either diagnostic or screening contexts to inform about an investigation or test, but with no reference to a specific healthcare situation. Information without context orientation was used in this study because the factors based approach to the design of patient information is a novel concept and the focus of the study was on examining the factors based approach. The second and third aspects are for future reference as it is envisaged to adapt patient information without context orientation to patient information for diagnostic and screening contexts should be a relatively simple exercise since only a small number of factors will be context specific (i.e. only for diagnostic and screening contexts).

The consideration of the factors for the three aspects was done so objectively. This involved considering each factor individually and what it represented, and whether the factor could be informed about when symptoms and/or medical conditions were not referred to (without context orientation), when symptoms were referred to (diagnostic context) and when medical conditions were referred to (screening context). Each of these considerations had to take into account an investigation or test with respect to the patient journey. So without context orientation there would be no reference to symptoms and/or medical conditions and the focus would be on an investigation or test solely; in a diagnostic context a patient would have presented symptoms to a GP in a primary care setting or would have been referred

to secondary care, and because of this there would be a requirement of an investigation or test to determine the cause of the symptoms; and in a screening context a patient would have no symptoms, but would have the option of an investigation or test to detect a medical condition to prevent its advancement to an untreatable state.

Similarly to the thematic analyses used in the first two studies, peer debriefing (Creswell and Miller, 2000) with colleagues at supervision meetings and project meetings was used to validate the consideration of the factors for the three aspects. This was often in the manner of an interrogation so that the consideration of the factors was rationalised, and the eventual factors considered appropriate for the three aspects were ascertained for their basis and reasoning. Figure 5.1 graphically represents all 20 factors to guide the design of patient information using the factors based approach, which is followed by an explanation of the factors considered appropriate for the three aspects. This explanation is a summary of Appendix 15, which provides a more detailed account of the factors individually for the three aspects.



**Figure 5.1** Guiding the design of patient information using all factors affecting attitudes towards diagnostic procedures and abdominal aortic aneurysm screening and the factors based approach

Five factors were considered not appropriate for all three aspects: 1) complexity; 2) embarrassment; 3) familiarity; 4) trust; and 5) understanding and improving health. They were considered not appropriate because they were either objective and/or subjective perspectives affected by other factors, symptoms, the optional or required investigation and test, relationships with clinicians and other healthcare professionals, healthcare experiences, and/or because they could not be directly informed about. Information provision for reducing embarrassment, which was discussed in the embarrassment factor, was, however, considered appropriate to be included in the physical involvement factor. Incidentally, side-effects was established as a separate factor from the risks and/or side-effects factor because risks and side-effects differ in the information they inform patients about, and the speak with surgeon factor was generalised to the speak with clinician and/or other healthcare professional factor. From the 20 factors, 9 were considered appropriate to guide the design of patient information for an investigation or test without context orientation, 11 were considered appropriate for diagnostic contexts and 13 were considered appropriate for screening contexts. The two factors not accounted for are the acceptance factor and the risks factors factor, which were considered appropriate to be included in the speak with clinician and/or other healthcare professional factor and the purpose factor, respectively. The 13 factors for the relevant three aspects are as follows:

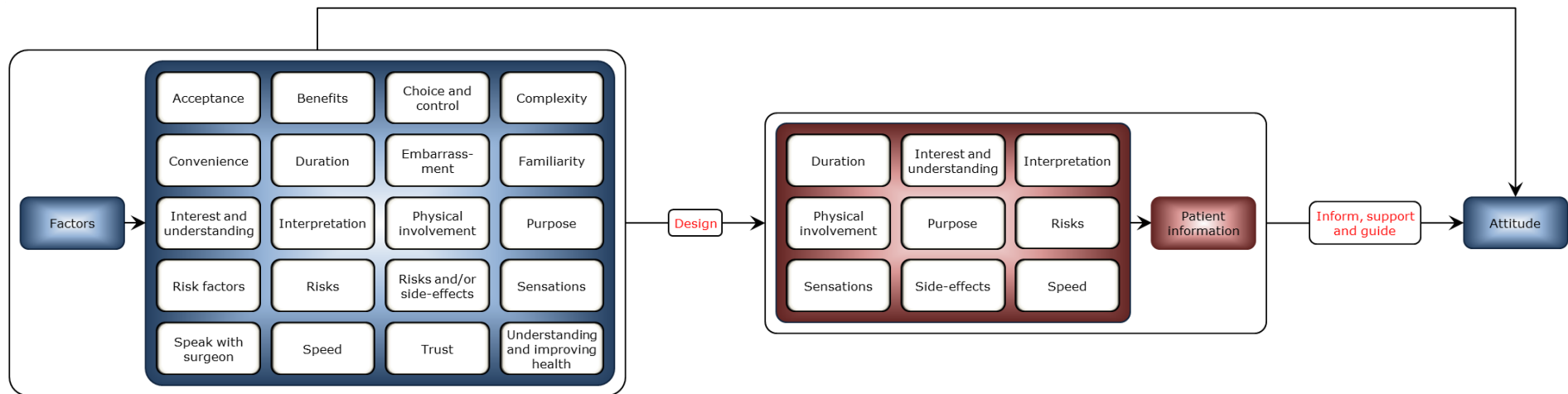
- Benefits (screening context only).
- Choice and control (diagnostic and screening contexts only).
- Convenience (diagnostic and screening contexts only).
- Duration (without context orientation and diagnostic and screening contexts).
- Interest and understanding (without context orientation and diagnostic and screening contexts).
- Interpretation (without context orientation and diagnostic and screening contexts).
- Physical involvement (without context orientation and diagnostic and screening contexts).
- Purpose (without context orientation and diagnostic and screening contexts).
- Risks (without context orientation and diagnostic and screening contexts).
- Sensations (without context orientation and diagnostic and screening contexts).

- Side-effects (without context orientation and diagnostic and screening contexts).
- Speak with clinician and/or other healthcare professional (screening context only).
- Speed (without context orientation and diagnostic and screening contexts).

The important point to remember about the factors is their suitability for the three aspects. For example, the benefits factor is considered appropriate only for a screening context because the factor is about a patient being made aware that they do or do not have a medical condition when they are asymptomatic (i.e. patient presents no symptoms). Therefore the patient needs to be informed about the benefits of an investigation or test because they would have no symptoms present that would require an investigation or test. Whilst for a diagnostic context a patient would have presented symptoms to a GP in a primary care setting or would have been referred to secondary care, and the benefits of an investigation or test would be to understand what is causing symptoms so that appropriate measures can be taken to improve health. Therefore the patient does not need to be informed about the benefits because the benefits instigated the patient journey, and any benefits with respect to health advice and/or healthcare if the patient is diagnosed with a medical condition should be discussed with their GP and/or , if referred, specialist clinician.

The above is similar reasoning to why the speak with clinician and/or other healthcare professional factor was considered appropriate only for a screening context; and because an investigation or test would have been recommended and/or requested by a GP or specialist clinician in a diagnostic context, and speaking with either or both following an investigation or test would be instigated from the recommendation and/or request. To clarify, the speak with clinician and/or other healthcare professional factor was considered appropriate only for a screening context because a patient would be asymptomatic and the support they would receive following a diagnosis may affect their decision whether to be or not be screened. Therefore the patient should be informed about the support they would expect to receive to aid their decision.

Without context orientation both the benefits factor and the speak with clinician and/or other healthcare professional factor were considered not appropriate because of their references to symptoms and/or medical conditions. The choice and control factor and the convenience factor were also considered not appropriate because they were associated with a patient having the option of an investigation or test, and the patient making arrangements to attend the investigation or test. Figure 5.2 graphically represents the nine factors without context orientation to guide the design of patient information using the factors based approach, and the information the nine factors are to inform patients about is described in Table 5.1.



**Figure 5.2** Guiding the design of patient information without context orientation using appropriate factors affecting attitudes towards diagnostic procedures and abdominal aortic aneurysm screening and the factors based approach

Factor	Information
Duration	Time investigation or test will take to complete.
Interest and understanding	<p>Informational output produced from investigation or test (e.g. image from an X-ray). Whether patients can view output during and/or after investigation or test. Whether clinicians and other healthcare professionals performing investigation or test will explain and/or if patients can ask questions about output.</p> <p><i>Suitable images and/or, media permitting, videos should be included to support information provision about investigation or test informational output.</i></p> <p><i>Since this factor, the interpretation factor and the speed factor are providing information about investigation or test informational output they will now be merged into a newly established factor: informational output.</i></p>
Interpretation	<p>Clinicians and other healthcare professionals involved in interpreting investigation or test informational output, and the interpretation process (e.g. image from an X-ray will be examined by a radiologist (a specialist healthcare professional)).</p> <p><i>Since this factor, the interest and understanding factor and the speed factor are providing information about investigation or test informational output they will now be merged into a newly established factor: informational output.</i></p>
Physical involvement	<p>Patient physical involvement with investigation or test and any different phases of involvement (i.e. before, during and/or after investigation or test). If there is the possibility of embarrassment then information about investigation or test being performed and assisted by qualified healthcare professionals who are trained in and have experience of the investigation or test, and who will not feel uncomfortable or embarrassed about it can be included.</p> <p><i>Suitable images and/or, media permitting, videos should be included to support information provision about patient physical involvement with investigation or test.</i></p>
Purpose	<p>Body part investigation or test is investigating or testing, respectively.</p> <p><i>Suitable images and/or, media permitting, videos should be included to support information provision about body part.</i></p>
Risks	<p>Potential dangers and consequences of investigation or test.</p> <p><i>Suitable quantitative evidence should be used to quantify risks, which should be appropriately formatted using numerical and/or graphical formats. Quantitative evidence could be accessed (i.e. linked), media permitting, from quantitative terms (e.g. small chance) so patients can decide whether they would or would not prefer to be informed about specific quantitative details.</i></p>
Side-effects	Physical limitations and/or sensations following investigation or test, including limitations and/or sensations from alleviating substances.
Sensations	Pain and/or discomfort that may be experienced from investigation or test. Alleviating substances used to relieve or



	reduce pain and/or discomfort. <i>If alleviating substances are optional then information about this should be provided.</i>
Speed	Time it will take investigation or test informational output to be interpreted to outcome or result, respectively, and become available.  <i>Since this factor, the interest and understanding factor and the interpretation factor are providing information about investigation or test informational output they will now be merged into a newly established factor: informational output.</i>

**Table 5.1** Descriptions of information based on factors without context orientation to inform patients about

Since the interest and understanding, interpretation and speed factors provide information about investigation or test informational output they were merged into a newly established factor: informational output. This results in seven factors to guide the design of patient information for an investigation or test without context orientation, and nine and eleven for diagnostic and screening contexts, respectively. The merging of the three factors is similar to when they were established as they were screening procedure output sub-factors in factors affecting attitudes towards AAA screening (see pages 130-134 for recap).

#### ***5.2.1.2 Examining the factors based approach using a patient information resource based on appropriate factors***

To examine the factors based approach to the design of patient information the factors established to guide the design of patient information for an investigation or test without context orientation were applied to an existing patient information resource. This resulted in two information resources: 1) the existing resource; and 2) the factors based resource. Both of these resources were then evaluated and compared in an online study, therefore examining the factors based approach to the design of patient information.

The investigation or test used in the patient information resources was colonoscopy, an investigation featured in the vignettes from the first study of the thesis, which is reported in Chapter 3. Findings from the study suggested information would be of particular benefit to patients who are experiencing investigations or tests for the first time, especially invasive ones. Therefore the use of colonoscopy was

appropriate because of its invasiveness. It also has different phases of patient physical involvement (i.e. before, during and after a colonoscopy), which would enable a broader examination of the factors based approach to the design of patient information.

The existing patient information resource for colonoscopy was developed from a number of patient information resources currently available for it to produce a homogeneous version so that the information resource was representative of a standard content and structure. Information resources that were researched include 20 leaflets, booklets and websites, 8 mobile phone applications and 14 videos. Four of the resources were chosen to develop the existing information resource; two booklets (Macmillan Cancer Support, 2010; NHS Bowel Cancer Screening Programme, 2006), one leaflet (Knott, 2012 (produced for patient.co.uk)) and one website (Bupa, 2013 (a 2011 version was used in this study)). The Macmillan Cancer Support booklet was in a screening context, and was written, revised and edited by the Macmillan Cancer Support's Cancer Information Development team; the NHS Bowel Cancer Screening Programme booklet was also in a screening context, and was developed by Cancer Research UK, in association with the NHS Bowel Cancer Screening Programme and with advice from the English Bowel Cancer Screening Pilot; the patient.co.uk leaflet was somewhat in a diagnostic context (possible symptoms and medical conditions linked with colonoscopy listed), and was developed by the patient.co.uk editorial team; and the Bupa website was also somewhat in a diagnostic context (possible symptoms and medical conditions linked with colonoscopy listed), and was developed by Bupa's Health Information Team. There was no information provided about the time it took to develop the four patient information resources, but their approaches seem top-down (i.e. from a clinician, other healthcare professional and researcher perspective) and may not truly reflect user centred design. This is discussed in the literature review (see pages 39-43 for recap), and is also mentioned with respect to the development of the draft version of the core text of the AAA screening decision aid used in the previous study (see pages 116-117 for recap).

The content and structure of the four patient information resources were collated into one document, which was gradually adjusted (four iterations) until a final

version was produced that was representative of a standard content and structure, and was not context orientated, as the factors based information resource was to be. This also involved removing information that was similar to avoid repetition. Appendix 16 provides the second version of the collated resources, which includes highlighted information and written remarks. The first version was the initial collation of the four resources, which involved excluding content that were clearly not appropriate (e.g. about possible symptoms linked with colonoscopy and alternatives to the investigation, which links in with the choice and control factor). It is worth noting for future reference that personal pronouns (i.e. you and your) were used frequently in the four resources and subsequently in the final version of the collated resources. Figures 5.3-5.5 provide the final version in its entirety, which will now be referred to as the 'standard patient information resource'. An image of a colonoscopy being performed is included in the standard patient information resource, which also depicts the colon (or large bowel as it is annotated). Risks from the investigation are descriptively and numerically communicated with numerical communications using statistical expressions of frequency ranges.

# Colonoscopy

## *Patient Information*

### ***What is a colonoscopy?***

A colonoscopy is an investigation used to look at the lining of the large bowel, which is also known as the large intestine or the colon. It is performed using a thin flexible tube called a colonoscope, which is passed into your rectum (back passage) and guided around your large bowel.

### ***What do you need to do before a colonoscopy?***

Your bowel needs to be completely empty during the colonoscopy so that the specialist doctor performing the investigation can clearly see. You will receive instructions telling you what you need to do to prepare. You will usually be asked to:

- stop taking any iron tablets – these make the inside of the bowel look black, which means it is hard for the doctor to clearly see;
- eat a special diet and drink lots of clear fluids in the days before the colonoscopy; and
- take a strong laxative the day before the colonoscopy, which will give you diarrhoea. You will need to stay close to a toilet.

It is important that you follow instructions very carefully to fully empty your bowel. Otherwise the doctor may not be able to clearly see the lining of your bowel during the colonoscopy and you will need to have the investigation again.

You may need to arrange for someone to accompany you home after the colonoscopy as patients are usually given a sedative and you may feel drowsy if given one.

### ***What happens during a colonoscopy?***

You will be asked by a nurse who will be assisting the specialist doctor performing the colonoscopy to put on a hospital gown that opens at the back. You will usually be given a sedative to help you relax, which is usually given by an injection into a vein in the back of your hand. If you have a sedative you will feel drowsy and won't remember much about the colonoscopy.

You will be asked to lie on your side and a thin flexible tube called a colonoscope is passed into your rectum and guided around your large bowel. Lubricating jelly will be used to make this as easy as possible. At the end of the colonoscope there is a small camera with a light attached, which allows the doctor to see the inside of your bowel on a TV screen. You may be able to see the screen too if you wish. During the colonoscopy you may be asked to change position, which will help the doctor investigate different areas of your bowel.

When the colonoscopy is being performed, some air will be pumped down a channel in the colonoscope into your bowel to allow the doctor to clearly see the lining of your bowel. This

**Figure 5.3** Standard patient information resource – page 1 of 3

may give you a bloating or cramping feeling in your abdomen, and may cause you to pass wind but this is normal and there is no need to feel embarrassed as the doctor and nurse will expect this to happen.



Sometimes a small tissue sample called a biopsy will be taken or polyps (small lumps of tissue that hang from the lining of the bowel) will be removed. This is done painlessly using instruments that are passed down the colonoscope. Tissue samples will be sent to a laboratory for testing and to be looked at under a microscope.

At the end of the investigation the colonoscope is gently pulled out. The colonoscopy should take between 30 and 45 minutes. Some patients find having a colonoscopy uncomfortable but most do not report that it is painful. Most patients are ready to go home a couple of hours after a colonoscopy.

### ***What happens after a colonoscopy?***

The specialist doctor who performed the colonoscopy will explain the outcome of the investigation to you. You will be told if any tissue samples or polyps were removed. If tissue samples were removed you should receive test results of the samples in three weeks.

You may notice traces of blood coming from your rectum if tissue samples or polyps were removed. Slight bleeding like this is not uncommon and may last for a few days. You should report any symptoms of prolonged or heavy bleeding (such as cramping, stomach pains, fever and heavy bleeding from your rectum) to the colonoscopy unit or your GP.

The effects of the sedative takes some time to wear off and you should make sure that you do not drive, use machinery or drink alcohol for at least 24 hours. You should also avoid making important decisions until 24 hours after the colonoscopy. You will need somebody to accompany you home and you should also have someone stay with you for 12 hours afterwards. It is a good idea for you to have someone with you when the doctor explains the outcome of the colonoscopy as you will still be feeling the effects of the sedative.

### ***Are there any side-effects or risks from having a colonoscopy?***

Taking a strong laxative the day before a colonoscopy may cause you to lose a lot of fluid from your body as you pass several bowel motions to empty your bowel. If you have heart problems you should let your GP know before you take any laxatives as this fluid loss can temporarily worsen your condition.

**Figure 5.4** Standard patient information resource – page 2 of 3

After having a colonoscopy you may feel bloated and uncomfortable due to trapped wind. You may find that lying on your front can help. Trapped wind usually passes after a few hours.

The specialist doctor performing the colonoscopy may not be able to pass the colonoscope along the whole length of your bowel. It is estimated that this happens in about five out of every 100 people who have a colonoscopy. This can happen because of a blockage (if your bowel is not completely empty) or difficulty in moving the colonoscope around your bowel. You may be asked to have another colonoscopy or a different investigation.

If tissue samples or polyps are removed during a colonoscopy this may cause heavy bleeding that needs further investigation or medical advice. It is estimated that this happens in about one out of every 150 people who have a colonoscopy.

The colonoscope could cause a hole (perforation) in the wall of your bowel. It is estimated that this happens in about one out of every 1,500 people who have a colonoscopy. If this happens you may need an operation.

You may have a reaction to the sedative that may make you have temporary breathing or heart problems. Serious problems are rare as you will be carefully monitored during a colonoscopy.

In extremely rare cases a colonoscopy could lead to death. It is estimated that this happens in about one out of every 10,000 people who have a colonoscopy.

**Figure 5.5** Standard patient information resource – page 3 of 3

Having developed the standard patient information resource for colonoscopy a factors based information resource could then be produced for the investigation. This involved applying the seven factors to guide the design of a patient information resource for an investigation or test without context orientation to the standard resource. This was a straightforward exercise and the factors based patient information resource is provided in its entirety in Figures 5.6-5.8. Information included in the factors based information resource was almost identical to that of the standard resource, but varied in that the organisation of the information was representative of the seven factors and consequently the factors based approach to the design of patient information. This variable was what was being examined in this study in order to examine the factors based approach. The seven factors were described using question titles, which was to replicate the question titles used in the standard resource and consequently the existing patient information resources the standard resource was developed from. The order of the factors was logical with respect to colonoscopy, as information in the standard resource was described, and is as follows:

- Purpose.
- Physical involvement.
- Informational output.
- Duration.
- Sensations.
- Side-effects.
- Risks.

# Colonoscopy

## Patient Information

### ***What is the purpose of a colonoscopy?***

To investigate the lining of the large bowel, which is also known as the large intestine or the colon.

### ***What is required of you before, during and after a colonoscopy?***

#### **Before a colonoscopy**

Your bowel needs to be completely empty during the colonoscopy. You will receive instructions telling you what you need to do to prepare and it is important that you follow these instructions very carefully. You will usually be asked to:

- stop taking any iron tablets – these make the inside of the bowel look black, which means it is hard for a specialist doctor performing the colonoscopy to clearly see;
- eat a special diet and drink lots of clear fluids in the days before the colonoscopy; and
- take a strong laxative the day before the colonoscopy, which will give you diarrhoea. You will need to stay close to a toilet.

#### **During a colonoscopy**

You will be asked by a nurse who will be assisting the specialist doctor performing the colonoscopy to put on a hospital gown that opens at the back. You will be asked to lie on your side and a thin flexible tube called a colonoscope is passed into your rectum and guided around your large bowel. Lubricating jelly will be used to make this as easy as possible. Some air will be pumped down a channel in the colonoscope into your bowel to allow the doctor to clearly see the lining of your bowel and you may be asked to change position, which will help the doctor investigate different areas of your bowel. At the end of the investigation the colonoscope is gently pulled out.



The colonoscopy is performed and assisted by qualified healthcare professionals who have

**Figure 5.6** Factors based patient information resource – page 1 of 3



been trained in and have experience of the investigation, and who will not feel uncomfortable or embarrassed about it.

The doctor may not be able to pass the colonoscope along the whole length of your bowel. It is estimated that this happens in about five out of every 100 people who have a colonoscopy. This can happen because of a blockage (if your bowel is not completely empty) or difficulty in moving the colonoscope around your bowel. You may be asked to have another colonoscopy or a different investigation.

#### **After a colonoscopy**

You will be monitored before you can go home.

#### ***What does a colonoscopy actually do?***

At the end of a colonoscope there is a small camera with a light attached, which allows the specialist doctor performing the colonoscopy to see the inside of your bowel on a TV screen. You may be able to see the screen too if you wish.

Sometimes a small tissue sample called a biopsy will be taken or polyps (small lumps of tissue that hang from the lining of the bowel) will be removed. This is done using instruments that are passed down the colonoscope. Tissue samples will be sent to a laboratory for testing and to be looked at under a microscope.

The doctor will explain the outcome of the investigation to you after the colonoscopy. You will be told if any tissue samples or polyps were removed. If tissue samples were removed you should receive test results of the samples in three weeks.

#### ***How long will a colonoscopy take?***

A colonoscopy should take between 30 and 45 minutes. Most patients are ready to go home a couple of hours after a colonoscopy.

#### ***Is there any pain or discomfort during a colonoscopy?***

You will usually be given a sedative to help you relax during a colonoscopy, which is usually given by an injection into a vein in the back of your hand. If you have a sedative you will feel drowsy.

A bloating or cramping feeling in your abdomen may be experienced when air is being pumped into your bowel during a colonoscopy. This may cause wind to be passed.

Some patients find having a colonoscopy uncomfortable but most do not report that it is painful. The removal of tissue samples or polyps is painless.

#### ***Are there any side-effects from having a colonoscopy?***

After having a colonoscopy you may feel bloated and uncomfortable due to trapped wind. You

**Figure 5.7** Factors based patient information resource – page 2 of 3

may find that lying on your front can help. Trapped wind usually passes after a few hours.

If you have a sedative you won't remember much about the colonoscopy. The effects of the sedative takes some time to wear off and you should make sure that you do not drive, use machinery or drink alcohol for at least 24 hours. You should also avoid making important decisions until 24 hours after the colonoscopy. You will need somebody to accompany you home and you should also have someone stay with you for 12 hours afterwards. It is a good idea for you to have someone with you when the doctor explains the outcome of the colonoscopy as you will still be feeling the effects of the sedative.

You may notice traces of blood coming from your rectum if tissue samples or polyps were removed during a colonoscopy. Slight bleeding like this is not uncommon and may last for a few days. You should report any symptoms of prolonged or heavy bleeding (such as cramping, stomach pains, fever and heavy bleeding from your rectum) to the colonoscopy unit or your GP as further investigation may be needed. It is estimated that this happens in about one out of every 150 people who have a colonoscopy.

### ***Are there any risks from having a colonoscopy?***

Taking a strong laxative the day before a colonoscopy may cause you to lose a lot of fluid from your body as you pass several bowel motions to empty your bowel. If you have heart problems you should let your GP know before you take any laxatives as this fluid loss can temporarily worsen your condition.

The colonoscope could cause a hole (perforation) in the wall of your bowel. It is estimated that this happens in about one out of every 1,500 people who have a colonoscopy. If this happens you may need an operation.

You may have a reaction to the sedative that may make you have temporary breathing or heart problems. Serious problems are rare as you will be carefully monitored during a colonoscopy.

In extremely rare cases a colonoscopy could lead to death. It is estimated that this happens in about one out of every 10,000 people who have a colonoscopy.

**Figure 5.8** Factors based patient information resource – page 3 of 3

Content of the standard and the factors based patient information resource are differentiated in Appendix 17 in order to demonstrate information that was identical in both information resources and information that was not. This involved using colour coding to demonstrate information that was provided only in the standard resource, only in the factors based resource, in both resources using the same wording and in both resources using different wording. The factors based resource is 78 words less than the standard resource, which is due to the specificity of the seven factors and the focus of the information on these. It is worth noting for future reference that the process of re-designing the standard patient information resource to produce the factors based information resource resulted in the inclusion of statistical expressions of frequency ranges in the side-effects section of the factors based resource. This is important because suitable quantitative evidence is not recommended in the information the side-effects factor is to inform patients about and so would probably benefit from having this included. Suitable quantitative evidence is recommended in the risks factor.

Both patient information resources were transferred online to The University of Nottingham's server. These were coded to be compatible with and consistent across the four major web browsers: 1) Firefox ; 2) Google Chrome; 3) Internet Explorer; and 4) Safari. A code was written so that when participants proceeded to one of the information resources from the study's introduction and consent webpage, the resource alternated between the standard and the factors based resource for each participant. This was an attempt to have an equal number of participants read each resource.

### **5.2.2 Data collection**

A questionnaire was developed to collect data following research into a number of tools available to assess patient information resources; measure information preferences, decision-making preferences and decision-making processes; and satisfaction with information and decisions. These tools were considered for their suitability to evaluate the standard and the factors based patient information resource, which could then be compared. Appendix 18 describes all tools and their suitability for evaluating the information resources, from which five tools or their adaptations were used. The five tools are as follows:

- Acceptability.
- Confidence to Decide about Treatment Scale.
- Knowledge.
- Process of Decision Making.
- Satisfaction with Decision.

(Kryworuchko *et al.*, 2008; Michie *et al.*, 1997; McBride *et al.*, 2002; O'Connor, 2004a; O'Connor and Cranney, 2002; O'Connor *et al.*, 1998a, O'Connor *et al.*, 1998b; O'Connor *et al.*, 1999b)

Additional questions were included that were based on none of the tools, including two from the questionnaire for the vignette study and distraction questions prior to the Knowledge questions to cause a delay and change of thought in participants.

The questionnaire was split into five sections, Sections A-E, with Section C consisting of the distraction questions and Section E collecting sample demographic information. Apart from two open-ended questions in Section B, Sections A, B and D consisted of closed questions with the majority of them answered using seven-point interval scales (minimum rating = 1.00; maximum rating = 7.00) with verbal anchors, and a small number answered using categories. These three sections were designed to evaluate three aspects of the standard and the factors based patient information resource: 1) decision-making facilitation; 2) acceptability of information; and 3) information recall.

The decision-making facilitation section measured how much information participants read (to filter out questionnaires where participants had read about half or less of the standard and the factors based patient information resource); how informed they felt about a colonoscopy; how prepared they would feel if they were to have the investigation; how much time they think they would spend thinking about the investigation if they had an appointment to have one in two weeks' time; how confident they would feel talking to a specialist doctor, nurse or their GP about the investigation; how helpful they think the information would be for them to talk to a family member or friend about the investigation if they were to have one; and how apprehensive and embarrassed they would feel if they were to have the investigation (taken from vignette questionnaire).

The acceptability of information section measured participants' satisfaction with 11 items of information (from body part a colonoscopy investigates to risks of the investigation); how they felt about the length of time it took to read through the information; how they felt about the amount of information provided; how they felt about the way the information was written, presented and structured; how important they felt the image of a colonoscopy was in helping them understand the investigation; and how helpful they felt the information would be if they were to have the investigation, which was followed by the two open-ended questions to ask participants to explain their selected rating and to provide suggestions for improvements.

The information recall section measured participants' recall of information using 10 statements (from what the bowel is also known as to the need for an operation if a colonoscope causes a perforation in the bowel). These were answered using true and false categories, and confidence in answers was also measured.

The questionnaire is provided in its entirety in Appendix 19 and was transferred to Qualtrics (2013), an online survey software, on its completion. Participants proceeded to the questionnaire having read one of the two patient information resources, and were advised before proceeding that the questionnaire was to be completed without referring back to the information resources. To differentiate data collected between the standard and the factors based resource (and to keep costs to a minimum) two questionnaires were created on Qualtrics for each resource, which meant that the questionnaire had to be transferred twice. Data was exported as Microsoft Excel Comma Separated Values files.

### **5.2.3 Data analysis**

Quantitative data from the online study were analysed using IBM SPSS Statistics 19 (IBM Corp., 2010) and before commencing with statistical analysis the two variables (the standard and the factors based patient information resource) were tested to examine whether they met the assumptions of parametric data or not. This was not required for the questions answered using categories, which used the multi-dimensional chi-square test or Fisher's exact test for categories that had a count of

less than five. Variables that met the assumptions of parametric data used the independent *t*-test and variables that did not used the Mann-Whitney test.

Participants' satisfaction with the 11 items of information were compared between each item within both patient information resources, as was confidence in true or false answers for recall of information for the 10 statements. The dependent *t*-test was used when both ratings being compared for the items and statements met the assumptions of parametric data; otherwise the Wilcoxon signed-rank test was used.

Statistical significance for each test was valued at  $p < 0.05$ . Means ( $\bar{x}$ ) and standard deviations (*SD*) are reported to summarise scores instead of medians for consistency and to accurately show differences in participant ratings, and because medians will likely be identical even when there are statistically significant differences.

Qualitative data from the two open-ended questions were, as for the first two studies, analysed using NVivo 9 (QSR International Pty Ltd., 2010) using a thematic data led approach (Howitt, 2010, p. 175). And as for the first two studies, peer debriefing (Creswell and Miller, 2000) with colleagues at supervision meetings and project meetings was used to validate the data and the data analysis. Appendix 20 provides a screenshot of the coding of the qualitative data, demonstrating preliminary coding. (See page 70 for a recap on a thematic data led approach and peer debriefing).

#### **5.2.4 Sample**

Adults aged 18 years or older who had not had a colonoscopy or a similar investigation, such as proctoscopy or sigmoidoscopy, were eligible to participate in the study. This was to avoid bias from past experiences, which was reasoned in a study conducted by Smith *et al.* (2013a) who recruited participants approaching colorectal cancer screening age to examine a booklet that informs about colorectal cancer screening in the United Kingdom. And similarly to the first two studies, what will not be known in this study is whether the responses of the participants would be the same if they were to actually encounter colonoscopy in the future.

### 5.2.5 Recruitment

The study gained ethical approval from the Faculty of Engineering Research Ethics Committee at The University of Nottingham. Participants were recruited through advertising in a local newspaper, posters promoting the study in the local community, emailing of staff and students at the university, social media (Facebook and Twitter), an online forum (Patient Information Forum members' forum), and handing study cards (similar to business cards) to people and asking them to participate and/or, if they were happy to, pass on details of the study to people they knew. Participants consented to participate by ticking a check box in the introduction and consent webpage before proceeding to one of the two patient information resources. To encourage participation £3 was donated to Cancer Research UK for each completed questionnaire, which was capped at 150 questionnaires.

## 5.3 Results

One hundred and sixty-one questionnaires were completed; 79 for the standard patient information resource and 82 for the factors based patient information resource. However, due to participants reading about half or less of the information resources only 74 standard and 79 factors based resources were accepted for statistical analysis. Therefore 153 participants took part in the study of which 71 (46.4%) were female and 82 (53.6%) male, and of which 46 (30.1%) were aged 18-23 years, 29 (19%) 24-29 years, 38 (24.8%) 30-39 years, 19 (12.4%) 40-49 years, 15 (9.8%) 50-59 years and 6 (3.9%) 60-69 years.

The results are discussed in four parts: 1) decision-making facilitation; 2) acceptability of information; 3) information recall; and 4) helpfulness of and improvements to the patient information resources. The first three report the quantitative findings and the last reports the qualitative findings from the two open-ended questions.

### 5.3.1 Decision-making facilitation

A statistically significant association was not found between the patient information resources and how much of the information resources participants read. The majority of participants read all or almost all of the resources (Table 5.2).

	<b>Standard patient information resource</b>	<b>Factors based patient information resource</b>
<b>Amount of information read</b>	<i>No. (%)</i>	<i>No. (%)</i>
All of it	54 (73)	53 (67.1)
Almost all of it	12 (16.2)	15 (19)
Most of it but a few bits skipped	8 (10.8)	11 (13.9)

**Table 5.2** Amount of information participants read from the patient information resources

There were no statistically significant differences between the patient information resources in the decision-making facilitation section (Table 5.3). Having read either the standard or the factors based information resource, participants felt very informed about a colonoscopy; felt prepared if they were to have the investigation; would spend a considerable amount of time thinking about the investigation if they had an appointment to have one in two weeks' time; would feel confident talking to a specialist doctor, nurse or their GP about the investigation; would think the information would be helpful for them to talk to a family member or friend about the investigation if they were to have one; and would feel moderately apprehensive and moderately embarrassed if they were to have the investigation.

	<b>Standard patient information resource</b>		<b>Factors based patient information resource</b>	
<b>Participants' responses to...</b>	<i><math>\bar{x}</math></i>	<i>SD</i>	<i><math>\bar{x}</math></i>	<i>SD</i>
How informed they felt about a colonoscopy	6.12	0.72	6.05	0.62
How prepared they would feel if they were to have a colonoscopy	5.61	1.04	5.65	1.10
How much time they would spend thinking about a colonoscopy if they had an appointment to have the investigation in two weeks' time	4.76	1.54	4.75	1.45
How confident they would feel talking to a specialist doctor, nurse or their GP about a colonoscopy	5.64	0.97	5.68	1.09
How helpful they think the	5.58	1.19	5.66	1.30



information would be for them to talk to a family member or friend about a colonoscopy if they were to have the investigation				
How apprehensive they would feel if they were to have a colonoscopy	4.84	1.69	4.75	1.32
How embarrassed they would feel if they were to have a colonoscopy	4.28	1.82	4.18	1.69

**Table 5.3** Participants' responses to the questions in the decision-making facilitation section (minimum rating = 1.00; maximum rating = 7.00)

### 5.3.2 Acceptability of information

There were no statistically significant differences between the patient information resources for participants' satisfaction with the 11 items of information, although satisfaction was high to very high for both information resources (Table 5.4).

Participants' satisfaction with information provided about...	Standard patient information resource		Factors based patient information resource	
	$\bar{x}$	<i>SD</i>	$\bar{x}$	<i>SD</i>
What body part a colonoscopy is investigating	6.72	0.56	6.68	0.73
What they would need to do to prepare for a colonoscopy	6.31	0.83	6.29	1.00
What they would expect to happen to them during a colonoscopy	6.32	0.70	6.27	1.01
What pain or discomfort they would experience during a colonoscopy	5.86	1.08	5.90	1.25
How a specialist doctor can see the inside of the bowel	6.30	0.87	6.46	0.89
How a specialist doctor takes tissue samples or removes polyps	5.57	1.25	5.68	1.20
What would happen to tissue samples	5.69	1.20	5.56	1.54
How long a colonoscopy should take	5.95	1.28	6.14	1.41
How long they would have to wait for test results	5.72	1.43	5.56	1.70
What side-effects there are from having a colonoscopy	6.08	0.95	6.00	1.30
What risks there are from having a colonoscopy	5.86	1.29	5.95	1.26

**Table 5.4** Participants' satisfaction with 11 items of information from the patient information resources (minimum rating = 1.00; maximum rating = 7.00)

When participants' satisfaction with the 11 items of information was compared between each item within both patient information resources there were a number of statistically significant differences in the standard (Table 5.5) and the factors based (Table 5.6) information resource.

In the standard patient information resource participants were statistically significantly most satisfied with information provided about what body part a colonoscopy is investigating. Following this participants were statistically significantly most satisfied with information provided about what they would expect to happen to them during a colonoscopy and how a specialist doctor can see the inside of the bowel. Participants were statistically significantly least satisfied with information provided about how a specialist doctor takes tissue samples or removes polyps. Following this participants were statistically significantly least satisfied with information provided about what would happen to tissue samples, how long they would have to wait for test results and what risks there are from having a colonoscopy.

In the factors based patient information resource participants were statistically significantly most satisfied with information provided about what body part a colonoscopy is investigating. Following this participants were statistically significantly most satisfied with information provided about how a specialist doctor can see the inside of the bowel. Participants were statistically significantly least satisfied with information provided about what would happen to tissue samples and how long they would have to wait for test results. Following this participants were statistically significantly least satisfied with information provided about how a specialist doctor takes tissue samples or removes polyps.

A) What body part a colonoscopy is investigating						G) What would happen to tissue samples					
B) What they would need to do to prepare for a colonoscopy						H) How long a colonoscopy should take					
C) What they would expect to happen to them during a colonoscopy						I) How long they would have to wait for test results					
D) What pain or discomfort they would experience during a colonoscopy						J) What side-effects there are from having a colonoscopy					
E) How a specialist doctor can see the inside of the bowel						K) What risks there are from having a colonoscopy					
F) How a specialist doctor takes tissue samples or removes polyps											
	A	B	C	D	E	F	G	H	I	J	K
A		$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$
B	$p < 0.001$		NS	$p < 0.01$	NS	$p < 0.001$	$p < 0.001$	$p < 0.05$	$p < 0.001$	NS	$p < 0.01$
C	$p < 0.001$	NS		$p < 0.001$	NS	$p < 0.001$	$p < 0.001$	$p < 0.05$	$p < 0.01$	$p < 0.05$	$p < 0.01$
D	$p < 0.001$	$p < 0.01$	$p < 0.001$		$p < 0.01$	NS	NS	NS	NS	NS	NS
E	$p < 0.001$	NS	NS	$p < 0.01$		$p < 0.001$	$p < 0.001$	$p < 0.05$	$p < 0.001$	$p < 0.05$	$p < 0.01$
F	$p < 0.001$	$p < 0.001$	$p < 0.001$	NS	$p < 0.001$		NS	$p < 0.05$	NS	$p < 0.01$	NS
G	$p < 0.001$	$p < 0.001$	$p < 0.001$	NS	$p < 0.001$	NS		NS	NS	$p < 0.01$	NS
H	$p < 0.001$	$p < 0.05$	$p < 0.05$	NS	$p < 0.05$	$p < 0.05$	NS		NS	NS	NS
I	$p < 0.001$	$p < 0.001$	$p < 0.01$	NS	$p < 0.001$	NS	NS	NS		$p < 0.05$	NS
J	$p < 0.001$	NS	$p < 0.05$	NS	$p < 0.05$	$p < 0.01$	$p < 0.01$	NS	$p < 0.05$		$p < 0.05$
K	$p < 0.001$	$p < 0.01$	$p < 0.01$	NS	$p < 0.01$	NS	NS	NS	NS	$p < 0.05$	
$p < 0.05$ (most satisfied)	10	6	7	0	7	0	0	1	0	4	0
$p < 0.05$ (least satisfied)	0	1	1	4	1	6	5	4	5	3	5

**Table 5.5** Statistically significant differences of participants' satisfaction with the 11 items of information for the standard patient information resource (NS = not significant)

A) What body part a colonoscopy is investigating						G) What would happen to tissue samples					
B) What they would need to do to prepare for a colonoscopy						H) How long a colonoscopy should take					
C) What they would expect to happen to them during a colonoscopy						I) How long they would have to wait for test results					
D) What pain or discomfort they would experience during a colonoscopy						J) What side-effects there are from having a colonoscopy					
E) How a specialist doctor can see the inside of the bowel						K) What risks there are from having a colonoscopy					
F) How a specialist doctor takes tissue samples or removes polyps											
	A	B	C	D	E	F	G	H	I	J	K
A		$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.05$	$p < 0.001$	$p < 0.001$	$p < 0.01$	$p < 0.001$	$p < 0.001$	$p < 0.001$
B	$p < 0.001$		NS	$p < 0.01$	NS	$p < 0.001$	$p < 0.001$	NS	$p < 0.001$	$p < 0.05$	$p < 0.05$
C	$p < 0.001$	NS		$p < 0.01$	NS	$p < 0.001$	$p < 0.001$	NS	$p < 0.01$	$p < 0.05$	$p < 0.05$
D	$p < 0.001$	$p < 0.01$	$p < 0.01$		$p < 0.001$	NS	NS	$p < 0.05$	NS	NS	NS
E	$p < 0.05$	NS	NS	$p < 0.001$		$p < 0.001$	$p < 0.001$	$p < 0.05$	$p < 0.001$	$p < 0.01$	$p < 0.001$
F	$p < 0.001$	$p < 0.001$	$p < 0.001$	NS	$p < 0.001$		NS	$p < 0.05$	NS	$p < 0.05$	NS
G	$p < 0.001$	$p < 0.001$	$p < 0.001$	NS	$p < 0.001$	NS		$p < 0.01$	NS	$p < 0.05$	$p < 0.05$
H	$p < 0.01$	NS	NS	$p < 0.05$	$p < 0.05$	$p < 0.05$	$p < 0.01$		$p < 0.01$	NS	NS
I	$p < 0.001$	$p < 0.001$	$p < 0.01$	NS	$p < 0.001$	NS	NS	$p < 0.01$		$p < 0.05$	$p < 0.05$
J	$p < 0.001$	$p < 0.05$	$p < 0.05$	NS	$p < 0.01$	$p < 0.05$	$p < 0.05$	NS	$p < 0.05$		NS
K	$p < 0.001$	$p < 0.05$	$p < 0.05$	NS	$p < 0.001$	NS	$p < 0.05$	NS	$p < 0.05$	NS	
$p < 0.05$ (most satisfied)	10	6	6	0	7	0	0	4	0	3	2
$p < 0.05$ (least satisfied)	0	1	1	5	1	6	7	2	7	4	4

**Table 5.6** Statistically significant differences of participants' satisfaction with the 11 items of information for the factors based patient information resource (NS = not significant)

There were no statistically significant differences between the patient information resources in the remainder of the acceptability of information section (Table 5.7). Participants felt it took quite a short time to read through the information resources; felt a moderate amount of information was provided in the resources; felt the resources were easy to understand; felt the resources were positively presented; felt the resources were well-structured; felt the image of a colonoscopy in the resources was quite helpful for them to understand the investigation; and felt the resources were very helpful if they were to have a colonoscopy.

<b>Participants' responses to...</b>	<b>Standard patient information resource</b>		<b>Factors based patient information resource</b>	
	$\bar{x}$	<i>SD</i>	$\bar{x}$	<i>SD</i>
How they felt about the length of time it took to read through the information	3.34	1.24	3.32	1.10
How they felt about the amount of information provided	4.43	0.81	4.23	0.92
How they felt about the way the information was written	2.47	1.64	2.11	1.27
How they felt about the way the information was presented	5.07	1.26	5.29	1.16
How they felt about the way the information was structured	5.57	1.09	5.70	1.10
How important they felt the image of a colonoscopy was in helping them understand the investigation	4.76	1.74	4.91	1.75
How helpful they felt the information would be if they were to have a colonoscopy	6.03	0.89	6.14	0.80

**Table 5.7** Participants' responses to the remainder of questions in the acceptability of information section (minimum rating = 1.00; maximum rating = 7.00)

### 5.3.3 Information recall

There were no statistically significant associations between the patient information resources and whether participants answered the 10 true or false statements correctly. There were also no statistically significant differences between the information resources and participants' confidence in their answers, although levels of confidence were high to very high for both resources (Table 5.8).

Statement	Standard patient information resource			Factors based patient information resource		
	CA	Confidence		CA	Confidence	
	No. (%)	$\bar{x}$	SD	No. (%)	$\bar{x}$	SD
The large bowel is also known as the large intestine or the colon (true)	66 (89.2)	5.57	1.46	69 (87.3)	5.61	1.48
Iron tablets help a specialist doctor performing a colonoscopy see inside the bowel (false)	71 (95.9)	6.80	0.64	73 (92.4)	6.56	0.97
There are no risks to taking a strong laxative the day before a colonoscopy (false)	61 (82.4)	5.84	1.32	66 (83.5)	5.85	1.60
You may be asked to change position during a colonoscopy (true)	66 (89.2)	6.38	1.42	65 (82.3)	6.10	1.52
A colonoscopy should take between 15 and 30 minutes (false)	49 (66.2)	5.31	1.91	62 (78.5)	5.44	1.63
If you have a sedative during a colonoscopy you will probably be ready to go home by yourself a couple of hours after the investigation (false)	68 (91.9)	6.26	1.17	68 (86.1)	6.00	1.46
If a specialist doctor takes tissue samples for testing they will explain to you after the colonoscopy the results of the samples (false)	55 (74.3)	5.78	1.42	56 (70.9)	5.39	1.60
If you have a sedative during a colonoscopy you should make sure that you do not drink alcohol for at least 24 hours after the investigation (true)	66 (89.2)	5.62	1.66	69 (87.3)	5.72	1.69
If you experience prolonged or heavy bleeding after a colonoscopy you should not worry as this is not uncommon and may last a few days (false)	73 (98.6)	6.26	1.15	78 (98.7)	6.22	1.34
You may need an operation if a colonoscope causes a hole (perforation) in the wall of your bowel during a colonoscopy (true)	72 (97.3)	6.41	1.17	73 (92.4)	6.25	1.34

**Table 5.8** Participants' correct answers (CAs) and confidence in their answers for the 10 true or false statements for the patient information resources (minimum rating = 1.00; maximum rating = 7.00)

When participants' confidence in their answers for the 10 true or false statements was compared between each statement within both patient information resources there were a number of statistically significant differences in the standard (Table 5.9) and the factors based (Table 5.10) information resource.

In the standard patient information resource participants were statistically significantly most confident with their answer provided for the statement stating 'iron tablets help a specialist doctor performing a colonoscopy see inside the bowel'. Following this participants were statistically significantly most confident with their answers provided for the statements stating 'you may be asked to change position during a colonoscopy', 'if you have a sedative during a colonoscopy you will probably be ready to go home by yourself a couple of hours after the investigation', 'if you experience prolonged or heavy bleeding after a colonoscopy you should not worry as this is not uncommon and may last a few days' and 'you may need an operation if a colonoscope causes a hole (perforation) in the wall of your bowel during a colonoscopy'. Participants were statistically significantly least confident with their answer provided for the statement stating 'a colonoscopy should take between 15 and 30 minutes'. Following this participants were statistically significantly least confident with their answers provided for the statements stating 'the large bowel is also known as the large intestine or the colon' and 'if you have a sedative during a colonoscopy you should make sure that you do not drink alcohol for at least 24 hours after the investigation'.

In the factors based patient information resource participants were statistically significantly most confident with their answer provided for the statement stating 'iron tablets help a specialist doctor performing a colonoscopy see inside the bowel'. Following this participants were statistically significantly most confident with their answers provided for the statements stating 'if you experience prolonged or heavy bleeding after a colonoscopy you should not worry as this is not uncommon and may last a few days' and 'you may need an operation if a colonoscope causes a hole (perforation) in the wall of your bowel during a colonoscopy'. Participants were statistically significantly least confident with their answer provided for the statement stating 'if a specialist doctor takes tissue samples for testing they will explain to you after the colonoscopy the results of the samples'.

Following this participants were statistically significantly least confident with their answer provided for the statement stating ‘a colonoscopy should take between 15 and 30 minutes’.



- A) The large bowel is also known as the large intestine or the colon  
 B) Iron tablets help a specialist doctor performing a colonoscopy see inside the bowel  
 C) There are no risks to taking a strong laxative the day before a colonoscopy  
 D) You may be asked to change position during a colonoscopy  
 E) A colonoscopy should take between 15 and 30 minutes  
 F) If you have a sedative during a colonoscopy you will probably be ready to go home by yourself a couple of hours after the investigation  
 G) If a specialist doctor takes tissue samples for testing they will explain to you after the colonoscopy the results of the samples  
 H) If you have a sedative during a colonoscopy you should make sure that you do not drink alcohol for at least 24 hours after the investigation  
 I) If you experience prolonged or heavy bleeding after a colonoscopy you should not worry as this is not uncommon and may last a few days  
 J) You may need an operation if a colonoscope causes a hole (perforation) in the wall of your bowel during a colonoscopy

	A	B	C	D	E	F	G	H	I	J
A		$p < 0.001$	NS	$p < 0.001$	NS	$p < 0.001$	NS	NS	$p < 0.001$	$p < 0.001$
B	$p < 0.001$		$p < 0.001$	$p < 0.05$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.01$
C	NS	$p < 0.001$		$p < 0.05$	$p < 0.05$	$p < 0.05$	NS	NS	$p < 0.05$	$p < 0.01$
D	$p < 0.001$	$p < 0.05$	$p < 0.05$		$p < 0.01$	NS	$p < 0.01$	$p < 0.01$	NS	NS
E	NS	$p < 0.001$	$p < 0.05$	$p < 0.01$		$p < 0.001$	$p < 0.05$	NS	$p < 0.001$	$p < 0.001$
F	$p < 0.001$	$p < 0.001$	$p < 0.05$	NS	$p < 0.001$		$p < 0.05$	$p < 0.01$	NS	NS
G	NS	$p < 0.001$	NS	$p < 0.01$	$p < 0.05$	$p < 0.05$		NS	$p < 0.05$	$p < 0.01$
H	NS	$p < 0.001$	NS	$p < 0.01$	NS	$p < 0.01$	NS		$p < 0.01$	$p < 0.01$
I	$p < 0.001$	$p < 0.001$	$p < 0.05$	NS	$p < 0.001$	NS	$p < 0.05$	$p < 0.01$		NS
J	$p < 0.001$	$p < 0.01$	$p < 0.01$	NS	$p < 0.001$	NS	$p < 0.01$	$p < 0.01$	NS	
$p < 0.05$ (most confident)	0	9	1	5	0	5	1	0	5	5
$p < 0.05$ (least confident)	5	0	5	1	7	1	5	5	1	1

**Table 5.9** Statistically significant differences of participants' confidence in their answers for the 10 true or false statements for the standard patient information resource (NS = not significant)

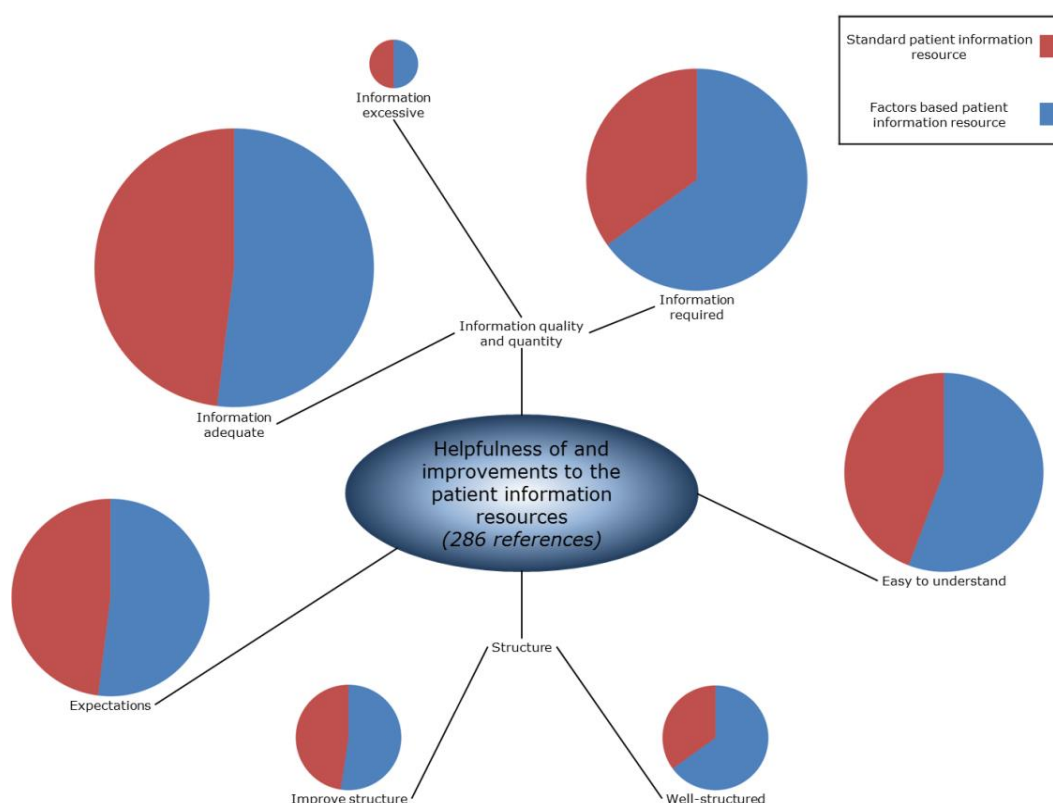
- A) The large bowel is also known as the large intestine or the colon  
 B) Iron tablets help a specialist doctor performing a colonoscopy see inside the bowel  
 C) There are no risks to taking a strong laxative the day before a colonoscopy  
 D) You may be asked to change position during a colonoscopy  
 E) A colonoscopy should take between 15 and 30 minutes  
 F) If you have a sedative during a colonoscopy you will probably be ready to go home by yourself a couple of hours after the investigation  
 G) If a specialist doctor takes tissue samples for testing they will explain to you after the colonoscopy the results of the samples  
 H) If you have a sedative during a colonoscopy you should make sure that you do not drink alcohol for at least 24 hours after the investigation  
 I) If you experience prolonged or heavy bleeding after a colonoscopy you should not worry as this is not uncommon and may last a few days  
 J) You may need an operation if a colonoscope causes a hole (perforation) in the wall of your bowel during a colonoscopy

	A	B	C	D	E	F	G	H	I	J
A		$p < 0.001$	NS	$p < 0.05$	NS	NS	NS	NS	$p < 0.01$	$p < 0.01$
B	$p < 0.001$		$p < 0.001$	$p < 0.01$	$p < 0.001$	$p < 0.01$	$p < 0.001$	$p < 0.001$	$p < 0.05$	$p < 0.05$
C	NS	$p < 0.001$		NS	NS	NS	$p < 0.05$	NS	$p < 0.05$	$p < 0.05$
D	$p < 0.05$	$p < 0.01$	NS		$p < 0.01$	NS	$p < 0.01$	NS	NS	NS
E	NS	$p < 0.001$	NS	$p < 0.01$		$p < 0.01$	NS	NS	$p < 0.001$	$p < 0.001$
F	NS	$p < 0.01$	NS	NS	$p < 0.01$		$p < 0.01$	NS	NS	NS
G	NS	$p < 0.001$	$p < 0.05$	$p < 0.01$	NS	$p < 0.01$		NS	$p < 0.001$	$p < 0.001$
H	NS	$p < 0.001$	NS	NS	NS	NS	NS		$p < 0.05$	$p < 0.05$
I	$p < 0.01$	$p < 0.05$	$p < 0.05$	NS	$p < 0.001$	NS	$p < 0.001$	$p < 0.05$		NS
J	$p < 0.01$	$p < 0.05$	$p < 0.05$	NS	$p < 0.001$	NS	$p < 0.001$	$p < 0.05$	NS	
$p < 0.05$ (most confident)	0	9	1	3	0	2	0	0	5	5
$p < 0.05$ (least confident)	4	0	3	1	5	1	6	3	1	1

**Table 5.10** Statistically significant differences of participants' confidence in their answers for the 10 true or false statements for the factors based patient information resource (NS = not significant)

### 5.3.4 Helpfulness of and improvements to the patient information resources

Helpfulness of and improvements to the patient information resources includes themes in response to the two open-ended questions in the acceptability of information section of the questionnaire about why participants felt the information would be helpful if they were to have a colonoscopy and what improvements could be made. The themes are graphically represented in Figure 5.9 and described in Table 5.11. As for the thematic analyses conducted in Chapter 3, the number of references in the graphical representation refers to the total number of sentences, comments and phrases included in the thematic analysis. The table describes the number of references for each theme, as well as the number of sources, which could be a possible maximum of four sources from the two open-ended questions and the two information resources.



**Figure 5.9** Helpfulness of and improvements to the patient information resources

Theme	Description	References	Sources
Information quality and quantity			
Information	Information sufficient and	77	4

adequate	satisfactory in informing about a colonoscopy and what a patient needs to do and/or what happens to the patient before, during and/or after the investigation.		
Information quality and quantity			
Information required	Further information required about a colonoscopy and what a patient needs to do and/or what happens to the patient before, during and/or after the investigation.	60	4
Easy to understand	Information well-explained and clearly understood.	52	4
Expectations	Value in understanding what a patient needs to do and/or what happens to the patient before, during and/or after a colonoscopy.	50	2
Structure			
Improve structure	Segmenting and/or bullet pointing of information to minimise and/or make the text easier to read.	21	4
Structure			
Well-structured	Information satisfactorily and orderly segmented and laid out.	20	4
Information quality and quantity			
Information excessive	Risk information perceived as too much and/or that it could be communicated differently.	6	4

**Table 5.11** Descriptions of the themes for helpfulness of and improvements to the patient information resources

#### 5.3.4.1 *Information quality and quantity: information adequate, information required and information excessive*

The most influential themes were *information adequate* and *information required*, which are *information quality and quantity* sub-themes, as is *information excessive*, which was the least influential theme overall. For the *information adequate* theme (77 references, 4 sources) participants remarked that the information would be what they would require, from its content to the actual amount of information, and that it answered a lot of questions they would have:

‘The leaflet covered almost all the topics that would interest a potential examinee. It fully assessed preparation, examination and post-examination phases.’ (Response to standard patient information resource)

‘It explains the procedure, gives advice on what to do before, warns of any possible discomfort, explains that there will be an assistant and a doctor and you can also see it on screen. I would feel relatively well informed.’  
(Response to factors based patient information resource)

‘Informative but not too much detail so as to put you off.’ (Response to standard patient information resource)

‘I like succinct material so 'short and sweet' is my preference and this was about right.’ (Response to factors based patient information resource)

‘It basically covers every question I had in mind before going through the information sheet.’ (Response to standard patient information resource)

‘The information details what the procedure entails, side effects etc. This is helpful because it answers a lot of questions that I would have probably had (if the information was not provided).’ (Response to factors based patient information resource)

The image of a colonoscopy was deemed helpful in informing about what happens during a colonoscopy:

‘The information has explained to me what will happen or what might happen if I have a colonoscopy, especially the picture, which can explain everything without any explanation.’ (Response to factors based patient information resource)

‘The picture helps explain a lot.’ (Response to factors based patient information resource)

For some participants, although the patient information resources were satisfactory they would still like to speak with a clinician:

‘Seems to cover all the bases of questions you may have, only reason it wasn't 7 out of 7 is that I imagine I would naturally feel more informed having spoken to a doctor directly and specifically about my colonoscopy, rather than reading a generic leaflet.’ (Response to standard patient information resource)

‘Should I need a colonoscopy, I think this information would help in understanding the procedure and prep for it. However, I would still seek information from a specialist or my doctor.’ (Response to factors based patient information resource)

For the *information required* theme (60 references, 4 sources) participants required varying and specific information, including information about a colonoscope and its insertion into the bowel, what causes death from a colonoscopy, what medical condition the investigation was investigating, what happens if something goes wrong, what pain to expect during the investigation and what the overall timescale of the investigation was:

‘More details e.g. for example how the insertion would take place, what it would feel like.’ (Response to factors based patient information resource)

‘More detail on how and why someone can die from the procedure.’  
(Response to standard patient information resource)

‘I also didn't understand what the doctor would be actually looking for. What sort of things can you see on a colonoscopy? I guess they are done for a variety of conditions and maybe these would be discussed on a case by case basis at the time. So maybe in a real colonoscopy situation I would know what the doctor was looking for.’ (Response to factors based patient information resource)

‘It was very informative and clear on what would the desired procedure is, but it gives a sense that something would likely go wrong with this procedure and it doesn't give an idea of what would happen/ timings/ side effects of that. I would want to Google it so I could find out the likelihood of those potential risks/ what would happen if a Polyp is removed, because

it does sound quite scary.’ (Response to factors based patient information resource)

‘I would like to know about the pain during the colonoscopy.’ (Response to standard patient information resource)

‘The information you presented is better than average but not a lot better. There are better guides available. Points you have missed would include the overall time scale from pre bowel prep to results and the nature of the discomfort during procedure (it can be substantial at points but usually passes after a few seconds).’ (Response to factors based patient information resource)

Participants also required information about whether clothes can be worn under gowns, whether patients can change into gowns in the same room as where a colonoscopy is performed and what if patients do not have someone with them. More information about dietary restrictions, laxatives, sedatives, biopsies and polyps and the notification of biopsy results would have also been beneficial for some participants:

‘Perhaps some more info about the 'special diet' required prior to the colonoscopy would be helpful.’ (Response to factors based patient information resource)

‘What type of laxative? Does every patient need to be sedated?’ (Response to standard patient information resource)

‘Whether you chose to have a sedative, who decides??’ (Response to standard patient information resource)

‘It’s very clear information, but I’m still unsure about the process of taking samples.’ (Response to standard patient information resource)

‘I would like more information on what the doctor would be looking for and what polyps actually are and what causes them.’ (Response to standard patient information resource)

‘I would want to know how I would get the results from tests. Are they sent directly to me? Do I have to phone my GP? Will they get back to me only if the results are "bad" or in all cases?’ (Response to factors based patient information resource)

Other beneficial information would be experiences from patients who have had a colonoscopy and contact details for patients who are apprehensive before or have problems after a colonoscopy:

‘Would be nice to have something from people who had been through the experience- not just based on what professionals think.’ (Response to factors based patient information resource)

‘Contact information for a person/body that you could get more information from if desired.’ (Response to standard patient information resource)

One participant queried the cleanliness of instruments used for biopsies and the removal of polyps, and another queried what being ‘monitored’ meant in the factors based patient information resource for what happens to patients after a colonoscopy. There were a number of remarks regarding the use of images and that the image of a colonoscopy could be improved and that more images could be used overall:

‘More realistic picture - but that might terrify others.’ (Response to factors based patient information resource)

‘Photographs of the instrument used etc. would also be useful.’ (Response to factors based patient information resource)

The *information excessive* theme (6 references, 4 sources), the final information quality and quantity sub-theme, was based on participants concern with information about the risks of a colonoscopy. This information was considered too much and that it would cause worry, and that it could also be communicated in a less disconcerting manner:

‘I feel the information was helpful; however, the details about the risks were too much. I wasn't sure I would want to know that I could die from the



procedure especially when it happens so infrequently. This would make me panic about it despite the very small likelihood of it happening.’ (Response to standard patient information resource)

‘Possibly present risk slightly differently. Might not need all the details of 1 in 150. Maybe a risk scale or use of words like infrequently, occasionally or very infrequently.’ (Response to factors based patient information resource)

#### *5.3.4.2 Easy to understand*

*Easy to understand* (52 references, 4 sources) was an influential theme in which participants considered the patient information resources to be clear and to a good standard, well-written and written in a suitable language rather than being too technical and medical, and that they enabled a comprehensive understanding of a colonoscopy:

‘The information was extremely helpful because it provided me with the whole patient journey, in a clear and concise manner.’ (Response to standard patient information resource)

‘It gives a clear explanation of all aspects of the examination.’ (Response to factors based patient information resource)

‘I think it was very well presented and written well - it was informative in plain language, without using technical jargon and being too wordy.’ (Response to standard patient information resource)

‘The leaflet was well written in simple to understand words not using medical terms that some people may not understand.’ (Response to factors based patient information resource)

‘All aspects of the procedure have been thoroughly explained, including those before and after the physical colonoscopy.’ (Response to standard patient information resource)

‘It explained exactly what would happen and what to expect - it referred directly to where the investigation would take place as in which part of your body.’ (Response to factors based patient information resource)

#### 5.3.4.3 *Expectations*

Another influential theme was *expectations* (50 references, 2 sources) and participants valued understanding expectations of patients who require a colonoscopy. This included an appreciation for information about the patient’s physical involvement, from preparing before to during the investigation, and side-effects that may be experienced afterwards:

‘It’s good to have an idea of exactly what will happen, before, during and afterwards - being informed would make most people more comfortable with the procedure.’ (Response to standard patient information resource)

‘Provided useful advice about dealing with side effects, e.g. make sure someone is with you when results are being discussed.’ (Response to factors based patient information resource)

Information about duration of a colonoscopy, possible sensations, sedatives and risks of the investigation was also valued:

‘I like the inclusion of approximate time to complete the investigation, advice about the sedative and the possible side effects.’ (Response to standard patient information resource)

‘The information is clear about what to expect, and gives quite specific details e.g. about the length of time and how it will feel.’ (Response to factors based patient information resource)

‘The quite detailed instructions of the steps previous to the colonoscopy and during the colonoscopy. I also found the different risks with the probabilities quite helpful.’ (Response to standard patient information resource)

‘Clear explanations of risks.’ (Response to factors based patient information resource)

#### *5.3.4.4 Structure: improve structure and well-structured*

*Improve structure* and *well-structured* are *structure* sub-themes and were moderately influential. For the *improve structure* theme (21 references, 4 sources) participants suggested minimising lengthy text through better lay out of information and the use of bullet points to summarise information so that the patient information resources were easier to read:

‘Think it would be better structured if there was less text with bullet points so you could read it with more ease.’ (Response to standard patient information resource)

‘Perhaps side effects, consequences of the procedures etc. could have been in bullet form. It would provide a better visual understanding for user and easier for one to recall what is expected. I.e. make presentation easier to follow than just to rumble on.’ (Response to standard patient information resource)

‘The final section was quite long compared to the others. It could be summarised into bullet points.’ (Response to factors based patient information resource)

‘Same information, less words. I found the document a bit 'wordy' (but I do prefer very concise summaries).’ (Response to factors based patient information resource)

The use of images was considered a way to minimise lengthy text and it was suggested that some information in the patient information resources could be positioned elsewhere:

‘It relies very heavily on written information written in an impersonal way. More use of images and also ways of punctuating and drawing out the key points would be good.’ (Response to standard patient information resource)

‘Maybe make it more concise or have more pictures because for a leaflet it is a heavy read.’ (Response to standard patient information resource)

‘Having someone with you for the outcome whilst still under the sedative should be mentioned a bit earlier, when it mentions receiving the outcome, as I was unsure if it meant the results (after 3 weeks) until I realised that you were still sedated.’ (Response to standard patient information resource)

‘The effects of the sedative are discussed only late in the document, I would prefer to know if somebody has to come with me at the beginning as I think it might be lost in all the information.’ (Response to factors based patient information resource)

‘The information about what would happen to you when the Polyps/ tissue samples are removed is quite far down compared to telling you that they might be removed so maybe putting the information about Polyps/tissue sample removal, and the results of that together.’ (Response to factors based patient information resource)

For the *well-structured* theme (20 references, 4 sources) participants generally considered the information in the patient information resources to be suitably presented:

‘Clear layout, short paragraphs, not too much information.’ (Response to standard patient information resource)

‘I thought it was presented well and easily understandable.’ (Response to standard patient information resource)

‘The information was clearly laid out. The flow of the information followed the stages of the procedure.’ (Response to factors based patient information resource)

‘The information was thorough, well laid out and would help the patient feel calm.’ (Response to factors based patient information resource)

For the factors based patient information resource participants remarked about the information being broken into small, concise sections and that it would be easy to refer back to, and the image of a colonoscopy was also remarked for its use to break the information up:

‘The information was broken up into small, concise, easy to understand sections. The diagram also helped to break-up the text and gave a different perspective.’ (Response to factors based patient information resource)

‘It is informative but not too much information; well-presented and easy to refer back to.’ (Response to factors based patient information resource)

‘Clear sections and pictures made it easy to understand.’ (Response to factors based patient information resource)

## 5.4 Discussion

The study examined the factors based approach to the design of patient information, which was conceptualised in Chapter 3 as a user centred design concept (see pages 103-107 for recap) and developed in Chapter 4 (see pages 156-158 for recap). The factors based approach was examined through evaluating and comparing two patient information resources for colonoscopy: 1) standard patient information resource (Figures 5.3-5.5); and 2) factors based patient information resource (Figures 5.6-5.8). The standard information resource was developed from a number of existing patient information resources that were currently available and the factors based resource was developed by applying seven factors that were considered appropriate to guide the design of a patient information resource for an investigation or test without context orientation to the standard resource. Quantitative data were collected and statistical analysis found no significant differences between the standard and the factors based resource (Tables 5.3, 5.4, 5.7 and 5.8), although there were significant differences within the resources (Tables 5.5, 5.6, 5.9 and 5.10). Qualitative data were also collected, and thematic analysis dictates both resources were well received but with contrasting themes (Figure 5.9).

The questionnaire used to evaluate both patient information resources was constructed from five existing tools that are available to assess patient information resources; measure information preferences, decision-making preferences and decision-making processes; and satisfaction with information and decisions. The five tools are as follows:

- Acceptability.
- Confidence to Decide about Treatment Scale.
- Knowledge.
- Process of Decision Making.
- Satisfaction with Decision.

(Kryworuchko *et al.*, 2008; Michie *et al.*, 1997; McBride *et al.*, 2002; O'Connor, 2004a; O'Connor and Cranney, 2002; O'Connor *et al.*, 1998a, O'Connor *et al.*, 1998b; O'Connor *et al.*, 1999b)

Additional questions were included that were based on none of the tools, including two from the questionnaire for the vignette study and distraction questions prior to the Knowledge questions to cause a delay and change of thought in participants. Apart from two open-ended questions, all questions were closed questions with the majority of them answered using seven-point interval scales with verbal anchors; a small number were answered using categories. The questionnaire was split into five sections, with three of them designed to evaluate three aspects of the standard and factors based patient information resource: 1) decision-making facilitation; 2) acceptability of information; and 3) information recall.

The decision-making facilitation section found no statistically significant differences between the patient information resources. Both information resources scored highly, especially for informing participants about colonoscopy; and if participants were to have the investigation, to prepare them for it, and to support them to talk with a relevant healthcare professional and family member or friend. This corresponds with the thematic analysis since both resources were valued for informing about what patients need to do and/or what happens to patients before, during and/or after a colonoscopy. A contrasting finding from the thematic analysis suggests the factors based resource was slightly better informing than the standard resource but that it was deficient also. What seems to have occurred is in the

information required theme, an information quality and quantity sub-theme, participants have provided more feedback on information they would require or prefer to be included, although similar information is required or preferred in the standard resource but to a lesser extent.

Overall the decision-making facilitation section demonstrates the value of the content in both patient information resources to facilitate decision-making for patients requiring colonoscopy, and consequently it demonstrates the value of the content of the four patient information resources (Bupa, 2013 (a 2011 version was used in this study); Knott, 2012; Macmillan Cancer Support, 2010; NHS Bowel Cancer Screening Programme, 2006) they were developed from. However, due to the development of the standard patient information resource, which involved four iterations, the content of the standard information resource and subsequently the factors based resource represent an enhanced colonoscopy patient information resource. Both resources may have performed worse if the standard resource was developed from less information resources and if the resources were less reputable. And what is not known is how the factors based resource would have performed if it was compared with each of the four resources individually, but one might assume it would have performed better. This does not change the fact that both the standard and factors based resource performed equally as well, and that the organisation of the content in the factors based resource had no effect in decision-making facilitation. This is also reflected in the acceptability of information section.

The acceptability of information section found no statistically significant differences between the patient information resources. Participants were highly satisfied with information provided in both information resources, which included information about what body part a colonoscopy is investigating, how a specialist doctor can see the inside of the bowel and what risks there are from having a colonoscopy. Such satisfaction would have positively affected the overall content of the resources and consequently decision-making facilitation. There were statistically significant differences within the resources, but the differences were similar and there was only a small disparity in the number of significant differences in the resources: 35 for the standard resource and 38 for the factors based resource. This does, however, suggest there is room for improvement in both resources,

especially for information about how a specialist doctor takes tissue samples or removes polyps, what would happen to tissue samples, how long patients would have to wait for test results and what risks there are from having a colonoscopy.

Information in both patient information resources was considered a moderate amount and relatively quick to read through, as well as easy to understand, positively presented and well-structured. Thematic analysis suggests the structure of the factors based information resource was better in comparison to the standard information resource but that it could also be slightly improved. Participants also remarked that information in the factors based resource was small and concise, and that it was easy to refer back to. There was a general consensus that the structure of both resources could be improved through minimising lengthy text and using bullet points to summarise information. There were also remarks about the use of images to minimise text and the repositioning of information. Information that could be repositioned included information about the use of sedatives and patients having someone with them. Themes also suggest both resources were well-explained and enabled a clear understanding of the investigation. The image of the colonoscopy in both resources was considered quite helpful and overall the resources were considered very helpful.

The information recall section found no statistically significant associations and differences between the patient information resources and whether participants answered true or false statements correctly and confidence in their answers, respectively. Participants were highly confident with their answers to the statements, which included correctly answering that the large bowel is also known as the large intestine or the colon, a colonoscopy should not take between 15 and 30 minutes and patients may need an operation if a colonoscope causes a hole (perforation) in the wall of the bowel during a colonoscopy. There were statistically significant differences within the resources, but the differences were similar and there was only a relatively small disparity in the number of significant differences in the resources: 31 for the standard resource and 25 for the factors based resource. Participants were least confident with their answers about the duration of a colonoscopy, about when a specialist doctor will explain the results of tissue samples, about what the large bowel is also known as, and about what patients can



and cannot do for 24 hours following a colonoscopy when a sedative is used. These seem similar in context with respect to participants levels of satisfaction with information provided about tissue samples, waiting for test results and risks from a colonoscopy.

Quantitative findings conclude the factors based approach to the design of patient information had no statistically significant effect on patient information for colonoscopy in comparison to information for the investigation based on a standardised presentation. Thematic analysis also dictates the factors based approach had minimal effect; however, contrasting themes emerged that suggest the information quality and quantity in the factors based patient information resource was adequate but further was required, and that the structure was well-structured but that this could be improved. This is an indication that the examination of both information resources and thus the factors based approach require further examination to further explore qualitative differences, and in particular differences in information quality and quantity and structure. This is somewhat referred to by Garner *et al.* (2011) who propose that communicative effectiveness in patient information leaflets cannot be ascertained by textual analysis alone but by the notion of ‘usability’. The next chapter will further explore this notion by directly comparing the standard and the factors based resource using focus groups.

## 5.5 Methodology considerations

A convenience sample was used and nearly half of the participants were aged 29 years or younger. Therefore the sample was not representative of a demographic that would be likely to require colonoscopy. However, adults aged 18 years or older who had not had a colonoscopy or similar investigation were eligible to participate in the study to avoid bias from past experiences. The focus of the study was also to compare both patient information resources to examine the factors based approach to the design of patient information and so a convenience sample was appropriate for this. Practical and ethical issues were also avoided through involving participants who did not have or had not had a colonoscopy, but what has not been examined in this study is the extent to which participant responses would be the

same if they were to actually encounter the investigation in the future. This was a trade-off as well as a limit.

Both patient information resources included content from existing patient information resources that were currently available, but were not context orientated and so had no reference to symptoms and/or medical conditions. Results may have differed if information about symptoms and/or medical conditions were included. This was another trade-off to focus on comparing both information resources to examine the factors based approach to the design of patient information and to avoid the effects associated with specific symptoms and/or medical conditions.

The questionnaire was constructed from a number of tools available to assess patient information resources; measure information preferences, decision-making preferences and decision-making processes; and satisfaction with information and decisions. These tools varied with respect to response types and ranges and so for consistency the majority of the closed questions were answered using seven-point interval scales with verbal anchors. With both patient information resources highly rated a ceiling effect may have occurred and a ten-point interval scale may have found some significant differences since none were found.

The qualitative data were collected in response to the two open-ended, which were enquiring about selected ratings in response to the closed question about helpfulness of the patient information resources and to provide suggestions for improving the information resources. Therefore it could be suggested that the qualitative data is limited to the selected ratings enquired about. However, the questionnaire, as well as the resources, was developed following sufficient piloting to ensure valid data were collected to compare the resources and to examine the factors based approach to the design of patient information.

Finally, as for the first two studies, the analysis of the qualitative data was from the perspective of the researchers involved in this study. If researchers with different perspectives analysed the data, the interpretation, coding and theming of the data may vary. Respondent validation or 'member checking' (Creswell and Miller, 2000; Mays and Pope, 2000) could have been used to examine the credibility of the themes, and Cohen's Kappa coefficient (Cohen, 1960) could have been used to

provide a statistical measure for inter-rater reliability for qualitative coding. However, the thematic analysis was rigorously conducted and peer debriefing (Creswell and Miller, 2000) was used, so the themes that emerged were discussed and rationalised to ascertain their basis and reasoning. (See page 109 for a recap on respondent validation and Cohen's Kappa coefficient).

## 5.6 Conclusion

There were no significant differences between the standard and the factors based patient information resource (Tables 5.3, 5.4, 5.7 and 5.8). Participants were highly satisfied with information provided in the information resources and both resources scored highly for facilitating decision-making. Participants were also highly confident with the answers they provided for recalling information from the resources. These findings suggest both resources performed equally as well and that the factors based approach to the design of patient information (Figure 3.12) had no effect on patient information in comparison to information based on a standardised presentation. Significant differences were found within the resources (Tables 5.5, 5.6, 5.9 and 5.10), but the differences were similar between both resources and there was only a small disparity.

Thematic analysis dictates both patient information resources were well received but with contrasting themes (Figure 5.9). Themes suggest the factors based information resource was slightly better informing than the standard resource but that it was deficient also, and that the structure of the factors based resource was better in comparison to the standard resource but that it could also be slightly improved. This is an indication that the examination of both resources and thus the factors based approach to the design of patient information require further examination to further explore qualitative differences, and in particular differences in information quality and quantity and structure. This will be further explored in the next chapter by directly comparing the standard and the factors based resource using focus groups.

## CHAPTER 6

# Focus groups to examine the factors based approach to the design of patient information

### 6.1 Introduction

Chapter 6 reports the findings from focus groups examining the factors based approach to the design of patient information, which was conceptualised in Chapter 3 as a user centred design concept (see pages 103-107 for recap), developed in Chapter 4 (see pages 156-158 for recap) and previously examined in Chapter 5 using an online study. The study is in response to the third research question, which is as follows:

- 3) How does patient information based on factors affecting patients' attitudes towards diagnostic and screening procedures affect the value of the information?

The introduction of Chapter 5 (see page 161 for recap) outlines the factors based approach to the design of patient information, and describes how factors arose from taking a human factors approach to medical devices from the perspective of potential patients and men in the contexts of diagnosis and screening, respectively. The factors were considered for their appropriateness to design patient information (see pages 162-170 for recap) and led to the development of two patient information resources: 1) standard patient information resource; and 2) factors based patient information resource (see pages 170-180 for recap). Both of these information resources were evaluated and compared in the online study (see pages 184-206 for recap) to examine the factors based approach. Quantitative data were collected and statistical analysis found no significant differences between the standard and the factors based resource (Tables 5.3, 5.4, 5.7 and 5.8), although there were significant differences within the resources (Tables 5.5, 5.6, 5.9 and 5.10). Qualitative data were also collected, and thematic analysis dictates both resources were well received but with contrasting themes (Figure 5.9).

The contrasting themes suggest the information quality and quantity in the factors based patient information resource was adequate but further was required, and that the structure was well-structured but that this could be improved. This is an indication that the examination of both information resources and thus the factors based approach to the design of patient information require further examination to further explore qualitative differences, and in particular differences in information quality and quantity and structure. This is somewhat referred to by Garner *et al.* (2011) who propose that communicative effectiveness in patient information leaflets cannot be ascertained by textual analysis alone but by the notion of ‘usability’. This chapter will further explore this notion by directly comparing the standard and the factors based resource using focus groups.

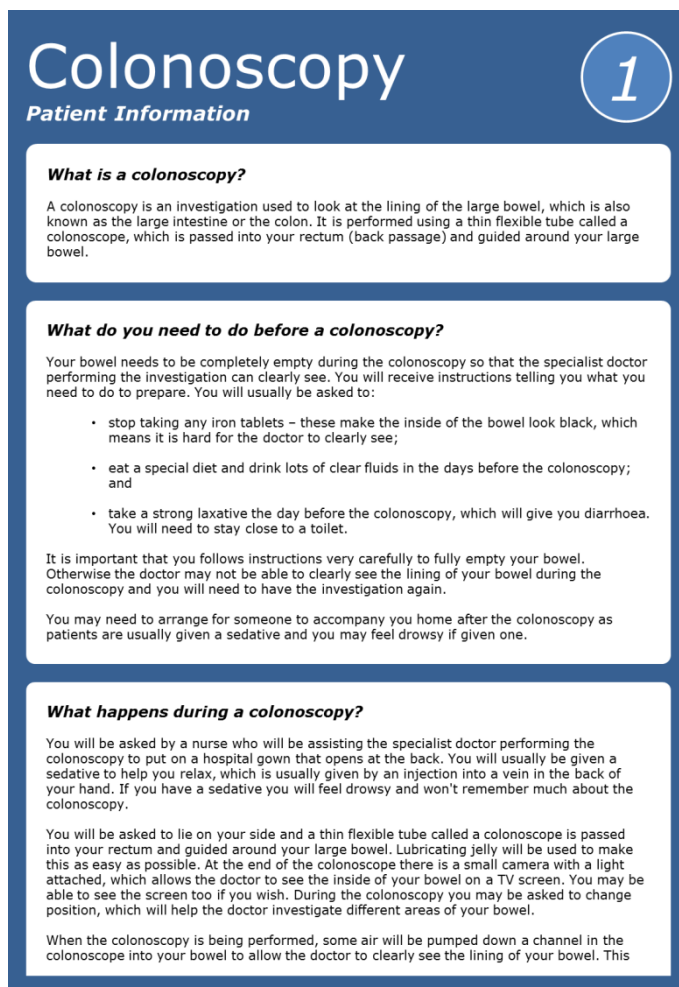
## 6.2 Methodology

### 6.2.1 Study design

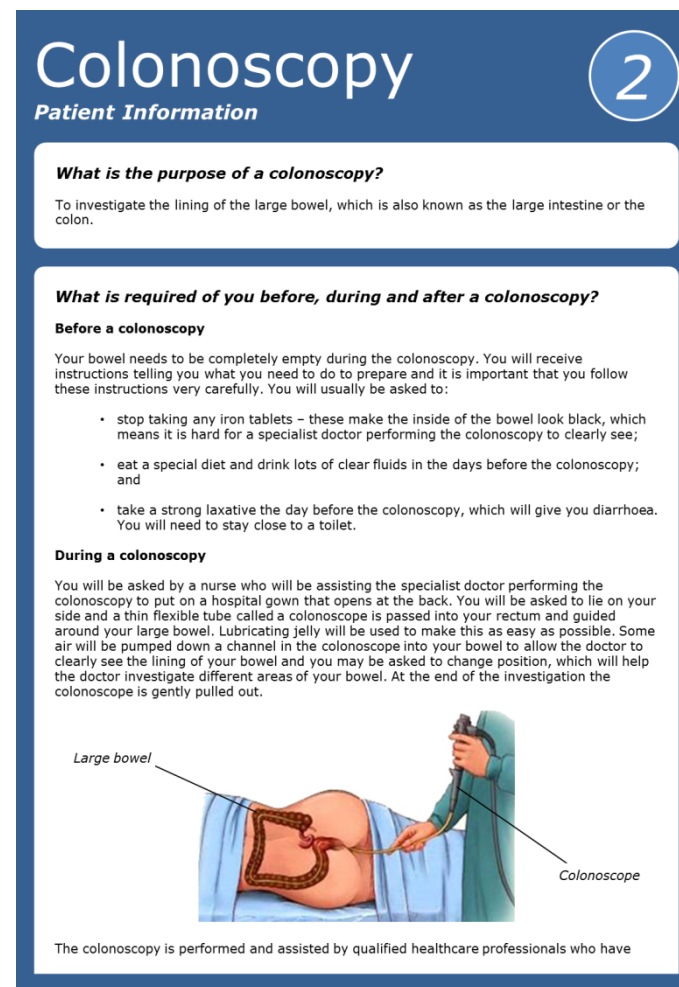
Both patient information resources developed and used in the online study were used in focus groups. And as explained in the online study, the investigation or test used in the information resources was colonoscopy, an investigation featured in the vignettes from the first study of the thesis, which is reported in Chapter 3. Findings from the study suggested information would be of particular benefit to patients who are experiencing investigations or tests for the first time, especially invasive ones. Therefore the use of colonoscopy was appropriate because of its invasiveness. It also has different phases of patient physical involvement (i.e. before, during and after a colonoscopy), which would enable a broader examination of the factors based approach to the design of patient information.

Both patient information resources were adjusted to include numbers in the top right hand corner of the first page to differentiate them. This was for the benefit of participants and the focus group moderator when referring to the information resources, and for the thematic analysis. The standard resource was number one and the factors based resource was number two. Figures 6.1 and 6.2 provide the first page of the standard and the factors based resource, respectively (Figures 5.3-5.5 and 5.6-5.8 provide the standard and the factors based resource in their entirety,

respectively). Participants were provided with A4 copies of both resources in focus groups and A2 copies were attached to the wall, which participants would sit in an arc facing towards. Participants also received A4 copies prior to focus groups via email to read through, although time was allocated at the start of focus groups to ensure they had been read by all participants.



**Figure 6.1** First page of the standard patient information resource to be used in focus groups



**Figure 6.2** First page of the factors based patient information resource to be used in focus groups

### **6.2.2 Focus groups**

Focus groups were semistructured and included questions to determine preferences between the patient information resources and reasons for such preferences. This included questions about the structure of information, as well as referring to information quality and quantity in other questions, such as about the understanding of colonoscopy and improvements that could be made. Focus groups were audio recorded and the focus group schedule is provided in its entirety in Appendix 21. An advantage of semistructured focus groups, as for the advantage of semistructured interviews used in Chapter 4, is their ability to better understand responses through the use of further questions to ‘probe’ for further information. However, focus groups also generate rich data from discussions amongst participants about responses.

### **6.2.3 Thematic analysis**

Qualitative data from the focus groups were transcribed verbatim and, as for the previous three studies, analysed using NVivo 9 (QSR International Pty Ltd., 2010) using a thematic data led approach (Howitt, 2010, p. 175). And as for the previous three studies, peer debriefing (Creswell and Miller, 2000) with colleagues at supervision meetings and project meetings was used to validate the data and the data analysis. Appendix 22 provides a screenshot of the coding of the qualitative data, demonstrating preliminary coding. (See page 70 for a recap on a thematic data led approach and peer debriefing).

### **6.2.4 Sample**

Adults aged 18 years or older who had not had a colonoscopy or a similar investigation, such as proctoscopy or sigmoidoscopy, were eligible to participate in the study. And as explained in the online study, this was to avoid bias from past experiences, which was reasoned in a study conducted by Smith *et al.* (2013a) who recruited participants approaching colorectal cancer screening age to examine a booklet that informs about colorectal cancer screening in the United Kingdom. And similarly to the previous three studies, what will not be known in this study is



whether the responses of the participants would be the same if they were to actually encounter colonoscopy in the future.

### **6.2.5 Recruitment**

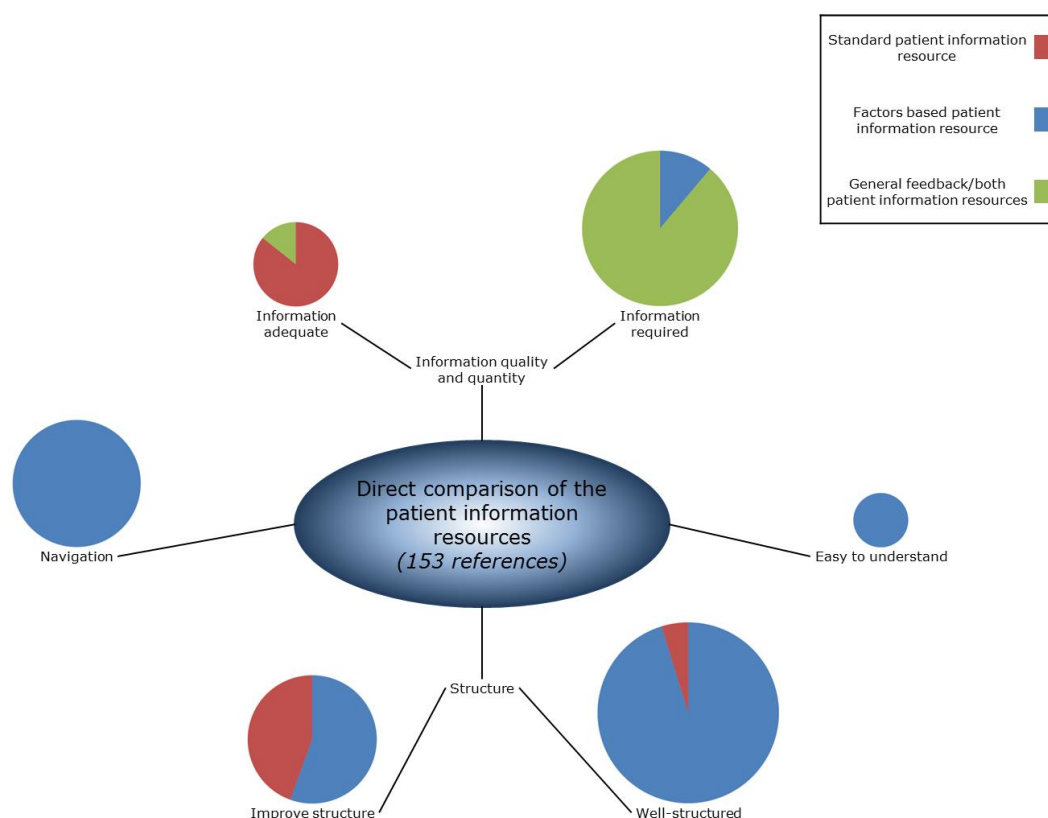
The study gained ethical approval from the Faculty of Engineering Research Ethics Committee at The University of Nottingham. Participants were recruited through posters promoting the study in the local community and the main campus of the university, and emailing of staff and students at the university. Participants provided written consent to participate and were remunerated with £15 in high street vouchers for their participation.

## **6.3 Results**

Eight participants took part in the study of which four (50%) were female and four (50%) male, and of which three (37.5%) were aged 18-23 years, one (12.5%) 24-29 years, two (25%) 30-39 years and two (25%) 50-59 years. Two focus groups were conducted with one focus group including participants aged 29 years or younger (focus group 1) and the other including participants aged 30 years or older (focus group 2). Two females and two males were included in both focus groups. The duration of the first focus group was 39 minutes and the second was 36 minutes.

### **6.3.1 Direct comparison of the patient information resources**

Themes are graphically represented in Figure 6.3 and described in Table 6.1. As for the thematic analyses conducted in Chapter 3 and Chapter 5, the number of references in the graphical representation refers to the total number of sentences, comments and phrases included in the thematic analysis. The table describes the number of references for each theme, as well as the number of sources, which could be a possible maximum of two sources from the two focus groups.



**Figure 6.3** Direct comparison of the patient information resources

Theme	Description	References	Sources
Structure			
Well-structured	Information satisfactorily and orderly segmented and laid out.	42	2
Information quality and quantity			
Information required	Further information required about a colonoscopy and what a patient needs to do and/or what happens to the patient before, during and/or after the investigation.	36	2
Structure			
Improve structure	Segmenting and/or bullet pointing of information to minimise and/or make the text easier to read.	27	2
Navigation	Ability to search between and find specific information.	26	2
Information quality and quantity			
Information adequate	Information sufficient and satisfactory in informing about a colonoscopy and what a patient needs to do and/or what happens to	14	2

	the patient before, during and/or after the investigation.		
Easy to understand	Information well-explained and clearly understood.	8	2

**Table 6.1** Descriptions of the themes for direct comparison of the patient information resources

#### 6.3.1.1 *Structure: well-structured and improve structure*

The most influential theme was *well-structured*, which is a *structure* sub-theme, as is *improve structure*, which was moderately influential. For the *well-structured* theme (42 references, 2 sources) participants remarks were predominantly for the factors based patient information resource and were generally about the suitable presentation of the stages of colonoscopy and that the information was broken into small, concise and manageable sections:

“Having, on the second one, ‘what is the purpose?’; it’s a nice, really simple one liner thing that says this is what the whole thing is about and then you go to; it’s like a simple introduction that gets you started.” (Response about factors based patient information resource from focus group 1, participant 2)

“Just because it’s in more manageable junks of information and you’ve got the procedure straight off, all in one section, as opposed to splitting that up. ...So it’s got the before, during and after so it’s like the whole time period.” (Response about factors based patient information resource from focus group 1, participant 2)

“I think two breaks it down better because obviously it’s broken down into smaller chunks with more specific questions taking into; and the subsections; the before, during and after; I know that’s done there, it’s pretty heavy going, well it’s not heavy going.” (Response about factors based patient information resource from focus group 2, participant 7)

“More concise information; I think there’s a bit too much information on number one. From number two, if I read number two; I would have probably gone back to my GP and asked for more information that was explained on number one.” (Response about factors based patient information resource from focus group 2, participant 5)

“I’m sticking to leaflet number two. It’s better, you know, I’m thinking of it as a patient; I’m stressed, I don’t know what’s happening and then I read number two; then I have a structure in my head and then I have a structure in my head about what I want to ask as well. So it structures my way of dealing with it and gaining some control over, you know, what I can ask as well. Whereas in number one, you know, it’s like the questions are hidden, and I may feel uncomfortable or I may not have been able to process information as well as number two.” (Response about factors based patient information resource from focus group 2, participant 6)

“I think I would go along with that as well. If someone was asking me or told me, ‘I was having a colonoscopy’, or, ‘what was it?’; after reading two I’d probably be able to explain it better than picking out information in number one.” (Response about factors based patient information resource from focus group 2, participant 5)

Separate sections for the risks and side-effects of a colonoscopy were also deemed a positive feature of the factors based patient information resource:

“I like how the side-effects and risks are split up in the second one because side-effects are something that you can deal with rather than risks, and risks are the things you need to but more seriously and take time out for reading. And in number one, you can’t really differentiate with yourself between the two things.” (Response about factors based patient information resource from focus group 1, participant 1)

“And I think breaking up the side-effects and the risks, because for some people who don’t know, they are actually very different things; there not; so to lump them together, I don’t think is very appropriate.” (Response about factors based patient information resource from focus group 2, participant 7)

It was remarked by two participants for an improved patient information resource for colonoscopy to have the information of the standard information resource and the structure of the factors based resource:

“[I]t’s almost like you want the combination of the two; the information from one with the formatting of two.” (Response about factors based patient information resource from focus group 2, participant 7)

“I would agree with that. The information in number one is better but the formatting in number two is better.” (Response about factors based patient information resource from focus group 2, participant 8)

The standard patient information resource was perceived as less disjointed and that it was easier to find out that that patients would need someone to take them home and stay with them after a colonoscopy compared to the factors based information resource:

“One good thing with number one is that it seems slightly smoother and less disjointed, and you’ve got your main four sections really; before, during and after, and then any issues with it.” (Response about standard patient information resource from focus group 1, participant 4)

“I think it’s easier to point out that you would need someone to look after you in the first leaflet than the second; I don’t know why that is but maybe it’s more of what could happen afterwards rather than a side-effect, which might happen.” (Response about standard patient information resource from focus group 1, participant 1)

For the *improve structure* theme (27 references, 2 sources) participants suggested that the positioning of the image of a colonoscopy in the factors based patient information resource could be elsewhere since it was on the first page, which was deemed a front page. It was also suggested that some information could be positioned elsewhere and for alternative sectioning of certain information:

“You see, I sway towards the first one because I really dislike the picture on the front, and if I read a leaflet and there was that picture on the front I would be like ‘err, I don’t want to read it’. Whereas, I can start to learn a bit more about it and sort of get easily approached to the study.” (Response about factors based patient information resource from focus group 1, participant 4)

“I think the text is better in the second one but it would be better if the picture was not on the first page.” (Response about factors based patient information resource from focus group 1, participant 3)

“I think it is better to say like, ‘30-45 minutes’ in that one rather than just ‘you will be monitored’.” (Response about factors based patient information resource from focus group 1, participant 3)

“Because you sort of, it symbolises that it’s final, that nothing much happens. But if you read more you can obviously see that it does happen a bit more. ... If you put ‘What does a colonoscopy actually do?’ and ‘How long will a colonoscopy take?’ behind the ‘what is the purpose?’ and in front of ‘what is required?’ on number two, I think that would be a lot better.” (Response about factors based patient information resource from focus group 1, participant 4)

“I quite like the idea of having a big section with the titles and not breaking it up. ... So instead of having a big section, like you have the before, during and after, and having it again with titles but in kind of the same square.” (Response about factors based patient information resource from focus group 1, participant 3)

“I’m still on two, I’m afraid. The only difference, perhaps, is to suggest to create different blocks for the before, during and after colonoscopy; again, to differentiate them for some people who want the specifics especially.” (Response about factors based patient information resource from focus group 2, participant 6)

It was deemed easier to find out that patients would need someone to take them home and stay with them after a colonoscopy in the standard patient information resource in comparison to the factors based information resource:

“I think it’s easier to point out that you would need someone to look after you in the first leaflet than the second; I don’t know why that is but maybe it’s more of what could happen afterwards rather than a side-effect, which

might happen.” (Response about factors based patient information resource from focus group 1, participant 1)

There was a general consensus in the standard patient information resource that some information could be positioned elsewhere and for separate sections for certain information, especially information about the risks and side-effects of colonoscopy:

“I think the first one, some of the things that are mentioned in that, the during, ‘What happens during a colonoscopy?’, can kind of put you off. Reading the rest of the text before you actually understand that; like it’s saying about you passing wind but don’t feel embarrassed about it; and that it might be painful; but I would rather know exactly what happens first and then know about all that afterwards.” (Response about standard patient information resource from focus group 1, participant 1)

“I think in number one, when it explains what happens during a colonoscopy, it keeps emphasising the negative aspects like, ‘you won’t remember much after’; you’re like, ‘well, why won’t I remember it?’; so it’s starting to put worry in your mind even, when you’re just trying to learn about what happens.” (Response about standard patient information resource from focus group 1, participant 1)

“When you look at number two, the more you read the more information you get. With number one, that first paragraph, to me; I could just be a bit stunned by that first paragraph, when you read that. Whereas number two, you sort of get that information but it’s more spread out and there seems to be more of a natural progression, for me.” (Response about standard patient information resource from focus group 2, participant 5)

“Well you can just look at the title, you know what it’s about to say and then you get the answer. Whereas with the ‘side-effects and risks’, you’ve got both of those so it’s less easy to remember the side-effects and remember the risks.” (Response about standard patient information resource from focus group 1, participant 4)

### 6.3.1.2 *Information quality and quantity: information required and information adequate*

Another influential theme was *information required*, which is an *information quality and quantity* sub-theme, as is *information adequate*, which was somewhat influential. For the *information required* theme (36 references, 2 sources) the general consensus from participants was for a summary of information at the end of the patient information resources to summarise the main points, and to provide a type of checklist for patients to check against to ensure they are fully prepared before a colonoscopy and have made appropriate plans for afterwards:

“I think how you prepared for it and what you need after it, so if you need someone to be with you for 12 hours then you have to kind of plan it, take the day off and get someone else to take the day off to be with you.”

(General feedback or response about both patient information resources from focus group 1, participant 3)

“So maybe a bullet point, summary of the issues at the backend.” (General feedback or response about both patient information resources from focus group 1, participant 4)

“Yeah, as already mentioned, a summary of points or a checklist at the end. Especially when you’re doing the beforehand of the procedure; so like someone to look after you.” (General feedback or response about both patient information resources from focus group 1, participant 2)

“Yeah, in terms of after your monitoring time because it says ‘you will be monitored’ but after that monitoring are you able to go home and drive? I think it’s just one of those practical things that people think about, you know, ‘do I need someone to pick me up or should I get a taxi?’; it’s just a practicality really. ... You could almost have a section entitled, ‘going home’, because I think for patients that’s a really crucial point.” (General feedback or response about both patient information resources from focus group 2, participant 7)

There was concern for patients who do not have anyone to take them home after a colonoscopy and stay with them, which led to suggestions for contact details of



relevant organisations and support groups for patients to contact for further information and support:

“My comments relate to that, I mean just quoting from number one, ‘you’ll need somebody to accompany you home and you should also have someone stay for you 12 hours afterwards’; there may be some people in the community who don’t have, yeah, are just on their own, completely on their own in a sense. And I think there needs to be something in both leaflets saying what happens in that situation; do they stay in hospital overnight or can social services provide someone? I think that needs to be in.” (General feedback or response about both patient information resources from focus group 2, participant 8)

“A back up if you’ve got no personal friends or relatives or whoever could do that.” (General feedback or response about both patient information resources from focus group 2, participant 5)

“How about just a list of references, not academic references, but phone numbers, helplines or web addresses, or something like that.” (General feedback or response about both patient information resources from focus group 2, participant 8)

“I mean the other thing, just thinking about getting more information in the; the NHS website pages provide loads of really good but accessible information, and I mean, where you know you’re talking about a colonoscopy; just have the web link for that as they will have more information than in the leaflet and it might be a reference point people might want to go to, to see if there’s any more detail. And also at that point you’re then avoiding people searching on the Internet randomly.” (General feedback or response about both patient information resources from focus group 2, participant 7)

Why a colonoscopy was being used or what medical condition was being investigated would have better justified the investigation for some participants:

“I think it might be good to have a section on why you’re doing it because sometimes they tell you to do it...after reading all that it’s quite, it makes you a bit worried that it’s going to happen but remember that it’s; the benefits of it.” (General feedback or response about both patient information resources from focus group 1, participant 3)

“Yeah, the good side of colonoscopy; what you’re doing it for.” (General feedback or response about both patient information resources from focus group 1, participant 2)

More information in the factors based patient information resource about what happens after a colonoscopy would have reassured some participants and one participant perceived the standard information resource to provide sufficient information whilst the factors based resource was a summary of this:

“So maybe in number two, ‘After a colonoscopy’, it needs a bit more information to have that reassurance for patients afterwards.” (Response about factors based patient information resource from focus group 1, participant 2)

“Just that there’s so little information in ‘the after’, which could be a bit confusing.” (Response about factors based patient information resource from focus group 1, participant 4)

“I feel number one gives more information about during, you know, before, during and after; in a sense, two just seems more of a summary. It’s just personal preference I guess. ... So I just feel if I read number two it would just, it might worry me not knowing something, not having that information. It’s a personal thing really.” (Response about factors based patient information resource from focus group 2, participant 8)

The *information adequate* theme (14 references, 2 sources) was generally about the standard patient information resource containing more information than the factors based information resource:

“I like both but I preferred number one because more information is given and if I had some serious illness I would want as much information as

possible.” (Response about standard patient information resource from focus group 2, participant 8)

“I felt more informed; I mean number two is well written, I thought that was quite well, but number one just gave that bit extra information that I really would have liked. There is one thing also, it says ‘it is important you follow instructions very carefully to fully empty your bowel’, and it gives the reasons why in number one but it doesn’t in number two, and I feel if you have that in number one more people might take notice; you always get one or two who don’t. ... If they contain the same information then it doesn’t matter. But I just feel, maybe it’s a trick, but I just feel after reading number one that I got more than number two. But that might be apparent rather than actual. It’s just the way it is.” (Response about standard patient information resource from focus group 2, participant 8)

“Yeah, probably two but I think what [participant 8] points out; a midway point; I know that doesn’t help you; a midway between the two would actually be better rather than selecting one or the other as they both have merits.” (Response about standard patient information resource from focus group 2, participant 7)

The image of a colonoscopy was remarked for its helpfulness in informing about what happens during a colonoscopy:

“I quite, I think the picture is quite helpful to help you understand what’s going on.” (General feedback or response about both patient information resources from focus group 1, participant 1)

“Yeah, it’s good to get a good idea, a visual; if people can’t be bothered to read it.” (General feedback or response about both patient information resources from focus group 1, participant 2)

### *6.3.1.3 Navigation*

*Navigation* (26 references, 2 sources) was a moderately influential theme and was only with respect to the factors based patient information resource. It was perceived

quicker and easier to acquire certain information from the factors based information resource and the question titles facilitated this:

“I think you can read the second one a lot quicker because you just see the big titles and you kind of get the key information from it, quicker than the other one.” (Response about factors based patient information resource from focus group 1, participant 3)

“I was going to say, the first thing I would be thinking, ‘is it going to be painful or any discomfort?’, and if you look at that you say, ‘I don’t know where to look’, if you look at that one you say, ‘yes, there’s the question and there’s the answer’.” (Response about factors based patient information resource from focus group 1, participant 4)

“It’s just easier to navigate, isn’t it? I think that one’s good in that it’s quite simple in its sections so it’s pretty much a before, during and after, and then side-effects. And that one, you’ve got loads of different questions you’ve got to navigate to.” (Response about factors based patient information resource from focus group 1, participant 2)

“I suppose for number two you get, if you get a patient who is very agitated for example, and they want to, you know; I think the leaflet is there to be read and re-read; so I would say that sometimes, because of stress you forget certain information; and then if you want the exact information, it’s easier to pinpoint with the second one. You know, you maybe stress and you’ll say, ‘how long will it take again?’, and then you just open it up and there it is.” (Response about factors based patient information resource from focus group 2, participant 6)

“Yeah, I think that’s correct. It is easier to pinpoint information in number two; obviously the information is in number one but it’s just the content sections; it’s like when you’re signposting people to information; that one doesn’t do it quite so well.” (Response about factors based patient information resource from focus group 2, participant 7)

“I think certainly regarding what I have said about the content of number one, number two is structured better in terms of; more like bullet points, which people can read and go straight to; in that sense it has a better structure.” (Response about factors based patient information resource from focus group 2, participant 8)

It was also remarked that information in the factors based patient information resource was easier to skip or skim over, if preferred:

“I think in the second one it would be a bit easier to just skip over a section if you didn’t want to read it rather than the first one; it kind of gives you the information and you can’t hide from it. ... I feel that you should be reading it all but sometimes it is good to being able to find it quickly if you want to read that part.” (Response about factors based patient information resource from focus group 1, participant 1)

“Yeah, it’s just; you can flip through; you can skim two and then just pick every out that your eyes draw to for all the bits that you need to know. So the order, it is relevant to a certain extent but then; it’s just easier to pick out the information you want to know, or I want to know.” (Response about factors based patient information resource from focus group 2, participant 5)

#### *6.3.1.4 Easy to understand*

The final and least influential theme was *easy to understand* (8 references, 2 sources), which was another theme that was only with respect to the factors based patient information resource. The factors based information resource was deemed clearer and that it enabled a quicker understanding of colonoscopy in comparison to the standard resource:

“I thought I understood more clearly in leaflet two about the biopsy section of it and explaining polyps in more detail; I don’t know if it says it exactly in leaflet one but I can’t remember it and I guess that makes a difference; making you understand things a bit easier.” (Response about factors based patient information resource from focus group 1, participant 1)

“It’s not just something you would do, ‘oh yeah, cool, let’s do it’. But in the second one it makes you understand it quicker so you’re like ‘okay, it’s fine’.” (Response about factors based patient information resource from focus group 1, participant 3)

The factors based patient information resource was also deemed friendlier and easier to digest:

“Just apparent to me that two seems a bit more informal but that’s just an impression. ... Perhaps a bit friendly.” (Response about factors based patient information resource from focus group 2, participant 8)

“Yeah, that’s what I think I prefer about number two.” (Response about factors based patient information resource from focus group 2, participant 5)

“Probably, you know, if you’re presented with this as a possible treatment, sorry diagnostic option, it’s pretty stressful and I think just in terms of digesting the information, two is easier to take in. (Response about factors based patient information resource from focus group 2, participant 7)

## 6.4 Discussion

The study examined the factors based approach to the design of patient information, which was conceptualised in Chapter 3 as a user centred design concept (see pages 103-107 for recap), developed in Chapter 4 (see pages 156-158 for recap) and previously examined in Chapter 5 using an online study. The factors based approach was examined through directly comparing, using two focus groups, two patient information resources for colonoscopy: 1) standard patient information resource (Figures 5.3-5.5); and 2) factors based patient information resource (Figures 5.6-5.8). Thematic analysis (Figure 6.3) dictates the factors based resource was favoured overall compared to the standard resource.

Themes suggest the structure and navigation of the factors based patient information resource was superior in comparison to the standard information resource. The factors based resource was favoured for its suitable presentation of the stages of colonoscopy and its small, concise and manageable sections. The

distinction between risks and side-effects was also positively acknowledged. The factors based resource was perceived to facilitate quicker and easier acquisition of certain information and the question titles contributed to this. It was also remarked that the factors based resource was better suited to be read and re-read, which may involve skipping or skimming over information. These are all positive attributes for patient information to have because most information will not be read once, as was the case in this study, but will be referred back to a number of times. The U.S. Department of Health and Human Services (2006, p. 58) comment that websites should enable users to effectively and efficiently find information, which the factors based resource seemed to facilitate. This would satisfy Garner's *et al.* (2011) notion of 'usability' for communicative effectiveness in patient information leaflets. The structure and navigation of the factors based resource may have also contributed to participants perceiving the resource easier to understand because not only was it considered clearer, it was considered friendlier, easier to digest and that it enabled a quicker understanding of colonoscopy.

Though themes suggest the factors based patient information resource had better structure in comparison to the standard information resource, contrastingly they also suggest that it required more improvements. This was with respect to the repositioning of information and in particular the repositioning of information about patients needing someone to take them home and stay with them. The standard resource was perceived as less disjointed and that it was easier to find out that patients would need someone to take them home and stay with them after a colonoscopy. The factors based resource was also considered deficient because of its lack of explanation about what happens after a colonoscopy since it only states that patients will be monitored before they can go home. This is actually a consequence of the factors based resource having the same content as the standard resource and so further information could be included to divulge more about what happens to patients after the investigation. There was also a misperception that the standard resource included more information, and it was remarked for an improved patient information resource for colonoscopy that it could have the information of the standard resource and the structure of the factors based resource.

Both patient information resources encouraged general but constructive feedback with respect to the information required theme, an information quality and quantity sub-theme. This included a summary of the main points and a patient checklist to be included at the end of the information resources, followed by relevant contact details for patients to contact if necessary. Through incorporating these features both resources may be improved. This may include improving the factors based resource without the need to reposition information about patients needing someone to take them home and stay with them.

Thematic analysis dictates the factors based patient information resource was favoured overall and demonstrates the potential of the factors based approach to the design of patient information, which is theory led and has taken inspiration from Ajzen's (2005, p. 126, see pages 25-26 for recap) theory of planned behaviour. The progressive structure of the factors based information resource with respect to colonoscopy and its signposting with the question titles to specific information seemed to be features that were important for its usability. These usability features also seemed to have made the factors based resource easier to understand compared to the standard resource, which could contribute to quality patient experiences through appropriately informing, supporting and guiding patients. The established factors themselves can assist information designers and others involved in patient information through their contribution to patient information guidelines. Such guidelines may satisfy Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. The next chapter outlines such guidelines for diagnostic procedures and screening, which will incorporate feedback from this study. And since there are currently no specific guidelines for information designers to follow when designing patient information for when patients have options of or require investigations or tests, these guidelines also aim to provide such specific guidance. A practical guide was considered a useful tool by the majority of healthcare information producers who took part in a recent survey by the Patient Information Forum (2013b, p. 10).



## 6.5 Methodology considerations

A convenience sample was used and half of the participants were aged 29 years or younger. Therefore the sample was not representative of a demographic that would be likely to require colonoscopy. However, adults aged 18 years or older who had not had a colonoscopy or similar investigation were eligible to participate in the study to avoid bias from past experiences. The focus of the study was also to compare both patient information resources to examine the factors based approach to the design of patient information and so a convenience sample was appropriate for this. Practical and ethical issues were also avoided through involving participants who did not have or had not had a colonoscopy, but what has not been examined in this study is the extent to which participant responses would be the same if they were to actually encounter the investigation in the future. This was a trade-off as well as a limit.

Both patient information resources included content from existing patient information resources that were currently available, but were not context orientated and so had no reference to symptoms and/or medical conditions. Results may have differed if information about symptoms and/or medical conditions were included. This was another trade-off to focus on comparing both information resources to examine the factors based approach to the design of patient information and to avoid the effects associated with specific symptoms and/or medical conditions.

The focus group schedule, as well as the patient information resources, was developed following sufficient piloting to ensure valid data were collected to compare the information resources and to examine the factors based approach to the design of patient information. Focus groups benefited from discussions amongst participants and four participants in each group worked well for group dynamics. The two focus groups provided valuable data following the qualitative findings from the online study.

Finally, as for the previous three studies, the analysis of the qualitative data was from the perspective of the researchers involved in this study. If researchers with different perspectives analysed the data, the interpretation, coding and theming of the data may vary. Respondent validation or 'member checking' (Creswell and

Miller, 2000; Mays and Pope, 2000) could have been used to examine the credibility of the themes, and Cohen's Kappa coefficient (Cohen, 1960) could have been used to provide a statistical measure for inter-rater reliability for qualitative coding. However, the thematic analysis was rigorously conducted and peer debriefing (Creswell and Miller, 2000) was used, so the themes that emerged were discussed and rationalised to ascertain their basis and reasoning. (See page 109 for a recap on respondent validation and Cohen's Kappa coefficient).

## 6.6 Conclusion

Thematic analysis (Figure 6.3) dictates the factors based patient information resource was favoured overall compared to the standard information resource. Themes dictate the factors based resource was better structured and had better navigational properties. These usability features seemed to facilitate participants' understanding of colonoscopy and enabled them to effectively and efficiently find information. Improvements that could be made to both resources following this study would be a summary of the main points and/or a checklist of what patients need to do to be positioned at the end of the resources, followed by relevant contact details for patients to contact if necessary. These improvements are included in patient information guidelines for diagnostic procedures and screening, which are outlined in the next chapter. The guidelines use the factors considered appropriate to guide the design of a patient information resource for an investigation or test without context orientation, and the factors considered appropriate for diagnostic and screening contexts (see pages 162-170 for recap).

# CHAPTER 7

## Patient information guidelines

### 7.1 Introduction

Chapter 7 outlines patient information guidelines that bring to an end the factors based approach to the design of patient information, which was conceptualised in Chapter 3 as a user centred design concept (see pages 103-107 for recap), developed in Chapter 4 (see pages 156-158 for recap), and examined in Chapters 5 and 6. Quantitative findings from Chapter 5, an online study, conclude the factors based approach to the design of patient information had no statistically significant effect on patient information. However, thematic analysis suggests information designed using the factors based approach was adequate but further was required and well-structured but that this could be improved. These contrasting themes were further explored in Chapter 6 using focus groups and thematic analysis dictates information designed using the factors based approach was favoured overall, and in particular was better structured and had better navigational properties.

The factors based approach to the design of patient information is theory led and has taken inspiration from Ajzen's (2005, p. 126, see pages 25-26 for recap) theory of planned behaviour. This may satisfy Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. And since there are currently no specific guidelines for information designers to follow when designing patient information for when patients have options of or require investigations or tests, these guidelines also aim to provide such specific guidance. A practical guide was considered a useful tool by the majority of healthcare information producers who took part in a recent survey by the Patient Information Forum (2013b, p. 10).

The patient information guidelines are outlined in four sections: 1) general advice; 2) guidelines for diagnostic procedures; 3) guidelines for screening; and 4) final comments. The first section refers to relevant research from the literature review to consider important aspects of patient information design, development and evaluation, and provides advice about implementing the guidelines. Findings from

the examination of the factors based approach to the design of patient information are also considered. The second and third sections provide the guidelines for diagnostic and screening contexts, respectively. The guidelines use the factors considered appropriate to guide the design of patient information without context orientation (i.e. with no reference to symptoms and/or medical conditions), and factors considered appropriate for diagnostic and screening contexts (see pages 162-170 for recap). The guidelines for diagnostic procedures will describe factors to enable patient information to be tailored for without context orientation. The final section discusses the quality of the guidelines, including their limitations, and the importance of involving target users.

These guidelines have also been made publicly available to use as a separate document and for further dissemination, and can be accessed and downloaded from the following link: <https://db.tt/e6BQeJuu>

## 7.2 General advice

### 7.2.1 Kitemarks and trustmarks

Kitemarks and trustmarks involve assessment protocols to ensure information attains minimum standards deemed acceptable and fit for purpose. They would therefore tend to be used following the design and development of patient information in the evaluation stage. However, they can also be beneficial in the initial stages of information design and be included in design specifications. Three marks that information designers may want to consider include: 1) The Information Standard (Figure 2.12); 2) Crystal Mark (Figure 2.13); and 3) Health On the Net Foundation Code of Conduct (Figure 2.14).

The Information Standard (2013a) represents evidence based health and care information for the public, and is discussed in the literature review (see pages 48-49 for recap).

The Crystal Mark is awarded by the Plain English Campaign (2013) when information is clearly written and comprehensible, although it does not ensure content accuracy. All that is required to be awarded the mark is to send the

document with the information to the Plain English Campaign for review. If the document is up to standard it can proceed to the actual application of the mark. However, if edits need making details of such will be provided, including a cost estimate for edits to be made by the Plain English Campaign.

The Health On the Net Foundation Code of Conduct (Health On the Net Foundation, 2013) holds website developers to ethical standards for information presentation and to ensure readers know the source and purpose of the data they are reading. There are eight principles to achieving the mark and the Health On the Net Foundation provide guidelines for each. The principles are as follows:

- Authoritative – information provided by a medically trained and qualified professional, unless otherwise stated.
- Complementarity – information is designed to support the clinician-patient relationship.
- Privacy – website does not violate data confidentiality of users.
- Attribution – where possible, clear references to sources of data, including hyperlinks if possible, and date of information modification are clearly displayed.
- Justifiability – any specific treatments, commercial products or services will be supported by evidence in the manner outlined in the above principle.
- Transparency – contact details provided for users who seek further information, including contact details of website developer or webmaster.
- Financial disclosure – sources of funding clearly displayed.
- Advertising policy – if advertising is present it should be stated and the website should clearly display its advertising policy.

With reference to attribution and date of information modification, the ‘evidence’ dimension of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009, see pages 46-47 for recap) includes an item for decision support technologies (also known as decision aids) or associated documents to provide a production or publication date, as well as an item for information about the proposed update policy.

## 7.2.2 Risk communication

Where information about risks is provided in patient information, risk communication is an important consideration. The Committee on Safety of Medicines Working Group on Patient Information provide variations and consider the suitability of statistical expressions for risk communication (MHRA, 2005, pp. 46-47). This includes:

- quantifying risk with absolute numbers (e.g. 1 in 10,000),
- using verbal descriptions of risk (e.g. very rare),
- conveying risk estimates and their uncertainty (e.g. about five extra cancers for every 1,000 patients),
- using frequency ranges (e.g. fewer than 1 in every 1,000),
- describing risk duration (e.g. risk applies to first two weeks of a five week period),
- reporting of frequency estimates based on spontaneous data as such (e.g. this data is based on reported data and is likely to be an underestimate of actual incidence or risk), and
- using constant denominators (e.g. 1 in 10,000 and 100 in 10,000 rather than 1 in 10,000 and 1 in 100).

Ahmed *et al.* (2012) provide a clinical review of risk communication to support practising clinicians with what they deem a difficult aspect of clinical practice. The review covers:

- framing,
- presenting risk reduction,
- personalising risk information,
- natural frequencies,
- decision aids, and
- uncertainty.

A number of helpful examples, including graphical representations, are included in the review.

For communicating risk in screening there is the consideration of true positives (i.e. correct diagnosis of medical conditions), true negatives (i.e. correct ruling out of medical conditions), false positives (i.e. incorrect diagnosis of medical conditions) and false negatives (i.e. incorrect ruling out of medical conditions). These are included in the ‘test’ dimension of the International Patient Decision Aid Standards instrument (Elwyn *et al.*, 2009, see pages 46-47 for recap).

### **7.2.3 Presenting written information**

The Medicines and Healthcare products Regulatory Agency (MHRA, 2012, p. 7) provide guidance about typography. They suggest that typeface and other elements of graphic design, including colour of text, need to be considered with the user in mind. They also suggest written text within white space helps create a feeling of openness about the information being presented.

The European Commission (2009, p. 7) suggest italics and underlining and the widespread use of capitals should be avoided due to difficulties in clarity of information. They provide guidance about text alignments and line spacing (p. 8), and state that line spacing is important for achieving clarity of information. They also provide guidance about syntax and writing style (p. 9-10). This includes the use of simple words of few syllables, avoiding long sentences and using an active rather than passive writing style (e.g. ‘do not eat for 24 hours before the procedure’ rather than ‘you should not have eaten for 24 hours before the procedure’).

Noted in the examination of the factors based approach to the design of patient information was the frequent use of personal pronouns (i.e. you and your) in the four patient information resources (Bupa, 2013; Knott, 2012; Macmillan Cancer Support, 2010; NHS Bowel Cancer Screening Programme, 2006) that the standard and subsequently the factors based patient information resource were developed from. It is therefore advised that personal pronouns are used wherever appropriate. The standard and the factors based information resource were checked for incorrect spellings and typos, which is also advised.

When several points are made under a heading or subheading, bullet points should be used to summarise information since this was suggested for both the standard

and the factors based patient information resource (see pages 204-206 for recap). Questions titles for the headings and subheadings were regarded positively in the factors based information resource (see pages 228-230 for recap) and it is therefore advised that question titles are used wherever appropriate.

#### **7.2.4 Implementing the guidelines**

The guidelines are aimed at the first stage of the design of patient information. They provide guidance about the inclusion and organising of information for diagnostic procedures and for screening. However, user testing with and feedback from target users is an important aspect of the development and evaluation of information. The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human provide a method that is commonly used for user testing package leaflets for medicinal products (CMDh, 2011). The method is the ‘Australian’ method and is discussed in the literature review (see page 45 for recap).

The way patient information will be organised using the guidelines for diagnostic procedures and for screening has the potential to enhance the usability of the information. There is the potential for interactivity that may be permitted by digital technologies, including online resources with interactive features. This may involve the highlighting and manipulating of information by the user (e.g. from most to least important information), and notes written (and removed) with reference to specific information, including comments and questions for the user to refer to at a later date, which may occur in consultation with a clinician or other healthcare professional. In the case of patients having diagnostic options a summary table, similar to Option Grids (Decision Laboratory, 2013; Elwyn *et al.*, 2013), could be used to directly compare procedure options and facilitate decision-making. In the case of screening, summary tables, where appropriate, could be used to directly compare being with not being screened.



## 7.3 Guidelines for diagnostic procedures

The factors to guide the design of a patient information resource for a diagnostic procedure are described as follows in logical order, but judgement on actual order should be determined by specific diagnostic procedure, information designer and user feedback:

- Choice and control.
- Purpose.
- Physical involvement.
- Informational output.
- Duration.
- Sensations.
- Side-effects.
- Risks.
- Convenience.

Question titles are used to describe the factors as advised in the previous section about presenting written information. It was suggested in the examination of the factors based approach to the design of patient information that a summary of the main points and/or a checklist of what patients need to do, as well as contact details for patients to contact for further information and support, be included at the end of both the standard and the factors based patient information resource (see pages 225-227 for recap). Therefore a summary of the main points, a patient checklist and contact details are added to the end of the guidelines, which will also use question titles. The information the duration factor is to inform patients about has been slightly modified to include information about when patients can go home after a diagnostic procedure, as this was included in both information resources and may be important to patients.

### 7.3.1 What are the patient's diagnostic options?

If patients have different diagnostic procedures to choose from and they have control in deciding which to choose, they should be informed about this. This is so they can consider the information provided about diagnostic procedures with a view

to making an informed decision about which to choose. It may suffice and/or be appropriate for this information to be provided by relevant clinicians and other healthcare professionals, and that the information about the specific procedures is provided in separate patient information resources. Alternatively the information about patients having different diagnostic procedures to choose from and the specific diagnostic procedures could be provided in one information resource.

### **7.3.2 What is the purpose of the diagnostic procedure?**

Describe what body part the diagnostic procedure is investigating or testing. Information about suspected medical condition(s) provided, media permitting, if optional and added by clinicians. This is to ensure the reliability of information and so that patients can decide whether they would or would not prefer to be informed of what suspected medical condition(s) their symptoms warranted further investigation for. Suitable images and/or, media permitting, videos should be included to support information provision about the body part and the suspected medical condition(s).

### **7.3.3 What happens to the patient before, during and after the diagnostic procedure?**

Describe patient physical involvement with the diagnostic procedure and any different phases of involvement (i.e. before, during and/or after diagnostic procedure). Use subheadings for different phases if required and beneficial to patients (user feedback may help in this decision). If there is the possibility of embarrassment then information about the procedure being performed and assisted by qualified healthcare professionals who are trained in and have experience of the procedure, and who will not feel uncomfortable or embarrassed about it can be included. Suitable images and/or, media permitting, videos should be included to support information provision about patient physical involvement with the diagnostic procedure.

### **7.3.4 What does the diagnostic procedure actually do?**

Describe informational output from the diagnostic procedure (e.g. image from an X-ray) and whether patients can view the informational output during and/or after the procedure. Describe clinicians and other healthcare professionals involved in interpreting the output and the interpretation process (e.g. image from an X-ray will be examined by a radiologist (a specialist healthcare professional)), and whether they will explain and/or if patients can ask questions about the output. Describe the time it will take for the output to be interpreted to an outcome or result and become available. Suitable images and/or, media permitting, videos should be included to support information provision about the diagnostic procedure informational output.

### **7.3.5 How long will the diagnostic procedure take?**

Describe the time the diagnostic procedure will take to complete and, if appropriate, the time patients are ready to go home after the procedure.

### **7.3.6 Is there any pain or discomfort during the diagnostic procedure?**

Describe pain and/or discomfort that may be experienced from the diagnostic procedure. Describe alleviating substances used to relieve or reduce pain and/or discomfort, and if substances are optional then provide information about this.

### **7.3.7 Are there any side-effects from the diagnostic procedure?**

Describe physical limitations and/or sensations following the diagnostic procedure, including limitations and/or sensations from alleviating substances. If appropriate, suitable quantitative evidence can be used to quantify side-effects, which should be appropriately formatted using numerical and/or graphical formats. Quantitative evidence could be accessed, media permitting, from quantitative terms (e.g. hyperlink from ‘small chance’) so that patients can decide whether they would or would not prefer to be informed about specific quantitative details.

### **7.3.8 Are there any risks from the diagnostic procedure?**

Describe potential dangers and consequences of the diagnostic procedure. Suitable quantitative evidence should be used to quantify risks, which should be appropriately formatted using numerical and/or graphical formats. Quantitative evidence could be accessed, media permitting, from quantitative terms so that patients can decide whether they would or would not prefer to be informed about specific quantitative details.

### **7.3.9 How to book the diagnostic procedure?**

If patients have to arrange attendance for the diagnostic procedure and/or they have different locations and/or times to choose from, they should be informed about this. Booking details and, media permitting, booking functionalities should be included and incorporated, respectively, in the patient information resource for patients to make arrangements.

### **7.3.10 What are the important points to remember about the diagnostic procedure?**

Summarise the main points of the diagnostic procedure if required and beneficial to patients (user feedback may help in this decision).

### **7.3.11 What does the patient need to remember to do for the diagnostic procedure?**

Provide a patient checklist to remind patients to follow instructions and/or make arrangements for before and/or after the diagnostic procedure if required and beneficial to patients (user feedback may help in this decision).

### **7.3.12 Who to contact if the patient needs further information and support about the diagnostic procedure or their diagnostic options?**

Provide contact details of relevant and reliable organisations and/or support groups if required and beneficial to patients (user feedback may help in this decision). This can include advising patients to speak with their GP if appropriate.

## 7.4 Guidelines for screening

The guidelines for screening are similar to those for diagnostic procedures except factors are tailored for screening and two additional factors are included. The order of the factors is as follows:

- Choice and control.
- Purpose.
- Physical involvement.
- Informational output.
- Duration.
- Sensations.
- Side-effects.
- Benefits.
- Risks.
- Convenience.
- Speak with clinician and/or other healthcare professional.

As for the diagnostic procedures a summary of the main points, a patient checklist and contact details are added to the end of the guidelines.

### 7.4.1 What are the patient's screening options?

Since patients are asymptomatic (i.e. patients present no symptoms) and they have control in deciding on whether to be or not to be screened, they should be informed about this. This is so that they can consider the information provided about the screening with a view to making an informed decision on whether to be or not be screened.

### 7.4.2 What is the purpose of the screening?

Describe the medical condition being screened, risk factors associated with the condition and introduce the screening procedure. Suitable images and/or, media permitting, videos should be included to support information provision about the medical condition.

### **7.4.3 What happens to the patient before, during and after the screening?**

Describe patient physical involvement with the screening procedure and any different phases of involvement (i.e. before, during and/or after screening procedure). Use subheadings for different phases if required and beneficial to patients (user feedback may help in this decision). If there is the possibility of embarrassment then information about the procedure being performed and assisted by qualified healthcare professionals who are trained in and have experience of the procedure, and who will not feel uncomfortable or embarrassed about it can be included. Suitable images and/or, media permitting, videos should be included to support information provision about patient physical involvement with the screening procedure.

### **7.4.4 What does the screening actually do?**

Describe informational output from the screening procedure (e.g. image from an X-ray) and whether patients can view the informational output during and/or after the procedure. Describe clinicians and other healthcare professionals involved in interpreting the output and the interpretation process (e.g. image from an X-ray will be examined by a radiologist (a specialist healthcare professional)), and whether they will explain and/or if patients can ask questions about the output. Describe the time it will take for the output to be interpreted to an outcome or result and become available. Suitable images and/or, media permitting, videos should be included to support information provision about the screening procedure informational output.

### **7.4.5 How long will the screening take?**

Describe the time the screening procedure will take to complete and, if appropriate, the time patients are ready to go home after the procedure.

### **7.4.6 Is there any pain or discomfort during the screening?**

Describe pain and/or discomfort that may be experienced from the screening procedure. Describe alleviating substances used to relieve or reduce pain and/or discomfort, and if substances are optional then provide information about this.

#### **7.4.7 Are there any side-effects from the screening?**

Describe physical limitations and/or sensations following the screening procedure, including limitations and/or sensations from alleviating substances. If appropriate, suitable quantitative evidence can be used to quantify side-effects, which should be appropriately formatted using numerical and/or graphical formats. Quantitative evidence could be accessed, media permitting, from quantitative terms (e.g. hyperlink from ‘small chance’) so that patients can decide whether they would or would not prefer to be informed about specific quantitative details.

#### **7.4.8 What are the benefits of the screening?**

Describe the benefits of being screened, including patients being made aware that they do or do not have the medical condition being screened, and receiving appropriate health advice and/or healthcare if screened and the condition is diagnosed.

#### **7.4.9 What are the risks of the screening?**

Describe the risks of being or not being screened, including potential dangers and consequences of the screening procedure. Suitable quantitative evidence should be used to quantify risks, which should be appropriately formatted using numerical and/or graphical formats. Quantitative evidence could be accessed, media permitting, from quantitative terms so that patients can decide whether they would or would not prefer to be informed about specific quantitative details.

#### **7.4.10 How to book the screening?**

Since patients are asymptomatic and they have control in deciding on whether to be or not to be screened, describe how they make arrangements to attend the screening procedure and if they have different locations and/or times to choose from. Booking details and, media permitting, booking functionalities should be included and incorporated, respectively, in the patient information resource for patients to make arrangements.

#### **7.4.11 What if the screening makes a diagnosis?**

Describe clinicians and other healthcare professionals patients would meet to discuss and/or gain advice about further investigations and tests (if any), and treatments if screened and the medical condition being screened was diagnosed. If there are different treatments for patients to choose from and they have control in deciding which to choose, they can be informed about the number of treatments and that they can decide about which one to choose. Information about actual further investigations, tests and treatments could be accessed, media permitting, from the patient information resource informing about the screening. This is so that patients can decide whether they would or would not prefer to be informed about what further investigations and tests are required, and what treatments are used to treat the medical condition they have the option of being screened for.

#### **7.4.12 What are the important points to remember about the screening?**

Summarise the main points of the screening if required and beneficial to patients (user feedback may help in this decision).

#### **7.4.13 What does the patient need to remember to do for the screening?**

Provide a patient checklist to remind patients to follow instructions and/or make arrangements for before and/or after the screening if required and beneficial to patients (user feedback may help in this decision).

#### **7.4.14 Who to contact if the patient needs further information and support about the screening?**

Provide contact details of relevant and reliable organisations and/or support groups if required and beneficial to patients (user feedback may help in this decision). This can include advising patients to speak with their GP if appropriate.



## 7.5 Final comments

These guidelines have been developed diligently, but are considered a draft and should be treated as such. This is not to undermine their efficacy, but to acknowledge that they are not final and that further development and refinement is encouraged. One limitation is that the factors used in the guidelines were established from two studies and other relevant factors for guidelines may exist that were not established from these. However, participants were highly to very highly satisfied with information provided in the factors based patient information resource (Table 5.4), and thematic analysis (Figure 6.3) dictates it was favoured overall compared to the standard information resource it was compared with. Themes dictate the factors based resource was better structured and had better navigational properties

Since the examination of the factors based approach to the design of patient information was without context orientation, it is not yet known how patient information for diagnostic and screening contexts designed using the factors based approach would perform. However, on top of the seven factors without context orientation, only two and four additional factors are required to tailor patient information for diagnostic and screening contexts, respectively. Therefore there would only be small variation in the content and organisation of information. Furthermore, as mentioned with respect to implementing the guidelines, they are aimed at the first stage of the design of patient information. It is important that target users are involved in the development and evaluation of information for user testing and feedback to refine and ensure the quality of patient information resources. Feedback from participants in the examination of the factors based approach led to a summary of the main points, a patient checklist and contact details to be added to the end of the guidelines.

It is hoped the guidelines assist information designers and others involved in patient information, and that they contribute to quality patient experiences through meeting patient informational needs and preferences. Although the guidelines are for diagnostic procedures and screening, principles from them can also be applied to the design of patient information for treatments.

# CHAPTER 8

## Discussion

### 8.1 Introduction

The thesis aimed to develop a user centred approach to the design, development and implementation of patient information that contributes to quality patient experiences. This was in response to the literature review, which demonstrated the value of information in the patient experience but also revealed that current methods used in the design and development of patient information are often top-down. The user centred approach was constructed from and in response to the following three research questions:

- 1) What factors affect patient attitudes towards diagnostic and screening procedures?
- 2) What are patient informational needs and preferences when encountering diagnostic and screening procedures?
- 3) How does patient information based on factors affecting patients' attitudes towards diagnostic and screening procedures affect the value of the information?

Four studies were designed and conducted in response to the research questions and to reflect a user centred approach to the design, development and implementation of patient information. The studies were designed based on and to reflect the modified onion component of the model by Sharples *et al.* (2012) (Figure 2.17). The original model (Figure 1.1) takes into consideration users or patients, medical device, interaction of users or patients and the device, and resultant consequences of the interaction. This describes a human factors approach that aims to understand the relationship between users and a medical device in a particular context of utilisation, and the effects this has on user behaviour. The modified onion component incorporates information, which sits in between the patient and device. This is to appropriately demonstrate the relationship information has between context and device, and the patient.

The first two studies were designed and conducted to establish factors affecting attitudes towards screening and diagnostic healthcare situations, and understand informational needs and preferences in the situations. Understanding informational needs and preferences includes understanding needs and preferences following the patient outcome (i.e. whether a diagnosis is made or not). Findings from the first two studies were then incorporated into the last two studies and specifically into the design of patient information. The patient information was evaluated and compared with information that is already available to examine whether it better met the needs and preferences of patients.

The process of incorporating findings from the first two studies into the design of patient information used in the last two studies was fitting of ISO 9241-201:2010 (ISO, 2010). This is an international standard that provides requirements and recommendations for human centred design. Key principles of the standard are that design is based upon an explicit understanding of users, tasks and environments, and that users involvements are active (i.e. users are involved in all design phases, from early conceptualisations to final user testing). The four studies and their findings are discussed and reflected on with respect to the research questions in the next section. This will involve linking back to literature from the literature review to demonstrate the contribution to knowledge made from the research.

## **8.2 Reflection of research questions and study findings**

### **8.2.1 What factors affect patient attitudes towards diagnostic and screening procedures?**

The first study established 10 factors affecting attitudes towards diagnostic procedures (Figure 3.11). Physical involvement, trust, familiarity and purpose were the most influential factors that affected attitudes, whilst embarrassment, duration and complexity were the least influential. Understanding and improving health, risks and/or side-effects and sensations were the other three factors that were moderately influential. The second study established 15 factors affecting attitudes towards screening (Figure 4.7), and benefits and risks were the most influential

factors, which are personal sub-factors. Although the other twelve factors were smaller and less influential, they were still important aspects of screening.

Of the established factors from both studies five of them were identical. This includes complexity, familiarity, physical involvement, sensations and trust. Additionally, other factors were similar, such as benefits (screening factor) and understanding and improving health (diagnostic factor). There is also the consideration of risks and/or side-effects since risks and/or side-effects were established as one factor in the diagnostic context and two separate factors in the screening context. The differences and similarities in the established factors demonstrate how patients' needs and preferences differ when encountering investigations and tests in screening healthcare situations when they are asymptomatic (i.e. patients presenting no symptoms) and in diagnostic healthcare situations when they are symptomatic (i.e. patients presenting symptoms).

Physical involvement when encountering diagnostic procedures was of huge interest and concern to participants, and of particular interest and concern was what was physically expected of patients and what would happen to them during procedures. This suggests understanding what was physically expected of and what would happen to patients is an important process for patients prior to diagnostic procedures. This may enable them to prepare themselves emotionally and psychologically, and to minimise expectation mismatch with experience, which can be detrimental to the patient experience if experiences are not consistent with or worse than expected (Figure 2.7). This has been observed in a study where there has been an apparent 'expectation-reality divide' (Nightingale *et al.*, 2012) and in another where experiences have been better than expected (Wagner *et al.*, 2009b).

Participants had less interest and concern with physical involvement in a screening context, although this would still be pivotal in deciding whether to be or not to be screened, as would risk factors. Risk factors would affect the personal value of being screened for a medical condition and this in turn would influence the level of necessity of being screened. This is referred to in the health belief model (Strecher *et al.*, 1997) with respect to an individual's subjective value (or evaluation) of personal susceptibility to and severity of disease, and the likelihood of reducing that threat through personal action (i.e. behaviour change). This has been observed in

studies where family history of a medical condition (Montaño *et al.*, 2004; Nekhlyudov *et al.*, 2003; Shah *et al.*, 2007; Wallner *et al.*, 2008) and advancing age (Livingston *et al.*, 2002; Nekhlyudov *et al.*, 2003; Underwood, 1999; Weinberg *et al.*, 2004) have facilitated screening attendance.

Pivotal to patient decision-making when deciding whether to be or not to be screened and of most influence would be personal benefits and risks. For benefits this would include patients being made aware that they do or do not have a medical condition, and receiving appropriate health advice and/or healthcare if screened and a condition was diagnosed. For risks this would include the risks of being or not being screened, including the risks of a screening procedure and/or treatments. The effects of benefits and risks can be theorised using the theory of planned behaviour (Ajzen, 2005, p. 126, see pages 25-26 for recap) and the health belief model (Strecher *et al.*, 1997, see pages 26-27 for recap), where information or beliefs about benefits and risks contribute to screening intentions. This was observed in studies conducted by Griffith *et al.* (2012), Montaño *et al.* (2004), Weinberg *et al.* (2004) and Yim *et al.* (2012) who found the belief that screening will reduce the likelihood of becoming ill with a treatable medical condition facilitated screening attendance.

Another known facilitator for screening is clinician recommendation (DeFrank *et al.*, 2012; Ling *et al.*, 2001; Hemsing Cruz *et al.*, 2008; Ogedegbe *et al.*, 2005); the lack of one has been commonly predictive of screening non-attendance (DeFrank *et al.*, 2012; Ogedegbe *et al.*, 2005; Salimzadeh *et al.*, 2011; Taylor *et al.*, 2002). Participants demonstrated the effect of clinician recommendation through trust in clinicians and/or clinical practice, and in particular trust in a doctor's recommendation. There was no specific trust with the screening procedure or medical technology, which does not fit with Montague and Asan's (2012, see pages 17-18 for recap) patient trust in medical technology model. This was also the case for trust in diagnostic procedures since participants also had trust in clinicians and/or clinical practice. This form of trust is typical of patients in paternalistic clinician-patient relationships where patients take lead from the clinician and put trust in the decisions they make on their behalf, believing that such decisions are done in their best interest (Beisecker and Beisecker, 1993). Trust in the diagnostic

context was a lot more influential in comparison to the screening context and may contribute to alleviating patient anxiety, which was observed in a study conducted by Zener and Bernstein (2011).

Familiarity with an investigation or test may also alleviate patient anxiety and was a factor in both a screening and diagnostic context, but which was more influential in the diagnostic context. Familiarity included participants' experience, knowledge or perceived knowledge of a diagnostic or screening procedure (and possible further investigations and tests in the context of screening), and perhaps the lack of familiarity affected expectations, which has been previously discussed with respect to minimising expectation mismatch with experience. And where there was a lack of familiarity with diagnostic procedures perhaps understanding the purpose of a procedure in response to symptoms may further contribute to alleviating anxiety. Understanding purpose may also contribute to relieving patient uncertainty with respect to a patient's confidence in a diagnostic procedure, which links with patients wanting to understand and improve their health (i.e. receive a diagnosis followed by the necessary treatment). This has been reported in studies where diagnostic procedures have been utilised to diagnose or rule out medical conditions and where patient uncertainty has been relieved following the procedures (Lapsley, 2013; Marton *et al.*, 1982; O'Connor *et al.*, 1994). Participants were willing to endure uncomfortable diagnostic procedures if they were to be of benefit, highlighting the influence of understanding and improving health in comparison to sensations.

Both sets of factors provide a constructive understanding of attitudes, and a detailed comparison of attitudes in the context of screening and diagnosis. They provide a thorough and objective account of investigations and tests from the patient perspective, contributing to research that is often based on patient experiences, which is subjective and retrospective. The established factors also inspired a concept to design information based on factors. The factors based approach (Figure 3.12) consists of including and organising information based on factors, which could also contribute to patient information guidelines (i.e. provide guidance for content and content structure of patient information). The factors based approach is theory led and has taken inspiration from Ajzen's (2005, p. 126, see pages 25-26

for recap) theory of planned behaviour. This theory led approach could be one that satisfies Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. There are currently no specific guidelines for information designers to follow when designing patient information for when patients have options of or require investigations or tests, and therefore guidance in the form of patient information guidelines may be a useful tool. A practical guide was considered a useful tool by the majority of healthcare information producers who took part in a recent survey by the Patient Information Forum (2013b, p. 10). The factors based approach to the design of patient information was examined in the last two studies, which are discussed and reflected on in the third research question.

### **8.2.2 What are patient informational needs and preferences when encountering diagnostic and screening procedures?**

Information was valuable in the first study to inform participants about diagnostic procedures and patients' physical involvement with them. Information was of particular importance when participants were unfamiliar with the procedures and if the procedures were invasive. It is commented in a cancer patient survey that young patients need to receive information that is given in a fashion that recognises their lack of hospital experiences (Department of Health, 2010, p. 11). This seems fitting of the participants from the first study as the majority of them were of a young demographic and lacked healthcare experiences that an older population is more likely to have.

Information about suspected medical condition(s) being investigated or tested, as well as information about possible clinical pathways in the event of a positive (i.e. medical condition is diagnosed), negative (i.e. medical condition is ruled out) or inconclusive (i.e. uncertain – neither positive nor negative) outcome or result, was also of value. Participants commented for information about possible clinical pathways that this would aid preparation for possible diagnosis, prognosis and clinical pathway. This relates to minimising expectation mismatch with experience, which is discussed in the first research question and may enable patients to prepare emotionally and psychologically. Preparation may also involve talking to family or

friend about symptoms and diagnostic procedures, which participants would highly likely do, although to a slightly lesser extent for gastroenterological based symptoms in comparison to musculoskeletal based symptoms.

Participants from the first study would prefer to receive a diagnostic procedure outcome or result, whether positive, negative or inconclusive, during or immediately after diagnostic procedures. This corresponds with the understanding and improving health factor discussed in the first research question, which also mentions the relieving of uncertainty through the utilisation of diagnostic procedures to diagnose or rule out medical conditions. A detailed amount of information when receiving a diagnostic procedure outcome or result was also of importance to participants. This would involve receiving explanations about outcomes and results, and any images and/or numerical data that might be produced from a procedure to be provided, as well as information on what happens next. The very high preference for receiving a diagnostic procedure outcome or result during or immediately after a procedure, as well as the preference for detailed information, fits the three characteristics Elder and Barney (2012) described that were important to patients for the notification of a hypothetical test result for a mildly elevated lipid profile. These were: 1) timeliness; 2) desire for clinician interpersonal connection (which would occur during or immediately after a procedure); and 3) desire for a hard copy (i.e. written result).

For such a detailed outcome or result, as well giving patients the ability to ask questions, notification from a specialist clinician or GP, either face to face or by phone call, was participants' preferred medium. Preferences for new media such as online access to personal healthcare record and email were low, and this was unexpected considering the young demographic of the sample. It was also mentioned by Jo Harcombe from the UK National Screening Committee (UK Screening Portal, 2013) that this was quite an interesting and surprising finding. Ensuring patients receive detailed outcomes and results and that they have the ability to ask questions may be an effective strategy for ensuring the success of new media. This should be taken into account by NHS England (2013, p. 6) who aim for all patients to be able to access their GP records online by 2015 and the Department of Health's Digital first initiative (Innovation Health & Wealth, 2012), which aims



to reduce unnecessary face to face contact between healthcare professionals and patients by incorporating technology.

Information was valuable in the second study to inform participants about a medical condition, screening for the medical condition, the screening procedure, the benefits of being screened, and the risks of being or not being screened. Information about what to expect if diagnosed with the condition was not required in the information resource, a decision aid (also known as decision support technology), when deciding whether to be or not to be screened, which was considered too much, too detailed and not relevant with the decision to be or not be screened. A similar observation was found in a study conducted by Smith *et al.* (2013a) where participants who examined a booklet that informs about colorectal cancer screening in the United Kingdom found the booklet too long and complex. Both of these information resources were developed with a top-down approach since they were produced following one or more design iterations from a clinician, other healthcare professional and researcher perspective. Another example of a top-down approach is the continued inclusion of a decision-making scale in a decision support technology to assist men considering prostate cancer screening with the prostate specific antigen test (Evans *et al.* (2007). The scale was not particularly used in field testing, yet was kept in case it would be of use in the future. Perhaps if there was patient involvement right from the start of patient information development, as advised by Duman (2003, pp. 33-38), and with continued focus on users, as advised by the U.S. Department of Health and Human Services (2006, p. 4), the resources may have better met the needs and preferences of participants. The alternative when a top-down approach is used is that the user is consulted following a design phase and therefore their input is constrained and limited by an information resource presented to them.

There were suggestions in the second study, media permitting, that information could be made accessible to patients who were interested and/or preferred to be further informed. This is somewhat similar to tailoring information, which patients in a study conducted by Jenkinson *et al.* (1998) reported would be beneficial with respect to a decision support technology that assists patients facing prostate cancer treatment decisions and the tailoring of information in the support technology to

meet specific informational needs (i.e. information to reflect prognosis of patient – from healthy to poor). Features of the Internet could help achieve access to further information (e.g. via hyperlinks), which was regarded positively as a medium for information provision in the second study, although drawbacks were acknowledged. Suitable quantitative evidence and images and videos were generally regarded positively to improve knowledge and understanding of screening. This has been observed in studies conducted by Frosch *et al.* (2003) where an Internet and a video based decision aid educated men about issues relevant to prostate cancer screening with the prostate specific antigen test, and by Gimeno-García *et al.* (2009) where a colorectal cancer educational video educated members of the public about the condition and available screening for it.

Informational needs and preferences for diagnostic and screening procedures tended to reflect factors affecting attitudes discussed in the first research question. Physical involvement was the most influential factor affecting attitudes towards diagnostic procedures and information provision about physical involvement was particularly valuable. Benefits and risks were the most influential factors affecting attitudes towards screening and information provision about benefits and risks was particularly valuable. The value of information is reflected in criteria developed by the NHS National Quality Board that are deemed crucial to achieving quality patient experiences (Department of Health, 2012a). This includes facilitating autonomy, self-care and health promotion, and supporting patient care transition and continuity. Respecting patient centred values, preferences and expressed needs is also included in the criteria, and information can be especially valuable for this when patients have healthcare options and choices since information is the pivot upon which all decisions are made, whether they are good, bad or neutral. Insights into the value of information from the first two studies were incorporated into the consideration of factors for designing patient information. The factors based approach to the design of patient information was examined in the last two studies, which are discussed and reflected on in the third research question.

### **8.2.3 How does patient information based on factors affecting patients' attitudes towards diagnostic and screening procedures affect the value of the information?**

The last two studies examined the content, design and structure of patient information for an invasive investigation. This involved examining and comparing two patient information resources that had almost the same content and design, but which varied in the structure of information. One of the information resources presented information based on the factors discussed in the first research question, and the other presented information based on a standardised presentation of information for the investigation. This involved researching patient information resources that were currently available for the investigation and synthesising the way information was structured within these into a homogeneous version. Four information resources were researched (Bupa, 2013 (a 2011 version was used in the studies); Knott, 2012; Macmillan Cancer Support, 2010; NHS Bowel Cancer Screening Programme, 2006) and all of them seemed to have been developed with top-down approaches. Top-down approaches are discussed in the second research question.

Quantitative findings indicated the patient information resource based on factors performed no better nor worse compared to the standardised patient information resource. However, what is not known is how the information resource based on the factors would have performed in comparison to the four patient information resources individually that the standardised resource was developed from. One might assume it would have performed better, but this does not change the fact that both the standardised resource and the resource based on factors performed as equally as well. What provided more interesting findings was thematic analysis of qualitative data. Themes from one thematic analysis (indirect comparison using a between subjects study design) suggests the information quality and quantity in the resource based on factors was adequate but contrastingly further information was required, and that the structure was well structured but that this could be improved. And themes from another thematic analysis (direct comparison using focus groups) dictate the resource based on the factors was favoured overall due to better structure and better navigational properties.

Garner *et al.* (2011) propose that communicative effectiveness in patient information leaflets cannot be ascertained by textual analysis alone but by the notion of 'usability'. The structure and navigational properties of the patient information resource based on factors represent this notion, and they also seem to have made the information resource based on factors easier to understand compared to the standardised resource, which could contribute to quality patient experiences through appropriately informing, supporting and guiding patients. These findings also demonstrate the potential of the factors based approach to the design of patient information, which, as mentioned the first research question, is theory led and has taken inspiration from Ajzen's (2005, p. 126, see pages 25-26 for recap) theory of planned behaviour.

Glenton (2002) comments that qualitative methods are particularly appropriate in the development of patient centred healthcare information and that it is important to channel evidence based healthcare information within a patient centred approach. The factors based approach to the design of patient information attempts to provide such a channelling since the factors are qualitatively sourced and developed, and the factors based approach is about organising information (evidence based healthcare information) based on factors. This 'channelling' has been further developed with the development of patient information guidelines based on the factors based approach, which also incorporate findings from the examination and comparison of the standardised patient information resource and the information resource based on factors. The guidelines aim to provide guidance for content and content structure of patient information, and to assist information designers and others involved in patient information for when patients have options of or require investigations or tests. The guidelines, as mentioned in the first research question, may satisfy Elwyn *et al.* (2010b) who see a role for existing theories and models in the design of decision support components that address cognitive tasks and provide guidance. And as mentioned in the first research question, there are currently no specific guidelines for information designers to follow when designing patient information for when patients have options of or require investigations or tests, and these guidelines aim to provide such specific guidance.

The patient information guidelines are provided in Chapter 7 and combine substantial data from four studies where a factors based approach to the design of patient information was conceptualised, developed and examined. The factors based approach constitutes a user centred approach to the design, development and implementation of patient information, and is a novel concept. Further research of the factors based approach and the guidelines is recommended, and since the guidelines are considered a draft, further development and refinement of them is encouraged. The next section outlines two recommendations for further research with respect to the factors based approach and the guidelines.

## 8.3 Recommended further research

### 8.3.1 Examining the effects of the patient information guidelines in patient decision-making

As mentioned in the second research question in the previous section, facilitating autonomy and self-care and health promotion, and respecting patient centred values, preferences and expressed needs is included in criteria developed by the NHS National Quality Board that are deemed crucial to achieving quality patient experiences (Department of Health, 2012a). Information can be valuable to achieving this and especially valuable for when patients have healthcare options and choices since information is the pivot upon which all decisions are made, whether they are good, bad or neutral. Decision aids are often used by patients when they have healthcare options and choices, and they are used to encourage and facilitate informed shared decision-making in which the patient is informed of their options, the options are discussed with the relevant clinician or other healthcare professional, and the decision that is made is one that is satisfactory to the patient's values and preferences (O'Connor *et al.*, 1999a; O'Connor *et al.*, 2004; O'Connor *et al.*, 2009; Wennberg *et al.*, 2002).

A relationship with an NHS screening programme is mentioned in Chapter 1 with respect to the original conceptualisation of the research questions and their change in focus due to the screening programme's changing circumstances (see pages 6-8 for recap). The plan was to work with the programme to evaluate an online decision aid that they were in the process of developing, and in which study designs were

being drafted and developed for the thesis. Tools available to assess patient information resources; measure information preferences, decision-making preferences and decision-making processes; and satisfaction with information and decisions were considered in the drafting of study designs. These tools are described in Appendix 18 and of which five tools or their adaptations were used in the questionnaire that was constructed for the third study, which is reported in Chapter 5.

An ideal study would be to work with an NHS screening programme and to compare two decision aids. One of the decision aids would be the existing decision aid the screening programme used and the other would be developed using the patient information guidelines. It would also be ideal if the decision aids were online since new media present many opportunities and challenges for information provision in healthcare, as alluded to in the second research question in the previous section. A mixed study design would be recommended to collect quantitative and qualitative data. It is recommended a questionnaire be constructed to collect quantitative data to measure acceptability of information and decision-making facilitation, and that it should be used in a between-subjects study design. Decision-making facilitation could take account of initial screening decision and satisfaction with decision after a period of time. The following tools from Appendix 18 are suggested for consideration for constructing a questionnaire to collect quantitative data:

- Acceptability
- Confidence to Decide about Treatment Scale
- Decisional Conflict Scale
- Decisional Regret Scale
- Measures of Decision/Choice Predisposition
- Preparation for Decision Making Scale
- Satisfaction with Decision
- Satisfaction with Decision Made Questionnaire
- Satisfaction with Decision Making Process Questionnaire
- Values

(Barry *et al.*, 1997; Bernstein *et al.*, 1998; Davison *et al.*, 1999; Dolan and Frisina, 2002; Goel *et al.*, 2001; Graham and O'Connor, 2010; Kryworuchko *et al.*, 2008; McBride *et al.*, 2002; Morgan *et al.*, 2000; O'Connor, 1995; O'Connor, 2003a; O'Connor, 2003b; O'Connor, 2004b; O'Connor, 2010; O'Connor and Cranney, 2002; O'Connor *et al.*, 1998a; O'Connor *et al.*, 1998b; O'Connor *et al.*, 1999b)

Eye tracking could be used, if the decision aids were online, to track where participants were looking on the decision aids. A within-subjects study design could be used for this aspect of data collection and eye tracking would produce data that would show frequencies and durations of participants' views on the decision aids, which may provide some interesting findings. This could then be followed by interviews with participants to obtain feedback and capture any issues with and suggestions for improvements to the decision aids. The use of eye tracking and interviews may better explore the notion of 'usability' as proposed by Garner *et al.* (2011) with respect to communicative effectiveness.

### **8.3.2 Examining the efficacy of the patient information guidelines**

To further develop and refine the patient information guidelines, their efficacy should be examined by information designers and others involved in patient information for when patients have options of or require investigations or tests. This could be a relatively simple study by providing the guidelines to information designers and others involved in patient information who about to start developing a patient information resource. Qualitative data could be collected through interviews, focus groups and/or feedback forms to understand how the guidelines assisted the development of the information resource and overall satisfaction with the guidelines. An aim of the data collected should be to improve the guidelines and so this should be considered in the devising of questions.

Alternatively or in addition, a more expansive study could be conducted to compare two groups of information designers who are given the same brief to develop a patient information resource for a particularly investigation or test. The investigation or test could be for a screening or diagnostic context, and one group of information designers would use their existing protocol for developing patient

information and the other would use the patient information guidelines. A questionnaire could be devised to collect quantitative data about the development of the information resource and the efficacy of the guidelines, including the time and cost it took to develop the resource. The questionnaire could also contain open-ended questions to acquire qualitative data, which may provide insights not obtained via closed questions. The two resources, once developed, could be presented to patients for evaluation and comparison. This evaluation and comparison may be better conducted using a within-subjects study design so direct comparison of the resources can be made, and data can imply strengths and weaknesses of the resources. Patients could read through both resources and then complete a questionnaire to provide quantitative and qualitative data. The tools listed in the previous research recommendation could be considered in the construction of the questionnaire.

The two recommendations for further research aim to further examine the factors based approach to the design of patient information through examining the patient information guidelines. The findings of the factors based approach from the thesis are not conclusive but demonstrate its potential, and this makes a valid and valuable contribution to knowledge. It is hoped the research recommendations can acquire further data to substantiate the factors based approach, which could then be considered by healthcare providers if findings demonstrate it can make a worthwhile contribution to healthcare and patient experiences. The next section provides a concluding statement to the thesis, which takes account of the user centred approach of the thesis that aimed to contribute to quality patient experiences.

## **8.4 Concluding statement**

The literature review took a user centred approach to the patient journey with the focus being on asymptomatic patients (i.e. patients presenting no symptoms) considering screening and symptomatic patients (i.e. patients presenting symptoms) requiring diagnosis, which involved reviewing information provision and the effects it has on the patient experience. Information was found to be vital for patients to make informed decisions when they have healthcare options and



choices, to generate realistic expectations and improve their experiences of investigations and tests, and to understand their own health and act accordingly in response to investigation outcomes and test results. However, current methods used in the design and development of patient information are often top-down, and what is not known from this is whether information presented to patients is fitting of what they require and that the presentation of this information fits within their cognitive processes. Engaging with patients in the design, development and evaluation of patient information, as well as considering their preferred media for the implementation of information, may better meet their needs and preferences. The thesis therefore aimed to develop a user centred approach to the design, development and implementation of patient information that contributes to quality patient experiences.

Two studies were conducted that examined attitudes to investigations and tests and informational needs and preferences. The first study inspired a user centred design concept for patient information, which involved designing information based on factors affecting attitudes. The concept, termed the factors based approach to the design of patient information, is theoretical and was developed in the second study and examined in two further studies. Findings demonstrated the potential of the factors based approach, which was found to have features that were important for patient information usability and this seemed to make information easier to understand. The potential of the factors based approach led to the development of patient information guidelines, and it is hoped the guidelines assist information designers and others involved in patient information. The guidelines also aim to contribute to quality patient experiences through better meeting patient informational needs and preferences. The thesis has made a valid and valuable contribution to knowledge through the user centred design concept for patient information, and it is hoped the recommendations for further research can acquire further data to substantiate the concept to better understand its potential.

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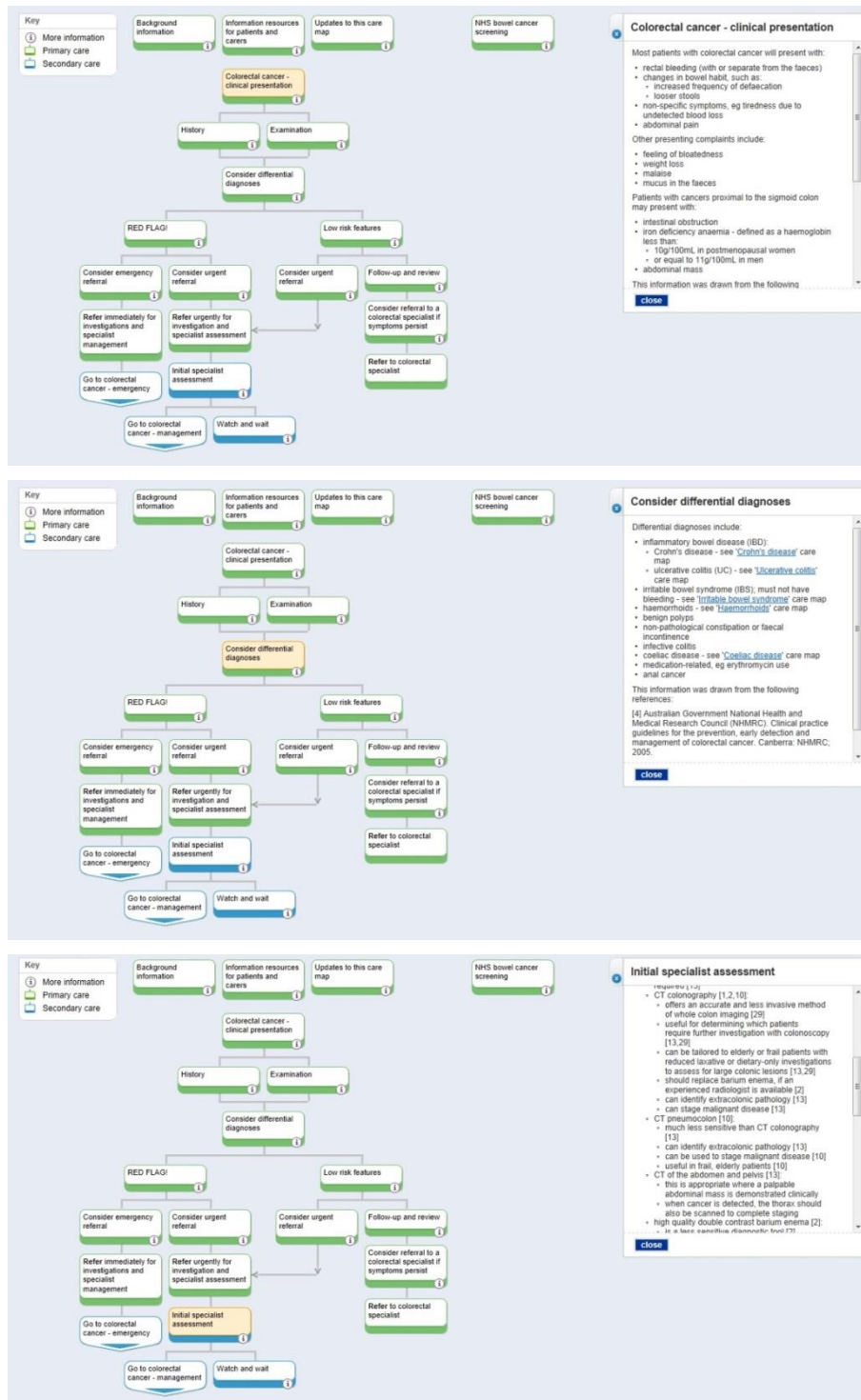
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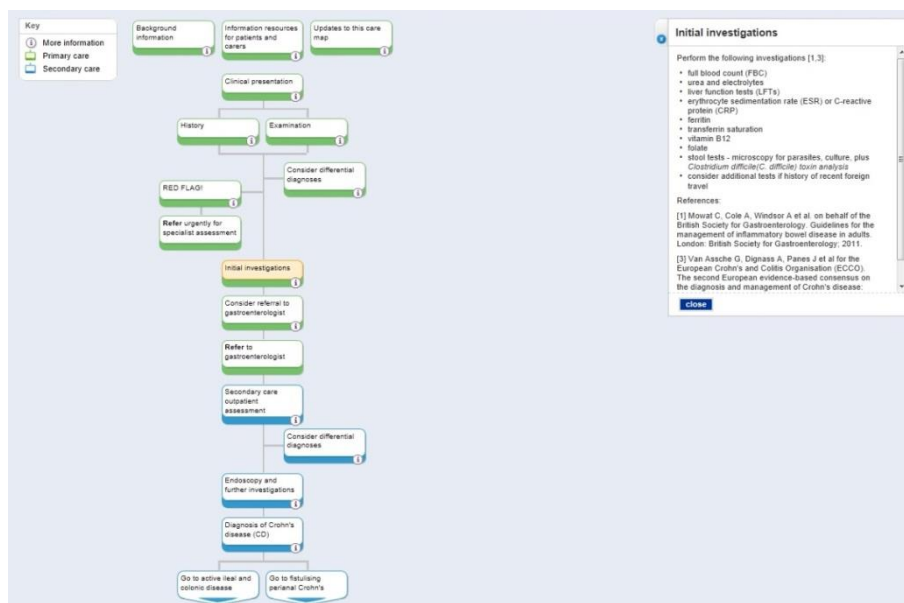
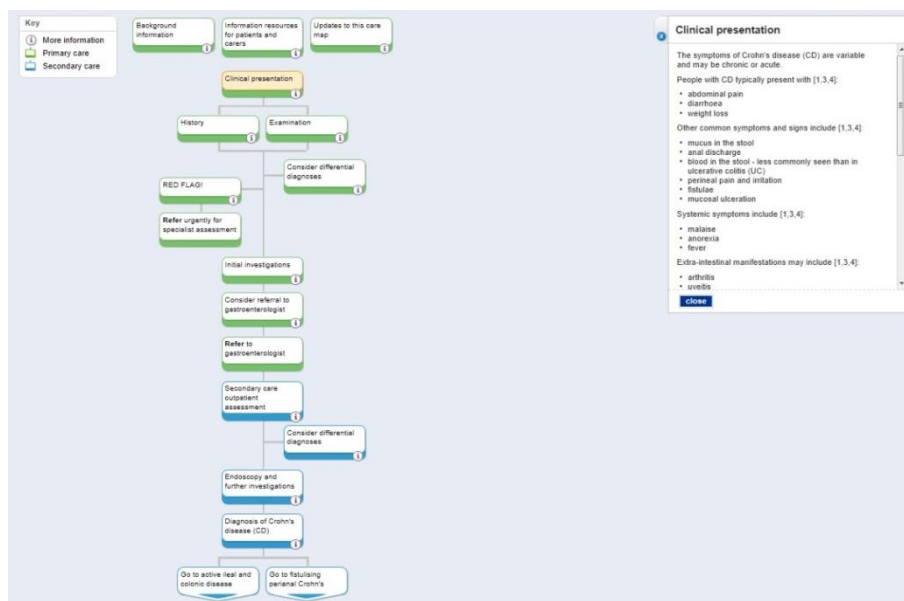
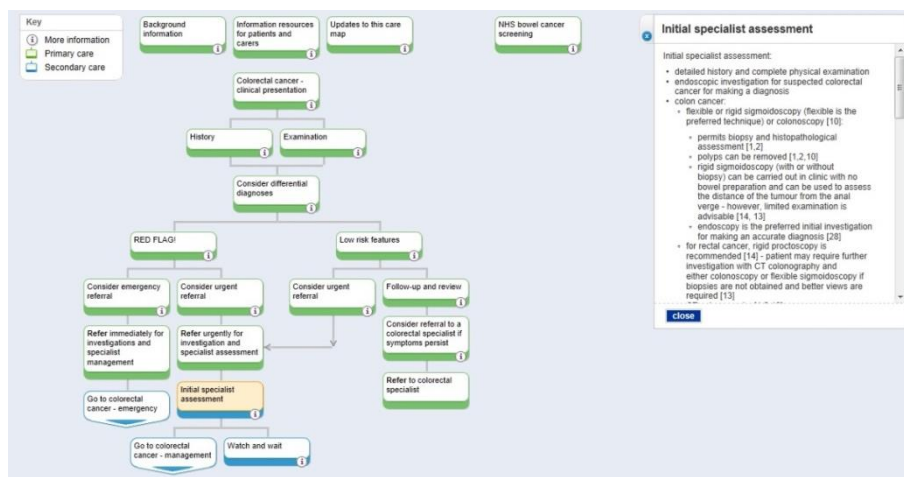
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# Appendices

## Appendix 1 Clinical pathways used to design and develop vignettes for gastroenterological symptoms (Map of Medicine, 2013)





## Appendix 2 Vignette for blood test to further investigate coronary symptoms

Vignette Code: Aa

You are presented with a vignette about a patient who is experiencing a number of symptoms and has a test to further understand the reason for their symptoms. Imagine that you are that patient, experiencing those symptoms and that you are having a test to further understand the reason for your symptoms.

Read through the vignette and then complete the questionnaire. You may refer back to the vignette when completing the questionnaire.

If you are unsure as to what to do or if you require any assistance at any time during reading the vignette and completing the questionnaire then please ask.

Your participation is greatly appreciated and your views are extremely important and valued.

Vignette:

You have been feeling unwell for a few weeks. Initially you were just feeling tired and didn't think too much about it. But you then began to notice that you were having irregular heartbeats from time to time. And in the last week you've been getting breathless climbing stairs when normally you would have been able to do such a task with ease. With these symptoms being a cause for concern you have made an appointment to see your GP.


On seeing your GP and reporting the symptoms you have experienced your GP asks whether you have had any chest pains. You recall that in the last few days you have felt some discomfort in your chest but you thought that it was probably just heartburn. Having taken account of your symptoms, family history (where there have been no similar cases within your family to report of) and having also carried out a physical examination your GP decides to refer you to a specialist clinician for further investigations.

On seeing the specialist clinician and reporting your symptoms as you had to your GP the specialist clinician decides that a test is required to further understand the reason for your symptoms.

The specialist clinician will be using a blood test to further understand the reason for your symptoms. Though the specialist clinician has decided to use a blood test they mention that no test is 100% accurate and that it is part of a process of elimination.

The blood test is being taken from your vein near the inner part of your elbow. The blood will be drawn through a needle into a small bottle. The blood will be sent to be analysed.

An image of a blood test is below.



You may now complete the questionnaire.

## Appendix 3 Vignette for imaging procedure to further investigate gastroenterological symptoms

Vignette Code: Bb

You are presented with a vignette about a patient who is experiencing a number of symptoms and has a test to further understand the reason for their symptoms. Imagine that you are that patient, experiencing those symptoms and that you are having a test to further understand the reason for your symptoms.

Read through the vignette and then complete the questionnaire. You may refer back to the vignette when completing the questionnaire.

If you are unsure as to what to do or if you require any assistance at any time during reading the vignette and completing the questionnaire then please ask.

Your participation is greatly appreciated and your views are extremely important and valued.

Vignette:

For a few weeks you have not been feeling well. Your symptoms began with feeling tired when normally you're full of energy. You also noticed that your stools /faeces were looser and you attributed this to bad food initially. A week ago you noticed that you had lost some weight when looking at your reflection in the mirror and on weighing yourself using scales this was confirmed. You book an appointment with your GP because of the accumulated symptoms being a cause for concern.


When you visit your GP you tell them about the accumulated symptoms you have been experiencing. Your GP asks whether any of your family have experienced similar symptoms, which they haven't. Your GP then carries out a physical examination, which includes examining your abdomen area by applying pressure at different points with their hands. This causes you to feel some discomfort. Your GP says that further investigations need to be carried out and so has referred you to a specialist clinician.

On seeing the specialist clinician and reporting your symptoms as you had to your GP the specialist clinician decides that a test is required to further understand the reason for your symptoms.

The specialist clinician will be using a CT scan to further understand the reason for your symptoms. Though the specialist clinician has decided to use a CT scan they mention that no test is 100% accurate and that it is part of a process of elimination.

The CT scan is a scan that takes a series of X-ray images and uses a computer to put them together. The CT scan will be of your abdomen area. The scan will probably be taken with you lying on your back but it may also be taken with you on your side or lying on your front. The person taking the images will set you and the machine into the right position before leaving whilst images are taken. You will be exposed to radiation during the CT scan but there are no harmful side-effects. The images taken from the CT scan will be processed and sent to be analysed.

An image of a CT scan is below.



You may now complete the questionnaire.

## Appendix 4 Vignette for invasive procedure to further investigate musculoskeletal symptoms

Vignette Code: Cy

You are presented with a vignette about a patient who is experiencing a number of symptoms and has a test to further understand the reason for their symptoms. Imagine that you are that patient, experiencing those symptoms and that you are having a test to further understand the reason for your symptoms.

Read through the vignette and then complete the questionnaire. You may refer back to the vignette when completing the questionnaire.

If you are unsure as to what to do or if you require any assistance at any time during reading the vignette and completing the questionnaire then please ask.

Your participation is greatly appreciated and your views are extremely important and valued.

**Vignette:**

A few weeks ago you noticed that your knee had swollen up and you assumed that you must have banged it on something but you can't recall doing such a thing. You then noticed that your knee was getting stiffer and that you had less of a range of movement with it. In the last week you have also noticed that you have been feeling more tired than normal. As you are concerned by your knee and feeling abnormally tired you make an appointment to see your GP.

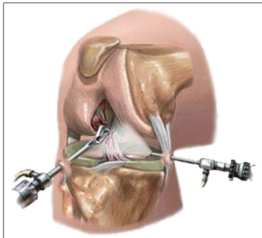
On seeing your GP and telling them about your symptoms your GP performs a physical examination on your knee. You feel some discomfort during the examination. Your GP then asks about your family history and whether a family member has experienced similar symptoms, which they haven't. Taking account of your symptoms your GP decides to refer you to a specialist clinician for further investigations.

On seeing the specialist clinician and reporting your symptoms as you had to your GP the specialist clinician decides that a test is required to further understand the reason for your symptoms.

The specialist clinician will be using arthroscopy to further understand the reason for your symptoms. Though the specialist clinician has decided to use arthroscopy they mention that no test is 100% accurate and that it is part of a process of elimination.

The arthroscopy will require a tube with a light and camera at its end called an arthroscope to be inserted into your knee. An examination probe will also be inserted into your knee to assist the arthroscope. Any damaged areas or unwanted tissue will be removed during the procedure.

An image of an arthroscopy is below.

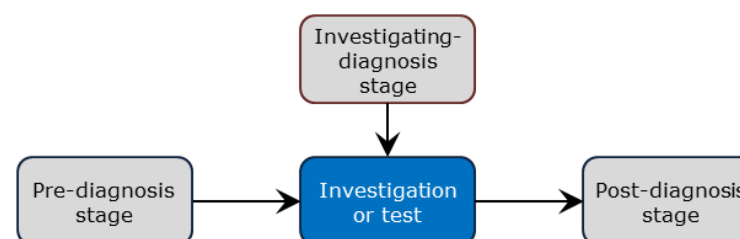


You may now complete the questionnaire.

## Appendix 5 Stages of information provision in the patient journey

As described in the literature review, information is vital for patients to make informed decisions when they have healthcare options and choices, to generate realistic expectations and improve their experiences of investigations and tests, and to understand their own health and act accordingly in response to investigation outcomes and test results. This distinguishes three stages of information provision, which are described as follows and then graphically represented:

- 1) Pre-diagnosis stage – information to inform patients of what to expect from investigations and tests, and to aid decision-making.
- 2) Investigating-diagnosis stage – information to prepare patients before and support them during investigations and tests.
- 3) Post-diagnosis stage – information to notify patients of investigation outcomes and test results.



Stages of information provision in the patient journey have been reported in the following conference paper: *Information provision and decision aids for diagnosis in clinical pathways*. Details of this paper are provided in the Publications (see page iv).

## Appendix 6 Vignette combinations and sequences for distribution

This appendix demonstrates the coding of the vignettes in order to produce the combinations and the sequences for the distribution of the vignettes, which follow.

Coding:

Set of condition based symptoms		Type of diagnostic procedure	
Coronary (A)		Blood test ( $\alpha$ )	
Gastroenterological (B)		Imaging procedure ( $\beta$ )	
Musculoskeletal (C)		Invasive procedure ( $\gamma$ )	
	$\alpha$	$\beta$	$\gamma$
<b>A</b>	A $\alpha$	A $\beta$	A $\gamma$
<b>B</b>	B $\alpha$	B $\beta$	B $\gamma$
<b>C</b>	C $\alpha$	C $\beta$	C $\gamma$

*Note that the top right hand corner of the vignettes demonstrated in Appendices 2-4 provide vignette codes, and the first page of the questionnaire for the vignette study (Appendix 7) provides a space for vignette codes to be inserted in the top right hand corner.*

Combinations:

With participants receiving three vignettes but encountering each set of condition based symptoms and type of diagnostic procedure only once, six vignette combinations were produced.

Combination	Vignette		
1	A $\alpha$	B $\beta$	C $\gamma$
2	A $\beta$	B $\gamma$	C $\alpha$
3	A $\gamma$	B $\alpha$	C $\beta$
4	A $\alpha$	B $\gamma$	C $\beta$
5	A $\beta$	B $\alpha$	C $\gamma$
6	A $\gamma$	B $\beta$	C $\alpha$

*From the six combinations each vignette is encountered twice.*

Sequences:

For each vignette combination to be received once every six participants but in a different sequence, 36 sequences were produced.

Participant count (1-6)	Sequence count	Vignette combination		
1	1	A $\alpha$	B $\beta$	C $\gamma$
2	2	A $\beta$	B $\gamma$	C $\alpha$
3	3	A $\gamma$	B $\alpha$	C $\beta$
4	4	A $\alpha$	B $\gamma$	C $\beta$
5	5	A $\beta$	B $\alpha$	C $\gamma$
6	6	A $\gamma$	B $\beta$	C $\alpha$
1	7	A $\alpha$	C $\gamma$	B $\beta$
2	8	A $\beta$	C $\alpha$	B $\gamma$
3	9	A $\gamma$	C $\beta$	B $\alpha$
4	10	A $\alpha$	C $\beta$	B $\gamma$
5	11	A $\beta$	C $\gamma$	B $\alpha$
6	12	A $\gamma$	C $\alpha$	B $\beta$
1	13	B $\beta$	A $\alpha$	C $\gamma$
2	14	B $\gamma$	A $\beta$	C $\alpha$
3	15	B $\alpha$	A $\gamma$	C $\beta$
4	16	B $\gamma$	A $\alpha$	C $\beta$
5	17	B $\alpha$	A $\beta$	C $\gamma$
6	18	B $\beta$	A $\gamma$	C $\alpha$
1	19	B $\beta$	C $\gamma$	A $\alpha$
2	20	B $\gamma$	C $\alpha$	A $\beta$
3	21	B $\alpha$	C $\beta$	A $\gamma$
4	22	B $\gamma$	C $\beta$	A $\alpha$
5	23	B $\alpha$	C $\gamma$	A $\beta$
6	24	B $\beta$	C $\alpha$	A $\gamma$
1	25	C $\gamma$	A $\alpha$	B $\beta$
2	26	C $\alpha$	A $\beta$	B $\gamma$
3	27	C $\beta$	A $\gamma$	B $\alpha$
4	28	C $\beta$	A $\alpha$	B $\gamma$
5	29	C $\gamma$	A $\beta$	B $\alpha$
6	30	C $\alpha$	A $\gamma$	B $\beta$
1	31	C $\gamma$	B $\beta$	A $\alpha$
2	32	C $\alpha$	B $\gamma$	A $\beta$
3	33	C $\beta$	B $\alpha$	A $\gamma$
4	34	C $\beta$	B $\gamma$	A $\alpha$
5	35	C $\gamma$	B $\alpha$	A $\beta$
6	36	C $\alpha$	B $\beta$	A $\gamma$

*The order of the sequences for the distribution of the vignettes was varied to ensure that the same set of condition based symptoms were not repeatedly encountered in the same order (i.e. 'A' 'B' and 'C' were not repeatedly encountered in the first, second and third vignettes, respectively). And since 72 participants took part in the study, each sequence was encountered twice.*

## Appendix 7 Questionnaire for vignette study to measure the effects of the sets of condition based symptoms and types of diagnostic procedure

For researcher			
Vignette code		PP no.	
<p>The majority of questions will be answered using a rating scale. The rating scale will have two responses to the question at each end with seven boxes in between these responses. The responses will be the opposite of each other and you will rate your answer on the rating scale to where you think it belongs in correspondence with these responses by ticking the appropriate box. For example:</p> <p>How comfortable do you feel about visiting your GP?</p> <p style="text-align: center;">Extremely    1    2    3    4    5    6    7    Extremely uncomfortable    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   comfortable</p> <p>If you felt extremely comfortable you would tick box 7 but if you felt extremely uncomfortable you would tick box 1. However, if you felt that your answer belonged somewhere in-between these two responses then you would tick a box that you believe corresponds with how you feel.</p> <p>If you tick a box and wish to change it then simply put a line through the tick to make it an 'X' and then tick your preferred box.</p> <p>If you have any questions please ask for assistance.</p>			
<p>1) How satisfied are you with the information provided in the vignette about what would happen to you while you were having the test procedure?</p> <p style="text-align: center;">Extremely    1    2    3    4    5    6    7    Extremely dissatisfied    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   satisfied</p> <p>Can you explain what has influenced your level of satisfaction?</p> <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div>			
<p>2) Would you like information about what condition(s) are being tested for?</p> <p style="text-align: center;">No, definitely    1    2    3    4    5    6    7    Yes, not    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   definitely</p>			
<p>3) Would you like information about what will happen after the test in the event of your result being positive (a condition is diagnosed), negative (a condition is not diagnosed) or inconclusive (the test result is neither positive nor negative)?</p> <p style="text-align: center;">No, definitely    1    2    3    4    5    6    7    Yes, not    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   definitely</p> <p>Can you explain what has influenced your preference for information about possible test result outcomes?</p> <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div>			

<p>4) How accurate do you think the test is?</p> <p style="text-align: center;">Extremely small    1    2    3    4    5    6    7    Extremely high level of accuracy    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   level of accuracy</p> <p>Can you explain what has influenced your perception of test accuracy?</p> <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div>
<p>5) How confident are you that the test is appropriate to further understand the reason for your symptoms?</p> <p style="text-align: center;">Not at all    1    2    3    4    5    6    7    Extremely confident    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   confident</p> <p>Can you explain what has influenced your level of confidence?</p> <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div>
<p>6) How apprehensive would you be about having the test procedure?</p> <p style="text-align: center;">Not at all    1    2    3    4    5    6    7    Extremely apprehensive    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   apprehensive</p> <p>Can you explain what has influenced your level of apprehension?</p> <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div>
<p>7) How embarrassed would you be about having the test procedure?</p> <p style="text-align: center;">Not at all    1    2    3    4    5    6    7    Extremely embarrassed    <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>   embarrassed</p> <p>Can you explain what has influenced your level of embarrassment?</p> <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div>

8) How likely would you be to talk to a family member or friend about your symptoms?

Not at all likely 1 2 3 4 5 6 7 Extremely likely

9) How likely would you be to talk to a family member or friend about the test?

Not at all likely 1 2 3 4 5 6 7 Extremely likely

Can you explain what has influenced your level of likelihood in talking to a family member or friend about the test?

10) How likely would you be to proceed to have the test?

Not at all likely 1 2 3 4 5 6 7 Extremely likely

Can you explain what has influenced your level of likelihood in proceeding to have the test?

11) If possible, would you like to receive the result of your test during or immediately after the test if your result was positive (a condition is diagnosed)?

No, definitely not 1 2 3 4 5 6 7 Yes, definitely

12) If possible, would you like to receive the result of your test during or immediately after the test if your result was negative (a condition is not diagnosed)?

No, definitely not 1 2 3 4 5 6 7 Yes, definitely

13) If possible, would you like to receive the result of your test during or immediately after the test if your result was inconclusive (the test result is neither positive nor negative)?

No, definitely not 1 2 3 4 5 6 7 Yes, definitely

please turn over

14) The following are three options detailing the amount of information you may receive in your result. Please read through all three and then select (tick) your preferred option. Please be aware that the result could be positive (a condition is diagnosed), negative (a condition is not diagnosed) or inconclusive (the test result is neither positive nor negative).

Receive result and information on what happens next.	
Receive result with an explanation about it and what it means, and information on what happens next.	
Receive result with an explanation about it and what it means, including images and/or numerical data from the test that might be produced, and information on what happens next.	

15) You have been given thirteen methods for how you may receive your result. Rate the extent to which you find each method acceptable using the rating scale below. Please be aware that the result could be positive (a condition is diagnosed), negative (a condition is not diagnosed) or inconclusive (the test result is neither positive nor negative).

Not at all acceptable 1 2 3 4 5 6 7 Completely acceptable

Method	Level of acceptance						
	1	2	3	4	5	6	7
Call GP practice automated test result notification phone service							
Collect from GP practice reception							
Email							
Face to face with your GP							
Face to face with specialist clinician							
Interactive kiosk/touchscreen monitor at your GP practice (in privacy)							
Letter through the post							
Mobile phone application that will notify and allow you to access result							
Mobile phone text message							
Online access to your own personal healthcare record							
Phone call from GP							
Phone call from GP practice reception							
Phone call from specialist clinician							

Can you explain what has influenced your level of acceptance for the different methods of receiving a test result?

You have completed all questions in response to the vignette.

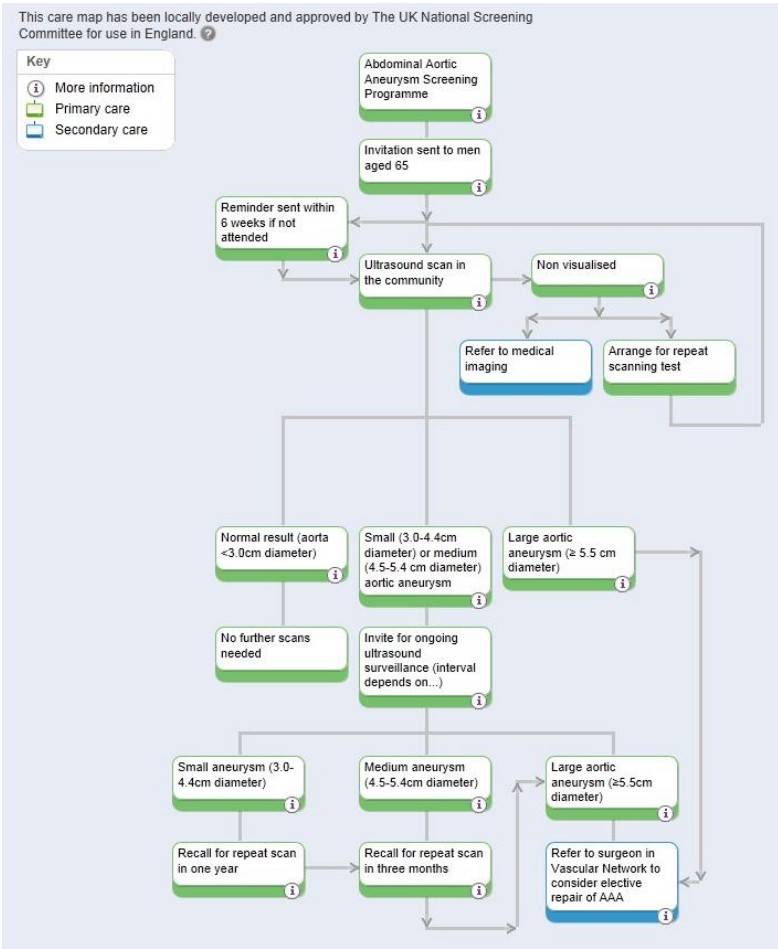
Thank-you for your participation.



**Appendix 8** Coding qualitative data using NVivo 9 (QSR International Pty Ltd., 2010) for different open-ended questions from questionnaire for vignette study

Nodes			
Name	Sources	References	
Q01 - satisfaction with information	9	258	
Complexity	4	8	
Duration	1	1	
Familiarity	7	25	
Fear	4	5	
Information provision	9	188	
Accuracy	3	4	
Alternative diagnostic procedure	5	8	
Comprehensive	9	81	
Blood test	3	29	
Coronary based symptoms	1	15	
Gastroenterological based symptoms	1	8	
Musculoskeletal based symptoms	1	6	
Imaging procedure	3	36	
Coronary based symptoms	1	10	
Gastroenterological based symptoms	1	11	
Musculoskeletal based symptoms	1	15	
Invasive procedure	3	16	
Coronary based symptoms	1	4	
Gastroenterological based symptoms	1	7	
Musculoskeletal based symptoms	1	5	
Require additional	9	79	
Uncertainty	5	9	
Understanding	5	7	
Physical involvement	5	9	
Risks and/or side-effects	5	15	
Sensation(s)	2	4	
Seriousness	1	1	
Trust	2	2	
Q03 - information about after diagnostic procedure	9	195	
Awareness	8	23	
Fear	1	1	
Inform and/or warn	3	5	
Information overload	4	4	
Information provision	5	6	
Physical involvement	1	2	
Preparation	9	111	
Blood test	3	33	
Coronary based symptoms	1	6	
Gastroenterological based symptoms	1	17	
Musculoskeletal based symptoms	1	10	
Imaging procedure	3	35	
Coronary based symptoms	1	11	
Gastroenterological based symptoms	1	11	
Musculoskeletal based symptoms	1	13	
Invasive procedure	3	39	
Coronary based symptoms	1	18	
Gastroenterological based symptoms	1	10	
Musculoskeletal based symptoms	1	11	

**Appendix 9** Abdominal aortic aneurysm screening clinical pathway (Map of Medicine, 2013)



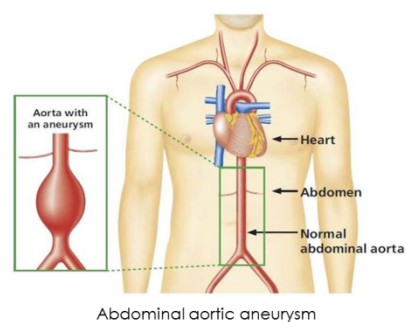
## Appendix 10 Handouts to inform about the stages of abdominal aortic aneurysm screening

### An introduction to abdominal aortic aneurysm screening

Abdominal aortic aneurysm screening is a screening programme run by the NHS that invites men aged 65 years to have their aortas screened.

The aorta runs from the heart and down through the chest and abdomen. As people age the wall of the aorta can become weak and swell causing an aneurysm. If the aneurysm is large then there is the possibility of it rupturing, which will more than likely result in death.

Men are more prone to this condition than women and the aim of the screening programme is to prevent this from happening.



### Screening procedure

The screening procedure to be used to screen for an abdominal aortic aneurysm is an ultrasound scan.



Ultrasound scan



Close-up of ultrasound probe

### Normal sized aorta

No further action is required.

### Small aneurysm

If a small aneurysm is found it means that the aneurysm will need surveillance with further ultrasound scans in order to check that it doesn't grow into a large aneurysm.

The regularity of such scans depends on the size of the aneurysm.

## Large aneurysm

If a large aneurysm is found there is the possibility of having one of two surgical interventions. However, before having either intervention further tests and procedures will be required in order to assess whether you are fit enough to have surgery. These normally include the following:



Blood test(s)



Electrocardiogram



Echocardiogram



Spirometry



CT scan

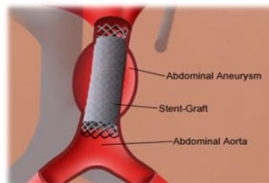


Chest X-ray

## Large aneurysm

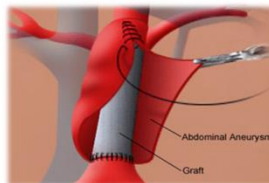
The two surgical interventions available to repair a large aneurysm are:

- 1) Endovascular repair



Endovascular repair is a 'keyhole' surgery technique where the aneurysm is repaired using a stent graft. This technique involves making two small cuts into the groins and guiding the stent graft into position using an X-ray.

- 2) Open surgery

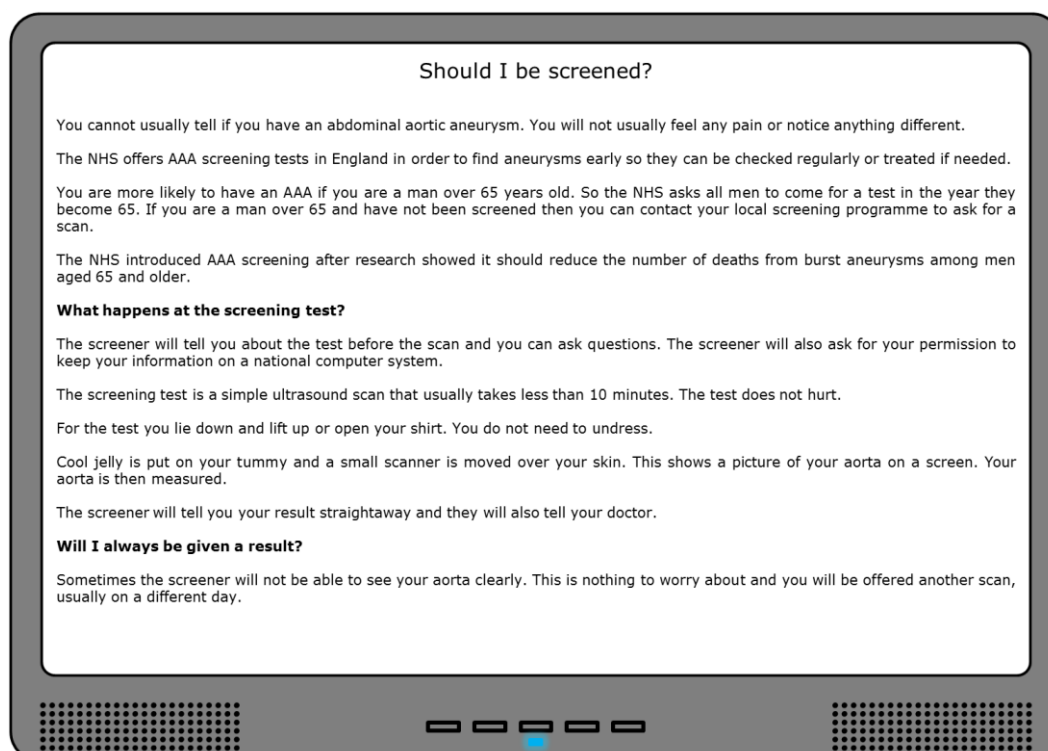
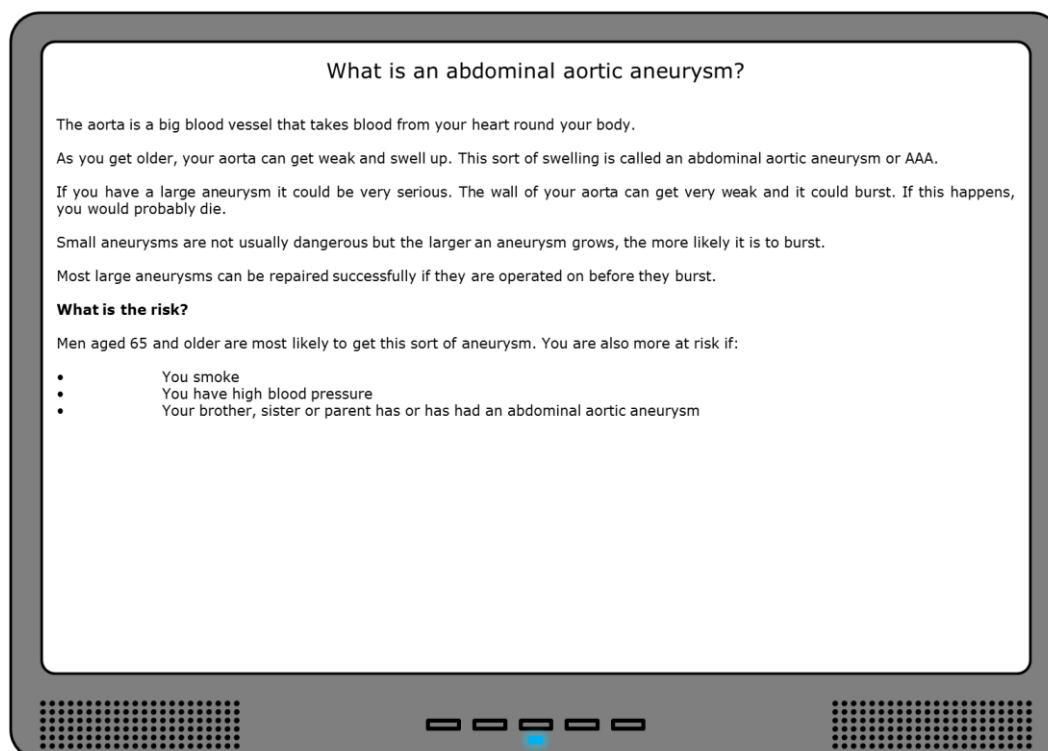


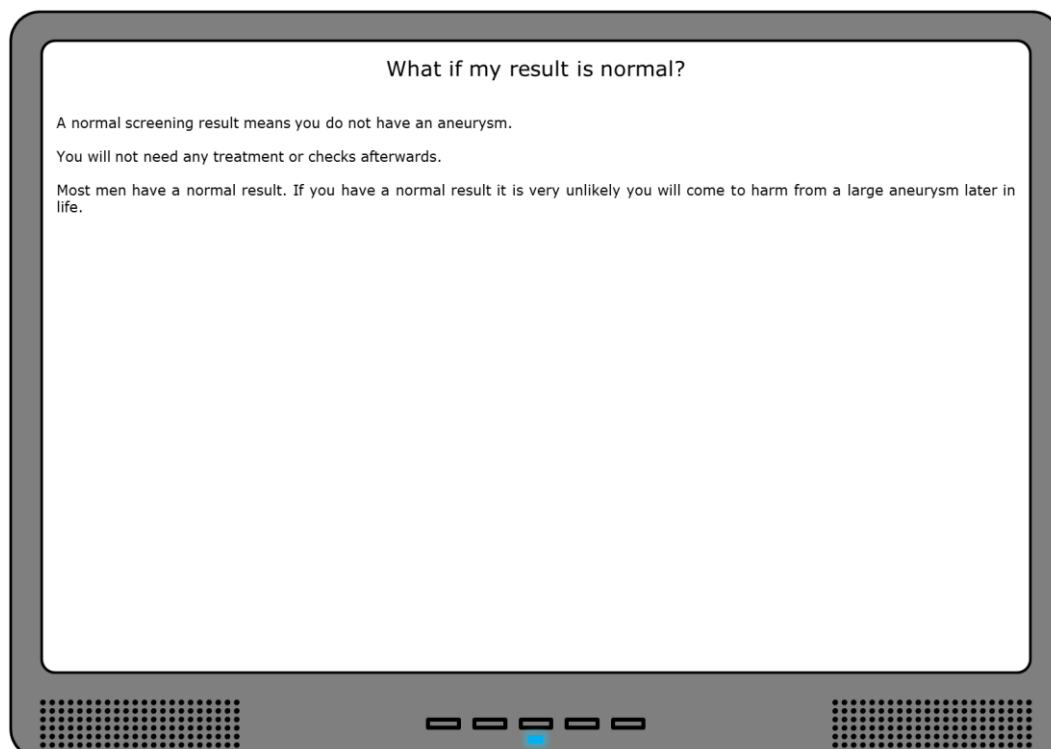
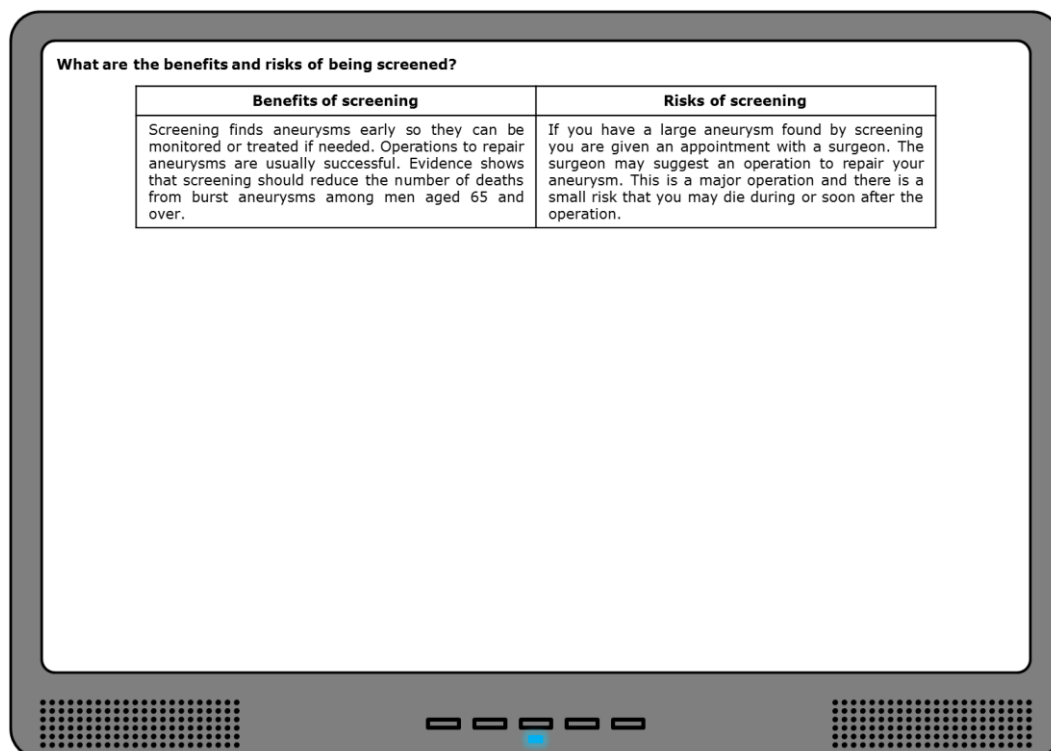
Open surgery involves accessing the aneurysm through cutting the stomach and replacing it with a graft. Occasionally a smaller cut may be needed in one or both of the groins.

Other option:  
watchful waiting

The surgical intervention performed will depend on the fitness of the man. If a man is not fit enough for either surgery then a surgical intervention will not be performed and the aneurysm will be checked-up on regularly. This is known as 'watchful waiting'. A man may also choose watchful waiting if they decide not to have a surgical intervention.

## Appendix 11 Booklet with the proposed content of a decision aid developed by the NHS Abdominal Aortic Aneurysm Screening Programme





What if my result shows I have a small aneurysm?

If you have a small aneurysm it means that your aorta is a bit wider than normal.

If you have a small aneurysm you will be invited to come back for regular tests and a nurse will give you advice on staying healthy.

The regular tests will check if your aneurysm is getting bigger. The tests will be every three months or once a year depending on how big your aneurysm is.

You will not usually need to come back if several tests in a row show that your small aneurysm is not getting bigger. This means it is unlikely to give you any problems.

What are the risks if I have a small aneurysm?

Size of aorta	Description	Risk of aneurysm bursting per year
3cm or less	No aneurysm	No real risk
3 - 5.5cm	Small aneurysm	About 1 in 100
5.5 – 7cm	Large aneurysm	About 15 in 100
over 7cm	Very large aneurysm	More than 25 in 100

**Can I do anything to stop an aneurysm getting bigger?**

If you have a small aneurysm, a nurse practitioner will give you advice on what you can do to help stop your aneurysm getting bigger. This will include eating healthy foods, regular exercise and not smoking.

Your own doctor will also give you pills or change medicines you take already. They may also check your blood pressure.

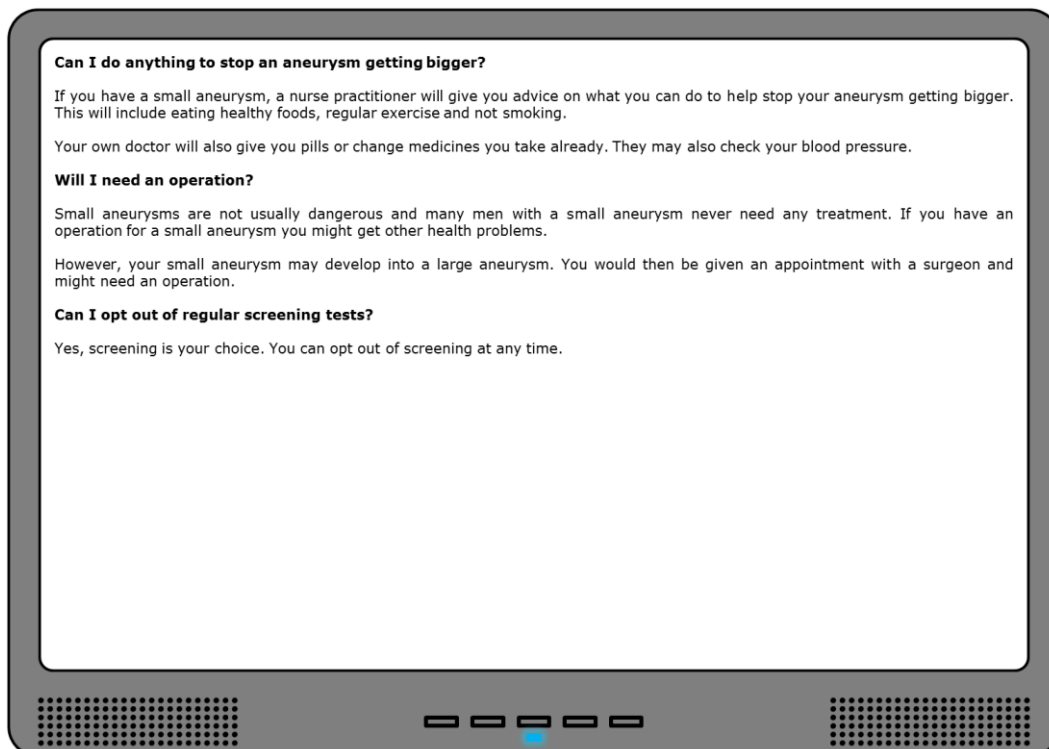
**Will I need an operation?**

Small aneurysms are not usually dangerous and many men with a small aneurysm never need any treatment. If you have an operation for a small aneurysm you might get other health problems.

However, your small aneurysm may develop into a large aneurysm. You would then be given an appointment with a surgeon and might need an operation.

**Can I opt out of regular screening tests?**

Yes, screening is your choice. You can opt out of screening at any time.



**What if my result shows I have a large aneurysm?**

A large aneurysm can be very serious. If the wall of your aorta gets very weak it could burst. If this happens, you would probably die.

If your screening test shows you have a large aneurysm then you will be given an appointment with a surgeon. Your GP will also be told.

The surgeon will explain what your treatment could be and tell you about any risks. They will also give you more tests and answer any questions you have.

**Are there any risks in having an operation?**

Operations to repair large aneurysms are usually successful. However, all operations have risks and there is a small chance you will die after an operation to repair a large aneurysm. If you have a large aneurysm, the surgeon will talk to you about treatment and the possible risks.

Not all aneurysms need treatment. But if some large aneurysms are not treated they could burst. If this happens you would probably die.

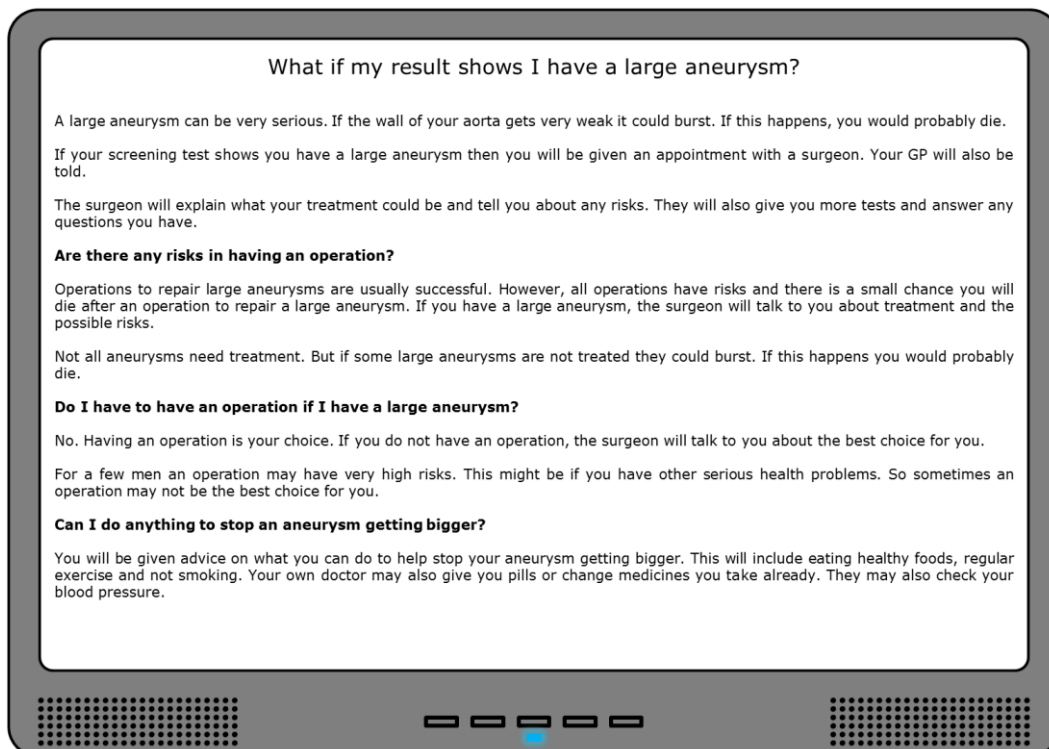
**Do I have to have an operation if I have a large aneurysm?**

No. Having an operation is your choice. If you do not have an operation, the surgeon will talk to you about the best choice for you.

For a few men an operation may have very high risks. This might be if you have other serious health problems. So sometimes an operation may not be the best choice for you.

**Can I do anything to stop an aneurysm getting bigger?**

You will be given advice on what you can do to help stop your aneurysm getting bigger. This will include eating healthy foods, regular exercise and not smoking. Your own doctor may also give you pills or change medicines you take already. They may also check your blood pressure.





#### What are the treatment options if I have a large aneurysm?

If you have a large aneurysm then your surgeon may offer you a choice of treatment options. However, not every patient or every aneurysm is suitable for all the options.

**Endovascular repair:** In this type of 'keyhole operation', the surgeon puts an artificial piece of artery, called a graft, inside your aneurysm. They do this by making small cuts in the top of your legs and then use X-rays to guide the graft into place.

**Open surgery:** In open surgery, the surgeon cuts open your stomach. They then replace your aneurysm with an artificial piece of artery, called a graft.

**Watchful waiting:** You may choose not to have an operation. For some men the risk of an operation may be too high because of other serious health problems. Watchful waiting means you do not have a planned operation but continue to have regular check-ups on your aneurysm. You may also be given medication.

Option	Benefits	Risks
Endovascular repair	The surgeon does not need to cut open your stomach. There is less risk of dying or of major complications than after open surgery.	The graft attachment is not as secure as with open surgery. You may need regular scans to check that the graft has not slipped. If the graft slips, you may need another operation.
Open surgery	Most open surgery repairs are successful and you usually make a full recovery. The graft usually works well for the rest of your life.	This is a major operation and there is a small chance you will die or suffer major complications during or shortly after the operation.
Watchful waiting	You may continue to live with a large aneurysm without it ever bursting.	If a large aneurysm bursts then you would probably die.

## Appendix 12 Interview schedule for interviews with men about abdominal aortic aneurysm screening

I will be presenting you with information about the different stages of screening for a vascular condition to find out what you think about it.

I will also be presenting you with some of the proposed content of a decision aid that will be provided to men to help them decide whether to be or not to be screened for the condition and asking you to highlight key information. This will involve underlining information that would make you more likely to be screened and putting a plus sign next to it, and underlining information that would make you less likely to be screened and putting a minus sign next to it. Information that doesn't make sense or is misleading may also be underlined and a question mark can be put next to this. You will then be asked to comment on the proposed content of the decision aid, with particular reference to the highlighted information.

Do you have any questions about this or do you have any other questions about the study and your participation?

Do you need any assistance reading?

If you don't understand some of the information or terminologies then please just ask for clarification.

For your information I have not had any involvement in the development of the decision aid so please feel free to comment on it in any way you like, whether it is what you think is good about it or what you think could be improved.

If you were considering screening for a health condition, what would be important to you when making a decision on whether to be or not to be screened?

What do you know about abdominal aortic aneurysm screening?

*If answer suggests some knowledge about AAA screening*

And how do you feel about it?

### An introduction to abdominal aortic aneurysm screening

Having been given information about what an abdominal aortic aneurysm is and the purpose of screening for the condition; how does this make you feel if you were to be invited for abdominal aortic aneurysm screening?

A decision aid is being developed that will be accessed and used through the Internet. What are your thoughts about accessing such a resource through the Internet and using it online?

**Decision aid – What is an abdominal aortic aneurysm?**

What are your thoughts about the explanation of what an abdominal aortic aneurysm is?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

### Screening procedure

How do you feel if you were to be screened for an abdominal aortic aneurysm using an ultrasound scan?

What are your thoughts about the accuracy of an ultrasound scan for abdominal aortic aneurysm screening and for other scanning purposes?

Would the procedure cause any apprehension or embarrassment?

The image demonstrating the use of an ultrasound scan to screen for an abdominal aortic aneurysm shows that the man is in a position where he is unable to view the image of the scan on the scanning machine's display screen. If you were being screened would you like to view this image?

### Decision aid – Should I be screened? (Page 1)

Is the information included in this section of the decision aid satisfactory in explaining the purpose of abdominal aortic aneurysm screening and the screening procedure itself?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

### Decision aid – Should I be screened? (Page 2)

The following information about the benefits and risks of being screened may also be included in this section of the decision aid; what are your thoughts about this information and how does it affect you and your attitude towards abdominal aortic aneurysm screening?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

How important to you is it that information about benefits and risks are included in a decision aid, whether it is for abdominal aortic aneurysm screening, a different screening condition, or possibly diagnostic or treatment options?

### Normal sized aorta

Obviously this is great news for men who are screened and what one would hope for.

---

#### Decision aid – What if my result is normal?

Do you have any comments about this section of the decision aid or is there anything that could improve it?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

---

### Small aneurysm

How does this information about a small aneurysm make you feel about abdominal aortic aneurysm screening?

In the context of a decision aid, is information about the regularity of further ultrasound scans important to you?

---

#### Decision aid – What if my result shows I have a small aneurysm? (Page 1)

Is the information included in this section of the decision aid satisfactory in explaining what happens if a small aneurysm is found?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

#### Decision aid – What if my result shows I have a small aneurysm? (Page 2)

This table may be included in this section of the decision aid about the risks of an aneurysm bursting; what are your thoughts about the table and how does it affect you and your attitude towards abdominal aortic aneurysm screening?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

Does this information change your previous response about viewing the image of an ultrasound scan on the scanning machine's display screen?

#### Decision aid – What if my result shows I have a small aneurysm? (Page 3)

The following information may also be included in this section of the decision aid; is there any information here that particular affects you and your attitude towards abdominal aortic aneurysm screening?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

---

### Large aneurysm (Page 1)

*Explain the purposes of the further tests and procedures*

How does this information about possible further tests and procedures to check for suitability for a surgical intervention make you feel about abdominal aortic aneurysm screening?

In the context of a decision aid, is this information important to you?

### Large aneurysm (Page 2)

How does this information about the two surgical interventions and the option of watchful waiting make you feel about abdominal aortic aneurysm screening?

In the context of a decision aid, is this information important to you?

---

#### Decision aid – What if my result shows I have a large aneurysm? (Pages 1 and 2)

What are your thoughts about the information included in this section of the decision aid about what happens if a man has a large aneurysm?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

#### Decision aid – What if my result shows I have a large aneurysm? (Page 3)

The following information about the benefits and risks of the three options may also be included in this section of the decision aid; what are your thoughts about this information and how does it affect you and your attitude towards abdominal aortic aneurysm screening?

*Refer to highlighted information that would make them more likely to be screened*

*Refer to highlighted information that would make them less likely to be screened*

*Refer to highlighted information that didn't make sense or was misleading*

How important to you is it that information about the benefits and risks of treatment options are included in a decision aid, whether it is for abdominal aortic aneurysm screening, a different screening condition, or possibly diagnostic or treatment options?

## Appendix 13 Coding qualitative data using NVivo 9 (QSR International Pty Ltd., 2010) from interviews with men about abdominal aortic aneurysm screening

How important to you are the inclusion of images and videos in a decision aid, whether it is for abdominal aortic aneurysm screening, a different screening condition, or possibly diagnostic or treatment options?

We are now nearing the end of the interview. If you were actually considering abdominal aortic aneurysm screening or possibly screening for a different condition, what would be important to you when making a decision on whether to be or not to be screened? [Repeat question from the start of the interview]

How likely do you think you would be to use a decision aid online via the Internet?

If you were to decide to have abdominal aortic aneurysm screening; what could possibly increase or decrease your likelihood of actually being screened?

If a significant other, such as a partner, sibling or close friend were given the option of being screened for abdominal aortic aneurysm screening; what advice would you provide them?

Would you seek advice from another person if actually considering abdominal aortic aneurysm screening?

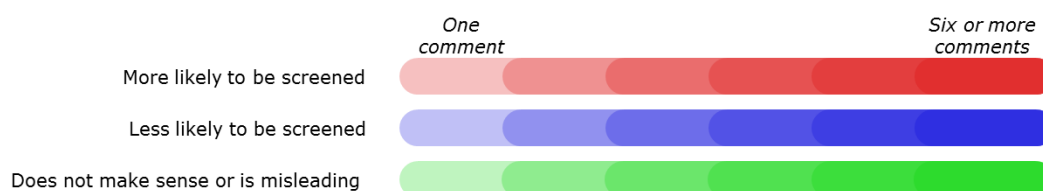
To conclude with the interview; if I were to report back to the developers of the decision aid for abdominal aortic aneurysm screening what would you have me report back to them and do have any specific recommendations or ideas for improvements? You may look back through the decision aid.

That is the end of the interview; do you have anything you would like to add about abdominal aortic aneurysm screening, the decision aid or the interview process?

Nodes		
Name	Sources	References
Information provision	20	642
Evidence	14	52
Images and videos	19	49
Internet	20	47
Questions and answers	1	6
Satisfactory	20	181
About a large aneurysm	17	56
DA booklet	14	43
Handout	7	13
About a normal sized aorta	9	10
About a small aneurysm	19	56
About the condition	16	24
About the screening	12	35
Unsatisfactory	20	300
About a large aneurysm	20	141
DA booklet	18	73
Handout	19	64
About a normal sized aorta	11	24
About a small aneurysm	19	77
About the condition	3	5
About the screening	16	52
Screening	20	910
Control	7	15
Convenience	14	27
Cost	4	8
Further tests and procedures	18	71
Acceptance	13	28
Duration	2	2
Familiarity	9	15
Fear	1	1
Find other things	3	3
Magnetic field	1	2
Physical involvement	9	16
Sensations	1	1
Speak to surgeon	2	3
Others' experiences	4	8
Personal	20	385
Benefits	20	172
Risk factors	20	87
Risks and, or side-effects	20	126
Procedure	20	311
Acceptance	3	3
Communication	12	14
Complexity	11	22
Duration	8	20
Embarrassment	1	2
Familiarity	18	31
Interpretation of result	7	17

## Appendix 14 Consolidated highlighted decision aid booklet

Highlighted information has been consolidated through underlining information using the following legend:



Some participants also added remarks and these are presented in square brackets:

*[Participant written remark]*

Some remarks are directed at specific information, which are indicated using arrows to the information.

What is an abdominal aortic aneurysm?

The aorta is a big blood vessel that takes blood from your heart round your body.

As you get older, your aorta can get weak and swell up, This sort of swelling is called an abdominal aortic aneurysm or AAA.

If you have a large aneurysm it could be very serious. The wall of your aorta can get very weak and it could burst. If this happens, you would probably die.

Small aneurysms are not usually dangerous but the larger an aneurysm grows, the more likely it is to burst.

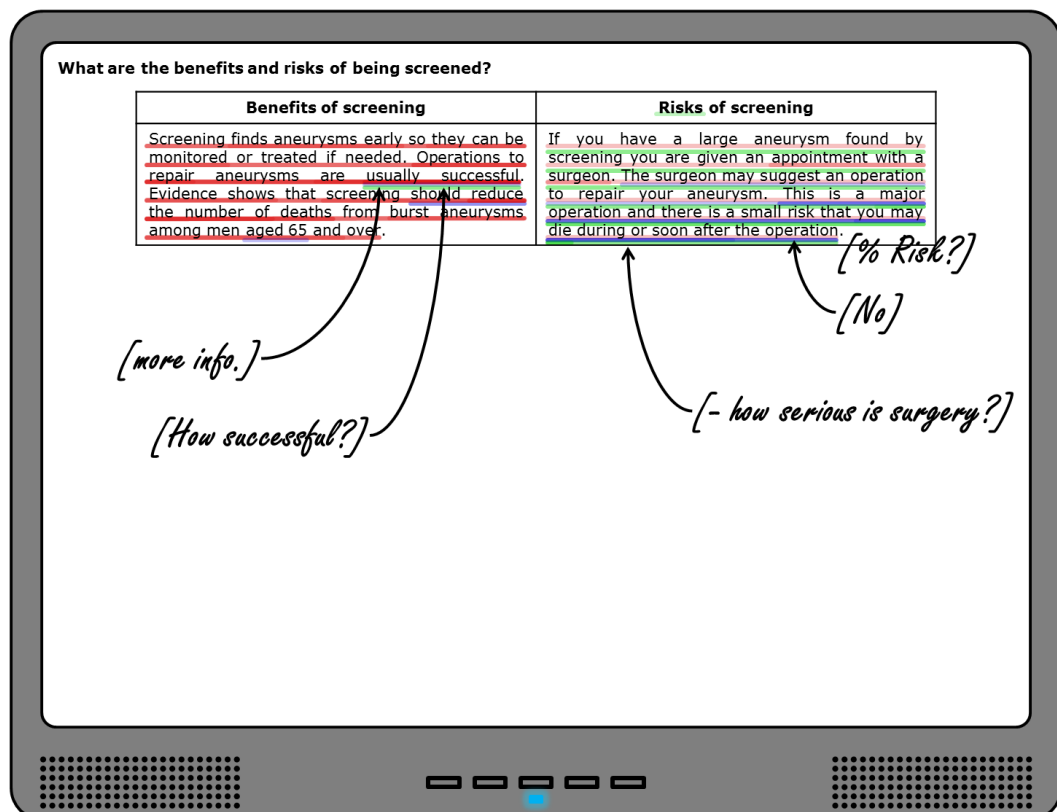
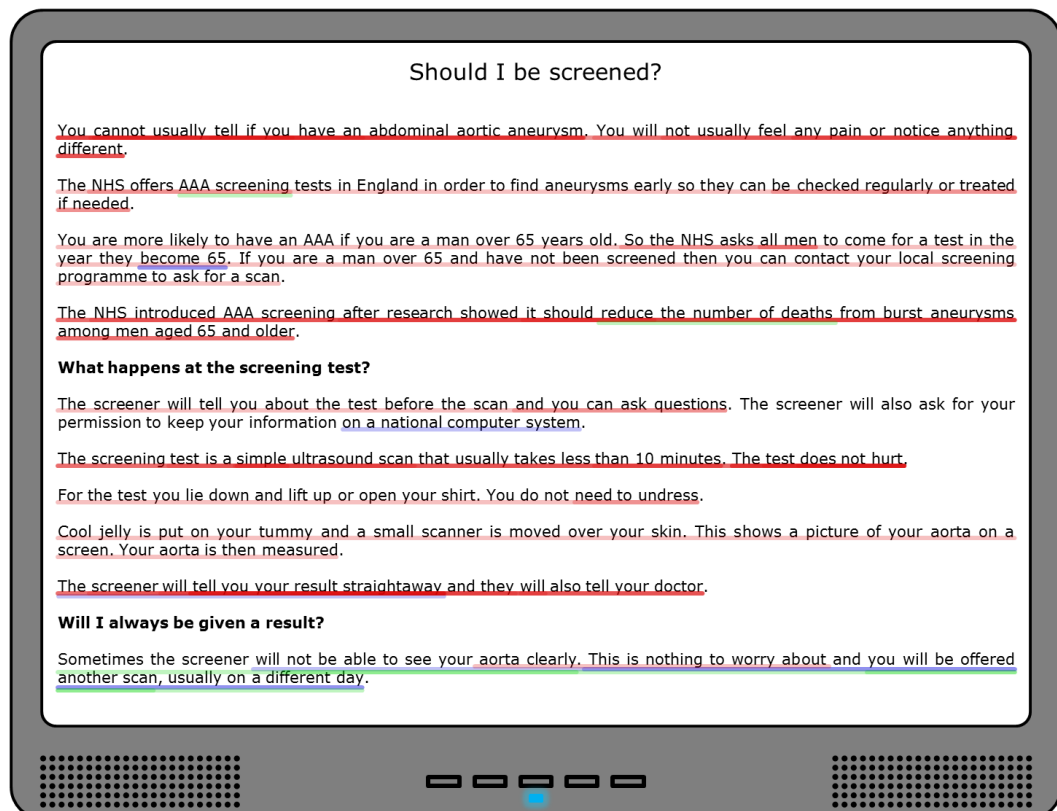
Most large aneurysms can be repaired successfully if they are operated on before they burst.

**What is the risk?**

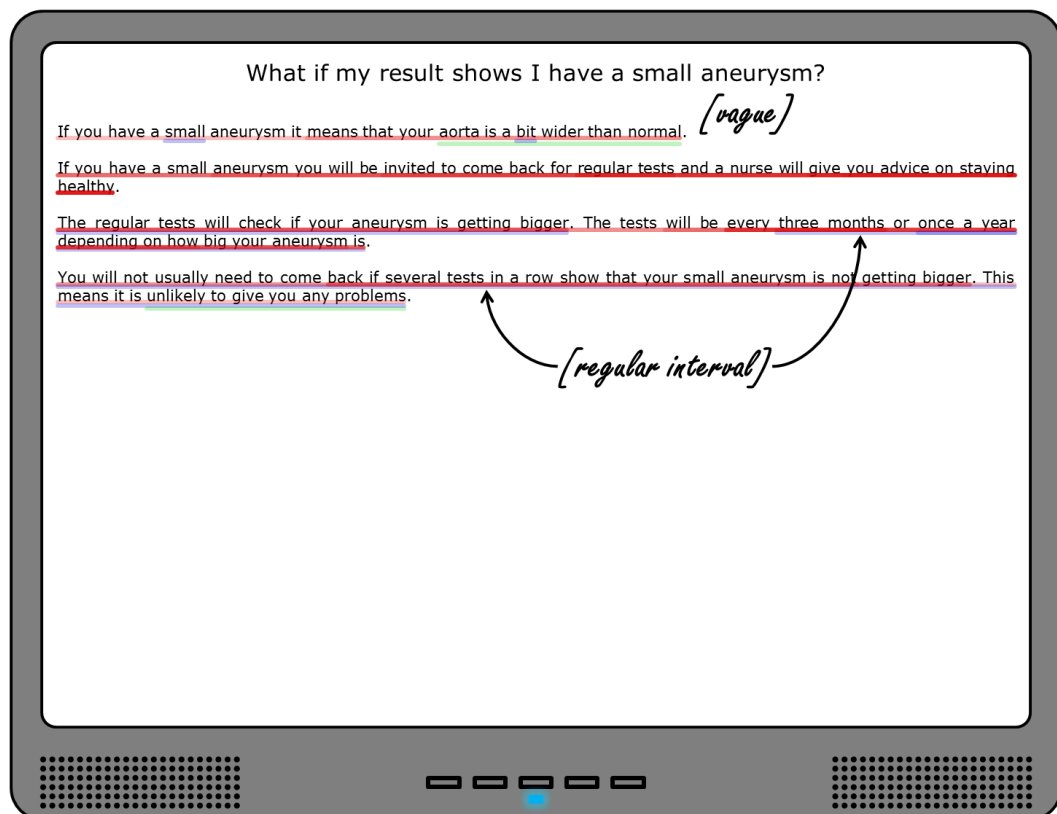
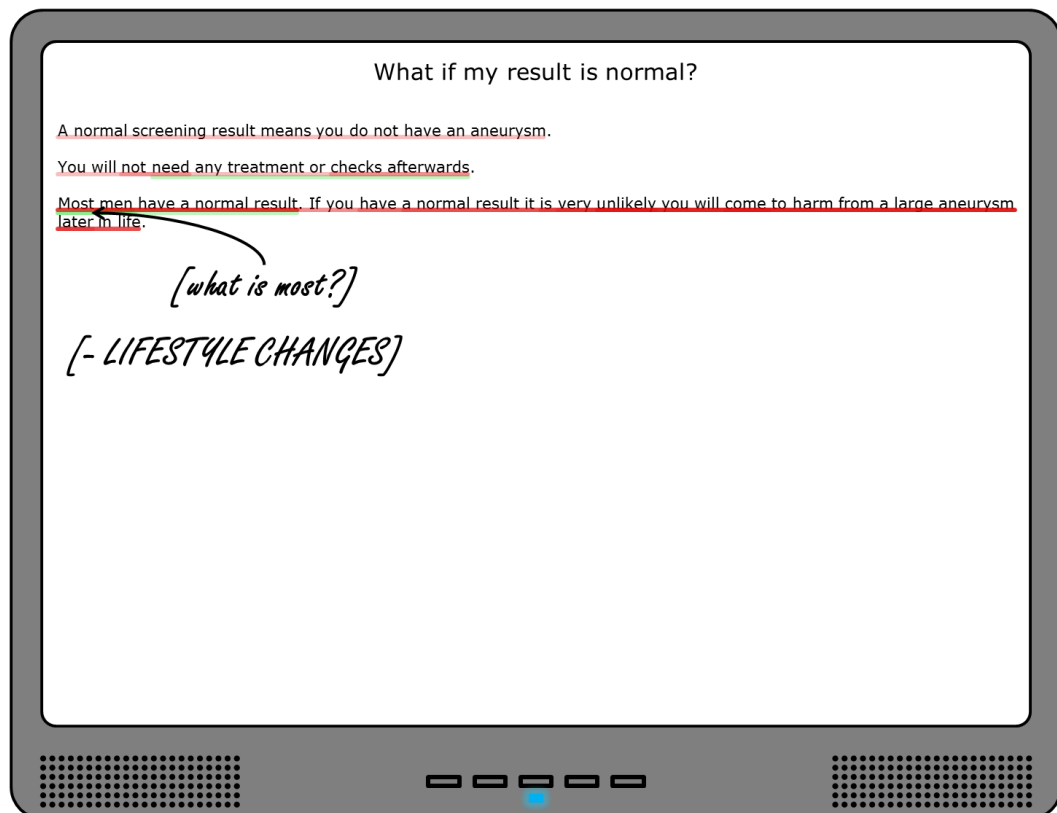
Men aged 65 and older are most likely to get this sort of aneurysm. You are also more at risk if:

- You smoke
- You have high blood pressure
- Your brother, sister or parent has or has had an abdominal aortic aneurysm

*[ : large to small ]*







What are the risks if I have a small aneurysm?

<u>Size of aorta</u>	<u>Description</u>	<u>Risk of aneurysm bursting per year</u>
<u>3cm or less</u>	<u>No aneurysm</u>	<u>No real risk</u>
<u>3 - 5,5cm</u>	<u>Small aneurysm</u>	<u>About 1 in 100</u>
<u>5,5 - 7cm</u>	<u>Large aneurysm</u>	<u>About 15 in 100</u>
<u>over 7cm</u>	<u>Very large aneurysm</u>	<u>More than 25 in 100</u>

*[Needs to be there]*

Can I do anything to stop an aneurysm getting bigger?

If you have a small aneurysm, a nurse practitioner will give you advice on what you can do to help stop your aneurysm getting bigger. This will include eating healthy foods, regular exercise and not smoking.

Your own doctor will also give you pills or change medicines you take already. They may also check your blood pressure.

Will I need an operation? *[1/100!]*

Small aneurysms are not usually dangerous and many men with a small aneurysm never need any treatment. If you have an operation for a small aneurysm you might get other health problems.

*a/* However, your small aneurysm may develop into a large aneurysm. You would then be given an appointment with a surgeon and might need an operation.

Can I opt out of regular screening tests?

Yes, screening is your choice. You can opt out of screening at any time.



### What if my result shows I have a large aneurysm?

A large aneurysm can be very serious. If the wall of your aorta gets very weak it could burst. If this happens, you would probably die.

If your screening test shows you have a large aneurysm then you will be given an appointment with a surgeon. Your GP will also be told.

The surgeon will explain what your treatment could be and tell you about any risks. They will also give you more tests and answer any questions you have.

#### Are there any risks in having an operation?

Operations to repair large aneurysms are usually successful. However, all operations have risks and there is a small chance you will die after an operation to repair a large aneurysm. If you have a large aneurysm, the surgeon will talk to you about treatment and the possible risks.

Not all aneurysms need treatment. But if some large aneurysms are not treated they could burst. If this happens you would probably die.

#### Do I have to have an operation if I have a large aneurysm?

No. Having an operation is your choice. If you do not have an operation, the surgeon will talk to you about the best choice for you.

For a few men an operation may have very high risks. This might be if you have other serious health problems. So sometimes an operation may not be the best choice for you.

#### Can I do anything to stop an aneurysm getting bigger?

You will be given advice on what you can do to help stop your aneurysm getting bigger. This will include eating healthy foods, regular exercise and not smoking. Your own doctor may also give you pills or change medicines you take already. They may also check your blood pressure.

### What are the treatment options if I have a large aneurysm? *[PATIENT OPTION]*

If you have a large aneurysm then your surgeon may offer you a choice of treatment options. However, not every patient or every aneurysm is suitable for all the options.

**Endovascular repair:** In this type of 'keyhole operation', the surgeon puts an artificial piece of artery, called a graft, inside your aneurysm. They do this by making small cuts in the top of your legs and then use X-rays to guide the graft into place.

**Open surgery:** In open surgery, the surgeon cuts open your stomach. They then replace your aneurysm with an artificial piece of artery, called a graft.

**Watchful waiting:** You may choose not to have an operation. For some men the risk of an operation may be too high because of other serious health problems. Watchful waiting means you do not have a planned operation but continue to have regular check-ups on your aneurysm. You may also be given medication.

*[PICTURES]*

*[After screening]*

	Option	Benefits	Risks
[7/10]	Endovascular repair	The surgeon does not need to cut open your stomach. There is less risk of dying or of major complications than after open surgery.	The graft attachment is not as secure as with open surgery. You may need regular scans to check that the graft has not slipped. If the graft slips, you may need another operation.
[1/10]	Open surgery	Most open surgery repairs are successful and you usually make a full recovery. The graft usually works well for the rest of your life.	This is a major operation and there is a small chance you will die or suffer major complications during or shortly after the operation.
[10/10]	Watchful waiting	You may continue to live with a large aneurysm without it ever bursting.	If a large aneurysm bursts then you would probably die.

## Appendix 15 Descriptions and appropriateness of all factors affecting attitudes towards diagnostic procedures and abdominal aortic aneurysm screening to guide the design of patient information using the factors based approach

Factor	Appropriateness
<p><b>Acceptance</b> (Screening factor) Acceptance of further investigations and tests and/or surgery if screened and a large aneurysm was diagnosed.</p> <p><i>The further investigations and tests were seen as good clinical practice and a necessity for assessing and preparing for surgery, which is similar to the benefits and understanding and improving health factors as the aims of these are to treat medical conditions.</i></p>	<p>Although information can inform patients about other possible investigations and tests and treatments that may be encountered in clinical pathways, acceptance of them would be accepting what is required to treat medical conditions at later stages in pathways rather than the requirement for such information at earlier stages. This was the case for information provision about a large aneurysm where participants differentiated between the initial screening decision and if a large aneurysm was diagnosed (see pages 145-146 for recap). However, there were also suggestions for being able to obtain more information about the further investigations and tests and treatments for those who were interested and/or preferred to be further informed. This was termed by one participant as a ‘what if’ scenario and by another like ‘peeling an onion’. Therefore the acceptance factor is considered: <b>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) not appropriate for diagnostic contexts; and 3) appropriate for screening contexts.</b></p> <p><i>Information provision for screening about further investigations and tests and treatments relates to support patients would receive following a diagnosis and so is considered appropriate to be included in the speak with surgeon factor.</i></p>
<p><b>Benefits</b> (Screening factor) Personal benefits of being screened, including being made aware that you do or do not have an aneurysm, and receiving appropriate health advice and/or healthcare if screened and an aneurysm was diagnosed.</p> <p><i>This factor is similar to the acceptance and understanding and improving health factors as the aims of these are to treat medical conditions.</i></p>	<p>Benefits are not relevant when not referring to symptoms and/or medical conditions. Benefits are also not relevant when patients are symptomatic (i.e. patients present symptoms) because investigations and tests are required to understand what is causing symptoms so that appropriate measures can be taken to improve health. However, information provision about benefits would be important for screening since patients are asymptomatic (i.e. patients present no symptoms) and they would have control in deciding whether to be or not to be screened for a medical condition, which may be affected by personal benefits of being screened for a condition. Therefore the benefits factor is considered: <b>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) not appropriate for diagnostic contexts; but 3) appropriate for screening contexts.</b></p>
<p><b>Choice and control</b> (Screening factor) Control in deciding whether to be or not to be screened, and if screened and</p>	<p>Choice and control is not relevant when not referring to symptoms and/or medical conditions. Choice and control is also more than likely not relevant when patients are symptomatic because investigations and tests are required to understand what is causing symptoms so that appropriate measures can be taken to improve health. It would only be relevant if patients had different investigations and tests to choose from and they had control in deciding which to choose. Information provision about choice and</p>

<p>a large aneurysm was diagnosed, control in deciding on which treatment.</p>	<p>control would be important for screening since patients are asymptomatic and they would have control in deciding whether to be or not to be screened for a medical condition. They may also have different treatments to choose from if they are screened and diagnosed with a condition; participants valued control of which treatments to proceed with if they were screened for an AAA and diagnosed with a large aneurysm (see pages 137-138 for recap). Therefore the choice and control factor is considered: <b>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts if patients have different investigations and tests to choose from; and 3) appropriate for screening contexts.</b></p> <p><i>Principles in this factor are related to the principle of informing patients about the option of using alleviating substances so that they can decide whether they would or would not prefer such substances, which is mentioned in the sensations factor.</i></p> <p><i>Information provision for screening about different treatments for patients to choose from relates to support patients would receive following a diagnosis and so is considered appropriate to be included in the speak with surgeon factor.</i></p>
<p><b>Complexity</b> (Diagnostic and screening factor) Perceived level of complexity of diagnostic procedure and screening procedure.</p>	<p>Patients' perceived levels of complexity of investigations and tests are objective perspectives that would be affected by other factors, such as duration, physical involvement and risks. Through informing about these factors patients would have better expectations and understandings of investigations and tests, and objective perspectives would reflect such expectations and understandings. Therefore the complexity factor is considered: <b>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) not appropriate for diagnostic contexts; and 3) not appropriate for screening contexts.</b></p>
<p><b>Convenience</b> (Screening factor) Convenience to arrange and/or attend screening, including duration of screening procedure.</p> <p><i>Duration is also a factor by itself.</i></p>	<p>Convenience is not relevant when not referring to symptoms and/or medical conditions. Convenience is also more than likely not relevant when patients are symptomatic because clinicians and other healthcare professionals and/or healthcare administrative staff would be responsible for arranging investigations and tests, which are required to understand what is causing symptoms so that appropriate measures can be taken to improve health. It would only be relevant if patients had to arrange investigations and tests and/or they had different locations and/or times to choose from; duration of investigations and tests may affect convenience to attend. Information provision about convenience would be important for screening since patients are asymptomatic and they would have control in deciding whether to be or not to be screened for a medical condition, which may be affected by the convenience to arrange and/or attend the screening investigation or test. Therefore the convenience factor is considered: <b>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts if patients have to make arrangements and/or they have different locations and/or times to choose from; and 3) appropriate for screening contexts.</b></p> <p><i>Booking details and, media permitting, booking functionalities should be included and incorporated, respectively, in patient information resources for patients to make arrangements to attend investigations and tests. A suggestion for an online booking system was made about arranging AAA screening (see pages 135-136 for recap).</i></p>
<p><b>Duration</b></p>	<p>Informing patients about the duration of investigations and tests will enable them to have an expectation of the time they will take</p>

(Diagnostic factor) Perceived time it will take to complete diagnostic procedure or the requirement for such information.	to complete. Therefore the duration factor is considered: <i>1) appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts; and 3) appropriate for screening contexts.</i>
<i>Duration is also mentioned in the convenience factor.</i>	
<b>Embarrassment</b> (Diagnostic factor) Level of embarrassment, if any, due to symptoms and/or diagnostic procedure.	<p>Patients' levels of embarrassment, if any, of investigations and tests are subjective perspectives that would be affected by symptoms and/or the investigations and tests themselves. Investigations and tests are also defined by symptoms, and are required to understand what is causing symptoms so that appropriate measures can be taken to improve health. Therefore the embarrassment factor is considered: <i>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) not appropriate for diagnostic contexts; and 3) not appropriate for screening contexts.</i></p> <p><i>If there is the possibility of embarrassment patients may benefit from being informed that investigations and tests are performed and assisted by qualified healthcare professionals who are trained in and have experience of such investigations and tests, and who will not feel uncomfortable or embarrassed about them. This information relates to patients' physical involvement with investigations and tests and so is considered appropriate to be included in the physical involvement factor.</i></p>
<b>Familiarity</b> (Diagnostic and screening factor) Experience/knowledge/perceived knowledge of diagnostic procedure, and screening procedure and/or further investigations and tests.	Through informing patients about other factors of investigations and tests they will become familiar with them. Therefore the familiarity factor is considered: <i>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) not appropriate for diagnostic contexts; and 3) not appropriate for screening contexts.</i>
<b>Interest and understanding</b> (Screening factor) Level of interest in screening procedure output and understanding of it.	<p>Informing patients about investigation and test informational outputs (e.g. image from an X-ray) will enable them to have an understanding of the outputs. Informing patients about whether they could view informational outputs during and/or after investigations and tests will enable them to consider whether they would or would not be interested in viewing the outputs. Informing patients about whether clinicians and other healthcare professionals involved in performing investigations and tests will explain and/or if patients can ask questions about informational outputs will enable patients to have an expectation that they may receive explanations and/or they can consider any questions they may want to ask, respectively. Therefore the interest and understanding factor is considered: <i>1) appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts; and 3) appropriate for screening contexts.</i></p> <p><i>Suitable images and/or, media permitting, videos should be included to support information provision about investigation and test informational outputs as they may improve knowledge and understanding. This was the case for information provision about AAAs</i></p>

	<i>and the screening procedure for the condition (see pages 149-150).</i>
<b>Interpretation</b> (Screening factor) Awareness that screening outcome is dependent on quality of interpretation of screening procedure output.	Informing patients about clinicians and other healthcare professionals involved in interpreting investigation and test informational outputs, and the interpretation process (e.g. image from an X-ray will be examined by a radiologist (a specialist healthcare professional)) will enable them to be aware of who is involved in interpreting outputs and to infer quality of such interpretations. Therefore the interpretation factor is considered: <b>1) appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts; and 3) appropriate for screening contexts.</b>
<b>Physical involvement</b> (Diagnostic and screening factor) Physical involvement with diagnostic procedure (i.e. what is expected and what will happen during diagnostic procedure), and level of physical involvement with screening procedure and/or further investigations and tests.	<p>Informing patients about physical involvement with investigations and tests and any different phases of involvement (i.e. before, during and/or after investigations and tests) will enable them to have an expectation of what would be physically required. Therefore the physical involvement factor is considered: <b>1) appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts; and 3) appropriate for screening contexts.</b></p> <p><i>Information provision for reducing embarrassment is discussed in the embarrassment factor and is considered appropriate to be included in this factor.</i></p> <p><i>Suitable images and/or, media permitting, videos should be included to support information provision about patients' physical involvement with investigations and tests as they may improve knowledge and understanding. This was the case for information provision about AAAs and the screening procedure for the condition (see pages 149-150 for recap).</i></p>
<b>Purpose</b> (Diagnostic factor) Understanding purpose of diagnostic procedure in response to symptoms.	Informing patients about the body part investigations and tests are investigating and testing, respectively, will enable them to have an understanding of their purpose in response to symptoms. Informing patients about suspected medical conditions being investigated or tested in response to symptoms will enable them to prepare for such conditions. This was the case for preferences for receiving information about possible clinical pathways in the event of a positive (i.e. medical condition is diagnosed), negative (i.e. medical condition is ruled out) or inconclusive (i.e. uncertain – neither positive nor negative) diagnostic procedure outcome or result (see pages 75-76 for recap). However, this information, media permitting, should be optional and added to patient information resources by clinicians so that the information is reliable and patients can decide whether they would or would not prefer to be informed of what suspected medical conditions their symptoms warranted further investigation for. This is similar to information about a large aneurysm, and further investigating and testing and treating one for those who would be interested in and/or preferred to be further informed, which was termed by one participant as a 'what if' scenario and by another like 'peeling an onion' (see pages 145-146 for recap). Information provision about specific medical conditions being screened is necessary for screening. Therefore the purpose factor is considered: <b>1) appropriate to guide the design of patient information for an investigation or test without context orientation if only detailing the body part being investigated or tested; 2) appropriate for diagnostic contexts if, media permitting, information provision about suspected medical conditions is optional and added by clinicians; and 3) appropriate for screening contexts about specific medical conditions being screened.</b>

	<p><i>Information provision about risk factors is discussed in the risk factors factor and is considered appropriate to be included in this factor.</i></p> <p><i>Suitable images and/or, media permitting, videos should be included to support information provision about body parts and suspected and specific medical conditions as they may improve knowledge and understanding. This was the case for information provision about AAAs and the screening procedure for the condition (see pages 149-150 for recap).</i></p>
<p><b>Risk factors</b> (Screening factor) Risk factors associated with medical condition being screened and personal value of being screened for the condition.</p>	<p>Risk factors are not relevant when not referring to symptoms and/or medical conditions. Risk factors are also not relevant when patients are symptomatic because investigations and tests are required to understand what is causing symptoms so that appropriate measures can be taken to improve health. However, information provision about risk factors would be important for screening since patients are asymptomatic and they would have control in deciding whether to be or not to be screened for a medical condition, which may be affected by risk factors associated with a condition being screened. Therefore the risk factors factor is considered: <b>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) not appropriate for diagnostic contexts; but 3) appropriate for screening contexts.</b></p> <p><i>Information provision about risk factors relates to the purpose of screening for specific medical conditions and so is considered appropriate to be included in the purpose factor.</i></p>
<p><b>Risks</b> (Screening factor) Personal risks of being or not being screened, including risks of screening procedure and/or treatments.</p> <p><i>Risks is also included in the risks and/or side-effects factor.</i></p>	<p>Informing patients about risks of investigations and tests will enable them to have an understanding of potential dangers and consequences. For screening, information provision about risks should include risks of being or not being screened for a medical condition since patients are asymptomatic and they would have control in deciding whether to be or not to be screened for a condition, which may be affected by personal risks of being or not being screened. Therefore the risks factor is considered: <b>1) appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts; and 3) appropriate for screening contexts.</b></p> <p><i>Suitable quantitative evidence should be used to quantify risks, which should be appropriately formatted using numerical and/or graphical formats. This was the case for quantifying the benefits and risks of AAA screening (see pages 147-148 for recap). It was also suggested that quantitative evidence could be accessed (i.e. linked), media permitting, from quantitative terms (e.g. small chance). This will enable patients to decide whether they would or would not prefer to be informed about specific quantitative details.</i></p>
<p><b>Risks and/or side-effects</b> (Diagnostic factor) Perceived level of risks and/or side-effects, if any, of diagnostic procedure.</p> <p><i>Risks is also a factor by itself.</i></p>	<p><i>For informing patients about risks see the risks factor, and since risks and side-effects differ in the information they inform patients about they will now be established as separate factors. So this factor will now be considered the 'side-effects' factor.</i></p> <p>Informing patients about side-effects of investigations and tests will enable them to have an expectation of physical limitations and/or sensations following investigations and tests. Therefore the side-effects factor is considered: <b>1) appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts; and</b></p>

	<b>3) appropriate for screening contexts.</b>
<b>Sensations</b> (Diagnostic and screening factor) Perceived level of pain and/or discomfort, if any, during diagnostic procedure and screening procedure, and/or use of an alleviating substance.	<p>Informing patients about sensations during investigations and tests will enable them to have an expectation of any pain and/or discomfort they may experience. Informing patients about the use of alleviating substances will enable them to expect any pain and/or discomfort that may be experienced to be relieved or reduced.</p> <p>Therefore the sensations factor is considered: <b>1) appropriate to guide the design of patient information for an investigation or test without context orientation; 2) appropriate for diagnostic contexts; and 3) appropriate for screening contexts.</b></p> <p><i>If alleviating substances are optional then patients should be informed about this so that they can decide whether they would or would not prefer such substances. This principle is related to principles in the choice and control factor.</i></p> <p><i>If alleviating substances are used then refer to the risks and/or side-effects factor since there may be side-effects from such substances.</i></p>
<b>Speak with surgeon</b> (Screening factor) Speak with surgeon to discuss and/or gain advice about treatment if screened and a large aneurysm was diagnosed.	<p><i>To generalise this factor it will now be considered the 'speak with clinician and/or other healthcare professional' factor.</i></p> <p>Speaking with clinicians and/or other healthcare professionals following investigations and tests is not relevant when not referring to symptoms and/or medical conditions. Speaking with clinicians and/or other healthcare professionals following investigations and tests is also not relevant when patients are symptomatic because investigations and tests are required to understand what is causing symptoms so that appropriate measures can be taken to improve health, which would have been recommended and/or requested by clinicians. However, information provision about speaking with appropriate clinicians and/or other healthcare professionals would be important for screening since patients are asymptomatic and they would have control in deciding whether to be or not to be screened for a medical condition, which may be affected by support they would receive following a diagnosis. Therefore the speak with clinician and/or other healthcare professional factor is considered: <b>1) not appropriate to guide the design of patient information for an investigation or test without context orientation; 2) not appropriate for diagnostic contexts; but 3) appropriate for screening contexts.</b></p> <p><i>Information provision for screening about further investigations and tests and treatments is discussed in the acceptance factor and is considered appropriate to be included in this factor.</i></p> <p><i>Information provision for screening about different treatments for patients to choose from is discussed in the choice and control factor and is considered appropriate to be included in this factor.</i></p> <p><i>Information provision for screening about actual further investigations and tests (if any) and treatments could be accessed (i.e. linked), media permitting, from patient information resources informing about screening. This will enable patients to decide</i></p>



	<i>whether they would or would not prefer to be informed about what further investigations and tests are required, and what treatments are used to treat the medical condition they have the option of being screened for. Such suggestions were made for further investigating and testing and treating large aneurysms, which was termed by one participant as a 'what if' scenario and by another like 'peeling an onion' (see pages 145-146 for recap).</i>
<b>Speed</b> (Screening factor) Speed at which screening procedure output is interpreted to screening outcome.	Informing patients about the time it will take for investigation and test informational outputs to be interpreted to outcomes and results, respectively, will enable them to have an expectation of when outcomes and results will become available. Therefore the speed factor is considered: <b>1) <i>appropriate to guide the design of patient information for an investigation or test without context orientation</i>; 2) <i>appropriate for diagnostic contexts</i>; and 3) <i>appropriate for screening contexts</i>.</b>
<b>Trust</b> (Diagnostic and screening factor) Trust in clinicians and/or clinical practice.	Patients' trust in clinicians and/or clinical practice are objective and subjective perspectives that would be affected by but not limited to relationships with clinicians and other healthcare professionals, and/or healthcare experiences. Therefore the trust factor is considered: <b>1) <i>not appropriate to guide the design of patient information for an investigation or test without context orientation</i>; 2) <i>not appropriate for diagnostic contexts</i>; and 3) <i>not appropriate for screening contexts</i>.</b>
<b>Understanding and improving health</b> (Diagnostic factor) Understanding what is causing symptoms so appropriate measures can be taken to improve health.	Investigations and tests are required to understand what is causing patient symptoms so that appropriate measures can be taken to improve health, and information provision does not affect such motivation. Therefore the understanding and improving health factor is considered: <b>1) <i>not appropriate to guide the design of patient information for an investigation or test without context orientation</i>; 2) <i>not appropriate for diagnostic contexts</i>; and 3) <i>not appropriate for screening contexts</i>.</b>
<i>This factor is similar to the acceptance and benefits factors as the aims of these are to treat medical conditions.</i>	

## Appendix 16 Second version of collated patient information resources for colonoscopy

*Marker 1*

### Colonoscopy

**What is a colonoscopy?**

- A colonoscopy is an examination of the lining of the bowel wall.
- A thin flexible tube called a colonoscope is passed into your rectum (back passage) when you are under sedation, and guided around your large bowel.
- A colonoscopy is the most effective way to diagnose bowel cancer.
- Treatments for bowel cancer are more likely to be effective if bowel cancer is detected early (NHS Bowel Cancer Screening Programme, 2006, p. 2).

*Purpose*  
*Physical involvement and sedation*  
*Bowel cancer info.*

A colonoscopy is a test where an operator (a doctor or nurse) looks into your colon. The colon is sometimes called the large intestine or large bowel. The colon is the part of the gut which comes after the small intestine. The last part of the colon leads into the rectum where faeces (stools or motions) are stored before being passed out from the anus.

*Purpose*

A colonoscope is a thin, flexible, telescope. It is about as thick as a little finger. It is passed through the anus and into the colon. It can be pushed all the way round the colon as far as the caecum (where the small and large intestine meet). Another test called sigmoidoscopy looks at the rectum and the lower part of the colon (see separate leaflet called 'Sigmoidoscopy' for more details).

*Physical involvement*

The colonoscope contains fibre optic channels which allow light to shine down so the operator can see inside your colon.

*Output*

The colonoscope also has a 'side channel' down which devices can pass. These can be manipulated by the operator. For example, the operator may take a small sample (biopsy) from the inside lining of the colon by using a thin 'grabbing' instrument which is passed down a side channel' (Knott, 2012).

*Physical involvement and output*

A colonoscopy is an investigation used to look at the lining of your large intestine. It is performed using a narrow, flexible, telescopic camera called a colonoscope. Your doctor will pass the colonoscope into your bowel through your anus (back passage) (Bupa, 2011).

*Purpose and Duration*  
*Physical involvement and Purpose*

A colonoscopy is a way of examining the lining of the bowel from the inside. The procedure is usually done in the hospital outpatient department and takes about an hour. It's the most thorough and effective way of diagnosing bowel cancer. The colonoscopy can also see if there are any polyps in your bowel (see pages 21-22) (Macmillan Cancer Support, 2010, p. 18).

*Bowel cancer info.*  
*Also mention of polyps which can potentially grow to become cancer.*

**Why have I been offered a colonoscopy?**

Before you have the procedure, a specialist nurse will fully explain what a colonoscopy involves. You will be given the opportunity to ask any questions, and your fitness for the procedure will be assessed.

*Physical involvement (before)*

The main reason you have been offered a colonoscopy is to examine the lining of your bowel wall to see if cancer is present. Treatments for bowel cancer are more likely to be effective if bowel cancer is detected early. A colonoscopy can also detect bowel polyps. Polyps are not cancer, but can sometimes change into cancer over a number of years. Polyps can be removed (usually during the colonoscopy), reducing your risk of developing bowel cancer in the future (NHS Bowel Cancer Screening Programme, 2006, pp. 2-3).

*Bowel cancer info.*

**What do I need to do before a colonoscopy investigation?**

Before a colonoscopy, you will have to completely empty your bowel to allow the specialist to see the lining of your bowel clearly.

*Physical involvement (before)*

You will receive a list of dietary restrictions and a bowel preparation medicine (a strong laxative) before the colonoscopy. You should take the strong laxative the day before the colonoscopy and it will cause diarrhoea. After taking the laxative, it is wise to stay close to a toilet and avoid travelling or going to work.

*Physical involvement (before)*

**It is important that you follow the instructions very carefully to fully empty your bowel.** Otherwise the specialist may not be able to clearly see your bowel lining during the colonoscopy and you will need to have the test again. You will also need to arrange for someone to take you home after your colonoscopy, as you will be given a sedative and may feel drowsy (NHS Bowel Cancer Screening Programme, 2006, pp. 4-5).

*Physical involvement (before) and side-effects*

You should get instructions from the hospital department before your test. The sort of instructions given include:

- The colon needs to be empty so that the operator can get a clear view. You will be instructed on how to take a special diet for a few days before the test. You will also be given some laxatives to take.
- You will need somebody to accompany you home, as you will be drowsy with the sedative (Knott, 2012).

*Physical involvement (before) and side-effects*

Colonoscopy is usually done in hospital as a day-case. This means you have the test and go home the same day.

*Duration*

Your hospital will write to you telling you what you need to do before your colonoscopy. You will usually need to begin preparing two days before your test.

*Physical involvement (before)*

Your bowel needs to be completely empty during the test so that your doctor can see clearly. You will usually be asked to:

- stop taking any iron tablets – these make the inside of your bowel look black, which means it is hard for your doctor to see clearly
- eat a special diet in the days before the test
- drink lots of clear fluids before your test – at least six to eight glasses a day
- take strong laxatives – these can be quite powerful and will give you diarrhoea, so you will need to stay close to a toilet.

*Physical involvement (before)*

If you normally take medication, for example tablets for high blood pressure, take them as usual, unless your doctor tells you not to. He or she may ask you to stop taking some of your usual medicines if they are likely to make you feel constipated. If you take medicines that affect the way your blood clots, such as warfarin or clopidogrel, tell the outpatient department staff when you receive your appointment letter. The staff will tell you whether you need to stop these before the test.

*Physical involvement (before)*

If you have diabetes and you're taking insulin or medicine to treat it, contact the outpatients department to tell them. They can arrange for you to be the first to your colonoscopy on the day of your appointment. You will be given specific information about when to take medicines or insulin and what to eat before the procedure.

*Risks!*

Your doctor will discuss with you what will happen before, during and after your procedure, and any pain you might have. This is your opportunity to understand what will happen, and you can help yourself by preparing questions to ask about the risks, benefits and any alternatives to the procedure. This will help you to be informed, so you can give your consent for the procedure to go ahead, which you may be asked to do by signing a consent form (Bupa, 2011).

The bowel has to be completely empty for a colonoscopy. This means following a careful diet for a few days before your test. You'll also need to take laxatives, which the screening centre or hospital pharmacy will provide. The department carrying out your colonoscopy will give you instructions about your diet, and about exactly when to take laxatives (Macmillan Cancer Support, 2010, pp. 18-19).

*Physical involvement (before)*



## What happens during a colonoscopy?

You will be given a sedative to help you relax and then asked to lie on your side. A thin flexible tube called a colonoscope is passed into your rectum (back passage) and guided around your large bowel. At the end of the colonoscope there is a small camera with a light attached which allows the specialist to see the inside of your bowel on a TV screen.

When the colonoscopy is carried out, some air is pumped into your bowel to allow the specialist to see the lining of your bowel wall clearly. This may give you a bloating or cramping feeling in your abdomen. The sedative you are given is likely to make you feel drowsy and you may not remember very much about the investigation. The colonoscopy should take between 30 and 45 minutes.

Sometimes a small tissue sample, called a biopsy, will be taken. Most polyps can also be removed painlessly, using a wire loop passed down the colonoscope tube. These tissue samples will be checked for any abnormal cells that might indicate cancer. Some people find having a colonoscopy uncomfortable, but most people do not report that it is painful (NHS Bowel Cancer Screening Programme, 2006, pp. 5-6).

Colonoscopy is usually done as an outpatient or day case. It is a routine test which is commonly done. You will usually be given a sedative to help you to relax. This is usually given by an injection into a vein in the back of your hand. The sedative can make you drowsy but it does not 'put you to sleep'. It is not a general anaesthetic.

You lie on your side on a couch. The operator will gently push the end of the colonoscope into your anus and up into the colon. The operator can look down the colonoscope and inspect the lining of the colon. Also, modern colonoscopes transmit pictures through a camera attachment on to a TV monitor for the operator to look at.

Air is passed down a channel in the colonoscope into the colon to make the inside lining easier to see. This may cause you to feel as if you want to go to the toilet (although there will be no faeces to pass). The air may also make you feel bloated, cause some mild 'wind pains', and may cause you to pass wind. This is normal and there is no need to be embarrassed, as the operator will expect this to happen.

The operator may take biopsies (small samples) of some parts of the inside lining of the colon - depending on why the test is done. This is painless. The biopsy samples are sent to the lab for testing, and to look at under the microscope. Also, it is possible to remove polyps, which may be found, with an instrument attached to a colonoscope. (Polyps are small lumps of tissue which hang from the inside lining of the colon.) At the end of the procedure the colonoscope is gently pulled out.

A colonoscopy usually takes about 20-30 minutes. However, you should allow at least two hours for the whole appointment to prepare, give time for the sedative to work, for the colonoscopy itself, and to recover. A colonoscopy does not usually hurt, but it can be a little uncomfortable, particularly when the colonoscope is first passed into the anus (Knott, 2012).

The procedure usually takes 30 to 60 minutes to complete.

Your nurse will ask you to put on a hospital gown that opens at the back.

You will probably be given a sedative and a painkiller before your colonoscopy, to make sure you're relaxed and comfortable during the procedure. These medicines are usually given through a small plastic tube which goes into a vein in the back of your hand. If you have a sedative, you won't remember much about the test.

You may have an oxygen sensor clipped to your finger to monitor how well you are breathing and you will be asked to wear an oxygen mask. Your pulse and blood pressure may also be recorded during the procedure. Your doctor will ask you to lie on your left side and he/she will gently insert the colonoscope into your rectum. Lubricating jelly will be used to make this as easy as possible.

Air is pumped into your bowel to make it expand slightly, which makes the colonoscope pass through your bowel more easily. When this happens, it might feel uncomfortable and you may pass

some wind. Your doctor will gently move the colonoscope up through your bowel. The colonoscope is flexible and the doctor can rotate the tip of the instrument so that it follows the curves in your bowel.

A camera lens at the end of the colonoscope sends images to a monitor; you may be able to see the monitor too if you wish. Your doctor will look at these images to examine your bowel. During the procedure, you may be asked to change your position - for example turning from your side on to your back. This helps your doctor to examine different areas of your bowel.

During the procedure your doctor may take a biopsy or remove small polyps. This is done using special instruments passed inside the colonoscope, and is quick and painless. The samples will be sent to a laboratory for testing to see if the cells are benign or malignant (cancerous).

When the test is finished the colonoscope is withdrawn quickly and easily, while sucking out the air that has been introduced during the procedure (Bupa, 2011).

Just before the colonoscopy, you may be given a sedative tablet to help you feel relaxed. Once you're lying comfortably on your side, the nurse or doctor will gently pass a thin flexible tube (a colonoscope) into your back passage. The tube is made up of flexible fibres. It can easily pass around the curves of the bowel so that its lining can be examined. A tiny light and camera on the end of the tube are used to show any abnormal areas.

During the colonoscopy, photographs and samples (biopsies) of the cells on the inside of the large bowel can be taken. Most polyps can be painlessly removed using a wire loop that is passed down the colonoscope. A colonoscopy can be uncomfortable, but the sedative will help you feel more relaxed.

The colonoscopy should take 30-45 minutes. Most people are ready to go home after a couple of hours after their test. You'll need to arrange for someone to collect you from the hospital as you shouldn't drive for several hours after a sedative. You should also have someone with you for about 12 hours afterwards (Macmillan Cancer Support, 2010, p. 19).

## What happens after a colonoscopy?

Immediately after the colonoscopy, the specialist will tell you if they have removed any tissue samples or polyps. If tissue samples are removed during your colonoscopy, you should receive the results in three weeks. There are three types of results that you could receive.

- A normal result means that no polyps or bowel cancers were detected during the colonoscopy. Half of the people who have a colonoscopy (about five in 10) will have a normal result.

The specialist will tell you after your colonoscopy if you had a normal result. As there is a small chance that the colonoscopy may miss a cancer, a normal result does not guarantee that you do not have or never will develop cancer. You will be offered screening for bowel cancer again in two years time.

- A polyp (or more than one polyp) was found during the colonoscopy. In most cases, the specialist will remove the polyp or polyps (this procedure is called a polypectomy) and analyse them. About four in 10 people will have polyps. It may prevent cancer developing if they are removed (NHS Bowel Cancer Screening Programme, 2006, p. 7).

The specialist who performed the colonoscopy will explain the outcome of your investigation to you. You will be told after your colonoscopy if any tissue samples were removed. You will receive the results of any biopsy within three weeks of the investigation. If tissue samples were removed, you may notice traces of blood coming from your back passage. Slight bleeding like this is not uncommon and may last for a few days. You should report any symptoms of prolonged or heavy bleeding (such as cramping, stomach pains and heavy bleeding from your back passage) to the colonoscopy unit or your doctor (GP).

'Because it takes a while for the sedative to wear off, you will need someone to take you home from the hospital. You should also have someone with you for 12 hours afterwards. It is a good idea to have someone with you when the specialist explains the results of the colonoscopy, as you will still be feeling the effects of the sedative. *side-effects*

'You should make sure that you do not drive, use machinery or drink alcohol for at least 24 hours. The sedative takes some time to get through your system and may have some effects on your reactions and judgement. You should also avoid making important decisions until 24 hours after your colonoscopy' (NHS Bowel Cancer Screening Programme, 2006, p. 10). *side-effects*

'Most people are ready to go home after resting for half an hour or so. You may need to stay a bit longer for observation if you have had any polyps removed. *reaction*

**If you have had a sedative** - you may take a bit longer to be ready to go home. The sedative will normally make you feel quite pleasant and relaxed. However, you should not drive, operate machinery or drink alcohol for 24 hours after having the sedative. You will need somebody to accompany you home and to stay with you for 24 hours until the effects have fully worn off. Most people are able to resume normal activities after 24 hours. *side-effects*

The operator writes a report and sends it to the doctor who requested the colonoscopy. The result from any biopsy may take a few days which can delay the report being sent. *output*

The operator may also tell you what they saw before you leave. However, if you have had a sedative you may not remember afterwards what they said. Therefore, you may wish to have a relative or close friend with you who may be able to remember what was said' (Knott, 2012). *side-effects*

'You will need to rest until the effects of the sedative have passed. You will usually be able to go home when you feel ready. You will need to arrange for someone to drive you home. Try to have a friend or relative stay with you for the first 24 hours after your colonoscopy. *side-effects*

'If you have had a biopsy or had polyps removed, your results will be sent to the doctor who recommended your test. At the hospital, your doctor may discuss other findings from the colonoscopy with you before you leave, or you may be given a date for a follow-up appointment' (Bupa, 2011). *output*

'If you need pain relief, you can take over-the-counter medicines, such as paracetamol or ibuprofen. Always read the patient information that comes with your medicine and if you have any questions, ask your pharmacist for advice. *reaction*

'Sedation temporarily affects your co-ordination and reasoning skills, so you must not drive, drink alcohol, operate machinery or sign legal documents for 24 hours afterwards. If you're in any doubt about driving, contact your motor insurer, so that you're aware of their recommendations, and always follow your doctor's advice. *side-effects*

'Most people have no problems after a colonoscopy, but you should contact your doctor if you:

- 'have heavy bleeding from your back passage
- 'have a swollen abdomen and abdominal pain that gets worse
- 'feel unwell and develop a fever (high temperature)' (Bupa, 2011). *side-effects and/or risks?*

'The specialist doing your colonoscopy will tell you if they have removed any tissue samples (biopsies) or polyps from your bowel. If they have taken samples, you'll have to wait up to three weeks for the results. *output*

'This can be an anxious time for you and it may help to talk things over with a relative or close friend, or one of the organisations listed on pages 37-40.

The possible results you could get include:

- 'a normal result
- 'benign polyps
- 'other benign causes, such as inflammatory bowel disease
- 'a cancer.

#### **Normal result**

'This means that no polyps or cancer have been found in your bowel. About half of people who have a colonoscopy will get a normal result.

'There is a small chance that the colonoscopy may miss a cancer, so a normal result doesn't guarantee that you don't have cancer, or won't develop it in the future. If your colonoscopy was normal you'll be offered bowel cancer screening again.

#### **Benign polyps**

If one or more polyps are found during your colonoscopy, they can usually be removed at the same time. This is known as polypectomy and it can help to prevent bowel cancer developing. Around 4 in 10 (40%) of people who have a colonoscopy following an abnormal FOB test are found to have polyps. In some cases, polyps may come back again after surgery.

'The removed polyps will be looked at in the laboratory and, depending on the results, you will be invited to have another colonoscopy. This will usually be in one or three year's time, or you may simply continue with your two-yearly bowel cancer screening.

#### **Other benign causes, such as inflammatory disease**

'If your colonoscopy results show that you have inflammatory bowel disease, such as Crohn's disease or ulcerative colitis, you'll usually be referred to a gastroenterologist, a doctor who specialises in these conditions' (Macmillan Cancer Support, 2010, pp. 21-22).

#### **Are there any side-effects or complications from having a colonoscopy?**

'For most people a colonoscopy is a straightforward procedure, but in rare cases there may be complications. These can include the following: *Physical involvement*

- 'Not being able to see all of the bowel. This can sometimes happen if your bowel is not completely empty or the colonoscope could not reach the end of your large bowel (you may be asked to have another colonoscopy or a barium enema - see page 13). *(Knott)*
- 'Heavy bleeding that needs further investigation or medical advice. Polyps or tissue samples that are removed during a colonoscopy may cause heavy bleeding. It is estimated that this could happen in around one in every 150 colonoscopies. *side-effects and/or risks*
- 'A perforated bowel. The colonoscope can cause a hole (perforation) in the wall of your bowel. The chances of this happening are about one in 1,500. If this happens, you may need an operation. *Risks*
- 'Breathing or heart problems. You may have a reaction to the sedative that may make you have temporary breathing or heart problems. Serious problems are rare as you are carefully monitored during the investigation. *Risks*

'Some of these complications may need further treatment, or even an operation. *side-effects and/or risks*

'In extreme rare cases, the procedure can lead to death. Current evidence suggests that this may happen in around one out of every 10,000 procedures' (NHS Bowel Cancer Screening Programme, 2006, pp. 9-10). *Risks*

'Most colonoscopies are done without any problem. The sedative may cause you to feel tired or sleepy for several hours afterwards. You may pass a small amount of blood from your anus if a *side-effects*



biopsy was taken, or if a polyp was removed.

Occasionally, the colonoscopy may cause damage to the colon. This may cause bleeding, infection and, rarely, perforation. If any of the following occur within 48 hours after a colonoscopy, consult a doctor immediately:

- 'Abdominal pain. (In particular if it becomes gradually worse, and is different or more intense to any 'usual' pains that you may have.)
- 'Fever (raised temperature).
- 'Passing a lot of blood from your anus' (Knott, 2012).

*Risks*

As with every procedure, there are some risks associated with colonoscopy. We have not included the chance of these happening as they are specific to you and differ for every person. Ask your doctor to explain how these risks apply to you.

#### 'Side-effects

These are the unwanted, but mostly temporary effects you may get after having the procedure.

After having a colonoscopy you may feel bloated and uncomfortable due to trapped wind. You may find that lying on your front can sometimes help. Trapped wind usually passes after a few hours. You may also bleed a little from your back passage if you have had a biopsy or polyp removed.

*Physical involvement (before)*

*Side-effects*

#### 'Complications

Complications are when problems occur during or after the procedure. Most people aren't affected. However, sometimes complications do occur. The main ones are listed below.

- 'Your doctor may not be able to see all of your bowel. This can happen if your bowel isn't empty or the colonoscope can't be passed round a curve. If this happens you may need to have the colonoscopy done again, or have other tests.
- 'You may have a reaction to the sedation, which can affect your breathing or your heart. You will be monitored throughout the procedure and treated quickly if any of these problems develop.
- 'The colonoscope and the other instruments used during the procedure can damage or tear your bowel. If this happens you may need an operation to repair it.
- 'You may have heavy bleeding if you have had biopsies or polyps removed' (Bupa, 2011).

*Physical involvement (before)*

*Risks*

*Risks*

*Side-effects and/or risks*

For most people a colonoscopy is a straightforward procedure and they'll have no side effects. Rarely however, complications can happen, including:

#### 'Fluid loss

Taking laxatives before having a colonoscopy may sometimes cause you to lose a lot of fluid from your body, as you pass several bowel motions. If you have heart problems, let your GP know before you take any laxatives as this fluid loss can temporarily worsen your condition.

*Side-effects and/or risks*

#### 'Breathing or heart problems

Some people react to the sedative that is used during a colonoscopy. This can cause temporary breathing or heart problems. It's rare to have a serious problem and you'll be monitored during the colonoscopy.

*Risks*

#### 'Not being able to see the whole bowel

Sometimes it's not possible to see the whole bowel during a colonoscopy. This can happen if the bowel isn't completely empty or if the colonoscope can't pass round a bend in the bowel to reach the end. If this happens, you may be asked to have another colonoscopy, or a barium enema (see page 24).

*Physical involvement (before)*

#### 'Heavy bleeding

About 1 in every 150 people who have a colonoscopy will have heavy bleeding afterwards. If tissue samples (biopsies) are taken or polyps removed there is a risk that the area may bleed. If you

*Side-effects and/or risks*

notice a lot of bleeding, contact the screening centre as soon as possible for further advice.

#### 'A perforated bowel

Rarely the colonoscope can make a hole (perforation) in the wall of your bowel. This happens to about 1 in 1,500 people who have a colonoscopy. If your bowel is perforated you may need an operation to mend the hole.

*Risks*

#### 'Risk of death

In extremely rare cases, a person may die as a result of having a colonoscopy. This is very rare and only happens in around 1 in every 10,000 colonoscopies. The benefits of having a colonoscopy far outweigh the risks' (Macmillan Cancer Support, 2010, pp. 19-20).

*Risks*

#### How reliable is a colonoscopy?

Although a colonoscopy is not a perfect procedure, it is over 90% accurate for detecting bowel cancer (Screening for colorectal cancer in adults of average risk. Annals of Internal Medicine, 2002, 137(2), 132-141). There is a small chance that the specialist will not see the cancer or polyp (about five in every 100 people having colonoscopy). This means that either the cancer could not be seen because the bowel was not completely empty or, on rare occasions, the specialist missed the polyp or cancer. There is also a small chance that the specialist was not able to pass the colonoscope along the whole length of the bowel (about five in every 100 people). This can happen because of a blockage or difficulty in negotiating the colonoscope around the bowel' (NHS Bowel Cancer Screening Programme, 2006, p. 8).

*Bowel cancer info*

Although having a colonoscopy is the best way to diagnose bowel cancer, there is a very small chance that the specialist will not see a cancer during the procedure. This may happen in around 1 out of every 20 people (5%). This can happen because the bowel wasn't completely empty, or the colonoscopist wasn't able to pass the colonoscope through the whole length of the bowel, or because the specialist missed the cancer during the investigation.

*Physical involvement (before)*

*Bowel cancer info*

If you are concerned about the results of colonoscopy, particularly if you have ongoing symptoms, you should discuss this with your GP' (Macmillan Cancer Support, 2010, p. 23).

#### What if treatment is needed?

Most polyps found during a colonoscopy can be painlessly removed during the investigation using a wire loop passed down the colonoscope. This is called a polypectomy.

*Outpatient?*

If the colonoscopy shows that you need more treatment, you will be able to discuss this with a team of specialists. Usually this involves more tests to work out the exact place and type of cancer, so that you and the team of specialists can decide on the best course of action and treatment. The three main treatments for bowel cancer are surgery, chemotherapy and radiotherapy. Depending on how advanced the cancer is when it is detected, two or more types of treatment may be used at the same time, or one following the other. Treatment will always be tailored to your needs, after discussions with the team involved with your care' (NHS Bowel Cancer Screening Programme, 2006, p. 11).

*Bowel cancer info*

#### What happens to tissue samples?

If tissue samples were taken during the colonoscopy, the result is recorded onto a database and the tissue sample is destroyed. We regularly review all screening records as part of our aim to offer you a quality service and to help increase the expertise of specialist staff. This means that staff who work elsewhere in the health service will need to see your records' (NHS Bowel Cancer Screening Programme, 2006, p. 13).

*Outpatient?*

*Bowel cancer info*

## Appendix 17 Differentiating the standard and the factors based patient information resource

The standard and the factors based patient information resource are differentiated using the following legend:

Standard patient information resource only

Factors based patient information resource only

Both patient information resources (same wording)

Both patient information resources (different wording)

*The word count for the standard and the factors based patient information resource, not including headings and subheadings, is 1,083 words and 1,005 words, respectively.*

## Standard patient information resource

# Colonoscopy

## Patient Information

### What is a colonoscopy?

A colonoscopy is an investigation used to look at the lining of the large bowel, which is also known as the large intestine or the colon. It is performed using a thin flexible tube called a colonoscope, which is passed into your rectum (back passage) and guided around your large bowel.

### What do you need to do before a colonoscopy?

Your bowel needs to be completely empty during the colonoscopy so that the specialist doctor performing the investigation can clearly see. You will receive instructions telling you what you need to do to prepare. You will usually be asked to:

- stop taking any iron tablets – these make the inside of the bowel look black, which means it is hard for the doctor to clearly see;
- eat a special diet and drink lots of clear fluids in the days before the colonoscopy; and
- take a strong laxative the day before the colonoscopy, which will give you diarrhoea. You will need to stay close to a toilet.

It is important that you follow instructions very carefully to fully empty your bowel. Otherwise the doctor may not be able to clearly see the lining of your bowel during the colonoscopy and you will need to have the investigation again.

You may need to arrange for someone to accompany you home after the colonoscopy as patients are usually given a sedative and you may feel drowsy if given one.

### What happens during a colonoscopy?

You will be asked by a nurse who will be assisting the specialist doctor performing the colonoscopy to put on a hospital gown that opens at the back. You will usually be given a sedative to help you relax, which is usually given by an injection into a vein in the back of your hand. If you have a sedative you will feel drowsy and won't remember much about the colonoscopy.

You will be asked to lie on your side and a thin flexible tube called a colonoscope is passed into your rectum and guided around your large bowel. Lubricating jelly will be used to make this as easy as possible. At the end of the colonoscope there is a small camera with a light attached, which allows the doctor to see the inside of your bowel on a TV screen. You may be able to see the screen too if you wish. During the colonoscopy you may be asked to change position, which will help the doctor investigate different areas of your bowel.

When the colonoscopy is being performed, some air will be pumped down a channel in the colonoscope into your bowel to allow the doctor to clearly see the lining of your bowel. This

may give you a bloating or cramping feeling in your abdomen, and may cause you to pass wind but this is normal and there is no need to feel embarrassed as the doctor and nurse will expect this to happen.



Sometimes a small tissue sample called a biopsy will be taken or polyps (small lumps of tissue that hang from the lining of the bowel) will be removed. This is done painlessly using instruments that are passed down the colonoscope. Tissue samples will be sent to a laboratory for testing and to be looked at under a microscope.

At the end of the investigation the colonoscope is gently pulled out. The colonoscopy should take between 30 and 45 minutes. Some patients find having a colonoscopy uncomfortable but most do not report that it is painful. Most patients are ready to go home a couple of hours after a colonoscopy.

#### **What happens after a colonoscopy?**

The specialist doctor who performed the colonoscopy will explain the outcome of the investigation to you. You will be told if any tissue samples or polyps were removed. If tissue samples were removed you should receive test results of the samples in three weeks.

You may notice traces of blood coming from your rectum if tissue samples or polyps were removed. Slight bleeding like this is not uncommon and may last for a few days. You should report any symptoms of prolonged or heavy bleeding (such as cramping, stomach pains, fever and heavy bleeding from your rectum) to the colonoscopy unit or your GP.

The effects of the sedative takes some time to wear off and you should make sure that you do not drive, use machinery or drink alcohol for at least 24 hours. You should also avoid making important decisions until 24 hours after the colonoscopy. You will need somebody to accompany you home and you should also have someone stay with you for 12 hours afterwards. It is a good idea for you to have someone with you when the doctor explains the outcome of the colonoscopy as you will still be feeling the effects of the sedative.

#### **Are there any side-effects or risks from having a colonoscopy?**

Taking a strong laxative the day before a colonoscopy may cause you to lose a lot of fluid from your body as you pass several bowel motions to empty your bowel. If you have heart problems you should let your GP know before you take any laxatives as this fluid loss can temporarily worsen your condition.

After having a colonoscopy you may feel bloated and uncomfortable due to trapped wind. You may find that lying on your front can help. Trapped wind usually passes after a few hours.

The specialist doctor performing the colonoscopy may not be able to pass the colonoscope along the whole length of your bowel. It is estimated that this happens in about five out of every 100 people who have a colonoscopy. This can happen because of a blockage (if your bowel is not completely empty) or difficulty in moving the colonoscope around your bowel. You may be asked to have another colonoscopy or a different investigation.

If tissue samples or polyps are removed during a colonoscopy this may cause heavy bleeding that needs further investigation or medical advice. It is estimated that this happens in about one out of every 150 people who have a colonoscopy.

The colonoscope could cause a hole (perforation) in the wall of your bowel. It is estimated that this happens in about one out of every 1,500 people who have a colonoscopy. If this happens you may need an operation.

You may have a reaction to the sedative that may make you have temporary breathing or heart problems. Serious problems are rare as you will be carefully monitored during a colonoscopy.

In extremely rare cases a colonoscopy could lead to death. It is estimated that this happens in about one out of every 10,000 people who have a colonoscopy.



## Factors based patient information resource

# Colonoscopy

## Patient Information

### What is the purpose of a colonoscopy?

To investigate the lining of the large bowel, which is also known as the large intestine or the colon.

### What is required of you before, during and after a colonoscopy?

#### Before a colonoscopy

Your bowel needs to be completely empty during the colonoscopy. You will receive instructions telling you what you need to do to prepare and it is important that you follow these instructions very carefully. You will usually be asked to:

- stop taking any iron tablets – these make the inside of the bowel look black, which means it is hard for a specialist doctor performing the colonoscopy to clearly see;
- eat a special diet and drink lots of clear fluids in the days before the colonoscopy; and
- take a strong laxative the day before the colonoscopy, which will give you diarrhoea. You will need to stay close to a toilet.

#### During a colonoscopy

You will be asked by a nurse who will be assisting the specialist doctor performing the colonoscopy to put on a hospital gown that opens at the back. You will be asked to lie on your side and a thin flexible tube called a colonoscope is passed into your rectum and guided around your large bowel. Lubricating jelly will be used to make this as easy as possible. Some air will be pumped down a channel in the colonoscope into your bowel to allow the doctor to clearly see the lining of your bowel and you may be asked to change position, which will help the doctor investigate different areas of your bowel. At the end of the investigation the colonoscope is gently pulled out.



The colonoscopy is performed and assisted by qualified healthcare professionals who have

been trained in and have experience of the investigation, and who will not feel uncomfortable or embarrassed about it.

The doctor may not be able to pass the colonoscope along the whole length of your bowel. It is estimated that this happens in about five out of every 100 people who have a colonoscopy. This can happen because of a blockage (if your bowel is not completely empty) or difficulty in moving the colonoscope around your bowel. You may be asked to have another colonoscopy or a different investigation.

#### After a colonoscopy

You will be monitored before you can go home.

### What does a colonoscopy actually do?

At the end of a colonoscope there is a small camera with a light attached, which allows the specialist doctor performing the colonoscopy to see the inside of your bowel on a TV screen. You may be able to see the screen too if you wish.

Sometimes a small tissue sample called a biopsy will be taken or polyps (small lumps of tissue that hang from the lining of the bowel) will be removed. This is done using instruments that are passed down the colonoscope. Tissue samples will be sent to a laboratory for testing and to be looked at under a microscope.

The doctor will explain the outcome of the investigation to you after the colonoscopy. You will be told if any tissue samples or polyps were removed. If tissue samples were removed you should receive test results of the samples in three weeks.

### How long will a colonoscopy take?

A colonoscopy should take between 30 and 45 minutes. Most patients are ready to go home a couple of hours after a colonoscopy.

### Is there any pain or discomfort during a colonoscopy?

You will usually be given a sedative to help you relax during a colonoscopy, which is usually given by an injection into a vein in the back of your hand. If you have a sedative you will feel drowsy.

A bloating or cramping feeling in your abdomen may be experienced when air is being pumped into your bowel during a colonoscopy. This may cause wind to be passed.

Some patients find having a colonoscopy uncomfortable but most do not report that it is painful. The removal of tissue samples or polyps is painless.

### Are there any side-effects from having a colonoscopy?

After having a colonoscopy you may feel bloated and uncomfortable due to trapped wind. You



may find that lying on your front can help. Trapped wind usually passes after a few hours.

If you have a sedative you won't remember much about the colonoscopy. The effects of the sedative takes some time to wear off and you should make sure that you do not drive, use machinery or drink alcohol for at least 24 hours. You should also avoid making important decisions until 24 hours after the colonoscopy. You will need somebody to accompany you home and you should also have someone stay with you for 12 hours afterwards. It is a good idea for you to have someone with you when the doctor explains the outcome of the colonoscopy as you will still be feeling the effects of the sedative.

You may notice traces of blood coming from your rectum if tissue samples or polyps were removed during a colonoscopy. Slight bleeding like this is not uncommon and may last for a few days. You should report any symptoms of prolonged or heavy bleeding (such as cramping, stomach pains, fever and heavy bleeding from your rectum) to the colonoscopy unit or your GP as further investigation may be needed. It is estimated that this happens in about one out of every 150 people who have a colonoscopy.

#### ***Are there any risks from having a colonoscopy?***

Taking a strong laxative the day before a colonoscopy may cause you to lose a lot of fluid from your body as you pass several bowel motions to empty your bowel. If you have heart problems you should let your GP know before you take any laxatives as this fluid loss can temporarily worsen your condition.

The colonoscope could cause a hole (perforation) in the wall of your bowel. It is estimated that this happens in about one out of every 1,500 people who have a colonoscopy. If this happens you may need an operation.

You may have a reaction to the sedative that may make you have temporary breathing or heart problems. Serious problems are rare as you will be carefully monitored during a colonoscopy.

In extremely rare cases a colonoscopy could lead to death. It is estimated that this happens in about one out of every 10,000 people who have a colonoscopy.


## Appendix 18 Description of tools for assessing patient information resources and their suitability for evaluating the standard and the factors based patient information resource


Tool	Suitability
<p><b>Acceptability</b> (O'Connor and Cranney, 2002; O'Connor <i>et al.</i>, 1998a, O'Connor <i>et al.</i>, 1998b; O'Connor <i>et al.</i>, 1999b) A questionnaire that measures comprehensibility of components of a decision aid, its length, pace (if audiovisual), amount of information, balance in presentation of information about healthcare options and overall suitability for decision-making. There is a patient version and healthcare professional version.</p>	<p>This <i>tool or an adaptation of it could be used</i> to measure the design and presentation of the patient information resources, and their suitability for decision-making. O'Connor and Cranney (2002) comment that 'acceptability questionnaires are used during the development process and early evaluation of a decision aid [and that feedback] is used to refine the decision aid'.</p>
<p><b>Autonomy Preference Index</b> (Barry <i>et al.</i>, 1997; Bernstein <i>et al.</i>, 1998; Ende <i>et al.</i>, 1989) A scale that measures decision-making and information-seeking preferences.</p>	<p>Though this may be an interesting measure, participants who decide to participate in the study may be more inclined to be involved in healthcare decisions and to seek health information when required. However, <i>brief questions could be used</i> to enquire about participants' preferred role in decision-making and their health information-seeking behaviours, which may be of interest.</p>
<p><b>Confidence to Decide about Treatment Scale</b> (Kryworuchko <i>et al.</i>, 2008; McBride <i>et al.</i>, 2002) A scale that measures level of confidence in ability to understand benefits and risks, ability to make a decision and ability to discuss with a healthcare professional about a possible treatment.</p>	<p>Though this tool measures level of confidence in deciding about treatments, an <i>adaptation of it could be used</i> to measure participants' abilities to understand benefits and risks; make a healthcare decision related and relevant to the patient information resources; and to discuss with a healthcare professional, if required, about such a decision.</p>
<p><b>Control Preferences Scale</b> (Almyroudi <i>et al.</i>, 2011; Davison and Breckon, 2012; Davison and Degner, 1997; Davison <i>et al.</i>, 1999; Kryworuchko <i>et al.</i>, 2008) A scale that measures preferred role in decision-making.</p>	<p>Though this may be an interesting measure, participants who decide to participate in the study may be more inclined to be involved in healthcare decisions. However, a <i>brief question could be used</i> to enquire about participants' preferred role in decision-making, which may be of interest.</p>
<p><b>Decisional Conflict Scale</b> (Davison <i>et al.</i>, 1999; Dolan and Frisina, 2002; Goel <i>et al.</i>, 2001; Kryworuchko <i>et al.</i>, 2008; O'Connor, 1995; O'Connor, 2010; O'Connor <i>et al.</i>, 1998a; O'Connor <i>et al.</i>, 1998b; O'Connor <i>et al.</i>, 1999b) A 16 item scale with five subscales that measure: 1) agreement with feeling informed; 2) clarity of benefits, risks and side-effects; 3) support to make a decision; 4) level of certainty in making a decision; and 5) satisfaction with decision.</p>	<p>This <i>tool or an adaptation of it could be used</i> to measure how informed participants felt after using the patient information resources, as well as clarity of benefits, risks and side-effects, and level of certainty in making a related and relevant healthcare decision.</p>
<p><b>Decisional Regret Scale</b></p>	<p>This <i>tool is not of relevance</i> as the study will not be measuring healthcare</p>

(O'Connor, 2003a; Goel <i>et al.</i> , 2001) A scale that measures past healthcare decisions after a period of time for reflection.	decisions after a period of time for reflection.
<b>Decision Self-Efficacy Scale</b> (O'Connor, 2002a) A scale that measures self-confidence or belief in decision-making abilities.	Though this may be an interesting measure, participants who decide to participate in the study may have more self-confidence or belief in their decision-making abilities. However, a <b>brief question could be used</b> to enquire about participants' self-confidence or belief in their decision-making abilities, which may be of interest.
<b>Genetic Testing Knowledge Questionnaire</b> (Green <i>et al.</i> , 2001; Lerman <i>et al.</i> , 1997; Kryworuchko <i>et al.</i> , 2008; Schwartz <i>et al.</i> , 2001) A questionnaire that measures the understanding and retention of information.	Though this tool measures understanding and retention of information for genetic testing, an <b>adaptation of it could be used</b> to measure whether participants can recall information from the patient information resources with clarity.
<b>Information Styles Questionnaire</b> (Almyroudi <i>et al.</i> , 2011; Cassileth <i>et al.</i> , 1980; Fallowfield <i>et al.</i> , 1995) A questionnaire that measures general and specific information preferences, and preferred role in decision-making.	An <b>adaptation of this tool could be used</b> to measure what information is desired by participants having used the patient information resources. Though for measuring preferred role in decision-making, this may be of less relevance as participants who decide to participate in the study may be more inclined to be involved in healthcare decisions. However, a <b>brief question could be used</b> to enquire about participants' preferred role in decision-making, which may be of interest.
<b>Knowledge</b> (O'Connor, 2004a; O'Connor <i>et al.</i> , 1998a; O'Connor <i>et al.</i> , 1998b) A questionnaire that measures knowledge of a clinical problem, its alternatives, rationale, main benefits, risks and side-effects; items considered essential for decision making.	An <b>adaptation of this tool could be used</b> to measure whether participants can recall information from the patient information resources with clarity.
<b>Measures of Decision/Choice Predisposition</b> (O'Connor, 2003b; O'Connor <i>et al.</i> , 1998a; O'Connor <i>et al.</i> , 1998b) A scale that measures propensity to a decision before or after a decision aid intervention, a questionnaire that measures decision intention just after a visit with a clinician, and a questionnaire that measures implemented decision several months after visit with clinician.	This <b>tool is not of relevance</b> as the study will not be measuring healthcare decisions, whether propensity to decisions, decision intentions or implemented decisions.
<b>Preparation for Decision Making Scale</b> (Graham and O'Connor, 2010) A scale that measures perception of how useful a decision aid intervention is in preparing to discuss with a healthcare professional a healthcare decision.	An <b>adaptation of this tool could be used</b> to measure participants' perceptions of how useful the patient information resources would be in preparing them to discuss with a healthcare professional a related and relevant healthcare decision.
<b>Process of Decision-Making</b> (Kryworuchko <i>et al.</i> , 2008; Michie <i>et al.</i> , 1997) A scale that measures how much time was spent thinking about a decision, how many people the	An <b>adaptation of this tool could be used</b> to measure whether the patient information resources would facilitate decision-making.

decision was discussed with, how many reasons were considered for and against the decision, and how difficult it was to make the decision.	
<b>Realistic Expectations</b> (O'Connor, 2002b; O'Connor <i>et al.</i> , 1998a; O'Connor <i>et al.</i> , 1998b) A questionnaire that measures perception of possible health outcomes.	This <b>tool is not of relevance</b> as the study will not be measuring perceptions of health outcomes.
<b>Satisfaction with Decision</b> (Kryworuchko <i>et al.</i> , 2008; McBride <i>et al.</i> , 2002) An instrument that measures agreement with feeling informed, whether a decision was consistent with values and overall satisfaction with a decision.	This <b>tool or an adaptation of it could be used</b> to measure how informed participants felt after using the patient information resources and whether they would facilitate decision-making for a related and relevant healthcare decision that would be consistent with their values.
<b>Satisfaction with Decision Made Questionnaire</b> (Barry <i>et al.</i> , 1997; Bernstein <i>et al.</i> , 1998; Kryworuchko <i>et al.</i> , 2008) A questionnaire that measures whether the right decision was made, satisfaction with that decision and the quality of the decision made.	This <b>tool is not of relevance</b> as the study will not be measuring implemented healthcare decisions.
<b>Stage of Decision Making</b> (O'Connor, 2003c) A questionnaire that measures readiness to engage in decision-making, progress in making a decision and receptivity to consider or reconsider decision.	This <b>tool is not of relevance</b> as the study will not be measuring healthcare decisions, whether readiness to engage in decision-making, progress in making decisions and receptivity to consider or reconsider decisions.
<b>Satisfaction with Decision Making Process Questionnaire</b> (Barry <i>et al.</i> , 1997; Bernstein <i>et al.</i> , 1998; Kryworuchko <i>et al.</i> , 2008; Morgan <i>et al.</i> , 2000) A questionnaire that measures agreement with feeling informed and satisfied with information received, support from healthcare professionals, and level of involvement in decision-making.	An <b>adaptation of this tool could be used</b> to measure how informed participants felt after using the patient information resources and their satisfaction with them.
<b>Values</b> (O'Connor, 2004b; O'Connor <i>et al.</i> , 1998a; O'Connor <i>et al.</i> , 1998b; O'Connor <i>et al.</i> , 1999b) A questionnaire that measures importance of benefits and risks of a decision.	This <b>tool is not of relevance</b> as the study will not be measuring healthcare decisions and benefits and risks of such decisions.

## Appendix 19 Questionnaire for online study to examine the factors based approach to the design of patient information





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This questionnaire is intended to be used after reading the patient leaflet for colonoscopy to assess the content, design and presentation of the information in it. Your feedback is valuable in producing information for colonoscopy and other investigations and tests that meet the needs of patients.

The questionnaire will take approximately 5 minutes to complete. £3 will be donated to Cancer Research UK for each completed questionnaire.

Thank you for your time and effort.

### Section A

- Select 'All of it', 'Almost all of it', 'Most of it but a few bits skipped', 'About half of it', 'Less than half of it', 'Hardly any of it' or 'None of it' to show **how much of the information you read**:
 

All of it	Almost all of it	Most of it but a few bits skipped	About half of it	Less than half of it	Hardly any of it	None of it
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
- Select a score between 1 (Not at all informed) and 7 (Extremely informed) to show **how informed you feel about a colonoscopy** having read the information:
 

Not at all informed	1	2	3	4	5	6	7	Extremely informed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
- Select a score between 1 (Not at all prepared) and 7 (Extremely prepared) to show **how prepared you would feel if you were going to have a colonoscopy** having read the information:
 

Not at all prepared	1	2	3	4	5	6	7	Extremely prepared
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
- Select a score between 1 (No time at all) and 7 (Extremely large amount of time) to show **how much time you think you would spend thinking about a colonoscopy if you had an appointment to have the investigation in two weeks' time**:
 

No time at all	1	2	3	4	5	6	7	Extremely large amount of time
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
- Select a score between 1 (Not at all confident) and 7 (Extremely confident) to show **how**

**confident you would feel about talking to a specialist doctor, nurse or your GP about a colonoscopy** having read the information:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- Select a score between 1 (Not at all helpful) and 7 (Extremely helpful) to show **how helpful you think the information would be for you to talk to a family member or friend about a colonoscopy if you were to have the investigation**:
 

Not at all helpful	1	2	3	4	5	6	7	Extremely helpful
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
- Select a score between 1 (Not at all apprehensive) and 7 (Extremely apprehensive) to show **how apprehensive you feel you would be if you were to have a colonoscopy**:
 

Not at all apprehensive	1	2	3	4	5	6	7	Extremely apprehensive
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
- Select a score between 1 (Not at all embarrassed) and 7 (Extremely embarrassed) to show **how embarrassed you feel you would be if you were to have a colonoscopy**:
 

Not at all embarrassed	1	2	3	4	5	6	7	Extremely embarrassed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### Section B

- Select a score between 1 (Extremely dissatisfied) and 7 (Extremely satisfied) to show **how satisfied you are with information provided about**:
 

	Extremely dissatisfied	1	2	3	4	5	6	7	Extremely satisfied
what body part a colonoscopy is investigating.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
what you would need to do to prepare for a colonoscopy.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
what you would expect to happen to you during a colonoscopy.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
what pain or discomfort you would experience during a colonoscopy.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
how a specialist doctor can see the inside of your bowel.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Continue to next page.

	<i>Extremely dissatisfied</i>	1	2	3	4	5	6	7	<i>Extremely satisfied</i>
how a specialist doctor can take tissue samples or remove polyps.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
what would happen to tissue samples.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
how long a colonoscopy should take.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
how long you should have to wait for test results.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
what side-effects there are from having a colonoscopy.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
what risks there are from having a colonoscopy.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

2) Select a score between 1 (Extremely short amount of time) and 7 (Extremely long amount of time) to show **how you feel about the length of time it took you to read through the information:**

<i>Extremely short amount of time</i>	1	2	3	4	5	6	7	<i>Extremely long amount of time</i>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

3) Select a score between 1 (Extremely too little information) and 7 (Extremely too much information) to show **how you feel about the amount of information provided:**

<i>Extremely too little information</i>	1	2	3	4	5	6	7	<i>Extremely too much information</i>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

4) Select a score between 1 (Extremely easy to understand) and 7 (Extremely difficult to understand) to show **how you feel about the way the information was written:**

<i>Extremely easy to understand</i>	1	2	3	4	5	6	7	<i>Extremely difficult to understand</i>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

5) Select a score between 1 (Extremely negative) and 7 (Extremely positive) to show **how you feel about the way the information was presented:**

<i>Extremely negative</i>	1	2	3	4	5	6	7	<i>Extremely positive</i>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

6) Select a score between 1 (Extremely badly structured) and 7 (Extremely well structured) to show **how you feel about the way the information was structured:**

*Continue to next page.*

	<i>Extremely badly structured</i>	1	2	3	4	5	6	7	<i>Extremely well structured</i>
		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

7) Select a score between 1 (Not at all important) and 7 (Extremely important) to show **how important you feel the picture of a colonoscopy was in helping you understand the investigation:**

<i>Not at all important</i>	1	2	3	4	5	6	7	<i>Extremely important</i>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

8) Select a score between 1 (Not at all helpful) and 7 (Extremely helpful) to show **how helpful you feel the information would be if you were to have a colonoscopy:**

<i>Not at all helpful</i>	1	2	3	4	5	6	7	<i>Extremely helpful</i>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Can you explain what has influenced your answer for how helpful you feel the information would be if you were to have a colonoscopy?

Is there anything that could improve the information?

**Section C**

1) Select 'Less than 1 hour', '1-5 hours', '5-10 hours', '10-15 hours' or 'More than 15 hours' to show **how many hours you spend using the Internet per week:**

<i>Less than 1 hour</i>	<i>1-5 hours</i>	<i>5-10 hours</i>	<i>10-15 hours</i>	<i>More than 15 hours</i>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2) Select 'Desktop computer', 'Laptop', 'Netbook', 'Smartphone', 'Tablet' or 'Other device' to show **what device(s) you use to access the Internet through** (select all that apply):

- ☐ Desktop computer
- ☐ Laptop
- ☐ Netbook
- ☐ Smartphone
- ☐ Tablet
- ☐ Other device

3) Of these devices select **the one that you mostly use to access the Internet through**:

- ☐ Desktop computer
- ☐ Laptop
- ☐ Netbook
- ☐ Smartphone
- ☐ Tablet
- ☐ Other device

4) Select 'All of it', 'Almost all of it', 'Most of it', 'About half of it', 'Less than half of it', 'Hardly any of it' or 'None of it' to show **how much time is spent on this device for personal (non work) use only**:

All of it	Almost all of it	Most of it	About half of it	Less than half of it	Hardly any of it	None of it
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### Section D

For the final section you will be given statements to which you will select 'True' or 'False' to show **which of the statements you think are true or false**. You will then select a score between 1 (Not at all confident) and 7 (Extremely confident) to show **how confident you are in your answer**.

1) **The large bowel is also known as the large intestine or the colon.**

- ☐ True
- ☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

2) **Iron tablets help a specialist doctor performing a colonoscopy see inside the bowel.**

- ☐ True
- ☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

3) **There are no risks to taking a strong laxative the day before a colonoscopy.**

- ☐ True
- ☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

4) **You may be asked to change position during a colonoscopy.**

- ☐ True
- ☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

5) **A colonoscopy should take between 15 and 30 minutes.**

- ☐ True
- ☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

6) **If you have a sedative during a colonoscopy you will probably be ready to go home by yourself a couple of hours after the investigation.**

- ☐ True
- ☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

7) If a specialist doctor takes tissue samples for testing they will explain to you after the colonoscopy the results of the samples.

- ☐ True  
☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

8) If you have a sedative during a colonoscopy you should make sure that you do not drink alcohol for at least 24 hours after the investigation.

- ☐ True  
☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

9) If you experience prolonged or heavy bleeding after a colonoscopy you should not worry as this is not uncommon and may last a few days.

- ☐ True  
☐ False

Confidence in answer:

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

10) You may need an operation if a colonoscope causes a hole (perforation) in the wall of your bowel during a colonoscopy.

- ☐ True  
☐ False

Confidence in answer:

Continue to next page.

Not at all confident	1	2	3	4	5	6	7	Extremely confident
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

## Section E

You have nearly finished the questionnaire. Before you do we would appreciate it if you could tell us your gender, age and ethnicity:

Gender:

- ☐ Female  
☐ Male

Age:

- ☐ 18-23  
☐ 24-29  
☐ 30-39  
☐ 40-49  
☐ 50-59  
☐ 60-69  
☐ 70 or older

Ethnicity:

- ☐ White  
☐ Black  
☐ Asian  
☐ Mixed  
☐ Other

You have now finished the questionnaire. Thank you for participating.

If you have any enquiries or concerns about the study please contact the main researcher, David Keane, via:

Email: eexdk1@nottingham.ac.uk

Telephone: 0115 846 8113

If the main researcher is unable to provide you with a satisfactory response please contact study supervisor, Dr Michael Craven, via:

Email: michael.craven@nottingham.ac.uk

Telephone: 0115 951 3804



## Appendix 20 Coding qualitative data using NVivo 9 (QSR International Pty Ltd., 2010) for two open-ended questions from online study to examine the factors based approach to the design of patient information

Nodes		
Name	Sources	References
Amount of information	2	69
Over informed	2	6
Under informed	2	20
Well informed	2	43
Before, during and/or after the procedure	2	37
Easy to understand, well explained and/or written	2	58
Information segmentation	2	9
Picture of a colonoscopy	2	12
Well laid out, presented and/or structured	2	9

## Appendix 21 Interview schedule for focus groups to examine the factors based approach to the design of patient information

### Introduction

Welcome and purpose of focus group:

*"The purpose of the focus group is to compare the design, content and presentation of two patient leaflets, leaflet one and leaflet two, for an invasive medical test, a colonoscopy, which is used to investigate the lining of the large bowel."*

*(Participants receive both leaflets).*

*"You will hopefully have read both leaflets already but you will have a chance to re-read them in a moment, after which I will ask you some questions. You can discuss your views between each other in response to these questions and the posters on the wall are here if you want to refer to and use them to show what you are actually discussing. The focus group will take approximately 45 minutes. Are there any questions before we begin?"*

*(5-10 minutes to read the leaflets).*

### Questions

*(Use prompts when necessary).*

*"Having just read both leaflets, which did you prefer reading to find out about the investigation?"*

*"Which leaflet has provided you with a clearer understanding of the investigation?"*

*"Do you have a preference for the way the information is structured or laid out in either leaflet?"*

*"And how about the way the information is ordered in both leaflets – do you have a preference for either?"*

*"If you were to have the investigation, what information would be important to you?"*

*"And which leaflet would you prefer for finding out about that information?"*

*"If you were to have the investigation, wanted to find out more about it and you had a choice between these two leaflets, which would you prefer?"*

*"And if you were to talk to a specialist doctor, nurse or your GP about the investigation; would you find it easier to do so having read leaflet 1 or leaflet 2?"*

*"Do you have a preference for the way the information is written in either leaflet?"*

*"Does either leaflet give a positive or negative impression of the investigation?"*

*"Does either leaflet sound more persuasive than the other?"*

*"Is there any information you would like included in either leaflet?"*

*"Is there anything else that could improve either leaflet?"*

### Ending

*"We're coming to the end of the focus group, is there anything anyone would like to add before we finish?"*

*"Or are there any questions?"*

## Appendix 22 Coding qualitative data using NVivo 9 (QSR International Pty Ltd., 2010) from focus groups to examine the factors based approach to the design of patient information

Nodes		
Name	Sources	References
Amount of information	2	53
Over-informed	2	5
General (both information resources)	1	2
Heuristics information resource	0	0
Master information resource	1	3
Under-informed	2	27
General (both information resources)	2	22
Heuristics information resource	2	5
Master information resource	0	0
Well-informed	1	21
General (both information resources)	1	6
Heuristics information resource	1	2
Master information resource	1	13
Easy to understand	2	6
General (both information resources)	1	2
Heuristics information resource	2	3
Master information resource	1	1
How it's written	2	8
General (both information resources)	1	2
Heuristics information resource	1	4
Master information resource	1	2
Navigation	2	27
General (both information resources)	0	0
Heuristics information resource	2	27
Master information resource	0	0
Structure	2	85
Improve structure	2	44
General (both information resources)	2	16
Heuristics information resource	2	18
Master information resource	1	10
Well-structured	2	41
General (both information resources)	0	0
Heuristics information resource	2	39
Master information resource	1	2