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Pharmacy Education: An Exploration of Global Competency-Based Education and the Development of a Localised Competency Framework in Kenya

Thesis submitted to the University of Nottingham for the degree of Doctor of Philosophy by

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Dedicated to Maeve, and to the memory of Tina and Martin. Always with me.

COVID-19 Impact Statement

The COVID-19 pandemic significantly disrupted the intended course of this research, which was initially designed to be carried out exclusively in Kenya. Delays in acquiring a research license were exacerbated by the pandemic's emergence, further complicating efforts to engage in direct, face-to-face interactions with collaborators in Kenya. Consequently, the envisioned Part 2, involving a social network analysis in Kenya, had to be re-evaluated.

The unprecedented disruptions caused by the pandemic led to unavoidable delays in the research timeline, prompting the need for an extension. In response to the challenges posed by the pandemic, a strategic pivot was made towards conducting remote global research on competency-based education (CBE) in pharmacy. This shift in focus allowed for a systematic review of recent literature and the distribution of a global online survey to gather data on CBE implementation challenges and practices across different regions.

Despite the logistical hurdles posed by the pandemic, this adapted approach proved fruitful, yielding valuable insights into the global landscape of CBE in pharmacy. The systematic review uncovered key trends and challenges, while the global survey provided rich data on the diverse implementation practices and barriers faced by pharmacy educators worldwide. By embracing flexibility and resilience in the face of adversity, this research not only adapted to the evolving circumstances but also contributed to a deeper understanding of the challenges and opportunities in modern pharmacy education.

Acknowledgments

This work is dedicated to my late husband Martin whose love, support and encouragement gave me the confidence to pursue this project. Without his unwavering belief in my ability to achieve my goals and aspirations I would not have made it this far. The memory of his positive and inspirational nature has sustained me through many of life's challenging endeavours, including this research. I owe the greatest gratitude to my late mother, Tina who instilled in me a strength and resilience I didn't know I had until I experienced the loss of her presence from my life. Thank you for all of your many sacrifices on the path towards raising an independent, strong, and resilient daughter and for instilling in me the importance of always being willing to learn and grow. I also dedicate this thesis to my own daughter, whose smiles and laughter have carried me through, and who continues to inspire my determination in the face of adversity.

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Publications and Conferences

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ARAKAWA, N., AKEL, M., ANDERSON, C., BAJIS, D., DARWISH, R., KOSTER, A., MCMULLEN, J., & MORRIS, M. 2023. Developing a FIP handbook for implementing competency-based education in pharmacy education. *Pharmacy Education*, *22*(4), p. 150–154. https://doi.org/10.46542/pe.2022.224.150154

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Conferences

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Plagiarism Statement

This thesis describes research conducted at the University of Nottingham between 2018 and 2024 under the supervision of Claire Anderson, Naoko Arakawa and Simon McGrath. I certify that this is original research and any collaborations are made clear. The text within is written by myself and any part of the thesis that has already appeared in publication is clearly indicated by suitable citation.

Signature: 

Date: 01.04.2024

Abstract

Modernisation of health professional education is required globally to meet rapidly evolving healthcare demands. This need is further compounded by anticipated health workforce shortages which are particularly pronounced in low- and middle-income countries. Pharmacists play a key role in the health system, thus underpinning the pressing requirement for pharmacy education to keep abreast of contemporary healthcare needs and create highly skilled competent practitioners capable of meeting those needs. Competency-based education (CBE) is a compelling educational model in which to achieve this due to its emphasis on linking theory to practice and aligning learning outcomes with population needs in a learner-centred approach which focuses on acquiring requisite competencies (skills, knowledge and abilities) rather than course hours or credits. CBE in pharmacy demonstrates a complex landscape influenced by diverse interpretations and implementations. Existing literature discusses various aspects of CBE, including assessment methods, the validity of competency frameworks, and barriers and facilitators to implementation. However, global uptake remains inconsistent. Gaps in the literature are evident in low- and middle-income countries despite the potential for CBE to address needs-based educational reform for pharmacy. The African region demonstrates the lowest growth of the pharmacy workforce worldwide exacerbating the urgency for focused inquiry in this area where relevant literature is limited.

The aim of this thesis is to provide evidence on the contemporary practices, challenges and opportunities surrounding the use of CBE in pharmacy education. Secondly, this thesis aims to investigate the applicability of the latest Global Competency Framework (GbcFv2) from the International Pharmaceutical Federation (FIP), and adapt this framework to create a locally relevant competency framework for early-career pharmacists in Kenya. The resulting framework provides a tangible resource that can be used as a tool for pharmacy practice development and educational reform. Additionally, this process yields valuable insights on current pharmacy practice in Kenya and highlights potential areas for advancement by shedding light on priority areas for development.

To achieve these aims the thesis comprises of four studies in two parts. The first study, Part 1 Stage (i), of the research is a systematic review of the literature from 2010 to 2021 pertaining to all levels of pharmacy education and training to identify the contemporary features of CBE for pharmacy. A total of 1178 studies were retrieved, 103 were screened and 28 studies met the inclusion criteria from across 14 different countries. Features were identified through an inductive narrative synthesis and compared to themes previously identified in the medical literature. Twenty features, and 21 supporting components of CBE for pharmacy were identified and grouped into 6 central themes; design, systems of instruction and learning methods, feedback and assessment, faculty, resources, and internal and external factors. Moreover, an overarching meta-level theme of a holistic and unified vision and

approach for CBE emerged as crucial to the successful utilisation of CBE. Furthermore, a lack of studies originating from Africa and South East Asia was discovered highlighting a need for further research in these regions.

The second study, Part 1 Stage (ii) of the research employs a global online survey questionnaire distributed to academic institutions delivering pharmacy and pharmaceutical science programmes. A total of 72 responses from 36 different countries underwent descriptive and inferential statistical analyses of the data relating to how CBE is used currently and the challenges experienced in using the CBE approach was conducted. A thematic analysis of the survey data relating to various challenges with using CBE was carried out in a deductive manner on 679 selected multiple choice option responses, using the features of CBE from stage (i) to contextualise the quantitative survey data to the current literature and provide a deeper understanding of the prevalence of challenges reported for each feature for the purpose of guiding future research and development. Challenges relating to the feature of CBE associated with faculty preparedness for the delivery of CBE was found to be the most frequently encountered obstacle to using CBE (n = 141, 20.8%). Additionally, perceived advocacy for CBE by the professional pharmacy and educational regulatory bodies for pharmacy was found to have a statistically significant ($p<0.05$) effect on the use of CBE when subjecting the data to a 2-sided Fisher's exact test. Responses were received from all 6 of the World Health Organization global regions, with the majority originating from Europe (45.8%). A limited number of responses from Africa (2.8%) and South East Asia (2.8%) were observed, reflecting the lack of representation form these regions in the first study and reinforcing the need for focused inquiry in these areas in the field of CBE for pharmacy.

The third study, Part 2 Stage (i), is a quantitative online survey questionnaire distributed to practicing pharmacists in Kenya. A total of 130 pharmacists, 72 in patient facing and 58 in non-patient facing roles with an average of 12.6 years of practice experience, ranked the relevance of the behavioural statements in the FIP GbCFv2 to their current practice. The results were presented descriptively and inferential statistical analysis was performed to determine any associations between the relevance ratings for pharmacists grouped in to patient facing (PF) and non-patient facing (NPF) core areas of practice. A high degree of relevance for Kenyan pharmacy practice to the FIP GbCFv2 was demonstrated where 56.1% of the 123 statements in this framework demonstrated a 90% or more agreement in relevance. Inferential analysis using 2-sided Fisher's exact test found that 17 statements demonstrated a statistically significant ($P<0.05$) difference across the Pharmaceutical Care and Professional/Personal competency domains between the PF and NPF groups. This suggests that consideration of a pharmacist's practice setting should be taken into account when assessing perception of relevance within a sector-wide framework. In addition, enhanced use of information technology and error reporting

were highlighted as potential priorities for the advancement of pharmacy practice in Kenya.

The final study utilised a modified Nominal Group Technique (mNGT) consensus development method, consisting of three rounds of voting and two rounds of discussion, with a panel of nine Kenyan pharmacy stakeholders. The panel included representatives from industry, community pharmacy, professional bodies, academia, research, and pharmacy students. Of 31 total amendments, the majority occurred in the largest, Pharmaceutical Care (PC) cluster (51.6%), followed by the Professional/Personal (PP) cluster (25.8%), the Organisation and Management (OM) cluster (12.9%), and finally the smallest, Pharmaceutical Public Health (PPH), cluster (n=9.7%). Major rewording occurred for 7 statements across the PC (n=3), OM (n=2) and PP (n=3) clusters and one competency title in the PC cluster. New statements (n=2) were added in the PPH and the PC clusters and both related to safe and environmentally friendly disposal of medicines. This process led to the adaptation of the FIP GbCFv2 to reflect local pharmacy practice, resulting in the creation of Kenya's first competency framework for pharmacists, containing 124 behavioural statements. In agreement with the 3rd study, a high degree of relevance (≥90% agreement) for the FIP GbCFv2 was demonstrated overall and the majority of amendments required were minor (re-numbering or grammatical changes, n=16). However, a gap in the FIP GbCFv2 regarding environmentally sustainable pharmacy practices was identified leading to the addition of 2 new statements. These statements focused on promoting green pharmacy practice and reducing pharmaceutical waste, which were considered critical to addressing Kenya's unique environmental challenges.

The research presented in this thesis offers a comprehensive overview of CBE practices worldwide and identifies gaps in the literature for 2 global regions. The focus on competency framework development in Kenya provides a much needed contribution to the literature in Africa. The robust systematic method adopted to create a tool in the form of a nationally relevant competency framework offers a sustainable resource for the further advancement of CBE and pharmacy practice specific to the Kenyan context. Furthermore, this process demonstrates promise for other countries in this region to carry out similar initiatives and represents the first study of its kind using the FIP GbCFv2 in Africa. The findings in this thesis present a comprehensive overview of modern CBE for pharmacy and puts a spotlight on the importance of a system-wide approach to CBE implementation. Particular focus should be paid to a unified and synergistic collaboration between pharmacy practice, regulation and education, echoing previous research in the closely linked medical field, and emphasising the influence of interconnected external factors on the pharmacy education system.

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List of Acronyms

BPharm	Bachelor of Pharmacy
CBE	Competency-based education
CCG	Clinical Commissioning Group
CUE	Commission for University Education
DFID	Department For International Development
ERIC	Education Resources Information Center
FIP	International Pharmaceutical Federation
FIP*Ed*	FIP Education
GbCF	Global Competency Framework
HNA	Health Needs Assessment
HRH	Human Resources for Health
IRB	Institutional Review Board
KAM	Kenyan Association of Manufacturers
KMA	Kenya Medical Association
MDGs	Millennium Development Goals
MMAT	Mixed Methods Analysis Tool
mNGT	Modified Nominal Group Technique
MoU	Memorandum of Understanding
MPharm	Masters of Pharmacy
NACOSTI	National Commission for Science, Technology & Innovation
NCDs	Non-communicable diseases
NNAK	National Nursing Association of Kenya
NHS	National Health Service
PharmD	Doctor of Pharmacy
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
REC	Research Ethics Committee
SA	Stakeholder's Analysis
SDGs	Sustainable Development Goals
SNA	Social Network Analysis
SPHEIR	Strategic Partnerships for Higher Education, Innovation and Reform
UHC	Universal Health Coverage

UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNITWIN	University Twinning and Networking Programme
UoN	University of Nottingham
USD	US dollars
WHO	World Health Organization

Chapter 1: Introduction

1.1 Background

1.1.1 Sustainable Development

The World Health Organization (WHO) estimates that at least half of the world's population are lacking access to sufficient health-care services. Furthermore, unexpected illness can drive people further into poverty hampering long-term economic development especially for the 100 million people living in extreme poverty (World Health Organization, 2019). Taking into account the magnitude of people failing to receive adequate health-care, and the impact this has on wider systems, the WHO has committed to striving for Universal Health Coverage (UHC). UHC denotes that 'all individuals and communities receive the health services they need without suffering financial hardship' (World Health Organization, 2019). Widespread adoption of this concept was accepted following the publication of the World Health Report 2010 entitled 'Health systems financing: the path to universal coverage' (World Health Organization, 2010b). This recognised that health is both an essential prerequisite, and a desirable product of development which intersects all three principal dimensions of sustainable development—societal, environmental and economic (World Health Organization, 2010b).

In 2015, the United Nations (UN) embraced UHC as a fundamental component of the 2030 Sustainable Development Agenda. In this agenda all member states of the UN agreed on the Sustainable Development Goals (SDGs)[1] in a unified objective to end poverty, protect humanity and secure the planet (United Nations, 2015). UHC falls under SDG3: 'Ensure healthy lives and promote well-being for all at all ages'. Given that better health precedes improved engagement in work and education for instance, it can be posited that UHC will contribute towards several goals, beyond that of simply SDG3 alone, and is therefore crucial to global and individual welfare. Conversely, progress in non-health SDGs will in turn support the attainment of UHC. For example, successful strategies which foster peace and prosperity, reduce inequality and provide quality education (SDGs 16, 10 and 4 respectively) facilitate circumstances complimentary to furthering the advancement of UHC. In other words, good health is not only a result of, but also a condition for development, security, and rights (Frenk et al., 2010).

1.1.2 Global Health Workforce Crisis

Workforce intelligence from the WHO projects a substantial deficit in health workers around the globe especially in low- and middle-income countries where, by 2030, a shortage of 18 million health care workers is expected (World Health Organization, 2016a). Consequently, priority has been placed on creating a strategy to address this global health workforce crisis as outlined in the 'Global strategy on human resources

[1] There are 17 Sustainable Development Goals each with a clear aim and a defining set of sub-goals. UHC is defined in SDG 3, target 3.8 'Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, quality and affordable essential medicines and vaccines for all' UNITED NATIONS. 2015. Transforming our world: The 2030 agenda for sustainable development. 2018. Available: https://sdgs.un.org/2030agenda [Accessed 8th March 2024].

for health: Workforce 2030' document published by the WHO in 2016 (World Health Organization, 2016a). In this document, emphasis is on strengthening health systems through enhancing the healthcare workforce. The challenge is more comprehensive than purely increasing the size of the workforce, as availability is not the only constituent of effective health service coverage. In addition the workforce must be equitably distributed and equipped with appropriate competency, motivation and empowerment to deliver quality healthcare relevant to the sociocultural needs and expectations of individual populations. Furthermore, together with consideration of specific strategies in terms of the healthcare workforce, otherwise referred to by WHO as 'human resources for health' (HRH). Workforce development also necessitates political will and resource mobilisation in order to achieve the required advancements in HRH crucial for accomplishing the desired outcome of improved health conditions worldwide (World Health Organization, 2016a).

In the post-2015 sustainable development 'good health and well-being' agenda, the importance of HRH in contributing to improved health outcomes is recognised in target 3.C: to 'substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States' (United Nations, 2015). It is logical to expect that considered efforts and investment in HRH would have positive impacts on effective health coverage. Evidence in favour of the incorporation of this target into the health agenda demonstrates that there is a correlation between improved health outcomes when there is dedicated investment and development in HRH for an assortment of countries with varying income levels (Campbell et al., 2013, Van Lerberghe et al., 2014).

The WHO acknowledges that although HRH progress has been made there are still significant limitations such as, but not restricted to; poor working conditions, inefficient use of resources, skewed gender distributions, ageing workforces, shortages and maldistribution (World Health Organization, 2016a). In addition to concerns regarding recognised HRH limitations, there are also concerns about shifting health care needs and demands. Globally over the past 35 years life expectancy from birth has increased by 10 years. With this ageing population there has been a significant reduction overall in deaths from communicable, maternal, neonatal and nutritional disease and an increase in non-communicable diseases (NCDs) (GBD Mortality And Causes Of Death, 2016). Healthcare demands are constantly evolving and the health workforce needs to have the necessary quantity, quality and relevance to be able to respond to new medical and technical developments in combination with contemporary health priorities; whether it is shifts in epidemiology, ageing populations, conflict, increasing obesity or pandemics (GBD Mortality And Causes Of Death, 2016).

In addition the WHO acknowledge that team-based care at the primary level, in studies of various medical conditions, is superior to that of physician-only led care (Milani and Lavie, 2015). Many countries are still however reliant heavily on physician-led services (World Health Organization, 2014b). Furthermore, people-centred and integrated health services are considered more responsive, financially sustainable and of better quality (World Health Organization, 2015). As a result the

global strategy on human resources for health incorporates a much wider typology of health worker than previous strategies moving beyond that of the conventional physician, nurse and midwifery cadres. Pharmacists and dentists are just some of those mentioned in the strategy to promote closer collaboration of health workers who should be encouraged to operate within the full scope of their practice in order to create a more sustainable and responsive mix of skills in primary care (World Health Organization, 2016a). Recognition is also growing for the healthcare workers role as agents for change in society with the potential to redirect attention to primary level care and combat social determinants of health (World Health Organization, 2014b).

1.1.3 Effective Health Coverage Necessitates an Effective Healthcare Workforce

Any health service is only as effective as those responsible for providing it (World Health Organization, 2014b). The issues concerning the global health workforce crisis are multifarious, extending further than that of a mere issue of shortages. In order to improve health outcomes worldwide, more focus is needed on all dimensions of developing and sustaining an effective workforce. As detailed in **Figure 1**, the dimensions requiring consideration include accessibility, acceptability, quality and productivity of the health workforce, with equity at the core of the agenda (World Health Organization, 2014b).

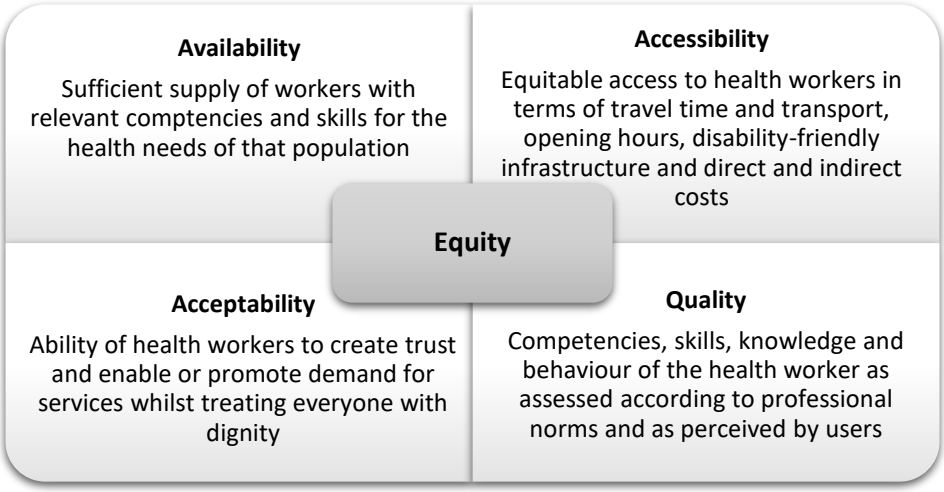


Figure 1 Human resources for health dimensions of Universal Health Coverage[2]

For the WHO, the dimension of quality is an area that has not received sufficient attention, according to their 2014 report entitled 'A Universal Truth: No Health without a Workforce'. The authors identified quality as a major challenge in all countries, citing an insufficient priority on both performance assessment and quality of care (World Health Organization, 2014b). To put it succinctly, deficits in quality for HRH are proving a significant and pervasive 'bottleneck' or barrier to the attainment of universal health coverage. Consequently, they summarise that there is still work

[2] Adapted from: WORLD HEALTH ORGANIZATION. 2014b. A Universal Truth: No Health Without a Workforce. Available: https://www.who.int/workforcealliance/knowledge/resources/hrhreport2013/en/.

to be done in ensuring that health workers achieve the appropriate competencies – their skills, knowledge and behaviour - to deliver the quality health services necessary to meet people's needs. Educational strategies therefore warrant a drive towards developing relevant competencies for an effective 21st century health workforce and the realisation of UHC (World Health Organization, 2014b).

1.2 Health Professional Education and Equitable Healthcare in the Twenty-first Century

1.2.1 Inadequacies of Health Professional Education

Effective healthcare requires a certain quality of human resources for health and health professional education that aligns with current epidemiological, demographic, and technological shifts, responding to the evolving health demands within an increasingly interconnected global health system (Frenk et al., 2010). However, existing health professional education systems have lagged behind due to a rapid decline in knowledge half-life, intensifying the complexity of the healthcare world (Gonczi and Hager, 2010). Major reports on health professional education in the twenty-first century, reveal that current health professional education is inadequate for contemporary needs (Frenk et al., 2010, Cooke. M., 2010). This is due to various reasons, including current focus on technical skills without broader contextual understanding, competencies that are mismatched with patient and population needs, weak professional leadership and imbalanced pressures on the health-professional labour market (Frenk et al., 2010).

Globalisation, driven by international information sharing and resource reliance, influences health professional education positively by promoting awareness and openness but also poses challenges, including workforce attrition through migration (Chen et al., 2004, Frenk et al., 2010, McPake et al., 2015, Global Health Workforce Alliance, 2008, World Health Organization, 2006). In recognition of this, both the WHO and The Commonwealth encourage countries to develop their own bespoke workforce supporting the retention of locally trained professionals (World Health Organization, 2010a, Commonwealth Secretariat, 2003).

The global burden of disease is at its highest in the region of Sub-Saharan Africa, yet this is not reflected in the distribution of professional education as it has the lowest concentration of medical schools worldwide (Frenk et al., 2010, Eastwood et al., 2005). Many countries in this region also fell below the sample mean for the quantity of pharmacy schools and faculties in a study conducted by the International Pharmaceutical Federation in 2013 (International Pharmaceutical Federation, 2013). Furthermore, in the more recent version of this report, despite the highest proportional increase, the Africa region has the lowest pharmacy workforce capacity of all the WHO regions (International Pharmaceutical Federation, 2018). Global collaboration initiatives have been adopted in an attempt to address some of the concerns regarding the distribution of medical training institutions, which is neither relative to levels of disease burden, nor population size (Horton, 2000). Collaboration between educational institutions aimed at increasing the capacity for educational, research, and service functions through the pooling of resources and talents, and strengthening the professional education knowledge base is encouraged (Frenk et al.,

2010, Horton, 2000). Regional and professional adaptation and relevance is key however, as mere transplantation of the approach of one institute into a disparate setting is likely to be poorly received and ineffective (Crisp, 2010).

In addition to these challenges, the health professions often operate in silos, hindering interdisciplinary coordination (Frenk et al., 2010). While professionalism should promote teamwork, it can inadvertently create barriers and protect privilege (Starr, 1982). To address these issues, health professional education reforms should adopt a multi-professional, systems-based approach to mitigate global inadequacies and foster equitable healthcare advances (Frenk et al., 2010).

1.2.2 Needs-based Education

The drivers of the health system, and therefore the health professional education system should be guided by the needs of the population, as reflected in the UHC agenda. Frenk et al (2010) attempt to highlight the interaction between the education and health systems through a framework that incorporates the needs of the population, due to the fact that this component is often depicted as an exogenous component to the interaction of these systems. As this paper is very much geared towards the Universal Health Coverage agenda, it can be understood why they developed the framework in this way. However, it does reflect only a small sub-section of the education system and detracts from its various other roles and functions. This is referred to later on however, as the authors recognise that the tenet of this framework is not to imply a subordinate position of the education system. In fact, they acknowledge its importance for the generation of evidence concerning shortcomings within the health system as well as recommending improvements, and producing professionals who can implement change.

This fundamental link between professional education and health is further complicated however by market forces. From an economic standpoint, students often seek out courses that provide them with the skills applicable to market needs, rather than population needs in order to maximise the return on their educational investment (McPake et al., 2015). Furthermore, recent surges in profit-driven private educational institutions particularly in lower and middle-income countries, where educational quality in these institutions is a concern (Altbach et al., 2010), and commercial funding has resulted in programmes influenced by market forces (McPake et al., 2015). Despite governmental and global attempts to steer healthcare workforce development towards population needs, in keeping with the SDGs for instance, these influential market forces can be a hindrance to the needs-based agenda. Therefore, imbalance between these systems is complex and ideally the education system needs to respond accordingly to prioritise and best serve population needs. There are multidimensional, and interdependent realities at play between health, education, and economic systems with a threefold relationship between curriculum content, professional roles, and professional status, ultimately influencing the quality, and quantity of the resulting workforce (McPake et al., 2015).

Crucially, what also needs to be taken into account are the needs of the population. Moreover, this is of greater significance in marginalised impoverished communities which do not possess a prominent voice. There needs to be consideration of these

underserved populations in order for the people to translate their educational and health needs into demand for services (McPake et al., 2015). Modernisation of education is considered a necessary component for the development of the professional labour market and related health services (McPake et al., 2015). Otherwise, the health service effective coverage gap will never be reduced and may even enter a state of retrogression, precluding the realisation of UHC. The concept of needs-based education is therefore relevant to the sustainable development agenda. Furthermore, the needs-based education model, **Figure 2,** is advocated for by the FIP when considering educational design and frameworks (International Pharmaceutical Federation, 2014). This approach ensures that pharmacists' education aligns with local health needs, equipping graduates with the knowledge, skills, and abilities needed to thrive in an ever-evolving healthcare system (Anderson et al., 2008).

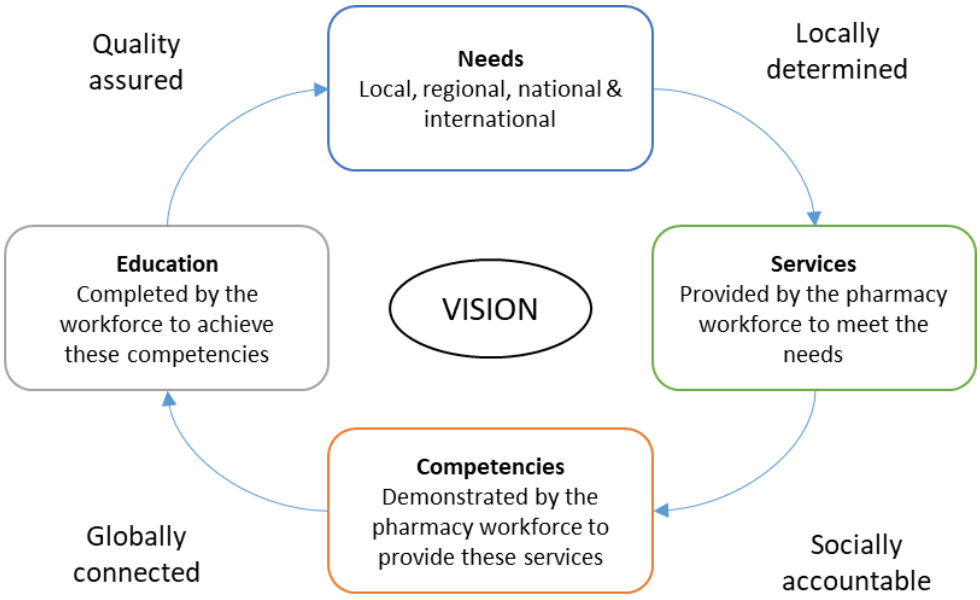


Figure 2 Needs-based education model[3]

1.3 Competency-based Education

1.3.1 The Competency-based Education Model

One of the proposed solutions to the current challenges facing health professional education is to focus more on professional competence and the outcomes of higher education. The competency-based education (CBE) model, aims to put more emphasis on the practical capabilities of the professional in the workplace, in contrast to the traditional knowledge-focused curriculum-led model.

Historically, curricula have been shaped by academic and professional leaders based on traditions, values, and priorities of the faculty. Faculties therefore have, in the past, designed curricula based on what they *want* to teach rather than based on the relevant necessary competencies for the contemporary health-care professional

[3] Adapted from: INTERNATIONAL PHARMACEUTICAL FEDERATION 2014. Quality assurance of pharmacy education: the FIP global framework. The Hague, The Netherlands: FIP.

(Frenk et al., 2010, Anderson et al., 2012). In order to reflect the reality of clinical practice beyond the classroom, Epstein and Hundert (2002) set out to create a universally accepted meaning of competence in the medical profession. They defined competence as:

'..the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and the community being served' (Epstein and Hundert, 2002).

The meaning of 'competencies' however has proved more difficult to define because it is often confused with goals and objectives and is dependent on context (Albanese et al., 2008). Primarily, *competencies* (singular: competency) focus on what the learner should be capable of doing, often detailed through performance standards that articulate the necessary knowledge and skills for demonstrating *competence* (Albanese et al., 2008, Bates and Bruno, 2008). The concept of transferring cognition in to behaviour is shown in **Figure 3**, which constitutes the framework for clinical assessment derived by George Miller (1990), designed as the basis for assessing competence in the medical profession.

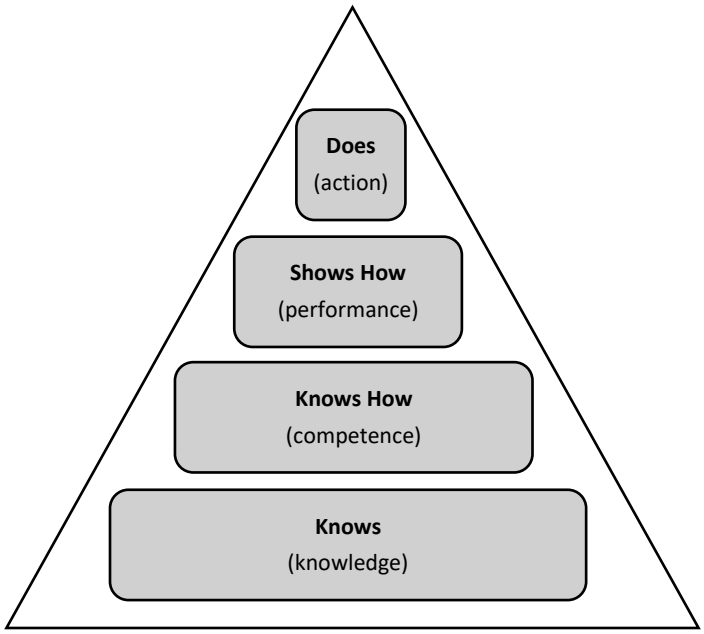


Figure 3 Miller's pyramid depicting the hierarchical levels in the development of clinical competence[4]

This framework guides students through progressively advanced stages of learning, culminating in the demonstration of their ability to perform to a specified standard. Assessing competence involves 'knows how' and entails applying knowledge to scenarios, while competencies involving 'shows how' and are assessed through practical application and the construction of a portfolio showcasing proven competence.

[4] Adapted from: MILLER, E. G. 1990. The assessment of clinical skills/competence/performance. *Academic Medicine,* 65:9**,** S63-7.

The underlying constituents of competence refer to knowledge, abilities, skills and attitudes (Gonczi and Hager, 2010). The attributes of competence underline the performance of observable tasks and activities outlined in performance descriptors which relate to competency standards but competence itself cannot be readily observed so it has to be inferred from samples of performance based on these standards (Gonczi, 2013).

CBE has further been defined as 'education that derives a curriculum from an analysis of a prospective or actual role in modern society and attempts to certify students' progress on the basis of demonstrated performance in some or all aspects of that role' (Hodges and Lingard, 2012) This definition stems from one that was designed to recognise the diversity within the competence-based movement in terms of theoretical orientation, scope of roles, extent of role reforms, and disciplinary focus (Grant, 1979). It is adapted from Grant (1979) who recognised that the competence-based approach could take many forms and so a broad definition was derived that sought to distinguish the competence-based approach to that of more conventional programmes. Grant expressed that the aim of this movement was to 'be able to state that their students are competent at something or to do something rather than that they have accumulated so many course credits. This is the heart of competence-based educational reforms' (Grant, 1979). He elaborates that institutions employing competence-based education evaluate student progress based on performance directly linked to their roles, often granting credits, degrees, or other accolades primarily based on these assessments rather than on the duration of their programme participation (Grant, 1979).

1.3.2 Cautionary Considerations Regarding the Competency-based Education Method

The problem with applying the concept of competence to education comes from viewing learning as a product rather than a process. Competence cannot be achieved through the performance of a discrete list of tasks where the whole is not greater than the sum of its parts, this view is reductionist and positivist ignoring the holistic character of quality of performance and often a source of concern from educationalists (Gonczi and Hager, 2010). It is important to recognise that CBE should be a progressive learning process which has to start with gaining foundational knowledge and requisite enabling skills, therefore competency standards are employed more usefully towards the end of a course. This developmental view of CBE is referred to by Gonczi (2013) as the 'integrated' approach, where theory should be linked to practice and curricula should be understood and presented in a way that incorporates the wide-ranging aspects of becoming a professional in the twenty-first century. Continuing professional development and learning in the workplace are also crucial, and necessary in order to acquire competence and progress to higher levels of expertise, such as excellence and brilliance within a profession (Rychen and Salganik, 2002, Gonczi and Hager, 2010, Mulder et al., 2010). The emphasis is on relating theory to practice, where an integrated competency-based approach can assist. In approaching education in this way the aim is to move away from historical views of knowledge which traditionally focuses on theoretical, or propositional, knowledge where the mind is viewed as separate to the body (Gonczi, 2013). This

view conceptualises the mind as a receptacle which can be filled with facts, beliefs and ideas that can be accessed and applied to solve problems when required, referred to as the 'banking model of education' (Freire, 1970).

This notion fails to recognise that there is a difference between thinking and doing due to the complexities of the real world and that not all thinking can come from the mind, as we are in fact influenced by the environment and the context in which we are placed. Consequently, as research suggests, professionals use their experience as a starting point but there is not always a full understanding of what they are going to do before they act (Schön, 1987, 1991). Further research in this field by Eraut (2004), proposes that professionals draw on a complex combination of codified and uncodified cultural knowledge in the workplace. Codified knowledge refers to that which originates from academic, personal and organisational sources, such as publications, manuals and assignments. Uncodified cultural knowledge refers to knowledge acquired through socialisation and personal knowledge (such as emotions and memories) which is often neglected as a recognised influencer on professional behaviour. Eraut (2004) therefore recommends that we avoid fragmented approaches to knowledge, as knowledge already exists in an integrated form. Therefore, as Gonczi (2013) argues, universities need to recognise that competence is not achieved by performing a discrete list of tasks in isolation but that the development of competence is a lifelong process that requires theoretical and practical learning to feed in to one another.

The overall objective is not to teach students codified knowledge in an attempt for them to *transfer* that to the professional workplace but to teach students how to *become* professionals through a model of skill acquisition that also includes acquiring personal authenticity and dispositions over time (Gonczi, 2013). This approach aspires to create enlightened change agents who possess the necessary leadership attributes and values to face new contexts and challenges and deliver enhanced comprehensive services (Gruppen et al., 2012, Frenk et al., 2010). This is by no means a simple task but when the notion of competence is applied correctly and based on real health needs, and not as curriculum driven from faculty preferences or via a set of performance descriptors, it can be educationally desirable and used as a basis for the promotion of integrated learning experiences to prepare students to function in increasingly challenging professional environment and as such, despite criticisms, CBE is an attractive prospect for health professional education and for the advancement of UHC in particular (Gonczi, 2013, Frenk et al., 2010).

1.3.3 Competency Frameworks

One approach to equip healthcare professionals with the necessary prerequisites to engage in patient and population-centred healthcare in a transformative, ethical, locally and globally responsive way is through the CBE approach. According to the WHO, significant obstacles hinder countries' capacity to oversee the education of healthcare professionals. These challenges encompass outdated and incongruous practice regulations, absence of well-defined core competencies guiding both education and practice, and insufficient capability to consistently assess and sustain competency attainment (World Health Organization, 2013). Developing competencies provides criteria for the 21st century health professional capable of

adapting to rapidly changing local and global conditions whilst also cultivating values around social accountability (Frenk et al., 2010).

Van Melle et al. (2019) recognised that efforts to analyse whether CBE is being implemented as intended, otherwise known as the fidelity of implementation, were being compromised by a lack of a common framework describing what CBE actually is, in relation to medical education. To remedy this they embarked on creating a draft framework which was examined for consensus using a modified Delphi approach with an international panel of medical CBE experts. Five core components for CBE curricula in medicine were established through the lens of a constructivist theoretical approach: outcome competencies, sequenced progression, tailored learning experiences, competency-focused instruction, and programmatic assessment (Van Melle et al., 2019). The identification of these core components helps to deepen the understanding of CBE and its implementation. The authors also highlight that the competencies required for practice should be clearly articulated and that these 'form the basis for the planning and delivery of all curricular elements' (Van Melle et al., 2019). One such way of organising these competencies for various disciplines is through the form of competency frameworks, which function as 'an organised and structured representation of a set of interrelated and purposeful competencies' (Englander et al., 2017).

The concept of competency frameworks has now been incorporated globally into healthcare professions, including pharmacy, to assist the pharmacy workforce to develop and advance their careers (Udoh et al., 2021a, b). One such framework is the Global Competency Framework (GbCF) published in 2012 by the International Pharmaceutical Federation (FIP) (International Pharmaceutical Federation, 2012). FIP, WHO and UNESCO embarked on a joint collaboration, established in 2008, termed the Pharmacy Education Taskforce. The purpose is to work globally to expand evidence-based and needs-based practice through international conference and country-level implementation of FIP tools. As part of this education taskforce the FIP created the GbCF for foundation pharmacists—those 5 years or less post-qualification (International Pharmaceutical Federation, 2019). This was later updated and version 2 of this framework was released in 2020 (International Pharmaceutical Federation, 2020b). Furthermore, the FIP Global Advanced Development Framework (GADF) also provides an extra validated tool to support advancing pharmacy practice worldwide (International Pharmaceutical Federation, 2020a). Additionally, the FIP competency framework for educators and trainers in pharmacy compliments the aforementioned frameworks with a structured and systematic approach to developing CBE aligned educational practices for pharmacy (International Pharmaceutical Federation, 2022b).

The aim of a framework is to avoid uneven focus on technical abilities and ensure representation of the full spectrum of necessary abilities for the contemporary practitioner (Englander et al., 2017). For example the FIP GbCF consists of 4 competency domains: 'Pharmaceutical Public Health', 'Pharmaceutical Care', 'Organisation and Management', and 'Professional/Personal'. Each competency within these domains has a list of behavioural indicators. The observation of these

indicators in practical contexts is integral to CBE. Demonstrating these behaviours signifies the attainment of associated competencies and provides measurable benchmarks guiding the learning outcomes of CBE programmes, modules, or units (Mills et al., 2005).

Frameworks offer a systematic structured approach to competency development, providing learners with the opportunity to concentrate on areas for improvement or aspects they may not have previously considered. However, it's essential to guard against an excessively rigid mechanistic adoption of competency frameworks, ensuring that the behaviours to be demonstrated and observed are grounded in an intentional and robust knowledge-driven foundation (Emmerson et al., 2000). This is particularly pertinent in health professional education, where students often transition into higher education from discipline-focused learning to a more integrated, practice-oriented approach. One such method of achieving this in a CBE curriculum is through a gradual integrated approach, known as a spiral curriculum, where isolated skills are applied to relevant professional contexts with increasing complexity as the curriculum advances through the utilisation of problem- and practice-based learning (Harden, 1999). An example of a practice-based learning approach designed to tackle the complex nature of translating theory to practice-based learning outcomes in CBE are entrustable professional activities (EPAs) (Westein et al., 2019). EPAs are professional activities that form the core of that specific healthcare profession and often require a number of competencies to be attained to the point where the trainee is entrusted with the responsibility of carrying out that activity in a safe manner, thus preparing them for bearing that responsibility in professional practice (Ten Cate et al., 2007).

Competency frameworks are in wide use across the globe in a number of different healthcare settings which cover a plethora of competency areas and levels, not only for clinical positions but also including health service management roles (Emmerson et al., 2000). There are even multidisciplinary frameworks such as the ‘Global Competency and Outcome Framework for Universal Health Coverage’ that have a much broader scope of relevance to health workers in general and aims to define a shared set of expectations and outcomes in terms of competence levels to increase the accountability between education, regulation, and practice (employers) (World Health Organization, 2022b). In addition to global frameworks like the FIP GbCF, country-level frameworks are also available for application to health professional, and pharmacy education and training (Mucalo et al., 2016, Royal Pharmaceutical Society, 2013, Advanced Pharmacy Practice Framework Steering Committee, 2012, The Pharmaceutical Society of Ireland, 2013). For example, the CanMEDS physician competency framework serves as the basis for the education and practice standards for medical practitioners in Canada (Frank, 2005). This framework has been embraced by the medical community in the Netherlands and customised for pharmacy practice, resulting in an integration and harmonisation of pharmacists' professional growth with other healthcare disciplines in the country (Koster et al., 2020).

1.3.4 Competency-based Education for Pharmacy

In the book, 'The Question of Competence: reconsidering Medical Education in the Twenty-First Century', Hodges and Lingard (2012) attempt to explore the complex idea of competence in relation to healthcare professionals, particularly in relation to the medical field. Hodges and Lingard (2012) suggest that the CBE educational model deemphasises the time spent learning, and emphasises the achievement of competencies and demonstrable outcomes especially given the increasing need for medical education to satisfy accreditation bodies and exhibit social accountability. CBE in pharmacy often follows developments in CBE for medicine and these principles outlined by Hodges and Lingard (2012) also apply to other healthcare professions, including pharmacy (Bajis et al., 2020). Similarly, Frank et al. (2010a) reviewed relevant medical CBE literature and found a high degree of heterogeneity between CBE definitions. A total of 173 records were analysed and a working definition of CBE specific to physicians was developed: 'Competency-based education (CBE) is an approach to preparing physicians for practice that is fundamentally orientated to graduate outcome abilities and organized around competencies derived from an analysis of societal and patient needs. It de-emphasises time-based training and promises greater accountability, flexibility, and learner-centeredness' (Frank et al., 2010a).

Both sector-wide, and sector specific competency frameworks for pharmacy have been developed in several countries across all of the WHO regions as outlined by Udoh et al (2021a). The FIP GbCF is sector-wide and aimed at early-career pharmacists, it was created through global consultation and review of previous country-specific frameworks and recently updated in 2020 to reflect further consultation and developments in the profession (International Pharmaceutical Federation, 2020b). However, the actual implementation of CBE, including the application of competency frameworks is a complex process (Koster et al., 2017). A firm understanding of the concept of competency is required by all pharmacy education stakeholders for the adoption of the CBE approach, where the rate and extent of CBE globally is inconsistent (International Pharmaceutical Federation, 2013). Relevant literature from the Global South is particularly scarce in comparison to the Global North, indicative of less extensive use of CBE in some lower-income countries (Bajis et al., 2016, Babar et al., 2013).

The CBE approach is a viable option for preparing health professional graduates to meet modern diverse healthcare needs (Wu et al., 2018, Carraccio et al., 2002). Previous systematic reviews for CBE in pharmacy cover specific aspects such as leadership definitions and assessment methods (Reed et al., 2019), and the applicability of competency frameworks (Udoh et al., 2021a). A more general narrative review on the application of CBE for pharmacy, including its potential benefits and challenges, provides a comprehensive summary of the literature (Katoue and Schwinghammer, 2020). These reviews highlight that although the use of CBE offers advantages for pharmacy education there is a disparity between the understanding, terminology and application of the concepts of CBE as similarly reported in the medical literature (Carraccio et al., 2002).

The implementation process of a CBE pharmacy curriculum can be time-consuming and requires significant resources, cooperation, and commitment (Katoue and Schwinghammer, 2020). A number or resources provide useful and practical guidance for developing a CBE curriculum (Frank et al., 2010b, Koster et al., 2017). However, the literature to date originates predominately from high-income countries which suggests there is a deficit of CBE related activity for pharmacy in low- middle-income countries despite the potential of this approach to advance education both for pharmacy (Katoue and Schwinghammer, 2020, Bruno et al., 2010) and healthcare professionals in general (Gruppen et al., 2012, Frenk et al., 2010).

As described by Bajis et al (2020), using pharmacy education as an example, CBE is actually a convergence of various educational paradigms which extend throughout a health professionals' career beyond initial education and into lifelong learning and continual professional development (CPD). In **Figure 4** the conceptual model proposed by Bajis is situated within these various educational models which are foundational to CBE: Miller's prism (Miller, 1990); Bigg's constructive alignment (Biggs, 1996); and Dreyfus & Dreyfus' development of expertise model (Dreyfus and Dreyfus, 2005).

A core principle of CBE is to place the student at the centre of their own learning journey. The nucleus of Bajis's model depicts this well and the idea behind this is that student-centred learning fosters self-motivation to learn as well as personal growth and development (O'Neil and McMahon, 2005), particularly crucial amid the evolving learning demands placed on contemporary health professionals (Frenk et al., 2010). In competency-based learning and assessment this is complimented by specially designed formative assessment, feedback, and observation (Bajis et al., 2020).

This model is valuable for emphasising the ongoing learning and development necessary for modern pharmacists, potentially surpassing the linear models depicted elsewhere (World Health Organization, 2022b). Moreover, this model also incorporates the importance of achieving expertise, beyond the minimum competency level, essential for acquiring the ability to adapt to uncertainty and respond to the different contexts of real-life practice (McLellan. L et al., 2012).

Even after expertise is attained in one domain, ever-evolving health needs, pharmaceutical advancements, technological innovations, and societal changes underscore the importance of self-reflection and re-entering the learning and assessment cycle, represented by the looped arrow in **Figure 4**. The notion of lifelong learning is depicted by a dotted line in this diagram and encircles the whole continuous cycle of developing competence and expertise.

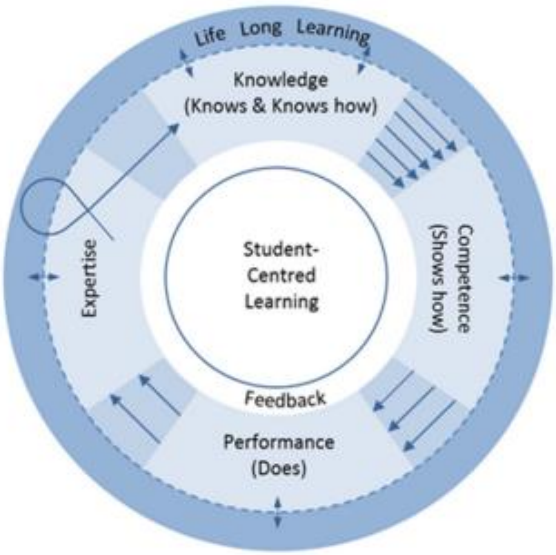


Figure 4 Competency-based learning and assessment cycle[5]

Pharmacy educators must anticipate future practice trends, integrate relevant competencies into the curriculum, and foster self-directed learning skills among future pharmacists. This approach ensures that pharmacists remain engaged in lifelong learning and competency development to adapt to the dynamic nature of pharmacy practice (Jungnickel et al., 2009).

1.4 Pharmacy Education in Kenya

Recent educational reforms in Kenya, in line with the long-term development plans for the country known as Kenya Vision 2030 (Kenya Vision 2030 Delivery Secretariat, 2020), have begun initiating a competency-based curriculum within the basic education levels. This reform has been designed in the context of sustainable development and described as a curriculum that will 'emphasize the importance of not only developing skills and knowledge but also applying these to real life situations' with the vision 'to enable every Kenyan to become an engaged, empowered and ethical citizen' (Republic of Kenya, 2017).

1.4.1 Pharmacy Practice in Kenya

The role of pharmacy in Kenya is evolving from manufacturing and distribution of medicinal products, to increasingly more patient and community orientated concerns (Aywak et al., 2017). This change mirrors global pharmacy developments but differs across the world according to local needs, available resources, challenges and public expectations and has resulted in the requirement for institutions to redesign their curricula and reform modern pharmacy education (Fatherlrahman and Ibrahim, 2018).

A systematic review of pharmacy education literature in low- and middle-income countries (Babar et al., 2013) revealed seven key themes of concern from

[5] Reproduced, with permission, from: BAJIS, D., CHAAR, B. & MOLES, R. 2020. Rethinking Competence: A Nexus of Educational Models in the Context of Lifelong Learning. *Pharmacy,* 8:2.

quantitative narrative analysis. The themes identified from the 36 studies included in this review, 8% from Africa, do correlate with professional education concerns broached by Frenk et al (2010). That is, technological and industrial shifts have contributed to change in the pharmacy profession resulting in a loss of function and social status, thus driving the need to reposition the role of the pharmacy profession (Babar et al., 2013). This reform is already evident as a driver for change in high-income countries resulting in the expansion of the delivery of clinical pharmacy-led services (Anderson et al., 2012). The limited number of publications in the systematic review however highlights the need for more empirical research in pharmacy education to gain the necessary insight into the situation in these individual countries, which will also assist with building evidence for future policy and practice decision making in comparable locations (Babar et al., 2013). Global action on pharmacy education is often conducted without the critical engagement of those on a strategic and functional level within low- and middle-income countries. For that reason, promoting effective collaboration of these countries with high-income countries has potential for consolidating empirical research gaps and prospective disconnects between local and global pharmacy education developments (Babar et al., 2013).

According to the Kenya National Bureau of Statistics (KNBS) there were 3,684 pharmacists registered in Kenya in 2022, 7 per 100,000 population, and 10,943 pharmaceutical technologists (Kenya National Bureau of Statistics, 2023). The gender distribution was not specified by the latest KNBS economic survey, although they state that in addition to these registered pharmacists there were 2,707 undergraduate pharmacy students attending public and private universities in 2022, 54.5% male and 45.5% female (Kenya National Bureau of Statistics, 2023). Between 2018 and 2022, male undergraduate numbers have consistently outnumbered females each year, however the 2022 data reveals the smallest margin of this discrepancy since 2018 (Kenya National Bureau of Statistics, 2023).

All undergraduate pharmacy courses must be accredited by the Commission for University Education (CUE). The individual institutions are responsible for creating their own curriculum based on the core curriculum guideline from the regulatory body for pharmacy in Kenya, the Pharmacy and Poisons Board (PPB), first published in 2008 and last revised in 2014 (Pharmacy and Poisons Board, 2014). The universities mostly follow the PPB guidelines which outline core courses for each year. The first two years are made up of ‘pre-clinical’ courses and commonly include topics such as human anatomy, physiology, biochemistry, behavioural sciences, mathematics, chemistry, and microbiology. The following three years comprise of more pharmacy specific content known as the ‘clinical’ courses. In addition to a research project in year five there is mandatory requirement for a work placement, known as an attachment period, in year four consisting of a minimum of 12 weeks split across community, hospital and industrial pharmacy (Pharmacy and Poisons Board, 2014). Following the five year Bachelor programme graduates must complete a one year internship, regulated by the PPB, which involves 6 months of hospital-based practice, 3 months in community practice and 3 months in pharmaceutical industry. In addition to the internship pharmacists must sit two professional examinations, regulated by

the PPB, in order to qualify and register as a pharmacist in Kenya (Pharmacy and Poisons Board, 2013a).

Postgraduate programmes require approval from CUE. The recent devolution of healthcare management from governmental to county level has impelled county hospitals to take on more specialised services such as renal dialysis and critical care (Aywak et al., 2017). This has in turn created the need for more specialised education which comes in the form of postgraduate residency programmes. However, the PPB does not formally recognise any additional specialist training, as of yet, and despite these local programmes the residency training approach is not yet universal in Kenya. In order to gain necessary clinical competencies some pharmacists seek this type of training in other countries (Aywak et al., 2017).

At present, Kenya lacks a national competency framework (CF) for pharmacists. However, a study evaluating the validity of the FIP GbCFv1 in several African countries, including Kenya, revealed that the competencies outlined in this framework are relevant to pharmacy practice within the study sample from these nations (Udoh et al., 2018). CBE is also not currently incorporated in undergraduate education but it is part of the post-registration continuing professional development (CPD) guidelines. There are 5 core competences outlined in the guidelines which are: (1) employing evidence based practices, (2) applying quality improvement, (3) providing patient centred-care, (4) working in inter-professional teams and (5) making use of ICT (Pharmacy and Poisons Board, 2013b). Undertaking CPD is mandatory in Kenya to maintain annual licensure and continue to practice pharmacy. Therefore, there is a need to improve the connection between undergraduate learning and lifelong learning post-registration.

1.4.2 Current Programmes

There are currently 9 institutions accredited by the regulatory board for the pharmacy profession, (PPB), in Kenya, all of which offer a five year Bachelor of Pharmacy (BPharm) undergraduate pharmacy degree programme shown in **Table 1**.

Table 1 Universities offering the BPharm currently accredited by the PPB in Kenya

	University Name[a]	Year pharmacy programme established[b]	Institution Type[a]	Location (Town/city and county)
1	University of Nairobi	1974	Public	Nairobi, Nairobi County
2	Kenyatta University	2004	Public	Nairobi, Nairobi County
3	Mount Kenya University	2006	Private	Thika, Kiambu County
4	Maseno University	2022	Public	Maseno, Kisumu County
5	Kisii University	2022	Public	Kisii, Kisii County
6	Jomo Kenyatta University of Agriculture and Technology	2010	Public	Juja, Kiambu County
7	United States International University-Africa	2014	Private	Nairobi, Nairobi County
8	Kenya Methodist University	2008	Mission	Meru, Meru County
9	Kabarak University	2016	Private	Nakuru, Nakuru County

[a] data from PPB website (Pharmacy and Poisons Board, 2024)
[b] data from institution websites and (Ogaji et al., 2016)

Until recently, institutions offering the BPharm degree were predominantly centrally located. However, with the recent accreditation of Maseno and Kisii universities, pharmacy education is now more evenly distributed across Kenya. These newly accredited universities, situated in the rural western regions of the country, contribute to a more widespread availability of pharmacy education as shown on the map in **Figure 5**. The map shows the locations of each institution, it is important to note however that Kenya now has a devolved system of governance where the previous 8 provinces have now been replaced by 47 distinct counties as directed by the Kenya Constitution of 2010[6] . The Constitution initiated transformation in governance and public administration resulting in the devolved system of governance and serving the 'Right to Health for every Kenyan' (World Health Organization and Government of Kenya, 2014).

Within the Kenya Health Policy (2014-2030) targets for health improvements include working toward the attainment of UHC along with 16% improvement in life expectancy and a 50% reduction in annual mortality from all causes (Republic of Kenya Ministry of Health, 2014a). Further details and strategies were outlined in the Kenya Health Sector Strategic and Investment Plan (KHSSP – 2014-2018) which mentions strengthening the functions of some bodies such as the PPB (Republic of Kenya Ministry of Health, 2014b).

[6] Each county is responsible for functions related to providing and delivering services, including primary education and healthcare, in conjunction with, yet distinct from that of the national government which continues to govern Higher Education AYWAK, D., JAGUGA, C. D. P., NKONGE, N. G., et al. 2017. Pharmacy Practice in Kenya. *The Canadian Journal of Hospital Pharmacy,* 70:6.

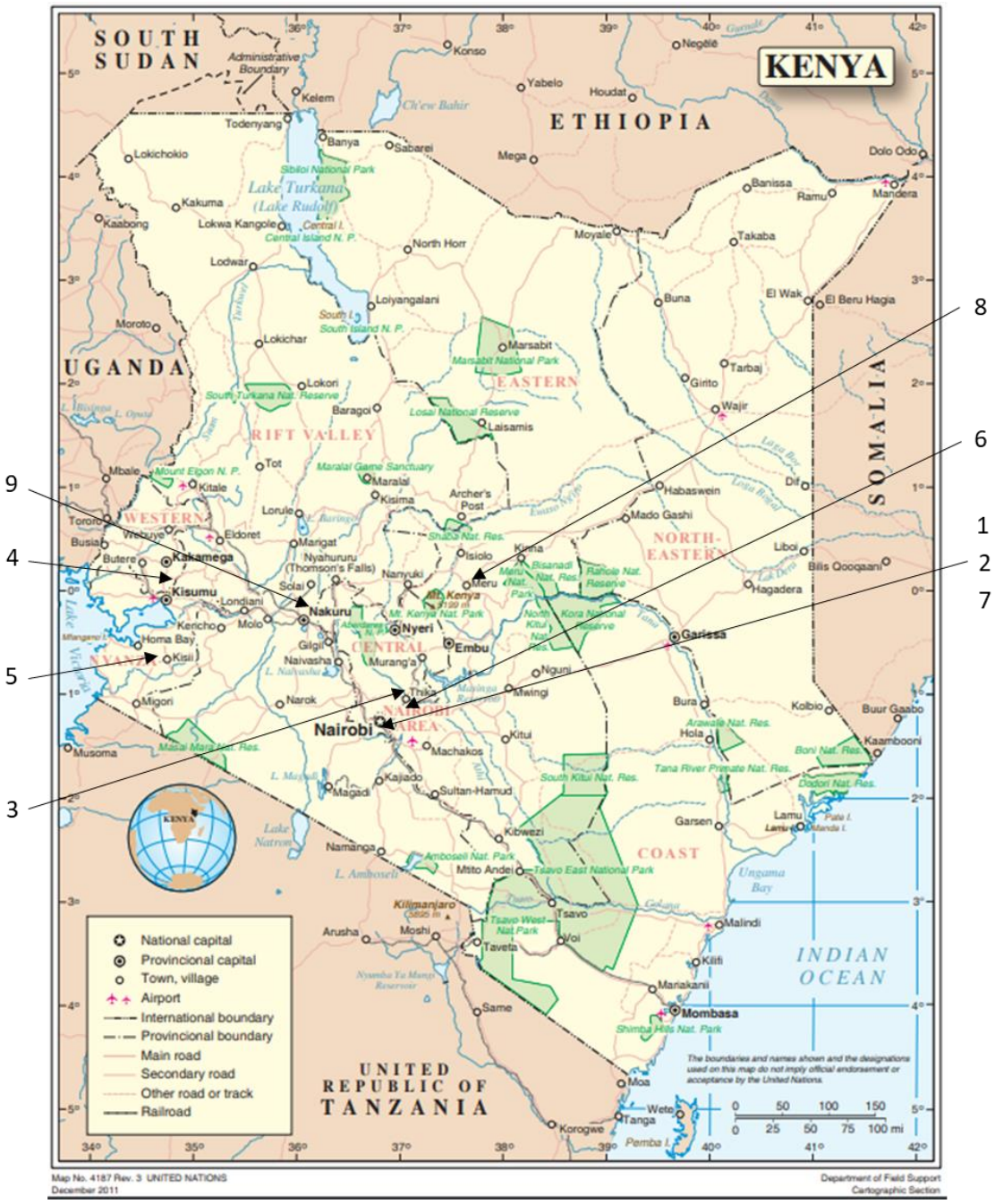


Figure 5 Location of universities in Kenya currently delivering an accredited Bachelor of Pharmacy programme, as numbered in Table 1[7]

[7] Adapted from: UNITED NATIONS (2011) Kenya- The United Nations [Online] Available: https://www.un.org/Depts/Cartographic/map/profile/kenya.pdf [Date accessed 9th Feb 2024]

1.4.3 Strategic Partnerships for Higher Education Innovation and Reform

The Department for International Development (DFID) in the UK created Strategic Partnerships for Higher Education Innovation and Reform (SPHEIR) in 2014 and allocated £45million of UK aid towards the progression of developmental outcomes in DFID priority countries with the intention of influencing practice related to the original Millennium Development Goals (MDGs), now revised and known as the SDGs (Department for International Development, 2019).

Kenya is a DFID priority country, which is undertaking a period of development with its own aspirations to transform itself into a middle-income country by 2030 (Kenya Vision 2030 Delivery Secretariat, 2020). The rapid industrialisation required to achieve this vision for Kenya as a globally competitive country relies, in part, on globally competitive graduates entering the job market thus solidifying the issue of higher education reform in Kenya as a pertinent concern for the country at present. This priority for Kenya sparked an interest in pharmacy and chemistry academics from The University of Nottingham, who secured funding as the lead partner in a SPHEIR initiative designed to transform the delivery of education for pharmacy and chemistry higher education programmes in Kenya. This interest in pharmacy education in Kenya is an advantageous platform on which to situate research, utilising this venture in pharmacy education and practice reform to address the healthcare needs of the community whilst promoting the advancement of the pharmacy profession in Kenya.

Early education systems in many countries, including Africa, are moving towards competency-based curricula but many curricula remain heavily content driven, linguistically and cognitively too demanding, and irrelevant to local context and needs of learners (Tikly, 2020 pp.25). This echoes the sentiment gathered via my initial visits to Kenya during verbal discussions with the academics involved with the SPHEIR project and with the delivery of pharmacy education in Kenya. Factors, originating from colonial times, of authoritarian and formalistic teacher-centric pedagogical practices coupled with wider unsustainable development workforce issues and higher education practices and structures contribute to a deep-rooted and complex environment for the alignment of the synergistic processes needed to enact change (Tikly, 2020 pp.26). Challenges to the adoption of learner-centred pedagogies, like CBE, have also proven pervasive in Sub-Saharan Africa particularly because socio-cultural influences are often over looked (Tabulawa, 2013). Tilky (2020) argues that solving this crisis in early education in Africa cannot be placed on the education systems alone: ‘Rather what is required are more fundamental and simultaneous processes of transformative change across all domains of development’ (Tikly, 2020 pp.26).

1.5 Research Questions

1.5.1 Primary Research Questions

The following research questions form the basis of this thesis which explores various aspects of CBE in the context of pharmacy and the pharmaceutical sciences in the global landscape, with a specific focus on Kenya. These questions were designed to examine the relevance of an existing global competency framework and identify the necessary adaptations for its use in Kenya. Furthermore, these inquiries aim to investigate the utilisation and extent of CBE features in education and training for pharmacists worldwide.

i. What are the features of contemporary CBE for pharmacy?
ii. How are CBE features used in education and training for pharmacy students and pharmacists?
iii. To what extent is CBE used for pharmacy and pharmaceutical science education globally?
iv. What are the perceived challenges associated with the use of CBE for pharmacy and the pharmaceutical sciences?
v. How relevant is the FIP Global Competency Framework version 2 (GbCFv2) to pharmacists practicing in Kenya?
vi. What adjustments are required to adapt the FIP GbCFv2 to early-career pharmacy practice in Kenya?
vii. Which competencies and behavioural statements should be included in a competency framework for early-career pharmacists in Kenya?

1.5.2 Rationale

CBE is receiving growing interest as an educational approach capable of preparing healthcare professionals to fulfil a diverse array of healthcare needs (Wu et al., 2018). The WHO's 'Global Competency Framework for Universal Health Coverage' endorses the CBE approach in health and recognises its potential to better align health worker's education with population health needs and demands (World Health Organization, 2022b).

The presence of competent pharmacists in the healthcare team is associated with improved health outcomes (Bond and Raehl, 2007). The key role that pharmacists occupy in the health system underpins the requirement of pharmacy education to create highly skilled, competent members of the workforce capable of meeting population health needs (Anderson et al., 2009). The FIP recognises the importance of an educational approach based on health needs and advocates for CBE as part of its Needs-based Education Model, applicable in any given context for the improvement of pharmaceutical care (International Pharmaceutical Federation, 2017). Additionally, the launch of the FIP Global Competency Framework Version 1 (FIP GbcFv1) provided the means to assist countries which adapting a competency framework to their own contexts and previous studies have demonstrated its applicability in various locations (Arakawa et al., 2020, Alfaifi et al., 2022a, Udoh et al., 2021a, Mucalo et al., 2016).

An African specific study also demonstrated a high degree of applicability of the GbCFv1 in a number of countries in this region (Udoh et al., 2018). Nevertheless, there is currently no literature regarding further steps in the process of adapting the GbCF to create a local bespoke framework for any of the African countries. There are also no studies to date that have included the recently updated second version of the GbCF (FIP GbCFv2), released after the onset of the COVID-19 pandemic. This updated version includes 23 additional behavioural statements encompassing statements relating to the use of digital communication technology, interprofessional collaboration, and healthcare emergencies (International Pharmaceutical Federation, 2020b).

Globally, the growth of the pharmacy workforce is lowest in the African region (International Pharmaceutical Federation, 2018). The scholarly literatures to date have examined the education of pharmacists in various communities globally but little research exists when it comes to pharmacy in Sub-Saharan Africa, including the use of CBE. The combination of a predicted health workforce deficit, comparably low growth of the pharmacy workforce, and an existing gap in the literature from the Africa region demonstrates the need for research which contributes towards pharmacy education reform and workforce development in this area.

Previous reviews on the use of CBE in pharmacy highlight that although the use of CBE offers advantages for pharmacy education there is a disparity between the understanding, terminology and application of the concepts of CBE (Reed et al., 2019). Implementing a CBE curriculum is time-consuming and resource-intensive, requiring substantial cooperation and commitment (Katoue and Schwinghammer, 2020). Additionally, there is confounding discourse on CBE in the literature to date in terms of its terminology, application and implementation. Couple this with the relatively resource intensive process of putting CBE into practice, and the result is a generally protracted uptake of CBE for the initial training and education for pharmacists across the globe (Gruppen et al., 2016, Katoue and Schwinghammer, 2020). There are also no systematic reviews for CBE in pharmacy that examine the research with the intention of capturing a global perspective on what features of CBE are used in pharmacy education.

This research will contribute to identifying the potential for pharmacy education in Kenya to adopt a CBE model in an attempt to modernise the curriculum, strengthen the application of learning to practice, and the role of pharmacy in the healthcare system in order to enhance workforce capacity and quality.

Research is needed to consolidate information on the initial stages of adopting a CBE model worldwide, especially in regions underrepresented in current literature. This study is positioned to globally examine the CBE model, offering insights into its features, implementation, and potential methods for developing a competency-based framework in Kenya. Such efforts aim to improve pharmacy education, training, and the development of the pharmacy workforce, essential components of the limited yet crucial community of healthcare professionals.

1.6 Aims and Objectives

1.6.1 Aim

This thesis explores the application of CBE in the field of pharmacy on a global scale. The primary aim is to develop tool to support the development of the pharmacy profession in Kenya in the form of a tailored competency framework specifically designed for early-career pharmacists, using the FIP GbCFv2 as a foundational reference. Furthermore, the research endeavours to identify current distinguishing aspects of CBE in the pharmacy domain and assess the prevalence of CBE in formal educational programmes for pharmacy and the pharmaceutical sciences worldwide. In addition to this the perceived challenges associated with using CBE will be explored. These findings aim to provide valuable insights to inform future advancements in the field of CBE for pharmacy which will also have some inherent transferable applicability to the education and training of other healthcare professionals.

1.6.2 Objectives

Part One

Provide a global picture of contemporary CBE related activity for pharmacy students and practitioners

(i) Global CBE systematic review of pharmacy education for students and practitioners

- Conduct a comprehensive systematic review of pharmacy education worldwide to identify and analyse the current features and practices of CBE related to pharmacy students and practitioners
- Describe the existing features of CBE in pharmacy education and training globally

(ii) Global Survey on the use of CBE in Pharmacy and Pharmaceutical Sciences Education

- Conduct a survey to explore the global extent of CBE related activity in pharmacy and the pharmaceutical sciences, identify how CBE is used and the potential challenges to effective implementation

Part Two

Create a bespoke localised competency framework for early-career pharmacists in Kenya using the FIP GbCFv2 as a baseline

(i) FIP GbCFv2 applicability survey

- Conduct a survey to determine the suitability of the FIP GbCFv2 for pharmacists in Kenya by assessing its applicability and analysing areas of misalignment

(ii) Consensus development panel workshop

- Discuss the FIP GbCFv2 behavioural statements and rate their applicability to current, future, and ideal pharmacy practice in Kenya with a local panel of pharmacy experts
- Adapt and amend the current FIP GbCFv2 behavioural statements, enhancing the relevance to Kenyan pharmacy practice until a consensus is reached on all behavioural statements for inclusion in a Kenyan competency framework are agreed
- Create a local competency framework for early-career pharmacists in Kenya

An overview of the individual stages of both parts of the research project are displayed diagrammatically in **Figure 6**

1.7 Research Project Overview

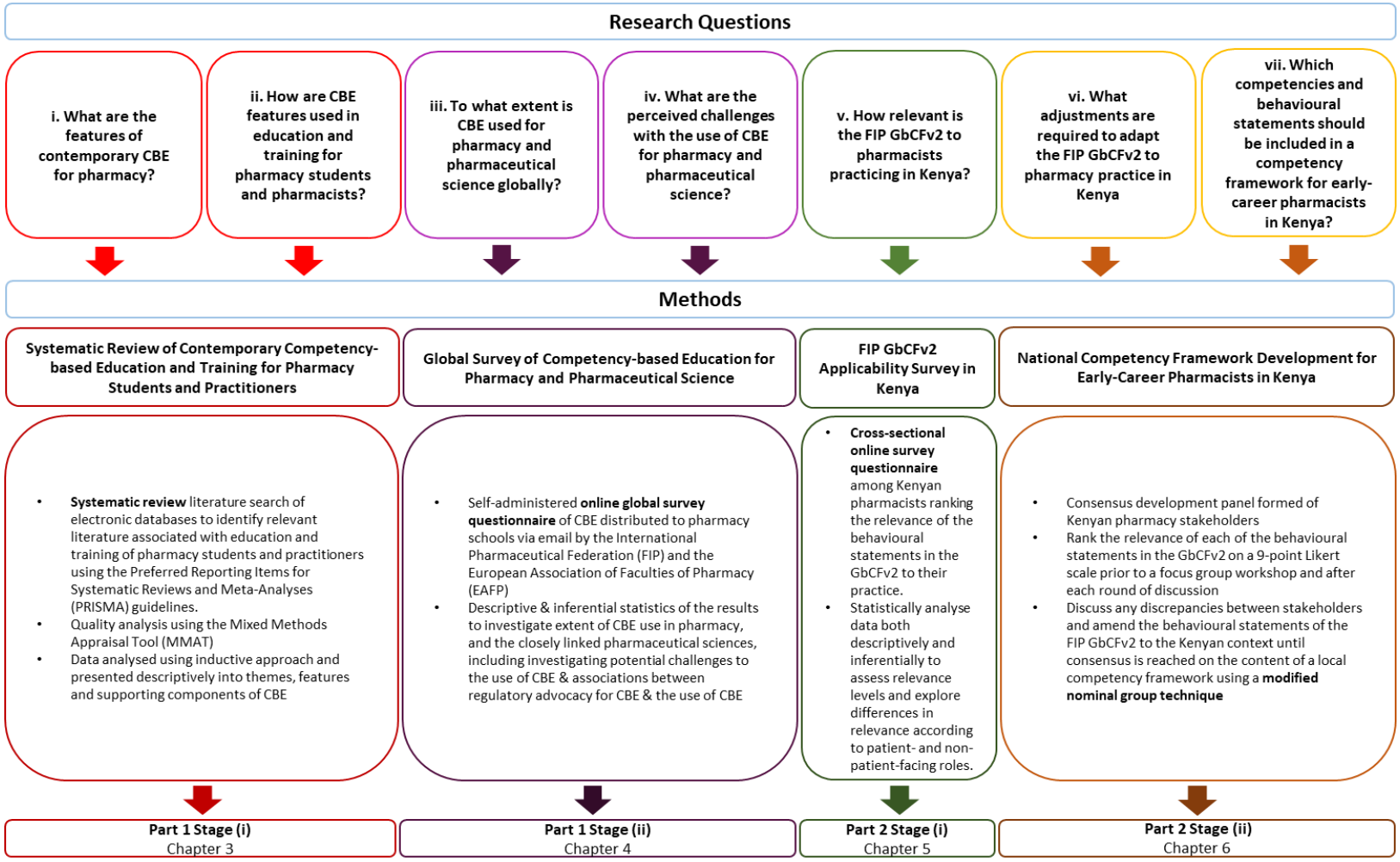


Figure 6 Research project overview

Chapter 2: Research Methods

2.1 Chapter Introduction

Research approaches are usually categorised as quantitative, qualitative or mixed methods. There is often a dichotomous distinction made between these categories, however they are more fluid than this and are better described as on a spectrum (Creswell, 2014). In other words, they needn't be as discrete in practice and exist on a continuum with mixed methods, studies which involves elements of both quantitative and qualitative procedures, in the centre (Newman and Benz, 1998). Thus, rather than adhering strictly to predefined methodological boundaries, researchers are encouraged to embrace a more holistic view of inquiry that leverages the strengths of both quantitative and qualitative methods.

Regardless of the chosen research approach and subsequent design, reliability (repeatability of the research) and validity (the extent to which the research instruments measure what they claim to measure) contribute to the overall quality of the findings. Moreover, rigorous adherence to systematic documentation, meticulous data collection, analysis, and thoughtful interpretation contributes to the overall quality of the research process. This commitment to methodological rigor not only enhances the credibility of the findings but also fosters transparency and accountability. By upholding these standards, researchers can instil confidence in their work, facilitating meaningful contributions to knowledge and understanding in their respective fields. (Bowling, 2014).

2.2 Research Design

Quantitative research

Numbered data is gathered during quantitative studies using various statistical methods to examine the relationship between different variables. A number of different research instruments can be used but the written report often has a standard structure and the focus is often on generalisability and replicability of the findings (Creswell, 2014).

Qualitative research

In contrast to quantitative research, the report style in qualitative research is often more flexible. There are number of different instruments for gathering data e.g. interviews, surveys, focus groups, observations but the data is usually based on words rather than numbers. The researcher is often looking to extract meaning from the data to help understand quite complex topics. The findings are commonly less generalizable as they depend on the specific context or setting and data is gathered in an inductive style to build themes, mostly around social or human problems (Creswell, 2014).

Mixed methods research

Mixed methods research is a combination of both quantitative and qualitative research designs, where the aim is to produce more detailed findings on a research topic than could have been achieved using either method in isolation. The qualitative data is integrated with the quantitative data in a way that elucidates a more complete understanding of the topic according to those philosophical assumptions and theoretical frameworks employed (Creswell, 2014).

In this chapter the focus will be an overview of the research principles relevant to the research presented in this thesis. For the majority, this research employs quantitative methodology. In the subsequent study chapters more specific explanations of the methodologies employed within each stage of the present research are provided which will explain any deviations and relevant rationale. Largely, the research decisions and approaches chosen for each study is grounded within the flexibility of the pragmatic worldview, more on this can be found at the end of this chapter.

2.3 Epistemological Considerations

2.3.1 Philosophical Worldviews

'Knowing' is often referred to as the relationship between ourselves and our world. How we process our surroundings is crucial to any theory of behaviour or mind. The underlying assumptions behind different ways of knowing is referred to, in philosophy, as epistemology which concerns the nature, origins, and limits of knowledge (Slife and Williams, 1995). Depending on the researcher's assumptions and values , there is a set of theoretical perspectives or paradigms that they can draw from to create the basis of any scientific enquiry (Bowling, 2014). Also referred to as their worldview—'a basic set of beliefs that guide action' (Guba, 1990 p.17). In other words, the way the research is approached will depend on what the researcher looks at and what previous visual-conceptual experiences they may have had (Kuhn, 1996 p. 200).

Although scientific research commonly strives to be objective and 'value-free', it is impossible to completely separate yourself as a researcher (or my work) from the cultural, social, and political context within which the research is based (Bowling, 2014). The approaches to scientific enquiry are multifarious and the data, analysis, results, or interpretations can be influenced both by the researcher and the research design. It is therefore important to make it clear what theoretical perspectives or paradigms have been employed for the research presented in this thesis. In **Figure 7**, a diagrammatic representation describes the stages of research design and the influencing factors on the many decisions that need to be made along the design process. The arrows denote the potential influences on the research approach and how that in turn influences the chosen research design, and ultimately the research methods.

In pharmacy education research we are often concerned with the study of human behaviour within the discipline of behavioural science. Therefore, there is commonly

a degree of ambiguity to be tolerated in this type of research, as this reflects the ambiguity of life (Slife and Williams, 1995). The extent to which philosophical assumptions or implicit biases influence research approaches cannot be overstated. Often, these foundational ideas remain unarticulated or unaddressed in scholarly reports, not necessarily due to deliberate omission, but rather as a reflection of established norms within academic discourse. Reports are often structured to cater to specific audiences, leading to an acceptance of underlying assumptions without explicit acknowledgment. For instance, the assumption that 'cold hard facts' derived from experiments and data constitute the pinnacle of research methodology pervades many disciplines, shaping research practices and scholarly conventions.

Acknowledging the implicit philosophical underpinnings of research approaches promotes transparency and encourages critical reflection on the diverse epistemological assumptions that underlie academic inquiry. In behavioural science there is a level of interpretation and human meaning that is applied to the data and 'scientific' method where the implicit ideas of the researcher are impossible to avoid as poignantly highlighted by Slife and Williams (1995 p.7), 'Remember that any piece of information contains the biases of the information's interpreter within it'. This recognition underscores the inherent subjectivity woven into the fabric of research endeavours, where the perspectives and implicit assumptions of the researcher unavoidably shape the analysis and conclusions drawn from the data.

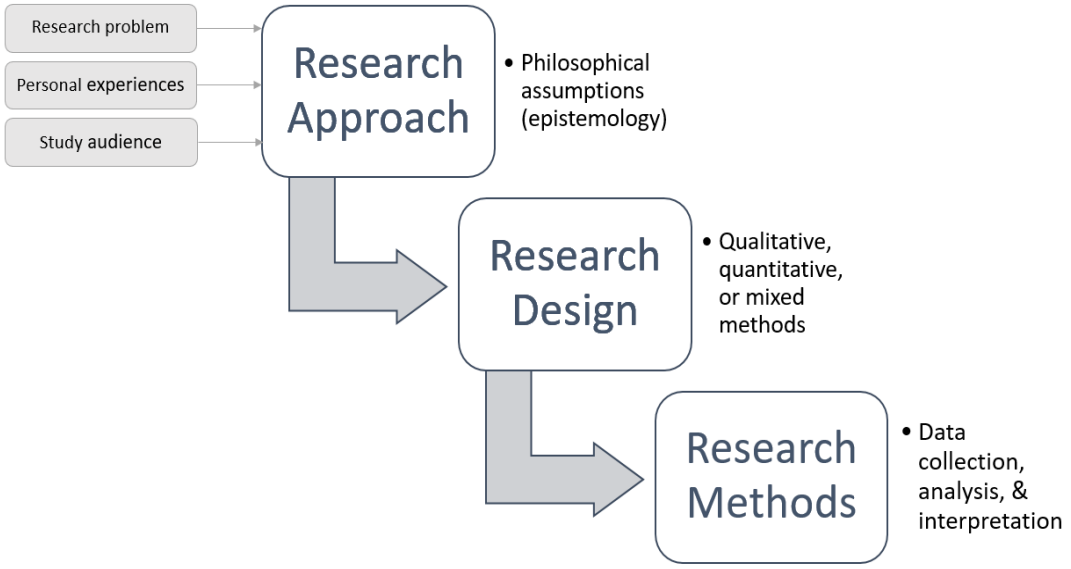


Figure 7 Influences on the research process[8]

Epistemologies underpin all the stages of the research process, as highlighted in **Figure 7**, they are therefore crucial to the creation and utilisation of research. Engagement with the epistemologies is central to learning the craft of research as well as understanding and appreciating the research of others. This appreciation is

[8] Adapted from: CRESWELL, J. W. 2014. *Research design : qualitative, quantitative, and mixed method approaches.,* Los Angeles, Calif.: SAGE.

essential for contributing to the collective conservation in any research field (Pallas, 2001). Moreover, the experienced researcher may take for granted their understanding of knowledge from their undergraduate and professional experiences. Conversely, the novice research may be overwhelmed by the vast assortment of beliefs, often in contrast to what they may have come across so far. As Pallas refers to this assortment of beliefs as a 'cacophony of diverse epistemologies' this confers just how challenging and confusing it can be to understand and keep up with (Pallas, 2001). Given that epistemology is therefore the foundation of research, this sub-chapter will explain the major epistemological paradigms employed in this research.

2.3.2 Postpositivism

In educational research, scientific data gathering is usually based on some measurement of the learner's experience of the external world, i.e. reading a book or watching a presentation. This links any learning to a sensory experience applied from the outside world which is separate to our consciousness. The epistemology known as *empiricism* (from the Latin *empiric(us)* which means 'experienced' describes the research paradigm where empiricists recognise the influence of the external world on behaviour, either directly or following a degree of processing in the mind (Slife and Williams, 1995). Empiricism is a form of inductive reasoning, research that begins with observations to develop ideas and hypotheses that can be tested with further observation (Bowling, 2014). It has been a widely used conventional epistemology for so long, tracing right back to the ancient Greek philosopher Aristotle, that it can be taken for granted as the underlying way to understand human behaviour in the vast majority of cases (Slife and Williams, 1995). It is valuable to examine alternative research philosophies, compare different epistemologies, and acknowledge that the act of this comparison in the research design process is useful to aid the researcher in considering which epistemological approach will be the best fit for their own particular worldview, audience and research problem at hand (Slife and Williams, 1995).

Contemporary research methods have developed from the original concept of empiricism, popularised by John Locke in the 17th century (Bowling, 2014). The practice of developing testable hypotheses and then creating investigations which attempt to disprove them, was advocated for by Karl Popper in 1959, as a popular deductive reasoning technique (Popper, 2002a). In this approach, known as the *hypothetico-deductive* method, hypotheses are created from general ideas before data is gathered and analysed in order to test those hypotheses (Bowling, 2014). Another term for empiricism is *positivism*, recent developments of this paradigm have resulted in the term *postpositivism*. The new approach of postpositivism was born out of critiques of positivism. Although there is still debate within this epistemological orientation, postpositivists reject the notion of absolute truths and agree that human knowledge is conjectural and based on solid but not irrefutable grounds (Phillips and Burbules, 2000). Furthermore, in 1963 Popper also challenged the positivist concept of ideal sources of knowledge where he argued that: *"there are all kinds of sources of knowledge; but none has authority" (Popper, 2002b p.32)*.

Postpositivism is the epistemology that now represents scientific research in the traditional sense (Creswell, 2014). In practice science often takes on a more fluid approach where the rules are flexible and inductive and deductive reasoning can be sometimes be mixed (Bowling, 2014). Positivism relies on there being one objective reality, or version of the 'truth' where the researcher begins with a theory, collects data and proceeds to either support or refute this theory which can then be amended and retested. However, hypotheses are usually partially supported or rejected, rather than completely, and so pure deductive reasoning is often adapted as theories are improved upon while further data emerges in an inductive manner based on probabilities. Consequently, strict application of a scientific method can limit the scope of the research adversely. Therefore, research approaches can be considered as guides and frameworks on which to base our methods and presentation, as opposed to the draconian enforcement of idealistic conventions (Bowling, 2014).

2.3.3 Constructivism

There are numerous paradigms that can be used to guide a researcher's approach, these are sometimes referred to as the 'lenses which the research is viewed through. To expand upon the rationale for the particular lens chosen for the present research, it is worth mentioning a few more of the most commonly used paradigms that differ from positivism/postpositivism. C*onstructivism,* for example, relies on the participants constructing some sort of subjective meaning to their experiences. This is a lens common to qualitative research that allows for broad and varied responses that are often complex and difficult to narrow down or contain within the typically objective and narrow measurements used in postpositivist approaches (Creswell, 2014). Moreover, the researcher acknowledges that that their own personal, cultural, and historical experiences have an effect on their interpretation of the research which they use to develop a theory, rather than test one.

One particular feature of constructivism is that it holds objectivity together with subjectivity and the subjects do not create meaning but they construct meaning from what is already there. Researchers in this paradigm are looking for meaning and often use open-ended questions to gather subjects' views. Understanding of the particular research context or setting is important as well as the researcher's own experiences and background which is acknowledged as a factor in their interpretation of meaning and thus the research findings (Creswell, 2014).

2.3.4 The Transformative Paradigm

During the 1980s and the 1990s the transformative approach was developed by researchers that felt that the postpositivist standpoint did not address concerns of marginalised groups in society or address pertinent issues relating to power, social injustice, oppression or discrimination (Creswell, 2014). In the same way that constructivism takes into account cultural and social influences, so does transformative research but with the agenda of helping marginalised groups, tackling social oppression and promoting political change (Creswell, 2014). Sometimes referred to as multicultural research, in reference to the focus on groups that have

historically been subject to racism, discrimination or exclusion. This approach aims to involve, benefit, and give these groups a voice (Green et al., 2006). Theoretical perspectives are therefore usually applied which are relevant to the people being studied e.g. feminist, racialized, and queer theory—to name a few (Creswell, 2014).

Situating the transformative paradigm within educational research, Green et al. (2006) remark on the effect that education can have on future social matters which can lead to conflict between groups with different political agendas. This can lead to politicisation of educational activity and conflict between different communities that advocate for certain educational methods or treatments. This makes epistemological and philosophical considerations particularly crucial to research standards and design and its subsequent utilisation and interpretation.

2.3.5 Pragmatism

The foundation of pragmatism is that each situation is unique. Therefore, there are no general laws or principles that can be imposed to every scenario dogmatically. As mentioned by Green et al. (2006), there is no one guaranteed way to conduct inquiry that will ensure discovery of the 'truth'. Furthermore, there is in fact no practical need for a rigid framework or ultimate views or assumptions (Green et al., 2006). In this worldview, knowledge is primarily concerned with what works at the time and the usefulness or intended consequences, i.e., where you want to go with the research (Creswell, 2014).

Pragmatists are free to choose whichever methods best meet their needs and purposes, driven by anticipated consequences. They are not committed to one system of philosophy or reality. Consequently, mixed methods are a suitable choice within this paradigm as it is not dependent on whether truth lies in qualitative or quantitative data, or within or outside of the mind (Creswell, 2014). Pragmatists agree with positivism in that there is an external world independent of our minds. However, political, social and historical contexts are important in pragmatic research, its interpretation and utilisation (Green et al., 2006). Ultimately, the pragmatist decides on which explanation or theories are best depending on which will produce desirable results (Cherryholmes, 1992). Cherryholmes (1992, p.16) explains how consequences are taken into account by pragmatists, *'Relevance and purposes go together. Without purposes, without being concerned with consequences, it is difficult to imagine how choices about relevance can be decided. When we decide upon purposes, some contexts and some relevancies come to the foreground'*. A major difference between the positivist and pragmatic viewpoints is that positivism maintains that descriptions, theories, and explanations precede values, social policy, and educational practice. Contrastingly, as explicated by Cherryholmes (1992), pragmatists suggest that decisions cannot be made without reference to values and values and preferences always come before research activity and interpretation. One fundamental feature of pragmatism is that the researcher is free to choose a variety of methods with multiple forms of data collection, analysis, interpretation and foundational assumptions and worldviews (Creswell, 2014).

2.3.6 Epistemology of the Present Research

One difficulty with philosophically situating this research arises with the cross-disciplinary considerations inherent to the research topic of competency-based education for pharmacy. The research questions concern both pharmacy practice and pharmacy education. Health, thus pharmacy, research are commonly linked to scientific research practices where dominant paradigms tend to be positivist in nature (Bowling, 2014). Educational research however, tends to have more frequently varied and debated philosophical standpoints (Phillips and Burbules, 2000). Within the 21st century however there have been calls for more research on evidence based educational interventions and for more 'scientifically based research' in the educational research field (Green et al., 2006) . This is where the audience for the findings of the present research also comes into play.

The present research is subject to a sustainable development agenda as it is partly situated in the wake of an initiative from the Department for International Development (DIFD) in the UK which awarded funding for a project intended to reform pharmacy education in Kenya. This project is intertwined with the sustainable development agenda and therefore has some political connotations of its own. Although the situation of the research is recognised within the wider developmental agenda, no such political or social theory has been applied. However, the present research was designed to facilitate joint ownership of the findings from the development of the Kenyan Competency Framework with the Pharmaceutical Society of Kenya (PSK). Kenyan stakeholders from the PSK also had opportunity to collaborate on the design of the data collection and dissemination of the research activities and results, more details regarding these processes are outlined in Stage (i) and Stage (ii) in Part 2 of this thesis.

Practically, pharmacy education is often designed and delivered by pharmacists and other disciplines linked to the healthcare sector. This by no means excludes research methods that are less frequently encountered within the research community relevant to pharmacists and pharmacy school staff. However, it is worth bearing in mind the practicalities of answering the research question in a way that is accessible to the pharmacy-based research audience. On the other hand, the research addresses educational methods and so is subject to the commonly accepted research practices within the educational research discipline also. Therefore, this raises the question: What knowledge is relevant to both the practice of education and pharmacy? What methods should be used to produce this knowledge legitimately? The answer to this is there are many different valid methods of producing valid data which will add to the literature on pharmacy education and CBE.

As a pharmacist, my educational background has been steeped in the postpositivist research paradigm, which has significantly influenced my approach to this research endeavour. Recognising the predominant readership comprising healthcare professionals and related academics, I have predominately opted for quantitative methods, aligning with the established tradition of positivist-leaning research within

the health and related disciplines. However, given the overarching aim of effecting change in pharmacy education on a global scale, it is imperative that the research design and presentation are both familiar and recognisable across diverse contexts. This necessitates a pragmatic approach, wherein the methods employed and findings presented are pertinent not only to academia but also to policymakers and regulators within the field.

Despite the frequent adherence to a positivist framework in the execution of the research, it is important to acknowledge the underlying pragmatism inherent in the overall worldview guiding this research. This recognition underscores the acknowledgment that absolute truth is elusive, and that the ultimate value of the research lies in its potential impact and utility within the realm of pharmacy education and practice. Therefore, it is recognised that there are a variety of different approaches that could have been taken and that complete objectivity is not realistic (Bowling, 2014).

As demonstrated by the discussion of some of the key philosophical research paradigms in this chapter, each approach could have generated knowledge with worthy relevance to add to the literature. Consequently, in this sense I recognise the pragmatic worldview that there is no way of knowing for sure the 'true' reality of a situation, which is actually in opposition to the general positivist worldview (Cherryholmes, 1992). Moreover, in this way, I sympathise with the pragmatists' perspective that absolute objectivity is impossible and that research decisions are often made with reference to values. Although it is not always desirable to eliminate one's positionality from research, it is a tenant of positivism to attempt to do so, hence this research endeavours to reduce the potential impact of my position as a practicing pharmacist, and hence previous pharmacy student, on the quantitative findings. In the vein of transparency however, it is realistic to recognise that my position has had an effect on the design, interpretations and presentation of this research. The approach in this work therefore, is just one of many potential compelling approaches which could have been selected to achieve the desired outcome of investigating the use of CBE in pharmacy education and add to the overall conversation. The design of the research from this perspective sits within the pragmatic worldview as it is ultimately designed to best meet the needs and purposes in relation to the desired outcomes and does not proclaim to strictly adhere to any one single philosophy or approach.

The broad aim of the present work is essentially to gather data from the relevant stakeholders and participants that can be used in a widely acceptable format, across different global contexts to provide information on the CBE approach to pharmacy education. This information should be used as part of a wider argument to drive change and improvement for the education of pharmacy students and pharmacy professionals, ultimately improving the health of individual patients and larger populations. Most importantly, this work follows the general principles succinctly

described by Green et al. (2006): '*Research needs to be factually and logically rigorous, sensitive to others, and conceived so as to bring about public benefit'* (p.28).

This present research combines elements of a quantitative survey approach with a qualitative research approach in the form of the analysis of the findings from the systematic review in Part 1 Stage (i) and the global survey in Part 1 Stage (ii). This allows some methodological triangulation within the research and although this can sometimes reveal discrepancies and disagreements, triangulation tends to counteract threats to validity (Robson, 2016). The mixed methods employed in this research actually attempts to mix objectivity with subjectivity. This takes shape in the form of relating the global survey results to the features of CBE in the systematic review via a thematic analysis. Analysing the results in this manner adds a perspective to the global survey results by positioning them within the wider context of the CBE for pharmacy literature. Conversely, this analysis allows for interpretation of the features of CBE in relation to quantifiable data from contemporary educational experiences in pharmacy and the pharmaceutical sciences.

2.4 An Introduction to Quantitative Research Methods

Various methods of quantitative data collection are available, although a comprehensive discussion of these is not within the scope of this thesis, some of the main approaches of quantitative methods employed in this research will be discussed briefly in this chapter. Specific details pertaining to the relevant individual stages of the study will be discussed in the subsequent corresponding chapters.

2.4.1 Quantitative Research Methods

2.4.1.1 Surveys

The purpose of a survey is to gather numerical descriptions of a population, usually a sample rather than the whole population. We use surveys to make inferences which describe unobserved phenomena based on observed phenomena (Groves et al., 2009). Surveys are a prevalent approach to educational and health research, principally due to their ability to collect data from a large amount of people more efficiently than is usually possible in experimental or quasi-experimental designs (Mertens, 2020).

Surveys can be a valuable tool for gathering information on the thoughts, behaviours, and feelings of both groups and individuals. However, in surveys this information is always self-reported in some way, whether that be on paper or in person. Validity is therefore dependent on the honesty of the respondent (Mertens, 2020). Various design issues integral to planning and conducting surveys must be taken in to account (Mertens, 2020). Some of these design issues will be discussed in the subsequent sections of this sub-chapter including aspects of questionnaire development, data collection and survey measurement errors.

Data collection

Data collection methods include: postal mail; telephone; personal interviews; email; online surveys; video-based surveys; mobile phone surveys; or a combination of these (Mertens, 2020). Mail and online survey methods are often preferable when collecting information in a closed-ended structure, mostly because they are relatively low-cost options which also permit respondents time to gather information to assist with their responses e.g. if asked to provide enrolment or expenditure figures. Furthermore, respondents may be more honest about socially undesirable activities (e.g. smoking or gambling) with online or mail surveys as opposed to interview methods (Callegaro et al., 2015). Conversely, response rates are generally low and it is not possible to determine the respondents understanding of the questions, plus they do not provide opportunity to encourage respondents to provide more in-depth answers (Mertens, 2020).

Fairly recent technological developments have brought about a steep rise in online, also referred to as a web survey, where the respondent interacts with the survey online in real time to provide their responses. The web surveys can be distributed through URL (Uniform Resource Locator) links on email, mobile phone messages or social media (Callegaro et al., 2015). In fact, response rates can sometimes be augmented by using a combination of these distribution channels (Mertens, 2020). A web survey is defined by Callegaro et al. (2015) as 'a survey mode using computerized self-administered questionnaires, stored on a specific computer connected to the Internet (i.e. server), which respondents access via a web browser'.

Greenlaw et al (2009) demonstrated that web survey response rates were higher than those for paper-based postal surveys, and over 7 times cheaper. Furthermore, in a cross-national study, Strabac and Aalberg (2011) found that web surveys also beat phone surveys on cost when the 'price per respondent' was compared for both formats over the same sample populations. Other advantages of the web survey include: faster responses; automated data collection, scoring and reporting; quick troubleshooting; more interactive or tailored formats; and ease of access to a larger sample size (Callegaro et al., 2015).

Survey errors

As with all measures in science, measurement in social surveys is not without error. Question design, data collection, and sampling procedures all impact the accuracy of the data being able to describe what it is intended to capture. Therefore, the careful application of these procedures combined is crucial for good survey design (Fowler, 2009).

The main goals of survey design are to minimise error in the data collected, and to measure the error that is inherently part of that survey. The extent to which the sample does not accurately describe the target population is the first fundamental source of potential error. Secondly, a survey is designed to describe the experiences, opinions, and other characteristics of those answering the questions. The extent to

which those answers are not accurate measures of those answering the survey is the second major source of error in survey research (Fowler, 2009).

Measurement error encompasses inaccuracies in responses, whether due to intentional misrepresentation, such as respondents underreporting socially unacceptable behaviours like drug use, or random fluctuations in answers over repeated surveys, termed response bias (Groves et al., 2009). Processing error arises during data processing, including editing responses where differences between the original and edited versions occur, and inconsistencies among coders in coding free-text responses (Groves et al., 2009). These errors affect individual responses directly. Conversely, non-observational errors, like sampling error, arise from limitations in sample representation due to systematic exclusions or chance selections, leading to discrepancies between the sample and target populations (Fowler, 2009). Coverage error occurs due to imperfect sample frames, either under- or over-representing the target population, while non-response error results from missing data due to incomplete responses, potentially skewing statistical analysis (Groves et al., 2009). Adjustment error refers to post-survey adjustments aimed at mitigating sampling, coverage, and non-response biases, often through weighting techniques (Groves et al., 2009).

2.4.2 Quantitative Methods in the Present Research

The present research utilises quantitative research methods in three different web-based survey approaches. The web survey format was chosen for Part 1 Stage (ii) and Part 2 Stage (i) and (ii) of the present research because of its convenience, low cost, better response rates, and relative ease of use for conducting international research. Preliminary discussions with the Kenyan collaborators on this research established that internet coverage and access was good and that PSK member engagement with their own web-based surveys in the past had been successful. The web-based approach was also chosen for the Global CBE Survey as the sample population of interest was academics working in higher education where internet, and email, access is commonplace and widespread.

2.4.2.1 Part 1 Stage (ii) Global CBE Survey

The FIP were the collaborators for this stage of the present research and they were able to distribute the web survey URL via their email databases. Again, time and cost constraints were a concern and the survey had to reach many diverse and widespread geographical locations in an attempt the get optimal global coverage. The web survey mode also allows respondents to spend some time collecting information at an institutional level and they could save their progress and come back to the survey at a later date. More personal survey methods may have elicited a higher response rate but within the restrictions of the context of this research it was not feasible. Moreover, the statistical credibility of the survey was not a main priority in this case as the goal of the research was to gather information on a broad spectrum of educational institutions which was not available by any other means.

2.4.2.2 Part 2 Stage (i) FIP GbCFv2 Applicability Survey

The web survey that was used in this stage of the present research was based on a Likert scale survey instrument. This mode of data collection was chosen because of the need to gather and analyse responses in a timely manner across a widespread population of pharmacists across the country. The web survey mode facilitates the ease of analysis as the results can be downloaded straight to an electronic database and processed in a statistical software package. Furthermore, the target population of qualified pharmacists in Kenya have a good level of computer literacy and access to the internet. Additionally, the collaborators from the PSK had email addresses for their members ready to hand which facilitated the ease of dissemination of the web survey URL.

2.4.2.3 Part 2 Stage (ii) Local Competency Framework Development

A modified version of the FIP GbCFv2 Applicability Survey was used as part of the consensus development process. Panel members were asked to rank the applicability of the GbCF v2 using a Likert scale prior to attending the face-to-face consensus development panel workshop and the level of agreement was also assessed again and discussed in sequential rounds. The web survey mode was chosen to facilitate ease of data collection and processing as the ranking scores had to be discussed with the participants immediately in order to complete the consensus development process within one day and it was an efficient method of gathering quantitative data for application in real time.

2.5 Sampling

The issue of sample size and sampling is crucial to the external validity (generalisability) of the results stemming from all methods, including experiments (Bowling, 2014). The probability that a test will produce a significant difference at a given level of significance is called the *power* of the test (p.198 Bowling, 2014). However, power calculations should be used realistically and are more crucial for certain study designs, such as with clinical trials. In some instances, power calculations can produce extremely large target sample sizes which are, in practice, unachievable (i.e. due to limited availability of people from the population of interest). Furthermore, not every study warrants a strict sample if the aim is to measure a range of ideas or opinions and numerical precision is not paramount (Fowler, 2009).

The key component of evaluating a sample is by considering the sample selection process, including how well the test sample represents the target population. Respondent characteristics, e.g. availability or initiative to take part, can affect the chances of selection and in this instance, there is no statistical basis for calculating how well, or how poorly the sample represents the population. Sample design, size, and selection methods all affect how well the sample is likely to reflect the characteristics of the whole population of interest (Fowler, 2009).

E-mail addresses can be a useful way of accessing a comprehensive sample of a population when they have universal access to this method of communication e.g. in universities or businesses. Accessing the whole population is still however not always possible due to; how up to date an email database is, how willing a respondent (sample unit) is to participate or whether they have access to the internet at the time of the study. Probability of selection can be taken into account and the data at time of analysis can be adjusted to reflect this, however it is not always possible to calculate the probability of each individual being selected so this is not universally feasible (Fowler, 2009).

2.5.1 Random (probabilistic) Sampling

This method generates a sample that is highly generalisable to the target population and the most rigorous method of selecting a sample (Creswell, 2014). In a simple random sample, each sample unit has an equal probability of being selected in a similar way to 'pulling a name out of a hat'. An equally precise method of sampling, especially where a sample frame is large, is systematic sampling where each sample unit is numbered and every x numbered units are selected depending on the number of units in the sample frame list and how many are to be selected (Creswell, 2014). Stratified sampling is where a sample is stratified according to selected characteristics (e.g. gender, age, income, education level). The researcher then ensures that they select the corresponding ratios of sample units at random within each stratum to reflect the distribution of the selected characteristics within the target population as a whole (Creswell, 2014).

2.5.2 Non-random (non-probabilistic) Sampling

It is not always possible to secure a probabilistic sample due to practical financial or time constraints. Therefore, non-probabilistic samples can be used although they are not as reliable and you cannot assess the risk of error as accurately as you can with probabilistic sampling techniques (Fowler, 2009).

Convenience sampling involves selecting sample units based on their availability and ease of recruitment, lacking generalisability but results are often targeted at policy makers (Bowling, 2014). Results obtained on the basis of this sampling method may not be representative but can be informative about the range of opinions found in the population, yet do not provide information about which proportions of that population have such opinions (Antonius, 2013). Purposive sampling intentionally selects units with specific characteristics or knowledge valuable to the research topic and can be useful for experimental studies. Snowball sampling relies on initial respondents to recruit others within their network, limiting sample units to connected individuals. Theoretical sampling, non-random and iterative, selects units based on the research concept or theory of interest, evolving as the research progresses (Bowling, 2014).

2.5.3 Sample Size

The size of the sample in relation to the whole population has very little effect on the ability of that sample to describe a certain population. Therefore, the fraction of a population sampled is not critical to determining the sample size. Sample size calculations based on confidence ranges for variability are available where the researcher can select a margin of error acceptable to them, together with a confidence interval for this margin and an estimate of the percentage of units in your sample that are likely to respond. However, these calculations are based on random samples and relate to sampling errors only and do not take in to account other sources of error in a survey design, such as nonresponse or reporting errors (Fowler, 2009). There is also no arbitrary number on which to centre sample size decisions based on the types of sample frames in question e.g. national scale or regional. As with most research design elements the sample size is context dependent and is determined by the particular aspects of each study and the overall objectives of that study (Fowler, 2009).

2.5.4 Response Rates

The response rate is calculated from the number of eligible respondents who successfully participated in the study as a percentage of the total eligible study population and there is no agreed standard for an accepted minimum response rate (Bowling, 2014). Therefore, if a complete sample population list is unavailable or the sample frame is unknown the researcher cannot calculate a response rate. It is always possible that non-respondents may differ in some of their characteristics compared to the respondents which can bias the results but it is not always possible to determine the direction of that bias (Bowling, 2014). Non-response reduces the effective sample size and reduces the precision of the results, and the procedures that a researcher decides to use for data collection can have a major influence on the response rate (Fowler, 2009). Therefore, it is important to consider non-response factors in the research design process (Cohen et al., 2018). Further details with regards to specific non-response factors are discussed in the subsequent individual study chapters.

2.5.5 Sampling in the Present Research

2.5.5.1 Part 1 Stage (ii) Global CBE Survey

A convenience snowball sampling method was employed to recruit participants for this stage of the research as there is no sample frame of all institutions offering pharmacy or pharmaceutical education programmes worldwide. The initial list of contacts was obtained from the FIP using their mailing list of Academic Institutional Members (AIM) and non-members. Collaborators from the FIP were also asked to distribute the survey through their personal networks, which led to further distribution through the European Association of Faculties of Pharmacy's (EAFP) mailing list. Respondents were also asked to invite further suitable participants to respond. No response rate was calculated due to this non-probability sampling technique.

2.5.5.2 Part 2 Stage (i) FIP GbCFv2 Applicability Survey

A convenience sampling strategy was adopting during the survey distribution phase whereby the pharmacists registered as members of the PSK were invited to participate via email. This cluster of pharmacists was selected to represent the population of practising pharmacists in Kenya. At the time of distribution, the PSK estimated they had a total of 2041 pharmacist registrants and approximately 1700-1800 of these were expected to be currently practising (verbal communication February 2020). However, there is no accurate sampling frame of all pharmacists practising in Kenya which precludes a probability sampling approach and therefore response rate was not considered for a sample size calculation.

2.5.5.3 Part 2 Stage (ii) Local Competency Framework Development

Participants in the consensus development panel were selected according to the purposive sampling method. A shortlist of stakeholders relevant to the Kenyan pharmacy workforce in terms of service delivery and education was created in partnership with collaborators from the PSK. This involved inviting participants from the network of members of the PSK to achieve an adequate mix of representatives from different sectors.

2.6 Introduction to Qualitative Research

In qualitative research there are a plethora of strategies to choose from but typically, qualitative research is about theory generation. The design process is flexible and emerges as the research process unfolds where inductive logic is used to develop theoretical and conceptual ideas (Punch, 2014). In contrast to quantitative research, context and meaning is more important than objectivity or generalisability (Robson, 2016). Because of this flexible inductive approach, the researcher must be open to a change of focus as dictated by the emerging data so plans of inquiry are often tentative and constantly evolving (Mertens, 2020). In the remainder of this sub-chapter we will consider aspects of the qualitative methods concerning the present research.

2.6.1 Qualitative Research Methods

2.6.1.1 An introduction to systematic reviews

A literature review aims to identify, locate, collate and analyse the existing literature—what is already known and written down about a particular research topic (Robson, 2016). The contrast between a literature review and a systematic review is that the latter also synthesises the findings from the literature to answer a research question. Systematic reviews therefore are research projects in their own right (Punch, 2014). They are a specific type of literature review which has an explicit and accountable systematic methodological approach (Gough et al., 2017). The objective is to pull together and integrate all of the available research to answer a particular question which can be achieved by using aggregative synthesis; pooling or adding up data from primary research studies, or by using a configurative approach to synthesis where data is organised and interpreted without necessarily being added up (Punch, 2014).

Aggregating and configuring individual studies in a systematic and rigorous way can provide answers to a problem via a study that is greater than merely the sum of its parts. That is, systematic reviews both examine previous theories and provide new ones, investigate discrepancies, make sense of large bodies of information, explore what works and what doesn't, provide recommendations for intervention and guidance for future research (Petticrew and Roberts, 2006). They can however be complicated and resource intensive and there are strict rules to abide by. One of the first protocols to be followed in the field of systematic review was the Cochrane collaboration in 1993, for randomised controlled trails (RCTs) in healthcare. Closely followed by the Campbell Collaboration for social sciences, including education and international development (Robson, 2016). There are other similar guidelines such as the Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA) statement originally released under that name in 2009, and recently updated in 2020 (Page et al., 2021).

2.6.1.2 Qualitative systematic reviews

A qualitative systematic review is concerned with concepts, themes and theories and can be used to investigate and understand health and social matters in terms of meaning, context, and processes from the perspective of the people involved in the selected studies (Harden and Thomas, 2010). In contrast, if the researcher was concerned with statistical measurements such as effect sizes or confidence intervals then a quantitative systematic review would be more suitable (Harden and Thomas, 2010).

Many different qualitative systematic review approaches exist, all of which involve a comparison of the studies in terms of their concepts, themes or theories. Examples include; meta-ethnography, thematic synthesis, and formal grounded theory. Furthermore, an assessment of the quality of the studies included in the review is also carried out. (Harden and Thomas, 2010)

Qualitative systematic review processes are relatively new and still evolving in comparison to quantitative systematic reviews (Seers, 2015). The Cochrane Collaboration does now have a 'Qualitative and Implementation Methods Group', and published its first qualitative systematic review in 2013 (Gülmezoglu et al., 2013). In this review by Glenton et al (2013), barriers and facilitators to the implementation of a lay health worker (LHW) programme for maternal and child health were addressed. This provided crucial evidence, which complimented a related Cochrane effectiveness review, for the development of a subsequent WHO guidance document and highlighted areas where direct evidence was absent (Gülmezoglu et al., 2013). This kind of contribution to international recommendations is vital knowledge as the acceptability and feasibility of such interventions can often determine their success just as much as their effectiveness. In other words, optimal planning for organisations involves considering challenges to the implementation of interventions as well as their expected benefits (Gülmezoglu et al., 2013). Effectively, by combing the qualitative systematic review with the effectiveness review a mixed methods

approach was adopted. A mixed methods systematic review can also be a stand-alone research study which 'combines the findings of qualitative and quantitative studies within a single review to address overlapping or complementary questions' (Harden and Thomas, 2010).

Qualitative systematic review methods are applied to primary research that is qualitative in nature. As previously discussed, qualitative and quantitative research in practice may not be that distinct and primary research studies can often exist on a continuum somewhere between the two. If the primary research studies are not sufficiently homogenous in their design approach, then it may not be suitable to apply a traditional quantitative or qualitative systematic review method.

2.6.1.2 Narrative synthesis

In narrative synthesis there is always a comparison of the findings from the primary studies included in the review, but depending on the evidence included, there may be elements of data integration and/or interpretation (Popay et al., 2006). In fact, synthesising the evidence in some circumstances may not have an exact clear linear path and so reviewers may use a variety of approaches in an iterative manner (Popay et al., 2006).

Popay et al (2006), suggest that narrative synthesis is appropriate; prior to performing a specialist approach e.g. meta-analysis or meta-ethnography; when studies are not sufficiently similar for a specialist approach; or when the review question requires the inclusion of a variety of research designs with a wide range of findings rendering other methods of synthesis as inappropriate. Moreover, social science studies are often heterogeneous and so narrative synthesis lends itself well to topics of practice and policy in the arena of health and education. Narrative synthesis is a useful option available to the reviewer interested in both the effects of an intervention as well as the factors influencing its implementation (Popay et al., 2006).

Translating both quantitative and qualitative data into a common rubric for evidence synthesis is also referred to as interpretation. Two common forms of translation which can be used within a narrative synthesis are thematic analysis and content analysis. The aim of translation is to identify any overlaps of related topics across the studies included in a review and to explore the differences and/or similarities (Noblit and Hare, 1988). This can allow for the transformation of quantitative finding into qualitative form or vice versa (Popay et al., 2006).

<u>Thematic analysis</u>

In thematic analysis researchers develop themes or categories from their database of information (Creswell, 2014). These themes unfold as more evidence is examined in an inductive manner. In other words, the researcher does not begin data extraction and analysis with a complete set of a priori themes (Popay et al., 2006). The researcher then takes a deductive approach, once the themes are established, and examines the database further to determine if additional information can be

gathered or more evidence supporting the themes can be identified (Creswell, 2014). Therefore, there is a forwards and backwards approach until the themes are finalised. This method means that the results can be quite different, depending on the processes used by the individual reviewer(s), hence it is important to be as explicit as possible with the details of how the thematic analysis was performed (Popay et al., 2006). Findings can then be summarised in the form of a table under the different thematic headings. This organisation of themes structured in a table can facilitate clear presentation of the synthesis, yet this method still affords the reviewer with a good degree of flexibility for the integration and interpretation of both qualitative and quantitative studies (Dixon-Woods et al., 2005).

It is possible to form new knowledge through this method, although it tends to from a synthesis reflective of the key ideas and conclusions already present in the primary data (Dixon-Woods et al., 2005). The criticisms of this method are generally to do with the difficulty of expanding knowledge beyond the conclusions of the original studies, and a lack of clarity in the analysis procedure—which can also be a problem with repeatability of the processes involved (Dixon-Woods et al., 2005).

2.6.2 Qualitative Methods in the Present Research

2.6.2.1 Part 1 Stage (i) Systematic Review

The systematic review procedure in the present research has elements of a qualitative approach through the use of the concepts of narrative synthesis and thematic analysis. The motivations for this were largely due to the types of studies included in the review and the original broad research questions. The inclusion of diverse study types within the systematic review also warranted a consideration of a mixed studies review approach. Where the purpose of a review method is to clarify key concepts and identify key characteristics or factors related to a concept, a scoping review could have been considered a potentially appropriate method of research suitable to part of the aim of this stage of the research (Munn et al., 2018). However, this study was primarily designed to answer the specific question of what the features of CBE are for pharmacy education internationally. This information would then be used to address similarities or variations with the literature compared to the medical field with the additional intent of also identifying areas for future research. Moreover, the study sought to synthesise and evaluate evidence from existing literature to derive meaningful conclusions about the contemporary features of CBE. This focused research question, requiring a rigorous and detailed evaluation of high-quality evidence, aligns more closely with the objectives of a systematic review. In this context a systematic review approach is considered more appropriate (Munn et al., 2018). In conclusion, while a scoping review could have been useful for exploring general themes in CBE, the focused nature of this research, coupled with prior availability of substantial literature, and the need for critical analysis and synthesis, made a systematic review the better choice. This approach ensured a comprehensive and methodical examination of the existing evidence, culminating in a detailed summary of the contemporary features of CBE for pharmacy education

Data on features of CBE were extracted from the studies using an inductive narrative synthesis approach. This method was chosen as a degree of interpretation of the data from the studies were required to extract the features of CBE and address this research question.

Existing data from the medical field was used to enhance the precision and reliability of our data extraction process. This approach bolstered the robustness of the study, and by comparing them with prominent practices observed in medical education valuable insights could be gained to enrich the analysis of the pharmacy literature.

2.7 Introduction to Mixed Methods Research

There is a historical debate in social research in regard to whether the quantitative or qualitative approaches are best suited to the study of human behaviour. However, although the two different discernible methods remain prevalent there is a growing recognition of combining elements of both quantitative and qualitative research styles under the label of multi-strategy, or mixed methods, design (Robson, 2016).

2.7.1 Mixed Methods Research Strategies

2.7.1.1 Systematic review

There are different types of systematic review, such as those that involve a statistical summary of the included studies are known as *meta-analysis*. Conversely, *narrative reviews* provide a descriptive, rather than a statistical, account of the included studies (Petticrew and Roberts, 2006). As with any research design decision, the chosen approach largely depends on the aim of the research and the related research questions. When comparing results from RCTs, for a certain medication efficacy for example, it is common to have studies that involve copious data and statistical analyses. In educational concept research however, this is less likely to be the case and hence a meta-analysis would not be appropriate and a narrative review would be the more fitting approach. In some cases, however the literature on a particular research topic might include quite a variety of study designs and a mixed methods approach can be useful in this instance.

Mixed method systematic reviews

A mixed method systematic review combines the findings of qualitative and quantitative studies within a single review to address overlapping or complementary questions (Harden and Thomas, 2010). It can often be beneficial to combine a narrative review with a meta-analysis as this provides the added benefit of supplementary useful details, characteristic of a mixed methods approach (Rodgers et al., 2009).

Quantitative systematic reviews and qualitative systematic reviews can tell us different things about a research problem. A meta-analysis, for example, can tell us which interventions are most effective but unlike a narrative review they cannot tell us whether patients find this intervention acceptable or appropriate. These 'mono-method' reviews therefore have limitations. A mixed method approach however,

confers the ability to include qualitative research alongside quantitative research (Harden and Thomas, 2010).

Mixed methods systematic reviews come in numerous forms and may involve a qualitative and a quantitative evidence synthesis that is then integrated (Harden and Thomas, 2010). However, this is not necessarily the case and either a predominantly qualitative or quantitative approach may be utilised throughout the review process.

In an effort to recognise the many divergent mixed method review approaches, which were principally referred to as 'integrative review' (Nurius and Yeaton, 1987), Pluye et al. (2009), advocate for the term 'Mixed Studies Reviews' (MSRs). MSRs are defined as: 'a form of literature review in which a reviewer or reviewer team concomitantly reviews qualitative and quantitative studies, and/or mixed methods studied, for the broad purpose of breadth and depth of understanding and corroboration of knowledge based on all types of empirical research, and synthesizes qualitative findings and quantitative results of primary studies' (Pluye et al., 2009 p.532).

For policy and practice concerns, the review question often requires the inclusion of different types of research that have used various different methods. When making decisions regarding health services, for example, the review questions often tend to be complex and multifaceted (Pope et al., 2007).

The Evidence for Policy & Practice Information Centre (EPPI-Centre), at the University College London (UCL), has produced a guide to methods for conducting systematic reviews. Two features characteristic of the EPPI-Centre reviews are; user involvement; and a two-stage process (EPPI-Centre, 2006). User involvement refers to when potential users of the review are involved in the design process and development of the review questions via advisory or steering groups (Harden and Thomas, 2010). Members of the groups can be those that have expertise in the review subject or are going to potentially use the review findings; such as teachers, pupils, or employers. This can also assist with external input to improve relevance and quality of the review. The different perspectives gained from these users can enrich the research, furthermore less experienced reviewers may benefit from working with more experienced ones. Advisory or steering group members can also come from many different locations adding further to the diversity of perspectives which can be useful for international projects (EPPI-Centre, 2006).

A two-stage review is essentially when reviewers first gather a picture of the research topic, perhaps via a descriptive map of the research gathered from preliminary examination of the existing literature. The scope of the research is then refined accordingly and this may be particular necessary when there is an unmanageable number of studies eligible for inclusion. Limited capacity of the review team may also warrant a concentration of time and effort on in-depth review on a more focused area rather than a less substantial review on a broader area (EPPI-Centre, 2006).

Generally speaking, broad, multifaceted and complex research areas are well suited to the mixed methods approach. In practice and policy research in particular reviews are usually conducted with a specific utilitarian purpose in mind. The EPPI model is an example of one that aims to synthesise evidence in a way that makes the findings useful to its relevant users. These findings would otherwise be difficult for these users to locate and interpret especially due to lack of time or research experience (EPPI-Centre, 2023). The end goal of a systematic review in this context, and in the context of the present research, is to contribute to improvements in practice in a meaningful way which is in alignment with the pragmatic research epistemology that underpins this research.

Quality Analysis

After deciding which studies are to be included in a review, it is critical to appraise the methodological quality of those studies (Popay et al., 2006). This quality analysis helps to uncover bias and error in the individual studies and can be used to make decisions about whether the study should be excluded altogether or whether a study should be given less weight in any subsequent analyses (Harden and Thomas, 2010). The quality of the individual studies can have an effect on the relevance and trustworthiness of the final review conclusions (Popay et al., 2006). A quality assessment is independent to the consideration of the individual studies in terms of the actual review question and is based on whether the study is well conducted according to what is customary for a piece of research of that type (EPPI-Centre, 2006).

There are many different tools available for the critical appraisal of quantitative, qualitative, and mixed methods research which ensure the process is systematic, transparent and reproducible (Petticrew and Roberts, 2006). It can be difficult to choose which tool to choose especially due to the heterogeneous nature of the studies include within a mixed methods review (Heyvaert et al., 2013b). One such critical appraisal tool, known as the Mixed Methods Analysis Tool (MMAT), has been shown to have reliability and feasibility in health science research (Pace et al., 2012). Furthermore, the MMAT is time efficient, easy to use and comprehensive (Hong et al., 2018a).

2.7.1.2 Consensus development methods

Developing a consensus about a particular topic involves achieving a general agreement or convergence of opinion (McMillan et al., 2016). In research, consensus development concerns generating ideas, determining priorities, or problem-solving (Van de Ven and Delbecq, 1972). There are a number of consensus development methods (CDMs), including the: Nominal Group Technique (NGT), Delphi Technique (DT), Consensus Development Conference (CDC), and a version of the NGT known as the RAND/UCLA appropriateness method (RAM) (Arakawa, 2022, Black, 2006). CDMs allow the exploration of subjective and objective information from the different perspectives of the various disciplines related to the topic at hand (Van de Ven and Delbecq, 1972). Furthermore, CDMs allow the researcher to obtain this information

in a rigorous and transparent manner which supports the validity of practice and policy decision making processes (Arakawa, 2022).

CDMs can be useful for decision making in both clinical guideline (Murphy et al., 1998), and framework (Martin and Kasperski, 2010) development, as well as for pharmacy practice (McMillan et al., 2016). Moreover, the WHO notably include the use of CDMs in its own official handbook for guideline development (World Health Organization, 2014c). The objective in a CDM is to use a quantitative approach to produce qualitative information on complex topics in a systematic manner (Arakawa, 2022). This is particularly desirable when a topic requires an element of exploration, discussion, debate or explanation that is not easily obtainable via other methods. CDMs facilitate association of information across the multiple professional disciplines, or other relevant stakeholders, for example, students and teachers may need to be involved in a decision making process for an educational intervention but may be likely to have differing perspectives which will need to be converged in some way (Van de Ven and Delbecq, 1972).

The NGT and the DT are the most common CDMs (Black, 2006). NGTs rely on being able to host face-to-face meetings of some description, this can now be facilitated via online video meeting platforms, but the DT can be completed remotely in a manner independent to the other participants. However, it can be a relatively slow process sometimes taking up to months to complete (McMillan et al., 2016). The DT can also be considered somewhat too complex for nonprofessional participants (McMillan et al., 2016). In addition to the time efficiencies of the NGT, one of the other noteworthy benefits is the chance for participants to hear divergent views in a group setting which can actually lead to a greater extent of agreement (Black, 2006). Higher participant numbers are customary with the DT compared to a NGT, maximum recommended numbers for each are 50 and 12 respectively (Black, 2006). CDMs can enhance ‘ownership’ of the guidelines, tools, and/or decisions that emerge (Black, 2006). This can be particularly useful when the participants consist of the users of the framework or guideline being produced from the research, as the end product is ultimately being designed for the participants, by the participants (Black, 2006). The convenience of small participant numbers and rapidity of the process, together with the superior level of consensus often reached with an NGT, makes this CDM particularly attractive to the researcher looking to produce an output in a relatively short space of time. In the remainder of this section, we will focus on salient aspects of the NGT process in more detail.

2.7.1.3 Nominal group technique

Originally developed in the 1960s, the NGT is a controlled and structured process of interaction between a small group of people who are closely associated with a problem area (Van de Ven and Delbecq, 1972). This area is one that is considered too complex to be defined by quantitative measures which are too reductive to achieve the exploration into the affectional (emotional and expressive), environmental, organisational, and political dimensions of a particular issue (Van de Ven and

Delbecq, 1972). As with other formal CDMs the likelihood of scientific validity is increased over informal methods, due to the clearly defined structure. This structure also helps to mitigate the influences of dysfunctional unbalanced participation from certain dominant characters in the group (Van de Ven and Delbecq, 1972, Grimshaw and Russell, 1993). Depending on the aims of the research, the types of specialist or professional categories included in the participant group can have an impact on the results. However, the individuals selected within those categories has little effect on the ratings within a group (Hutchings and Raine, 2006).

This structure commonly consists of four stages: silent generation; round robin; clarification; and ranking—conducted via structured questionnaires using Likert scales (Black, 2006). The extent of agreement is agreed prior to beginning the process and the clarification and ranking stage can be repeated until a consensus is reached (Arakawa, 2022).

The silent generation and round robin stages can in some occasions be replaced with alternative ways to generate ideas or statements that can be discussed, clarifies and ranked (McMillan et al., 2016). These alternative variations to the traditional NGT are referred to as a 'modified nominal group technique' (mNGT) (McMillan et al., 2016). An initial survey can be sent out to participants prior to the mNGT meeting to establish the initial consensus. Typically, a 9-point Likert scale ranging from strongly agree to strongly disagree is used to establish the ratings of particular statements. The researcher should then calculate the median rating score for each statement and calculate how much each participant has strayed from that median. The mean deviation from each median for the individual participants and statements can then be calculated. An a priori decision must be made about what level of consensus is acceptable and will depend on the particular needs of the research, for example, if the median rating is 7 or above that indicates a high overall consensus on that statement (Allen et al., 2004, Vella et al., 2000). The statements with a low median score and/or a wide range of responses, which can be measured by calculating the interquartile range (IQR), should be flagged for discussion in the clarification stage. Statements are then amended and re-ranked and the clarification and re-ranking process is continued until all statements meet the agreed consensus level, i.e. median, and median deviation limits, set at the beginning of the research (Vella et al., 2000, Allen et al., 2004, McMillan et al., 2016, Arakawa et al., 2020).

Reporting the specific elements of the consensus development process is key to ensuring quality in the results when using CDMs for health policy and practice decision-making. However, in a systematic review Arakawa and Bader (2022), found that the majority of studies (60%) using a consensus development approach did not use a formal CDM. A transparent and socially accountable approach which reports the explicit consensus development procedures, including the number of participants and the consensus criteria, augments the utility and acceptability of the CDM outcomes and their application to health system and policy development (Arakawa, 2022).

2.7.2 Mixed Methods in the Present Research

The systematic review in the present research is a mixed methods review in that it combines a diverse array of study types. Therefore, the review design is a 'Mixed Studies Review' and hence necessitated a mixed methods quality analysis. The evidence was synthesised via the identification of the features of CBE which required a degree of interpretation in accordance with an inductive thematic analysis approach, hence also placing this method on the qualitative research continuum. On the other hand, the review follows traditional quantitative systematic review PRISMA guidelines designed to minimise bias and error. However, the interpretive nature of the synthesis does place the onus on the individual judgement of the reviewers as to what the findings will consist of and therefore reproducibility is inherently restricted. Nevertheless, the validity of the review findings is strengthened by the inclusion of different study types via triangulation. The use of more than one reviewer to interpret the studies also assists with the credibility of the review, specific details of the review process including limitations are outlined further in Part 1 Stage (i).

2.7.2.1 Part 1 Stage (i) Systematic Review

The main review question in this stage was about what the features of CBE are, therefore, the stance adopted in the present research is 'a-paradigmatic' in certain cases in that the study paradigms are considered independent to the syntheses of the review data. The foundation for the mixed studies review is a pragmatic one as the research question is broad and complex and requires the inclusion of any relevant literature regardless of the paradigm of the primary research. In other words, a pragmatic approach allows the reviewer to take a route outside of the dichotomous choice between postpositivism and constructivism according to its usefulness for answering the question at hand (Heyvaert et al., 2013a).

Research questions relating to pharmacy, and educational, practice are usually multi-faceted and a mixed methods approach offers a rich understanding of the research topic by taking a more holistic view than quantitative or qualitative approaches alone (Day et al., 2008). The systematic review was designed to gather the required information, via a custom approach that compares pharmacy and medical literature. This approach contributes an original perspective to the existing body of knowledge regarding CBE and training in pharmacy.

2.7.2.2 Part 1 Stage (ii) Global CBE Survey

The systematic review results are to be considered in tandem with those of the FIP Global CBE Survey. Although an in-depth mixed methods evidence synthesis has not been applied between the two data sets resulting from Part 1 (stages i and ii), the qualitative systematic review results did inform the design of the questions in the FIP Global CBE Survey. The overall aim being to better understand how CBE is being applied in pharmacy education currently around the globe to provide insights on what CBE actually looks like in real practice. This includes some insight into barriers and facilitators, identifies gaps in the literature, and provides a basis to guide further research. Furthermore, the features of CBE identified in Part 1 Stage (i) were used to

organise and examine the quantitative data from Part 1 Stage (ii) and contextualise the challenges to CBE implementation in relation to the current literature. The result is intended to provide a summary from the evidence on how the concept of CBE manifests in real life and how it is being interpreted and utilised in various settings internationally to guide future practice and research.

2.7.2.3 Part 2 Stage (ii) Local Competency Framework Development

A NGT CDM was chosen for the present research as discussions with the PSK in the design of this study concluded that a face-to-face method would be more effective and efficient for Kenyan stakeholder participation (verbal communication February 2020). The synthesis of qualitative data, and the final a bespoke Kenyan competency framework for early-career pharmacists was achieved using a quantitative approach to rate and rank each statement of the FIP GbCFv2 followed by repeated consultation and consensus development. This combination of methods allowed for in-depth exploration of opinion and nuance specific to the Kenyan context using a systematic and rigorous method.

2.8 Ethical Approval

2.8.1 An Introduction to Ethics

Ethical considerations must continue throughout the research process from data collection and analysis, reporting, storage and dissemination (Creswell, 2014). The governing principle is that there should be no harm to the participants and that they should be giving informed consent to participate which confirms voluntary participation, or abstention, protecting both the participant and the researcher as it protects against legal liability (Bowling, 2014).

Ethics applies not only to the process of conducting the research but also why the research is being carried out in the first place. In other words the research problem must be a meaningful one that will benefit the participants which are involved (Creswell, 2014). Ethical considerations can also become more complex when research activities are undertaken outside of the country that the original research conception and design has taken place. Particular attention should be given to following the principles of equitable partnerships when working with partners from a more resource-poor setting to counteract any inherent power imbalances (UK Research and Innovation, 2023). Helicopter research, also known as parachute research or neo-colonial research, is when researchers from higher income countries extract data from lower income countries and analyse and publish the findings with little involvement from local experts (Minasny et al., 2020). This type of research can be damaging for the reputation of international research and should be avoided by ensuring the research is genuinely beneficial to both parties (Minasny et al., 2020).

Ethical approval is obtained by submitting research plans to an institutional review board (IRB) or Research Ethics Committee (REC). In the case of international research it is vital that local permissions are sought before the research commences even if

ethics approval has already been obtained in the high-income setting (Schroeder et al., 2019).

2.8.2 Ethical Considerations of the Present Research

All of the research activities in the present research have been approved by the IRB at the pharmacy school in the University of Nottingham (UoN) and follow the university's code of ethics which stipulates that local permissions are necessary where the research is to be conducted before commencing international research (University of Nottingham, 2021).

Part 1 was approved in November 2020 (approval number 012-2020). Part 2 was originally approved in June 2019 (approval number 009-2019) but could not go ahead according to the original timeline because of the termination of the SPHEIR project and the need to secure independent collaboration with the Pharmaceutical Society of Kenya (PSK), followed shortly by the onset of the COVID-19 pandemic. Once the research license was obtained from Kenya and COVID-19 restrictions were relaxed to allow travel the ethics application for Part 2 of the research was updated and approved by the UoN IRB in Oct 2021 (approval number 001_2021).

A Kenyan research license was obtained from the National Commission for Science, Technology & Innovation (NACSOTI) for both stages of Part 2 of the present research. This was awarded in November 2021 after first gaining the requisite ethical approval from a NACOSTI affiliated IRB, provided by Jomo Kenyatta University of Agriculture and Technology (JKUAT) in May 2021. Overall, this was a protracted process that was difficult to coordinate remotely. It took over a year to complete and ultimately necessitated input from the university's Pro-Vice Chancellor for Global Engagement following failed attempts to communicate with NACOSTI via telephone and email. This experience fortifies the importance of factoring in the ethical approval process into the research design.

Active engagement of Kenyan pharmacy stakeholders in shaping the research design was sought to build a robust foundation and ethical justification for the research's purpose. This was achieved in a number of ways. Firstly, prior to completing the research proposal and submitting the plans informal discussions were held in Kenya with academics from 5 public Kenya universities that were part of the Strategic Partnership for Higher Education, Innovation and Reform (SPHEIR) Nottingham-Kenya Partnership. During these discussions it was possible to obtain local opinion on the relevance of the CBE approach for pharmacy education development in Kenya. In these initial explanatory conversations, review of the current curricula, and explanations of the CBE approach with the Kenyan academics, the local opinion was that the proposed research had potential value for the development of education for pharmacy students and pharmacists in Kenya (verbal communication March 2019). Secondly, this opinion was supported following a meeting with the CEO of the PSK who felt that the CBE approach, and the creation of a localised competency

framework for pharmacists, was in line with the PSK's vision to create improved standardisation of pharmacy practice in Kenya (verbal communication February 2020).

The PSK agreed to act as the local collaborator for Part 2 of the present research and it was agreed that they would be involved in the survey design, distribution, data collection and dissemination of the findings and would have ownership of the final competency framework. Finally, the research plans were also presented to the Kenyan Commission for University Education (CUE) who further endorsed the prospective benefits of the CBE approach locally and supported the proposed research for exploring a competency framework for pharmacy in Kenya which could be used to help modernise curricula (verbal communication January 2020).

Part 1 (Stage I and ii) of the research was conducted in collaboration with the International Pharmaceutical Federation (FIP), according to a memorandum of understanding (MoU) between the UoN and the FIP, who collaborated with the design and distribution of the global CBE survey and the interpretation of the features of CBE for the systematic review. Part 2 (Stage i and ii) was conducted in collaboration with the PSK who assisted with dissemination of the GbCF applicability survey and organisation of the consensus development panel.

The utmost care has been taken to maintain the safe storage and General Data Protection Regulation (GDPR) requirements as outlined in the UoN's code of ethics for all of the data collected, handled, shared and stored during this research (University of Nottingham, 2021). Data remained under the control and guardianship of the main researcher at all times and although the research supervisors were permitted to access the data, this was only if strictly necessary.

Collaboration with local and global researchers, experts, organisations and communities was essential for this present research to take place and endeavour for a fair partnership whilst still maintaining data protection and research integrity in line with the principles of the 'Trusted Research Guidance for Academics' (National Cyber Security Centre, 2023). Importantly, this research was also conducted in accordance with the 'Global Code of Conduct for Research in Resource-Poor Settings' (Schroeder et al., 2019), where all research activities performed in partnership with Kenyan collaborators and participants were based on fairness, respect, care and honesty.

Chapter 3: Systematic Review of Contemporary Competency-based Education and Training for Pharmacy Students and Practitioners

The research presented in this chapter incorporates material previously published as an open-access, peer-reviewed article (McMullen et al., 2022) and within the International Pharmaceutical Federation's handbook on Competency-based Education for Pharmacy and Pharmaceutical Sciences (International Pharmaceutical Federation, 2022a). The inclusion of the content from the aforementioned article and handbook within this chapter is conducted in compliance with the author rights granted by the publisher.

3.1 Chapter Introduction

It is recognised that there is an ongoing lack of consensus and comprehensive understanding regarding the definition of Competency-based Education (CBE) (Carraccio et al., 2002). The research approach seeks to include studies that could be relevant to different aspects of CBE, even in situations where the education or training discussed in the research doesn't perfectly match a fully established CBE-focused curriculum or programme. This approach attempts to capture ensures that valuable insights related to CBE are not overlooked.

The methods described in this chapter attempt to address the principal research questions proposed in chapter 1, section 1.5.1, i and iii:

i. What are the features of contemporary CBE for pharmacy?
ii. How are CBE features used in education and training for pharmacy students and pharmacists?

3.2 Aims and Objectives

The primary objective of this research phase is to provide a comprehensive description of current global CBE initiatives within the field of pharmacy. The purpose behind this endeavour is to generate valuable insights that can serve as a foundation for shaping and advancing future developments in CBE. The specific goal was to pinpoint the various characteristics and key components of CBE that are documented in the contemporary landscape of pharmacy education and training literature worldwide.

3.3 Methods

This systematic review of global literature centres on the identification of key attributes that characterise CBE for pharmacy. The study's scope encompasses both pharmacy students and practicing pharmacists as its target population, without any specific restrictions on the diverse fields of pharmacy practice included.

3.3.1 Search Strategy

Scopus, Web of Science, Medline, Embase and the Education Resources Information Center (ERIC) electronic databases were used to identify relevant literature. The database search strategy is shown in **Table 2**, terms used consisted of a combination of the following: “competency-based”, “outcome-based”, “CBE”, “OBE”, “pharmacy”, “pharmacist”, “education”, “training”, “curricula”, “curriculum”. The terms were combined using Boolean operators “AND” & “OR”. The database search also included truncation of the search terms (for example competenc*, pharmac*, education*, curricul*). Relevant Medical Subject Headings (MeSH) terms were used, where appropriate, to ensure inclusion of relevant literature from Medline and Embase. Pharmacy related journals were manually searched for relevant studies, including; Currents in Pharmacy Teaching and Learning (CPTL), Research in Social and Administrative Pharmacy (RSAP), American Journal of Pharmacy Education (AJPE), International Journal of Pharmacy Practice (IJPP), Pharmacy Education Journal (PEJ). The review protocol is published on PROSPERO under the registration number CRD42022296424.

Table 2 Database search strategy

Database*	**Search Terms**		**Results**
ERIC	(pharmacy or pharmacies or pharmacist or pharmacists) AND (competenc* or outcome*) AND (educat* or school or curricul* or training or learning or teaching or classroom or education system)		91
Embase/ Medline	ID	Search Term	
	1	exp Pharmacy/	
	2	exp Pharmacists/	
	3	(pharmacy or pharmacist*).mp.	
	4	1 or 2 or 3	
	5	exp Education, Pharmacy/	
	6	exp Education/	
	7	(competenc* adj3 educat*).mp.	
	8	(outcome* adj3 educat*).mp.	
	9	("competenc* based educat*" or "outcome* based educat*").mp.	
	10	exp Competency-Based Education/	
	12	7 or 8 or 9 or 10	
	12	4 and 11	
	13	(educat* or training or curricul*).mp.	
	14	5 or 6 or 13	
	15	12 and 14	
	16	limit 15 to (English language and last 11 years)	572
Scopus	(TITLE-ABS-KEY (pharmac*) AND (TITLE (competenc* OR "CBE" OR "OBE" OR {outcome-based}s9 OR {competency-based} OR {outcome based} OR {competency based})) AND TITLE-ABS-KEY (education* OR training OR curricul*)) AND (LIMIT-TO (DOCTYPE , "ar")) AND (LIMIT-TO (PUBYEAR , 2021) OR LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014) OR LIMIT-TO (PUBYEAR , 2013) OR LIMIT-TO (PUBYEAR , 2012) OR LIMIT-TO (PUBYEAR , 2011) OR LIMIT-TO (PUBYEAR , 2010)) AND (LIMIT-TO (LANGUAGE , "English"))		307
Web of Science	TOPIC:((pharmacy OR pharmacist* OR pharmacies)) *AN* TITLE: (("competenc* based educat*" OR "outcome* based educat*" OR competenc*)) *AND* TOPIC: ((educat* OR training OR curricul*))		206

*All searches completed on the 29th January 2021

3.3.2 Inclusion and exclusion criteria

Literature was restricted to studies published in English from 2010 to 2021. The literature was limited to this date range to capture studies relevant to current pharmacy education and training and recent CBE related developments, such as the FIP GbCF in 2012 (International Pharmaceutical Federation, 2020b), and the influential 2010 Lancet report on healthcare professionals' education (Frenk et al., 2010). Studies relating to all levels of education and training in pharmacy including undergraduate (initial education or pre-registration degree e.g. MPharm or BPharm), postgraduate (graduate students studying for a second qualification e.g. Masters or Post Graduate Diploma), and professionals undertaking workplace-based training (post pre-registration degree) were included. Firstly, to enable description of a wide picture of educational activity that may be valuable in guiding any level of pharmacy CBE related development. Secondly, to capture details relevant to the continuum of competency development across the various stages of education and training in pharmacy, as it is paramount that the competencies attained in initial education are maintained and developed in professional practice (Bajis et al., 2020). For the purposes of this review, we adopted the broad and generalizable definition, as described by Hodges and Lingard. (2012), of competency-based education as:

'...a form of education that derives a curriculum from an analysis of a prospective or actual role in modern society and attempts to certify student progress on the bases of demonstrated performance in some or all of the aspects of that role' (Hodges and Lingard, 2012 p. 2).

This definition served as a guiding principle for literature selection, capturing the core concept of CBE, which emphasises the outcome of education in terms of what students can do in relation to a specific role. This foundational principle also underpins Miller's prism of clinical competence (Miller, 1990). The principles of CBE in the field of medicine are frequently applicable to modern pharmacy practice. Hence, the themes of CBE for medical education previously outlined by Frank et al (2010a), were also employed in this review to guide literature selection and the identification of pertinent themes.

Any study that fulfilled the above criteria and was related to CBE, or elements of CBE in line with the core concepts of a competency-based approach (i.e. a focus on the outcome of education in terms of what students can *do* in relation to a specific role) were considered for inclusion. This included studies, even if not part of a fully realised CBE curriculum, concerned with relevant individual elements of CBE.

The inclusion criteria was intentionally broad to capture any studies related to CBE activity in recognition that the achievement of a fully integrated CBE curriculum can be a complicated and resource intensive process (Koster et al., 2017). Therefore, it was expected that availability of global studies relating only to fully integrated CBE programmes may be limited and that useful information could still be gathered from studies that were associated with programmes or curriculums that were using some principles of CBE but were not part of a fully integrated and purposively designed CBE curriculum. Furthermore, information from these studies was considered relevant to

the objective of this study which is to characterise the global picture of pharmacy education related to CBE.

Studies were excluded if they were commentaries, reviews and letters or pertained to one narrow subject topic only e.g. nutrition or geriatrics. Studies that focused on the process of creating competencies or competency frameworks were included if they involved broader discussion of subsequent application, or evaluation of these competencies or frameworks in relation to education and training in pharmacy but were excluded if the study referred only to the process of gathering or creating competencies or frameworks.

3.3.3 Literature Selection and data extraction

Two reviewers (myself and LP—see acknowledgements) independently screened article titles and abstracts for relevance to the research topic and population. Full studies meeting inclusion and exclusion criteria were evaluated for selection, reaching consensus through a third reviewer for any disparities. Lists of specific CBE features were identified by two authors, then categorized into overarching themes. Following an inductive and deductive approach of gathering information, forming themes, and comparing with literature and experiences, data extraction and analysis took place (Creswell, 2014). Given the review's diverse research methods and contexts, interpreting and categorizing data into features required refinement. Discrepancies were addressed through group discussions involving the entire research team and collaborators with competency-based education expertise in pharmacy (see acknowledgments) and compared with previous findings from Frank et al (2010a).

3.3.4 Quality Analysis

The Mixed Methods Appraisal Tool (MMAT) (Hong et al., 2018b), was selected for quality analysis of the studies in the review as a tool with established reliability and validity suitable for a number of different research designs (Pace et al., 2012).

3.4 Results

3.4.1 Study Characteristics

The search identified 1178 studies. After the removal of duplicates and screening of the titles and abstracts for relevance, 103 studies remained. Eligibility of the remaining studies against the inclusion and exclusion criteria was performed, resulting in the selection of 28 studies for review. The locations of the research from the studies, according to the World Health Organization (WHO) regions, and the level of education or training referenced as the focus of the study are presented in **Figure 8**.

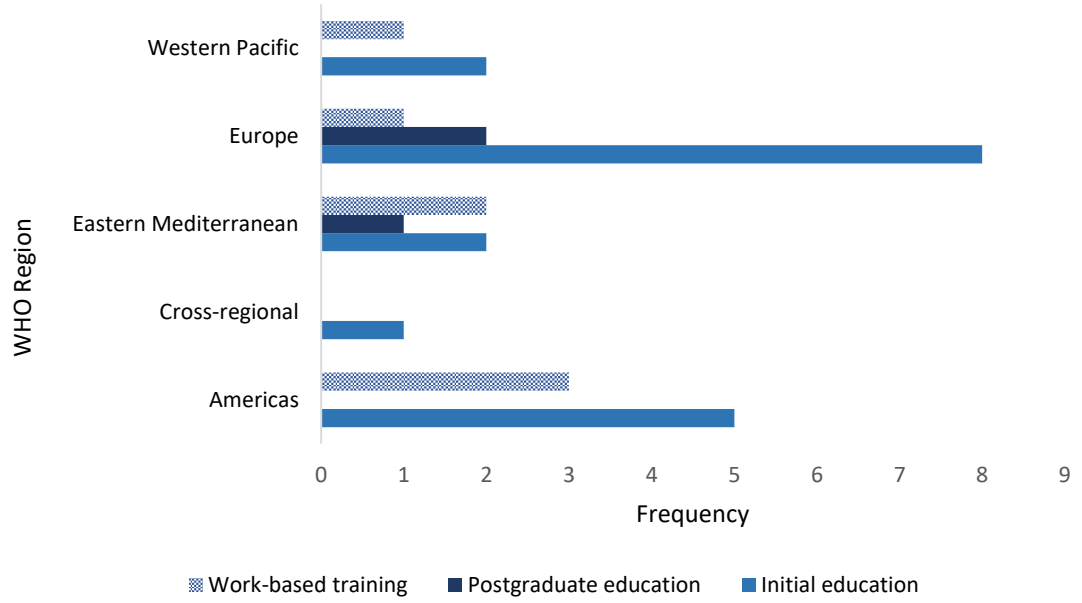


Figure 8 Locations of review studies according to WHO regions and level of pharmacy education or training

Most research was based in high-income countries, none of the studies relate to CBE activity in the African or South-East Asian regions and one study was cross-regional. The majority of the studies focused on initial education, 18 (64%), followed by post-qualification training, 7 (25%), and then postgraduate education, 3 (11%).

A summary of the literature selection process can be seen in **Figure 9**, presented using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Page et al., 2021).

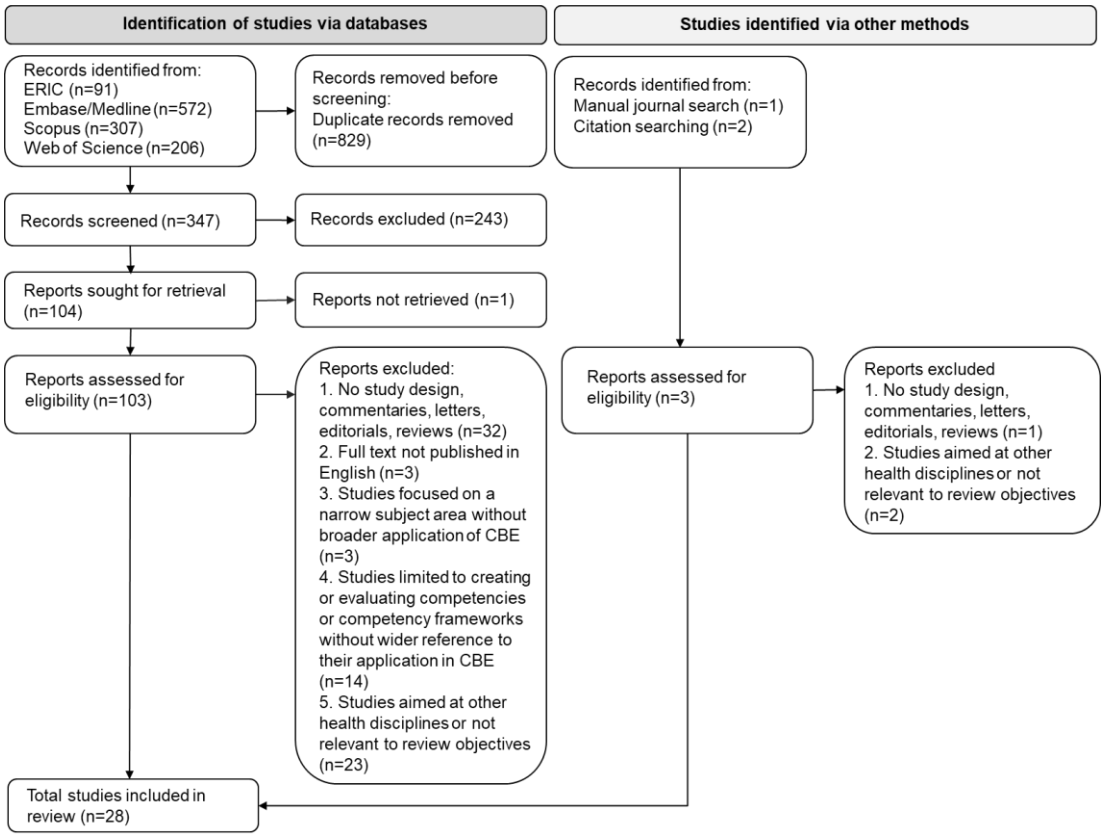


Figure 9 PRISMA flow diagram of search strategy and selection of studies

3.4.2 Features of CBE

The studies and their methods, sample size, participants, and main CBE related findings and conclusions relevant to the review are displayed in **Table 3**. This provides an overview of the current picture of CBE related activity for pharmacy across the globe according to the available relevant literature. The quality analysis summary using the MMAT is then displayed in **Table 4.** In **Table 5** the features of CBE identified are summarised and linked to the themes defined by Frank et al (2010a), shown in **Appendix 1,** where supporting components of these CBE features are also outlined. Features relating to all 4 of the CBE definition themes outlined by Frank et al (2010a) were identified from the literature. A total of 20 features of CBE for pharmacy were defined and grouped in to 6 central themes, along with a further 21 supporting components. In the following text, specific benefits, challenges, or recommendations mentioned by the study authors with respect to these features and/or components are also summarised and may be useful for institutions that are wishing to implement or develop their own CBE activities. The majority of these studies could not be classed as 'true CBE', in terms of a fully integrated CBE curriculum design, but instead discuss separate elements that are related to the core concepts of CBE. These features however show many of the elements of CBE that are being used and developed for pharmacy and provides an idea of what supporting components are commonly employed.

Table 3 Summary of Studies

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
1	Al-Haqan et al (2020)	Kuwait	Evaluation of the effectiveness and feasibility of a structured Continuing Professional Development (CPD) training programme supplemented by the Kuwait Foundation Competency Framework (KFCF).	a. Mid-point survey with a 5-point Likert scale to assess perceptions of impact and satisfaction with the training programme b. Post-intervention survey to inform larger scale implementation c. CPD record content analysis for effectiveness, adaptation and feasibility of the programme d. Focus group interviews on experience and perceptions for content, delivery, barriers to CPD, feasibility and implementation recommendations.	Hospital pharmacists in Kuwait enrolled on the structured CPD programme. a. n=15 b. n=16 c. n= 35 (18 1st entry, 17 2nd entry) d. n=10	A guiding competency framework in addition to a continuous feedback structure was found supportive to pharmacists during the CPD programme and considered to help deliver an impactful translation of education to practice. Using the KFCF as a structured self-assessment tool helped pharmacists identify strengths and areas to improve. More support from colleagues and higher authorities was suggested in the focus groups. Policies and regulations were highlighted as an important component for sustainability of the programme.
2	Al-Haqan et al (2021a)	Kuwait	Description of the development, implementation, and evaluation of OSCEs for final year pharmacy students in Kuwait. Comparison of students' performance in two academic years (2015-16 and 2016-17).	a. Student OSCE scores were correlated to total course grade. Median percentage total OSCE scores from 2015-16 and 2016-17 were compared. Percentage competency scores and frequencies from 2015-16 and 2016-17 were compared. b. Student survey of the OSCE experience using a 5-point Likert scale and open-ended questions. c. Staff feedback form to assess perception of the OSCE experience in terms of difficulty, timing, comments and suggestions.	Final year pharmacy students at Kuwait University a. n=84 b. n=84 c. n=66	Design, implementation, and evaluation of the OSCE was technically feasible and provided a broad assessment of competency to ensure an acceptable level before graduation. Correlation between a high OSCE score and a high total course grade was observed. Students reported OSCEs as a positive experience for the opportunity to practice real-life scenarios in a safe learning environment. They suggested more formative practical sessions earlier in the curriculum to prepare for summative OSCEs. A working group reviewed literature and followed a systematic evidence-based approach to OSCE design and implementation. Blueprinting was deemed crucial for ensuring relevance and validity, clarifying competencies and providing a road map for the development of case scenario and training for assessors.
3	Al-Haqan et al (2021b)	Kuwait	Develop a Kuwait Foundation Competency Framework (KFCF) for pharmacists using the FIP GbCF in an adopt and adapt approach	a. Initial consensus panel validation on degree of relevance of GbCF behavioural statements using a 4-point Likert scale and panel discussions. Delphi process not applied due to small number of participants. b. National online cross-sectional survey of relevance of GbCF using 4-point Likert scale. c. Final consensus panel discussion with policy and decision makers and pharmacists using focus groups.	a. n=9 Mixture of early career (n=5) and experienced pharmacists (n=4) b. n=1483 pharmacists registered with Kuwait Pharmaceutical Association (KuPhA), c. n=23 pharmacists (n=18), and policy and decision makers (n=5)	Competencies should be separated in to 3 domains: core for all pharmacists, supplementary for private sector and supplementary for public sector because of the differences in practice for the public/private sectors. A national foundation pharmacy training programme delivered through collaboration with Kuwait University (KU), KUPhA and the Ministry of Health (MoH) is recommended to provide continuing support and training necessary to master the KFCF behaviours. Future work should focus on expanding the scope of practice based on advanced pharmaceutical services via collaboration between education, practice and policy due to the lack of clear policies and regulations that would facilitate the advancement of pharmacy practice in Kuwait.
4	Allen et al (2016)	United Kingdom	Determine students views on their experience with using the iSED® (individualised Skills	a. Retrospective questionnaire. Five-point Likert scale was used and extent of students indicating favourable views towards iSED® was reported as a mean where a score >3 indicated a positive view. b. Focus groups	a. n=108 Year 2 pharmacy students, the first to use iSED® in their first year b. n=7 Year 2 students	Following data entry, iSED® generates feedback on performance compared to gold standard and is colour coded (red, amber, and green) to indicate competence in 4 areas: communication skills, information retrieval, the recommendation, and follow-up advice. Feedback is also provided according to behavioural indicators of competence within these 4 areas.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
			Evaluation and Development) programme developed by the Leicester School of Pharmacy and understand how students perceive their own learning when using iSED® in a simulated clinical exercise.	c. Focus groups divided into smaller groups of 7 or 8 Focus group discussions were audio recorded, transcribed and analysed according to a qualitative thematic framework.	c. n=30 Year 3 students (with no experience of iSED®) invited to attend an iSED® workshop prior to the focus group.	The colour-coding of feedback was indicated by students to be a helpful visualisation for identifying strengths and weaknesses Students particularly found instant feedback, visualisation of feedback, video feedback and reflection on their own performance according to gold standards to be positive aspects.
5.	Alves da Costa et al (2020)	Portugal	A case study of sharing best practice between academics, practitioners and the Portuguese Pharmaceutical Society (PPS), developing the Education and Practice Platform (EPP). The EPP bridge the interests of academia and practice, gathering information about key competencies.	a. The EPP's mission, vision and values were set by the steering group creating a common path and a one-year plan. Activities included workshops on teaching methods and internships, involvement in international events, updating EPP representatives on global advances in pharmacy education and facilitating national sharing of curricular details for constructive criticism and benchmark b. Narrative review exploring the alignment of education and professional practice with the research question; 'Are there teaching experiences at the undergraduate level that better meet the needs of pharmacy practitioners?'	a. A representative from each pharmacy faculty, of which there are 9, and from the 6 Councils of Speciality Boards of Practice (CSBP). b. 21 studies included in qualitative synthesis	The EPP envisions aligning education and practice with PPS statutes to validate competencies and follow international guidance. Workshops aimed to create student-centred curricula considering student input. Common concerns among academia, hospitals, and community pharmacies included the need for more clinical training, with practice partnerships as a solution. Sustainability requires EPP independence for alignment, regardless of political support. The literature review found limited research on educational programmes and specific competencies. Insufficient evidence prevented addressing the research question due to few relevant publications. To build a competent workforce, involving stakeholders is vital; developing curricula without practitioner, service, user, and professional input is unacceptable.
6.	Bajis et al (2018)	Eastern Mediterranean Region	Exploration of the perspective of pharmacy stakeholders on pharmacy education and quality assurance.	Semi-structured interviews thematically analysed and mapped to FIP Global Quality Assurance Framework.	n=31 Participants all had post graduate qualifications in pharmacy and were made up of educators, practitioners, employers, regulators, and policymakers.	Political and socioeconomic barriers hindered pharmacy education advancement. Political and social struggles led to a lack of specialised educators due to migration. Bridging knowledge to practice was vital; modern methods and diverse assessments were needed for competency evaluation. Absence of quality assurance bodies was evident; some programmes gained credibility through Western accreditation. Variable procedures within countries impacted graduate competence. Hospitals used competency-based training, especially with Western affiliations. Sectors—academic, regulatory, and practice—lacked cohesion, necessitating increased collaboration. Curricula needed modernisation and alignment with societal needs. PharmD mismatches with available careers and services necessitated a needs-based approach, particularly with Western educational models. Competency frameworks ensured curricula conformed to standards across schools.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
7.	Bayram and Köksal (2019)	Turkey	The National Council of Deans of Faculties of Pharmacy in Turkey defined competencies for pharmacy. This is a quantitative mapping of a particular curriculum to analyse if it fulfils the competency requirements.	Each member of academic staff on the pharmacy programme evaluated if their course content did or did not meet the sub-competencies defined by the council by assigning a score of 0 (not met) or 1 (met). The average of the scores for the sub-competencies were expressed for the competency as a whole using a percentage. The scores for each course (the 63 compulsory courses of the programme were included in the analysis) were then collated to indicate the overall score indicative of how the competencies were met for the entire 2017-2018 programme.	Each member of academic staff on the pharmacy programme at the University of Yeditepe, Turkey. Full-time (n=34) and part-time (n=6) faculty members.	Strengths and weaknesses of the programme were highlighted by the competency scores. Lowest scores were in 'prepares biotechnological products', 'develops a drug formulation', 'performs microbiological controls during drug production' and 'performs the microbiological analysis of cosmetics'. The academic members of the relevant departments revised the content of their course to address these weaknesses. Higher competency scores were found in the topics of clinical pharmacy and analytical techniques, two areas which the author describes as previous priorities for the university. The author suggests that binary rating scores are preferred over a Likert-type scale to avoid ambiguity and argues that curricula could be mapped in this way according to any chosen predefined competencies.
8.	Boyle and Myford (2013)	United States of America and Canada	Determine whether pharmacist's expectations of the competency of entry-level pharmacists differ according to their degree level, practice setting or preceptor experience.	Analysis of pre-existing online cross-sectional survey data. The National Association of Boards of Pharmacy (NABP) distributed a National Pharmacy Practice Survey in 2009. Pharmacists rated 43 competency statements using criticality and frequency scales from a 1 (low) to 5 (high) score. The study analysed the ratings for criticality against the variables of: pharmacy degree, practice setting and preceptor experience.	Pharmacists licensed in the USA or Canada and actively practicing or engaged in the education of pharmacists. n=2986 (n=2244 from the United States and n=714 from Canada)	Pharmacists working in inpatient settings rated the competencies higher than those in outpatient or 'no-patient' settings No significant difference in competency measures for practice setting or preceptor experience. Preceptors did not rate competencies higher or lower than non-preceptors. Academics rating of criticality was higher than non-academics. Variety in practice settings appeared to have no significant effect on ratings Authors suggest that this type of analysis can be used to align educational outcomes with standards of practice and highlight the need for regulators, educators and practitioners to share their visions for the profession.
9.	Bray et al (2017)	United States of America	Measurement of student performance and experience after the development and implementation of a CBE assessment model using Honours, Satisfactory and Fail (H-S-F) levels of performance.	Cohort Study Student scores were collected and compared to previous cohorts. Preceptors rated student performance. Student experience of the assessment model was assessed via survey. Student performance was aggregated according to semester and the 155 competency sub-categories within the overarching 6 outcome categories in the curriculum Attrition and progress of students was measured against 2 previous cohorts (class of 2015 and 2016)	PharmD students and staff at Washington State University starting year one in 2013 with the CBE assessment model with subsequent sequential adoption as the cohort transition into year 2 and 3 (n=85-134 depending on class size)	Feedback was to be given within 48hrs using ExamSoft® software. Computer based tagging and coding categorised questions according to competency-based curriculum outcomes for the school and ACPE accreditation standards and Bloom's taxonomy. Majority of students on all assessments demonstrated competency in 1 or 2 attempts. Students were given 3 attempts to pass and varied methods of re-engagement to identify and resolve knowledge gaps – a process the authors describe as important for self-directed learning. Preceptor evaluations were consistent with those from the previous letter graded system. Progression statistics for students improved within the Honours, Satisfactory, or Fail (H-S-F) assessment model. Administrative staff included a block-testing coordinator was employed to coordinate this.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
10.	Kary et al (2019)	Canada	Compare strategies of Canadian residency programmes for assessing and evaluating competencies set by the Canadian Pharmacy Residency Board (CPRB). Looking at tools used, persons involved, frequency, scheduling and repetition of curricular components.	Survey of residency programmes distributed electronically between February and March 2018. Programme coordinators for CPRB accreditation programmes were invited to respond. Categorical data were analysed descriptively. Open responses and comments were summarised with those from academic modules associated with pharmacy practice.	n=20 programmes, including 100% of general practice programmes and 70% of multicentre organisations largely focused on direct patient care (37 invited to participate).	Programmes exhibited similarities in their assessment methods. All programmes incorporated care plan reviews, direct observations, journal clubs, project timeline creation, and ethics submissions. Primary evaluation techniques encompassed presentations, written manuscripts, drug information rotations, and longitudinal evaluations. Uniform assessment forms were employed, delineated by Bloom's taxonomy and the CPRB "levels and ranges" guidance document. Both self-assessment and assessment by the pharmacy team were utilised for all competencies. The CPRB's 2010 publication of accreditation standards outlined competencies that currently align with practice. This alignment prompted the shift to competency-based education for pharmacy residents. These standards concur with the professional competencies for Canadian pharmacists at entry to practice, as established by the National Association of Pharmacy Regulatory Authorities (NAPRA). The majority of programmes were in accordance with these guidelines. This study highlights areas warranting attention during the implementation of national alignment.
11.	Kirton and Kravitz (2011)	United Kingdom	Compare objective structured clinical examinations (OSCEs) and traditional assessment methods for recent pharmacy graduates from the University of Hertfordshire (UH).	Test scores for OSCEs were compared with those from academic modules associated with pharmacy practice using Pearson's correlation coefficient. OSCE scores for year 1, 3, and 4 were also compared for measures of progress.	Students who graduated from the UH School of Pharmacy in the summer of 2009, n=39.	There was no observed correlation between the Year 3 OSCE score and the Year 3 Medicines and Pharmacy Practice (MPP3) examination grade (r=0.6). In Year 1, 100% of students outperformed their Year 3 OSCEs, while 80% improved their Year 4 performance compared to Year 1 OSCEs. These variations might be due to differing skill requirements between OSCEs and conventional exams. Despite a robust knowledge base potentially enhancing clinical competence, a correlation may not be anticipated due to the distinct aspects being evaluated. Personal circumstances and environmental factors can impact competency and performance, as noted in the Cambridge Model for assessing competence. The authors propose this could also explain the outcomes, such as the stress inherent in a multi-station assessment. Furthermore, the authors emphasise the significance of the MPP3 exam for advancement to the final year, unlike the OSCE. However, 20% did not exhibit improved performance in Year 4 compared to Year 3 OSCEs, attributed to external factors like the simultaneous deadline for the final-year project dissertation. The authors highlight the need for repeated OSCE performances for accurate competence assessment. They acknowledge the resource-intensive nature of these assessments, suggesting it's impractical to conduct such repetitive testing. They also express reservations about using their current OSCEs as progression barriers. Nonetheless, they underline that OSCEs evaluate distinct skills compared to traditional methods and should complement them.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
12.	Mann et al (2018)	United States of America	Examine opinions of pharmacists regarding competency development in terms of departmental value, personal confidence and frequency of use for 9 competency topics	An electronic survey to better understand the perceptions of pharmacists on competency-based programmes and identify which 9 competencies should take priority to guide future programme development. Department values and personal confidence with the competencies were measured on a 5-point Likert scale (strongly disagree – strongly agree). Frequency of competency utilisation was measured on a 4-point scale range (never-always).	Pharmacists and pharmacy residents from a large non-profit academic medical centre in the southeast of the USA. Including clinical, operational and leadership pharmacists which were proportionally representative of the pharmacy positions in the department, n=105 eligible survey responses included in the analysis.	The goal was to formulate a competency programme that encompassed pharmacist requirements from a professional standpoint, while also aligning with organizational and individual perspectives. Early involvement of pharmacists through a survey during programme development was seen as beneficial. This approach ensured stakeholder engagement, increased awareness of competency development initiatives, garnered employee support, and directed resource allocation. All nine competencies were deemed valuable, with a consensus on their importance regardless of the practice setting. "Therapeutic knowledge" stood out as highly prized, frequently utilized, yet an area where individuals lacked confidence. Consequently, it was chosen for initial piloting to encourage pharmacist engagement and participation in the new competency programme. The authors propose that extending research to participants beyond pharmacy would be advantageous, especially considering the growing prominence of team-based patient care in healthcare models.
13.	Meštrović et al (2012)	Croatia	Measure community pharmacists' progress in competency development using the General Level Framework (GLF) as an educational tool in a longitudinal study	Patient care competencies of 100 community pharmacists were evaluated before and after the introduction of an educational programme based on the GLF using an overt observation method. This included new services, standard operating procedures (SOPs) and pharmacists keeping patient care contribution portfolios. Pharmacists' performance was rated against the GLF behavioural statements on a 4-point scale.	Pharmacists employed in Croatia's largest community pharmacy chain in different regions and in different pharmacy sizes situated in small and large towns, n=100.	During the study period, post-qualification training for pharmacists primarily relied on conventional continuing education and passive learning. The renewal of pharmacists' licenses every 6 years was linked to CPD points. Therefore, the introduction of this competency-based approach was innovative and distinctive. It aimed to identify educational and developmental needs and subsequently deliver customised education and training. Before the training, the concept of competency in pharmacy practice was introduced to pharmacists through lectures and workshops. Recording pharmaceutical care activities in mandatory portfolios was implemented by the chain in 2009, along with complementary patient care SOPs. Following the GLF, pharmacists conducted self-assessments to pinpoint competencies requiring further development. Notably, significant differences ($p<0.05$) emerged between values (never, rarely, mostly, consistently) from 2009 to 2010 for all competencies. The study observed a 50% reduction in variability between pharmacists' ratings from 2009 to 2010. The authors posit that the GLF serves as an educational tool capable of enhancing standards and consistency in pharmaceutical care.
14.	Nash et al (2016)	Australia	An analysis of data from the Traffic Light Report (TLR) project which combines Miller's pyramid, technology and student voice to examine a curriculum for Assurance of Learning (AoL). The "Traffic Light Reporting" aspect	Summative assessments were mapped to the National Competency Standards Framework for Pharmacists in Australia (NCS) alongside level of performance as per Miller's pyramid of competence and students' self-reflected performance. Students and educators describe different understanding of expected performance levels and this paper seeks to explore possible reasons for this. There were four units per semester. Each unit has 2-8 summative assessments. Educators mapped each assessment unit against the NCS and the level of performance expected on	a. Students across all 4 years of study were invited to self-reflect on their performance in each competency standard after the semester exams against the NCS and Miller's pyramid level of performance and the TLR system via an online survey, n=69 semester 1	In 21.14% of cases, students self-evaluated their performance as higher than their educators did. In 33.07% of cases, students' self-reflection aligned with educators' assessments. Conversely, in 45.79% of cases, students rated their performance lower than their educators did, citing lack of confidence compared to the educator's evaluation. Notably, scaffolding within Domain 3 (Leadership and Management) was comparatively weaker, suggesting a need for earlier introduction in the curriculum to foster graduates' leadership abilities. Some disagreement might stem from students' incomplete grasp of Miller's pyramid. For instance, students might assess themselves at the "does" performance level without the necessary foundational knowledge for safety assurance, such as pharmacology and therapeutics knowledge in dispensing.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
			involves the students to identify where more work is needed on a competency standard by marking it as red, amber or green.	Miller's pyramid into a database.	(42% response rate), n=52 semester 2 (26% response rate). b. Student feedback comments, n=73 semester 1 (45% response rate), n=31 (16% response rate). c. Educator's mapping of performance level was compared to that selected by the students	Certain students' comments revealed a divide between theoretical and practical aspects. Some students struggled to connect the NCS with the curriculum, pointing to a possible deficiency in integrating knowledge, skills, and attributes for "does" level performance. Authors suggest using authentic assessments to enhance integration and competency evaluation, fostering students' confidence in their practical abilities. The authors underscore the significance of assurance of learning (AoL) achieved through well-structured curriculum design. This entails building a strong knowledge base, integrating professional standards, and ensuring that assessed curriculum aligns with intended learning outcomes.
15.	Nash et al (2017)	Australia	Determine how competence training can help with quality in professional development.	a. Quantitative survey on how pharmacists understand the Pharmacy Board of Australia's continued professional development (CPD) framework. b. Qualitative and quantitative survey on pharmacists' current knowledge, use and acceptance of the National Competency Standards Framework (NCS) c. Thematic analysis of social media comments posted on Australian pharmacist forums relating to CPD plans.	a. n=278 (1% of 25,944 registered Australian pharmacists) b. n=158 (less than 1% of registered Australian pharmacists) c. pharmacists commenting on commonly accessed professional pharmacy forums, n=55 comments.	The majority of pharmacists (77%) didn't incorporate NCS in their CPD planning, while slightly over half (57%) didn't use NCS for annual registration. Combining two surveys and social media comments, this study highlights pharmacists' desire for mentoring, support, education, and clear guidance on NCS application in CPD and lifelong learning. Australian pharmacy courses are mandated by the Pharmacy Board of Australia to demonstrate alignment with NCS. Surveys were conducted before the Pharmacy Board's 2015 requirement for NCS use in self-assessment for annual re-registration. Enhancing comprehension of the CPD process and NCS utilisation is crucial. Authors recommend integrating NCS referencing into an e-portfolio during undergrad studies for learning documentation. They also propose formative and summative assessments of students' CPD cycle implementation abilities. Self-assessment proficiency is intricate and challenging. Preparing students and pharmacists for meaningful lifelong learning should initiate at the undergraduate level.
16.	Nunes-Da-Cunha and Fernandez-Llimos (2019)	Spain	This study analyses the quality of the competency allocation to courses in the pharmacy curricula of Spanish universities according to the CIN/2137/2008 Ministerial order.	The CIN/2137/2008 Ministerial order depicts the duration of the pharmacy degree, the requirements on the curriculum and the competencies for pharmacy practice in Spain. A list of all the CIN/2137/2008 competencies assigned to each course of the curriculum was compiled for pharmacy schools in Spain. The courses were classified into 7 knowledge areas according to the proportion of competencies from each area assigned to that course, or classified as non-specific in the event of a tie. Courses without online syllabi, elective courses and courses that specifically focus on the internship period or final dissertation were excluded.	Courses from Spanish pharmacy schools with online syllabi detailing description of objective, learning outcomes and educational teaching and assessment methods, n=881 courses (44.7% private universities and 55.3% public universities)	Out of the courses, 57.5% were linked to general competencies, with 2 universities having none and 2 assigning all 15. Mismatches frequently existed between competencies and course content, and discrepancies in competency-course pairings were notable across universities. Despite course syllabi similarities, substantial variations emerged in competency alignments, suggesting inaccuracy in pairing competencies. Authors suggest that course titles, not content, influenced competency assignment, potentially creating a misleading curriculum portrayal. The authors advocate for competency pairings grounded in content and assessment methods. They propose aggregating competencies into EPAs for clear curriculum mapping. The recommendation is for educational and professional bodies to establish a shared database for this purpose.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
17.	Paradis et al (2018)	Canada	To identify how the 2010 Association of Faculties of Pharmacy of Canada (AFPC) roles have been included in the curriculum at the Leslie Dan Faculty of Pharmacy (LDFP), Toronto. AFPC roles are based on the CanMEDS competency framework.	Content analysis of interviews exploring understanding of the AFPC roles, their significance for teaching strategies, students, patients and the profession, and specific examples of how the roles are being addressed, their perspectives of the AFPC outcomes and their import to the curriculum, how they are perceived by their colleagues and students, and how they may contribute to interprofessional education	Core members of the PharmD faculty who were instructors involved with curricular and course design for courses where AFPC 'non-expert' roles were identified as educational outcomes in the PharmD programme.	All faculty members regarded the AFPC roles as highly significant, recognising their pivotal role in cultivating well-rounded professionals. They believed these roles were instrumental in distinguishing pharmacists within the healthcare landscape. While some emphasised the importance of underlying knowledge (particularly those with social science and humanities backgrounds), most viewed the roles as imparting technical skills, often learned through active or experiential learning. The authors propose that external pressures, rather than internal motivations, influenced the AFPC's Education Outcomes. They highlight differing understandings of competency-based frameworks and the unclear relationship between roles and competencies. Consequently, the authors stress the need for educators to align on how to teach roles and competencies, including their nature in relation to skills and knowledge. They recommend embedding competency development explicitly into the curriculum, rather than relying on individual instructors.
18.	Reardon et al (2016)	Qatar	Qatar University's (QU) pharmacy programme is accredited by the Canadian Council for Accreditation of Pharmacy Programmes (CCAP). A new registration exam (known as a final cumulative assessment) based on the Canadian format was piloted with pharmacy graduates and a sample of practising pharmacists.	Qualitative focus groups, with open and closed-ended questions, were held to examine the perceptions of the exam candidates on the competency-based exam format. The objective was to inform exam developers of barriers and facilitators to implementation of the new exam format and to identify the resources required to support future candidates.	All undergraduate pharmacy students in their final year at QU, practising pharmacist's that had taken the pilot exam, and a convenience sample of pharmacists involved with experiential training of graduates and undergraduates from QU. Three focus groups, n=3, n=5, and n=8. (11 pharmacists and 5 students)	Participants voiced concerns that the current exam lacked clinical application, focusing primarily on basic pharmaceutical sciences knowledge. They believed a standardised exam would bolster public trust and pharmacist confidence, ensuring all practitioners meet minimal competence requirements. Challenges to implementation included fears of existing pharmacists failing a competency-based exam due to lack of preparation time. Furthermore, concerns arose about equitable assessment for community and hospital pharmacy settings and potential resistance from physicians. On the other hand, incentives like higher salaries and a new professional designation for successful candidates, along with preparatory training and mock OSCEs, were seen as facilitators. To ease concerns about the new format, comprehensive information dissemination is recommended to increase awareness and acceptance. The authors suggest revisiting laws to expand the scope of pharmacy practice.
19.	Rich (2019)	Canada	Comparison of professionals' descriptions and structures of competence, examining tensions between different views of competence.	Content and inductive thematic analysis of publicly accessible Canadian entry-to practice competence frameworks	Frameworks from 10 professions (medicine, nursing, occupational therapy, pharmacy, psychology, social work, teaching, engineering, law, and planning)	Six of the ten frameworks (including pharmacy) depict a relational structure between meta-competencies, key competencies, and enabling competencies. Those employing this structure view competence as integrated and holistic, exceeding the sum of its components. In contrast, frameworks lacking this structure view competence as the sum of its components. This underscores tensions between differing competence conceptions. The author emphasises the significance of language and framework architecture in influencing stakeholders and recommends careful consideration before designing CBE programmes and related teaching and assessment methods.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
20.	Skowron et al (2017)	Poland	Determine whether the Jagiellonian University Medical College (FP-JUCM) Master Diploma in Pharmacy (MDPharm) undergraduate curriculum meets the criteria of the European Competence Framework (ECF)	Academics from FP-JUCM mapped the specific learning outcome (sLO) to the ECF which were then mapped to the courses of the MDPharm programme. They also subjectively categorised the level of competence students could acquire from these sLO according to the 5 levels of the Dutch Standard Framework	Four academics from the FP-JUCM, all had previously obtained their pharmacy education from the JUCM and had experience as community pharmacists.	Integration of competencies across all programme years was lacking. Personal competencies were mainly covered in later years, while 'research and industrial pharmacy' competencies spanned all years. Just one competency, 'knowledge of design, synthesis, isolation, characterisation, and biological evaluation of active substances' matched level 5 of the Dutch Standard Framework. The authors recommend further research, as the study focused on the intended curriculum via documents only. Student perception of achieved competencies should also be assessed. National regulations would need revision to adopt a competency-based curriculum aligned with the ECF, considering the identified gaps and imbalances.
21.	Stupans et al (2012)	Australia	Create a graduated descriptors tool for competency development during experiential placements. The tool aims to ensure uniformity across Australian universities, aiding students in self-assessment and preceptor discussions.	a. Participatory action research to develop the tool, including a series of collaborative workshops and individual consultations. n=201 b. The tool was the trialled at 2 universities by students on their final year placements where they were asked to give their opinion on the tool in a post-placement debrief session via a paper survey using a 5-point Likert scale (n=162, 57% response rate) Preceptors at one of the universities (university 2) were also given a similar survey (n=30, 36% response rate)	a. Academics (n=47), students (n=102), professional/registration board representatives and preceptors (n=52) in eight states and territories in Australia. b. Australian undergraduate pharmacy students that had trialled the tool while on placement in their final year (n=117 students from university 1 and n=45 students from university 2).	Feedback on the tool highlighted concerns about its impact on the roles of universities and the mandatory 12-month internship. Some believed continuity with the internship was important for a seamless transition. Students had mixed feelings, while preceptors were generally positive. Lack of student engagement was linked to confusion about its relevance and usage, suggesting the need for clearer explanations before placements. Some preceptors found the tool complex and time-consuming due to limited interaction time. More work is needed as the tool's language and complexity require refinement. Universities planning to implement it should ensure clear competency explanations in the curriculum and provide prior self-assessment practice for students.
22.	Stupans et al (2016)	Australia, Canada, United Kingdom and United States of America	A comparison of the learning outcomes for pharmacy graduates from Australia, Canada, United Kingdom and United States through mapping to the International Pharmaceutical Federation (FIP) Global Competency Framework (GbCF)	Comparative document analysis to review the level of commonality and the differences between expectations of pharmacy graduates' learning outcomes from these countries aligning them to the global pharmacy workforce practice via the GbCF.	End of degree expectations from 4 pharmacy programmes	The overall alignment across jurisdictions was evident between learning outcomes and the GbCF for basic public health, pharmaceutical care, and personal attributes. Dispensing and compounding exhibited less emphasis in Canada, UK, and US compared to Australia, possibly due to differing roles of pharmacy technicians. Australian outcomes omit organisation and management. US outcomes specifically mention innovation and entrepreneurship for adaptability. Teamwork and leadership, not in the GbCF, are present in 3 of 4 countries' learning outcomes. Given the GbCF's use of practitioner development frameworks from these countries, similarities are expected. Future revisions could harmonise learning outcomes for transferability and pharmacist mobility. Institutional networking is recommended for a common assessment tool. Despite degree title differences, these jurisdictions align pharmacists as patient-oriented experts, bridging professional and university systems closely.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
23.	Vitor et al (2019)	United Kingdom	Explore pharmacist practitioners' post-MSc. in Advanced Pharmacy Practice (MScAPP) perceptions and how the University College London (UCL) programme facilitates advanced practice development.	Semi-structured interviews underwent thematic grouping and matrix coding. Independent variables included years since MScAPP graduation and pre-programme professional roles, assessing impact on career progression and adaptability across pharmacy specialisations. Dependent variables were current role, RPS Faculty engagement, and workplace representation. MScAPP employs the RPS's Advanced Practice Framework (APF) for competency-based education.	Pharmacists of any background that graduated from the programme, n=15, 14 were working in a clinical role and 1 in an academic setting. (Specialisations couldn't be compared because most participants had a clinical role.)	Participants found the APF useful for benchmarking their education and identifying learning gaps. Students utilized it for learning portfolios and one used it for career progression suitability. Graduates continued using the framework post-graduation for ongoing career development. No experience-level differences were found in research and evaluation skills, implying that this area isn't developed during practice. The APF aids skill acquisition and enhancing prior competencies, assuring quality and safety. It strengthens advanced level competencies.
24.	Volmer et al (2017)	Estonia	Evaluate the University of Tartu's (UT) MSc Pharm undergraduate pharmacy programme in Estonia using the European Pharmacy Competence Framework (EPCF). The EPCF was employed to identify curriculum gaps, assess competency levels of curriculum outcomes, and align the programme with international standards.	Qualitative assessment of the pharmacy programme was performed with a convenience sample of different pharmacy stakeholders. Both obligatory and elective subjects were included in the analysis. Subject areas were defined using predetermined subject groups. Competency levels to be achieved by the outcomes of the curriculum were identified according to the Dutch competency standards framework which has a 5-point scale based on increasing professional independence.	Pharmacy stakeholders from academia, wholesale and retail sale of medicines, hospital pharmacy, pharmaceutical industry and other fields (e.g. State Agency of Medicines). Recently graduated pharmacists were also included to analyse the programme from the point of view of both students and pharmacists, n=14.	Pharmacy sector representatives raised concerns about the structure and training methods of the programme, urging for early inclusion of patient care competencies, clearer guidelines for internships, more practical application of theoretical knowledge, interdisciplinary collaboration, and enhanced self-reflection methods for students. The suitability of the EPCF for evaluating this type of curriculum was questioned, as it primarily caters to community pharmacy without specialisation. Estonia approved occupational qualification standards for pharmacists in 2016, offering detailed competency descriptions that could guide future pharmacy education. Patient care competencies were well-defined, while personal competencies were more broadly covered, potentially affecting competency assessment. Continuous development of professional competency involves both undergraduate and postgraduate education. It's recommended to involve curriculum development specialists and education experts in future evaluations.
25.	Walter et al (2018)	Canada	The Canadian Experiential Education (CanExEd) project recommends core competencies for preceptors training undergraduates. This work expands on The Pharmacy Experiential Programmes of Canada (PEP-C) list of desired preceptor qualities to identify preceptor competencies.	The authors developed a list of competencies and performance indicators, aligning them with the PEP-C's desired qualities of a preceptor. They adapted themes from the literature based on their expertise and created a list of competencies, comparing it against various educational and professional competency standards. Feedback from a steering committee and experts further refined the framework.	Eight articles from pharmacy, medicine, nursing, and higher education.	Competency measurement and minimum requirements for preceptors have gained significance due to extended experiential training as Canada's BPharm programme shifts to the PharmD. Despite professional obligations and regulatory mandates, preceptor training is undervalued, affecting undergraduate training quality. Three key themes surfaced in the literature: commitment to teaching, role modelling, and promoting self-directed learning. The final framework outlines nine competencies, including commitment to teaching, creating learning opportunities, fostering reflection and lifelong learning, effective communication, modelling best practices, adapting to student needs, nurturing critical thinking, and assessing student performance. Stakeholder input remains limited, suggesting that involving preceptors, programme directors, and regulators through a Delphi process could enhance validity. Full stakeholder endorsement is vital to support preceptor development and engagement with the national PDP.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
26.	Waterfield (2017)	United Kingdom	This study aimed to understand pharmacy educators' perceptions of the term "competence" by collecting perspectives from educators across various pharmacy schools. Contrasts were drawn between science-based and practice-based educators, revealing connections between definitions and theoretical viewpoints of competence.	Semi-structured interviews analysed by a reflexive framework analysis. Participants were selected from 29 volunteers to reflect a balance of gender, experience and areas of specialism. (representing two groups—science-based and practice-based)	n=12 (4 academic members of staff from 3 different pharmacy schools in England, including a school with a long established MPharm programme and one that was relatively new).	Four main themes were identified: 1. Social Definition of Competence: Both educator groups saw competence as socially defined by peers. 2. Focus on the Present: Competence was seen as a snapshot of the present, raising concerns about its relevance in changing practice settings. 3. Differing Views on Competence Assessment: Science-based educators were more positive about competence than practice-based educators. 4. Contrasting Views on Assessment: Differences emerged between the groups, transitioning from absolute to relative definitions during assessment discussions. The study suggests that a holistic approach combining clinical understanding and a CBE approach is necessary. An overly structured approach may not adequately prepare pharmacists to apply knowledge to clinical problems, leading to a potential fragmentation of pharmacy knowledge. There is a tension between perceived objective science and subjective clinical practice.
27.	Westein et al (2019)	Netherlands	Implement, evaluate and revise a two-year workplace-based postgraduate CBE curriculum introduced for community pharmacist specialists in the Netherlands in 2012.	Development of the CBE postgraduate education programme for community pharmacy. Evaluation of workplace-based learning and assessment using surveys of trainees and supervisors which were used to define 3 themes to evaluate in more depth via 2 focus group discussions focusing on ways of improving the curriculum. The results of the focus groups were then discussed by a review committee	Stakeholders – community pharmacists, teachers, policy advisors, stakeholder organisations e.g. the Young Pharmacists' Association, a total of 100 community pharmacists contributed to the defining task areas. Eighty-two trainees enrolled in the first year of the course in 2012. Details of the survey and focus group participants were not provided.	A list of 10 task areas were compiled by the programme director. (Royal Dutch Pharmacists Association, 2012) They used the CanMEDS model, adopted for medical specialists' education in the Netherlands in 2006, to define required competencies. Survey themes included trainee/supervisor workload, workplace learning opportunities, and assessment system utility. Focus groups noted programme improvement for community pharmacists as high-standard healthcare professionals. Concerns included heavy workload, unclear expectations for trainees/supervisors, and difficulties with assessment instruments/portfolios. Review committee recommendations involved reducing assessments, clarifying assessment tools, enhancing portfolio appearance, improving supervisor training, and conducting further impact/relevance evaluations. In 2016, the MPharm programme in the Netherlands also adopted the CanMEDS model, creating a seamless education continuum for pharmacists. (Schalekamp and Haisma, 2016) Pharmacists regularly juggle educator and evaluator roles while leading their teams, but adding more qualified supervisors like mentors is often impractical. The CanMEDS framework found acceptance, yet ongoing research and enhancements are required. This workplace-oriented curriculum approach can extend to other specialisations worldwide.

Table 3 (continued)

	Author (year)	Location	Description	Methods	Sample	CBE related conclusions
28	Zeind et al (2012)	United States of America	Determine the level of inclusion of the 5 core competencies outlined by the Institute of Medicine (IOM), to improve the quality and safety of health care in the US. These competencies have been acknowledged by The Accreditation Council for Pharmacy Education (ACPE) and included in their standards.	An electronic survey using IOM language to explore the extent of the desire to incorporate the IOM competencies, and the extent to which each competency was included in the PharmD curriculum as well as how the competency was incorporated.	Pharmacy practice chairs (or designated individuals) from US colleges and schools of pharmacy, n=91 (79.1% response rate). Public universities made up 58%, and private universities made up 42% of the total respondents which was representative of the distribution of public and private schools of pharmacy in the US.	Evidence-based practice and patient-centred care competencies were well integrated into the PharmD curricula. However, competencies related to informatics, interdisciplinary learning, and quality improvement had lower levels of inclusion. Challenges in designing and implementing educational experiences and assessments in these areas might explain the lower incorporation rates. This study didn't explore the barriers to integrating IOM competencies, but it did observe a disconnect between the desire to include these competencies and the actual inclusion rates. The study evaluated the overall inclusion of competencies throughout the PharmD programme but didn't assess their appropriate integration into the curriculum. Future research should focus on evaluating the adequacy of competency integration. The study identified diverse approaches to incorporation and highlighted areas needing improvement. The authors suggest a more standardised integration of competencies, given the variations in findings, and propose the potential benefits of additional national guidance for the integration of IOM competencies.

Table 4 MMAT quality analysis of systematic review studies

Qualitative								
Study Number	**S1. Are there clear research questions?**	**S2. Do the collected data allow to address the research questions?**	**1.1. Is the qualitative approach appropriate to answer the research question?**	**1.2. Are the qualitative data collection methods adequate to address the research question?**	**1.3. Are the findings adequately derived from the data?**	**1.4. Is the interpretation of results sufficiently substantiated by data?**	**1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?**	**Comments**
5. (Alves da Costa et al., 2020)	Yes[a]	Yes	Yes	Yes	Yes	No	Yes	[a]This is an exploratory study so research questions are not explicitly defined in detail.
6. (Bajis et al., 2018)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
17. (Paradis et al., 2018)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
18. (Reardon et al., 2016)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
19. (Rich, 2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
21. (Stupans et al., 2012)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
22. (Stupans et al., 2016)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
23. (Vitor et al., 2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
24. (Volmer et al., 2017)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
25. (Walter et al., 2018)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
26. (Waterfield, 2017)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	

Table 4 (Continued)

Quantitative non-randomized								
Study Number	**S1. Are there clear research questions?**	**S2. Do the collected data allow to address the research questions?**	**3.1. Are the participants' representative of the target population?**	**3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?**	**3.3. Are there complete outcome data?**	**3.4 Are the confounders accounted for in the design and analysis?**	**3.5. During the study period, is the intervention administered (or exposure occurred) as intended?**	**Comments**
13. (Meštrović et al., 2012)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Quantitative descriptive								
Study Number	**S1. Are there clear research questions?**	**S2. Do the collected data allow to address the research questions?**	**4.1. Is the sampling strategy relevant to address the research question?**	**4.2. Is the sample representative of the target population?**	**4.3. Are the measurements appropriate?**	**4.4 Is the risk of nonresponse bias low?**	**4.5. Is the statistical analysis appropriate to answer the research question?**	**Comments**
7. (Bayram and Köksal, 2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
8. (Boyle and Myford, 2013)	Yes	Yes	Yes	Can't tell[b]	Yes	No[c]	Yes	[b]Although authors state no extreme departure from known demographics of the pharmacist population, this is not explicitly proven. [c]This study uses previous survey data where a snowballing sampling strategy was utilised thus response rate could not be determined.
9. (Bray et al., 2017)	Yes	Yes	Yes	Can't tell[d]	Yes	Yes	Yes	[d]For the survey aspect of the study the response rates are quoted as 'always above 50%' for each cohort but no comment on the representativeness of this sample is made.

Table 4 (Continued)

Quantitative descriptive								
Study Number	**S1. Are there clear research questions?**	**S2. Do the collected data allow to address the research questions?**	**4.1. Is the sampling strategy relevant to address the research question?**	**4.2. Is the sample representative of the target population?**	**4.3. Are the measurements appropriate?**	**4.4 Is the risk of nonresponse bias low?**	**4.5. Is the statistical analysis appropriate to answer the research question?**	**Comments**
10. (Kary et al., 2019)	Yes	Yes	Yes	Can't tell[e]	Yes	No[e]	Yes	[e]A relatively high response rate was achieved but the authors do acknowledge that the voluntary self-selection participation in the survey may introduce nonresponse bias and affect the true representativeness of the sample. Additionally, authors acknowledge that only select competencies were surveyed which may affect representation of true practice.
11. (Kirton and Kravitz, 2011)	Yes	Yes	Yes	Yes	Yes	No[f]	Yes	[f]Data from the year 2 OSCEs in the programme were not complete, leading to their exclusion from the analysis. As a result, the intended information from a valid unit was not obtained hence potentially introducing bias.
12. (Mann et al., 2018)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
16. (Nunes-Da-Cunha and Fernandez-Llimos, 2019)	Yes	Yes	Yes	Can't tell[g]	Yes	Yes	Yes	[g]Courses without online syllabi were excluded, although the exact count of such courses is not reported.
28. (Zeind et al., 2012)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	

Table 4 (Continued)

Mixed Methods								
	S1. Are there clear research questions?	**S2. Do the collected data allow to address the research questions?**	**5.1. Is there an adequate rationale for using a mixed methods design to address the research question?**	**5.2. Are the different components of the study effectively integrated to answer the research question?**	**5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?**	**5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?**	**5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?**	**Comments**
1. (Al-Haqan et al., 2020)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
2. (Al-Haqan et al., 2021a)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
3. (Al-Haqan et al., 2021b)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
4. (Allen et al., 2016)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No divergences reported*
14. (Nash et al., 2016)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
15. (Nash et al., 2017)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No divergences reported*
20. (Skowron et al., 2017)	Yes	Yes	Yes	Yes	Yes	Can't tell[h]	Yes	[h]Qualitative mapping of a curriculum to a competency framework was performed and this data was subsequently quantified to evaluate gaps and so analysing divergences was not applicable
27. (Westein et al., 2019)	Yes	Yes	Yes	Yes	Yes	Can't tell[i]	Can't tell[j]	[i]This is a programme development and evaluation study rather than a traditional mixed methods research study. [j]Not enough detail provided to adequately assess. However, it still offers valuable insight into the contemporary features of CBE.

*As outlined in the MMAT analysis guide when there are no divergences between qualitative and quantitative results, criterion 5.4 can be rated as 'Yes' (Hong et al., 2018b)

Table 5 Features of CBE in pharmacy and related supporting components

Overarching Theme	Features of CBE identified from the studies	Corresponding studies cited in this review	Related CBE definition theme as per Frank et al (2010a)	Supporting components relevant to CBE related activity of the features identified	Corresponding studies cited in this review
A. Design	Curriculum/programme development using competency framework mapping	(Al-Haqan et al., 2020, Al-Haqan et al., 2021a, Nash et al., 2016, Paradis et al., 2018, Skowron et al., 2017)	1.a	*Based on accreditation standards from regulatory bodies*	(Bajis et al., 2018, Kary et al., 2019, Paradis et al., 2018, Reardon et al., 2016, Stupans et al., 2016, Walter et al., 2018, Zeind et al., 2012, Nash et al., 2017)
	Competencies integrated throughout curriculum	(Nash et al., 2016, Paradis et al., 2018, Skowron et al., 2017, Westein et al., 2019)	1.b		
	Emphasis on abilities	(Westein et al., 2019)	1.c	*Use of meta-competencies in conjunction with enabling competencies* *Include generic Skills*	(Rich, 2019, Vitor et al., 2019, Walter et al., 2018) (Nash et al., 2017, Paradis et al., 2018) (Rich, 2019, Vitor et al., 2019, Volmer et al., 2017, Walter et al., 2018)
	Scaffolded development (attention to sequencing of learning)	(Kirton and Kravitz, 2011, Nash et al., 2016, Stupans et al., 2012, Zeind et al., 2012)	1.d		
	Needs-based approach	(Alves da Costa et al., 2020, Bajis et al., 2018)	2.b		
	Patient-centred approach	(Mann et al., 2018, Paradis et al., 2018, Reardon et al., 2016, Stupans et al., 2016, Volmer et al., 2017, Westein et al., 2019)			
B. Systems of instruction and learning methods	Learner-centred pedagogy	(Meštrović et al., 2012, Vitor et al., 2019, Volmer et al., 2017)	2.a		
	Translate learning to practice	(Bajis et al., 2018, Nash et al., 2016, Paradis et al., 2018, Vitor et al., 2019, Volmer et al., 2017, Westein et al., 2019)		*Interdisciplinary learning* *Experiential learning* *Use of teacher-practitioners/practice preceptors*	(Zeind et al., 2012) (Paradis et al., 2018, Stupans et al., 2012, Volmer et al., 2017, Walter et al., 2018, Westein et al., 2019) (Paradis et al., 2018, Stupans et al., 2012, Volmer et al., 2017, Westein et al., 2019, Walter et al., 2018)
	Prepare students for adaptability and resilience (for changing healthcare landscape)	(Stupans et al., 2016, Vitor et al., 2019)			
	Lifelong learning preparation	(Stupans et al., 2012, Vitor et al., 2019, Volmer et al., 2017, Walter et al., 2018)		*Education and training on the concept of competence/competency frameworks*	(Meštrović et al., 2012, Nash et al., 2016, Nash et al., 2017, Paradis et al., 2018, Reardon et al., 2016, Rich, 2019, Stupans et al., 2012)
	Learner flexibility (self- directed and/or self-pacing)	(Stupans et al., 2012, Vitor et al., 2019, Westein et al., 2019)	2.a and 3		

Table 5 (continued)

Overarching Theme	Features of CBE identified from the studies	Corresponding studies cited in this review	Related CBE definition theme as per Frank et al (2010a)	Supporting components relevant to CBE related activity of the features identified	Corresponding studies cited in this review
C. Feedback and assessment	Criterion-based assessment	(Bray et al., 2017)	1.d	*Official methods for recognising excellence* *Standardised form for assessment* *Entrustable Professional Activities (EPAs)* *Objective Structured Clinical Examinations (OSCEs)* *Portfolios*	(Bray et al., 2017) (Meštrović et al., 2012, Reardon et al., 2016, Al-Haqan et al., 2021a) (Westein et al., 2019) (Reardon et al., 2016, Al-Haqan et al., 2021a, Kirton and Kravitz, 2011, Allen et al., 2016) (Westein et al., 2019, Nash et al., 2017, Vitor et al., 2019, Meštrović et al., 2012)
	Learner self-assessment	(Al-Haqan et al., 2021b, Allen et al., 2016, Kary et al., 2019, Meštrović et al., 2012, Nash et al., 2016, Nash et al., 2017, Vitor et al., 2019, Volmer et al., 2017, Walter et al., 2018)	2.a		
	Continuous Feedback	(Al-Haqan et al., 2020, Kary et al., 2019, Allen et al., 2016, Westein et al., 2019)		*Longitudinal assessment of competencies in various scenarios/contexts* *Combination of formative and summative assessment*	(Rich, 2019, Kary et al., 2019, Westein et al., 2019) (Kary et al., 2019, Nash et al., 2017, Westein et al., 2019)
D. Faculty	Inform and involve the whole faculty with CBE activities	(Paradis et al., 2018)	4		
	Department acceptance and participation	(Paradis et al., 2018, Westein et al., 2019)			
	Training on the use of CBE related teaching & learning practices and assessment methods	(Volmer et al., 2017, Westein et al., 2019, Paradis et al., 2018)		*Scholarly approach to teaching and learning*	(Rich, 2019, Al-Haqan et al., 2021a)
E. Resources	Intensive implementation process	(Volmer et al., 2017, Zeind et al., 2012, Bray et al., 2017)	4	*Use of IT for teaching & learning/ course planning/ tracking student progress* *Additional staff with expertise in instructional design/teaching & learning/curriculum development* *Designated course or curriculum coordinators*	(Bray et al., 2017, Nash et al., 2016) (Walter et al., 2018, Volmer et al., 2017) (Paradis et al., 2018, Westein et al., 2019)
F. Internal & External Factors	Formal institutional and departmental support for CBE	(Nash et al., 2017, Walter et al., 2018)	4		
	Support from higher authorities/policies/regulators	(Al-Haqan et al., 2020, Al-Haqan et al., 2021b, Bajis et al., 2018, Skowron et al., 2017, Volmer et al., 2017, Westein et al., 2019)		*Coordination of education quality assurance efforts across national and/or international borders* *Collaboration with schools outside of the pharmacy school.* *Collaboration with other HEIs.*	(Paradis et al., 2018, Stupans et al., 2016, Reardon et al., 2016, Walter et al., 2018, Westein et al., 2019, Zeind et al., 2012, Bajis et al., 2018) (Rich, 2019, Westein et al., 2019) (Rich, 2019, Stupans et al., 2012, Stupans et al., 2016)

3.4.2.1 Design

The studies often referred to a patient-centred (Stupans et al., 2016, Westein et al., 2019, Reardon et al., 2016, Mann et al., 2018, Paradis et al., 2018, Volmer et al., 2017) and needs-based approach (Alves da Costa et al., 2020, Bajis et al., 2018) to CBE programme design that incorporates generic skills (Nash et al., 2017, Paradis et al., 2018, Vitor et al., 2019, Rich, 2019, Volmer et al., 2017, Walter et al., 2018). In one study, focus group participants identified that the supporting abilities students develop during a CBE programme are important as they align with the demands of pharmacists to work as high-standard healthcare professionals (Westein et al., 2019). Several studies referred to a recent change in the accreditation standards from pharmacy education regulators, often following reform of professional standards, which guided their CBE design (Reardon et al., 2016, Al-Haqan et al., 2021a, Bray et al., 2017), or were used to identify gaps in an existing curriculum (Bayram and Köksal, 2019, Skowron et al., 2017, Zeind et al., 2012). Other features are less related to content and associated with the progressive process of competency development including the sequence of competency development (Kirton and Kravitz, 2011, Nash et al., 2016, Stupans et al., 2012, Zeind et al., 2012) and the extent to which competencies are integrated throughout the curriculum (Nash et al., 2016, Paradis et al., 2018, Skowron et al., 2017, Westein et al., 2019). Stupans et al. (2016) describe an overall alignment of the learning outcomes for pharmacy graduates across the four selected jurisdictions in their study when mapped against the GbCF, but noted that the GbCF is missing competencies related to team work and leadership.

Endorsement of CBE by all stakeholders contributes to ensuring that learners are supported throughout their education or training (Walter et al., 2018). Working groups (Al-Haqan et al., 2021a), steering committees (Alves da Costa et al., 2020, Walter et al., 2018), retreats (Bray et al., 2017), and workshops (Alves da Costa et al., 2020, Stupans et al., 2012) are examples of ways in which organisations can begin to prepare and outline their visions for CBE. Establishment of a shared vision, together with strong leadership for the conversion to CBE process, is therefore important to address when considering implementation of CBE and help mitigate potential challenges (Westein et al., 2019).

3.4.2.2 Systems of instruction and learning methods

Numerous teaching and learning approaches were identified, with a primary emphasis on training in the concept of competency itself (Meštrović et al., 2012, Nash et al., 2016, Nash et al., 2017, Paradis et al., 2018, Reardon et al., 2016, Rich, 2019, Stupans et al., 2012). Studies highlighted the importance of acquainting students with competencies, frameworks, and definitions to connect competencies with learning outcomes (Paradis et al., 2018, Rich, 2019). Additionally, this enables students to engage with a continuum of competence tailored to professional standards corresponding to their practice level (Nash et al., 2016, Nash et al., 2017). This is especially crucial when introducing the concept of competency for the first time to learners (Meštrović et al., 2011, Reardon et al., 2016), faculty (Rich, 2019), or

preceptors (Stupans et al., 2012). Rich (2019) illuminated tensions arising from differing interpretations of competence, highlighting integrated meta-competencies present in medical, nursing, and pharmacy frameworks, fostering holistic competency development. In contrast, engineering, law, and clinical psychology frameworks lacked supporting meta-competencies, adopting a list-based structure for performances or behaviours. Rich (Rich, 2019) contends that these conceptual disparities influence curricular teaching and learning approaches.

Studies indicated a focus on preparing for lifelong learning (Stupans et al., 2012, Vitor et al., 2019, Volmer et al., 2017, Walter et al., 2018), closely tied to self-directed learning (Stupans et al., 2012, Vitor et al., 2019, Westein et al., 2019), as well as resilience and adaptability (Stupans et al., 2016, Vitor et al., 2019). Lifelong learning and continuing professional development (CPD) were denoted as interchangeable concepts to equip learners, not only to successfully complete their current education and training but also to continue learning in an environment where expanding scopes of practice and uncertainty for the future skills of pharmacists reinforces the need for adaptability (Nash et al., 2017). Self-directed learning, fostering autonomy and motivation, was deemed valuable for professional advancement (Vitor et al., 2019). This approach aligns with a learner-centred paradigm (Frank et al., 2010b), wherein students identify learning gaps, reflect on progress, and pursue research projects aligned with their interests. Learners appreciated the flexibility of this individualised approach (Meštrović et al., 2012, Vitor et al., 2019). Furthermore, learning flexibility was a recurring feature in CBE-related studies (Stupans et al., 2012, Vitor et al., 2019, Westein et al., 2019).

Experiential learning is valued for its practical application and skill acquisition compared to knowledge-focused teaching (Paradis et al., 2018). Balancing foundational knowledge with technical skills is crucial. Depending on background; i.e. pharmacy, humanities or social sciences, faculty tend to favour one approach over the other and therefore a unified strategy would promote consistency (Paradis et al., 2018). The dominance of PharmD programmes, where experiential learning time is a significant proportion of the curriculum, in some countries—like Canada, the United States (US) and Australia—highlights the importance of high-quality experiential education and competent preceptors. Strengthening the competencies of the preceptors themselves is therefore paramount (Walter et al., 2018, Stupans et al., 2012). However, challenges arise, such as supervisor feedback inadequacy and reliance on the same supervisor for the majority of assessment which can be strenuous and lack objectivity (Westein et al., 2019). Some locations lack a longstanding practice of experiential learning and identified a need for enhanced experiential learning support (Volmer et al., 2017), and more partnerships between educational institutions and practice (Alves da Costa et al., 2020). Integrating case studies, simulations, and workplace-based learning bolsters authentic teaching and learning across diverse contexts (Rich, 2019).

In addition to experiential learning, interdisciplinary learning is also advocated for inclusion in the PharmD CBE curriculum as outlined by Zeind et al. (2012). Despite the inclusion of interdisciplinary competencies in the Accreditation Council for Pharmacy Education (ACPE) standards, a low proportion of US pharmacy schools (34%) indicated that these competencies were well covered by the curriculum. Although this study does not capture data on the reasons for this, interdisciplinary learning and associated competencies are recognised as a key component of education for healthcare professionals, and thus the authors suggest that this area requires improvement in the US (Zeind et al., 2012).

3.4.2.3 Feedback and assessment

Portfolios served as assessment tools in four studies (Meštrović et al., 2012, Westein et al., 2019, Vitor et al., 2019, Nash et al., 2017), with two of those emphasising an online format (Meštrović et al., 2012, Nash et al., 2017). Portfolio use, when combined with other assessment methods, can minimise interrater variability (Meštrović et al., 2012). Portfolios are also used in conjunction with competency frameworks, which help to structure documentation of the learner's development (Meštrović et al., 2012, Westein et al., 2019). A longitudinal study on community pharmacists demonstrated significant enhancement of patient care competencies through a tailored education programme incorporating a mandatory competency-based portfolio (Meštrović et al., 2012). Furthermore, portfolios were found to contribute to learner's motivations to enrol on a MSc in Advanced Pharmacy Practice in the UK and utilised as an instrument to consolidate learning activities for career development and professional recognition (credentialing) (Vitor et al., 2019). However, feedback on portfolios revealed they could be difficult to use and so attention to their user-friendliness is recommended to ensure they are clear and efficient to employ, thus improving their acceptance and usability (Meštrović et al., 2012, Nash et al., 2017).

Another common CBE assessment method identified from the studies was the Objective Structured Clinical Examination (OSCE). Recommendations for improving the experience and performance during OSCEs include performing prior formative OSCEs, which helps to allay any anxieties particularly for students and pharmacists that are new to this method, in preparation for summative or registration OSCE assessments (Al-Haqan et al., 2021a, Reardon et al., 2016). Kirton and Kravitz (2011) describe that there is a weak correlation between performance in OSCEs and more traditional assessments as the different formats examine different skills. They recommended that OSCEs should be used in conjunction with a variety of assessment formats and that performance may be related to external factors rather than ability. Therefore, attention should be paid to the examination environment, structure, timing and the amount of weight they carry towards any final summative grade (Kirton and Kravitz, 2011).

Entrustable Professional Activities (EPAs) emerge as a significant assessment component. Westein et al. (2019) describe the process of a thorough evaluation of a CBE programme for community pharmacists and conclude that EPAs are an assessment method for postgraduate pharmacy education that is adaptable to changes in pharmacy practice without needing to change the underlying competency framework. However, care must be taken to limit the amount of EPAs to avoid administrative burden and assessment trivialisation (Westein et al., 2019).

Learner self-assessment was a salient feature employed in pharmacy education both at undergraduate level (Nash et al., 2016, Allen et al., 2016), post-qualification (Meštrović et al., 2012, Al-Haqan et al., 2021b, Vitor et al., 2019, Nash et al., 2017, Al-Haqan et al., 2020, Kary et al., 2019), and for the development of pharmacy education preceptors (Walter et al., 2018). Competency frameworks provide standards which learners can assess themselves against and use to plan future learning (Meštrović et al., 2012, Al-Haqan et al., 2021b, Walter et al., 2018, Vitor et al., 2019, Nash et al., 2017, Kary et al., 2019, Al-Haqan et al., 2020). Self-assessment is referred to as a skill that needs to be developed at an early (undergraduate) level as pre-career habits influence the performance of the future pharmacist and their lifelong learning, reflected by the mandatory self-assessment CPD requirement for pharmacists in Australia (Nash et al., 2017). Furthermore, Nash et al. (2016) describe that asking students to self-assess on their performance using Miller's pyramid can contribute to a programme's assurance of learning by providing data reflective of the actual "learnt" curriculum as experienced by students. In the UK, one study utilised video self-observation of students' performance, participants reported this to be more valuable than third party feedback as it enabled them to see themselves in the eyes of others and acknowledge things about themselves that they may not have otherwise accepted (Allen et al., 2016). Allen et al. (2016) argue that this approach of self-observation improves learning in accordance with Bigg's theory of constructive alignment—enabling "learning through choice and engagement with relevant learning activities", where the learner is at the centre of their own learning experience which encourages active self-reflection. As with EPAs and OSCEs, it is noted that learner self-assessment should not be used in isolation but as part of a profile of varied CBE feedback and assessment strategies (Kary et al., 2019).

A number of studies referred to providing regular feedback, particularly soon after completing assessments (Westein et al., 2019, Allen et al., 2016, Kary et al., 2019), and learning activities (Al-Haqan et al., 2020). The combined use of formative and summative assessment can aid the regulation of learner's competency development to engage in a continual learning process (Rich, 2019, Nash et al., 2017). The individualised nature of CBE assessment and feedback also requires attention in relation to the way assessment grading is referenced. Bray et al. (2017) argue that traditional relative grading scales (e.g. alphabetical) are reliant on the performance of other students in the cohort and this does not lend itself well to the absolute and individualised nature of the attainment of competence. In this study a criterion-

referenced grading model was implemented which allowed students to demonstrate competency for all outcomes measured whilst still allowing for the demonstration of excellence deemed necessary for purposes such as applying for residency or scholarship (Bray et al., 2017).

Feedback in CBE can be given in a variety of ways and digital platforms are often utilised. Al-Haqan et al. (2020) reported an improvement in CPD and associated documentation after a 6-month period of continuous feedback through a variety of online platforms. An online feedback tool was found to be helpful for students following OSCEs, especially as their performance was colour-coded (red, amber, green) which enabled them to visualise their progress (Allen et al., 2016). In this study, students found detailed, individualised, immediate feedback useful for contributing to learning and suggest that tracking performance in this way increases students' motivation, enabling them to identify and target particular areas for development to define and redefine their own learning goals (Allen et al., 2016). Feedback should be specific and meaningful and come from a variety of sources, including other healthcare professionals and even patients, which contributes to objectivity (Kary et al., 2019).

In Canada the majority of assessments for pharmacy resident programmes (75%) were longitudinal (Kary et al., 2019), where one of the few assessment stipulations of the accreditation standards of the Canadian Pharmacy Residency Board (CPRB) is the requirement for longitudinal assessments (Canadian Council for the Accreditation of Pharmacy Programs (CCAPP), 2018). Rich suggests that measuring competence in this manner as a pattern of performance overtime is more useful than measuring competencies in isolation (Rich, 2019). Using competency frameworks to develop standardised forms for the demonstration of competence can reduce variability between pharmacists' self-assessment in practice (Meštrović et al., 2012), and application of a standardised entry-to practice assessment may also contribute towards improved public, and other professionals' perceptions of pharmacists as well as enhanced self-perception (Reardon et al., 2016).

3.4.2.4 Faculty

The involvement of practice-based trainers is often fundamental, as better translation of learning to practice is a desirable feature of CBE facilitated through experiential educational activities (Volmer et al., 2017). These trainers are often pharmacists, and occasionally other healthcare professionals, who are involved in teaching and supervision of a substantial portion of CBE and training. In some cases this can be whole years of study (Paradis et al., 2018), entire programmes (Westein et al., 2019), and significant periods of supervised practice prior to licensure as a pharmacist (Stupans et al., 2012). However, they are not necessarily trained educators and may not have much knowledge of CBE and related assessments. A graduated descriptors tool, developed in Australia for pharmacy graduates pre-licensure, provides a rubric for learners to self-assess and identify learning gaps

according to competency standards, which preceptors found useful for their role in supporting learners (Stupans et al., 2012). In recognition of the crucial role of preceptors in CBE, a preceptor competency framework has been developed in Canada to enhance the quality of practice-based learning experiences (Walter et al., 2018). In addition to CBE training for practice-based trainers, support and familiarisation with the concept of competence and related teaching circumstances are also essential for academic faculty members (Paradis et al., 2018). Different epistemological understandings of CBE within faculty members can lead to disjointed approaches to teaching, therefore a unified approach is recommended (Paradis et al., 2018). Additionally, involvement of all faculty members, and other higher education stakeholders, in the design and evaluation of CBE programmes helps to facilitate faculty buy-in and acceptance for the considerable changes needed to adapt to a CBE curriculum (Volmer et al., 2017, Westein et al., 2019, Paradis et al., 2018).

3.4.2.5 Resources

CBE is widely endorsed by the profession, but implementation can be an intensive process requiring considerable change and disruption (Bray et al., 2017, Volmer et al., 2017). To help alleviate this, recommendations include collaboration within the pharmacy sector and with other healthcare professions to share experiences and improve the success of curricular CBE integration (Volmer et al., 2017, Zeind et al., 2012).

Information Technology (IT) and web-based systems are utilised in CBE to aid feedback, organisation and evaluation. Allen et al. (2013) describe a web-based tool (individualised Skills Evaluation and Development, iSED®) specifically designed for formative feedback with OSCEs that facilitates self-regulated learning. Similarly, Bray et al. (2017) describe using the Examsoft® computer software to aid students with self-assessment and the provision of timely feedback, but also for question coding and rubrics. Educators' perspectives of the 'assessed' curriculum and students' perspectives of the 'learnt' curriculum do not always align, in one study a database of information from educators' and students' perspectives for curriculum mapping and the co-creation of rubrics was a useful for highlighting issues with scaffolding of learning and the integration of professional standards (Nash et al., 2016).

Different approaches to teaching in CBE, and the difficulties faculty have in articulating these approaches, calls for better coordination of the curriculum, which can be facilitated by specific leadership and curriculum mapping (Paradis et al., 2018). Westein et al. (2019) describe a process of careful curriculum design, coordination, and evaluation of a CBE post-graduate education programme through the use of a programme director and a 'Director of Education' responsible for overall management. On a similar note, the limitations of using evaluators without expertise in curriculum development suggest that consultation with curriculum specialists is required to progress further with CBE (Volmer et al., 2017). Furthermore, the engagement of additional staff with expertise in CBE related features, such as

experiential education, has been advantageous in the design of a competency framework for preceptor development that has relevance internationally, both for pharmacy and across other health disciplines (Walter et al., 2018).

3.4.2.6 Internal and external factors

In addition to specific CBE aspects discussed so far, there are further features which augment successful CBE implementation and ongoing use. Formal support from both inside and outside of educational institutions is valuable for CBE. For example, in a study of undergraduate curricula and the use of the Spanish competency framework, alignment was found to be insufficient despite legal enforcement since 2008. Consequently, the authors suggest that professional regulatory bodies should work with educational bodies to support improved pairing of competencies and curricula content (Nunes-Da-Cunha and Fernandez-Llimos, 2019).

A supportive academic leadership team, understanding of the disruption necessary to enact change, is key to adopting and sustaining a competency-based assessment model (Bray et al., 2017). Substantial change requires cooperation from educational and governmental institutions (Volmer et al., 2017). Moreover, stakeholder endorsement can be vital for guaranteeing the requisite support for implementing CBE initiative, such as the integration of a preceptor competency framework (Walter et al., 2018).

Workplace organisational support impacts effective experiential learning (Westein et al., 2019), and the adoption of CPD approaches (Al-Haqan et al., 2020). Higher support from regulation, practice, and policy is correspondingly required to expand the scope of pharmacy practice, in line with educational developments, to promote excellence and achieve higher quality patient-orientated care, which is ultimately the aim of CBE for pharmacy (Al-Haqan et al., 2021b, Bajis et al., 2018, Skowron et al., 2017).

Quality assurance in CBE is highlighted by the studies from the description of the processes involved in defining and selecting competencies and competency frameworks according to national standards. The Canadian Medical Education Directions for Specialists (CanMEDS) (Frank, 2005), framework was applied in both postgraduate curriculum development in the Netherlands (Westein et al., 2019) and in programme development for preceptors in Canada (Walter et al., 2018). In addition, Canadian pharmacy education standards were applied in exploring the perceptions of pharmacists surrounding a national licensing exam by the college of Pharmacy at Qatar University—due to the accreditation of their pharmacy programme being granted by the Canadian Council for Accreditation of Pharmacy Programmes (CCAPP) (Reardon et al., 2016). Bajis et al. (2018) also state that Western accreditation standards are used in other pharmacy schools in the Eastern Mediterranean Region (EMR), reportedly enhancing credibility of their programmes and influencing integration of competency standards. However, context- and needs-based specificity is still advised for CBE initiatives due to heterogeneity between

countries in the EMR (Bajis et al., 2018). A common theme from the studies is that CBE efforts should be coordinated to strengthen the consensus on optimal standards of practice and education for pharmacists, which was recommended on interprofessional (Paradis et al., 2018, Westein et al., 2019, Zeind et al., 2012), national (Reardon et al., 2016, Walter et al., 2018, Bajis et al., 2018, Zeind et al., 2012), and international levels (Stupans et al., 2016, Walter et al., 2018). Stupans et al. (2016) reported that high-income countries with comparable health needs displayed alignment between their undergraduate learning outcomes and the FIP GbCF. Additionally, there was agreement on the role of pharmacists as 'patient focused medicines experts', irrespective of degree title (Stupans et al., 2016). The authors also suggest that their findings support the feasibility of a common assessment tool for pharmacy education that would support transferability of skill, and thus mobilisation of the workforce across these jurisdictions (Stupans et al., 2016).

CBE in pharmacy should involve interdisciplinary collaboration, as seen in a Dutch postgraduate programme for community pharmacists aligning competencies with other health professions (Westein et al., 2019). In an analysis of 10 entry-to-practice competency frameworks in Canada, Rich (2019) indicates similarity in intrinsic competency domains across professions. The author draws attention to the importance of integrating these competencies, often referred to as 'soft skills', i.e. communication, ethics, and professionalism, with discipline specific technical knowledge where partnerships across institutions can address shared challenges in competency assessment (Rich, 2019).

3.5 Discussion

This review was designed to establish a broad overview of CBE related activity for pharmacy over recent years. The aim being to document and increase the understanding of what CBE and training entails for the current pharmacy profession, in order to drive CBE forward it is prudent to exam its existing state. It is evident from the previous literature that despite progression and increasing popularity, the operationalisation of CBE is not straight forward. Additionally, in alignment with the findings presented here, there is a great deal of heterogeneity across the globe in both the interpretation of CBE and the extent of its use.

There is no universally accepted approach to adopting the CBE model currently, and geographical, socio-political and cultural contextual differences mean it is unlikely that a one-size-fits all approach would be appropriate. In the medical field, issues with evaluating the implementation of a programme as designed, referred to fidelity of implementation (Van Melle et al., 2019), in CBE have been stunted by a lack of a shared understanding of what constitutes a CBE programme (Glasgow et al., 2008). This review does however, bring together some generic features of CBE for pharmacy in relation to those already identified in the closely linked field of medical education whilst highlighting some of the more general elements of education which can typically support a CBE approach. This review is the first to collate a broad cross-

section of CBE related activity across the whole pharmacy profession, capturing information and lessons to be learnt from all stages of competency development. There is valuable information from all the stages of pharmacy education and training that can be used to inform CBE programmes and curricula for initial (pre-registration undergraduate) education, and as such the intention was to not only examine initial education but all parts of the professional development journey. By including this diversity in level of education and training, this review illustrates that there are some features of CBE related activity common to more than one level of education. Furthermore, this allowed for the inclusion of a wealth of detail on factors that are contributory to the CBE approach, such as the quality and development of preceptors or basic training on the concept of competency or use of competency frameworks, enriching the description of the overall picture of CBE related activity for pharmacy whist also recognising the importance of a continuum of competency development which extends beyond initial education.

In concordance with similar findings in pharmacy CBE related literature, this review revealed a paucity of literature originating from South-East Asia and Africa. This suggests that CBE development, or at least research and publication, is confined to a select few countries predominately in the Global North. Further work is therefore recommended in the Global South, where there is a particular need to improve health outcomes, and where the principles of CBE are likely to be beneficial due to the global shortage of adequately trained healthcare professionals acutely affecting the lower-income countries (World Health Organization, 2016b). Research on the development of CBE in resource limited settings would therefore be of value, including how to overcome the challenges of the resource intensive nature of CBE implementation in these settings. For example, strategies for beginning to adopt particularly useful features of the CBE approach, such as local health needs-based education which could still be advantageous where a fully comprehensive and integrated overhaul of the whole curriculum is not feasible.

A study by Udoh et al. (2021a) has previously recognised the FIP GbCF's suitability and credibility as a model for implementing a competency framework in the context of CBE, particularly when tailored to the national setting. This is in keeping with the study included in this review by Stupans et al. (2016). However, it is worth mentioning that in 2016, these authors stated that 3 of the 4 jurisdictions in their study make reference to teamwork and leadership but that the GbCF did not (Stupans et al., 2016). Yet, on examination the FIP GbCF 2012 (Version 1) does in fact include behavioural standards; “3.2.5 Recognise the value of the pharmacy team and of a multidisciplinary team”, and “4.6.2 Demonstrate leadership and practice management skills, initiative and efficiency” (International Pharmaceutical Federation, 2012). Moreover, the revised GbCF (Version 2), released in 2020, has further expanded these topics and now includes behavioural standards specifically addressing flexibility, adaptability, resilience, and interprofessional collaboration (International Pharmaceutical Federation, 2020b). Notably, this flexibility in the workplace parallels the flexible learning approach identified as a feature of CBE in this review and is a welcomed addition to the GbCF, as students are expected to

manage their own work and learning which translates to preparation for flexible working and learning as practitioners (Loon, 2021).

The conceptualisation and associated definitions and terminology associated with CBE requires harmonisation, as illustrated by several of the studies explicitly referring to a need for CBE to include training of both staff and students on the concept of competency itself. This need for a consensus on CBE components has previously been noted elsewhere (Udoh et al., 2021a), and permeates through all 6 overarching themes of the CBE features identified in this review, particularly as the approach to CBE can have an impact on whether it is viewed as a 'state of being' or reduced to a list of tasks that may have limited applicability to the dynamics of actual practice (Rich, 2019). Change at the regulatory level is often required for successful CBE implementation but also to expand the scope of practice so that pharmacists can put their competencies to use effectively and develop them further towards the ultimate goal of CBE, which is to translate education and training in to improved patient and population health outcomes. Without a unified approach and understanding, the outcomes may not reflect the holistic and integrated approach that is required for CBE and its intended application towards the development of the healthcare workforce and subsequent improvements in health outcomes and patient care (Gonczi, 2013). Therefore, further tools or guidance on adopting CBE for pharmacy is warranted which is also reflected by the scarcity of studies available that are truly reflective of a fully integrated CBE design.

3.6 Limitations

This review does have some limitations as only studies published in English were included. This potentially led to the exclusion of data from some regions possibly contributing to the lack of data from SEA, particularly as literature relating to competency frameworks suggests some CBE-related activity is present in this region within Thailand (Suwannaprom et al., 2020). Some studies from the literature search were also not accessible to the researchers, including one study from India. This may have restricted the scope of the review in terms of capturing data from a greater variety of countries. Secondly, identification of features took a certain level of interpretation and although the authors worked in collaboration with experts, best judgement decisions had to be made within the context of the individual studies which may have resulted in certain misinterpretations or unintentional omissions. Lastly, the heterogeneity of study designs limited direct comparisons of the results although commonality across CBE features was demonstrated between different study sizes as well as locations and educational levels.

3.7 Summary

The list of features identified in this review is not intended to be exhaustive, but rather a reflection of just over a decade of the most recent research in this area within the timeframe of the publication of a global competency framework for pharmacy. The review bolsters findings from previous research that suggests the FIP's GbCF has relevance across a variety of contexts and has been shown to facilitate harmonisation of CBE efforts transnationally. However, there are disparities in the way that CBE is

conceptualised and the variations in terminology and definitions can have an impact on all of the features of CBE identified in this review. It is therefore imperative that a consensus and shared vision for all stakeholders is reached to bridge any gaps between intended curricula and that which is experienced by the learner to enable them to engage in a lifelong learning and adaptation process that is in alignment with the realities of contemporary pharmacy practice.

The evidence presented in this review, supporting the suitability of the GbCF in different contexts, forms the foundation for the studies described in Chapters 5 and 6 of this thesis, where the second iteration of the GbCF is tailored to the Kenyan context. Additionally, these findings inform the consensus development method in Chapter 6 which is designed with the intention of engaging a diverse group of stakeholders with the purpose of enhancing the validity of the resulting framework. Furthermore, this approach serves as an opportunity to introduce competency concepts, CBE, and competency frameworks to pharmacy stakeholders in Kenya and with the aim of promoting understanding of the concept of competency itself and fostering a shared vision among participants for the utilisation of features of CBE. Moreover, this shared vision will also have the potential to permeate the participants' respective organisations or institutions, promoting endorsement of the final framework in alignment with crucial principles outlined by these findings with respect to encouraging support of CBE approaches across the profession as a whole.

The review offers a timely consolidation of the key aspects of CBE in pharmacy, particularly pertinent given recent advancements in this field. It stands as a valuable resource for those contemplating the implementation or enhancement of CBE, leveraging the existing knowledge base. However, it's important to acknowledge that these advancements are not universally distributed worldwide. Hence, there is a pressing need for further research in regions such as Africa and South East Asia, where such research can inform the application of CBE in diverse contexts with varying needs and resources. In Chapter 4, my objective is to contribute to this ongoing research effort by conducting a global survey. This survey aims to examine the nature and scope of CBE features currently in use, thereby complementing this systematic review to construct a comprehensive global overview of CBE within the field of pharmacy.

3.8 Acknowledgements

I would like to thank the International Pharmaceutical Federation (FIP) and the University of Nottingham (UoN) for their support with this study. In particular, thank you to Luke Pattison (LP-second reviewer) and Claire Anderson (CA-third reviewer) from the UoN. Special thanks also to the pharmacy CBE experts; Dalia Bajis, Rula Darwish, Marwan El-Akel, Andries Koster and Marilyn Morris for their collaboration on interpreting the features of CBE presented in this chapter.

Chapter 4: Global Survey of Competency-based Education for Pharmacy and Pharmaceutical Science

Elements of the data from the research study presented in this chapter have been used in contribution to an existing publication by the International Pharmaceutical Federation's (FIP) handbook for the implementation of competency-based education and training for pharmacy and the pharmaceutical sciences (International Pharmaceutical Federation, 2022a) and are included in this thesis in accordance with the author's rights.

4.1 Chapter Introduction

The study described in this chapter addresses the principal research questions relating to competency-based education (CBE) proposed in Chapter 1, section 1.5.1, iii. and iv:

iii. To what extent is CBE used for pharmacy and pharmaceutical science education globally?

iv. What are the perceived challenges associated with the use of CBE for pharmacy and the pharmaceutical sciences?

4.2 Aims and Objectives

This stage of the research contributes to the broader aim of Part One of the thesis, which is to provide a global picture of contemporary CBE related activity for pharmacy.

The objective was to:

- Investigate the worldwide challenges to implementing CBE, and the scope of CBE for the initial education of the subjects of pharmacy and pharmaceutical sciences.

This survey aims to elucidate the various applications of CBE, as well as potential obstacles hindering its successful implementation. The purpose being to understand the current picture of CBE for pharmacy across the globe to add to the current literature and knowledge available and inform enhancements for the future, driving positive changes in CBE practices.

4.3 Methods

To meet the objective of this study a self-administered online survey questionnaire was distributed to academic institutions around the globe that offered programmes in pharmacy and/or the pharmaceutical sciences.

4.3.1 Survey Questionnaire

The online survey questionnaire was created using Qualtrics software and was designed to be completed by individuals on behalf of their academic institution.

Participants were asked to provide demographical information and specific details about their school or department, particularly regarding programmes that encompass either full or partial CBE curricula e.g., units or modules that were related to the CBE approach. The survey incorporated a cover page that explained the study's objectives and offered contextual information on the concept of CBE, along with relevant definitions for clarity. Within the survey a link was also provided further explaining the concept of needs-based education (McMullen, 2022).

The survey was not anonymous as respondents were asked to provide contact details for the purposes of clarifying responses, if required, but these details remained confidential and were stored securely. Respondents were asked for consent via an electronic consent form and all respondents received an information sheet via email outlining the details of the study prior to completing the survey, provided in **Appendix 2.**

The confidential questionnaire was designed based on information gathered during the initial literature review process for this thesis detailed in Chapter 1, and the features of CBE identified in Chapter 3. The questionnaire then underwent face validation from a team of CBE experts for pharmacy and the pharmaceutical sciences through collaboration with the FIP, see acknowledgements. Feedback and suggested enhancements for the questionnaire were received both individually via email and discussed as a group during an online meeting in October 2021. This diverse team included representatives from various regions worldwide, including the UK, Jordan, The Netherlands, The US, Japan, and Australia, ensuring comprehensive input and refinement of the questionnaire's content and wording to make it relevant for a global audience. Additionally, in the survey invitation email, an offer of translation assistance for multiple languages, including Chinese, Spanish, French, Portuguese, Arabic, and Japanese, was extended to further encourage global participation. A copy of the survey is provided in **Appendix 3**.

4.3.2 Sampling and Distribution

The survey distribution process was organised to ensure comprehensive and widespread dissemination. The assistance of two international organisations, the FIP and the European Association of Faculties of Pharmacy (EAFP), was employed to distribute the survey to pharmacy schools globally via their existing mailing lists using a convenience sampling method. These organisations distributed email invitations incorporating the online survey URL and the study information sheet to potential respondents in November 2021. Subsequently, monthly email reminders to participants were sent out until the closing date which was March 14th 2022. A snowballing sampling method was also employed where personal contacts of the research team and collaborators were contacted to further increase the distribution of the survey. Additionally, supplementation of these efforts was facilitated by the FIP on social media platforms notifying institutions to engage with these survey invitation emails.

Due to the lack of available data on the number of pharmacy schools worldwide and the use of a snowball sampling method, it was not possible to calculate, or aim for, a particular response rate. However, this multifaceted sampling and distribution strategy ensured a robust approach to target a broad representation of responses from the global pharmacy education community.

The field of pharmaceutical science incorporates numerous foundational sciences relevant to pharmacy education programmes, resulting in a close connection between the two subjects (Nouri et al., 2020). Faculty members are often shared across these subjects and in some locations where a pharmacy programme is not available, there may be a pharmaceutical science programme in place. Furthermore, this survey was produced and distributed in collaboration with the International Pharmaceutical Federation (FIP) which serves the fields of both pharmacy and the pharmaceutical sciences. Therefore, in an attempt to gather as much information as possible about the use of CBE relevant to the field of pharmacy globally, both subjects were included for the survey.

4.3.3 Data Analysis

Data was extracted from Qualtrics electronically and manually cleaned using Microsoft Office Excel 2016. The IBM SPSS Statistics software package, version 28, was used to analyse the data. The demographic data was analysed and presented descriptively. Each response was coded according to its country of origin. In cases where there were multiple responses from the same country, a numerical identifier was added to the code to distinguish between these responses. For example, there were three responses from Australia, so they were each assigned the code 'Australia1,' 'Australia2,' or 'Australia3,' respectively.

For most survey questions, nominal data allowed multiple participant responses. A frequency-based analysis was used due to the nominal data, small sample size, and primary aim of providing a global CBE overview in pharmacy and pharmaceutical sciences. The primary emphasis for the remainder of this chapter is therefore on describing prevalence, rather than exploring causation for example. However, for certain regulatory and quality assurance background variables, the Fisher's exact test for association was applied to explore potential relationships between these variables and the use of CBE within this dataset using a 0.05% confidence level to determine statistical significance.

Descriptive statistics are predominately used in this study combined with a thematic analysis of qualitative data collected using open-ended questions about the challenges faced when using CBE which links the themes discovered from data in this survey to the features of CBE identified in the systematic review detailed in Chapter 3. An intuitive deductive approach was taken for the thematic analysis as the coding scheme was predetermined by the existing theory developed in Chapter 3. The decision not to use multiple coders was taken as thematic analysis requires familiarity with the data, where more or fewer coders is not necessarily better (Fugard and

Potts, 2019). The development of the features of CBE required myself as the primary researcher to go through the material multiple times and this familiarity was necessary to interpret the data, particularly the open-ended responses, and thematically link all of the responses to the features of CBE.

Quantitative and qualitative strategies are therefore used simultaneously to interpret the data to provide a description of the current state of CBE usage across the globe, and identify challenges associated with the initial education of pharmacy and pharmaceutical science students.

4.4 Results

72 valid responses were extracted for the analysis. Not all questions were mandatory and incomplete responses were included even if respondents did not finish the whole survey. Responses were excluded however if they did not supply a country and institution of origin, and/or supply an answer to question 12: 'Do you use Competency-based Education (CBE) in any of your pharmacy/pharmaceutical science academic programmes?'

The distribution method for this survey utilised various outlets resulting in the potential submission of more than one response from the same institution. In cases where duplicate responses were received, the response with the highest number of completed questions was selected and retained for analysis. In one case, there were 3 responses from the same institution and one of these responses had answered 'no' to question 12 but had not provided any further details. The remaining two responses were examined further and it was discovered that they had been completed by 2 different members of faculty. One had selected 'yes' for question 12 and one had selected 'no'. To resolve this discrepancy, I contacted both of the faculty members individually, retaining confidentiality for each respondent, asking them to clarify their response. One of the participants responded and I arranged a telephone interview where more details relating to the use of CBE within their institution were gathered. The participant was a senior member of faculty at the school of pharmacy and was able to confirm that they had indeed not been using CBE in their pharmacy or pharmaceutical science programmes in relation to the definitions provided within the survey and information letter. Therefore, this participant's response was retained and the other responses from this institution were excluded.

4.4.1 Demographics

The demographic data provided by each respondent, representing their respective academic institutions, is summarised in **Table 6**. In this table the mode for each category within the dataset is identified, highlighting the most frequently occurring options selected. Participation was attained from every region, as defined by the World Health Organisation (World Health Organization, 2021). Notably, the European region is the most frequently represented, which is consistent with the assistance of the EAFP and the distribution of the survey via their existing mailing list. The majority of the institutions are publicly owned, and most of their founding dates precede the start of the 21st century. Among the academic programmes offered by these

institutions, the most prevalent were Masters (33.3%) and Bachelors level (28.5%) and the 3rd most frequent programme offered by the responding institutions was the PharmD (21.5%).

Table 6 Global CBE survey demographic characteristics of the responding academic institutions

Category		Distribution, n (%)
WHO Region (Total N=72)	Africa	2 (2.8)
	Americas	14 (19.4)
	Eastern Mediterranean	11 (15.3)
	Europe	33 (45.8) = mode
	South-East Asia	2 (2.8)
	Western Pacific	10 (13.9)
Year of Establishment (Total N=72)	1600-1900	7 (9.7)
	1901-1930	9 (12.5)
	1931-1950	3 (4.2)
	1951-1970	6 (8.3)
	1971-1980	8 (11.1)
	1981-1990	3 (4.2)
	1991-2000	9 (12.5)
	2001-2010	14 (19.4) = mode
	2011-2022	10 (13.9)
	No data	3 (4.2)
Ownership (Total N=72)	Public state/government	49 (68.1) = mode
	Public/private mix	2 (2.8)
	Private not for profit	14 (19.4)
	Private for profit	7 (9.7)
Schools that collaborate with the pharmacy or pharmaceutical science faculty, school or department in the same academic institution (total responses, N=241)	Medicine	49 (20.9) = mode
	Nursing	41 (17.4)
	Dentistry	26 (11.1)
	Physiotherapy	23 (9.8)
	Nutrition and dietetics	21 (8.9)
	Other[a]	16 (6.8)
	Occupational therapy	14 (6.0)
	Social Work	10 (4.3)
	Mental Health	10 (4.3)
	Physician/ surgical assisting	10 (4.3)
	No collaboration	8 (3.4)
	Midwifery	7 (3.0)
Academic Programmes Offered (total responses, N=146)	Diploma	9 (6.3)
	Baccalaureate/Bachelor's Degree (e.g. BPharm or BSc)	41 (28.5)
	Master's Degree (e.g. MPharm or MSc)	48 (33.3) = mode
	PharmD	31 (21.5)
	Other[b]	15 (10.4)

a Other = Allied Health, Athletic Training, Chemistry, Clinical Analysis, Food Sciences, Forensic Science, Medical Technology, Odontology, Optometry, Osteopathic medicine, Pharmacology, Psychology, Public Health, Radiology, Speech and Language Therapy, Speech and Language Therapy, Veterinary Medicine

b Other = '*PhD*' (n=11), '*MPhil and PhD'*, '*Graduate Certificate Programmes'*, '*Integrated Bachelor and Master Programme', and 'Degree'* (n=1)

The individual responding countries, and the number of responses from each of these countries are presented in **Figure 10**. Notably, both the South-East Asia, and Africa

regions exhibit relatively lower response rates, accounting for 2.8% of the total responses each.

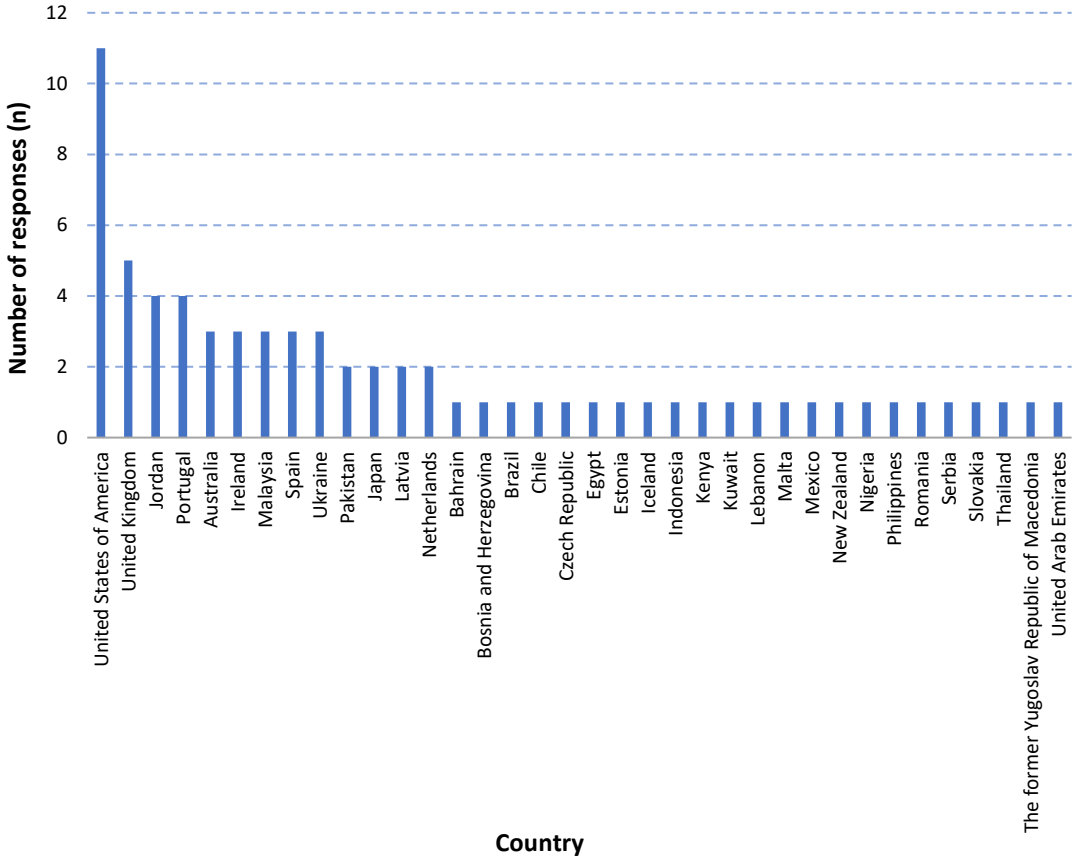


Figure 10 Number of responses from each country participating in the global CBE survey

4.4.2 CBE Usage Across Institutions

There were 62 (86.1%) institutions that indicated they were currently using CBE within their pharmacy and/or pharmaceutical science programmes. On the contrary, 10 (13.9%) responding institutions indicated that they were currently not using CBE. These institutions were one each from: Australia, Bosnia and Herzegovina, Japan, Malaysia, Pakistan and Nigeria. Additionally, Portugal and the United States of America had 2 responding institutions each that reported not using CBE.

Institutions not currently using CBE

In this survey, Bosnia and Herzegovina and Nigeria indicated a current lack of CBE, and both countries were represented by single responses. Interestingly, the remaining countries that were not using CBE submitted more than one response to the survey including those from institutions that were currently using CBE. These results suggest therefore, that the use of CBE is widespread across this sample of academic institutions and that a lack of CBE usage is not necessarily tied to the country of origin. In other words, CBE practices appear to vary and are not solely determined by the nation in which the academic institution is situated. A breakdown of these results, according to WHO regions, are presented graphically in **Figure 11**.

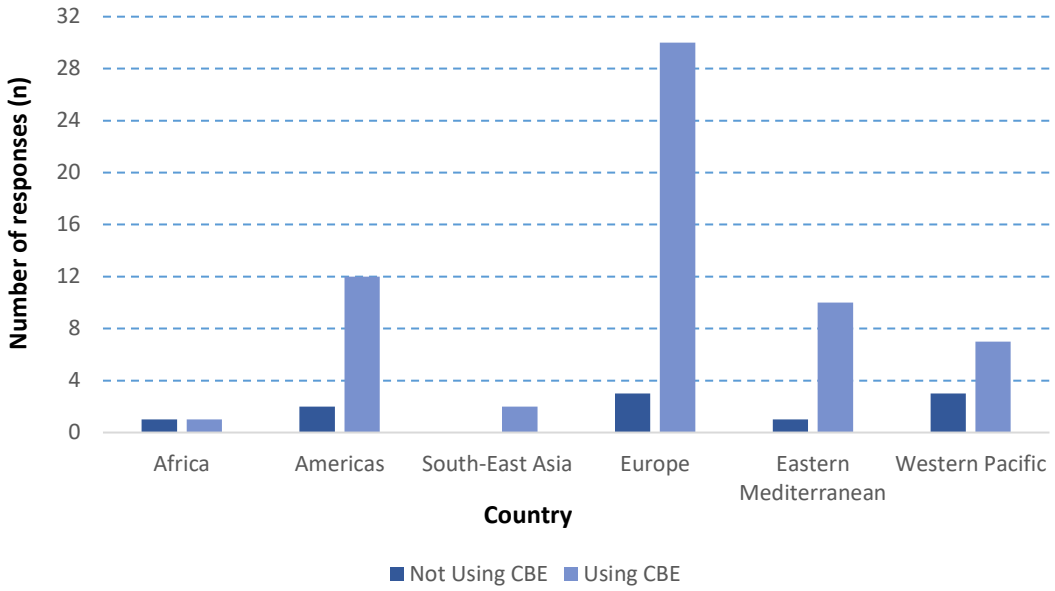


Figure 11 Usage of CBE across the responding institutions according to WHO region

Respondents were asked to indicate the reasons for not using CBE at their academic institution via a multiple response question, including a free text option for additional details. Reasons were provided from 7 out of the 10 institutions not using CBE. In instances where respondents utilised the free text option (n=4), the prevalence of another dominant and established educational method already in place was frequently given as the reason for not using CBE. These results are summarised in **Table 7**. Those not using CBE were also asked to indicate if their institution was planning to implement CBE within the next 5 years, 1 institution indicated they were not and 6 indicated that they were.

Table 7 Reasons given by global survey respondents for not implementing CBE

Response Options	Respondents	
Unable to implement due to lack of experience	United States of America8	
Not convinced of usefulness	Australia3, United States of America8	
Unable to implement due to lack of support from the department/institution	Australia3, United States of America8	
Don't know	Nigeria, United States of America8	
Other (please provide details)	Japan1	*'GIO, SBOs system is more popular'.**
	Pakistan2	*'There is a designed curriculum in the country which is based on obsolete system of teaching /lecturing mainly involve dictations'*
	Portugal 1	*'Course organized in different methodologies'*
	United States of America2	*'We only have EPAs, which are not a partial or full implementation. We will consider implementing if the academy wants to pilot or move that direction'*

*GIO= General Instructional Objective, SBOs= Specific Behavioural Objective (Komoda et al., 2009)

Respondents that were not currently using CBE were also asked if there were any specific needs that they thought may help their institution to implement CBE. There were 4 respondents that said 'yes', and 3 that said 'no'. Those that replied 'yes' were asked to give further details. The statements given suggest a need for a better understanding of the concept of CBE and more support with the implementation and delivery of CBE, as follows:

- *'More information on what CBE entails'* (Nigeria)
- *'Specific training for teachers and staff'* (Portugal1)
- *'Technology support, instructional design, valid and reliable competency-based rubrics*' (USA8)
- *'We really need a core set of competencies that are agreed upon by the academy. That way, we can be somewhat consistent. We can handle implementation'* (USA2)

CBE programme structure and capacity

Those institutions that were using CBE were asked to indicate how these programmes were designed and to what extent CBE was used across the programmes. These results are summarised in **Table 8**. For both pharmacy (n=57) and pharmaceutical science (n=24), the majority of responding institutions implemented CBE as whole programmes (71.9% and 62.5% respectively). Modification of an existing programme was more common than designing a completely new programme and the mean capacity of the pharmacy programmes offered was 150 for pharmacy and 37 for pharmaceutical sciences.

Table 8 Level of CBE integration and capacity of CBE pharmacy and pharmaceutical science programmes

Pharmacy	Frequency, n (%)			
CBE used in part of the programme (n=57)	16 (28.1)			
CBE used in the whole programme (n=57)	41 (71.9)			
Design of CBE part programmes (n=18)	Completely new programme		Modification of existing programme	
	3 (16.7)		15 (83.3)	
Design of CBE whole programmes (n=42)	Completely new programme		Modification of existing programme	
	16 (39)		25 (61)	
Maximum capacity of programmes that incorporate CBE (n=50)	Mean	Median	SD	Range
	150	125	97	25-400
Pharmaceutical Science	**Frequency, n (%)**			
CBE used in part of the programme (n=24)	9 (37.5)			
CBE used in the whole programme (n=24)	15 (62.5)			
Design of CBE part programmes (n=8)	Completely new programme		Modification of existing programme	
	1 (12.5)		7 (87.5)	
Design of CBE whole programmes (n=13)	Completely new programme		Modification of existing programme	
	6 (46.2)		7 (53.8)	
Maximum capacity of programmes that incorporate CBE (n=18)	Mean	Median	SD	Range
	37	30	49	2-250

CBE aspects currently in use

In this survey questionnaire respondents were asked to provide details on how the following aspects were used in their current CBE programmes, units, or modules:

- Health-Needs underpinning
- Mapping learning objectives to competencies
- Competencies and competency frameworks
- Systems of instruction and learning methods
- Feedback and assessment
- Pacing
- Resources
- Faculty involvement and readiness

The key findings for each of these subheadings is presented below in the remainder of this chapter sub-section and provides a snapshot of the CBE activities that are currently in operation across the diverse array of responding institutions.

Health-needs underpinning

Respondents were asked, with multiple answers permitted, what form of health-needs underpinning was used in their CBE design. 48 institutions responded and, 13 (27%) stated that they used some form of health-needs assessment (HNA) method to underpin the design of their CBE programme, module or unit. The majority (n=35, 73%), however, said they did not use any HNA methods.

For those using HNA methods to underpin their CBE, the methods of performing the initial HNA are outlined in **Figure 12**. The total number of responses was 57, and the most frequently selected methods were stakeholder meetings (n=10, 17.5%) and literature reviews (n=9, 15.8%). When asked for further details under the 'other' response option, one response was received which stated, *'previous experience'* as a method used in that institution's HNA process.

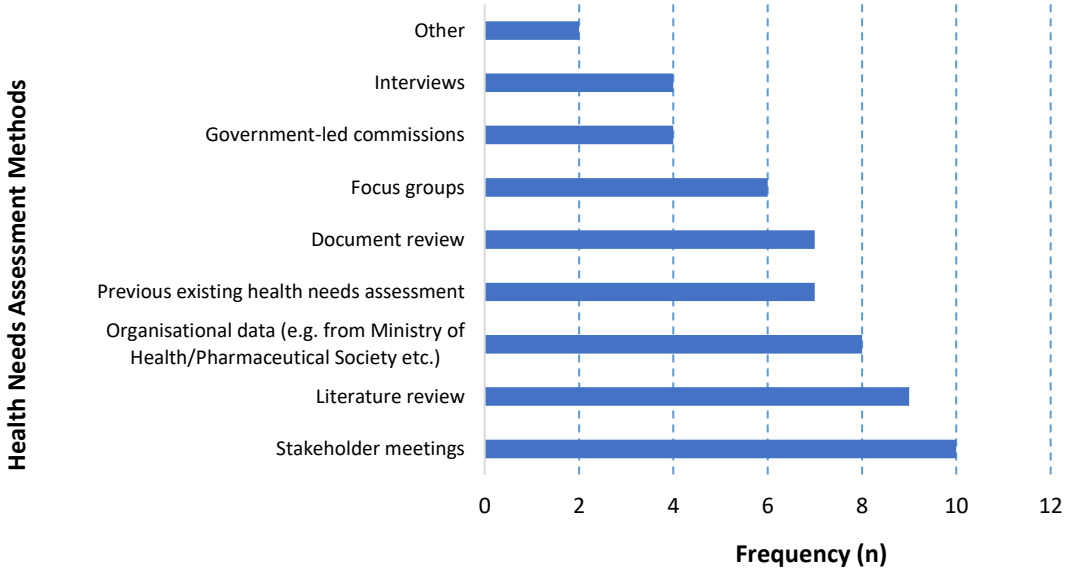
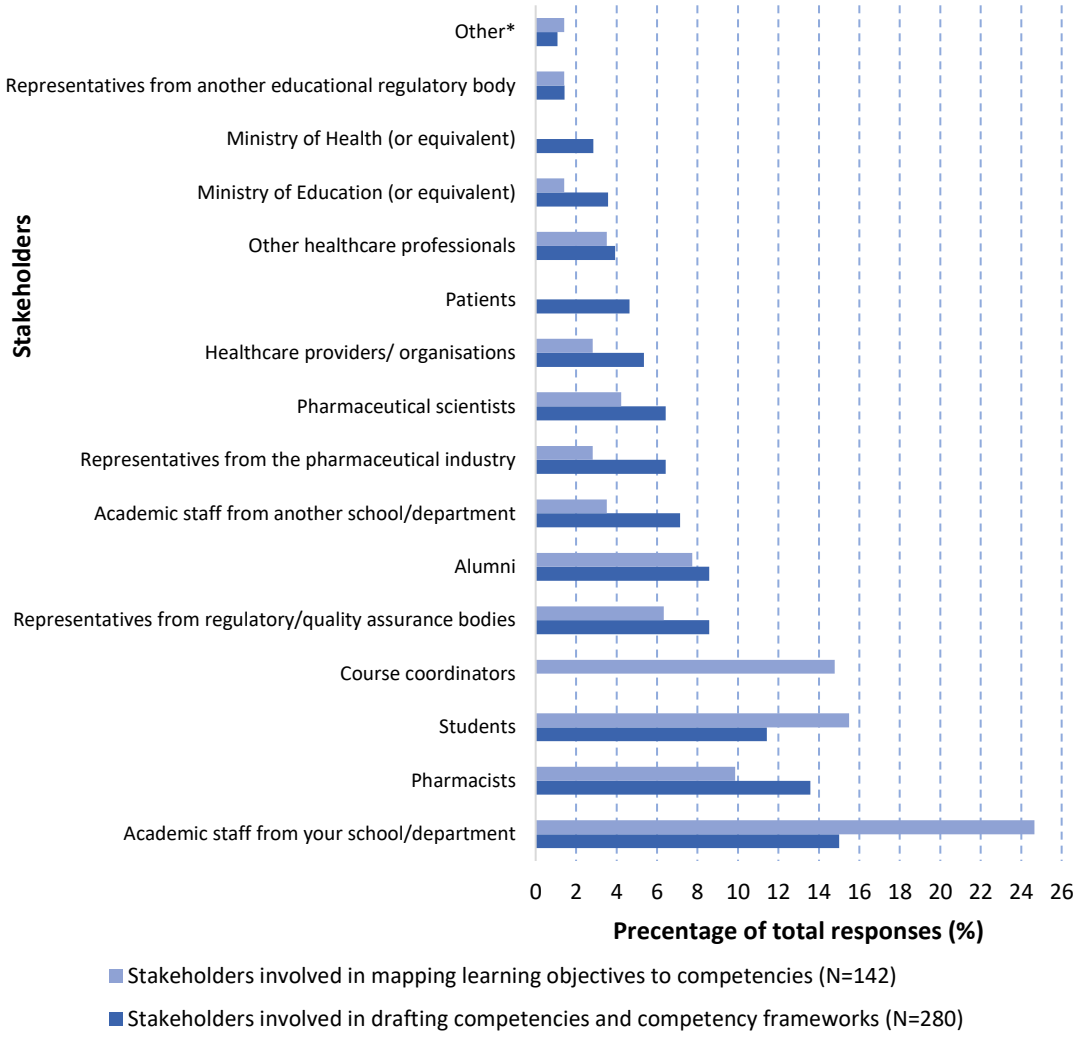


Figure 12 Methods of health needs assessment used for designing CBE related programmes, units or modules

Mapping learning objectives to competencies

The majority of institutions indicated that they had completed a process of mapping their learning objectives to competencies (n=35, 74.5% of 47 responses). Out of these 47 respondents, 30 provided further details with regards to the number of rounds of mapping to learning objectives that took place. Many that answered indicated that they performed one round of mapping (n=11, 36.7% of 30 responses), some used two rounds (n=7, 23.3%), or three rounds (n=7, 23.3%). There were also a few who indicated using multiple rounds (n=1, 3.3%) each for; 4, 5, 7, 9, and even 10 rounds. During the process of selecting competencies and/or drafting frameworks institutions indicated the stakeholders that were involved and these results are summarised in **Figure 13** and compared to the stakeholders that were used for the mapping of learning objectives to competencies.



*'Other' responses: **mapping learning objective to competencies** - *'Representatives of university quality assurance body and from the learning and assessment support group of the university'* (Ireland2), *'University Center of educational development'* (Chile). 'Other' responses: **drafting competencies and frameworks** - *'All of the above, but none were listened to by the Accreditation body'* (Ireland2), *'External stakeholders as defined by the National CBE framework + modifications related to specifics in pharmaceutical sector are possible'* (Slovakia).

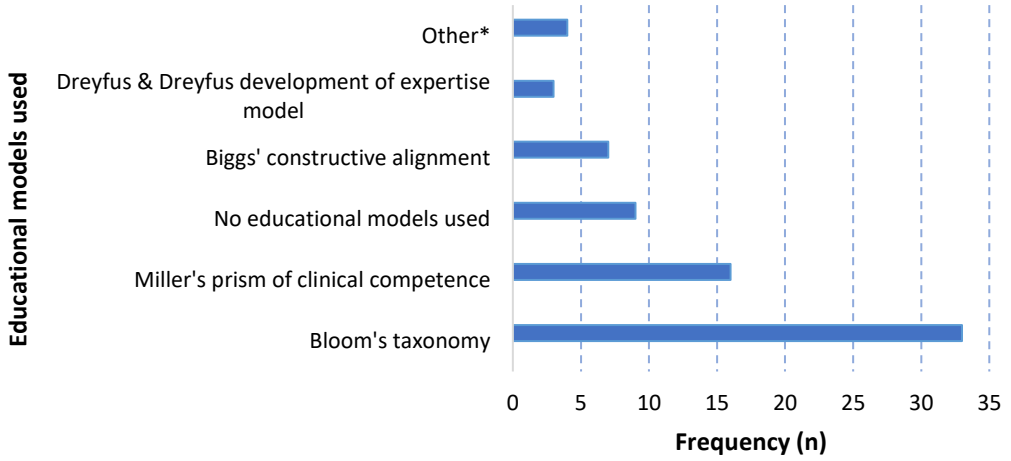
Figure 13 Stakeholders involved in drafting competencies and competency frameworks or mapping learning objectives to competencies in the CBE unit, module, or programme

Competencies and competency frameworks

The competency frameworks that were used were mainly existing local frameworks (n=29, 43.3% of 67 responses). The second most common response was that institutions developed their own new competency framework (n=12, 17.9%) and the third most common framework was the Global Competency Framework (GbCF) from the FIP, (n=9, 13.4%). Institutions also indicated that they used frameworks from other countries (n=8, 11.9%), and professions (n=5, 7.5%).

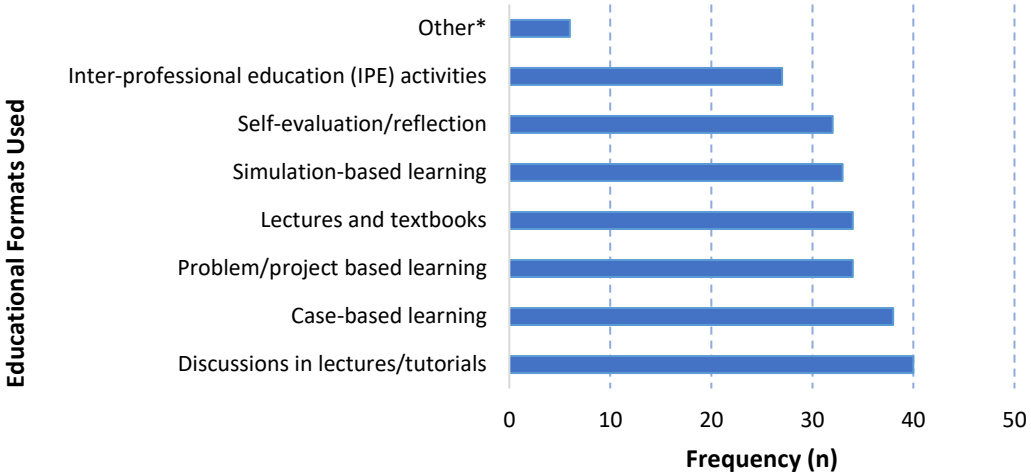
Systems of instruction and learning methods

The educational models and formats used by the institutions in CBE programmes, units, or modules are presented in **Figure 14** and **Figure 15**, respectively.



*'Other' responses: *'Abilities Based Education by Villarini AR, et. al'* (USA6), *'Edu models have not been specified this way so far'* (Slovakia)

Figure 14 Educational models used in the CBE units, modules, and programmes



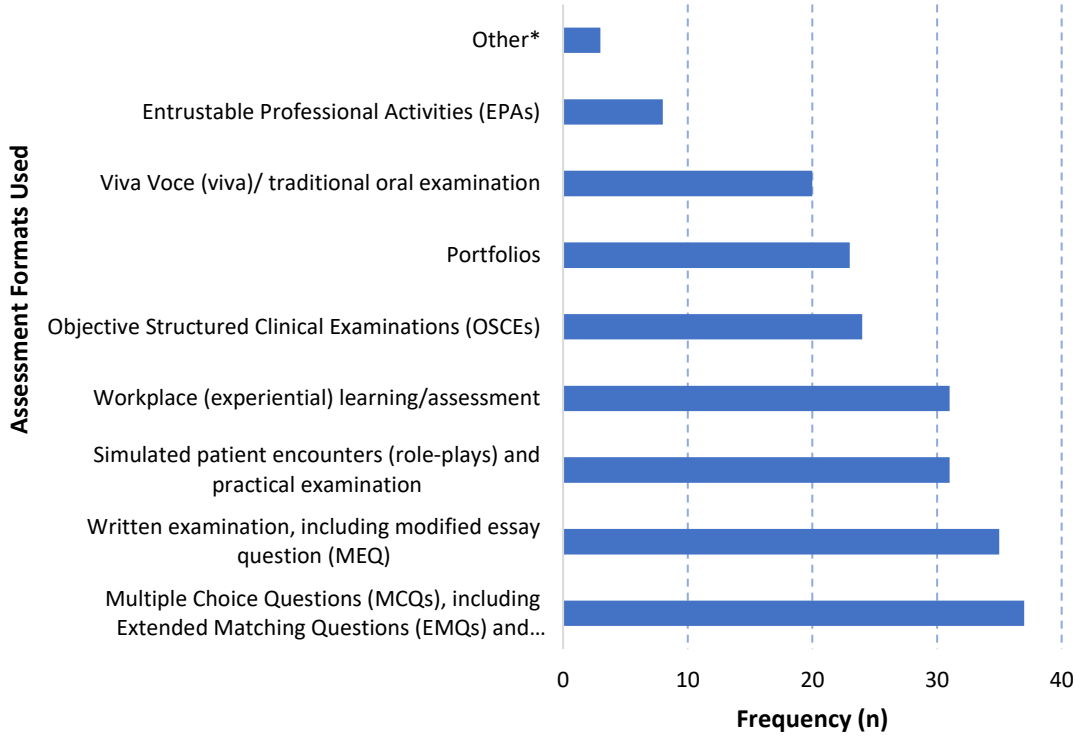
*'Other' responses: *'Experiential'* (USA1), *'CBE Assessment Portfolio'* (USA6), *'Practical courses'* (Indonesia), *'National Licence Examination'* (Thailand), *'Student´s practice in pharmacy, visit of pharmaceutical production site, etc.'* (Slovakia), *'Experiential learning activities in a Public health pharmacy in the University (managed by the faculty)'* (Brazil), *'Flipped classroom'* (Chile)

Figure 15 Educational learning formats used in the CBE units, modules, or programmes

Bloom's taxonomy was the most frequently used educational model in CBE (45.8% of 72 responses), Miller's prism was also popular (22.2%). Notably, the third most common response (12.5%) indicated that there were no educational models being used by the institutions. There were a total of 244 responses to the question on educational learning formats employed in CBE and frequencies for each option selected were relatively close in magnitude, which suggests a wide variety of learning formats are in use across the responding institutions.

Feedback and assessment

Input from survey respondents was sought on the most commonly used grading system for their CBE unit, module, or programme assessments. The most frequently selected response was a numerical grading system (41.3% of 47 respondents), followed by percentages (34.8%), alphabetical (13%), and criterion-based (8.7%). One respondent selected the 'other' option (2.2%) but did not provide further details. Despite the identification of criterion-based assessment as a feature of CBE in the previous chapter, these findings suggest that institutions are predominately using traditional numerical grading systems. Similarly, out of 207 selected responses for the types of assessment formats being used by the institutions for their CBE, traditional formats were dominant. Multiple choice questions (MCQs) and written examinations were the most frequently selected options, accounting for 33.8% (n=70) of the responses combined. Assessment formats usually more specifically associated with CBE, such as Objective Structured Clinical Examinations (OSCEs), portfolios, and Entrustable Professional Activities (EPAs) represented 26.6% (n=55) of the responses combined. These results are summarised graphically in **Figure 16**.



*'Other' responses: *'Self-assessment'* (Ireland2),*'Laboratorial examination'* (Portugal4)

Figure 16 Assessment formats used in the CBE units, modules, or programmes

Assessments were mostly performed continuously throughout the CBE units, modules, or programmes with only a small amount of respondents indicating that assessments occurred only at the end of the academic year. These results are summarised in **Table 9**.

Table 9 Timing of CBE related assessments

Timing of CBE related assessments	Frequency (n)	
	Summative assessment (total respondents, N=47)	**Formative assessment (total respondents, N=42)**
At various time points throughout the unit/module or programme	21	31
At the end of each unit/module	18	6
Other*	4	3
At the end of the academic year	4	2

*'Other' responses: *'At the end of each semester'* (Jordan1), *'End of semester'* (Jordan3)

Pacing

Respondents were asked to indicate if students were given the opportunity to regulate their own pace of learning through things like; repeated course-offerings per academic year, mobile learning, or e-learning. The majority said 'no' (67.4% of 46 responses), for those that responded 'yes' (32.6%) they were asked to provide further details. Responses most commonly related to the use digital of technology and the internet to support students with learning at their own pace, and 2 institutions mentioned opportunities to repeat courses or assessments, as follows:

- *'Continuous assessment'* (Spain1)
- *'Students are encouraged to work on their assignments both individually or in team whenever they can'* (Indonesia)
- *'Repeated course offerings, e-learning, additional study task/s'* (Slovakia)
- *'E-learning, personal instruction'* (Japan2)
- *'Mobile learning'* (Ireland3)
- *'All lectures are delivered in-person, live-streamed and recorded and made available for students to watch again. This supports students from non-traditional backgrounds, e.g. students who are parents.'* (UK1)
- *'Repeated evaluation or exam'* (Mexico)
- *'Many materials are provided online for asynchronous learning'* (UK5)

Resources

Survey participants were asked to identify which resources were needed for them to complete the implementation of CBE at their respective institutions. The most frequently selected option related to increasing the academic staff appropriately trained in using CBE (13.4%). The second most common response related to the need to increase associated clinical staff (12.9%). Increasing the supporting staff was also commonly selected as a required resource, such as the recruitment of curriculum managers (11.6%), CBE specialists (7.1%), and administrative staff (6.7%). Some institutions indicated that they needed to increase the hours of their existing academic, clinical, and administrative staff (11.2% combined). Many of the

institutions also indicated that in order to use CBE they required additional learning spaces (10.3%). Notably, internal funding requirements also placed high on the list of commonly required resources (9.4%) and some institutions reported gaining funding from external sources (5.8%). Additionally, new materials were also identified as crucial (7.1%) and two of the open-ended responses suggested that enhancements of educational technologies was required.

Table 10 Resources needed to implement CBE units, modules or programmes

Resources	Frequency, n (%) (total responses N=224)
Increased academic staff with CBE training or training of existing staff	30 (13.4)
Increased clinical/practitioner/practice based staff	29 (12.9)
Formation of a curriculum management team	26 (11.6)
New learning spaces/classrooms	23 (10.3)
Internal funding (from within your institution)	21(9.4)
New materials/consumables	16 (7.1)
Appointment of specialist staff e.g. stream coordinators, consultants/CBE specialiists	16 (7.1)
Increased administrative/auxiliary staff	15(6.7)
External funding	13 (5.8)
Increased working hours of existing academic staff	12 (5.4)
Increased working hours of existing clinical/practitioner/practice based staff	10 (4.5)
Other*	6 (2.7)
Appointment of a director of education	3 (1.3)
Increased working hours of existing administrative/auxiliary staff	3 (1.3)
No additional resources needed	1 (0.4)

'Other' responses: *'We have established this already years ago, so difficult to say what was then required. Maintenance and keeping it up to date also requires staff and finances/resources. It is a continuous process to keep our curriculum up to date according to the competencies outlined in our national framework.'* (Netherlands1)*, 'Key aspect was staff for provision of placements - management of experiential learning on placement'* (Ireland1), *'Better educational technologies'* (USA4)*, 'Increased tech capability for simulation and for assessment'* (Ireland2)*, 'Council (Committee) of Quality Assurance has been formed - potential source to develop and implement CBE trainings too'* (Slovakia)

Faculty involvement and readiness

In some institutions not all the faculty members were made aware of the complete outline of the CBE units, modules, or programmes (21.7% of 46 respondents), however in the vast majority of cases they were (78.3%).

As indicated by the responses in the previous sub-section, regarding the necessary resources for CBE implementation, training emerged as a vital aspect. Respondents were surveyed about the training opportunities organised to support faculty in delivering CBE. The results, as summarised in **Figure 17**, reveal that a wide range of training formats were utilised. Notably, a small proportion of responses (3.2%) indicated an absence of any training.

Training on CBE teaching (12.2% of 189 responses) and assessment (11.6%)

methodologies were the most commonly provided faculty development initiatives, followed closely by informal small-scale training (10.1%). Collaborative learning experiences (9.5%) and opportunities for knowledge exchange on a national-level (9%), the provision of educational literature (9%), mentoring (9%), and self-reflection (9%) were the next most frequently adopted faculty training methods.

*'Other' responses: *'Again, we have switched long ago to competency based teaching/curriculum, so we need ongoing resources to maintain this'* (Netherlands1)

Figure 17 Training provided to faculty for the implementation and delivery of CBE related units, modules and programmes

4.4.3 Regulatory Information

Respondents were asked to indicate whether registration/licensure was required before graduates were permitted to practice pharmacy in their respective countries. Additionally, respondents were asked to indicate whether their institution was within a country that had its own regulatory body for the profession and/or own quality assurance body for the accreditation of pharmacy education. Furthermore, respondents were asked to indicate if they knew whether the regulatory and/or quality assurance bodies were advocates of CBE. These responses are summarised in **Table 11**.

Table 11 Registration/licensure requirements of the responding countries, and the presence of regulatory and quality assurance bodies and whether they are advocates of CBE

Regulation and quality assurance	**Frequency, n (%)**		
	Yes	**No**	
Pharmacy graduates require registration/licensure from a regulatory body to practice pharmacy in the responding country (N=72)	67 (93.1)	5 (6.9)[a]	
Responding country has its own regulatory body related to registration/licensure of the pharmacy profession (N=67)	65 (90.3)	2 (2.8)[b]	
Responding Country has its own quality assurance body related to accreditation of pharmacy education (N=72)	58 (80.6)	14 (19.4)[c]	
Advocacy	**Yes**	**No**	**Don't Know**
If responding country has its own regulatory body, they are advocates of CBE (N=65)	38 (52.8)	7 (9.7)[d]	20 (27.8)
If responding country has its own quality assurance body they are advocates of CBE (N=58)	43 (59.7)	3 (4.2)[e]	12 (16.7)

a = Ukraine (n=2), Chile, Cyprus*, Spain*, (n=1)
b = United States of America* (n=2)
c = Bahrain, Bosnia and Herzegovina, Chile, Cyprus*, Czech Republic, Iceland, Ireland*, Kuwait, Latvia*, Lebanon, Netherlands*, Spain*, The former Yugoslav Republic of Macedonia, Ukraine*, (n=1)
d = Japan, Kuwait, Latvia, Lebanon, Pakistan*, Serbia, United States of America*, (n=1)
e = United States of America*, Japan, Serbia
*other responses from the same country conflict with these respondents

In certain cases conflicting responses from different countries were received, irrespective of whether their institution was offering only a pharmaceutical science programme, and these cases are highlighted in **Table 11** with an asterisk (*). Some respondents with the same country of origin answered 'yes' to questions regarding regulation and quality assurance, while others answered 'no'. This inconsistency may suggest a level of ambiguity surrounding these topics or hint at potential challenges respondents faced in interpreting the questions. Regarding the assessment of advocacy by the respective registration and quality assurance bodies concerning CBE, when there may be a lack of clear and definitive information from these organisations, respondents' answers rely on their subjective interpretations.

Therefore, resulting in discrepancies which suggests that these results should be interpreted with caution and further work to explore additional clarification is warranted. Nevertheless, potential relationships between registration/licensure prerequisites, the presence of regulatory and educational quality assurance bodies, and their position on advocating for CBE was explored using the Fisher's exact test, as summarised in ***Table 12***

Table 12 Relationship between regulatory and quality assurance factors and the use of CBE

Regulatory and quality assurance factors		CBE is currently used in responding academic institution (n)		p-value (2-sided)
		Yes	No	
Pharmacy graduates require registration/licensure from a regulatory body to practice pharmacy in the responding country (N=72)	Yes	57	10	1.000
	No	5	0	
Responding country has its own regulatory body related to registration/licensure of the pharmacy profession (N=67)	Yes	55	10	1.000
	No	2	0	
If responding country has its own professional regulatory body, they are advocates of CBE (N=45)*	Yes	37	1	0.009
	No	4	3	
Responding Country has its own quality assurance body related to accreditation of pharmacy education (N=72)	Yes	49	9	0.675
	No	13	1	
If responding country has its own quality assurance body, they are advocates of CBE (N=46)*	Yes	41	2	0.017
	No	1	2	

*those responding 'don't know' were excluded from the analysis (n=12)

The data associations, presented in **Table 12**, investigates potential relationships and suggest that the requirement for registration or licensure prior to practicing pharmacy is independent to the institution's use of CBE ($p>0.05$). Similarly, the presence of a regulatory body or education quality assurance body in the responding country is also independent to the responding institution's use of CBE ($p>0.05$). However, for both the regulatory and education quality bodies that are present, the use of CBE for the responding institutions is dependent on the respondent's perception of whether the regulatory and/or quality assurance bodies present in their country of origin are advocates of CBE or not ($p<0.05$).

4.4.4 Challenges When Using CBE

The nominal survey data on the challenges encountered when using CBE, including the open-ended responses, from each survey question category were aggregated and linked thematically to the features of CBE identified in the systematic review presented in Chapter 3. To perform this thematic analysis, each multiple response option and open-ended response was coded, these codes were then linked to the relevant CBE feature. The codes were then re-examined for appropriateness to the linked featured and amended and refined where necessary and code descriptors

were defined to aid the process of linking the coded responses to the relevant features using a coding table, presented in **Table 13**.

Once all the responses had been coded, the number of responses linked to each feature were aggregated providing a total frequency for the linked features of CBE associated with challenges reported. These results were mapped out in **Figure 18**, which provides a diagrammatic representation of the frequency data for the challenges that respondents expressed they encountered when using CBE in relation to the features of CBE.

These findings reveal that the most frequently reported challenging feature of CBE was: 'training on the use of CBE related teaching & learning practices and assessment methods' (20.8%). Interestingly the second most frequently reported option selected overall was the 'no challenge encountered' (13%) response which suggests that there were a relatively large proportion of aspects of using CBE that the institutions did not find challenging.

The questions relating to challenges were separated into sections in the survey questionnaire, and the section with the lowest proportion of 'no challenge encountered' responses was related to faculty readiness and involvement (4.8%). This finding aligns with the most commonly selected resources needed to implement CBE being related to appropriately trained staff, see **Table 10**. Similarly, the results in **Figure 18**, show the most frequently linked challenging feature of CBE is related to faculty training on the use of CBE teaching, learning, and assessment. The section the institutions found the least challenging, according to the proportion of 'no challenge encountered' responses, was related to selecting competencies and developing competency frameworks (28.1%) which suggests that accessing or developing appropriate competency frameworks and competencies is one of the least challenging aspects to using CBE.

Challenges related to department participation and acceptance (0.6%) and the intensive implementation process were relatively low (0.9%). Other factors relating to internal support (4.9%), however were more frequently associated with challenges when using CBE but not as frequently as those related to external support from higher authorities, policies and regulators (12.1%).

Issues associated with specific technical aspects of delivering CBE were reported, including those relating to the translation of learning to practice (10.6%), continuous feedback (7.8%), criterion-based assessment (4.3%), lifelong learning preparation (2.9%), and other educational environment challenges not specific to CBE (8.1%); such as traditional methods of learning and assessment, e.g. lectures and written examinations.

Features of CBE relating to programme design were also found challenging, particularly aspects associated with curriculum design using competency framework

mapping (9.3%) and incorporating a Needs-based approach (4.9%); a key element of CBE (International Pharmaceutical Federation, 2013).

Table 13 CBE challenges coding table

Category	Challenges	Code	Code definition	Thematically linked features of CBE	Frequency, n (%)
Health needs underpinning (total respondents =49, total responses N=72)	Inadequate faculty training/skills to perform needs analysis/ assessment	Insufficient resources for application of health-needs methodology	Challenges specific to resources necessary for the application of health-needs methodology within the context of CBE	Needs-based approach	19 (26.4)
	Difficulty obtaining stakeholder engagement	Lack of external engagement	Challenges related to stakeholder engagement which could be mitigated by supportive collaboration with external bodies	Support from higher authorities/policies/regulators	15 (20.8)
	Lack of adequate health needs data available	Insufficient health-needs resources	Challenges specific to resources necessary for the application of health-needs methodology within the context of CBE	Needs-based approach	14 (19.4)
	Lack of support from management/leadership	Lack of internal engagement	Challenges related to departmental support for CBE	Formal institutional and departmental support for CBE	5 (6.9)
	No challenge encountered	N/A			13 (18.1)
	Open-ended responses under the 'Other' option				6 (8.3)
	1. 'Accreditation body mandated structure of MPharm' (Ireland2)	Higher authority mandates	Challenges stemming from external regulations or mandates that impact the pharmacy department, emphasising the potential benefits of collaboration between academic institutions and regulatory bodies for mitigation	Support from higher authorities/policies/regulators	1 (0.01)
	2. 'Applying the competencies stated by the regulatory body into our curriculum is challenging' (Indonesia)	Higher authority mandates	Challenges stemming from external regulations or mandates that impact the pharmacy department, emphasising the potential benefits of collaboration between academic institutions and regulatory bodies for mitigation	Support from higher authorities/policies/regulators	1 (0.01)
	3. 'Faculty development during the development of the programme was a key factor' (USA6)	Training and development	Challenges related to enhancing skills of faculty	Training on the use of CBE related teaching & learning practices and assessment methods	1 (0.01)
	4. 'Space' (USA7)	Internal logistics	Challenges related to internal factors that would require departmental support and resources to be allocated	Formal institutional and departmental support for CBE	1 (0.01)
	5. 'There is still a room for improvement in acceptance of change by stakeholders, educators, mainly' (Slovakia),	Faculty acceptance	Challenges related to faculty understanding and embracing the concept of CBE	Department acceptance and participation	1 (0.01)
	6. 'Time needed to plan, discuss, implement and evaluate' (Malta)	Requirement for additional resources	Challenges related to the resources needed to implement CBE features	Intensive implementation process	1 (0.01)
Selecting competencies and developing competency frameworks (total respondents =49, total responses N = 135)	Socio-political issues such as: regulations, law, policies, and traditions	Higher authority mandates	Challenges stemming from external regulations or mandates that impact the pharmacy department, emphasising the potential benefits of collaboration between academic institutions and regulatory bodies for mitigation	Support from higher authorities/policies/regulators	30 (22.2)
	Difficulty obtaining stakeholder engagement	Lack of external engagement	Challenges related to stakeholder engagement which could be mitigated by supportive collaboration with external bodies	Support from higher authorities/policies/regulators	15 (11.1)
	Inadequate faculty training/ skills to select appropriate competencies	Lack of resources required to design CBE curriculum	Challenges related to enhancing skills of faculty to design a CBE curriculum	Curriculum/programme development using competency framework mapping	15 (11.1)

Table 13 (continued)

Category	Challenges	Code	Code definition	Thematically linked features of CBE	Frequency, n (%)
	Inadequate faculty training/ skills to create a suitable framework	Lack of resources required to design CBE curriculum	Challenges related to enhancing skills of faculty to design a CBE curriculum	Curriculum/programme development using competency framework mapping	18 (13.3)
	No suitable competency framework identified	Lack of a competency framework	Insufficient resources to for the application of a competency framework within the context of CBE	Curriculum/programme development using competency framework mapping	7 (5.2)
	Lack of support from management/ leadership	Lack of internal engagement	Challenges related to departmental support for CBE	Formal institutional and departmental support for CBE	5 (3.7)
	No challenge encountered	N/A			38 (28.1)
	Open-ended responses under the 'Other' option				7 (5.2)
	Drafting Frameworks: *1. 'Accreditation body mandated framework which is based upon supply not care' (Ireland2),*	Higher authority mandates	Challenges stemming from external regulations or mandates that impact the pharmacy department, emphasising the potential benefits of collaboration between academic institutions and regulatory bodies for mitigation	Support from higher authorities/policies/regulators	1 (0.01)
	2. 'Corona pandemic' (Jordan2),*	Unique circumstance – COVID-19 impact	Challenges related to unforeseen events not specific to CBE	No explicit link to predefined features of CBE	1 (0.01)
	3. 'Framework developed by regulator is very detailed' (Ireland1),	Higher authority mandates	Challenges stemming from external regulations or mandates that impact the pharmacy department, emphasising the potential benefits of collaboration between academic institutions and regulatory bodies for mitigation	Support from higher authorities/policies/regulators	1 (0.01)
	4. 'Lack of internal advocators = to be developed' (Slovakia),	Faculty acceptance	Challenges related to faculty understanding and embracing the concept of CBE	Department acceptance and participation	1 (0.01)
	5. 'Lack of time and human resource' (UK5)	Requirement for additional resources	Challenges related to the general resources needed to implement CBE features	Intensive implementation process	1 (0.01)
	Selecting Competencies: *6. 'Developed by regulator' (Ireland1)*	Higher authority mandates	Challenges stemming from external regulations or mandates that impact the pharmacy department, emphasising the potential benefits of collaboration between academic institutions and regulatory bodies for mitigation	Support from higher authorities/policies/regulators	1 (0.01)
	7. 'Recently established the Committee for Quality Assurance - will focus on rooms for improvement, incl. attracting more and more advocators, training/skills development, increasing level of stakeholders engagement, etc.' (Slovakia)	a. Faculty acceptance	Challenges related to faculty understanding and embracing the concept of CBE	Department acceptance and participation	1 (0.01)
		b. Training and development	Challenges related to enhancing skills of faculty	Training on the use of CBE related teaching & learning practices and assessment methods	1 (0.01)
		c. External engagement	Challenges relating to collaboration with other pharmacy and education representatives	Support from higher authorities/policies/regulators	1 (0.01)
Curriculum design (total respondents =49, total responses N = 76)	Difficulty of reaching a consensus on a new curriculum	Agreeing a new CBE curriculum	Challenges related to the complexities and difficulties in achieving consensus among stakeholders when designing or implementing a new curriculum	Curriculum/programme development using competency framework mapping	21 (27.6)

Table 13 (continued)

Category	Challenges	Code	Code definition	Thematically linked features of CBE	Frequency, n (%)
	Resistance to change from management/leadership	Unwillingness to implement CBE	Challenges related to departmental support for CBE	Formal institutional and departmental support for CBE	10 (13.2)
	Difficulty obtaining stakeholder engagement	Lack of external engagement	Challenges related to stakeholder engagement which could be mitigated by supportive collaboration with external bodies	Support from higher authorities/policies/regulators	10 (13.2)
	Lack of internal support (e.g. from faculty)	Lack of internal engagement	Challenges related to departmental support for CBE	Formal institutional and departmental support for CBE	7 (9.2)
	Socio-political issues such as: regulations, laws, policies, and traditions	Higher authority mandates	Challenges stemming from external regulations or mandates that impact the pharmacy department, emphasising the potential benefits of collaboration between academic institutions and regulatory bodies for mitigation	Support from higher authorities/policies/regulators	6 (7.9)
	Resistance to change from management/leadership	Unwillingness to implement CBE	Challenges related to departmental support for CBE	Formal institutional and departmental support for CBE	5 (6.6)
	No challenge encountered				12 (15.8)
	Open-ended responses under the 'Other' option				5 (6.6)
	'1. Defining the most appropriate level of competencies' (Netherlands2)	Selecting competencies	Challenges related to integrating competencies into the curriculum	Curriculum/programme development using competency framework mapping	1 (0.01)
	2. 'Ongoing improvement' (Slovakia),	Continual curriculum improvement	Challenges related to evaluating and improving CBE on a continuous bases	Intensive implementation process	1 (0.01)
	3. 'Required external educational experts for faculty training' (USA6),	Requirement for additional resources	Challenges related to the resources needed to implement CBE features	Intensive implementation process	1 (0.01)
	4. 'Some competencies are difficult to be implemented' (Indonesia)	Integrating competencies	Challenges related to integrating competencies into the curriculum	Curriculum/programme development using competency framework mapping	1 (0.01)
	5. 'Time' (UK5),	Requirement for additional resources	Challenges related to the general resources needed to implement CBE features	Intensive implementation process	1 (0.01)
Systems of instruction and learning methods (total respondents =49, total responses N = 128)	Inter-professional education (IPE) activities	Incorporating IPE	Challenges relating to 'real world' training opportunities such as IPE	Translate learning to practice	24 (18.8)
	Self-evaluation/reflection	Incorporating self-evaluation/reflection	Challenges relating to students developing skills for lifelong learning such as self-evaluation/reflection	Lifelong learning preparation	19 (14.8)
	Active learning strategies including simulation and role play	Incorporating active learning	Challenges relating to educational opportunities based on 'real world' scenarios	Translate learning to practice	15 (11.7)
	Virtual learning	Incorporating virtual learning strategies	Challenges relating to educational environment that supplement CBE aspects of teaching and learning	Other educational environmental challenges not specific to features of CBE	13 (10.2)
	Problem/project-based learning	Incorporating problem/project based learning	Challenges relating to educational opportunities based on 'real world' scenarios	Translate learning to practice	12 (9.4)
	Work-based activities	Incorporating work-based educational activities	Challenges relating to educational opportunities based on 'real world' scenarios	Translate learning to practice	12 (9.4)
	Discussion in lectures/tutorials	Incorporating discussions in lectures and tutorials	Challenges relating to educational environment that supplement CBE aspects of teaching and learning	Other educational environmental challenges not specific to features of CBE	8 (6.3)

Table 13 (continued)

Category	Challenges	Code	Code definition	Thematically linked features of CBE	Frequency, n (%)
	Case-based learning	Incorporating problem/project based learning	Challenges relating to educational opportunities based on 'real world' scenarios	Translate learning to practice	8 (6.3)
	Lectures and textbooks	Incorporating lectures and textbooks	Challenges relating to educational environment that supplement CBE aspects of teaching and learning	Other educational environmental challenges not specific to features of CBE	6 (4.7)
	No challenge encountered	N/A			8 (6.3)
	Open-ended responses under the 'Other' option				3 (2.3)
	1. 'IPE was not established at the beginning, but was later incorporated'	Delayed incorporation of IPE	Challenges relating to 'real world' training opportunities such as IPE	Translate learning to practice	1 (0.01)
	2. 'Oral workshops were online by using zoom meeting' (Jordan2)	Unique circumstance – COVID-19 impact	Challenges related to unforeseen events not specific to CBE *Considering the respondent's earlier mention of the COVID-19 pandemic as a challenge affecting the use of CBE features, the comment about online oral workshops has been interpreted within the context of the pandemic's potential impact. Therefore, this comment has not been categorised under a predefined CBE feature, as it is likely connected to the pandemic's influence on the transition to online instructional methods.	No explicit link to predefined features of CBE	1 (0.01)
	3. 'It is strengthening, all aspects, except self-evaluation, are included' (Slovakia)	Lack of self-evaluation elements in CBE approach	Challenges related to learning methods crucial for lifelong learning and continuing professional development	Lifelong learning preparation	1 (0.01)
Feedback and assessment (total respondents =49, total responses N = 119)	Workplace (experiential) learning/assessment	Difficulties with experiential learning and assessment	Challenges relating to assessment opportunities in varied contexts	Continuous feedback	23 (19.3)
	Objective Structured Clinical Examinations (OSCEs)	Difficulties with performing OSCEs	Challenges related to criterion based assessment such as OSCEs and EPAs	Criterion-based assessment	18 (15.1)
	Simulated patient encounters (role-plays) and practical examination	Difficulties with practice-based assessment	Challenges relating to assessment opportunities in varied contexts	Continuous feedback	15 (12.6)
	Portfolios	Difficulties with portfolio based assessments	Challenges relating to assessment opportunities in varied contexts	Continuous feedback	14 (11.8)
	Multiple Choice Questions (MCQs), including Extended Matching Questions (EMQs) and computer-adaptive tests (CATs)	Difficulties with traditional assessment methods in the context of CBE	Challenges relating to educational environment that supplement CBE aspects of teaching and learning	Other educational environmental challenges not specific to features of CBE	13 (10.9)
	Entrustable Professional Activities (EPAs)	Difficulties with assessment of EPAs	Challenges related to criterion based assessment such as OSCEs and EPAs	Criterion-based assessment	11 (9.2)
	Written examination, including modified essay question (MEQ)	Difficulties with traditional assessment methods in the context of CBE	Challenges relating to educational environment that supplement CBE aspects of teaching and learning	Other educational environmental challenges not specific to features of CBE	7 (5.9)

Table 13 (continued)

Category	Challenges	Code	Code definition	Thematically linked features of CBE	Frequency (n)
	Viva Voce (viva)/ traditional oral examination	Difficulties with traditional assessment methods in the context of CBE	Challenges relating to educational environment that supplement CBE aspects of teaching and learning	Other educational environmental challenges not specific to features of CBE	6 (5.0)
	No challenge encountered				10 (8.4)
	Open-ended responses under the 'Other' option				2 (1.7)
	1. 'It is strengthening in all aspects, however not everywhere, but improving in general' (Slovakia)	Inconsistent improvement in feedback and assessment	Challenges related to implementing a cohesive, consistent and structured feedback and assessment process in the context of CBE	Continuous Feedback	1
	2. 'Resources for infrastructure and support personnel' (Ireland2)	Requirement for additional resources	Challenges related to the resources needed to implement CBE features	Intensive implementation process	1 (0.01)
Faculty involvement and readiness (total respondents =49, total responses N =147)	Formal large-scale training	Faculty training and development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	22 (15)
	Opportunities for exchange of good practice and training/coaching in international networks	Difficulties with external collaborative faculty development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	21 (14.3)
	Evidence based development of teaching	Faculty training and development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	16 (10.9)
	Opportunities for exchange of good practice and training/coaching in national networks	Difficulties with external collaborative faculty development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	16 (10.9)
	Mentoring	Faculty training and development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	15 (10.2)
	Self-reflection on teaching experiences	Faculty training and development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	15 (10.2)
	Opportunities for collaborative teaching development/learning	Difficulties with internal collaborative faculty development and training	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	14 (9.5)
	Use of educational research literature	Faculty training and development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	11 (7.5)
	Informal small-scale training	Faculty training and development	Challenges related to faculty training and development on the use of CBE	Training on the use of CBE related teaching & learning practices and assessment methods	9 (6.1)
	No challenge encountered				7 (4.8)
	Open-ended responses under the 'Other' option				1 (0.7)
	1. 'Resistance to change teaching practices' (Brazil)	Faculty acceptance	Challenges related to faculty understanding and embracing the concept of CBE	Department acceptance and participation	1 (0.01)

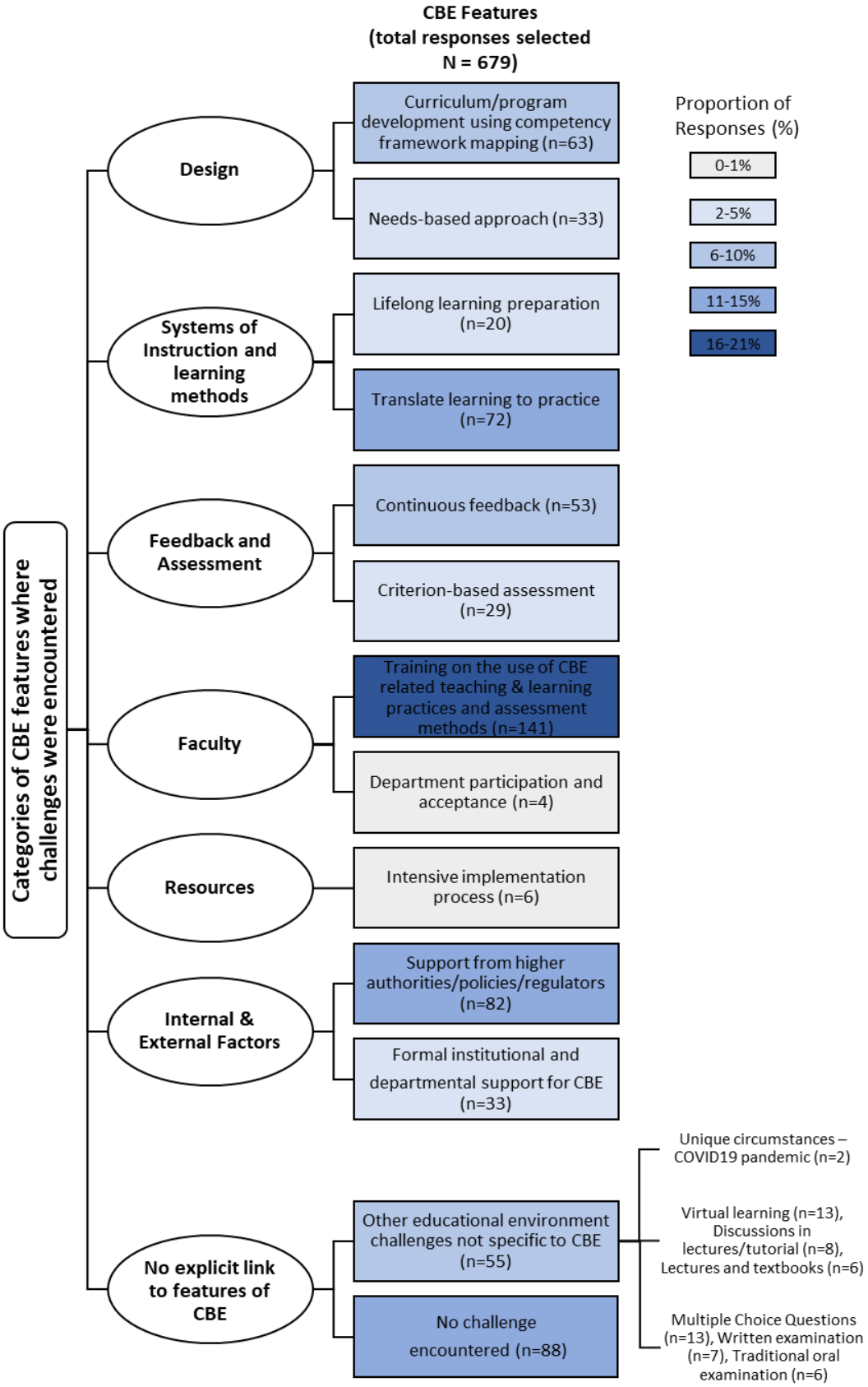


Figure 18 Distribution of challenges encountered when using CBE grouped according to the features of CBE identified by McMullen et al. (2023)

4.5 Discussion

This study represents a novel attempt to comprehensively profile the utilisation of CBE in pharmacy and the pharmaceutical sciences on a global scale, cross-cutting all of the WHO regions, and revealing a widespread of CBE incorporated within a diverse array of responding institutions.

The data collected highlights the prevalence of CBE adoption across the disciplines of pharmacy and pharmaceutical science with the majority of participating institutions integrating CBE throughout their whole curricula. However, it is crucial to note that this survey exhibited limited participation from South-East Asia and Africa. Therefore, to gain a holistic understanding of the extent of CBE use in these regions, further research is recommended.

While, for certain countries in these regions, there is some evidence of engagement with CBE (Suwannaprom et al., 2020, Ngassapa et al., 2012), further targeted investigations in these areas would be valuable. Such explorations can serve as a worthy resource for potential educational reforms, especially in light of the paucity of literature on the application of CBE in pharmacy in these regions, as previously emphasised in Chapter 3. Furthermore, additional research into the challenges of implementing CBE in low to middle-income countries is valuable for identifying necessary adaptations. These adaptations can facilitate the implementation process, considering unique factors affecting higher education system reform in these countries, such as educational infrastructure, resource constraints, faculty shortages, and external influences such as national autonomy and policy restrictions (Schendel and McCowan, 2016). CBE has potential to be especially advantageous in resource limited settings, as it provides a customisable educational approach to align education with a country's priorities, particularly in the context of careful consideration of the essential competencies for the local healthcare workforce (Gruppen et al., 2012).

By analysing the survey responses relating to the challenges encountered when using CBE according to the features of CBE identified in Chapter 3, we gain a clear and visually informative overview, detailed in **Figure 18**, of the most prevalent challenges encountered with CBE in the context of the recent literature. This method of data organisation revealed that faculty preparedness stands out as the most frequent hurdle faced by institutions when using CBE. This correlates with the foremost resource needed to implement CBE, as detailed in **Table 10**, which is 'Increased academic staff with CBE training or training of existing staff'. Additionally, the scarcity of 'no challenge encountered' responses within the faculty preparedness section of the survey questionnaire, see **Table 13**, further aligns with these findings. This convergence of data strongly suggests that a significant obstacle to the use of CBE is the training and recruitment of appropriately skilled staff. This finding underscores a pressing need for initiatives aimed at enhancing CBE training efforts. Furthermore, it also emphasises the importance of additional research into the intricacies of the

challenges related to adequately upskilling and recruiting the right personnel which is crucial for a successful transition to CBE (Frank et al., 2010b). This insight can serve as a valuable guide for current and future institutions looking to implement or expand CBE programmes.

Influences external to the individual academic institution, can have an effect on the adoption of educational models such as CBE. Rouse's International Pharmaceutical Federation (2008) conceptual framework, see **Figure 19**, depicting the dynamic and complex interplay between the education, regulation, and practice sectors in any profession, illustrates the push-pull factors that are crucial in the development and advancement of the pharmacy profession. The results, presented in **Table 11**, align with the principles of this framework, by demonstrating a statistically significant association between an institution's use of CBE and the presence of advocacy for CBE from the relevant professional and educational regulatory bodies. Additionally, as shown in **Figure 9**, the second most frequently reported feature of CBE found to be challenging was 'support from higher authorities, policies, and regulators'. This underscores the regulatory sector's influence on the educational sector and highlights a potential disconnect between the two when it comes to the application of CBE for pharmacy and pharmaceutical science.

As previously demonstrated by Bader et al. (2017), using the principles of this framework to trace challenges back to disconnects between sectors offers a practical diagnostic lens for better understanding challenges for educational reform and professional advancements, such as existing barriers to the use of CBE highlighted by these findings. Further in-depth examination of the underlying complexities contributing to these barriers is therefore justified in the pursuit of furthering the dissemination of CBE, particularly for those countries that are not currently using CBE or not represented by this survey.

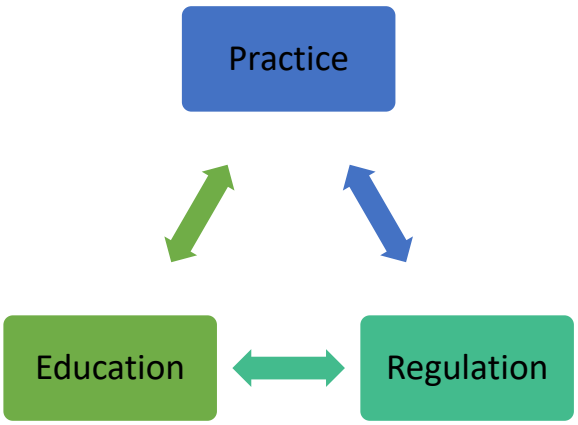


Figure 19 The dynamic relationship between practice, regulation and education[9]

[9] Adapted from: INTERNATIONAL PHARMACEUTICAL FEDERATION. 2008. *A Global Framework for Quality Assurance of Pharmacy Education,* The Hague, The Netherlands: International Pharmaceutical Federation.

The educational and regulatory disconnect highlighted by this study is not necessarily unique to CBE, but it does reinforce the importance of having all 3 sectors of the framework in alignment when initiating any major change in educational practice. The challenges to CBE are multifactorial and complex and, although not examined by this survey, the way pharmacy is practiced within the country where an institution wishes to embark on CBE will also influence its adoption (Koster et al., 2017). Moreover, students' satisfaction and engagement are at stake if the practice of pharmacy or pharmaceutical science does not align with the nature of the curriculum they have been taught or the competencies they have acquired (International Pharmaceutical Federation, 2014). It is only when all three sectors—education, regulation, and practice—are in harmony and alignment that the implementation of CBE is most likely to be effective. This highlights the holistic nature of educational reform and accentuates the need for the cooperation and coordination of all stakeholders involved in order to achieve successful change.

Progressing towards successful CBE implementation unfolds in gradual stages within each sector, often as a consequence of a series of developments over an extended period. For instance, availability of a suitable competency framework can be a challenge to implementing CBE, and difficulties in adopting a country-specific competency framework can be due to a lack of cohesion and shared vision between the key stakeholders from practice, regulation, and education (Bajis et al., 2018). The creation of an agreed national competency framework can be one step towards reaching that crucial unified vision, when all of the appropriate stakeholders are involved (Moreau et al., 2019), and tools such as the FIP GbCF are designed to facilitate countries in developing their own frameworks (International Pharmaceutical Federation, 2012).

Many of the institutions surveyed in this study were using an existing local competency framework, and when asked about challenges directly related to selecting competencies or competency frameworks, a relatively high proportion of institutions did not report any challenges in this area. This suggests that, at least in the context of the studied sample, the process of obtaining or constructing competency frameworks is not a predominant barrier to the adoption of CBE. It is important to note, however, that the majority of the responses to this survey are from Europe and the US where CBE is relatively well-established (Katoue and Schwinghammer, 2020). Therefore, availability of competency frameworks may well be more of a challenge in those regions underrepresented by this study. There are examples of some countries in these regions working towards national framework development (Kapol et al., 2008, Alfaifi et al., 2022b). Suggested priorities for implementing CBE in resource limited contexts include first starting with selecting a suitable competency framework (International Pharmaceutical Federation, 2022a). The lack of literature available from certain regions however suggests that more work is needed in many countries including those that are not sampled by this survey to develop competency frameworks, which may have the potential to act as a

cornerstone for a unified vision towards CBE if all relevant parties are actively engaged. These insights correspond to the methods in the remainder of this thesis where a diverse array of stakeholders are involved in the creation of a local competency framework for pharmacy in Kenya, as detailed in Chapter 6, adding to the limited data on CBE from one of the regions underrepresented by both this study and by the systematic review presented in Chapter 3.

4.6 Limitations

This study presents several limitations which should be acknowledged. Firstly, the sample size is small. Although this study does not claim to be fully representative of all academic institutions offering pharmacy and pharmaceutical science programmes, a wide range of opinions from varied geographical locations were collected. However, caution is recommended when interpreting the results which may not accurately represent the entire global picture. Due to the unavailability of precise data on the number of academic institutions offering pharmacy and pharmaceutical science programmes globally, it was not feasible to calculate a response rate. While a low response rate does not inherently indicate low validity, it does suggest there may be a greater risk of validity concerns (Morton et al., 2012). In surveys of this nature however, the most important indicator of validity often lies in comparing the characteristics of the respondents and non-respondents (Cook et al., 2000). Unfortunately, this comparison was not possible with the present study design.

A second, and third limitation pertains to the potential for self-selection bias and under-coverage, common challenges with web-based surveys (Bethlehem, 2010). In the absence of random sampling, individuals are left to decide for themselves whether to participate or not (Bethlehem, 2010). As a result, the survey may be more appealing to those already familiar with, or particularly interested in, CBE. The shortage of data from Africa and South-East Asia may suggest a lack of CBE usage in these regions but it is not possible to decipher if that is the case from these results. Nevertheless, underrepresentation from these regions highlights a potential under-coverage concern where access to the survey invitation may have been an issue due to the extent of the organisational mailing lists utilised for the survey distribution, or potential limitations concerning internet accessibility. The survey questionnaire was also solely distributed in English. While translation options were offered, they were not utilised, possibly limiting the scope of responses due to language barriers.

Furthermore, despite efforts to provide detailed definitions and explanations for survey questions, there remains the possibility of varying interpretations among respondents, especially given the lack of consensus on the definition of CBE as reported in previous research (Frank et al., 2010a). This variation was evident in the conflicting responses received from the same country, although attempts were made to clarify these discrepancies through direct contact with respondents when possible. In light of these limitations the findings presented in this chapter should be interpreted with caution in the context of these potential sources of error and bias.

4.7 Summary

This study provides valuable global insights into the use of CBE in pharmacy and the pharmaceutical sciences. While CBE is prevalent, challenges are evident, particularly regarding faculty preparedness which highlights a pressing need for enhanced training and further research. Additionally, there is a clear call for more studies in regions underrepresented in this research to better understand the challenges, priorities, and requisite adaptions necessary for implementing CBE particularly in low- and middle-income countries. These findings reinforce the importance of a unified vision across education, regulation, and practice when embarking on educational reform. The successful implementation of CBE hinges on achieving alignment across these sectors, facilitating a smooth transition. This transition not only benefits students and the education system but also holds great promise for the future of pharmacy and pharmaceutical sciences, ultimately improving the quality of care provided to patients in these disciplines.

4.8 Acknowledgements

I would like to thank the FIP for their collaboration with this study and the EAFP for their assistance with distributing the survey. In particular, thank you to Nilhan Usman from the FIP and Amanda Calleja from the EAFP for coordinating the distribution of the online survey questionnaire. Special thanks also to the pharmacy CBE experts consulted for the face validation of this survey; Dalia Bajis, Rula Darwish, Marwan El-Akel, Andries Koster and Marilyn Morris.

Chapter 5: FIP GbCFv2 Applicability Survey in Kenya

5.1 Chapter Introduction

The study described in this chapter addresses the principal research question proposed in Chapter 1, section 1.5.1, v:

v. How relevant is the FIP GbCFv2 to pharmacists practicing in Kenya?

5.2 Aims and Objectives

The aim of this stage of the research is to assess the applicability of the FIP GBcFv2 to pharmacy practice in Kenya.

The objective was to:

- Determine the suitability of the FIP GbCFv2 for pharmacists in Kenya by assessing its applicability and analysing areas of misalignment

The purpose of this study is to contribute to the broader aim of Part One of the thesis, which is to create a local competency framework for early-career, also referred to as foundation-level, pharmacists in Kenya. This aim is detailed in Chapter 6, where the study's findings are integrated in to the method to develop the localised competency framework.

5.3 Methods

To fulfil the research objective of this study an online cross-sectional survey questionnaire was distributed to pharmacists practicing in Kenya, investigating their perception of relevance of the behavioural statements in the FIP GbCFv2 to their current practice.

5.3.1 Survey Questionnaire

The online survey questionnaire was created using the Qualtrics software and included demographical questions to gather general background information on the respondents. An information sheet was sent to participants via email, see **Appendix 4**, and a cover page providing an explanation of the study purpose was included in the survey along with a consent form. The anonymous questionnaire was designed using the FIP GbCFv2, which consists of 4 competency clusters further broken down into a total of 123 behavioural statements and a copy of this survey is included in **Appendix 5**. Respondents were asked to rate the relevance of each statement to their own practice. This is a method that has been previously used in the literature to evaluate relevance of pharmacist's current practice to the GbCFv1 in various settings around the globe, including in Europe, Japan, Saudi Arabia and Africa (Arakawa et al., 2020, Udoh et al., 2018, Bruno, 2011, Alfaifi et al., 2022a). This is the first study of its kind to evaluate applicability of the second version of the FIP GbCF in Kenya.

A face validation of the survey for the Kenyan context, including discussion of each individual behavioural statement, took place in January 2020 with collaborators from

the Pharmaceutical Society of Kenya (PSK), the professional body for pharmacists in Kenya. Modifications included description of key terms used in the survey, such as 'CPD (Continual Professional Development)' and 'relevance'. A further modification was applied due to the relatively small number of pharmacists registered in Kenya and the expressed lack of clear definition between early career (foundation-level—specifically the first 1000 days of practice) and advanced practice (verbal communication January 2020). To obtain a larger sample size, it was deemed appropriate for the context to invite all practicing pharmacists registered with the PSK would be invited to participate, thus respondents were not limited to early career pharmacists only. The core areas of practice to be included in the survey were determined during the validation discussions to ensure suitability to Kenyan pharmacy practice, where it was suggested that hospital pharmacy should be categorised in to primary care (levels 1-3) and secondary care (levels 4-6) (verbal communication January 2020).

5.3.2 Sampling and Distribution

The cross-sectional online questionnaire survey was distributed to registered pharmacists via the PSK between December 2021 and March 2022. There were 2,041 registered members of the PSK at the time of the survey distribution, currently membership is not compulsory to practise pharmacy in Kenya (Pharmaceutical Society of Kenya, 2020). However, the PSK work closely with the regulatory body, the Pharmacy and Poisons Board (PPB), and facilitate much of the CPD activity, which is mandatory for pharmacists in Kenya (Pharmacy and Poisons Board, 2022a).

A convenience sampling method was employed due to the ease of access to PSK members. The survey URL and information sheet was distributed directly to PSK registrants via email and WhatsApp and also indirectly to all pharmacists in the country through the PSK's Facebook and Twitter social media outlets. Potential participants were encouraged to share the survey URL with colleagues and contacts as a snowball sampling method in an attempt to reach pharmacists that may not be PSK registrants or present on their mailing list. Due to the snowballing method of sampling a response rate calculation was not applicable. The PSK estimate that 1,700-1,800 of their members are active practising members of the pharmacy profession in Kenya (verbal communication February 2020). Reminders were sent via the above platforms on a monthly basis and respondents were recruited continuously throughout the study period. Only those that agreed to consent to participate with the survey, from the information on the cover page, were permitted to fulfil the questionnaire.

5.3.3 Data Analysis

The data from the survey was extracted electronically from Qualtrics, manually cleaned using Microsoft Office Excel 2016 and then analysed using the IBM SPSS Statistics software version 28. Demographic data was collected and presented descriptively. The perception of relevance to the respondent's practice for each behavioural statement in the GbCFv2 was evaluated using a 4 point Likert scale. The respondents were asked to rate each behaviour as 'highly relevant', 'relevant', 'low relevance', or 'not relevant'. For analysis, these results were dichotomised into 2

distinct categories: 1. 'not relevant' which included the 'low relevance' and 'not-relevant' ratings, and 2. 'relevant' which included the 'highly relevant' and 'relevant' rantings. Descriptive analysis was performed and relevance was evaluated by comparing the percentage of respondents who rated statements within each dichotomised category as a proportion of the total ratings for each statement. These ratings were then examined in more detail according to the GbCFv2 competency clusters and demographic variables.

Similar to consensus development methods, where there are no clear guidelines on which consensus level to set, there are also no hard and fast rules for determining thresholds for relevance in this context (Keeney et al., 2006). For this study, relevance to practice was considered agreed when 90% or more of the respondents rated a statement as within the 'relevant' category for two main reasons. Firstly, due to the importance of the research topic, i.e. the quality of pharmacy practice and subsequent healthcare services. Secondly, the ≥90% relevance threshold was chosen for pragmatic purposes due to the overall high degree of relevant rankings observed from the respondents in this study and in accordance with evidence from similar previous studies (Bruno, 2011, Udoh et al., 2018).

In addition to descriptive analysis of relevance ratings, the data was further aggregated according to core area of practice for the purposes of inferential analysis. Dichotomous groups were formed according to whether the nature of the respondents' field of practice could conventionally be considered 'patient facing', or 'non-patient facing'—where the latter group typically has minimal, or no contact with patients in their daily practice. The 'patient-facing' group consists of those that work in a setting where they would more commonly interact with patients, such as in hospital and community pharmacy. A two-tailed Fisher's exact test was performed on this aggregated data for the behavioural statements that showed disagreement to examine any relationship between relevance ratings and the patient vs non-patient facing fields of pharmacy practice, using a 0.05% confidence level to determine statistical significance. This test was chosen as a number of frequencies in the 2x2 contingency tables created from the data had values that were less than 5. When such frequencies are low, and the overall sample size is relatively small, there is a high probability that the sampling distribution is too deviant from the chi-square distribution to be accurate and in such cases the Fisher's exact test is preferred (Field, 2018). The application of the Fisher's exact test attempts to discern whether the core area of practice of the respondent affects their perception of relevance of certain behavioural statements, which may need to be taken into account when using these results to apply to the creation of a sector-wide competency framework.

5.3.4 Ethical Consideration

The Study was approved by the Research Ethics Committee of the School of Pharmacy at the University of Nottingham, UK (approval number 012-2020), and the Jomo Kenyatta University of Agriculture and Technology, Kenya (approval number JKU.IERC/02316/0123) and has been granted a Kenyan research license by the National Commission for Science, Technology & Innovation (license number NACOSTI/P/21/12536).

5.4 Results

5.4.1 Demographics

An initial 161 respondents agreed to consent and participate in the survey. After data cleaning, 31 incomplete responses were excluded from the analysis. The remaining 130 responses were subjected to descriptive and inferential analyses, and the demographic characteristics of this diverse array of respondents is displayed in **Table 14**. The sample distribution shows that the majority of the responding pharmacists are male (61.5%) and aged between 32 and 50 (56.9%) which does correlate with recent demographic data on the distribution of the general population of pharmacists in Kenya (Okoroafor et al., 2022).

Table 14 Demographic characteristics of Kenyan FIPBGbCFv2 applicability survey respondents

Demographic characteristics of respondents (Total n=130)		**Number (n)**	**Percentage (%)**
Gender	Male	80	61.5
	Female	49	37.9
	Prefer not to say	1	0.8
Age (years)	20-25	3	2.3
Mean 38.5, Standard	26-31	36	27.7
Deviation 10.0, Range 21-71	32-40	46	35.4
	41-50	28	21.5
	51-60	12	9.2
	61-71	5	3.8
Years qualified as a	≤1	4	4.0
pharmacist	2-5	31	23.8
Mean 12.6, Standard	6-10	34	26.2
Deviation 9.9, Range ≤1-48	11-15	22	16.9
	16-20	16	12.3
	21-30	14	10.8
	≥31	9	6.9
Current core area of	Community Pharmacy	18	13.8
practice	Hospital Pharmacy (level 1-3)	6	4.6
	Hospital Pharmacy (level 4-6)	48	36.9
	Academia	12	9.2
	Industrial Pharmacy	13	10.0
	Supply Chain Pharmacy	13	10.0
	Public Health & Regulatory Organisations	8	6.2
	Other*	12	9.2
Number of years in current	≤1	13	10.0
core area of practice	2-5	51	39.2
Mean 7.7, Standard	6-10	38	29.2
Deviation 7.1, Range ≤1-43	11-15	15	11.5
	16-20	6	4.6
	21-30	5	3.8
	≥31	2	1.5

Table 14 (continued)

Demographic characteristics of respondents (Total n=130)		Number (n)	Percentage (%)
Previous career break	Yes	22	16.9
	No	108	83.1
Duration of career break (years)	≤1	6	27.3
	2-5	8	36.4
Mean 4.9, Standard	6-10	7	31.8
Deviation 3.8, Range ≤1-16	>10	1	4.5

*Other current core areas of practice as stated by respondents, where each n=1, were: "Programmes Management and Healthcare Financing", "Importer and distributor", "Monitoring and Evaluation in the health sector in Baringo county", "Healthcare Financing", "Oncology pharmacy", "Regulatory pharmacist", "Regulatory Affairs in Pharmaceutical Industry", "Sub County Pharmacist", "Pharmacovigilance", "Managerial", "Regulatory-National quality control as a Pharmaceutical Analyst", "Policy"

In **Figure 20** the distribution of the respondents is displayed according to the number of years that they have been qualified as a pharmacist. As shown, hospital pharmacy (level 4-6) is consistently the individual sector within each time period with the highest proportion of pharmacists (0-5 years n=13, 37.1%; 6-10 years n=18, 52.9%; 11-20 years n=12, 31.6%; and ≥21 years n=5, 21.7%).

Hospital and community pharmacy are typically clinical patient facing areas of practice while the other core areas commonly encompass less patient facing roles. The proportion of pharmacists in these patient facing core areas consistently decreases with the increasing duration of qualification (0-5 years n=23, 65.7%; 6-10 years n=21, 61.8%; 11-20 years n=18, 47.4%; and ≥21 years n=10, 43.5%).

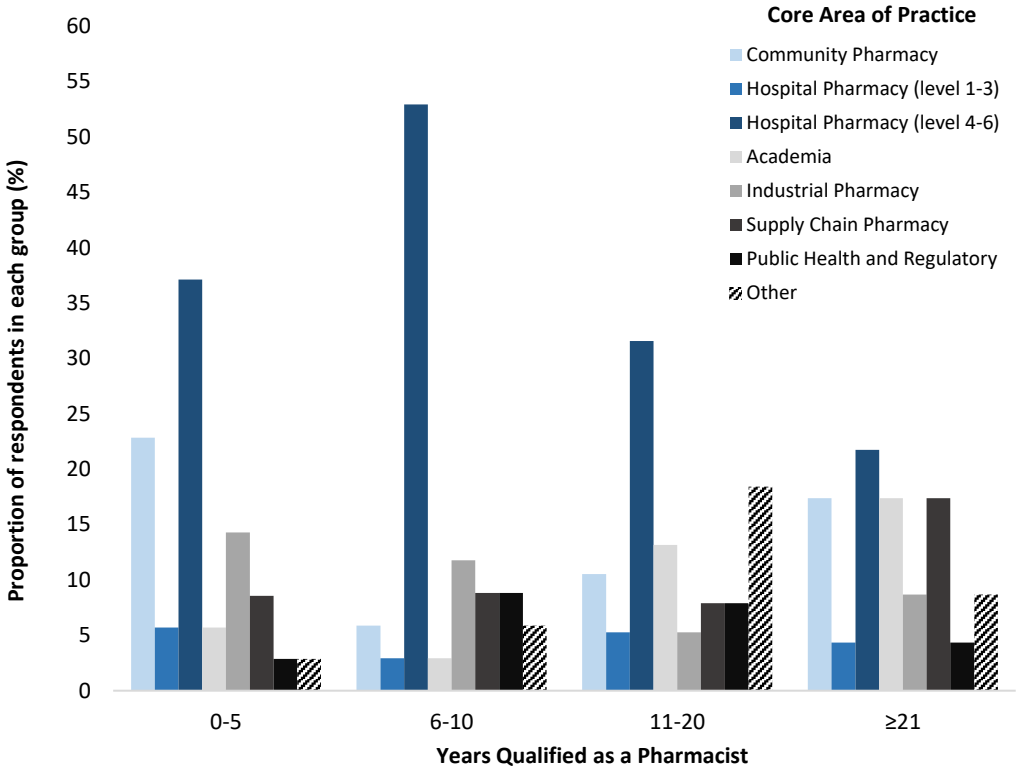


Figure 20 Distribution of pharmacists in each core area of practice according to the number of years qualified

5.4.2 Relevance Ratings

5.4.2.1 Overall relevance

The dichotomised data for each behavioural statement is displayed in **Table 15**. To provide a visual representation, **Figure 21** illustrates the overall percentage of statements that received a 'relevant' or 'not relevant' response, corresponding to each of the competency clusters. Across all clusters the total proportion of responses was 89.4% for 'relevant' and 10.6% for 'not relevant'.

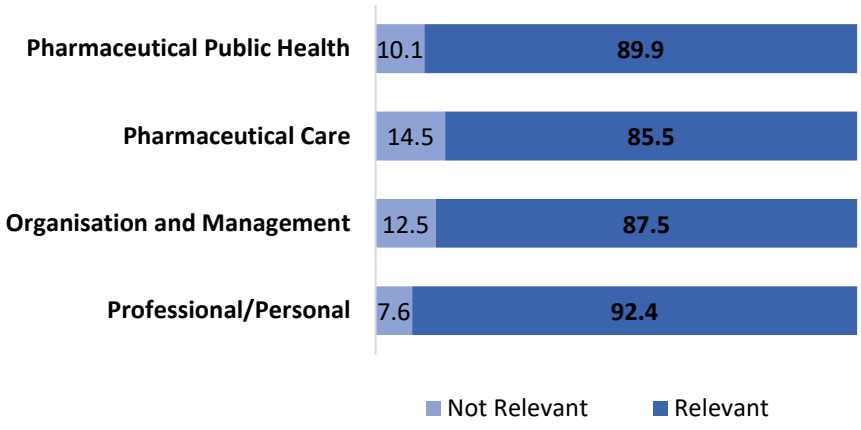


Figure 21 Overall relevance ratings of each FIP GbCFv2 competency cluster

Within the FIP GBcFv2, a total of 123 statements were analysed, and 69 of these statements (56.1%) demonstrated agreement in relevance.

In the PPH cluster, the statement that received the lowest percentage of 'relevant' ratings (78.5%) was statement 1.3.3: 'Support the patient's use of health information technologies and digital communication (including IT driven health solutions)'. This statement was not present in the original GbCF and is a new addition for version 2 of the framework.

In the PC cluster, the percentage of 'relevant' ratings was the lowest of all the clusters, see **Figure 21.** Statements that received some of the lowest proportion of 'relevant' ratings were statements; 2.2.1: 'Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)' (n=101, 77.7%), statement 2.2.2: 'Compound under the good manufacturing practice for pharmaceutical (GMP) medicines' (n=100, 76.9%), statement 2.3.6: 'Implement and maintain a dispensing error reporting system and a 'near misses' reporting system' (n=102, 78.5%), and statement 2.6.1: 'Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care' (n=102, 78.5%).

The 5 statements in the OM cluster that received the lowest proportion of 'relevant' rating were statement 3.1.3: 'Manage appropriate claims for reimbursements' (n=94,72.3%), statement 3.1.5: 'Ensure proper reference sources for service reimbursement' (n=96, 73.8%), statement 3.4.5: 'Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms' (n=103, 79.2%), statement: 3.4.7 'Supervise procurement activities' (n=101, 77.7%), and statement: 3.4.8 'Understand the tendering methods and evaluation of tender bids' (n=97, 74.6%).

The statement in the PP cluster with the lowest proportion of 'relevant' ratings was statement 4.8.4: 'Ensure appropriate quality control tests are performed and managed appropriately' (n=103, 79.2%).

The statements with the lowest agreement of relevance suggest that they are not wholly applicable to the pharmacy workforce in Kenya. Therefore, these findings indicate that modification of these statements would be required for inclusion in a local competency framework. These results and statements that received the lowest proportion of 'relevant' ratings (less than 80% of the respondents), shown in **Appendix 8**, were used to inform competency framework development workshop discussions to adapt the GbCF to the Kenyan context, marking the second stage of Part One in this thesis. Further elaboration can be found in Part 2 Stage (ii).

Table 15 Dichotomised survey data showing the overall relevance ratings for each behavioural statement in the FIP GbCFv2

Competency Group	GbcFv2 Behavioural Statement	Relevance Rating			
		Relevant		Not Relevant	
		(N)	(%)	(N)	(%)
Cluster 1 Pharmaceutical Public Health					
1.1 Emergency response	1.1.1 Participate in the response to public health emergencies	114	87.7	16	12.3
	1.1.2 Assist the multidisciplinary healthcare teams in emergency situation	114	87.7	16	12.3
1.2 Health promotion	1.2.1 Assess the patient's/population's primary healthcare needs (taking into account the cultural and social setting of the patient/populations)	118	90.8	12	9.2
	1.2.2 Advise and provide services related to health promotion; disease prevention and control (e.g. vaccination); and healthy lifestyle	117	90	13	10
	1.2.3 Identify and support national and local health priorities and initiatives	120	92.3	10	7.7
1.3 Medicines information and advice	1.3.1 Counsel population on the safe and rational use of medicines and medical devices (including the selection, use, contraindications, storage, and side effects of non-prescription and prescription medicines)	124	95.4	6	4.6
	1.3.2 Identify sources, retrieve, evaluate, organise, assess and provide relevant medicines information according to the needs of patients and clients	124	95.4	6	4.6
	1.3.3 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	102	78.5	28	21.5
Cluster 2 Pharmaceutical Care					
2.1 Assessment of medicines	2.1.1 Gather, analyse, research, and interpret information about the patient and patient's medicines-related needs (e.g. indication, effectiveness, safety and adherence)	114	87.7	16	12.3
	2.1.2 Retrieve relevant patient information (including drug history, or immunisation status for example) and record of allergies to medicines and Adverse Drug Reactions (ADR) in medication record.	107	82.3	23	17.7
	2.1.3 Identify, prioritise, resolve and follow up on medicine-medicine interactions; medicine-disease interactions; medicine-patient interactions; medicines-food interactions	110	84.6	20	15.4
	2.1.4 Appropriately select medicines (e.g. according to the patient, hospital, government policy, etc.)	117	90	13	10

Table 15 (continued)

Competency Group	GbcFv2 Behavioural Statement	Relevance Rating			
		Relevant		Relevant	
		(n)	(%)	(n)	(%)
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	101	77.7	29	22.3
	2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines	100	76.9	30	23.1
2.3 Dispensing	2.3.1 Accurately dispense medicines for prescribed and/or minor ailments, including an embedded checking process	113	86.9	17	13.1
	2.3.2 Accurately report defective or substandard medicines to the appropriate authorities.	116	89.2	14	10.8
	2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal	115	88.55	15	11.5
	2.3.4 Dispense devices (e.g. inhaler or a blood glucose meter)	112	86.2	18	13.8
	2.3.5 Document and act upon dispensing errors	110	84.6	20	15.4
	2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system	102	78.5	28	21.5
	2.3.7 Label the medicines (with the required and appropriate information)	116	89.2	14	10.8
	2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors'	111	85.4	19	14.6
2.4 Medicines	2.4.1 Advise patients on proper storage conditions of the medicines and ensure that medicines are stored appropriately (e.g. humidity, temperature, expiry date, etc.)	118	90.8	12	9.2
	2.4.2 Appropriately select medicine formulation and concentration for minor ailments (e.g. diarrhoea, constipation, cough, hay fever, insect bites, etc.)	117	90	13	10
	2.4.3 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients	114	87.7	16	12.3
	2.4.4 Package medicines to optimise safety (ensuring appropriate re- packaging and labelling of the medicines)	120	92.3	10	7.7
2.5 Monitor medicines therapy	2.5.1 Apply guidelines, medicines formulary system, protocols and treatment pathways	118	90.8	12	9.2
	2.5.2 Apply therapeutic medicines monitoring and assess impact, and outcomes (including objective and subjective measures)	107	82.3	23	17.7
	2.5.3 Identify, prioritise and resolve medicines management problems (including errors)	116	89.2	14	10.8

Table 15 (continued)

Competency Group	GbcFv2 Behavioural Statement	Relevance Rating			
		Relevant		Not Relevant	
		(n)	(%)	(n)	(%)
2.6 Patient consultation and diagnosis	2.6.1 Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care	102	78.5	17	13.1
	2.6.2 Appropriately refer the patient or carer	113	86.9	17	13.1
	2.6.3 Assess and diagnose based on objective and subjective measures (where applicable)	105	80.8	25	19.2
	2.6.4 Evaluate, assess, and develop health literacy education and counselling on medicines and healthcare needs	112	86.2	18	13.8
	2.6.5 Discuss and agree with the patient on the appropriate use of medicines, taking into account patients' preferences	114	87.7	16	12.3
	2.6.6 Document any intervention (e.g. document allergies, such as from medicines and nutrition in the patient medicines history)	106	81.5	24	18.5
	2.6.7 Obtain, reconcile, review, maintain and update relevant patient medication and disease history	107	82.3	23	17.7
Cluster 3 Organisation and Management					
3.1 Budget and reimbursement	3.1.1 Acknowledge the organisational structure	118	90.8	12	9.2
	3.1.2 Effectively apply and set budgets	112	86.2	18	13.8
	3.1.3 Manage appropriate claims for reimbursements	94	72.3	36	27.7
	3.1.4 Ensure financial transparency	109	83.8	21	16.2
	3.1.5 Ensure proper reference sources for service reimbursement	96	73.8	34	26.2
3.2 Human resources management	3.2.1 Demonstrate organisational and management skills (e.g. plan, organise and lead on medicines management, risk management, self-management, time management, people management, project management, policy management)	120	92.3	10	7.7
	3.2.2 Identify and manage human resources and staffing issues	112	86.2	18	13.8
	3.2.3. Recognise and manage the potential of each member of the staff and utilise systems for performance management (e.g. conduct staff appraisals)	111	85.4	19	14.6
	3.2.4. Recognise the value of pharmacy team and of a multidisciplinary team	122	93.8	8	6.2
	3.2.5 Support and facilitate staff training and continuing professional development	120	92.3	10	7.7
3.3 Improvement of service	3.3.1 Identify and implement new services (according to local needs)	115	88.5	15	11.5
	3.3.2 Resolve, follow up and prevent medicines related problems	119	91.5	11	8.5
3.4 Procurement	3.4.1 Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality	113	86.9	17	13.1

Table 15 (continued*)*

Competency Group	GbcFv2 Behavioural Statement	Relevance Rating			
		Relevant		Not Relevant	
		(n)	(%)	(n)	(%)
	3.4.2 Develop and implement contingency plans for shortages	112	86.2	18	13.8
	3.4.3 Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms	109	83.8	21	16.2
	3.4.4 Ensure there is no conflict of interest	107	82.3	23	17.7
	3.4.5 Identify and select reliable supplier(s)	103	79.2	27	20.8
	3.4.6 Select reliable supply of high-quality products (including appropriate selection and procurement processes, cost effectiveness, timely delivery)	113	86.9	17	13.1
	3.4.7 Supervise procurement activities	101	77.7	29	22.3
	3.4.8 Understand the tendering methods and evaluation of tender bids	97	74.6	33	25.4
3.5 Supply chain and management	3.5.1 Demonstrate knowledge in store medicines to minimise errors and maximise accuracy	123	94.6	7	5.4
	3.5.2 Verify the accuracy of rolling stocks	115	88.5	14	11.5
	3.5.3 Ensure effective stock management and running of service with the dispensary	120	92.3	10	7.7
	3.5.4 Ensure logistics of delivery and storage	117	90	13	10
	3.5.5 Implement a system for documentation and record Keeping	122	93.8	8	6.2
	3.5.6 Take responsibility for quantification and supply chain forecasting	116	89.2	14	10.8
3.6 Workplace management	3.6.1 Address and manage day to day management issues	122	93.8	8	6.2
	3.6.2 Demonstrate the ability to take accurate and timely decisions and make appropriate judgements	126	96.9	4	3.1
	3.6.3 Ensure the production schedules are appropriately planned and managed	111	85.4	19	14.6
	3.6.4 Ensure the work time is appropriately planned and managed	118	90.8	12	9.2
	3.6.5 Improve and manage the provision of pharmaceutical services	126	96.9	4	3.1
	3.6.6 Recognise and manage pharmacy resources (e.g. financial, infrastructure)	120	92.3	10	7.7
Cluster 4 Professional/Personal					
4.1 Communication skills	4.1.1 Communicate clearly, precisely and appropriately while being a mentor or tutor	124	95.4	6	4.6
	4.1.2 Communicate effectively with health and social care staff, support staff, patients, carer, family relatives and clients/customers, using lay terms and checking understanding	123	94.6	7	5.4

Table 15 (continued)

Competency Group	GbcFv2 Behavioural Statement	Relevance Rating			
		Relevant		Not Relevant	
		(n)	(%)	(n)	(%)
	4.1.3 Tailor communication that is appropriate to the patient's needs (including health literacy, cultural or language barriers, social needs, and emotional status)	121	93.1	7	5.4
	4.1.4 Use appropriate communication skills (e.g. verbal and non-verbal) to establish and maintain rapport with the patient and others including when communicating through digital and electronic platforms	120	92.3	10	7.7
4.2 Continuing Professional Development (CPD)	4.2.1 Document CPD activities	124	95.4	6	4.6
	4.2.2 Engage with students/interns/residents	122	93.8	8	6.2
	4.2.3 Evaluate accuracy of knowledge and skills	119	91.5	11	8.5
	4.2.4 Identify learning and development needs	120	92.3	10	7.7
	4.2.5 Evaluate learning and development progress	117	90	13	10
	4.2.6 Identify if expertise is needed outside current scope of knowledge	118	90.8	12	9.2
	4.2.7 Recognise own limitations and act upon them	126	96.9	4	3.1
	4.2.8 Reflect on performance	125	96.2	5	3.8
	4.2.9 Demonstrate engagement/ participation in professional development and lifelong learning activities	125	96.2	5	3.8
4.3 Digital literacy	4.3.1 Identify, manage, organise, store, and share digital information	123	84.6	7	5.4
	4.3.2 Critically appraise, analyse, evaluate, and/or interpret digital information and their sources	120	92.3	10	7.7
	4.3.3 Where applicable, participate in digital health services that promote health outcomes and engage with digital technologies (e.g. social media platforms & mobile applications) to facilitate discussions with the patient and others	112	86.2	8	6.2
	4.3.4 Maintain patient privacy and security of digital information related to the patient and workplace	122	93.8	8	6.2
4.4 Interprofessional collaboration	4.4.1 Respect and acknowledge the expertise, roles and responsibilities of colleagues and other health professionals	128	98.5	2	1.5
	4.4.2 Participate, collaborate, advise in therapeutic decision-making, and use appropriate referral in a multi-disciplinary team	120	92.3	10	7.7
	4.4.3 Engage in collaborative practice, research and service provision to optimise patient health outcomes	124	95.4	6	4.6

Table 15 (continued)

Competency Group	GbcFv2 Behavioural Statement	Relevance Rating			
		Relevant		Not Relevant	
		(n)	(%)	(n)	(%)
	4.4.4 Engage in relationship-building with health professionals allowing conflict resolution, teamwork, communication, and consultation	125	96.2	5	3.8
	4.4.5 Demonstrate mutual respect and adopt shared values of the workplace and toward patient care	128	98.5	2	1.5
4.5 Leadership and self-regulation	4.5.1 Apply assertiveness skills (inspire confidence)	128	98.5	2	1.5
	4.5.2 Demonstrate leadership and practice management skills, initiative and efficiency	129	99.2	1	0.8
	4.5.3 Document risk management (critical incidents)	116	89.2	14	10.8
	4.5.4 Prioritise work, practice punctuality and time management	124	95.4	6	4.6
	4.5.5 Develop, implement and monitor innovative ideas	121	93.1	9	6.9
	4.5.6 Recognise and describe emotional information about self and others (e.g. self-awareness, self-regulation, motivation, social skills and empathy)	122	93.8	8	6.2
	4.5.7 Demonstrate flexibility and adaptability to a variety of conditions and circumstances	125	96.2	5	3.8
	4.5.8 Recognise when affected by setback or stress and manage with effective coping strategies (resilience)	124	95.4	6	4.6
4.6 legal and regulatory practice	4.6.1 Apply regulatory affairs and the key aspects of pharmaceutical registration and legislation	117	90	13	10
	4.6.2 Apply the principles of business economics and intellectual property rights including the basics of patient interpretation	107	82.3	23	17.7
	4.6.3 Be aware of and identify the new medicines coming to the market	118	90.8	12	9.2
	4.6.4 Comply with legislation for drugs with the potential for abuse	125	96.2	5	3.8
	4.6.5 Apply the principles of marketing and sales	104	80	26	20
	4.6.6 Engage with health and medicines policies	119	91.5	11	8.5
	4.6.7 Recognise the steps needed to bring a medical device or medicine to the market including the safety, quality, efficacy and pharmacoeconomic assessments of the product	106	81.5	24	18.5
4.7 Professional and ethical practice	4.7.1 Demonstrate awareness and employment of local/national codes of ethics	123	94..6	7	5.4
	4.7.2 Fulfil duty of care to the patient and the public	126	96.9	4	3.1

Table 15 (continued)

Competency Group	GbcFv2 Behavioural Statement	Relevance Rating			
		Relevant		Relevant	
		(n)	%	(n)	%
	4.7.3 Maintain privacy and confidentiality (with the patient and other healthcare professionals)	126	96.9	4	3.1
	4.7.4 Comply with patient privacy legislation including documentation of information	122	93.8	8	6.2
	4.7.5 Consider available evidence and support the patient to make informed choices about medicine use	121	93.1	9	6.9
	4.7.6 Obtain patient consent (it can be implicit on occasion)	119	91.5	11	8.5
	4.7.7 Recognise professional limitations of self and others in the team	127	97.7	3	2.3
	4.7.8 Demonstrate professional responsibility for all decisions made and actions taken	129	99.2	1	0.8
	4.7.9 Demonstrate awareness of socially accountable practice (including cultural and social needs; cultural safety, respect, and responsiveness; diversity, equity and inclusiveness)	122	93.8	8	6.2
4.8 Quality assurance and research in the workplace	4.8.1 Apply research findings and understand risk-benefit analyses (e.g. pre-clinical, clinical trials, experimental clinical pharmacological research, and risk management)	117	90	13	10
	4.8.2 Audit quality of service (meet local and national standards and specifications)	113	86.9	17	13.1
	4.8.3 Develop and implement Standard Operating Procedures (SOPs)	123	94.6	7	5.4
	4.8.4 Ensure appropriate quality control tests are performed and managed appropriately	103	79.2	27	20.8
	4.8.5 Ensure medicines are not counterfeit and adhere to quality standards	115	88.5	15	11.5
	4.8.6 Identify and evaluate evidence-base to improve the use of medicines and services	118	90.8	12	9.2
	4.8.7 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice)	110	84.6	20	15.4
	4.8.8 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)	119	91.5	11	8.5
	4.8.9 Initiate and implement audit research activities	104	80	26	20

5.4.2.2 Relevance according to years qualified as a pharmacist

The dichotomised relevance data is represented via a heat map to compare the percentage relevant ratings for each cluster with the numbers of years the respondents had been qualified as a pharmacist, shown in **Figure 22**. In this visual representation, the lighter coloured squares highlight where a lower percentage of pharmacists rated these clusters as 'relevant' to their own practice.

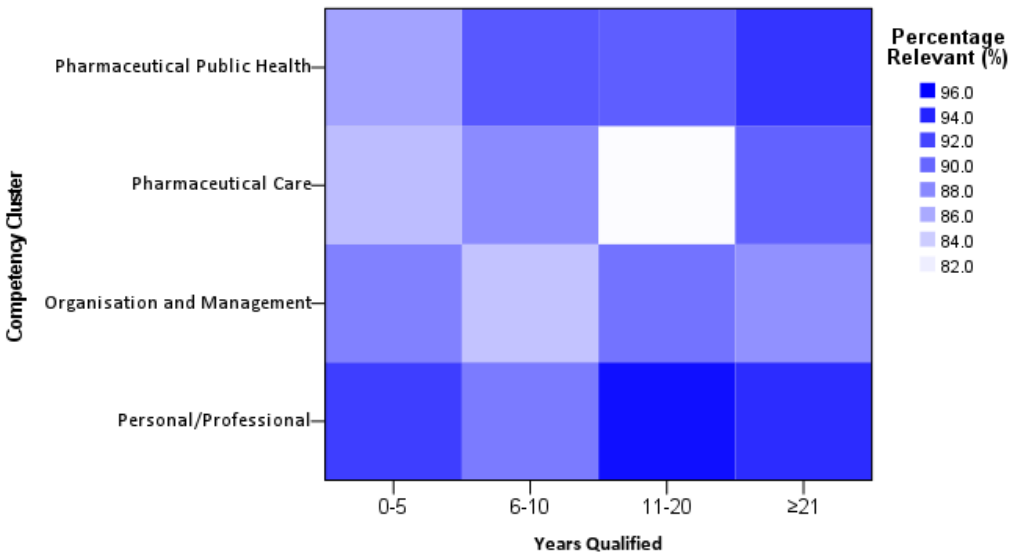


Figure 22 Heat map for the percentage of 'relevant' responses for each cluster according to the number of years qualified as a pharmacist

The percentage of 'relevant' responses is slightly higher in those pharmacists qualified the longest (≥21 years = 91.1% and 11-20 years = 90.1%) compared to those qualified for a shorter time period (0-5 years =89.2% and 6-10 years = 87.6%). The lowest percentage of 'relevant' responses are seen in the PC cluster as rated by those qualified for 11-20 years (11-20 years = 81.2%, 0-5 years = 84.9%, 6-10 years = 87.8%, and ≥21 years = 90.2 years).

The 11-20 years qualified group is also the group with respondents reporting the most diverse assortment of areas of practice as it contains the highest proportion of respondents selecting the 'other' category as their core area of practice (0-5 years 'other' = 2.9%, 6-10 years 'other' = 5.9%, 11-20 years 'other' = 18.4%, and ≥21 years 'other' = 8.7%). This diversity of core areas of practice in the 11-20 years qualified group might explain why the engagement with the PC cluster is particularly low for these pharmacists, as indicated by the lightest square in the heat map shown in **Figure 22**. This may be attributed to the fact that the areas of practice specified by pharmacists under the 'other' category are predominantly linked to regulatory and managerial positions, see **Table 14**. Consequently, pharmacists in these roles are less likely to be involved in the duties encompassed by the patient-care orientated competencies of the PC cluster.

5.4.2.3 Relevance according to years in current core area of practice

The dichotomised data was also examined in relation to the length of time the pharmacists had been working in their current core area of practice, as depicted in **Figure 23**. In this data comparison, the lowest relevance is seen in the OM cluster for those respondents in their current core area of practice for 6-10 years (6-10 years = 81.8%, 0-5 years = 88.9%, 11-20 years = 91.4, and ≥21 years = 93.8%). This is also the duration of qualification grouping that had the highest proportion of hospital (level

4-6) pharmacists. Despite a predicted tendency for pharmacists to take on more management roles the longer they are working in a given role, the results do not suggest a consistent increased engagement with this cluster as the time working in their current core are of practice increases.

Similarly to the results presented in **Figure 22** for the pharmacists qualified for the longest time period, those working in their current core area of practice for longer also demonstrated a higher percentage of 'relevant' ratings across all clusters. (≥21 years = 97.2%, 11-20 years = 91.3%) compared to those with a shorter duration in their current core area of practice (0-5 years =89.9% and 6-10 years = 86.1%).

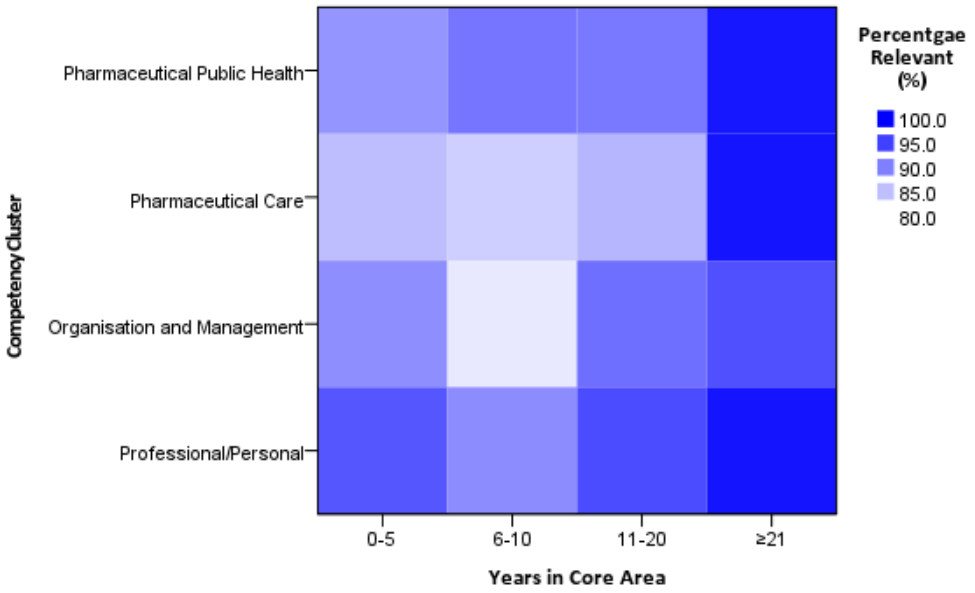


Figure 23 Heat map for the percentage of 'relevant' responses for each cluster according to the respondents number of years working in their current core area of practice

5.4.2.4 Relevance according to current core area of practice

In **Figure 24**, the dichotomised results are represented as a heat map to compare the respondent's core area of practice and the percentage of 'relevant' responses for each cluster. For the PC cluster, pharmacists working in hospital (all levels) and community pharmacy show a higher percentage of 'relevant' responses compared to the pharmacists working in other core area of practice (hospital pharmacy (level 1-3) = 92.9%, hospital pharmacy (level 4-6) = 91.9%, and community pharmacy = 91.9%, industrial pharmacy = 80.5%, academia = 80.4%, supply chain pharmacy = 79.1%, 'other' = 78.6%, and public health and regulatory = 64.3%).

The public health and regulatory sector shows the lowest percentage of 'relevant' ratings (79.8%), the highest percentage is in the supply chain pharmacy group (92.7%), followed by the community pharmacy (92.2%), and hospital pharmacy (level1-3) (91.3%) sectors. The remainder of the results for the other core areas of

practice lie in between these two extremes ('other' = 86.1%, academia = 88.8%, industrial pharmacy = 89.1%, hospital pharmacy (level 4-6) = 89.9%).

The highest percentage of 'relevant' ratings across all clusters was seen from the supply chain pharmacy sector in the OM cluster (98.3%). As with the overall relevance and the PC cluster relevance, the public health and regulatory sector also had the lowest percentage of 'relevant' ratings for this cluster (81.6%). However, it is important to approach these findings with caution due to the relatively small number of respondents in certain core areas of practice, such as the public health and regulatory sector (n=8). This limited sample size could introduce the potential for bias in the results.

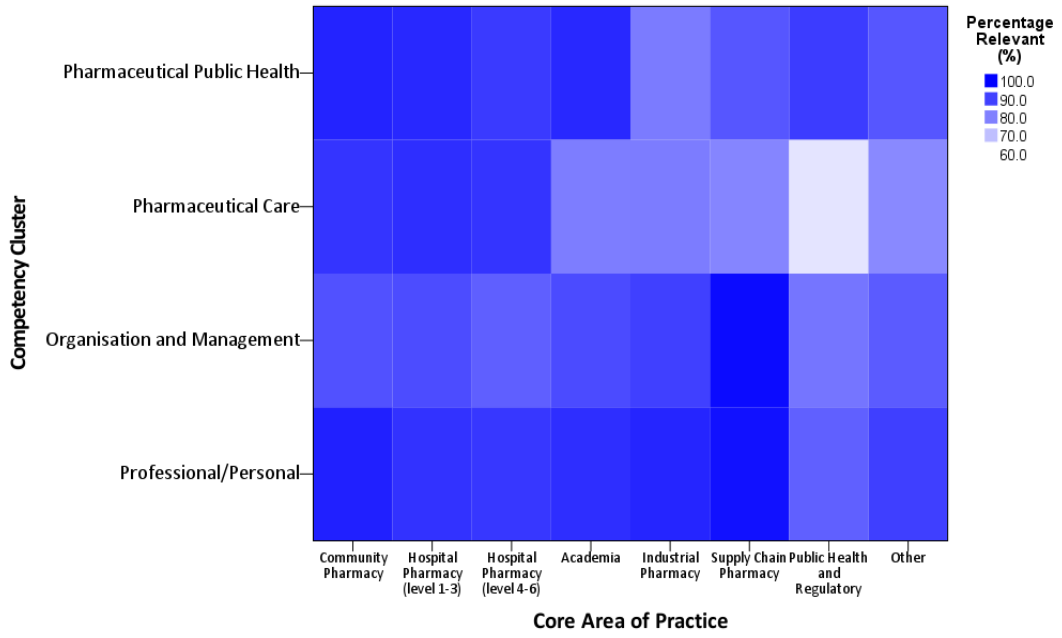


Figure 24 Heat map for the percentage of 'relevant' responses for each cluster according to the respondents current core are of practice

5.4.2.5 Relevance according to patient facing and non-patient facing groups of practice

To investigate any differences in responses according to the nature of the pharmacists' core area of practice, the data was aggregated in to patient facing (PF) and non-patient facing (NPF) groups. The PF group consists of the community pharmacy and hospital pharmacy (level 1-3 and level 4-6) core areas of practice, and the NPF group consists of academia, industrial pharmacy, supply chain pharmacy, public health and regulatory and the 'other' categories of practice. Examining associations between respondents' PF or NPF nature of practice and their responses to this survey can provide valuable insights as to whether statements are considered 'not relevant' to the pharmacy profession as a whole or likely to just not be relevant in certain areas of practice.

Following aggregation, the dichotomised responses for those statements with a 'relevant' rating percentage of less than 90% was subjected to a Fisher's exact test to identify any associations between the PF and NPF variables and the 'not relevant' responses. The statements with statistically significant differences are presented graphically in **Figure 25**.

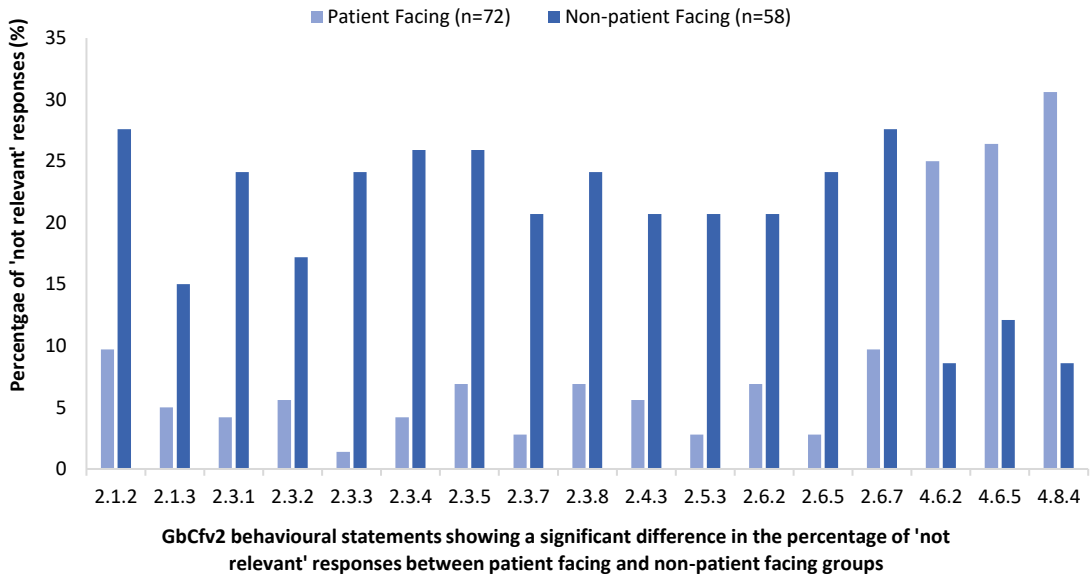


Figure 25 Two-sided hypothesis results for statements showing significant differences between the 'not relevant' responses for patient facing and non-patient facing core areas of practice

The percentage of 'not relevant' responses for all of the statements showing disagreement, according to the aggregated groups, are presented in **Table 16**, where the statements with statistically significant different responses ($p < 0.05$) are highlighted in bold.

A higher percentage of the NPF group rated all of the dissenting PC cluster statements as 'not relevant' compared to the PF group, and 14 out of 23 of the statements in this cluster showed a statistically significant difference ($p<0.05$). This suggests that the degree of relevance of the majority of the behavioural statements in the PC cluster is dependent on the patient facing nature of the respondents' core area of practice.

There were no statistically significant differences in the 'not relevant' ratings between the PF and NPF groups for the statements in the PPH or the OM cluster. These results suggest therefore, that the relevance of the statements in these clusters is not dependent on the patient facing nature of the respondent's core area of practice.

Three statements in the PP cluster exhibited a significantly different percentage of 'not relevant' responses between the two groups ($p < 0.05$). These statements, related to business and production, had a higher percentage of 'not relevant' ratings from the PF group compared to the NPF pharmacists. These findings suggest that

these behaviours are more commonly found within NPF roles, such as industrial or supply chain pharmacy compared to community or hospital pharmacy settings.

Overall, these results highlight how the relevance of the behavioural statements varies across different competency clusters and may be influenced by the patient-facing nature of the pharmacists' practice. The findings shed light on the importance of considering the specific focus of each cluster when assessing the perception of relevance of sector wide competency frameworks in pharmacy practice

Table 16 Prevalence of 'not-relevant' ratings for the behavioural statements showing disagreement aggregated in to patient facing and non-patient facing groups of practice

GbcFv2 Behavioural Statement	'Not Relevant' Ratings (%)		p-value (2-sided)
	Patient Facing (n=72)	**Non-patient Facing** (n=58)	
Cluster 1 Pharmaceutical Public Health			
1.1.1 Participate in the response to public health emergencies	12.5	12.1	1
1.1.2 Assist the multidisciplinary healthcare teams in emergency situation	9.7	15.5	0.422
1.3.3 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	18.1	25.9	0.293
Cluster 2 Pharmaceutical Care			
2.1.1 Gather, analyse, research, and interpret information about the patient and patient's medicines-related needs (e.g. indication, effectiveness, safety and adherence)	8.3	17.2	0.179
2.1.2 Retrieve relevant patient information (including drug history, or immunisation status for example) and record of allergies to medicines and Adverse Drug Reactions (ADR) in medication record.	**9.7**	**27.6**	**0.011**
2.1.3 Identify, prioritise, resolve and follow up on medicine-medicine interactions; medicine-disease interactions; medicine-patient interactions; medicines-food interactions	**5**	**15**	**0.004**
2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	16.7	29.3	0.094
2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines	19.4	27.6	0.301
2.3.1 Accurately dispense medicines for prescribed and/or minor ailments, including an embedded checking process	**4.2**	**24.1**	**0.001**
2.3.2 Accurately report defective or substandard medicines to the appropriate authorities.	**5.6**	**17.2**	**0.046**
2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal	**1.4**	**24.1**	**<0.001**

Table 16 (continued)

GbcFv2 Behavioural Statement	'Not Relevant' Ratings (%)		p-value (2-sided)
	Patient Facing (n=72)	**Non-patient Facing** (n=58)	
2.3.4 Dispense devices (e.g. inhaler or a blood glucose meter)	**4.2**	**25.9**	**<0.001**
2.3.5 Document and act upon dispensing errors	**6.9**	**25.9**	**0.004**
2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system	16.7	27.6	0.141
2.3.7 Label the medicines (with the required and appropriate information)	**2.8**	**20.7**	**0.001**
2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors'	**6.9**	**24.1**	**0.011**
2.4.3 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients	**5.6**	**20.7**	**0.014**
2.5.2 Apply therapeutic medicines monitoring and assess impact, and outcomes (including objective and subjective measures)	13.9	22.4	0.25
2.5.3 Identify, prioritise and resolve medicines management problems (including errors)	**2.8**	**20.7**	**0.001**
2.6.1 Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care	16.7	27.6	0.141
2.6.2 Appropriately refer the patient or carer	**6.9**	**20.7**	**0.034**
2.6.3 Assess and diagnose based on objective and subjective measures (where applicable)	13.9	25.9	0.117
2.6.4 Evaluate, assess, and develop health literacy education and counselling on medicines and healthcare needs	12.5	15.5	0.621
2.6.5 Discuss and agree with the patient on the appropriate use of medicines, taking into account patients' preferences	**2.8**	**24.1**	**<0.001**
2.6.6 Document any intervention (e.g. document allergies, such as from medicines and nutrition in the patient medicines history)	12.5	25.9	0.069
2.6.7 Obtain, reconcile, review, maintain and update relevant patient medication and disease history	**9.7**	**27.6**	**0.011**
Cluster 3 Organisation and Management			
3.1.2 Effectively apply and set budgets	16.7	10.3	0.322
3.1.3 Manage appropriate claims for reimbursements	31.9	22.4	0.244
3.1.4 Ensure financial transparency	16.7	15.5	1
3.1.5 Ensure proper reference sources for service reimbursement	31.9	19	0.111
3.2.2 Identify and manage human resources and staffing issues	12.5	15.5	0.621
3.2.3. Recognise and manage the potential of each member of the staff and utilise systems for performance management (e.g. conduct staff appraisals)	13.9	15..5	0.808
3.3.1 Identify and implement new services (according to local needs)	11.1	12.1	1

Table 16 (continued)

GbcFv2 Behavioural Statement	'Not Relevant' Ratings (%)		p-value (2-sided)
	Patient Facing (n=72)	**Non-patient Facing** (n=58)	
3.4.1 Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality	12.5	13.8	1
3.4.2 Develop and implement contingency plans for shortages	15.3	12.1	0.799
3.4.3 Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms	18.1	13.8	0.633
3.4.4 Ensure there is no conflict of interest	18.1	17.2	1
3.4.5 Identify and select reliable supplier(s)	23.6	17.2	0.395
3.4.6 Select reliable supply of high-quality products (including appropriate selection and procurement processes, cost effectiveness, timely delivery)	13.9	12.1	0.8
3.4.7 Supervise procurement activities	25.0	19.0	0.526
3.4.8 Understand the tendering methods and evaluation of tender bids	31.9	17.2	0.069
3.5.2 Verify the accuracy of rolling stocks	15.3	6.9	0.173
3.5.6 Take responsibility for quantification and supply chain forecasting	12.5	8.6	0.576
3.6.3 Ensure the production schedules are appropriately planned and managed	19.4	8.6	0.133
Cluster 4 Professional/Personal			
4.3.3 Where applicable, participate in digital health services that promote health outcomes and engage with digital technologies (e.g. social media platforms & mobile applications) to facilitate discussions with the patient and others	13.9	13.8	1
4.5.3 Document risk management (critical incidents)	12.5	8.6	0.576
4.6.2 Apply the principles of business economics and intellectual property rights including the basics of patient interpretation	**25.0**	**8.6**	**0.02**
4.6.5 Apply the principles of marketing and sales	**26.4**	**12.1**	**0.049**
4.6.7 Recognise the steps needed to bring a medical device or medicine to the market including the safety, quality, efficacy and pharmacoeconomic assessments of the product	20.8	15.5	0.5
4.8.2 Audit quality of service (meet local and national standards and specifications)	18.1	6.9	0.071
4.8.4 Ensure appropriate quality control tests are performed and managed appropriately	**30.6**	**8.6**	**0.002**
4.8.5 Ensure medicines are not counterfeit and adhere to quality standards	13.9	8.6	0.416
4.8.7 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice)	18.1	12.1	0.465
4.8.9 Initiate and implement audit research activities	25.0	13.8	0.128

5.5 Discussion

This is the first study examining the applicability of the second version of the global competency framework in Kenya. The findings suggest that, in general, the pharmacist's perception of relevance of the GbCFv2 to their own practice is high, thus demonstrating strong applicability of the framework to pharmacy practice in Kenya. These findings align with analogous studies from around the globe which similarly demonstrated applicability of the original FIP GbCFv1 (Alfaifi et al., 2022a, Arakawa et al., 2020, Al-Haqan et al., 2021b) and the FIP GbCFv2 (Almaghaslah et al., 2022) in their prospective settings.

A preceding comparable study in Africa by Udoh et al (2018), investigating the applicability of the GbCFv1, also found that pharmacists demonstrated a high agreement on relevance overall (90%). However, as the responses were aggregated from various African countries, a direct comparison to the Kenya-specific context is not possible. Nonetheless, the present research discloses a lower agreement on relevance than reported by Udoh et al (2018). Possible contributing factors to the lower agreement on relevance could be due to shifts in pharmacy practice, disparities between the 1st and 2nd versions of the GbCFv2, or distinct characteristics of the survey samples. This survey was distributed shortly after the release of the GbCFv2 and amid the unprecedented COIVD-19 pandemic, a pivotal time in the landscape of modern healthcare. Consequently, this survey offers a valuable and timely insight in to the contemporary picture of pharmacy practice in Kenya and is one of the few studies globally examining the applicability of the updated version of the GbCF.

In light of the high overall relevance rating (89.4%), a rigorous standard for agreement on relevance was enforced with the intent of thoroughly scrutinising those statements pharmacists' perceived as less relevant to their current practice. These findings serve as a foundation for future research aimed at identifying priority areas for the development of pharmacy education and practice in Kenya. Furthermore, examination of the statements with the lowest proportion of 'relevant' ratings was performed in the second phase of this part of the thesis (Chapter 6) in the development of a Kenyan competency framework for early-career pharmacists.

The second iteration of the FIP GbCF was launched in September 2020 (International Pharmaceutical Federation, 2020b). The World Health Organization declared a COVID-19 pandemic shortly after this on the 11th March 2020 (World Health Organization, 2020). The survey in this study was distributed in the wake of this global health crisis between December 2021 and March 2022. The PPH cluster, receiving the second highest overall proportion of 'relevant' responses, is the smallest cluster of the GbCFv2. Interestingly, all of the statements within this cluster that exhibited disagreement were novel inclusions to the latest version of the global framework and particularly pertinent in the evolving, post-pandemic, landscape of pharmacy. Given the increase in the use of digital technology to deliver healthcare across the globe during the pandemic (Mbunge et al., 2022, Keesara et al., 2020, Abd-Alrazaq et al., 2021), and the vast contribution of the pharmacy workforce to the multidisciplinary

healthcare demands during that time (International Pharmaceutical Federation, 2022c), it is interesting that the statements exhibiting disagreement within the PPC cluster are related to; responding to public health emergencies (statement 1.1.1), assisting healthcare team in emergencies (statement 1.1.2), and supporting the use of digital communication and IT driven health solutions (statement 1.3.3).

Although outside of the scope of this research, possible reasons for the low relevance of the statements in this cluster, despite the post-pandemic timing of this survey, could be due to the specific pharmacy practice environment in Kenya during the COVID-19 pandemic. Research does indicate that pharmacists in Kenya experienced a reduced demand for services at the beginning of the pandemic and a general feeling of disconnect with the national COVID-19 response programme (Mugo et al., 2022). These findings imply potential barriers in pharmacists fulfilling these duties in Kenya, necessitating further research to investigate these issues and identify possible solutions.

Despite the low engagement with these statements from the survey sample, the competencies they signify seem logical inclusions in a competency framework for early career pharmacists in any context. Such disagreements can be instrumental in pinpointing areas of pharmacy practice requiring development. For instance, Almaghaslah et al (2022) used similar applicability survey data to map the 'not relevant' statements to the FIP workforce development goals to identify priorities for pharmacy practice and workforce development in Saudi Arabia. As outlined by the FIP; the aim of the GbCF is not only to contribute to individual career development but also to support national workforce progression (International Pharmaceutical Federation, 2020b). Thus, further research is advocated to identify developmental strategies supporting the acquisition and application of sought-after competencies for Kenya's future pharmacy workforce, achieved through educational and healthcare system reform.

The dissenting statements within the PC cluster pertain to direct patient-care as well as dispensing and compounding-specific behaviours. Therefore, it is not surprising that the results from the statistical association test indicate that the majority of 'not relevant' statements in the PPC cluster are more likely to be rated as 'not relevant' by NPF pharmacists in comparison to their PF counterparts. Moreover, engagement with this cluster exhibited an overall higher frequency among respondents from the individual PF core areas of practice.

Furthermore, it's notable that although the PF group displayed higher agreement on relevance ($p<0.05$) concerning most of the dissenting PC behaviours, the overall level of agreement for this cluster is the lowest of all the GbCFv2 clusters. This observation may arise due to the fact that many of these duties in Kenya are fulfilled by pharmaceutical technologists (Aywak et al., 2017), or it could signify Kenya's alignment with the global shift in pharmacy practice. This transformation involves transitioning from dispensing-oriented services to an increased emphasis on patient-centred clinical duties (Fatherlrahman and Ibrahim, 2018). As pharmacy practice

evolves, with pharmacy technicians increasingly handling more dispensing responsibilities and pharmacists taking on expanded clinical roles, continuous evaluation becomes imperative for adapting to impending changes (Fatherlrahman and Ibrahim, 2018). This adaptability gains particular significance in shaping educational and curricular approaches for undergraduate pharmacy programmes, effectively preparing graduates to meet the evolving demands of pharmacy practice in their early careers.

Also of note in the PC cluster is the low relevance of statement 2.3.6; 'Implement and maintain a dispensing error reporting system and a 'near misses' reporting system', which did not show a significant difference ($p>0.05$) in response according to the patient facing nature of the pharmacists' core area of practice. Studies show that there is an issue with preventable medication errors in the Africa region and that error reporting is inconsistent (Wilson et al., 2012). Furthermore, despite the presence of pharmacovigilance systems and legal support, engagement in error reporting is still low in comparison with global adverse event reporting rates (Barry et al., 2020). These findings may suggest that error reporting systems are not common in pharmacy practice in Kenya, which reinforces the importance of this topic for review to improve practice and ensure patient safety, particularly as similar findings were observed in this region in previous comparable studies (Udoh et al., 2018).

Both the OM and the PPH clusters demonstrated no significant difference between relevance ratings for the PF and NPF groups for the dissenting behavioural statements. Nevertheless, pharmacists from the PF group did more commonly rate these statements in the OM cluster as 'not relevant'. This is particularly evident in 3 of the statements (3.5.2, 3.5.6, 3.6.3), which met the overall parameters for a disagreement in relevance. However, when PF and NPF aggregated responses were examined separately the NPF group actually exhibited an agreement (≥90% of respondents rated the statement as 'relevant'). These statements were related to pharmacy production and supply management, therefore is not a surprising finding given the nature of these behaviours which are more applicable to the NPF industrial and supply chain pharmacy sectors of practice. Conversely, there were 4 statements (3.2.3, 3.3.1, 3.4.1, 3.4.2) in the OM cluster that were more commonly rated as 'relevant' by a small margin of pharmacists from the PF group and these were related to human resources, the implementation of new services and managing adequate quality and quantities of cost-effective medicines.

In a similar investigation in Saudi Arabia involving the latest iteration of the GbCF, the OM cluster and the PC cluster showcased the least substantial overall share of 'relevant' responses (Almaghaslah et al., 2022). These findings also align with previous findings from Japan on the earlier version of the GbCF, where engagement in the OM cluster also does not consistently increase the longer that pharmacists are working in their current core area of practice (Arakawa et al., 2020). However, when examining the dissenting statements more closely they are related to supply,

financial, and human resources management. Likewise to specific behaviours in the PC cluster, the dissenting statements within this cluster pertain to activities that may be performed by other members of the pharmacy workforce. Furthermore, these duties are frequently fulfilled on an organisational rather than an individual level, as evident with aspects of pharmacovigilance in Kenya (Barry et al., 2020). This perspective offers insight in to why certain statements within the OM cluster showed relatively lower engagement. For example, statement 3.1.3, 'Manage appropriate claims for reimbursement', received the lowest percentage of relevant ratings (72.3%) across the entire GbCFv2 and no significant difference was observed in the ratings based on the nature of the pharmacists' area of practice.

As it is common for pharmacists to take on more managerial duties as they progress in their career, a trend of increased engagement in the OM cluster with length or practice would have been a logical expectation. Extra support and training may therefore be needed in relation to the OM competencies to enable pharmacists to progress in their career and achieve an advanced level of practice. This need for expanding competency development beyond the foundational framework level has been recognised globally. The recently developed, and transnationally validated, Global Advanced Competency Development Framework (International Pharmaceutical Federation, 2020a), offers a useful resource for further expansion of competency framework development in Kenya (Meilianti et al., 2023).

The PP cluster exhibits the highest overall 'relevant' ratings thus a strong degree of applicability in Kenya. Interestingly, within the 18.2% of statements from this cluster that show disagreement, the theme of health services utilising digital technology emerges again as a dissenting statement (statement 4.3.3), akin to the observation within the PC cluster. This implies that pharmacy services in Kenya have not extensively adopted technology to support patient care, despite evidence that the potential for growth in this area in Kenya is high (Suzuki et al., 2020). Further research is therefore recommended on barriers to, and strategies for, improved participation in digital pharmacy initiatives in Kenya. This is particularly relevant considering the potential advantages amid broader challenges, including the impact of COVID-19, limited healthcare workforce availability and areas lacking physical infrastructure in the African region (Mbunge et al., 2022, World Health Organization, 2016b, Suzuki et al., 2020).

Another critical aspect for advancing pharmacy practice in Kenya, highlighted by these findings and corroborated by the pan-African study conducted by Udoh et al. (2018), is the necessity for enhanced involvement in research. Irrespective of the patient-facing nature of practice, the survey revealed that statements in the PP cluster relating to research (statements 4.8.7 and 4.8.9) demonstrated disagreement on relevance. Although challenges to pharmacist involvement in research is not unique to Africa (Armour et al., 2007, Awaisu et al., 2015, Fagan et al., 2006), there is also a prevailing scarcity of pharmacy research output from Africa at large as unveiled during the systematic review process outlined in Chapter 3 (McMullen et al., 2023).

Health research and development is currently a priority area in Kenya's wider developmental strategy (Kenya Vision 2030 Delivery Secretariat, 2020). In accordance with these findings, it is evident that the involvement of the pharmacy profession should be included in this strategic vision.

It is important to recognise that with several of the dissenting statements across all clusters, the apparent low engagement by Kenyan pharmacists with these responsibilities in their current roles doesn't diminish the significance of the need for awareness or competence to execute the associated behaviours, particularly within their foundational training. A competency framework serves as an inclusive cornerstone to initiate a pharmacy career. While certain areas may align more closely with their current role and consequently become more or less relevant to pharmacists' practice as time progresses, the establishment of a comprehensive foundation remains paramount. The findings of this study do not definitively establish the ultimate appropriateness of implementing the GbCFv2 in Kenya. However, in conjunction with the subsequent research detailed in Chapter 6, I aim to discern the competencies suitable for integration into a Kenyan competency framework for early-career pharmacists and implement any required adjustments of the GbCFv2 for contextual appropriateness.

This study highlights multiple areas with potential for development In Kenya, contributing to the identification of key priorities for further investigation. Such priorities include, developing a national advanced competency framework, enhancing pharmacy workforce engagement with pharmacovigilance reporting, dedicating efforts to enhancing research capacity and directing resources to bolstering the utilisation of digital technology.

5.6 Limitations

Caution is warranted when interpreting the findings of this study due to several inherent limitations. The small sample size and employment of a snowball sampling method constrain the ability to generalize the results to the whole pharmacist community in Kenya. Consequently, the outcomes might not be fully representative of the entire spectrum of pharmacist perspectives.

Furthermore, the self-completion survey methodology introduces potential sources of bias. Respondents might misconstrue questions or respond in a socially desirable manner, which can distort the accuracy of the data collected. While subjective influences impacting respondents' perspectives are difficult to measure directly, they can undoubtedly affect responses. Additionally, there's the possibility of selection bias, as participants who chose to take part could differ in characteristics from those who did not which can skew the overall findings and conclusions (Fowler, 2009).

The design of the survey itself might have influenced response rates, given the longer time required for completion. Research suggests that response rates tend to decline as survey length increases (Edwards et al., 2004). The effect of this phenomenon was observed by the respondents often not completing cluster 4, resulting in exclusion of

several responses in the final analysis due to incompleteness. This effect could have been mitigated somewhat however if the online survey function available in Qualtrics to 'force response', alerting respondents that they have not completed the section correctly, had been utilised. The online survey format may have excluded individuals without internet access, possibly exacerbated by COVID-19 restrictions during the survey period. Therefore, the survey deadline was extended in an attempt to accommodate the increased demands on the pharmacy workforce in the wake of the pandemic and the potential impact on the reliability of internet, especially for those confined to their homes.

The exclusive reliance on quantitative data limits the depth of insight into participants' rationale for their relevance ratings. While the employed statistical tests unveil associations, they do not uncover causal relationships. A multitude of factors could contribute to pharmacists' individual perceptions regarding the applicability of the GbCFv2 in Kenya. Further work on the nuances and intricacies of these perceptions is advocated and requires qualitative exploration.

5.7 Summary

This study demonstrates an overall strong alignment of Kenyan pharmacists' perceptions with the relevance of the GbCFv2, reflecting its viability for guiding pharmacy practice in the country. The high overall relevance rating laid the foundation for stringent relevance criteria to unveil statements considered less pertinent to current practice. This identification not only informs future research directions but also sets the groundwork for shaping pharmacy education and practice in Kenya. Furthermore, the exploration of statements with limited 'relevant' ratings was carried forward into Chapter 6 to develop a competency framework tailored to early-career Kenyan pharmacists.

Each cluster analysis revealed distinctive facets of the applicability of the GbCFv2 and this study acts as a compass, charting the course for pharmacy practice development in Kenya. It unveils areas of opportunity and not only advances our understanding of Kenya's pharmacy landscape but also contributes to the collective global knowledge shaping the evolution of pharmacy practice paradigms.

5.8 Acknowledgements

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Chapter 6: National Competency Framework Development for Early-Career Pharmacists in Kenya

6.1 Chapter Introduction

The study outlined in this chapter addresses the primary research questions proposed in Chapter 1, specifically ii and iii:

vi. What adjustments are required to adapt the International Pharmaceutical Federation's (FIP) Global Competency Framework version 2 (GbCFv2) to early-career pharmacy practice in Kenya?

vii. Which competencies and behavioural statements should be included in a competency framework for early-career pharmacists in Kenya?

6.2 Aims and Objectives

The aim of this stage of the research is to develop a robust localised competency framework specifically for early-career, also known as foundation-level, pharmacists in Kenya.

The objectives were to:

- Establish an expert panel of Kenyan pharmacy stakeholders to discuss the GbCFv2 behavioural statements and rank their applicability to current, future, and ideal pharmacy practice in Kenya
- Adapt and amend the GbCFv2 behavioural statements to ensure their alignment with the local pharmacy practice in Kenya. This adaptation process will continue until a consensus is reached among the expert panel regarding the inclusion of all behavioural statements in a Kenyan competency framework.
- Create a comprehensive local competency framework tailored to early career pharmacists which will serve as a guide outlining the necessary skills and capabilities for successful pharmacy practice in Kenya.

6.3 Methods

6.3.1 Study Design

A nominal group technique (NGT) method was used a way to measure agreement, resolve disagreement and ultimately achieve consensus on the contents of a Kenyan competency framework for early career pharmacists. There are usually 4 stages to a NGT: silent generation; round robin; clarification; and ranking—conducted via structured questionnaires using Likert scales (Black, 2006). The research participants invited to take part in the NGT are usually experts relevant to the pre-defined topic and are referred to as 'panel members' or 'panelists' (Jones and Hunter, 1995).

For the purposes of this research the relevant experts invited to participate in the NGT were pharmacy practice stakeholders in Kenya. Another important individual in the NGT is the panel moderator, who should have a broad understanding of the topics to be discussed and the intended outcomes of the process (Jones and Hunter, 1995). The moderator's role is to present the consensus measurements, explain the process, facilitate discussion, and ensure that all panelists have fair and equal opportunity to express their views.

In this study a modified NGT (mNGT) was employed where the silent generation and round robin stages are replaced with a survey before face-to-face group meetings (McMillan et al., 2016). This modification allowed for in-depth consideration, by the individual panelists, of each behavioural statement of the existing GbCFv2. In doing this, the GbCFv2 was employed as a baseline tool for creating a locally relevant competency framework.

The mNGT was preferred over other consensus development methods in this context as the direct interaction and discussion can lead to a stronger consensus than other methods performed remotely, such as the Delphi technique (McMillan et al., 2016). Furthermore, during the design phase discussions, research collaborators in Kenya were in general agreement that direct face-to-face interaction would be a more effective and efficient method of communicating to enhance the required debate and discussion needed for this type of research (verbal communication February 2020). The clarification stage of the mNGT in this research was therefore designed as a face-to-face workshop consisting of a consensus development panel (CDP) of local pharmacy stakeholders and took place in Nairobi, Kenya on the 27th April 2022.

6.3.2 Consensus Development Procedure

The mNGT involved a first round of ranking, followed by rounds of clarification and re-ranking. This process is outlined schematically in **Figure 26**. Discussion and clarification (consensus development), followed by re-ranking (consensus measurement) ceased when no further modifications to the behavioural statements were seen.

At the ranking stage in figure 1, panelists were asked to rank their agreement with each of the individual behavioural statements of the GbCFv2, using a 9-point Likert scale, according to whether they should be included in a competency framework for early-career pharmacists in Kenya. Panelists were asked to consider how applicable they thought the statements were to current, ideal and future pharmacy practice, where 1=strongly disagree, 5=neutral, and 9= strongly agree. The reason for asking panelists to consider ideal and future practice is to ensure that the resulting competency framework reflects best practice for early-career pharmacists, and prepares them for their own career progression and for future developments in the profession.

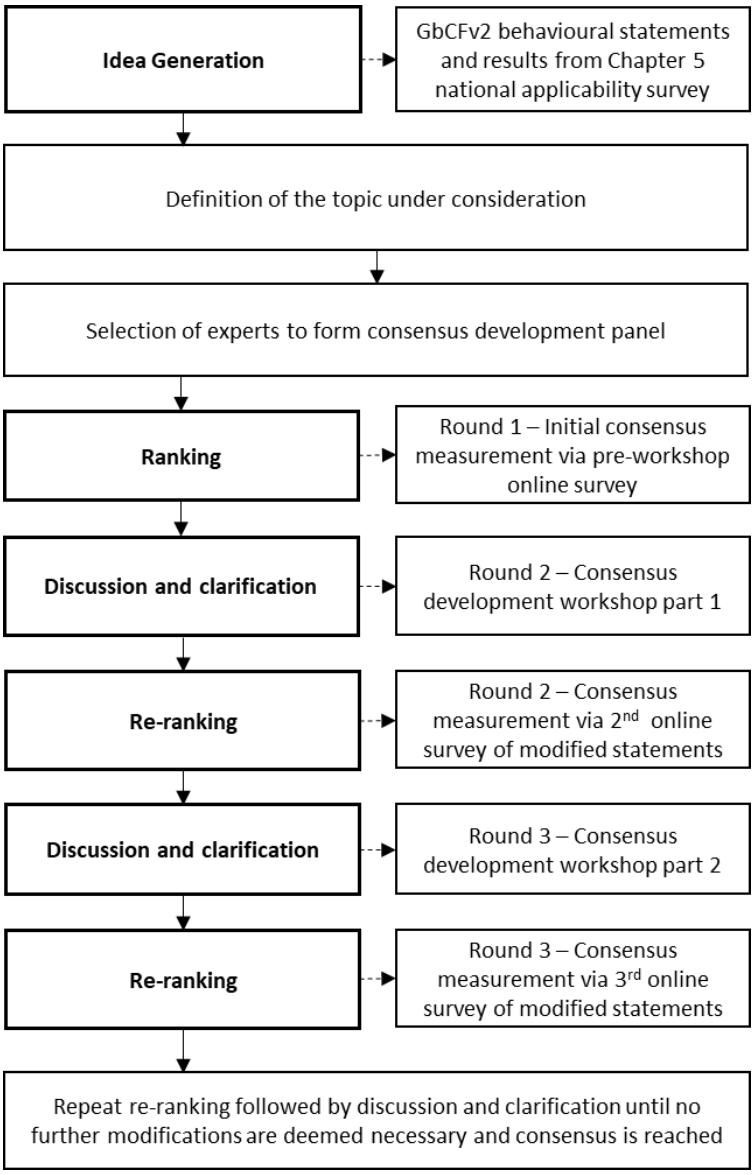

Figure 26 Overview of the modified Nominal Group Technique (mNGT) consensus development process[10]

The consensus measurement surveys used in the ranking and re-ranking stages were designed with Qualtrics online survey software and included a cover sheet with background information and an electronic consent form. The surveys had the same design as the survey in Chapter 4, **Appendix 5**, but a 9-point Likert scale was used this time to provide opportunity for richer detail in the responses on the level of agreement for discussion between panelists in the workshops. Workshop discussions were audio recorded, with consent from the panelists, in case any points needed revisiting for clarification.

[10] Adapted from MCMILLAN, S. S., KING, M. & TULLY, M. P. 2016. How to use the nominal group and Delphi techniques. *International journal of clinical pharmacy,* 38:3**,** 655-662. Reproduced under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/)

Results from the national GbCFv2 applicability survey in Kenya (Chapter 4) were also brought to the group meeting—referred to as the 'consensus development workshop'. These results were the statements, listed in **Appendix 8,** where less than 80% of the respondents ranked them as relevant to their current pharmacy practice. Bringing these statements to the CDP provided an opportunity for the expert panel to consider the perceptions of the general pharmacist population in Kenya, as well as their own perceptions, to encourage further discussion. During these discussions, panelists were asked to consider whether or not these statements would benefit from clarification to enhance their applicability to Kenyan pharmacy practice. Panellists were each provided with a customised form, referred to as a Personalised Panellist Rating Sheet (PPRS)—see example in **Appendix 9,** to facilitate discussion by reminding them of their own response, as well as providing a summary of the group's response to the pre-workshop consensus measurement survey (Fitch et al., 2001).

6.3.3 Sampling

Representatives from the education and health system in Kenya, relevant to pharmacy practice, were invited to form a CDP and attend a workshop in Nairobi, Kenya in April 2022.

Panelists were invited from the following groups:

- Ministry of Health (MoH)
- Pharmaceutical Society of Kenya (PSK)
- Pharmacy & Poisons Board (PPB)
- Industrial pharmacy
- Community pharmacy
- Hospital pharmacy
- Supply chain pharmacy
- Academia
- Pharmacy research body
- Pharmacy Student body (4^{th} or 5^{th} year)

Each panelist was selected via purposive sampling. Kenyan collaborators and the research team accessed their personal networks to select participants for invitation ensuring representation from rural as well as urban backgrounds where possible. Purposive sampling enables the research team to use their judgement to satisfy the specific needs of a project (Robson, 2016), such as the requirement to represent differing settings for pharmacy service provision across Kenya. To ensure that the discussions are manageable and effective within a practical time frame, the maximum amount of participants in a NGT is usually restricted to 12 (Black, 2006). However, an initial aim of 15 panel members was permitted to allow for any participant attrition.

Participation and action from stakeholders with various levels of knowledge, motivation and interest is required to translate the concept of a professional competency framework into action. Overall, a pragmatic approach was applied to achieve an appropriate mix of participants for the consensus development workshop, depending on the accessibility, availability and experience of the participant and in

accordance with researcher judgment. An information sheet with further details of the consensus development procedure, shown in **Appendix 6**, was distributed via email to the initial shortlist of purposively selected participants.

6.3.4 Data Analysis

Survey data was downloaded from Qualtrics into Microsoft Excel 2016 where it was cleaned and descriptive statistical analysis was performed using the Statistical Package for Social Sciences (SPSS), version 27. A score of 1-3 on the Likert scale indicated disagreement, a score of 4-6 indicated neither agreement nor disagreement, and a score of 7-9 indicated agreement. The overall median of the scores for each behavioural statement was used to identify agreement or disagreement, and the interquartile range (IQR) was used to assess the extent of that agreement.

The 9-point Likert scale for the consensus measurement surveys is such that an agreement with a behavioural statement in the GbCF is in the range of points 7-9 on the scale. Therefore, for each statement an overall median score of <7 was set as the a priori parameter for disagreement. However, the pre-workshop survey results showed a high median level of agreement in general across the statements and no statements scored <7. Therefore, to encourage debate and investigate any potential for clarification, all statements scoring a median of <9 were brought to the discussion in the consensus development stages of the mNGT. This provided an opportunity for examination of the statements for fine tuning to a high level of detail. Furthermore, the IQR was used as a measure of variability in the responses and an IQR of >3 was used as a second a priori parameter of disagreement. Additionally, any statement with a score of 1-3 was flagged for discussion. Survey comments and the related statements were also discussed and clarified if necessary. Therefore, the final disagreement parameters for identifying statements for discussion and potential clarification were a median ranking score of <9, an IQR of >3, one or more individual ranking scores between 1-3, and any statements relating to free-typed comments.

Statements were then amended and the surveys were updated accordingly on Qualtrics and subsequently distributed via email to perform the re-ranking stages. For each survey the same disagreement parameters were used to identify statements for discussion and the re-ranking process continued until no further modifications were deemed necessary, signifying that a consensus was reached (McMillan et al., 2016).

6.3.5 Ethical Approval

The Study was approved by the Research Ethics Committee of the School of Pharmacy at the University of Nottingham, UK (approval number 012-2020), and the Jomo Kenyatta University of Agriculture and Technology, Kenya (approval number JKU.IERC/02316/0123) and has been granted a Kenyan research license by the National Commission for Science, Technology & Innovation (license number NACOSTI/P/21/12536).

6.4 Results

6.4.1 Panel Member Demographics

The 9 CDP members consisted of pharmacy practice stakeholders in Kenya from a variety of sectors. A summary of the demographic characteristics of the panelists is displayed in ***Table 17***.

Table 17 Demographic characteristics of the consensus development panel members

Characteristics		Number (n)
Gender	Female	3
	Male	6
Age (years)	<30	2
	30-40	2
	41-50	3
	51-60	1
	61-70	1
Pharmacy Sector	Industry	2
	Community	1
	Hospital	1
	Professional body	1
	Academia	2
	Research	1
	Undergraduate pharmacy student	1
Years of Experience	≤1	2
	1-5	2
	6-10	1
	11-20	3
	>20	1

6.4.2 Consensus Development Process

29 participants were invited to take part in the consensus development process, 13 accepted and 12 completed the pre-workshop survey. Out of those 12 participants, 9 attended the face-to-face consensus development workshop. These remaining 9 participants formed the final CDP and completed all stages of the mNGT. The 3 participants that expressed an interest, but were unable to take part in the final panel were from; the pharmacy regulatory authority (n=1), a county health service authority (n=1), and the Ministry of Health (n=1). Some panelists worked in more than one sector but were asked to indicate their *main* sector of practice, and the number of years of experience in that sector. For example, the undergraduate pharmacy student was currently working an internship in hospital pharmacy and so indicated that as her main sector of practice.

6.4.3 Round 1 Consensus Measurement

The results of the pre-workshop survey are displayed in **Table 18**, where 21 statements fulfilled one or more of the disagreement parameters, including 8 statements from both the Pharmaceutical Care (PC) and Organisation and Management (OM) clusters, 3 from the Pharmaceutical Public Health (PPH) cluster and 2 from the Pharmaceutical Care (PC) cluster.

Table 18 Round 1 consensus measurement results

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
Cluster 1 Pharmaceutical Public Health			
1.1 Emergency response	**1.1.1 Participate in the response to public* health emergencies**	**9**	**3**
	1.1.2 Assist the multidisciplinary healthcare teams in emergency situation*	**9**	**3**
1.2 Health promotion	**1.2.1 Assess the patient's/population's primary healthcare needs (taking into account the cultural and social setting of the patient/populations)**	**8**	**1.5**
	1.2.2 Advise and provide services related to health promotion; disease prevention and control (e.g. vaccination); and healthy lifestyle	9	1
	1.2.3 Identify and support national and local health priorities and initiatives	9	1
1.3 Medicines information and advice	1.3.1 Counsel population on the safe and rational use of medicines and medical devices (including the selection, use, contraindications, storage, and side effects of non-prescription and prescription medicines)	9	0
	1.3.2 Identify sources, retrieve, evaluate, organise, assess and provide relevant medicines information according to the needs of patients and clients	9	0
	1.3.3 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	9	1.5
Cluster 2 Pharmaceutical Care			
2.1 Assessment of medicines	2.1.1 Gather, analyse, research, and interpret information about the patient and patient's medicines-related needs (e.g. indication, effectiveness, safety and adherence)	9	2
	2.1.2 Retrieve relevant patient information (including drug history, or immunisation status for example) and record of allergies to medicines and Adverse Drug Reactions (ADR) in medication record.	9	0.5
	2.1.3 Identify, prioritise, resolve and follow up on medicine-medicine interactions; medicine-disease interactions; medicine-patient interactions; medicines-food interactions	9	0.5
	2.1.4 Appropriately select medicines (e.g. according to the patient, hospital, government policy, etc.)	9	0

NB Behavioural statements showing a disagreement are highlighted in bold
*these statements received one individual rating each of 1-3 shown in Appendix 9

Table 18 (continued)

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	9	1.5
	2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines	9	0.5
2.3 Dispensing	2.3.1 Accurately dispense medicines for prescribed and/or minor ailments, including an embedded checking process	9	1
	2.3.2 Accurately report defective or substandard medicines to the appropriate authorities.	9	1
	2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal	9	1
	2.3.4 Dispense devices (e.g. inhaler or a blood glucose meter)	9	1
	2.3.5 Document and act upon dispensing errors	9	0.5
	2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system	**8**	**1.5**
	2.3.7 Label the medicines (with the required and appropriate information)	9	1
	2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors'	9	1.5
2.4 Medicines	2.4.1 Advise patients on proper storage conditions of the medicines and ensure that medicines are stored appropriately (e.g. humidity, temperature, expiry date, etc.)	9	0
	2.4.2 Appropriately select medicine formulation and concentration for minor ailments (e.g. diarrhoea, constipation, cough, hay fever, insect bites, etc.)	9	0.5
	2.4.3 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients	9	0
	2.4.4 Package medicines to optimise safety (ensuring appropriate re- packaging and labelling of the medicines)	9	0
2.5 Monitor medicines therapy	2.5.1 Apply guidelines, medicines formulary system, protocols and treatment pathways	9	0
	2.5.2 Apply therapeutic medicines monitoring and assess impact, and outcomes (including objective and subjective measures)	9	0.5
	2.5.3 Identify, prioritise and resolve medicines management problems (including errors)	9	0.5
2.6 Patient consultation and diagnosis	2.6.1 Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care	9	1.5

NB Behavioural statements showing a disagreement are highlighted in bold

Table 18 (continued)

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
2.6 Patient consultation and diagnosis	2.6.1 Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care	9	1.5
	2.6.2 Appropriately refer the patient or carer	9	1
	2.6.3 Assess and diagnose based on objective and subjective measures (where applicable)	**8**	**2**
	2.6.4 Evaluate, assess, and develop health literacy education and counselling on medicines and healthcare needs	9	0.5
	2.6.5 Discuss and agree with the patient on the appropriate use of medicines, taking into account patients' preferences	9	0
	2.6.6 Document any intervention (e.g. document allergies, such as from medicines and nutrition in the patient medicines history)	9	0.5
	2.6.7 Obtain, reconcile, review, maintain and update relevant patient medication and disease history	9	1.5
Cluster 3 Organisation and Management			
3.1 Budget and reimbursement	3.1.1 Acknowledge the organisational structure	9	2
	3.1.2 Effectively apply and set budgets	**8**	**2**
	3.1.3 Manage appropriate claims for reimbursements	**8**	**4**
	3.1.4 Ensure financial transparency	9	1.5
	3.1.5 Ensure proper reference sources for service reimbursement	**9**	**3.5**
3.2 Human resources management	3.2.1 Demonstrate organisational and management skills (e.g. plan, organise and lead on medicines management, risk management, self-management, time management, people management, project management, policy management)	9	1.5
	3.2.2 Identify and manage human resources and staffing issues	**8**	**2**
	3.2.3. Recognise and manage the potential of each member of the staff and utilise systems for performance management (e.g. conduct staff appraisals)	9	2
	3.2.4. Recognise the value of pharmacy team and of a multidisciplinary team	9	1
	3.2.5 Support and facilitate staff training and continuing professional development	9	2
3.3 Improvement of service	3.3.1 Identify and implement new services (according to local needs)	9	1.5
	3.3.2 Resolve, follow up and prevent medicines related problems	9	0
3.4 Procurement	3.4.1 Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality	9	1

NB Behavioural statements showing a disagreement are highlighted in bold

Table 18 (continued)

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
	3.4.2 Develop and implement contingency plans for shortages	9	1
	3.4.3 Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms	9	1
	3.4.4 Ensure there is no conflict of interest	9	2
	3.4.5 Identify and select reliable supplier(s)	**8**	**1.5**
	3.4.6 Select reliable supply of high-quality products (including appropriate selection and procurement processes, cost effectiveness, timely delivery)	9	1.5
	3.4.7 Supervise procurement activities	**7**	**2**
	3.4.8 Understand the tendering methods and evaluation of tender bids	**8**	**1.5**
3.5 Supply chain and management	3.5.1 Demonstrate knowledge in store medicines to minimise errors and maximise accuracy	9	1
	3.5.2 Verify the accuracy of rolling stocks	9	1.5
	3.5.3 Ensure effective stock management and running of service with the dispensary	9	1
	3.5.4 Ensure logistics of delivery and storage	9	1.5
	3.5.5 Implement a system for documentation and record Keeping	9	1
	3.5.6 Take responsibility for quantification and supply chain forecasting	9	1.5
3.6 Workplace management	3.6.1 Address and manage day to day management issues	9	1.5
	3.6.2 Demonstrate the ability to take accurate and timely decisions and make appropriate judgements	9	1
	3.6.3 Ensure the production schedules are appropriately planned and managed	**8**	**1.5**
	3.6.4 Ensure the work time is appropriately planned and managed	9	1.5
	3.6.5 Improve and manage the provision of pharmaceutical services	9	1
	3.6.6 Recognise and manage pharmacy resources (e.g. financial, infrastructure)	9	1.5
Cluster 4 Professional/Personal			
4.1 Communication skills	4.1.1 Communicate clearly, precisely and appropriately while being a mentor or tutor	9	0
	4.1.2 Communicate effectively with health and social care staff, support staff, patients, carer, family relatives and clients/customers, using lay terms and checking understanding	9	0

NB Behavioural statements showing a disagreement are highlighted in bold

Table 18 (continued)

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
	4.1.3 Tailor communication that is appropriate to the patient's needs (including health literacy, cultural or language barriers, social needs, and emotional status)	9	0.5
	4.1.4 Use appropriate communication skills (e.g. verbal and non-verbal) to establish and maintain rapport with the patient and others including when communicating through digital and electronic platforms	9	1
4.2 Continuing Professional Development (CPD)	4.2.1 Document CPD activities	9	1.5
	4.2.2 Engage with students/interns/residents	9	0.5
	4.2.3 Evaluate accuracy of knowledge and skills	9	1
	4.2.4 Identify learning and development needs	9	1.5
	4.2.5 Evaluate learning and development progress	9	1.5
	4.2.6 Identify if expertise is needed outside current scope of knowledge	9	1.5
	4.2.7 Recognise own limitations and act upon them	9	1
	4.2.8 Reflect on performance	9	1.5
	4.2.9 Demonstrate engagement/ participation in professional development and lifelong learning activities	9	1
4.3 Digital literacy	**4.3.1 Identify, manage, organise, store, and share digital information**	**8**	**2.5**
	4.3.2 Critically appraise, analyse, evaluate, and/or interpret digital information and their sources	**8**	**1.5**
	4.3.3 Where applicable, participate in digital health services that promote health outcomes and engage with digital technologies (e.g. social media platforms & mobile applications) to facilitate discussions with the patient and others	9	1
	4.3.4 Maintain patient privacy and security of digital information related to the patient and workplace	9	2
4.4 Interprofessional collaboration	4.4.1 Respect and acknowledge the expertise, roles and responsibilities of colleagues and other health professionals	9	1
	4.4.2 Participate, collaborate, advise in therapeutic decision-making, and use appropriate referral in a multi-disciplinary team	9	0
	4.4.3 Engage in collaborative practice, research and service provision to optimise patient health outcomes	9	0

NB Behavioural statements showing a disagreement are highlighted in bold

Table 18 (continued)

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
	4.4.4 Engage in relationship-building with health professionals allowing conflict resolution, teamwork, communication, and consultation	9	0
	4.4.5 Demonstrate mutual respect and adopt shared values of the workplace and toward patient care	9	0
4.5 Leadership and self-regulation	4.5.1 Apply assertiveness skills (inspire confidence)	9	0.5
	4.5.2 Demonstrate leadership and practice management skills, initiative and efficiency	9	1
	4.5.3 Document risk management (critical incidents)	9	1.5
	4.5.4 Prioritise work, practice punctuality and time management	9	1
	4.5.5 Develop, implement and monitor innovative ideas	9	2
	4.5.6 Recognise and describe emotional information about self and others (e.g. self-awareness, self-regulation, motivation, social skills and empathy)	9	1
	4.5.7 Demonstrate flexibility and adaptability to a variety of conditions and circumstances	9	1
	4.5.8 Recognise when affected by setback or stress and manage with effective coping strategies (resilience)	9	1
4.6 legal and regulatory practice	4.6.1 Apply regulatory affairs and the key aspects of pharmaceutical registration and legislation	9	1
	4.6.2 Apply the principles of business economics and intellectual property rights including the basics of patient interpretation	**8**	**2**
	4.6.3 Be aware of and identify the new medicines coming to the market	9	1.5
	4.6.4 Comply with legislation for drugs with the potential for abuse	9	0.5
	4.6.5 Apply the principles of marketing and sales	**8**	**2**
	4.6.6 Engage with health and medicines policies	9	1.5
	4.6.7 Recognise the steps needed to bring a medical device or medicine to the market including the safety, quality, efficacy and pharmacoeconomic assessments of the product	9	1.5
4.7 Professional and ethical practice	4.7.1 Demonstrate awareness and employment of local/national codes of ethics	9	1
	4.7.2 Fulfil duty of care to the patient and the public	9	0
	4.7.3 Maintain privacy and confidentiality (with the patient and other healthcare professionals)	9	1

NB Behavioural statements showing a disagreement are highlighted in bold

Table 18 (continued)

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
	4.7.4 Comply with patient privacy legislation including documentation of information	9	1
	4.7.5 Consider available evidence and support the patient to make informed choices about medicine use	9	0
	4.7.6 Obtain patient consent (it can be implicit on occasion)	9	0.5
	4.7.7 Recognise professional limitations of self and others in the team	9	1
	4.7.8 Demonstrate professional responsibility for all decisions made and actions taken	9	0.5
	4.7.9 Demonstrate awareness of socially accountable practice (including cultural and social needs; cultural safety, respect, and responsiveness; diversity, equity and inclusiveness)	9	1
4.8 Quality assurance and research in the workplace	4.8.1 Apply research findings and understand risk-benefit analyses (e.g. pre-clinical, clinical trials, experimental clinical pharmacological research, and risk management)	9	2
	4.8.2 Audit quality of service (meet local and national standards and specifications)	**8**	**1**
	4.8.3 Develop and implement Standard Operating Procedures (SOPs)	**8**	**2**
	4.8.4 Ensure appropriate quality control tests are performed and managed appropriately	**8**	**2.5**
	4.8.5 Ensure medicines are not counterfeit and adhere to quality standards	9	1
	4.8.6 Identify and evaluate evidence-base to improve the use of medicines and services	9	1
	4.8.7 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice)	9	2
	4.8.8 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)	9	1
	4.8.9 Initiate and implement audit research activities	**8**	**2**

NB Behavioural statements showing a disagreement are highlighted in bold

6.4.4 Round 2 Consensus Development

Round 2 commenced with panel discussions with the results from round 1 along with results from the national GbCFv2 applicability survey. The behavioural statements that were brought to the CDP to stimulate further discussion from the national GbCFv2 applicability survey are listed in **Appendix 8**. There were three statements; 2.3.6, 3.1.3, and 3.4.8 flagged for discussion by the panel which also showed a low relevance ranking in the national survey (Chapter 5).

After the consensus development process in round 2, panelists opted to keep the text of 118 of the statements the same as the original GbCFv2. A total of 20 changes were made including new statements (n=2), re-wording statements (n=5), re-ordering statements (n=11), and moving statements to different competency clusters (n=2). To improve the framework's applicability to Kenyan practice, the panel discussed statements in detail and agreed upon amendments which were made to 5 of the existing behavioural statements (4.8.5, 4.6.6, 3.1.3, 2.6.3, and 2.3.2) and 2 new statements were added in positions 1.3.2, and 2.4.2. These new statements were added by the panel to expand the current statements pertaining to the disposal of medicines and devices, as it was deemed relevant to specify that disposal should be safe for both people *and* the environment. The addition of the environmental aspect of the disposal of medicines and devices was relevant both in advising patients in the PPH cluster (statement 1.3.2), and also for the pharmacists' own handling of waste in the PC cluster (statement 2.4.2).

The order of some of the statements were also changed to keep related statements together in succession within the framework (2.3.2, 3.1.5, and 3.1.4). Furthermore, these changes resulted in the overall movement of some of the other statements which subsequently had to be re-numbered (1.3.2, 1.3.3, 2.4.2, 2.4.3, 2.4.4, 4.8.6, 4.8.8, 4.8.9, and 4.8.10). Panelists also deemed it necessary to rename the 'Dispensing' competency group to, 2.3 'Dispensing/Prescription Processing' to clarify the remit of this category of statements. All amendments are summarised in **Table 19,** where any changes are underlined, and any new statements added are italicised.

The panelists agreed that the wording needed to be slightly adjusted on statement 2.3.2 as the use of the word 'substandard' also applies defective medicines. However, falsified medicines and products were identified as a problem for pharmacists in Kenya and so it was felt that it is important to distinguish between falsified and substandard medicines. Statement 2.3.2 was therefore clarified to; 'Report falsified or substandard medicines to the appropriate authorities'. This is when panelists also agreed to move this statement to cluster 4 as part of the quality assurance competency and place it with the related original statement in position 4.8.5; 'Ensure medicines are not counterfeit and adhere to quality standards'. This statement was subsequently adjusted to compliment the amended statement, moved from 2.3.2 to 4.8.6, and changed to; 'Identify falsified and substandard medicines and adhere to quality standards'. The intention being to reflect that both the identification *and* reporting of falsified medicines is paramount to pharmacy practice in Kenya.

For statement 2.3.6; 'Assess and diagnose based on objective and subjective measures (where applicable)', panelists felt it was prudent to clarify the importance of pharmacists working only within their appropriate scope of practice and the statement was therefore amended to this effect as shown in **Table 19**. Clarification for statement 3.1.3 was deemed necessary in relation to what the statement was referring to in terms of reimbursement, and so the addition of the wording; 'of health

products and technologies, and pharmaceutical care services' was added to the original statement of; 'Manage appropriate claims for reimbursements'. Finally statement 4.6.6 caused some controversy as panelists were unsure of the exact meaning of this statement and so the phrasing was changed from; 'Engage with health and medicines policies' to; 'Be aware of and engage with health and medicines policies'. The panellist felt that this wording would be clearer to early-career pharmacists in Kenya.

Following the round 2 consensus development workshop, the statements that were amended were then redistributed to the panelists to re-rank via a second online consensus measurement survey prior to a refreshment break and the commencement of round 3.

Table 19 Amendments to the behavioural statements during round 2 consensus development

Competency Group	Original GbcFv2 Behavioural Statements	Amendment
Cluster 1 Pharmaceutical Public Health		
1.3 Medicines Information and Advice		New statement added in position 1.3.2 to cover safe disposal aspects of medicines information and advice: 1.3.2 *Advise patients on the safe and environmentally friendly disposal of medicines and devices*
	1.3.2 Identify sources, retrieve, evaluate, organise, assess and provide relevant medicines information according to the needs of patients and clients	Change to 1.3.3
	1.3.3 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	Change to 1.3.4
Cluster 2 Pharmaceutical Care		
2.3 Dispensing	Original competency group title: 2.3 Dispensing	Change to differentiate between dispensing and processing prescriptions: 2.3 Dispensing/<u>Prescription Processing</u>
	2.3.2 Accurately report defective or substandard medicines to the appropriate authorities.	Change wording and move to quality assurance competency group, cluster 4: 4.8.6 Report <u>falsified</u> or substandard medicines to the appropriate authorities.
2.4 Medicines		New statement added: 2.4.2 *Appropriately dispose of medicines and devices in a safe and environmentally friendly manner.*

NB modifications to original statements are underlined, and any new statements added are italicised

Table 19 (continued)

Competency Group	Original GbcFv2 Behavioural Statements	Amendment
	2.4.2 Appropriately select medicine formulation and concentration for minor ailments (e.g. diarrhoea, constipation, cough, hay fever, insect bites, etc.)	Change to 2.4.3
	2.4.3 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients	Change to 2.4.4
	2.4.4 Package medicines to optimise safety (ensuring appropriate re-packaging and labelling of the medicines)	Change to 2.4.5
2.6 Patient consultation and diagnosis	2.6.3 Assess and diagnose based on objective and subjective measures (where applicable)	Change to include scope of practice: 2.6.3 Assess and diagnose <u>within appropriate scope of practice</u> based on objective and subjective measures (where applicable)
Cluster 3 Organisation and Management		
3.1 Budget and reimbursement	3.1.3 Manage appropriate claims for reimbursements	Change wording to clarify activities for reimbursement: 3.1.3 Manage appropriate claims for reimbursements <u>of health products and technologies, and pharmaceutical care services</u>
	3.1.4 Ensure financial transparency	Move to 3.1.5
	3.1.5 Ensure proper reference sources for service reimbursement	Move to 3.1.4, as related to 3.1.3
Cluster 4 Professional/Personal		
4.6.Legal and regulatory practice	4.6.6 Engage with health and medicines policies	Wording change to emphasise need to be familiar with policies and engage with them: *4.6.6 <u>Be aware of and</u>* engage with health and medicines policies
4.8 Quality assurance and research in the workplace	4.8.5 Ensure medicines are not counterfeit and adhere to quality standards	Change to: <u>4.8.5 Identify falsified and substandard medicines and adhere to quality standards</u> Statement moved from 2.3.2 and added to position 4.8.6 to keep relevant statements together but keep separate to emphasise importance of identifying *and* reporting falsified and substandard medicines: 4.8.6 *Report falsified and substandard medicines to relevant authority*

NB modifications to original statements are underlined, and any new statements added are italicised

Table 19 (continued)

Competency Group	Original GbcFv2 Behavioural Statements	Amendment
	4.8.6 Identify and evaluate evidence-base to improve the use of medicines and services	Change to 4.8.7
	4.8.7 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice)	Change to 4.8.8
	4.8.8 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)	Change to 4.8.9
	4.8.9 Initiate and implement audit research activities	Change to 4.8.10

NB modifications to original statements are underlined, and any new statements added are italicised

6.4.5 Round 2 Consensus Measurement

The round 2 consensus measurement survey showed that a quantitative consensus was reached as all re-ranked statements achieved a ranking score of 9 and an IQR ≤1, as shown in **Table 20**.

Table 20 Round 2 consensus measurement results

Competency Group	Original GbcFv2, or Round 2 Amended Behavioural Statements	Median Agreement Score	Interquartile Range (IQR)
Cluster 1 Pharmaceutical Public Health			
1.3 Medicines information and advice	1.3.2 Advise patients on the safe and environmentally friendly disposal of medicines and devices	9	0
	1.3.3 Identify sources, retrieve, evaluate, organise, assess and provide relevant medicines information according to the needs of patients and clients	9	1
	1.3.4 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	9	0
Cluster 2 Pharmaceutical Care			
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	9	0
	2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines	9	0

Table 20 (continued)

Competency Group	Original GbcFv2, or Round 2 Amended Behavioural Statements	Median Agreement Score	Interquartile Range (IQR)
2.3 Dispensing/ Prescription Processing	2.3.1 Accurately dispense medicines for prescribed and/or minor ailments, including an embedded checking process	9	0
	2.3.2 Report falsified or substandard medicines to the appropriate authorities.	9	0
	2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal	9	0
	2.3.4 Dispense devices (e.g. inhaler or a blood glucose meter)	9	0
	2.3.5 Document and act upon dispensing errors	9	0
	2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system	9	0
	2.3.7 Label the medicines (with the required and appropriate information)	9	0
	2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors'	9	0
2.4 Medicines	2.4.1 Advise patients on proper storage conditions of the medicines and ensure that medicines are stored appropriately (e.g. humidity, temperature, expiry date, etc.)	9	0.5
	2.4.2 Appropriately dispose of medicines and devices in a safe and environmentally friendly manner.	9	0
2.6 Patient consultation and diagnosis	2.6.3 Assess and diagnose within appropriate scope of practice based on objective and subjective measures (where applicable)	9	0.5
Cluster 3 Organisation and Management			
3.1 Budget and reimbursement	3.1.2 Effectively set and apply budgets	9	0
	3.1.3 Manage appropriate claims for reimbursements of health products and technologies, and pharmaceutical care services	9	0
	3.1.4 Ensure the use of appropriate reference sources for service reimbursement	9	0
	3.1.5 Ensure financial transparency	9	0
3.4 Procurement	3.4.8 Understand the tendering methods and evaluation of tender bids	9	0
Cluster 4 Professional/Personal			
4.6 Legal and regulatory practice	4.6.6 Be aware of and engage with health and medicines policies	9	0
4.8 Quality assurance and research in the workplace	4.8.5 Identify falsified and substandard medicines and adhere to quality standards	9	0
	4.8.6 Report falsified and substandard medicines to relevant authority	9	0
	4.8.9 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)	9	0

Despite the survey results suggesting a statistical consensus, according to the a priori parameters, there were a number of free-typed comments which are displayed in **Table 21**, suggesting that further clarifications were necessary. Hence, a 3rd round of consensus development was held to fine tune any behavioural statements with comments.

Table 21 List of panellist comments from the round 2 consensus measurement survey

Competency Group	Original GbcFv2, or Round 2 Amended Behavioural Statements	Comments
Cluster 1 Pharmaceutical Public Health		
1.3 Medicines Information and Advice	1.3.4 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	*"Making sure to include those without access to smart phones"*
Cluster 2 Pharmaceutical Care		
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	*"Include the conjunction 'and' in the behaviour statement 2.2.1"*
2.3 Dispensing/ Prescription Processing	2.3.1 Accurately dispense medicines and medical devices (e.g. inhaler or a blood glucose meter) for prescribed and/or minor ailments, including an embedded checking process	*"Pharmacist may prescribe prescription only on special circumstances"*
	2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal	*"Language not clear"*
2.4 Medicines	2.4.1 Advise patients on the appropriate storage of medicines and medical devices (e.g. humidity, temperature, expiry date, etc.)	*"The statement is compounded and unclear"*
Cluster 3 Organisation and Management		
3.1 Budget and reimbursement	3.1.4 Ensure the use of appropriate reference sources for service reimbursement	*"Adjust behaviour 3.1.4 to Ensure the use of appropriate reference sources for reimbursements (e.g. health products and technologies, pharmaceutical care services). The current statement refers to the reimbursement of services only"*
Cluster 4 Professional/Personal		
4.8 Quality assurance and research in the workplace	4.8.9 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)	*"4.8.9 Could read "Identify and report adverse drug reactions and other unexpected drug effects". This is because a PV* system would usually encompass 4.8.6" (Report falsified and substandard medicines to relevant authority)*

*PV = pharmacovigilance

6.4.6 Round 3 Consensus Development

Changes were made to 8 statements (2.2.1, 2.3.1, 2.3.3, 2.3.7, 2.4.1, 2.6.3, 3.1.4, and 4.6.6) in the round 3 consensus development workshop which were either original statements, or those amended in the previous round. There was 1 statement that was removed (2.3.4) and incorporated elsewhere (into 2.3.1), and there were 6 statements that moved position and were re-numbered as a result (2.3.2, 2.3.2, 2.3.5, 2.3.6, 2.3.7, 2.3.8). The competency group that was changed in the previous round to 2.3 'Dispensing/Prescription Processing' was also further amended to 'Prescription processing and dispensing'. A summary of the statements amended in round 3 are shown in **Table 22**.

Statement 4.6.6, was discussed at length in the previous round in terms of how best to word it to reflect pharmacists' involvement with both *following* policies and *informing* policy development. Subsequently, this statement was further amended to 'Engage with the development and improvement of health and medicines policies'. Panelists felt that using policies was already covered by the PC and OM clusters under original statements 2.1.4 and 3.2.1, and that it is important for Kenyan pharmacists to be able to not only use existing policies but also contribute to developing or improving new ones. Hence, it was agreed that this distinction should be reflected in the new wording of this statement.

Table 22 Amendments to the behavioural statements during round 3 consensus development

Competency Group	Original GbcFv2, or Round 2 Amended Behavioural Statements	Amendment
Cluster 2 Pharmaceutical Care		
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	Change wording to: 2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), <u>and</u> determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)
2.3 Dispensing	Round 2 amended competency group title: 2.3 Dispensing/Prescription Processing	Change to: 2.3 <u>Prescription processing and</u> dispensing
	2.3.1 Accurately dispense medicines for prescribed and/or minor ailments, including an embedded checking process	Change to combine with 2.3.4 devices: 2.3.1 Accurately dispense medicines <u>and medical devices (e.g. inhaler or a blood glucose meter)</u> for prescribed and/or minor ailments, including an embedded checking process
	2.3.2 Accurately report falsified or substandard medicines to the appropriate authorities.	Move 2.3.2 to position 4.8.6 to group with more relevant statements

NB modifications to original statements are underlined

Table 22 (continued)

Competency Group	Original GbcFv2, or Round 2 Amended Behavioural Statements	Amendment
	2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal	Wording and number change position to 2.3.2: 2.3.2 Validate prescriptions, ensuring that they are correctly interpreted and legal
	2.3.4 Dispense devices (e.g. inhaler or a blood glucose meter)	Remove and incorporate into 2.3.1
	2.3.5 Document and act upon dispensing errors	Change to 2.3.3
	2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system	Change to 2.3.4
	2.3.7 Label the medicines (with the required and appropriate information)	Change to 2.3.6 and remove brackets
	2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors'	Move to 2.3.5 as related to original 2.3.5 and 2.3.6 (now 2.3.3 and 2.3.4)
2.4 Medicines	2.4.1 Advise patients on proper storage conditions of the medicines and ensure that medicines are stored appropriately (e.g. humidity, temperature, expiry date, etc.)	Change wording to: 2.4.1 Advise patients on appropriate storage of the medicines and medical devices (e.g. humidity, temperature, expiry date, etc.)
2.6 Patient consultation and diagnosis	2.6.3 Assess and diagnose within appropriate scope of practice based on objective and subjective measures (where applicable)	Change to include prescribing: 2.6.3 Assess, diagnose, and prescribe within appropriate scope of practice based on objective and subjective measures (where applicable)
Cluster 3 Organisation and Management		
3.1 Budget and reimbursement	3.1.4 Ensure the use of appropriate reference sources for service reimbursement	Change to differentiate between reimbursement of services and products: 3.1.4 Ensure the use of appropriate reference sources for reimbursement of health products and technologies, and pharmaceutical care services.
Cluster 4 Professional/Personal		
4.6 Legal and regulatory practice	*4.6.6 Be aware of and* engage with health and medicines policies	Clarify to emphasise the continued input into improving policies: 4.6.6 Engage with the development and improvement of health and medicines policies (2.1.4 and 3.2.1 cover using the policies)

NB modifications to original statements are underlined

6.4.7 Round 3 Consensus Measurement

The behavioural statements amended in the consensus development discussion were distributed to the 9 panelists and re-ranked, these results are summarised in **Table 23**. The round 3 consensus measurement survey results did not show any further quantitative disagreements, as per the a priori parameters, and there were no qualitative comments that required clarification. All panelists ranked each behavioural statement in this round as 9 ('strongly agree') with an IQR of zero and therefore a consensus was reached and the consensus development workshop was terminated.

Table 23 Round 3 consensus measurement results

Competency Group	GbcFv2 Behavioural Statement	Median Agreement Score	Interquartile Range (IQR)
Cluster 2 Pharmaceutical Care			
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	9	0
2.3 Prescription processing and dispensing	2.3.1 Accurately dispense medicines and medical devices (e.g. inhaler or a blood glucose meter) for prescribed and/or minor ailments, including an embedded checking process	9	0
	2.3.2 Validate prescriptions, ensuring that they are correctly interpreted and legal	9	0
	2.3.5 Learn from and act upon previous 'near misses' and 'dispensing errors'	9	0
	2.3.6 Label the medicines with the required and appropriate information	9	0
2.4 Medicines	2.4.1 Advise patients on appropriate storage of the medicines and medical devices (e.g. humidity, temperature, expiry date, etc.)	9	0
2.6 Patient consultation and diagnosis	2.6.3 Assess, diagnose, and prescribe within appropriate scope of practice based on objective and subjective measures (where applicable)	9	0
Cluster 3 Organisation and Management			
3.1 Budget and reimbursement	3.1.3 Manage appropriate claims for reimbursements of health products and technologies, and pharmaceutical care services	9	0
	3.1.4 Ensure the use of appropriate reference sources for reimbursement of health products and technologies, and pharmaceutical care services.	9	0
Cluster 4 Professional/Personal			
4.6 Legal and regulatory practice	4.6.6 Engage with the development and improvement of health and medicines policies	9	0
4.8 Quality assurance and research in the workplace	4.8.8 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)	9	0

The final national competency framework for early career pharmacists developed in this study is displayed in **Table 24**. Amendments have been marked in this table and statements/competency titles highlighted in bold. The resulting framework has a total of 124 behavioural statements. Amendments included those that were purposely moved to better connect related statements together or moved to combine it with another statement, as is the case with original statement 2.3.4 which was combined with statement 2.3.1. Other amendments include; major wording changes, minor amendments (e.g. grammatical), new statements, and re-numbering of statements due to previous amendments to surrounding statements.

Overall, the majority of amendments occurred in the PC cluster (n=16), followed by the PP cluster (n=8), the OM cluster (n=4), and finally the PPH cluster (n=3). The most common amendment was re-numbering (n=14), followed by major wording changes (n=8), moved statements (n=4), new statements (n=2), minor grammatical changes (n=2) and finally competency group title re-wording (n=1).

Table 24 Localised Kenyan competency framework for early-career pharmacists

Competency Group	Behavioural Statement
Cluster 1 Pharmaceutical Public Health	
1.1 Emergency response	1.1.1 Participate in the response to public health emergencies
	1.1.2 Assist the multidisciplinary healthcare teams in emergency situation
1.2 Health promotion	1.2.1 Assess the patient's/population's primary healthcare needs (taking into account the cultural and social setting of the patient/populations)
	1.2.2 Advise and provide services related to health promotion; disease prevention and control (e.g. vaccination); and healthy lifestyle
	1.2.3 Identify and support national and local health priorities and initiatives
1.3 Medicines information and advice	1.3.1 Counsel population on the safe and rational use of medicines and medical devices (including the selection, use, contraindications, storage, and side effects of non-prescription and prescription medicines)
	1.3.2 Advise patients on the safe and environmentally friendly disposal of medicines and devices[a]
	1.3.3 Identify sources, retrieve, evaluate, organise, assess and provide relevant medicines information according to the needs of patients and clients[b]
	1.3.4 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)[b]
Cluster 2 Pharmaceutical Care	
2.1 Assessment of medicines	2.1.1 Gather, analyse, research, and interpret information about the patient and patient's medicines-related needs (e.g. indication, effectiveness, safety and adherence)
	2.1.2 Retrieve relevant patient information (including drug history, or immunisation status for example) and record of allergies to medicines and Adverse Drug Reactions (ADR) in medication record.
	2.1.3 Identify, prioritise, resolve and follow up on medicine-medicine interactions; medicine-disease interactions; medicine-patient interactions; medicines-food interactions

a=new statement; b=re-numbered statement; c=minor amendment; d=major wording change; e=moved statement

Table 24 (continued)

Competency Group	Behavioural Statement
	2.1.4 Appropriately select medicines (e.g. according to the patient, hospital, government policy, etc.)
2.2 Compounding medicines	**2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), and determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)[c]**
	2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines
2.3 Prescription processing and dispensing[d]	**2.3.1 Accurately dispense medicines and medical devices (e.g. inhaler or a blood glucose meter) for prescribed and/or minor ailments, including an embedded checking process[de]**
	2.3.2 Validate prescriptions, ensuring that they are correctly interpreted and legal[bd]
	2.3.3 Document and act upon dispensing errors[b]
	2.3.4 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system[b]
	2.3.5 Learn from and act upon previous 'near misses' and 'dispensing errors'[e]
	2.3.6 Label the medicines with the required and appropriate information[bc]
2.4 Medicines	**2.4.1 Advise patients on appropriate storage of the medicines and medical devices (e.g. humidity, temperature, expiry date, etc.)[d]**
	2.4.2 Appropriately dispose of medicines and devices in a safe and environmentally friendly manner.[a]
	2.4.3 Appropriately select medicine formulation and concentration for minor ailments (e.g. diarrhoea, constipation, cough, hay fever, insect bites, etc.)[b]
	2.4.4 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients[b]
	2.4.5 Package medicines to optimise safety (ensuring appropriate re-packaging and labelling of the medicines)[b]
2.5 Monitor medicines therapy	2.5.1 Apply guidelines, medicines formulary system, protocols and treatment pathways
	2.5.2 Apply therapeutic medicines monitoring and assess impact, and outcomes (including objective and subjective measures)
	2.5.3 Identify, prioritise and resolve medicines management problems (including errors)
2.6 Patient consultation and diagnosis	2.6.1 Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care
	2.6.2 Appropriately refer the patient or carer
	2.6.3 Assess, diagnose, and prescribe within appropriate scope of practice based on objective and subjective measures (where applicable)[d]
	2.6.4 Evaluate, assess, and develop health literacy education and counselling on medicines and healthcare needs
	2.6.5 Discuss and agree with the patient on the appropriate use of medicines, taking into account patients' preferences
	2.6.6 Document any intervention (e.g. document allergies, such as from medicines and nutrition in the patient medicines history)
	2.6.7 Obtain, reconcile, review, maintain and update relevant patient medication and disease history

a=new statement; b=re-numbered statement; c=minor amendment; d=major wording change; e=moved statement

Table 24 (continued)

Competency Group	Behavioural Statement
Cluster 3 Organisation and Management	
3.1 Budget and reimbursement	3.1.1 Acknowledge the organisational structure
	3.1.2 Effectively apply and set budgets
	3.1.3 Manage appropriate claims for reimbursements of health products and technologies, and pharmaceutical care services[d]
	3.1.4 Ensure the use of appropriate reference sources for reimbursement of health products and technologies, and pharmaceutical care services[de]
	3.1.5 Ensure financial transparency[b]
3.2 Human resources management	3.2.1 Demonstrate organisational and management skills (e.g. plan, organise and lead on medicines management, risk management, self-management, time management, people management, project management, policy management)
	3.2.2 Identify and manage human resources and staffing issues
	3.2.3. Recognise and manage the potential of each staff member and utilise systems for performance management (e.g. conduct staff appraisals)
	3.2.4. Recognise the value of pharmacy team and of a multidisciplinary team
	3.2.5 Support and facilitate staff training and continuing professional development
3.3 Improvement of service	3.3.1 Identify and implement new services (according to local needs)
	3.3.2 Resolve, follow up and prevent medicines related problems
3.4 Procurement	3.4.1 Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality
	3.4.2 Develop and implement contingency plans for shortages
	3.4.3 Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms
	3.4.4 Ensure there is no conflict of interest
	3.4.5 Identify and select reliable supplier(s)
	3.4.6 Select reliable supply of high-quality products (including appropriate selection and procurement processes, cost effectiveness, timely delivery)
	3.4.7 Supervise procurement activities
	3.4.8 Understand the tendering methods and evaluation of tender bids
3.5 Supply chain and management	3.5.1 Demonstrate knowledge in store medicines to minimise errors and maximise accuracy
	3.5.2 Verify the accuracy of rolling stocks
	3.5.3 Ensure effective stock management and running of service with the dispensary
	3.5.4 Ensure logistics of delivery and storage
	3.5.5 Implement a system for documentation and record keeping
	3.5.6 Take responsibility for quantification and supply chain forecasting
3.6 Workplace management	3.6.1 Address and manage day to day management issues
	3.6.2 Demonstrate the ability to take accurate and timely decisions and make appropriate judgements
	3.6.3 Ensure the production schedules are appropriately planned and managed
	3.6.4 Ensure the work time is appropriately planned and managed
	3.6.5 Improve and manage the provision of pharmaceutical services
	3.6.6 Recognise and manage pharmacy resources (e.g. financial, infrastructure)

a=new statement; b=re-numbered statement; c=minor amendment; d=major wording change; e=moved statement

Table 24 (continued)

Competency Group	Behavioural Statement
Cluster 4 Professional/Personal	
4.1 Communication skills	4.1.1 Communicate clearly, precisely and appropriately while being a mentor or tutor 4.1.2 Communicate effectively with health and social care staff, support staff, patients, carer, family relatives and clients/customers, using lay terms and checking understanding 4.1.3 Tailor communication that is appropriate to the patient's needs (including health literacy, cultural or language barriers, social needs, and emotional status) 4.1.4 Use appropriate communication skills (e.g. verbal and non-verbal) to establish and maintain rapport with the patient and others including when communicating through digital and electronic platforms
4.2 Continuing Professional Development (CPD)	4.2.1 Document CPD activities 4.2.2 Engage with students/interns/residents 4.2.3 Evaluate accuracy of knowledge and skills 4.2.4 Identify learning and development needs 4.2.5 Evaluate learning and development progress 4.2.6 Identify if expertise is needed outside current scope of knowledge 4.2.7 Recognise own limitations and act upon them 4.2.8 Reflect on performance 4.2.9 Demonstrate engagement/ participation in professional development and lifelong learning activities
4.3 Digital literacy	4.3.1 Identify, manage, organise, store, and share digital information 4.3.2 Critically appraise, analyse, evaluate, and/or interpret digital information and their sources 4.3.3 Where applicable, participate in digital health services that promote health outcomes and engage with digital technologies (e.g. social media platforms & mobile applications) to facilitate discussions with the patient and others 4.3.4 Maintain patient privacy and security of digital information related to the patient and workplace
4.4 Interprofessional collaboration	4.4.1 Respect and acknowledge the expertise, roles and responsibilities of colleagues and other health professional 4.4.2 Participate, collaborate, advise in therapeutic decision-making, and use appropriate referral in a multi-disciplinary team 4.4.3 Engage in collaborative practice, research and service provision to optimise patient health outcomes 4.4.4 Engage in relationship-building with health professionals allowing conflict resolution, teamwork, communication, and consultation 4.4.5 Demonstrate mutual respect and adopt shared values of the workplace and toward patient care
4.5 Leadership and self-regulation	4.5.1 Apply assertiveness skills (inspire confidence) 4.5.2 Demonstrate leadership and practice management skills, initiative and efficiency 4.5.3 Document risk management (critical incidents) 4.5.4 Prioritise work, practice punctuality and time management 4.5.5 Develop, implement and monitor innovative ideas 4.5.6 Recognise and describe emotional information about self and others (e.g. self-awareness, self-regulation, motivation, social skills and empathy)

a=new statement; b=re-numbered statement; c=minor amendment; d=major wording change; e=moved statement

Competency Group	Behavioural Statement
	4.5.7 Demonstrate flexibility and adaptability to a variety of conditions and circumstances
	4.5.8 Recognise when affected by setback or stress and manage with effective coping strategies (resilience)
4.6 Legal and regulatory practice	4.6.1 Apply regulatory affairs and the key aspects of pharmaceutical registration and legislation
	4.6.2 Apply the principles of business economics and intellectual property rights including the basics of patient interpretation
	4.6.3 Be aware of and identify the new medicines coming to the market
	4.6.4 Comply with legislation for drugs with the potential for abuse
	4.6.5 Apply the principles of marketing and sales
	4.6.6 Engage with the development and improvement of health and medicines policies[d]
	4.6.7 Recognise the steps needed to bring a medical device or medicine to the market including the safety, quality, efficacy and pharmacoeconomic assessments of the product
4.7 Professional and ethical practice	4.7.1 Demonstrate awareness and employment of local/national codes of ethics
	4.7.2 Fulfil duty of care to the patient and the public
	4.7.3 Maintain privacy and confidentiality (with the patient and other healthcare professionals)
	4.7.4 Comply with patient privacy legislation including documentation of information
	4.7.5 Consider available evidence and support the patient to make informed choices about medicine use
	4.7.6 Obtain patient consent (it can be implicit on occasion)
	4.7.7 Recognise professional limitations of self and others in the team
	4.7.8 Demonstrate professional responsibility for all decisions made and actions taken
	4.7.9 Demonstrate awareness of socially accountable practice (including cultural and social needs; cultural safety, respect, and responsiveness; diversity, equity and inclusiveness)
4.8 Quality assurance and research in the workplace0	4.8.1 Apply research findings and understand risk-benefit analyses (e.g. pre-clinical, clinical trials, experimental clinical pharmacological research, and risk management)
	4.8.2 Audit quality of service (meet local and national standards and specifications)
	4.8.3 Develop and implement Standard Operating Procedures (SOPs)
	4.8.4 Ensure appropriate quality control tests are performed and managed appropriately
	4.8.5 Identify falsified and substandard medicines and adhere to quality standards[d]
	4.8.6 Report falsified and substandard medicines to relevant authority[de]
	4.8.7 Identify and evaluate evidence-base to improve the use of medicines and services[b]
	4.8.8 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice)[b]
	4.8.9 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)[b]
	4.8.10 Initiate and implement audit research activities[b]

a=new statement; b=re-numbered statement; c=minor amendment; d=major wording change; e=moved statement

6.5 Discussion

This is the first competency framework development study to date in Kenya for pharmacists. The consensus development method employed here is a commonly used approach in health research that has been utilised across the globe (Jones and Hunter, 1995). The GbCFv2 provides an evidence based tool which can be used as the basis for adapting its competencies and behavioural statements to varying contexts for the organisation, credentialing and improvement of pharmacy education and practice within different regions or countries (International Pharmaceutical Federation, 2020b). The research in this chapter follows the precedent set by previous studies which adapted the GbCFv2 (Alfaifi et al., 2022b) and the GbCFv1 (Mucalo et al., 2016, The Pharmaceutical Society of Ireland, 2013, Al-Haqan et al., 2021b) and found that the framework was well suited to these individual study locations. The findings in this chapter demonstrate a high level of initial agreement overall for suitability of the global framework to the Kenyan context. Furthermore, a full consensus was reached on the content of the final framework without an overly arduous modification process suggesting the GbCFv2 is also well suited to this study location.

These findings support those in Chapter 5 which found a high level of applicability for the GbCFv2 overall for practising pharmacists in Kenya. This is also consistent with a study on the applicability of the GbCFv1 across various countries in Africa, including Kenya (Udoh et al., 2018). This study builds on previous research, and the findings in Chapter 5, by looking specifically at the modifications necessary to translate the recently updated second version of the GbCF to local pharmacy practice in Kenya. As previously mentioned by Mucalo et al (2016), adaptation of the generic global framework to country-specific needs and circumstances is important as these reflect the requirements of, and the requisite competencies for, the profession locally. Moreover, the level of development within a country, and of the pharmacy profession itself, differs from nation to nation.

Despite the initial high agreement on the inclusion of the original GbCFv2 statements within a Kenyan competency framework, several modifications took place to fine tune and adapt the framework to local needs. The majority of overall amendments occurred within the PC cluster, followed by the PP cluster. The fewest amendments were made within the OM cluster, followed by the PPH cluster. The PC cluster also had the majority of major amendments, followed by the PP cluster. Interestingly, to some extent, this is in agreement with the survey results in Chapter 5 as they also showed overall that pharmacists ranked the relevance of the PC cluster as the lowest. This may suggest that pharmaceutical care related competencies relevant in Kenya have the least alignment compared to the other clusters within the global framework.

When examining the actual changes that took place within the PC cluster; the most significant was the creation of a new competency related to safe and environmentally friendly disposal of medicines which reflects the contemporary surge in ‘green’ health

care practices across the globe in general, and in the wake of the COVID-19 pandemic (World Health Organization, 2022a).

The OM cluster on the other hand had the least amendments following the mNGT process in this study, yet overall it had the second lowest relevance ranking in the previous chapter. The OM cluster was also shown to be one of the least relevant clusters overall in comparable studies across the globe when pharmacists were asked to rank the relevance of their own *current* practice to the global framework (Alfaifi et al., 2022a, Arakawa et al., 2020, Al-Haqan et al., 2021b, Udoh et al., 2018). Notably, a previous GbCF modification process, using a method similar to this study, in Croatia also asked panelists to consider *current* practice. Unlike the GbCFv2 modifications in this study, the OM cluster was the most amended cluster in the Croatian study.

In the consensus measurement surveys, in recognition of the developing state of pharmacy practice in Kenya, the panelists were asked to rate their level of agreement on whether the behavioural statements should be included in a Kenyan competency framework according to current *and* ideal/future practice for pharmacists in the country. The intention being to 'future-proof' the framework so that it retains relevance for a number of years as pharmacy practice shifts and develops. Therefore, this could explain some of the differences between the similar studies already mentioned, and the results in Chapter 5, due to what the respondents were asked to consider when answering the different surveys. In other words, pharmacists' perceptions of their own current practice are likely to differ to an expert's judgment of ideal and future practice. This may particularly be the case when looking at the OM cluster as this pertains to a number of management duties which may not be applicable in practice until further career progression has been achieved. Therefore, the OM competencies may not apply currently to pharmacists but are likely to apply at some point in the future and hence were deemed suitable for inclusion in the Kenyan framework by the panelists.

Competencies related to organisation and management are ones that a well-rounded pharmacist should possess at graduation and in turn can strengthen the ability to develop and maintain clinical or patient-orientated knowledge, skills, and behaviours (Meštrović, 2012). Furthermore, advanced practice frameworks are in use across the globe (Coombes et al., 2011, Royal Pharmaceutical Society, 2013, Ministry of Health Singapore, 2017). The use of competency frameworks facilitates the development of skills and expertise (Katoue and Schwinghammer, 2020), and embedding competencies at a foundation level augments the transition to an advanced level of practice (Bajis et al., 2020). Therefore, even though many pharmacists may not find OM competencies as relevant to their current practice as those in some of the other clusters; it would make sense that panelists might on agree on including such competencies in a Kenyan competency framework with long term development in mind.

Respondents to the national applicability survey from the hospital pharmacy sector heavily outweighed those from other sectors, which although reflective of the spread of pharmacists between the different sectors in Kenya (Aywak et al., 2017), may affect the results in comparison to the findings of this stage of the research. Panelists were asked to consider all sectors of pharmacy practice and so particular clusters of statements may be generally applicable in Kenya but have less relevance to certain sectors of practice, providing further explanation for discrepancies between levels of relevance of the competency clusters in Chapter 5, and the level of modifications completed to the clusters during the framework development. This is particularly relevant to the OM cluster as hospital pharmacists are more likely to perform predominantly clinical duties compared to community pharmacists in Kenya that have more of a managerial role (Aywak et al., 2017). This accentuates the importance of having a well-balanced consensus development panel, as was achieved in this study, when considering a sector-wide framework. Hospital pharmacists are also more likely to take on more clinical duties compared to community pharmacists in Kenya that have more of a managerial role (Aywak et al., 2017).

There is no longstanding system widely operated in Kenya for the recognition of advanced practice for pharmacists (Aywak et al., 2017). Bearing in mind the complexities of implementing competency-based education and associated frameworks (Katoue and Schwinghammer, 2020, Koster et al., 2017); it is likely to take a considerable amount of time to make progress with the implementation of a competency framework for pharmacy practice in Kenya. This emphasises the importance of the future-orientated approach of this study as it allows for designing a framework with enduring applicability. Pharmacy practice advancement is one of the priorities of the Pharmaceutical Society of Kenya (verbal communication February 2020), and as collaborators in this research and co-owners of the final framework, it was paramount to ensure the ability of the framework to remain relevant by time its implementation could potentially be realised to facilitate a consistent approach to all levels of practice, both now and in the near future.

This research was designed with professional pharmacy practice development in mind and in anticipation of the need for tools such as a competency framework to help guide this process. In fact, developments for pharmacy professionals have materialised since the time of the initial design of this research, Continuing Professional Development (CPD) became mandatory in Kenya following an amendment to the Pharmacy and Poisons Act in 2019 (Pharmacy and Poisons Board, 2022a). As accredited CPD providers the PSK support pharmacy professionals, including pharmaceutical technologists, towards achieving the minimum requirement to attain 40 CPD points per year. Additionally, since the completion of this study the PSK have entered into a Memorandum of Understanding (MoU) with the pharmacy regulators in Kenya, the Pharmacy and Poisons Board (PPB), to work on promoting good pharmacy practice by supporting the self-regulation of pharmacists to ensure they contribute to the appropriate use of medicines

(Pharmacy and Poisons Board, 2022b). The creation of this competency framework is therefore well timed as it can be used as a basis for designing CPD activities and supporting pharmacists towards identifying their learning needs and tracking their own progress (Al-Haqan et al., 2020).

The PPB are responsible for regulating the licensure of pharmacy professionals and the undergraduate pharmacy curriculum in Kenya. The education system in Kenya is has begun moving towards a competency-based approach across all levels (Republic of Kenya Ministry of Education, 2015) . A national entry-level competency framework can be used as a basis for curriculum design for undergraduate pharmacy programmes (Koster et al., 2017). There is also scope to extend the competency-based approach to registration level assessment further standardising the baseline knowledge, skills, and abilities of each pharmacist entering the workforce while simultaneously offering the potential to elevate professional identity and public perception of the pharmacy profession (Reardon et al., 2016). Consequently, the framework has potential for utilisation not only in undergraduate curriculum design but also in professional development, registration assessments and promoting the standards of professional pharmacy practice to the general population in Kenya.

6.6 Limitations

In order to facilitate thorough and balanced discussion in a nominal group technique method, such as the one presented in this study, a maximum of 12 participants is recommended (Black, 2006). The final panel of 9 members therefore is appropriate for a study of this nature. However, one of the major limitations of this study is the withdrawal of panel members from relevant government bodies (i.e. the MoH and representatives from the county level health service), and from the pharmacy regulatory body (PPB). Furthermore, there were no representatives from the pharmaceutical supply chain pharmacy sector. However, pharmacists do have a general knowledge of supply chain issues, and community pharmacists in particular do have some roles in supply chain management in Kenya (Aywak et al., 2017). Nevertheless, the presence of the missing representatives in this study would have ensured a more comprehensive selection of pharmacy practice stakeholders, consequently strengthening the validity of the findings. A greater number of panel members can also be associated with enhanced reliability (Black, 2006).

A further limitation relates to the fact that the representativeness of this study's CDP to the pharmacy profession in Kenya is unknown. As is common in this type of research, panelists are purposively selected for their level of expertise however and care was taken with local collaborators to ensure a varied mix of appropriate knowledge levels within the nominal group. Nonetheless, there is an element of subjectivity inherent in this type of research, which although desirable to stimulate discussion and explore different perspectives (Van de Ven and Delbecq, 1972), can affect the repeatability of consensus development methods. Conversely, although the inclusion of specific specialist groups can affect the results, the individual members selected are unlikely to exhibit any significant effect on the findings

(Hutchings and Raine, 2006). Certain panel members can however sometimes dominate discussions which can be a further limitation with the nominal group technique method. Therefore, measures were taken to mitigate this effect with the presence of a panel moderator and second panel facilitator but the effect of this phenomenon on the present study is unknown. Likewise, it is unknown whether all panel members understood and interpreted the meaning of the behavioural statements of the GbCFv2 in the same way which is further compounded by the general complexity and debate that surrounds the conceptualisation of competency-based education (McMullen et al., 2023).

The panelists in this study are also dominated by males and those aged 30-50 years, thus conferring a further potential limitation in terms of fair representation of diverse ages and genders in this study's particular sample. This distribution does however correlate with the general population of pharmacists in Kenya which are predominately male and aged between 35 and 44 years (Okoroafor et al., 2022).

6.7 Summary

This study utilises well-established consensus development methods to create a bespoke competency framework in Kenya through the iterative adaptation of a global framework with recognised applicability internationally. As many countries, including Kenya, embrace competency-based education a competency framework is key to facilitating the necessary transitions across the many stages of professional development throughout a pharmacists' undergraduate studies and career. Feedback from additional stakeholders such as the PPB and the MOH on the suitability of the framework for implementation in Kenya is required. Further work is also required to assess the applicability, validity and acceptability of the proposed national framework once put in to practice or preliminary pilot study. Additionally, studies to expand this work into the creation of an advanced level framework and a framework for pharmaceutical technologists are recommended. The evidence-based approach adopted in the creation of this framework, together with the involvement of local stakeholders and ownership of the final framework by the Kenyan professional pharmacy body places the output of this research in a strong position for Kenya to utilise in further pharmacy professional development initiatives and research.

6.8 Acknowledgments

I would like to thank all of the panellists for taking part in the consensus development panel. I would also like to thank the Pharmaceutical Society of Kenya, particularly Lucas Nyabero and Eric Muringu, for their assistance with the recruitment of the panellists and with the organisation of the workshop in Nairobi. Special thanks also to Naoko Arakawa and Claire Anderson for acting as workshop facilitators.

Chapter 7: Summary Discussion and Conclusion

7.1 Principal Findings

The research project presented in this thesis is composed of four separate studies, utilising both quantitative and qualitative methods in two parts. This approach not only identified a gap in the literature on the topic of competency-based education (CBE) in the Africa region but also provided a means to contribute towards filling that gap in the research. One of the overarching key findings from this project is that information, evidence, and literature on the use of CBE for pharmacy in Africa is lacking. Similarly, a paucity in relevant data from South-East Asia was discovered. In fact, two entirely different methods utilised in the first part of this thesis both came up with the same result in terms of a lack of data on CBE for pharmacy in both of these regions.

The systematic review and the global survey findings share a common theme: the crucial need for a holistic and unified approach to successfully implement CBE in pharmacy. This approach hinges on the collaboration of three essential components within the pharmacy system– education, regulation, and practice. Notably, the support from higher authorities within the regulatory system for both education and practice emerges as a catalyst for the adoption of CBE. The absence of such support can pose significant challenges to the implementation process for academic institutions.

Taking a comprehensive view of the project, the principal findings coalesce around four central topics: the global extent of CBE in pharmacy, the distinctive features of CBE for pharmacy, challenges in the implementation of CBE, and the applicability and modification of the FIP GbCFv2 to pharmacy practice in Kenya.

7.1.1 Global Extent of CBE for Pharmacy

Findings relating to this theme meet the following original objectives of **Part 1** of the research:

<u>Stage (i)</u>

- Conduct a comprehensive systematic review of pharmacy education worldwide to identify and analyse the current features and practices of CBE related to pharmacy students and practitioners

<u>Stage (ii)</u>

- Conduct a survey to explore the global extent of CBE related activity in pharmacy and the pharmaceutical sciences, identify how CBE is used and the potential challenges to effective implementation

Both Stage (i) and Stage (ii) studies identified that the majority of CBE activity for pharmacy originates from Western, mainly high-income, countries. Examples of literature are found from countries outside of the Western world but are also largely high-income nations, such as Kuwait and Qatar in the Eastern Mediterranean Region (EMR). Literature published following the completion of the systematic review in Part

1 Stage (i) also suggests that CBE activity is on the rise for some countries in the EMR (Alfaifi et al., 2022a, Alfaifi et al., 2022b, Hajj et al., 2023, Almaghaslah et al., 2022). This is a progressive step in comparison to a previous systematic review which highlighted the lack of a competency framework in the Middle-East as a barrier to the quality assurance of pharmacy education (Katoue and Schwinghammer, 2020). From the responses to the global survey we can also see that response from non-Western regions was the highest for the EMR. Literature from high-income countries however does still dominate the field of pharmacy education and the findings of this study are no exception.

7.1.2 Features of CBE for Pharmacy

Findings related to this theme meet the following original **Part 1** research objectives:

Stage (i)

- Conduct a comprehensive systematic review of pharmacy education worldwide to identify and analyse the current features and practices of CBE related to pharmacy students and practitioners
- Describe the existing features of CBE in pharmacy education and training globally

Stage (ii)

- Conduct a survey to explore the global extent of CBE related activity in pharmacy and the pharmaceutical sciences, identify how CBE is used and the potential challenges to effective implementation

These findings provide a comprehensive understanding of how CBE is practically applied in real-world settings. This understanding serves as a foundational contribution, akin to setting the scene, and informs the development of CBE implementation strategies in alignment with comparable principles of process evaluation from the field of implementation research (Bauer et al., 2015).

Part 1 Stage (i) results show that very few studies are based around a whole curricula change to, or evaluation of CBE. In fact, if the review had exclusively focused on literature pertaining to whole CBE programmes, only the study by Westein et al. (2019) would have met the criteria, and that study was solely concentrated on post-graduate training. Furthermore, a lack of research on the effectiveness of this type of reform reflects the challenges to conducting conclusive studies on the outcomes of CBE compared to traditional methods in the realities of educational environments. For example, in the study of test score comparisons between traditional assessments and objective structures clinical examinations (OSCEs), Kirton and Kravitz (2011) highlight the difficulties of excluding all other variables such as personal circumstances and environmental factors.

Although CBE for health professionals is widely endorsed (Frenk et al., 2010), comprehensive data on the impact of CBE over other methods on professional performance and patient outcomes in particular seems to be lacking from the studies included in the systematic review. Therefore, in line with recommendations from the

medical literature (Frenk et al., 2010), it appears that further scholarship is still warranted on the evidence of impact of CBE. Such evidence could play a pivotal role in overcoming resistance from faculty members who may be hesitant to invest the necessary efforts in implementing CBE (Kinyaduka et al., 2019). Therefore, addressing this gap in the understanding of CBE's impact becomes imperative for fostering informed decision-making and promoting broader acceptance within academic circles.

Nevertheless, the systematic review studies and the global survey respondents span various levels of education or training, implemented at different levels of integration across the CBE research landscape. By adopting this broad approach, I aimed to capture a multifarious range of perspectives and practices, resulting in rich and nuanced data that contribute to a thorough understanding of the various elements influencing the features of contemporary CBE in pharmacy.

As Westein et al. (2019) elude to in their paper, a lot of the theories and experiences for CBE in pharmacy originate from the medical field. In Part 1 Stage (i) it was found that the CBE literature for pharmacy demonstrated a correlation to all 4 themes of CBE defined previously in the medical literature by Frank et al. (2010a). In this review 20 features of CBE were defined and grouped into 6 overarching themes of: design, systems of instruction and learning methods, feedback and assessment, faculty, resources, and internal &external factors. A further 21 ancillary components relating to these features were also pinpointed and assimilated into this collection of contemporary CBE features for pharmacy. From this analysis three distinct levels of a CBE structure emerged: the supporting components (micro-level), outlining individual technical aspects; the features (meso-level), investigating those wider elements uniquely attributed to a CBE approach; and the macro-level, identifying overarching themes that contribute to the broader structure of CBE and education in general. The organisation of the findings in this manner provides an evidence-based blueprint, although not exhaustive of up-to-date, quality appraised global data which offers valuable insights for academic institutions wishing to implement CBE for pharmacy. And these features were used to guide the survey questionnaire design in Part 1 stage (ii).

One of the most significant points to consider from the work on identifying the features of CBE is the importance of the macro-level factors that influence CBE implementation which parallels findings from a Delphi approach to identifying a core components framework for evaluating the implementation of competency-based medical education (Van Melle et al., 2019). Specifically the findings of this research calls for a holistic and unified approach within the educational system (Westein et al., 2019), facilitated through strategies such as stakeholder engagement (Volmer et al., 2017, Westein et al., 2019, Paradis et al., 2018) and dedicated steering committees (Alves da Costa et al., 2020, Walter et al., 2018). These foundational elements of successful CBE delivery, coupled with a profound comprehension of the concept of competency itself (Nash et al., 2016, Nash et al., 2017, Paradis et al., 2018, Reardon

et al., 2016, Rich, 2019, Stupans et al., 2012, Meštrović et al., 2012), emerged from the global survey in stage (ii) and the systematic review in stage (i) as critical steps to CBE implementation. The convergence of similar thematic findings derived from two distinct research methodologies underscores the paramount importance of these foundational elements. Their absence not only undermines the effectiveness of implementation efforts but also threatens to reduce CBE to a superficial compilation of lists and tasks, detracting from its core objective of promoting transformative learning (Rich, 2019, Gonczi, 2013).

This need for a dedicated, unified vision across the educational sub-systems and the wider pharmacy system as a whole reflects the sentiment of previous recommendations for implementing CBE for pharmacy from the literature (Katoue and Schwinghammer, 2020, Koster et al., 2017, Gonczi, 2013) and indeed for educational reforms in general (International Pharmaceutical Federation, 2014). Furthermore, this highlights that the implementation of CBE goes beyond the individual technical elements represented by the features of CBE but also requires an understanding and appreciation for the processes of undergoing successful educational reform and the overarching concept of competency. This project therefore utilises a mixed methods perspective to gain a deeper understanding of the features of CBE for pharmacy and serves to highlight the intricate details and broader considerations essential for the effective implementation of CBE based on evidence and experience from a wide range of contemporary global pharmacy education settings.

7.1.3 Challenges to CBE Implementation

The findings related to challenges with the implementation of CBE for pharmacy were established as part of the following original research objective from **Part 1** of the study:

Stage (ii)

- Conduct a survey to explore the global extent of CBE related activity in pharmacy and the pharmaceutical sciences, identify how CBE is used and the potential challenges to effective implementation

A major finding of this work emerged through thematic processing of this data to align the challenges with the features of CBE, therefore integrating the findings from this Stage (ii) objective with the Stage (i) objective:

Stage (i):

- Describe the existing features of CBE in pharmacy education and training globally

This mixed methods approach in combining the survey data with the features of the systematic review offers tangible real-world evidence on employing CBE for pharmacy and quantifies the frequency with which certain features present obstacles offering an extra layer of understanding to separate analyses of the individual study results.

The analysis of the responses to the survey revealed that among the potential many challenges to the adoption of CBE, the most prominent hurdle lies within faculty preparedness. These results therefore emphasise the importance of dedicating concerted effort towards training faculty on the principles of CBE in practice. What the survey does not tell us is the nature of the challenges faced in this area of CBE for pharmacy. However, it is clear from these results that further work is required to delve further in to this issue to identify potential solutions. The vast majority of the academic institutions surveyed were using CBE in some capacity and most of these were whole CBE programmes. This suggests that challenges in faculty preparedness are not unsurmountable but may be a significant hindrance or rate limiting step.

Despite existing recommendations and suggestions to equip faculty with the necessary expertise to delivery CBE, such as small-scale and large-scale formal teaching, professional collaboration, and a scholarly approach to teaching and learning (Koster et al., 2017), along with effective communication and active engagement with faculty to dispel scepticism (Frank et al., 2017), these results suggest that implementation of these strategies remains challenging in practice. The findings from the systematic review also emphasise that in addition to academic staff, clinicians as preceptors have an important role to play in the delivery of CBE (Walter et al., 2018).

Greater attention towards preceptor development is therefore warranted within the scope of faculty preparedness, especially as in most cases clinicians are not trained educators (Gonczi, 2013). Additionally, differing epistemological understandings of CBE amongst academic and clinical staff must be unified to ensure a cohesive approach (Paradis et al., 2018). This project focuses attention on the issue of faculty preparedness and therefore suggests that institutions utilise tools such as the FIP Global Competency Framework for Educators & Trainers in Pharmacy (FIP-GCFE) to support the development of their faculty and educators (International Pharmaceutical Federation, 2022b). Moreover, additional understanding of potential barriers is needed to avoid recurrence of the problems, particularly as faculty development is necessary for both successful implementation and delivery of CBE and crucial for ensuring educational quality (International Pharmaceutical Federation, 2014). To expedite progress in the adoption and enhancement of CBE, particularly in educational settings unfamiliar with this model, we recommend a qualitative study and analysis of the barriers to faculty preparedness based on these findings.

The global survey results also revealed that challenges with using CBE were commonly encountered in regard to support from higher authorities, policies and regulators. Furthermore, the statistically significant finding of an association between advocacy for CBE by both educational and professional regulatory bodies and the utilisation of CBE in academic institutions highlights the influential relationship between the regulatory and educational sectors. This aligns with perspectives deduced from the systematic review which emphasise the influence of educational

and professional regulatory bodies in both driving the adoption of and shaping the design of CBE (Reardon et al., 2016, Al-Haqan et al., 2021a, Bray et al., 2017). Additionally, such bodies play a complimentarily role in expanding the scope of pharmacy practice (Al-Haqan et al., 2021b, Bajis et al., 2018, Skowron et al., 2017), an expansion which is necessary in accordance with CBE developments to promote the ultimate goal of CBE which is an enhanced quality of patient care (Al-Haqan et al., 2021b, Bajis et al., 2018, Skowron et al., 2017).

Unsurprisingly, the overarching challenge of educational and professional regulatory alignment with the implementation of CBE is also echoed in the medical literature, compounded by outdated and rigid policies, with regulatory bodies operating in silos isolated from each other and the health system as a whole (Caverzagie et al., 2017). It therefore stands to reason that as pharmacy education advancements for CBE mirror that of the medical field, we will also benefit from heeding messages from the medical literature advising collaborative approaches between educators, policymakers, leaders, and regulators to address these common problems (Caverzagie et al., 2017).

Despite CBE being a seemingly straightforward rationale and plan for pharmacy education, the practical implementation of CBE faces significant challenges. Political, cultural, financial, regulatory, and professional obstacles, coupled with the emigration of the pharmacy workforce, underscore the complexities of CBE reform for pharmacy in practice (Hajj et al., 2023). Consequently, the research findings call for more extensive efforts to uncover CBE developments and address the barriers to CBE, particularly in Africa and South-East Asia. The challenges identified in stage (ii) of this research along with issues from other resource-limited contexts, such as those reported by Hajj et al. (2023), offer valuable insights for guiding these future research endeavours.

7.1.4 Applicability, and Modification of the FIP GbCFv2 to Pharmacy Practice in Kenya

Part 2 stage (i) of the thesis is the first study of its kind examining the applicability of the FIP GbCFv2 in Kenya. Additionally, **Part 2** Stage (ii) presents a final bespoke competency framework for early-career pharmacists in Kenya. Valuable insights into the landscape of pharmacy practice in the country were also established as a results of completing the following primary research objectives in **Part 2** of the thesis:

<u>Stage (i)</u>

- Conduct a survey to determine the suitability of the FIP GbCFv2 for pharmacists in Kenya by assessing its applicability and analysing areas of misalignment

<u>Stage (ii)</u>

- Discuss the International Pharmaceutical Federation's (FIP) Global Competency Framework version 2 (GbCFv2) behavioural statements and rate their applicability to current, future, and ideal pharmacy practice in Kenya with a local panel of pharmacy experts

- Adapt and amend the current FIP GbCFv2 behavioural statements, enhancing the relevance to Kenyan pharmacy practice until a consensus is reached on all behavioural statements for inclusion in a Kenyan competency framework are agreed
- Create a local competency framework for early-career pharmacists in Kenya

The primary conclusion drawn from this study is that the FIP GbCFv2 is highly relevant and applicable to the Kenyan context, aligning with previous studies using the original, Version 1, of the FIP GbCF (Udoh et al., 2018). However, this works adds a timely perspective, following the impact of the COVID-19 pandemic on pharmacy services and considering the applicability of the new behavioural standards in the second version of the FIP GbCF. Notably, despite the surge of technology adoption around the globe during the time of the pandemic (Mbunge et al., 2022, Keesara et al., 2020, Abd-Alrazaq et al., 2021), dissenting statements from the survey results highlight a potential underutilisation of technology for pharmaceutical services in Kenya, identifying a potential area of growth for pharmacy practice nationally.

One of the major changes of the FIP GbCFv2 during the 'adopt and adapt' framework development process was the addition of new statements. A consensus was reached on the inclusion of these distinct statements to address both patient and professional sustainable disposal of medicines. These statements are a timely addition given the importance of sustainability in pharmacy practice and provides valuable insight towards recommendations for future refinement of the FIP GbCFv2 in-line with recent developments for healthcare in general to be more environmentally aware (Janik-Karpinska et al., 2023, World Health Organization, 2014a).

The PC competencies demonstrated the lowest overall relevance to Kenyan pharmacy practice, in alignment with general global trends potentially signifying a shift for pharmacists away from performing traditional compounding and dispensing duties (Fatherlrahman and Ibrahim, 2018). Examination of the applicability results therefore not only helps establish the practicalities of using the FIP's global competency framework in Kenya but can also contribute to guiding the country's agenda for development of the profession in general (Almaghaslah et al., 2022).

Similarly to the survey in Part 2 stage (i), the results of the consensus development panel pre-workshop survey in Part 2 stage (ii) of the research also suggests a high relevance of the FIP GbCFv2 to the pharmacy practice in Kenya. However, despite the low relevance demonstrated for the PC cluster in stage (i), this was the cluster with the least number of dissenting statements in the stage (ii) pre-workshop survey. This intriguing convergence of findings suggests a nuanced perspective: while pharmacy practice may be evolving, stakeholders still perceive traditional skills associated with the PC cluster as essential for early-career pharmacists. There's a clear expectation that graduating pharmacists should possess and demonstrate these competencies, reflecting a balance between evolving practice needs and the enduring importance of foundational skills.

It is crucial to note that the consensus development panel members were specifically instructed to consider early-career pharmacists in their responses. In contrast, pharmacists in the applicability survey, where the mean length of time qualified was 12.6 years, were asked to reflect on their own practice. This difference in perspective could potentially explain the observed variation in responses between the two surveys.

Further work is suggested in compliment to this study to investigate local development of an advanced-level competency framework to distinguish between the requisite competencies at early and later career stages and support a continual competency progression. A similar applicability study is recommended for Kenya using the FIP's Global Advanced Development Framework (GADF) (International Pharmaceutical Federation, 2020a). This would be a sensible next step to further inform the country's agenda for the development of the profession and support the workforce development needed in line with sustainable development goals and progress towards Universal Health Coverage (UHC). With the support of national professional pharmacy bodies, and other regulatory bodies, accelerated workforce advancement is achievable regardless of a country's socioeconomic status where advanced competency frameworks may support upskilling the workforce in a rapid and sustainable manner (Bates et al., 2022).

7.2 Project Summary

This research initiative originated during the University of Nottingham's leadership in a Department for International Development (DFID) project aimed at transforming the delivery of pharmacy and chemistry higher education in Kenya, operating under the Strategic Partnerships for Higher Education Innovation and Reform (SPHEIR) initiative. Initial discussions revealed significant concerns among academics from five Kenyan universities participating in this collaboration. They expressed apprehensions about the outdated pharmacy curriculum which did not meet the current demands of the profession.

Pharmacy education literature from Kenya was limited but the preliminary information during these scoping discussions in the field suggested that in order to advance the profession the pharmacy education system needed to look to the future and adopt a needs-based approach. Given that CBE inherently adopts a needs-based approach, and recognising the pivotal role of a competency framework in facilitating CBE, the research was strategically designed to develop a local competency framework. This framework aimed to establish a direct correlation between the pharmaceutical care needs of the country and both the pharmacy profession and the educational system, thereby creating a valuable resource for professional and curriculum development. The FIP GbCF provided an ideal starting point from which to do this and the previously validated, including in Africa, applicability survey approach was promptly adopted to investigate its appropriateness in this context.

Subsequently the Nominal Group Technique (NGT) method was chosen as a systematic and robust approach to adapting the FIP GbCFv2 to Kenyan practice.

To ensure a comprehensive and inclusive perspective, a collaborative approach was adopted, involving the professional pharmacy body in Kenya and engaging a diverse array of stakeholders. This strategy sought to foster awareness and garner support for the CBE approach. The outcome of this collaborative effort materialised in a tangible output of the research in the form of a localised competency framework. Importantly, this framework was designed to be seamlessly integrated and owned by the Pharmaceutical Society of Kenya (PSK), promoting the sustainability of the initiative. An advantage of using the FIP GbCF is that it was developed by an international body and although used on a country-level for this situational research, data generated from the research also adds to the global evidence base. This is a method that has been used in both high and low-income situations and by using the same tool and methods it lends itself well to international comparative reviews and analyses. The evidence gained from Kenya also directly contributes towards filling voids in the literature from developing regions of the world.

The initial CBE literature review prior to the final research design revealed that regulatory, educational and professional stakeholder collaboration can yield substantial benefits for achieving successful implementation (Caverzagie et al., 2017, Frenk et al., 2010, Al-Eraky, 2012, Farris et al., 2009). Consequently, the initial plan was to compliment the applicability survey and the NGT with a social network analysis (SNA) to determine the social systems in place between these key stakeholders and decision makers in terms of initiating change in pharmacy education and practice. Moreover, focusing on technical problems and neglecting the socio-cultural context can be a potential barrier to the successful adoption of educational innovations particularly in Sub-Saharan Africa where despite unprecedented pedagogical reform attempts there has been minimal real change (Tabulawa, 2013). Therefore, with this approach the aim was not only to examine what the competencies are for pharmacy practice in Kenya, but also how they can be implemented successfully in the realities of the social systems in place within the relevant health and higher education environments.

The idea behind using SNA was to analyse the network, and the position of the actors within that network, responsible for enacting change in the Kenya pharmacy education system. Namely because a competency framework would provide the ‘what’ in terms of competencies for curricular reform but insights into the pharmacy network in Kenya would provide vital information on ‘how’ to realise successful implementation. For example, network analyses can be useful for detecting key actors that can facilitate the diffusion of an initiative throughout a network or identify those that may inhibit integration and benefit from some kind of intervention (Borgatti et al., 2018).

Unfortunately, obtaining a research license in Kenya became a much more protracted experience than expected. Furthermore, while waiting to obtain this license the COVID-19 pandemic unfolded, resulting in additional challenges with performing research involving international actors within health care systems. Experience in the field up to this point revealed that face-to-face interactions with collaborators in Kenya were often more productive than remote ones. I was able to delay the consensus development workshop until COVID-19 related travel restrictions were lifted, however it was imperative to continue research remotely in the meantime and change the original research plan. Therefore, aware of the potential challenges to CBE implementation, the decision was made to explore the current landscape of CBE in pharmacy with a deep-dive into the relevant recent literature via the systematic review. The global online survey further acted as a remote means to gather data on the use of CBE in pharmacy and its challenges to implementation. This part of the research yielded valuable information in terms of areas around the world in need of more concerted efforts towards CBE and additional research. Furthermore, it enabled me to relate challenges back to the features of CBE for pharmacy, cross-referenced to the closely linked field of medicine, and identify specific troublesome areas that require focus for future development and research in the modern pharmacy CBE arena.

Interestingly, the systematic review and global survey results both identified a theme in the data that supported my original literature review findings on the importance of internal and external collaboration and support. The global survey results identified that advocacy of CBE from the professional and regulatory professions' was significantly associated with an institution's use of CBE. Furthermore, the systematic review studies frequently highlighted that change at the regulatory and professional level goes hand in hand with successful CBE initiatives and that a unified approach from all sectors involved is crucial to ensure that efforts are effective. Support from higher authorities, policies, and regulators also ranked highly in the global survey results as a feature for CBE that institutions encountered challenges with. Focus on the harmony and alignment both within and between the pharmacy education, practice and regulation sectors is therefore a pertinent take away from this research and suggests that a SNA would still be a useful endeavour for future studies, or for locations that wish to implement CBE reforms and achieve the holistic vision that will support the success of those endeavours.

The originality of this research lies in the creation of new knowledge in terms of the construction of a local competency framework for pharmacists in Kenya where no such framework existed previously. Moreover, this research represents a pioneering endeavour in Africa, being the first study of its kind to examine the suitability of the second version of the FIP GbCF within the Kenyan context. The findings offer compelling evidence supporting the feasibility of implementing this framework in Kenya's pharmacy practice landscape. The analysis of the applicability of the FIP GbCFv2 to Kenyan pharmacy offers insights on the current potential priorities for the development of pharmacy practice in Kenya and also adds new information to the

body of material surrounding post-COVID specific considerations. Additionally, insights from the consensus development panel contribute novel reflections on the FIP GbCFv2 which apply internationally, such as its alignment with the healthcare sustainability agenda.

The systematic review offers new information to the field by collating the features of CBE used in pharmacy education focusing on the last decade. Additionally, the novel approach of comparing this data to previous medical literature offers new cross-disciplinary interpretations of known material providing data on pharmacy education in relation to other health professions' perspective on CBE. This information highlights the similarities and emphasises the benefit of interdisciplinary collaboration and the leveraging of insights already gained from these disciplines. The challenges of CBE are extensively reported in the literature, however, no such global survey of pharmacy schools has been conducted to date. Therefore, the global survey brings new evidence to bear on the challenges of implementing and conducting CBE. Furthermore, the integration of the qualitative themes and features from Part One stage (i) with the data from stage (ii) offers a new perspective in terms of the relative frequency of certain challenges to CBE. The triangulation of data from the literature and the survey also reinforces the particular areas for attention for future research and consideration by those institutions embarking on the adoption of a CBE approach. Primarily this study draws focus to the need for improving efforts for CBE implementation in faculty preparedness, external and internal support, and cross-sector collaboration and coordination.

Finally, this research contributes detail on the identified gaps in the literature, highlighting the pressing necessity for additional studies and initiatives in Africa and Southeast Asia, regions with substantial potential to leverage CBE effectively. However, numerous factors, encompassing political, socio-cultural, economic, and regulatory dimensions, contribute to the elusive nature of implementing a comprehensive shift to CBE in these regions. Consequently, a mere transplantation of this predominantly Westernised educational model is likely to falter. Thus, we advocate for a nuanced approach that considers and addresses these multifaceted factors in future CBE reform efforts, ensuring sensitivity to the unique contexts of Africa and Southeast Asia.

7.3 Implications of the Findings

7.3.1 Pharmacy Education Sector

The features of CBE identified from this research provide a useful foundation for academic institutions wishing to embark on CBE for pharmacy and for other health care professionals as the alignment with the medical literature shows that these elements are universal across health disciplines. The supporting components identified also further helps to break down individual elements and the summary of literature highlights useful ways these can be employed in the delivery, design, and operation of a CBE curriculum. For example, the evidence suggests that learner self-

assessment is a salient feature of CBE that can be used at all levels, including for the development of preceptors, to plan future learning, encourage lifelong learning and foster engagement with learning activities. Part One, stage (i) therefore offers a valuable resource that adds supporting contemporary knowledge to existing material and has contributed to guiding documents such as the FIP handbook for the implementation of competency-based education and training for pharmacy and the pharmaceutical sciences. (International Pharmaceutical Federation, 2022a). Any institution that is implementing, or developing existing CBE should refer to this research, and other relevant resources, to ensure that the principles of CBE are used in an accurate and meaningful way.

In addition to the practical considerations and supporting details from this research, the findings also echo the broader sentiments of the medical literature and the principles of educational quality assurance. Educational systems must understand and instil the concept of competency itself and apply a unified holistic approach to adopting and delivering CBE. Many useful strategies are highlighted in Chapter 3 which can be used to achieve this, such as facilitating stakeholder engagement and endorsement in CBE design and delivery which can facilitate the requisite support for success, and deepen the comprehensive understanding of the concept of CBE.

Furthermore, educational systems should take careful consideration on their approaches to prepare the faculty for the adoption and delivery of CBE. As suggested by Frenk et al. (2010), in the seminal global independent Lancet commission on the education of healthcare professionals, instructional reforms should adopt competency-driven approaches with special emphasis on faculty development. The findings of this research support that recommendation which was made over 10 years ago and suggests that faculty development still remains a challenging aspect of health professional CBE reform. We therefore recommend that educational institutions dedicate time and resources in their reform processes to create a comprehensive plan to support faculty development in CBE initiatives, and ensure that this include practice-based trainers and preceptors.

These recommendations for the education sector guarantees that CBE efforts align with the concepts of the methodology, thereby facilitating optimal and effective outcomes and ensuring that the true essence of CBE is captured, where ‘time and place will be the variable and achievement will be the constant’ (Bramante and Colby, 2012 pp.15).

7.3.2 Recommendation for the Development of CBE Globally

The rigorous and methodical adopt and adapt approach of Part 2 of this thesis provides valuable evidence on the high applicability of the FIP GbCFv2 to the Kenyan pharmacy practice and provides a concrete resource as a structured and detailed roadmap to guide pharmacists through professional development. Furthermore, detailed insights into the different competency clusters’ areas of lesser applicability highlight potential areas for local advancement of the profession. This framework can

be used to facilitate the alignment of educational curricula, professional regulations and practice standards.

The country-level specific data also has international relevance as findings on the content of the FIP GbCFv2 itself can also be used for guiding enhancements of future iterations of the framework. Moreover, these findings indicate that other comparable countries in Africa may also demonstrate a high relevance of the FIP GbCFv2 and benefit from employing these same standardised research methods towards the advancement of CBE for pharmacy and resulting improvements for patient and population health goals. In essence, the competency framework stands as a multifaceted and dynamic resource, fostering ongoing professional development, guiding educational initiative, and promoting the highest standards of pharmacy practice in alignment with evolving healthcare needs and societal expectations.

However, even with this knowledge and tool the realisation of CBE for pharmacy in Kenya is a long way off and by no means an easy task. Although the systematic review and survey results suggest that CBE is widespread in the Western world, the lack of literature and data from the survey originating from lower-income countries, corroborates with previous research (Katoue and Schwinghammer, 2020) and suggests that there is some sort of barrier to uptake of CBE in these regions. This research was not designed to identify these barriers but in fulfilling the aims to evaluate the current state of CBE globally it uncovered this geographical gap in the use of CBE for pharmacy. Despite the recognition of the potential for this educational model for the healthcare professions in resource limited contexts (Gruppen et al., 2012).

Furthermore, early education systems in many countries, including Africa, are moving towards competency-based curricula but many curricula remain heavily content driven, linguistically and cognitively too demanding, and irrelevant to local context and needs of learners (Tikly, 2020 pp.25). This echoes the sentiment gathered via my initial visits to Kenya during verbal discussions with the academics involved with the SPHEIR project and with the delivery of pharmacy education in Kenya. Factors, originating from colonial times, of authoritarian and formalistic teacher-centric pedagogical practices coupled with wider unsustainable development workforce issues and higher education practices and structures contribute to a deep-rooted and complex environment for the alignment of the synergistic processes needed to enact change (Tikly, 2020 pp.26). Challenges to the adoption of learner-centred pedagogies, like CBE, have also proven pervasive in Sub-Saharan Africa particularly because socio-cultural influences are often over looked (Tabulawa, 2013). Tilky (2020) argues that solving this crisis in early education in Africa cannot be placed on the education systems alone: ‘Rather what is required are more fundamental and simultaneous processes of transformative change across all domains of development’ (Tikly, 2020 pp.26). A key takeaway from this research aligns with this perspective and calls for a systems approach to educational reform and CBE implementation.

Stagnant systems in a changing world inhibit development and in the context of CBE, time-based educational structure inherited from the industrial age no longer cater to the needs and demands of learners, communities, and industries (Ruyle, 2018 pp.15, Frenk et al., 2010). The educational system however does not sit in isolation, and is part of an interconnected and dynamic system that also includes the pharmacy practice and regulatory sectors (Rouse, 2004). We recommend therefore that any CBE implementation endeavours take into account the principles of this dynamic system in a similar fashion to the theories of implementation science which studies the application of evidence-based medicine in practice (Damschroder et al., 2009) and systems change theory (World Health Organization, 2009). Educational change theory also supports these principles as eloquently depicted by a key contributor to this field, Michael Fullan:

'Systems thinking in each level means focusing on the way the constituent parts interrelate, and how the system works over time. The policy may set the direction in conjunction with the other two levels, but the successful journey must be both independent and shared. At the end of the day you can always fall back on your own (and your group's) autonomy; but if you do not strengthen within-group connection and cross-level rapport, you will not be able to achieve system change' (Fullan, 2021).

Fullan argues that change cannot occur without all levels of a system having a sense of ownership for that change and refers to this concept as 'systemness'; one of his outlined 'right drivers' for educational change (Fullan, 2021). We argue that this also applies to any system, including the pharmacy system, where regulatory, educational, and practice sectors act as subsystems within a broader framework. This system is further embedded in the larger context of the interconnected health system that encompasses various disciplines contributing to its functioning and influencing one another.

In light of our research findings, which underscore the necessity for collaborative efforts across the education, regulatory, and practice sectors to advance CBE successfully, it becomes imperative to not only ensure a profound understanding and accurate implementation of CBE but also to consider holistic strategies for promoting harmonious collaboration among these interconnected systems. Our study reveals that each sector plays a crucial role—education must prepare adequately for and endorse CBE, regulatory bodies must credential new CBE programmes, and the practice sector must advocate for the profession, support competency development, and drive the profession forward in a professional an ethical manner. Achieving harmony between these sectors is paramount, and, while individual efforts are essential, a shared vision is indispensable. Committees with diverse representation can sanction policies and initiatives, making efficient use of resources and avoiding wasted efforts. Therefore, we recommend that future projects, especially those aligning with SPHEIR initiatives, should not only focus on understanding and implementing CBE but also prioritise fostering collaborative relationships between systems and their sub-systems. Building on established models, we propose the

existence of a synergistic nexus, representing a higher level of collaboration that transcends individual contributions, serving as a focal point for effective system collaboration in projects of this nature.

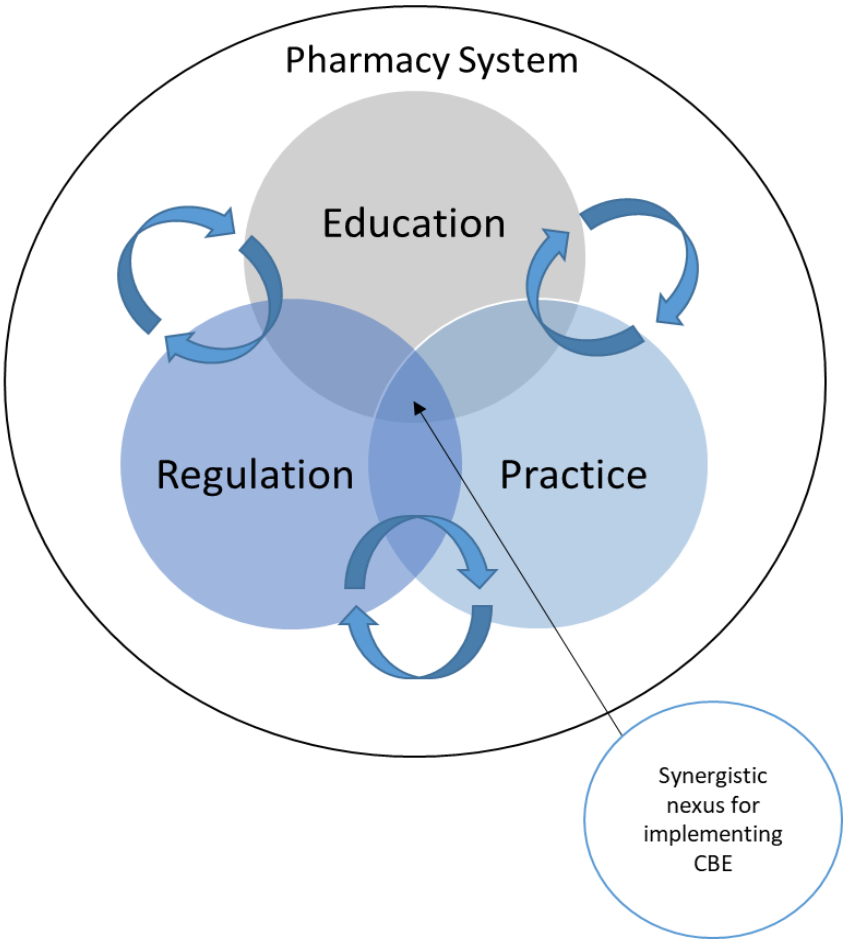

Figure 27 The synergistic nexus model for maximising effective implementation of CBE using a systems approach

In **Figure 27** we introduce the proposed synergistic nexus model, which not only mirrors the influential connections outlined by Rouse (2004) but also places additional emphasis on the distinctive central dynamics that emerge when all sectors collaborate in harmony. This convergence point, aligning with the principles of 'systemness,' becomes a focal point where we propose dedicated attention should be paid to overcome stagnation and enhance motivation for change. Focusing solely on the individual sub-systems perpetuates existing challenges without addressing disconnects that often exacerbate these issues (Bader et al., 2017). As illustrated in **Figure 27**, the sub-systems indeed overlap, and we suggest that there is substantial power in facilitating collaboration within this overlap which surpasses the impact of individual connections.

In my observation of the Kenya-Nottingham SPHEIR partnership during the completion of this research, it became evident that the expectations of the funder's programme managers regarding the project aims and objectives did not align with the vision of the project team, or the principles of systemness. There was a notable

pressure to provide granular data on short-term 'quick-win' measurements of progress, overlooking the broader context and intricacies inherent in such a comprehensive reform project. Analogous to critiques of international development targets like the Sustainable Development Goals (SDGs), this sub-sectoral quantitative approach to gauging development exhibits a highly reductionist perspective (McGrath, 2016 p.402). Unfortunately, the funder's programme managers, being somewhat technocratic in their approach, decided to end the project prematurely due to this mismatch of expectations. This heavily technical approach to international education development tends to overshadow philosophical and theoretical debates while jeopardising space for practical action (McGrath, 2016 p.401). Fortunately, this research was able to persevere with the collaboration of Kenyan partners independently, and with the PSK holding ownership of the Kenyan pharmacy competency framework, there is optimism that the sustainability of this work can extend beyond the conclusion of this research phase.

To effectively harness the influential power of a synergistic nexus point, we propose the engagement of systems change experts as well as CBE specialists when undertaking significant reform projects. While this research underscores the widespread adoption of CBE for pharmacy globally, it highlights a lag in progress in Africa and South-East Asia. To address this disparity and enhance the impact of future CBE development initiatives, we advocate not only for further research into the utilisation of CBE in these regions, and the underlying factors hindering its uptake, but also for a comprehensive examination of socio-cultural factors and whole-system challenges. This broader perspective is essential for achieving a more significant impact on CBE development in these regions.

7.4 Cautionary Notes and Limitations

The findings presented in this thesis add considerable value to the CBE for pharmacy literature; however, it is crucial to acknowledge and carefully consider the inherent limitations encountered within each phase of the investigations. Namely, the interpretation of the features in the systematic review, despite collaboration with experts on CBE, is susceptible to a certain degree of subjectivity, potentially leading to unintended misinterpretations or omissions. This is turn influences some of the data interpretation of the challenges to CBE in the global survey that were linked back to the features identified in the systematic review.

In the global survey itself, small sample sizes and the potential for self-selection bias, under-coverage and challenges with the response rate warrants the need for caution in extrapolating the findings on a global scale. Potential language barriers, translation issues and exclusive distribution of the survey in English may have further compounded the comprehensiveness of the responses.

Considerations on the limitations of the consensus development panel lie in the withdrawal of key representatives, although efforts were made to garner representation from the regulatory and governmental bodies, the absence of these

crucial stakeholders compromised the system-wide approach that this research advocates. The resulting effect is a potential dominance by certain areas of the pharmacy system on the findings which should be taken into account when interpreting these findings. Furthermore, the subjective nature inherent in consensus development methods introduces and element of variability, justifying a careful consideration of the results.

Despite these limitations, the insights gained from this research provide a foundation for understanding CBE in pharmacy and addressing the original research questions. Future research endeavours should aim to address these limitations to foster a more nuanced and comprehensive understanding of competency-based education in the field of pharmacy practice.

7.4 Conclusion

This thesis undertook a comprehensive exploration of CBE in pharmacy, spanning global perspectives with a particular focus on Kenya. The principal findings of the research underscored the pervasive lack of information and evidence on CBE in Africa and South-East Asia. The global overview from the systematic review and survey collectively emphasised the critical need for a unified approach involving education, regulation, and practice for successful CBE implementation in pharmacy. The identified challenges, particularly in faculty preparedness and regulatory alignment, pose significant hurdles but also present opportunities for targeted interventions.

This research makes a distinct contribution by creating a localised competency framework tailored for early-career pharmacists in Kenya, in alignment with the FIP GbCFv2. Through this study, the relevance of the latest FIP framework within the Kenyan context is affirmed, while also pinpointing key priorities for the advancement of pharmacy practice in the country in the coming years. The deliberate involvement of the Pharmaceutical Society of Kenya in Part 2 of this research was a strategic decision aimed at enriching the study's outcomes and fostering a sense of ownership among Kenyan stakeholders. This collaboration ensures the sustainability of the project, paving the way for its continued utilisation in driving the implementation of CBE initiatives within the Kenyan pharmacy sector.

Moreover, the research illuminates the intricate features of CBE in pharmacy education globally and emphasises the importance of macro-level factors and stakeholder collaboration. This thesis acknowledges and partially addresses a critical gap in the literature from low- and middle-income countries but also calls for concerted efforts to advance CBE, particularly in regions where its impact has capacity to be transformative. The findings serve as a valuable foundation for future research, policy development, and educational reforms in pharmacy, urging a holistic and collaborative approach to reshape the landscape of pharmacy education and practice.

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Appendices

Appendix 1 Themes and frequency count of the definitions of CBE in medical education as identified by Frank et al

Theme (major)/Sub-themes	Definition	Records, *n*
1. Organizing framework	All descriptions of competency-based education (CBE) as an approach to education explicitly oriented to graduate outcomes.	165
a. Defined outcomes and milestones	Refers to the identification of specific competencies that are aligned to the outcomes of a training programme. These outcomes are derived from the abilities required of physicians for practice or to meet the standards of the profession. Competencies may also be described in terms of milestones or benchmarks that indicate progression of competence in one domain.	144
b. Curriculum of competencies	Includes all references that describe how curricula are organized around the identified competencies. The curriculum node includes references to learning strategies, teaching methods, and instructional design.	50
c. Demonstrable abilities	Includes all references that articulate the need for the components of competency-based education to be observable and comparable to objective criteria for all learners.	20
d. Assessment of competencies	Contains all citations that refer to the assessment of pre-defined standards or milestones that indicate progress toward the defined outcomes of a curriculum. Assessment is criterion-referenced, in that learners are measured against set standards and not other learners. Assessment may also involve threshold standards that must be achieved before further progression of the learner through the curriculum.	73
2. Rationale	Includes all arguments as to the rationale for employing competency-based education as an approach to medical education. This may include how patient needs are a driver to use CBE, how physicians are better prepared for practice or the next stage of training, how it is better for learners, or how it can increase educational efficiency.	53
a. Learner-centred	Includes all discussion of the use of CBE to ensure curricula are aligned with the learning needs of diverse medical learners. It includes all references to organizing teaching and learning around facilitating the progression of trainee competence toward the defined outcome abilities for a programme. This involves active engagement of learners in managing their learning, in regular self-assessment, and in ongoing frequent assessment of progress. This thread includes discussion of learner awareness of transparent goals, curriculum design, and assessment methods. It also includes mention of the self-directed continuing professional development of physicians in practice, and flexibility of curriculum processes to meet learners' needs.	29
b. Societal needs	Includes all discussions of the need for CBE to ensure that graduates have the essential abilities to effectively serve patients and populations once in practice. It also encompasses references to CBE as a mechanism to align curriculum goals with patient needs and optimal health care delivery.	26
3. Contrast with time	Includes all discussions that contrast time- or process-based medical education designs with CBE. All references to the pace of learning being tied to the acquisition of competence by a learner are incorporated. In this thread, training time is seen as a resource for instruction and not the organizing framework for medical education and credentialing.	35
4. Implementing CBE	Includes all discussions of CBE implementation designs, components, and ingredients.	20

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Appendix 2 Information Sheet - Global Survey of Competency-based Education for Initial Pharmacy/ Pharmaceutical Science Education and Training

FIPEd Global Survey of Competency-based Education for Initial Pharmacy/Pharmaceutical Science Education and Training

Information Sheet

Project Lead: Dr Naoko Arakawa

Principal Researcher: Miss Jessica McMullen

On behalf of the competency-based education (CBE) handbook project team we would like to invite you to take part in our research study. In order for you to understand the research before you decide whether or not to participate please read the following information.

What is the purpose of this research?

This global survey aims to investigate the drivers and challenges for the implementation, and the current use of, CBE for the initial education and training (undergraduate and professional degrees) of pharmacists and pharmaceutical scientists. These findings will provide the evidence-based information needed to design guidance in the form of a handbook for institutions teaching these subjects that wish to implement CBE.

Do I have to take part?

No, it is completely up to you to decide whether or not you want to take part in this research. If you do decide to take part you will be asked to give consent to participate via the online survey. We also ask that your provide contact details this is purely for the purposes of clarifying any of the responses if necessary and your information will not be shared outside of the core research team.

What will happen during the research?

You will be asked to complete a survey in the form of an online questionnaire. This will ask you to answer general background questions about your university or institution. Additionally, you will also be asked about the use (or lack of use) of CBE and any related challenges you encountered at your university or institution. Finally, you will be asked about any current experience of using CBE in relation to some of the core aspects of CBE. The survey should take approximately 30 minutes to complete.

Please access the survey by using the URL link, or scanning the QR code below: https://nottinghampharmacy.fra1.qualtrics.com/jfe/form/SV_7P1pjRGmu9KyEpE

Who should answer this survey?

One response per school is required please select the member of staff most suitable to answer questions on the topic of CBE or answer collectively as a team. If you have received this research invitation and feel you are not best placed to respond please forward to a suitable colleague.

What are the possible benefits of taking part?

There may not be any direct benefit to you from taking part in this research but the information that we collect can help us to understand how to educate pharmacists and pharmaceutical scientists in the best possible way to contribute to improved healthcare and pharmacy related education globally.

What happens when the research study stops?

This information will be used to help design a handbook for the implementation of CBE in the initial education of pharmacy and pharmaceutical science. The aim of the handbook is to guide countries and schools to implement CBE in order to assist with preparing pharmacy and pharmaceutical science graduates to be well equipped to serve populations and improve national and global health through enhanced workforce development.

What if there is a problem?

Should you have any concerns about anything to do with this research, contact details are provided at the bottom of this form. If, despite talking to the principal researcher, you still have any concerns you can contact the project lead, Naoko Arakawa at: naoko.arakawa@nottingham.ac.uk.

Will my information be kept confidential?

The study will be conducted in accordance with research guidelines approved by the University of Nottingham Ethics Committee.

All information provided by you and collected during the course of the study will be kept strictly confidential and will be stored in a secure locked location at the University of Nottingham. Any digital information will be stored on a password protected and secure online database. No personal information will be shared with any other parties. Any names and addresses or other personal information will only be accessible to the principle researcher and research team. Personal information will be removed from the research documents prior to analysis and you will not be personally identifiable in any of the findings released.

We will keep any written information for a minimum of 7 years but may keep it for longer up to a maximum of 25 years. During this time there will be a designated team member responsible for ensuring that your information is kept secure and access is restricted at all times.

The University of Nottingham is registered as a Data controller under the Data Protection act 1998 (registration No. Z5654762 – https://ico.org.uk/ESDWebPages/Entry/Z5654762) in the United Kingdom.
The University will process your personal data in accordance with the General Data Protection Regulation (GDPR) of the European Union and the Data Protection Act 2018 in the United Kingdom. For information about the University's obligations with respect to your data, who you can get in touch with and your rights as a data subject, please visit: https://www.nottingham.ac.uk/utilities/privacy.aspx.
If you are concerned about how your personal data is being processed, please contact the University's Data Protection Officer at:
Data Protection Officer
Legal services
A5 Trent Building
University of Nottingham
dpo@nottingham.ac.uk

What will happen if I want to leave the study?

You are free to decide to leave the study at any time without any affect to your legal rights. The information collected during your participation so far in the study however cannot be erased and may still be including in the study analysis. All information will still be treated with the strictest confidence as per national data protection and university guidelines if you choose to withdraw at any time.

Who is organising the research?

The research is organised by the International Pharmaceutical Federation (FIP) with support from the University of Nottingham, UK.

Contact details for further information

Miss Jessica McMullen
PhD Student
Pharmacy School Building
University Park
Nottingham
NG7 2RD
jessica.mcmullen@nottingham.ac.uk

Thank you for your time and for your interest in this research study.

Appendix 3 Global Survey of Competency-based Education for Initial Pharmacy/Pharmaceutical Science Education and Training

FIPEd Global Survey of Competency-based Education for Initial Pharmacy/Pharmaceutical Science Education and Training

Introduction

Competency-based education is a common educational model for pharmacists, and other healthcare professionals, around the globe (Bruno et al., 2010). The driving force behind adoption of this model is the requirement to prepare students to fulfil their societal role for the benefit of enhanced patient care and safety in an ever-advancing healthcare landscape (Miller et al., 2010).

Survey Aim

This global survey aims to investigate the drivers and challenges for the implementation, and the current use of competency-based education (CBE) in initial education and training (undergraduate and professional degrees) of pharmacists and pharmaceutical scientists. These findings will provide the evidence-based information needed to develop guidance for institutions teaching these subjects that wish to implement CBE.

Who should answer this survey?

One response per school is required please select the member of staff most suitable to answer questions on the topic of CBE or answer collectively as a team. If you have received this research invitation and feel you are not best placed to respond please forward to a suitable colleague.

Contact Details for Further Information

Miss Jessica McMullen
Pharmacy School Building
University Park
Nottingham
NG72RD
jessica.mcmullen@nottingham.ac.uk

Ethical Approval

This research has been granted ethical approval from The University of Nottingham, School of Pharmacy. Ethics application number is 001-2021 PharmUoN and was awarded in October 2021

What is Competency-based Education (CBE)?

In the context of medical education, Hodges et al (2012) define competency-based education as 'education that derives a curriculum from an analysis of a prospective or actual role in modern society and attempts to certify students' progress on the basis of demonstrated performance in some or all aspects of that role'. It is also suggested that this definition can be applied to the education and training of other healthcare professionals, including pharmacists (Bajis et al., 2020).

Competence* is the ability to carry out a job or task. **Competencies** (singular: **competency**) are the building blocks of competence. In this context we will be referring to competencies as the observable components of knowledge, skills, attitudes and values expressed as actual behaviour which can be measured and assessed (Koster et al., 2017). Competencies can be formulated into a framework that supports the development of safe and effective practitioners. Competency frameworks consist of a structured assembly of behavioural standards which describe the capabilities necessary to achieve a defined competency. When demonstrated collectively these determine the overarching competence, or capability, of a practitioner (International Pharmaceutical Federation, 2012).

BAJIS, D., CHAAR, B. & MOLES, R. 2020. Rethinking Competence: A Nexus of Educational Models in the Context of Lifelong Learning. Pharmacy (Basel, Switzerland), 8

BRUNO, A., BATES, I., BROCK, T. & ANDERSON, C.2010. Towards a global competency framework. American Journal of Pharmaceutical Education, 74.

HODGES, B. D., LINGARD, L. & PROQUEST 2012. The question of competence: reconsidering medical education in the twenty-first century / edited by Brian D. Hodges and Lorelei Lingard, Ithaca: ILR Press.

INTERNATIONAL PHARMACEUTICAL FEDERATION. 2012. Pharmacy Education Taskforce. A Global Competency Framework. Version 1, The Hague: INTERNATIONAL PHARMACEUTICAL FEDERATION.

KOSTER, A., SCHALEKAMP, T. & MEIJERMAN, I. 2017. Implementation of Competency-Based Pharmacy Education (CBPE). Pharmacy, 5, 10.

MILLER, B. M., MOORE, D. E., JR., STEAD, W. W. & BALSER, J. R.2010. Beyond Flexner: a new model for continuous learning in the health professions. Academic medicine: journal of the Association of American Medical Colleges, 85, 266-72.

**The term 'competence' is a dynamic one with many interpretations around the globe, while we are aware that the definitions vary we will be referring to competency, competencies and competence in this context according to the definitions described above.*

Please continue with the survey even if you are not familiar with these specific definitions.

Please reply to this survey either as an individual or as a team on behalf of **your higher education institution/university**

Electronic Informed Consent Form

Your participation in this survey is entirely voluntary. You can also withdraw from the survey at any time. However, please be aware that this data cannot be discarded if the analysed data has been published at the time of the withdrawal request.
You will be asked to provide contact details at the end of the survey, this will not be shared and is only to be used by the principal researcher if further information is necessary regarding answers to the survey questions for clarification purposes. This information will be stored safely and securely at the University of Nottingham.
Please fill in the following online survey if you agree to participate in this survey, which will take you approximately 25 minutes in total to complete.
By clicking the 'agree' button, you indicate that: You have read the information above and understand what the study involves, and you voluntarily agree to participate in the survey.

☐ Agree

☐ Disagree

FACULTY, SCHOOL OR DEPARTMENT OF PHARMACY/ PHARMACEUTICAL SCIENCE INFORMATION

Country information			
1.	Select the country of your faculty, school or department	{Dropdown list of countries}	
Full official name of the FACULTY, SCHOOL or DEPARTMENT (e.g. National University for the Health Sciences, School of Pharmacy)			
2.	In English		
Year of establishment			
3.	In which CALENDAR YEAR was your faculty, school or department of pharmacy/pharmaceutical science established?		
OWNERSHIP of the faculty, school or department of pharmacy/ pharmaceutical science			
4.	a) Public state/government owned	☐	
	b) Private not for profit	☐	
	c) Private for profit	☐	
	d) Public/private mix	☐	
	e) Others (please provide details in the space provided on the right)	☐	Details:
Do any of the following healthcare-related departments, faculties, or schools in your institution/university collaborate with your department, school, or faculty interprofessionally (select all that apply)			
5.	a) Medicine	☐	
	b) Dentistry	☐	
	c) Nursing	☐	
	d) Midwifery	☐	
	e) Physiotherapy	☐	
	f) Social Work	☐	
	g) Mental Health	☐	
	h) Occupational Therapy	☐	
	i) Physician/ surgical assisting	☐	
	j) Nutrition and dietetics	☐	
	h) No collaborations		
	k) Other	☐	Details:

ACADEMIC PROGRAMMES

Definition: An academic programme is a combination of courses or learning modules that g access to a degree, diploma, certificate, or other credentials, which is recognized in society the educational institution such as a Diploma, Baccalaureate/Bachelor's Degree, or Master

Level of academic programme(s) offered by the faculty, school, or department of pharmacy/ pharmaceutical science (select all that apply)			
6.	a) Diploma	☐	
	b) Baccalaureate Degree (e.g. BPharm or BSc)	☐	
	c) Master's Degree (e.g. MPharm or MSc)	☐	
	d) PharmD	☐	
	e) Other	☐	Details:

REGULATION/QUALITY ASSURANCE

Regulation/ Quality Assurance				
7.	Do pharmacy graduates require registration/ licensure from a regulatory body to practice pharmacy in your country?	Yes ☐	No ☐	
8. (display only if answer to Q7. Is yes)	Does your country have its own regulatory body (related to licensure) for the pharmacy profession?	Yes ☐	No ☐	
9. (display only if answer to Q8 is yes)	Are the regulatory body, related to registration/licensure, for the pharmacy profession in your country advocates of CBE?	Yes ☐	No ☐	Don't know ☐
10.	Does your country have its' own quality assurance body, related to accreditation, for pharmacy education?	Yes ☐	No ☐	
11. (only display this question if answer to Q8 is yes)	Is the quality assurance body, related to accreditation, in your country advocates of CBE?	Yes ☐	No ☐	Don't know ☐

COMPETENCY-BASED EDUCATION

Please answer the remaining questions in relation to your pharmacy or pharmaceutical science programme which has a competency-based approach. This may be a whole programme/degree that is competency-based or may only be part of a programme. If only part of your programme is competency-based please answer on behalf of your main CBE specific unit/module.

Programme(s) information			
12.	Do you use Competency-based Education (CBE) in any of your pharmacy/pharmaceutical science academic programmes?	☐ Yes (go to Q12) ☐ No (go to not using CBE branch)	
Institutions/universities not currently using CBE (Branch)			
a)	Reasons for not using CBE in your school, faculty, or department	☐ Not permitted ☐ Not convinced of usefulness ☐ Unable to implement due to lack of stakeholder buy in ☐ Unable to implement due to lack of support from the department/institution ☐ Unable to implement due to lack of experience	☐ Other (please provide details below) _____ ☐ Don't know
b)	Do you expect to be experimenting with CBE (or elements of CBE) in your school, faculty, or department within the next 5 years?	☐ Yes (please provide details) ☐ No	
c)	Are there any specific needs for your institution/university that would help with the use of CBE?	☐ Yes (please provide details) ☐ No	

Further Information for Institutions not currently using CBE

Thank you for your time, your response is greatly valued. Please fill out the contact details in the next section and we will ensure that we disseminate the survey results to you. We are also working on a handbook to assist with the implementation of CBE which we will be forwarded to you once completed.

In the meantime, for more information about CBE, including the Global Competency Framework (GbCF) for foundation pharmacists, please access the International Pharmaceutical Federation (FIP) website: https://www.fip.org/ *(go to further information and then end of survey)

13.	What is the current maximum capacity for new admissions to the first year for the academic programme (s) which incorporate CBE?	Please only input figures for those programmes containing CBE	
		Pharmacy : Pharmaceutical Sciences:	
14.	In what way is CBE incorporated in to this programme(s)? (tick all that apply)	Pharmacy	Pharmaceutical Science
		☐ Integrated throughout the whole programme ☐ Incorporated in parts of the programme only (e.g. specific units, or modules) only ☐ Not applicable	☐ Integrated throughout the whole programme ☐ Incorporated in parts of the programme only (e.g. specific units, or modules) only ☐ Not applicable
15.	In what way was the CBE <u>whole</u> programme designed? (this question is only displayed if 1 or more whole programme options are selected)	Pharmacy	Pharmaceutical Science
		☐ Completely new programme ☐ Modification of an existing programme	☐ Completely new programme ☐ Modification of an existing programme
16.	In what way was the CBE <u>part-programme</u> unit/module designed? (this question is only displayed if 1 or more of the part programme options are selected)	Pharmacy	Pharmaceutical Science
		☐ Newly designed unit/module ☐ Modification of an existing unit/module ☐ Not applicable	☐ Newly designed unit/module ☐ Modification of an existing unit/module ☐ Not applicable

CORE ASPECTS OF COMPETENCY-BASED EDUCATION (CBE)

This section of the survey will require you to answer questions related to some of the core aspects of CBE as follows:

- Health needs underpinning (Needs-Based Education*)
- Competencies/competency frameworks
- Design/curriculum mapping of learning objectives to competencies
- Systems of instruction and learning methods
- Feedback and assessment
- Timing/pacing
- Resources
- Faculty involvement and readiness

*For more information on Needs-based Education please click here (select to open in new window/tab is suggested)

CHALLENGES AND NEEDS

Specific challenges and needs required of your institution/faculty/school or department in order to use CBE		
17.	**Health Needs-based Education Underpinning** Did/do you encounter any challenges with health needs underpinning (needs-based education) when using CBE? (select all that apply)	☐ Difficulty obtaining stakeholder engagement ☐ Inadequate faculty training/skills to perform needs analysis/assessment ☐ Lack of support from management/leadership ☐ Lack of adequate health needs data available ☐ Other (please provide details) ☐ No challenge encountered
18.	**Competency frameworks** Did/do you encounter any of the following challenges in drafting a competency framework when using CBE? (select all that apply)	☐ No suitable competency framework identified ☐ Inadequate faculty training/skills to create a suitable framework ☐ Difficulty obtaining stakeholder engagement ☐ Lack of support from management/leadership ☐ Socio-political issues such as regulations, laws, policies and traditions ☐ Other (please provide details) ☐ No challenge encountered
19.	**Selecting competencies** Did/do you encounter any of the following challenges in selecting competencies when using CBE? (select all that apply)	☐ Difficulty in obtaining stakeholder engagement ☐ Inadequate faculty training/skills to select appropriate competencies ☐ Lack of support from management/leadership ☐ Socio-political issues such as regulations, laws, policies or traditions ☐ Other (please provide details) ☐ No challenge encountered
20.	**Curriculum design/mapping** Did/do you encounter any of the following challenges with curriculum design/mapping when using CBE? (select all that apply)	☐ Lack of external support of CBE (e.g. from accreditation or professional bodies) ☐ Lack of internal support of CBE (e.g. from faculty) ☐Resistance to change from management/leadership ☐ Lack of effective management/monitoring of the change process ☐ Socio-political issues such as: regulations, laws, policies and traditions ☐ Difficulties in reaching a consensus on a new curriculum ☐ Difficulty in obtaining stakeholder engagement ☐ Other (please provide details) ☐ No challenge encountered
21.	**Systems of instruction and learning methods** Did/do you encounter any challenges with the following	☐ Self-evaluation/reflection ☐ Problem/project-based learning ☐ Case-based learning ☐ Inter-professional education (IPE) activities

	aspects of teaching and learning when using CBE? (select all that apply)	☐ Discussions in lectures/tutorials ☐ Lectures and textbooks ☐ Active learning strategies including simulation and role play ☐ Work-based activities ☐ Virtual learning ☐ Other (please provide details) ☐ No challenge encountered
22.	**Feedback and assessment** Did/do you encounter any challenges with the following aspects of feedback and assessment when using CBE? (select all that apply)	☐ Multiple Choice Questions (MCQs), including Extended Matching Questions (EMQs) and computer-adaptive tests (CATs) ☐ Written examination, including modified essay question (MEQ) ☐ Viva Voce (viva)/ traditional oral examination ☐ Simulated patient encounters (role-plays) and practical examination ☐ Objective Structured Clinical Examinations (OSCEs) ☐ Workplace (experiential) learning/assessment ☐ Entrustable Professional Activities (EPAs) ☐ Portfolios ☐ Other (please provide details) ☐ No challenge encountered
23.	**Faculty involvement and readiness** Did/do you encounter any challenges related to any of the following aspects of training, or preparing, faculty to deliver CBE? (select all that apply)	☐ Informal small-scale training ☐ Formal large-scale training ☐ Self-reflection on teaching experiences ☐ Use of educational research literature ☐ Opportunities for collaborative teaching development/learning ☐ Evidence-based development of teaching ☐ Mentoring ☐ Opportunities for exchange of good practice and training/coaching in national networks ☐ Opportunities for exchange of good practice and training/coaching in international networks ☐ Other (please provide details) ☐ No challenge encountered
24.	**Additional comments** Are there any specific needs for your institution/university that you think would be helpful for implementing CBE?	☐ Yes (please provide details) ☐ No

CURRENT CBE ASPECTS USED AT YOUR UNIVERSITY/INSTITUTION

Health Needs Underpinning		
25.	Did you use any form of health needs assessment to underpin the design of your CBE programme/module/unit?	☐ Yes (please provide details) ☐ No (skip to Q26)
26.	Which of the following did you use to assess the local health needs to underpin the competencies used in the design of your CBE programme/unit/module? (select all that apply)	☐ Previous existing health needs assessment ☐ Literature review ☐ Stakeholder meetings ☐ Focus Groups ☐ Interviews ☐ Government-led commissions ☐ Organizational data (e.g. from the Ministry of Health or Pharmaceutical Society, or equivalent) ☐ Other (please provide details)
Competencies/ competency frameworks		
27.	Which frameworks (if any) were used for your CBE programme/unit/module? (select all that apply)	☐ An existing national pharmacy/pharmaceutical science framework ☐ An existing pharmacy/pharmaceutical science competency framework from another country or supra-national organization (please state which) ……. ☐ An existing local competency framework from another profession, other than pharmacy/pharmaceutical science (please state which) ……. ☐ A new competency framework developed at your institution ☐ The International Pharmaceutical Federation (FIP) Global Competency framework (GbCF) for foundation pharmacists ☐ No competency framework used ☐ Other, please provide details
28.	Which stakeholders were involved in the identification of competencies/ drafting competency frameworks for your CBE programme/unit/module? (select all that apply)	☐ Academic staff from your school/faculty/department ☐ Academic staff from another school/faculty/department ☐ Alumni ☐ Pharmacists ☐ Pharmaceutical scientists ☐ Representatives from the pharmaceutical industry ☐ Representatives from a pharmacy/pharmaceutical science regulatory/quality assurance body ☐ Other healthcare professionals ☐ Ministry of Education (or equivalent)

		☐ Representatives from another educational regulatory body ☐ Ministry of health (or equivalent) ☐ Healthcare providers/ organisations ☐ Patients ☐ Students ☐ Other, please provide details:
Mapping of Learning Objectives to Competencies		
29.	Have you used mapping of learning objectives to competencies in any of your programmes (CBE or non-CBE)?	☐ Yes ☐ No(skip to Q31)
30.	If yes, how many rounds of mapping were performed?	Drop down box (1-10+)
31.	Which stakeholders were involved in mapping learning outcomes to competencies? (select all that apply)	☐ Academic staff from your school/faculty/department ☐ Academic staff from another school/faculty/department ☐ Alumni ☐ Course coordinators ☐ Pharmacists ☐ Pharmaceutical scientists ☐ Representatives from the pharmaceutical industry ☐ Representatives from a pharmacy/pharmaceutical science regulatory/quality assurance body ☐ Other healthcare professionals ☐ Ministry of Education (or equivalent) ☐ Representatives from another educational regulatory body ☐ Ministry of health (or equivalent) ☐ Healthcare providers/ organisations ☐ Students ☐ Other, please provide details:
Systems of Instruction and Learning Methods		
32.	Have you used any of the following educational models in the design of your CBE programme, unit or module? (select all that apply)	☐ Miller's prism of clinical competence ☐ Bloom's taxonomy ☐ Dreyfus & Dreyfus development of expertise model ☐ Bigg's constructive alignment ☐ No educational models used ☐ Other (please provide details)
33.	Which of the following educational formats are used in your CBE programme/unit/module? (select all that	☐ Self-evaluation/reflection ☐ Problem/project based learning ☐ Case-based learning ☐ Inter-professional education (IPE) activities ☐ Discussions in lectures/tutorials

	apply)	☐ Simulation-based learning ☐ Lectures and textbooks ☐ Other (please provide details)
Feedback and Assessment ***Definitions*** *Summative assessment: all assessments which contribute to course grades and/or high-stakes decisions (assessment <u>of</u> learning)* *Formative assessment: the monitoring of students learning in order to provide feedback to staff and students (assessment <u>for</u> learning)*		
34.	Estimate the percentage of formative and summative assessment, respectively for your whole CBE unit/module/programme (please ensure the sum of your answers for summative plus formative assessment estimates do not exceed 100%)	Formative percentage slider Summative percentage slider
35.	What grading systems do you mostly use for your CBE units/module/programmes?	☐ Criterion Based (e.g. pass/fail) ☐ Percentages ☐ Numerical ☐ Alphabetical ☐ Other Please Specify _____
36.	Which of the following assessment formats are used in your CBE programme, unit or module? (select all that apply)	☐ Multiple Choice Questions (MCQs), including Extended Matching Questions (EMQs) and computer-adaptive tests (CATs) ☐ Written examination, including modified essay question (MEQ) ☐ Viva Voce (viva)/ traditional oral examination ☐ Simulated patient encounters (role-plays) and practical examination ☐ Objective Structured Clinical Examinations (OSCEs) ☐ Workplace (experiential) learning/assessment ☐ Entrustable Professional Activities (EPAs) ☐ Portfolios ☐ Other (please provide details)
37.	When do your assessments usually take place for your CBE unit/module/programme?	matrix
	Summative	At the end of / At the end of / At various / Other

		the academic year	each unit/module	time points throughout the unit/module	(please provide details)
	Formative	At the end of the academic year	At the end of each unit/module	At various time points throughout the unit/module	Other (please provide details)
38.	If skills are assessed as 'insufficient' following an assessment is additional training and re-testing of skills offered?	☐ Yes ☐ No			
Timing/Pacing					
39.	Does your CBE programme, unit or module offer any opportunities for students to regulate their own pace of study? (e.g. repeated course offerings per academic year, mobile learning, e-learning)	☐ No ☐ Yes (Please provide details)			
Resources					
40.	What additional resources, if any, did/do you require to implement CBE? (select all that apply)	☐ Increased academic staff with CBE training or training of existing staff ☐ Increased administrative/ auxiliary staff ☐ Increased clinical/practitioner/practice based staff ☐ Increased working hours for existing academic staff ☐ Increased working hours of existing administrative/ auxiliary staff ☐ Increased working hours for existing clinical/practitioner/practice based staff ☐ New learning spaces/ classrooms ☐ New materials/ consumables ☐ Internal funding (from your within institution) ☐ External funding ☐ Appointment of specialist staff e.g. stream coordinators, consultants/CBE specialists ☐ formation of a curriculum management team ☐ appointment of a director of education ☐ other (please provide details) ☐ No additional resources needed			

Faculty		
41.	Did your institution provide/organise any of the following additional training for faculty in order to implement and deliver your CBE programme/unit/module? (select all that apply)	☐ Assessment methodology ☐ Teaching methodology ☐ Informal small-scale training ☐ Formal large-scale training ☐ Self-reflection on teaching experiences ☐ Use of educational research literature ☐ Opportunities for collaborative teaching development learning exercises ☐ Evidence-based development of teaching ☐ Mentoring ☐ Opportunities for exchange of good practice and training/coaching in national networks ☐ Opportunities for exchange of good practice and training/coaching I international networks ☐ Other (please provide details) ☐ No training organised/provided
42.	Are faculty members informed of the complete curriculum outline of your CBE programme/unit/module?	☐ Yes ☐ No

CONTACT DETAILS for the person responding to this questionnaire

Please provide the contact details of the person completing this survey, in doing so you give permission or us to contact you should we need to clarify any of your responses.

43.	Full name	
44.	Place of work	
45.	Position at work	
46.	Email address (E.g. the email format is xxxx@yyyy.zzz)	
47.	Mobile phone number (if easier to contact on WhatsApp)	

Thank you for your participation

If you have any further questions please email

Jessica.mcmullen@nottingham.ac.uk

Appendix 4 Information Sheet - Global Competency Framework Applicability Study in Kenya

International Pharmaceutical Federation Global Competency Framework Applicability Study in Kenya

Information Sheet

Principal Researcher: Jessica McMullen, School of Pharmacy, the University of Nottingham, UK

Supervisors: Prof Claire Anderson, School of Pharmacy, the University of Nottingham, UK
Prof Simon McGrath, School of Education, the University of Nottingham, UK
Dr Naoko Arakawa, School of Pharmacy, the University of Nottingham, UK

Collaborators: Daniella Munene, CEO of the Pharmaceutical Society of Kenya

Background

The Pharmaceutical Society of Kenya (PSK) and the University of Nottingham would like to invite you to participate in research to shape the future of pharmacy practice and education in Kenya.

The trend in pharmacy practice, both in Kenya and internationally, has been evolving from a role predominately focused on manufacture and supply to a more patient-centred clinical role. In order to keep up with this trend, and contribute to the development of healthcare, pharmacy education and training will need to adapt to equip pharmacists with the skills required for competent up-to-date pharmacy practice in Kenya.

Previous research demonstrates that the improvement of pharmacists' performance is facilitated when competency frameworks are used alongside standards of practice. Therefore, we are looking to create a locally relevant pharmacy competency framework.

A competency framework outlines the pre-requisite knowledge, skills, attitudes and behaviours obtained through education and training which determine the overall competency of a pharmacist.

The International Pharmaceutical Federation (FIP) developed a Global Competency Framework (GbCF) in 2012 for foundation level pharmacy practice (for the purpose of this survey foundation level practice refers to the first 1000 days of practice post-qualification). Since then many countries adapted the GbCF to their own settings for advancing Continual Professional Development (CPD) support for foundation level pharmacists. The FIP has since released version 2 of the GbCF in 2020 which includes amendments to some of the statements in version 1 and the addition of new competencies and related behavioural statements.

What is the purpose of this research?

The results of this survey will be used to assess how Kenyan pharmacy practice aligns with the Global Competency Framework Version 2 (GbCFV2). The findings will then be discussed with key stakeholders for the pharmacy profession in Kenya to enrich the bespoke, and locally relevant competency framework already created by the PSK. The final framework will be used to support future reform of Kenyan pharmacy education and practice.

Do I have to take part?

No, it is completely up to you to decide whether or not you want to take part in this research. If you do decide to take part you will be asked to give consent to participate electronically via the online survey.

What will happen during the research?

You will be asked to complete a survey in the form of an online questionnaire. This will ask you to answer general background questions about yourself. Additionally, you will also be asked to rate the applicability of each of the behavioural statements in the GbCFV2 to your own pharmacy practice. The survey should take approximately 20 minutes to complete.

Who should answer this survey?

We are asking for any pharmacist, registered and practising in Kenya, to kindly take part in this survey.

What are the possible benefits of taking part?

There may not be any direct benefit to you from taking part in this research but the information that we collect can help us to understand how to educate pharmacists and develop pharmacy practice in the best possible way to contribute to improved healthcare and pharmacy related education in Kenya.

What if there is a problem?

Should you have any concerns about anything to do with this research, contact details are provided at the bottom of this form. If, despite talking to the principal researcher, you still have any concerns you can contact Prof Claire Anderson at the University of Nottingham at claire.anderson@nottingham.ac.uk or Daniella Munene at the PSK at ceo@psk.or.ke.

Will my information be kept confidential?

This is an **anonymous survey** and the study will be conducted in accordance with research guidelines approved by the University of Nottingham Ethics Committee.

All information provided by you and collected during the course of the study will be kept strictly confidential and will be stored in a secure locked location at the University of Nottingham. Any digital information will be stored on a password protected and secure online database. No personal information will be shared with any other parties. Personal information will be removed from the research documents prior to analysis and you will not be personally identifiable in any of the findings released.

We will keep any written information for a minimum of 7 years but may keep it for longer up to a maximum of 25 years. During this time there will be a designated team member responsible for ensuring that your information is kept secure and access is restricted at all times.

The University of Nottingham is registered as a Data controller under the Data Protection act 1998 (registration No. Z5654762 – https://ico.org.uk/ESDWebPages/Entry/Z5654762) in the United Kingdom.

The University will process your personal data in accordance with the General Data Protection Regulation (GDPR) of the European Union and the Data Protection Act 2018 in the United Kingdom. For information about the University's obligations with respect to your data, who you can get in touch with and your rights as a data subject, please visit: https://www.nottingham.ac.uk/utilities/privacy.aspx.
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Who is organising the research?

The research is organised by the University of Nottingham, UK and the Pharmaceutical Society of Kenya (PSK).

Ethical Approval

This study had been granted ethical approval by the University of Nottingham (approval number 012-2020), and the Jomo Kenyatta University of Agriculture and Technology (approval number JKU/IERC/02316/0123) and has been granted a Kenyan research license by the National Commission for Science, Technology & Innovation (license number NACOSTI/P/21/12536).

Contact details for further information

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Please click the link, or scan the QR code below to participate in this survey

https://nottinghampharmacy.fra1.qualtrics.com/jfe/form/SV_9ZBAtfl511GeShL

Thank you for your time and for your interest in this research study.

Appendix 5 Survey - Global Competency Framework Applicability Study in Kenya

Kenya GbCF Applicability Study

Start of Block: Introduction & consent form

Introduction

Title of Project **International Pharmaceutical Federation (FIP) Global Competency Framework Version 2 (GbCFv2) applicability study in Kenya**

Researcher Miss Jessica McMullen, School of Pharmacy, University of Nottingham

Collaborators Pharmaceutical Society of Kenya

Supervisors Prof Claire Anderson, School of Pharmacy, University of Nottingham. Prof Simon McGrath, School of Education, University of Nottingham. Dr Naoko Arakawa, School of Pharmacy, University of Nottingham

What is the purpose of this study? The trend in pharmacy practice, both in Kenya and internationally, has been evolving from a primarily manufacture and supply orientated role to a more patient-centered clinical role. In order to contribute to healthcare development and keep up with this demand pharmacy education and training also needs to adapt to equip pharmacists with the skills necessary for contemporary practice. In order to achieve this, the use of competency frameworks in healthcare professional workforce development receives much attention globally. The International Pharmaceutical Federation (FIP) developed a Global Competency Framework (GbCF) version 1 in 2012 for foundation level pharmacy practice (for the purpose of this survey foundation level practice refers to the first 1000 days of practice post-qualification). Since then many countries adapted the GbCF to their own settings for advancing Continual Professional Development (CPD) support for foundation level pharmacists. The FIP has since released version 2 of the GbCF in 2020 which includes amendments to some of the statements in version 1 and the addition of new behavioural statements under competencies such as 'digital literacy' and 'interprofessional collaboration' which reflects the ever changing field of pharmacy practice especially in these challenging times of the COVID-19 pandemic. FIP defines competencies as a set of skills, attitudes, knowledge and behaviours necessary to practice safely and effectively which are acquired by pharmacists through education and training and is expected to be a continuous processes throughout their career.

The purpose of the survey is to identify necessary competencies and associated behaviours for effective performance of foundation-level pharmacists across all sectors in Kenya by investigating the applicability of the FIP GbCF in a Kenyan pharmacy practice environment. The findings will then be discussed with key stakeholders for the pharmacy profession in Kenya to enrich the bespoke, and locally relevant competency framework already created by the Pharmaceutical Society of Kenya (PSK). The final framework will be used to support future reform of Kenyan pharmacy education and practice.

This study has been granted a Kenyan research license by NACOSTI, license number: NACOSTI/P/21/12536. All contributions are highly valued, and we appreciate your time and effort. If you have any questions or concerns about the survey, please contact Jessica

McMullen jessica.mcmullen@nottingham.ac.uk in the first instance, however if you still have concerns please contact Prof Claire Anderson at claire.anderson@nottingham.ac.uk or Daniella Munene at ceo@psk.or.ke

Consent Form **Electronic Informed Consent Form**

This is an anonymous, confidential questionnaire, and we will not collect any personal identifiable information of you. Your participation in this survey is entirely voluntary. You can also withdraw from the survey at any time. However, please be aware that this data cannot be discarded if the analysed data has been published at the time of request for withdrawal. You will be asked specific questions about 123 behavioural statements that constitute the provision of pharmaceutical services. The items are divided into four separate clusters: 'pharmaceutical public health', 'pharmaceutical care', 'organisation and management', and 'professional/personal'.

Please fill in the following online survey if you agree to participate with this survey, **which will take you approximately 20 minutes in total to complete.** The results will be published as a report that will be available online and via peer reviewed journal articles after aggregating answers while anonymity is maintained. Non-personal research data may be used by other members of the research group for future research with maintained confidentiality and anonymity.

Consent Please select your choice below. By clicking the "agree" button, you indicate that: You have read the information above and understand what the study involves, you voluntarily agree to participate in the survey and you are a registered pharmacist in Kenya.

- ○ Agree (1)
- ○ Disagree (0)

End of Block: Introduction & consent form

Start of Block: Demographic Information

Demographics Please answer the following questions about yourself

Q1 1. What is your gender? (please select one of the following)

- ○ Male (1)
- ○ Female (2)
- ○ Prefer not to say (3)

Q2 2. What is your age? (Please select one answer from the following dropdown list)

▼ 20 (1) ... 75 (56)

Q3 3. How many years have you been qualified as a pharmacist? (please select one answer from the following dropdown list)

▼ 1 year or less (1) ... 55 (55)

Q4 4. What is your current core area of practice?

▼ Community Pharmacy (1) ... Other (8)

Q5 If you selected 'other', please specify:

_____

Q6 5. How many years have you been working in your **current core area of practice**? (please select one option from the following dropdown list)

▼ 1 year or less (1) ... 55 (55)

Q7 6. Have you ever had a career break from working as a pharmacist?

- Yes (1)
- No (0)

Skip To: End of Block If 6. Have you ever had a career break from working as a pharmacist? = No

Q8 7. How many years in total have you had as a break from your pharmacy career? (please select one option from the following dropdown box)

▼ 1 year or less (1) ... 55 (55)

End of Block: Demographic Information

Start of Block: FIP Global Competency Framework

Cluster 1 **1. Pharmaceutical Public Health**

This cluster of the Global Competency Framework focuses on health promotion, medicines information and advice that pharmacists provide. Please rate each individual behavioural statement as highly relevant, relevant, low relevance, or not relevant to your own pharmacy practice. When choosing your answers please consider the following explanations of the rating options: *Highly relevant:* refers to the behavioural statements which you fulfil in your own practice and consider to have a strong degree of relation to your work as a pharmacist. *Relevant:* refers to the behavioural statements that you consider to have a moderate degree of relation to your own practice. *Low relevance*: refers to the behavioural statements that you consider to have a slight degree of relation to your own practice. *Not Relevant:* refers to the behavioural statements that you consider to not have any degree of relation to your own

practice. **Please answer all questions, reflecting *actual* practice rather than ideal or desired practice.**

Q19 Pharmaceutical Public Health Competencies1.1 Emergency Response

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 1.1.1 Participate in the response to public health emergencies (Q19_1)	○	○	○	○
Behaviour 1.1.2 Assist the multidisciplinary healthcare teams in emergency situations (Q19_2)	○	○	○	○

Page Break

Q20 1.2 Health Promotion

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 1.2.1 Assess the patient's/population's primary healthcare needs (taking into account the cultural and social setting of the patient/populations) (Q20_1)	○	○	○	○
Behaviour 1.2.2 Advise and provide services related to health promotion; disease prevention and control (e.g. vaccination); and healthy lifestyle (Q20_2)	○	○	○	○
Behaviour 1.2.3 Identify and support national and local health priorities and initiatives (Q20_3)	○	○	○	○

Q21 1.3 Medicines information and advice

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 1.3.1 Counsel the patient/population on the safe and rational use of medicines and devices (including the selection, use, contraindications, storage, and side effects of non-prescription and prescription medicines) (Q21_1)	○	○	○	○
Behaviour 1.3.2 Identify sources, retrieve, evaluate, organise, assess and provide relevant and appropriate medicines information according to the needs of patients and clients (Q21_2)	○	○	○	○
Behaviour 1.3.3 Support the patient's use of health information technologies and digital communication (including IT driven health solutions) (Q21_3)	○	○	○	○

Q22 Please add any comments or additional behaviours that you would consider useful for this cluster

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End of Block: FIP Global Competency Framework

Start of Block: FIP Global Competency Framework

Q23 **2. Pharmaceutical Care**

This cluster of the Global Competency Framework focuses on the role of pharmacists in patient consultation and diagnosis, and assessing, compounding, dispensing and monitoring services. Please rate each individual behavioural statement as highly relevant, relevant, low relevance, or not relevant to your own pharmacy practice. When choosing your answers please consider the following explanations of the rating options: *Highly relevant:* refers to the behavioural statements which you fulfil in your own practice and consider to have a strong degree of relation to your work as a pharmacist. *Relevant:* refers to the behavioural statements that you consider to have a moderate degree of relation to your own practice. *Low relevance*: refers to the behavioural statements that you consider to have a slight degree of relation to your own practice. *Not Relevant:* refers to the behavioural statements that you consider to not have any degree of relation to your own practice. **Please answer all questions, reflecting *actual* practice rather than ideal or desired practice.**

Q24 2.1 Assessment of medicines

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 2.1.1 Gather, analyse, research, and interpret information about the patient and patient's medicines-related needs (e.g. indication, effectiveness, safety and adherence) (Q24_1)	○	○	○	○
Behaviour 2.1.2 Retrieve relevant patient information (including drug history, or immunisation status for example) and record of allergies to medicines and Adverse Drug Reactions (ADR) in medication record. (Q24_2)	○	○	○	○
Behaviour 2.1.3 Identify, prioritise, resolve and follow up on medicine-medicine interactions; medicine-disease interactions; medicine-patient interactions; medicines-food interactions (Q24_3)	○	○	○	○
Behaviour 2.1.4 Appropriately select medicines (e.g. according to the patient, hospital, government policy, etc.) (Q24_4)	○	○	○	○

Q25 2.2 Compounding medicines

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.) (Q25_1)	○	○	○	○
Behaviour 2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines (Q25_2)	○	○	○	○

Q26 2.3 Dispensing

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 2.3.1 Accurately dispense medicines for prescribed and/or minor ailments, including an embedded checking process (Q26_1)	○	○	○	○
Behaviour 2.3.2 Accurately report defective or substandard medicines to the appropriate authorities (Q26_2)	○	○	○	○
Behaviour 2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal (Q26_3)	○	○	○	○
Behaviour 2.3.4 Dispense devices (e.g. inhaler or a blood glucose meter) (Q26_4)	○	○	○	○
Behaviour 2.3.5 Document and act upon dispensing errors (Q26_5)	○	○	○	○
Behaviour 2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system (Q26_6)	○	○	○	○

Behaviour 2.3.7 Label the medicines (with the required and appropriate information) (Q26_7)	○	○	○	○
Behaviour 2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors' (Q26_8)	○	○	○	○

X→

Q27 2.4 Medicines

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 2.4.1 Advise patients on proper storage conditions of the medicines and ensure that medicines are stored appropriately (e.g. humidity, temperature, expiry date, etc.) (Q27_1)	○	○	○	○
Behaviour 2.4.2 Appropriately select medicine formulation and concentration for minor ailments (e.g. diarrhoea, constipation, cough, hay fever, insect bites, etc.) (Q27_2)	○	○	○	○
Behaviour 2.4.3 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients (Q27_3)	○	○	○	○
Behaviour 2.4.4 Package medicines to optimise safety (ensuring appropriate re-packaging and labelling of the medicines) (Q27_4)	○	○	○	○

X→

Q28 2.5 Monitor medicines therapy

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 2.5.1 Apply guidelines, medicines formulary system, protocols and treatment pathways (Q28_1)	○	○	○	○
Behaviour 2.5.2 Apply therapeutic medicines monitoring, impact and outcomes (including objective and subjective measures) (Q28_2)	○	○	○	○
Behaviour 2.5.3 Identify, prioritise, and resolve medicines management problems (including errors) (Q28_3)	○	○	○	○

Q29 2.6 Patient consultation and diagnosis

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 2.6.1 Support urgent care needs (physical and mental) of patients and others and act upon arranging follow-up care (Q29_1)	○	○	○	○
Behaviour 2.6.2 Appropriately refer the patient or carer (Q29_2)	○	○	○	○
Behaviour 2.6.3 Assess and diagnose based on objective and subjective measures (where applicable (Q29_3)	○	○	○	○
Behaviour 2.6.4 Evaluate, assess, and develop health literacy education and counselling on medicines and healthcare needs (Q29_4)	○	○	○	○
Behaviour 2.6.5 Discuss and agree with the patient on the appropriate use of medicines, taking into account patients' preferences (Q29_5)	○	○	○	○
Behaviour 2.6.6 Document any intervention (e.g. document allergies, such as from medicines and nutrition, in patient medicines history) (Q29_6)	○	○	○	○

Behaviour 2.6.7 Obtain, reconcile, review, maintain and update relevant patient medication and disease history (Q29_7)	○	○	○	○

Q48 Please feel free to add any comment and additional behaviours that you would consider useful for this cluster

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End of Block: FIP Global Competency Framework

Start of Block: FIP Global Competency Framework

Q30 **3. Organisation and Management**

This cluster of the Global Competency Framework focuses on the organisation and management related to budget and reimbursement, human resources, service improvement, procurement, supply chain and workplace. Please rate each individual behavioural statement as highly relevant, relevant, low relevance, or not relevant to your own pharmacy practice. When choosing your answers please consider the following explanations of the rating options: *Highly relevant*: refers to the behavioural statements which you fulfil in your own practice and consider to have a strong degree of relation to your work as a pharmacist. *Relevant*: refers to the behavioural statements that you consider to have a moderate degree of relation to your own practice. *Low relevance*: refers to the behavioural statements that you consider to have a slight degree of relation to your own practice. *Not Relevant:* refers to the behavioural statements that you consider to not have any degree of relation to your own practice. **Please answer all questions, reflecting actual practice rather than ideal or desired practice.**

Q31 3.1 Budget and reimbursement

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 3.1.1 Acknowledge the organisational structure (Q31_1)	○	○	○	○
Behaviour 3.1.2 Effectively set and apply budgets (Q31_2)	○	○	○	○
Behaviour 3.1.3 Manage appropriate claims for reimbursements (Q31_3)	○	○	○	○
Behaviour 3.1.4 Ensure financial transparency (Q31_4)	○	○	○	○
Behaviour 3.1.5 Ensure proper reference sources for service reimbursement (Q31_5)	○	○	○	○

Q32 3.2 Human Resources management

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 3.2.1 Demonstrate organisational and management skills (e.g. plan, organise and lead on medicines management, risk management, self-management, time management, people management, project management, policy management) (Q32_1)	○	○	○	○
Behaviour 3.2.2 Identify and manage human resources and staffing issues (Q32_2)	○	○	○	○
Behaviour 3.2.3 Recognise and manage the potential of each staff member and utilise systems for performance management (e.g. conduct staff appraisals) (Q32_3)	○	○	○	○
Behaviour 3.2.4 Recognise the value of the pharmacy team and of a multidisciplinary team (Q32_4)	○	○	○	○
Behaviour 3.2.5 Support and facilitate staff training and continuing professional development (Q32_5)	○	○	○	○

Q33 3.3 Improvement of service

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 3.3.1 Identify and implement new services (according to local needs) (Q33_1)	○	○	○	○
Behaviour 3.3.2 Resolve, follow up and prevent medicines related problems (Q33_2)	○	○	○	○

Q34 3.4 Procurement

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 3.4.1 Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality (Q34_1)	○	○	○	○
Behaviour 3.4.2 Develop and implement contingency plans for shortages (Q34_2)	○	○	○	○
Behaviour 3.4.3 Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms (Q34_3)	○	○	○	○
Behaviour 3.4.4 Ensure there is no conflict of interest (Q34_4)	○	○	○	○
Behaviour 3.4.5 Identify and select reliable supplier(s) (Q34_5)	○	○	○	○
Behaviour 3.4.6 Select reliable supply of high-quality products (including appropriate selection and procurement processes, cost effectiveness, timely delivery) (Q34_6)	○	○	○	○

Behaviour 3.4.7 Supervise procurement activities (Q34_7)	○	○	○	○
Behaviour 3.4.8 Understand the tendering methods and evaluation of tender bids (Q34_8)	○	○	○	○

Q35 3.5 Supply chain and management

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 3.5.1 Demonstrate knowledge in store medicines to minimise errors and maximise accuracy (Q35_1)	○	○	○	○
Behaviour 3.5.2 Verify the accuracy of rolling stocks (Q35_2)	○	○	○	○
Behaviour 3.5.3 Ensure effective stock management and running of service with the dispensary (Q35_3)	○	○	○	○
Behaviour 3.5.4 Ensure logistics of delivery and storage (Q35_4)	○	○	○	○
Behaviour 3.5.5 Implement a system for documentation and record keeping (Q35_5)	○	○	○	○
Behaviour 3.5.6 Take responsibility for quantification and supply chain forecasting (Q35_6)	○	○	○	○

Q36 3.6 Workplace management

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 3.6.1 Address and manage day to day management issues (Q36_1)	○	○	○	○
Behaviour 3.6.2 Demonstrate the ability to take accurate and timely decisions and make appropriate judgements (Q36_2)	○	○	○	○
Behaviour 3.6.3 Ensure the production schedules are appropriately planned and managed (Q36_3)	○	○	○	○
Behaviour 3.6.4 Ensure the work time is appropriately planned and managed (Q36_4)	○	○	○	○
Behaviour 3.6.5 Improve and manage the provision of pharmaceutical services (Q36_5)	○	○	○	○
Behaviour 3.6.6 Recognise and manage pharmacy resources (e.g. financial, infrastructure) (Q36_6)	○	○	○	○

Q47 Please feel free to add any comment and additional behaviours that you would consider useful for this cluster

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End of Block: FIP Global Competency Framework

Start of Block: FIP Global Competency Framework

Q37 **4. Professional/personal**

This cluster of the Global Competency Framework focuses on the application of the professional responsibilities and personal development related to communication skills, continuing professional development (CPD), legal and regulatory practice, professional and ethical practice, quality assurance (QA) and research in the workplace, and self-management. Please rate each individual behavioural statement as highly relevant, relevant, low relevance, or not relevant to your own pharmacy practice. When choosing your answers please consider the following explanations of the rating options: *Highly relevant:* refers to the behavioural statements which you fulfil in your own practice and consider to have a strong degree of relation to your work as a pharmacist. *Relevant:* refers to the behavioural statements that you consider to have a moderate degree of relation to your own practice. *Low relevance:* refers to the behavioural statements that you consider to have a slight degree of relation to your own practice. *Not Relevant:* refers to the behavioural statements that you consider to not have any degree of relation to your own practice. **Please answer all questions, reflecting actual practice rather than ideal or desired practice.**

Q38 4.1 Communication skills

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.1.1 Communicate clearly, precisely and appropriately while being a mentor or tutor (Q38_1)	○	○	○	○
Behaviour 4.1.2 Communicate effectively with health and social care staff, support staff, patients, carer, family relatives and clients/customers, using lay terms and checking understanding (Q38_2)	○	○	○	○
Behaviour 4.1.3 Tailor communication that is appropriate to the patient's Needs (including health literacy, cultural or language barriers, social needs, and emotional status) (Q38_3)	○	○	○	○
Behaviour 4.1.4 Use appropriate communication skills (e.g. verbal and non-verbal) to establish and maintain rapport with the patient and others including when communicating through digital and electronic platforms (Q38_4)	○	○	○	○

Q39 4.2 Continuing professional development (CPD)

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.2.1 Document CPD activities (Q39_1)	○	○	○	○
Behaviour 4.2.2 Engage with students/interns/residents (Q39_2)	○	○	○	○
Behaviour 4.2.3 Evaluate accuracy of knowledge and skills (Q39_3)	○	○	○	○
Behaviour 4.2.4 Identify learning and development needs (Q39_4)	○	○	○	○
Behaviour 4.2.5 Evaluate learning and development progress (Q39_5)	○	○	○	○
Behaviour 4.2.6 Identify if expertise is needed outside current scope of knowledge (Q39_6)	○	○	○	○
Behaviour 4.2.7 Recognise own limitations and act upon them (Q39_7)	○	○	○	○
Behaviour 4.2.8 Reflect on performance (Q39_8)	○	○	○	○
Behaviour 4.2.9 Demonstrate engagement/participation in professional development and lifelong learning activities (Q39_9)	○	○	○	○

X→

Q40 4.3 Digital literacy

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.3.1 Identify, manage, organise, store, and share digital information (Q40_1)	○	○	○	○
Behaviour 4.3.2 Critically appraise, analyse, evaluate, and/or interpret digital information and their sources (Q40_2)	○	○	○	○
Behaviour 4.3.3 Where applicable, participate in digital health services that promote health outcomes and engage with digital technologies (e.g. social media platforms & mobile applications) to facilitate discussion with the patient and others (Q40_3)	○	○	○	○
Behaviour 4.3.4 Maintain patient privacy and security of digital information related to the patient and workplace (Q40_4)	○	○	○	○

Q41 4.4 Interprofessional collaboration

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.4.1 Respect and acknowledge the expertise, roles	○	○	○	○

and responsibilities of colleagues and other health professionals (Q41_1)				
Behaviour 4.4.2 Participate, collaborate, advise in therapeutic decision-making, and use appropriate referral in a multi-disciplinary team (Q41_2)	○	○	○	○
Behaviour 4.4.3 Engage in collaborative practice, research and service provision to optimise patient health outcomes (Q41_3)	○	○	○	○
Behaviour 4.4.4 Engage in relationship-building with health professionals allowing conflict resolution, teamwork, communication, and consultation (Q41_4)	○	○	○	○
Behaviour 4.4.5 Demonstrate mutual respect and adopt shared values of the workplace and toward patient care (Q41_5)	○	○	○	○

X→

Q42 4.5 Leadership and self-regulation

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.5.1 Apply assertiveness skills (inspire confidence) (Q42_1)	○	○	○	○
Behaviour 4.5.2 Demonstrate leadership and practice management skills, initiative and efficiency (Q42_2)	○	○	○	○
Behaviour 4.5.3 Document risk management (critical incidents) (Q42_3)	○	○	○	○
Behaviour 4.5.4 Prioritise work practice punctuality and time management (Q42_4)	○	○	○	○
Behaviour 4.5.5 Develop, implement and monitor innovative ideas (Q42_5)	○	○	○	○
Behaviour 4.5.6 Recognise and describe emotional information about self and others (e.g. self-awareness, self-regulation, motivation, social skills and empathy) (Q42_6)	○	○	○	○

Behaviour 4.5.7 Demonstrate flexibility and adaptability to a variety of conditions and circumstances (Q42_7)	○	○	○	○
Behaviour 4.5.8 Recognise when affected by setback or stress and manage with effective coping strategies (resilience) (Q42_8)	○	○	○	○

Q43 4.6 Legal and regulatory practice

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.6.1 Apply regulatory affairs and the key aspects of pharmaceutical registration and legislation (Q43_1)	○	○	○	○
Behaviour 4.6.2 Apply the principles of business economics and intellectual property rights including the basics of patent interpretation (Q43_2)	○	○	○	○
Behaviour 4.6.3 Be aware of and identify the new medicines coming to the market (Q43_3)	○	○	○	○
Behaviour 4.6.4 Comply with legislation for drugs with the potential for abuse (Q43_4)	○	○	○	○
Behaviour 4.6.5 Apply the principles of marketing and sales (Q43_5)	○	○	○	○
Behaviour 4.6.6 Engage with health and medicines policies (Q43_6)	○	○	○	○
Behaviour 4.6.7 Recognise the steps needed to bring a medical device or medicine to the market including the safety, quality, efficacy and pharmacoeconomic assessments of the product (Q43_7)	○	○	○	○

X→

Q44 4.7 Professional and ethical practice

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.7.1 Demonstrate awareness and employment of local/national codes of ethics (Q44_1)	○	○	○	○
Behaviour 4.7.2 Fulfil duty of care to the patient and the public (Q44_2)	○	○	○	○
Behaviour 4.7.3 Maintain privacy and confidentiality (with the patient and other healthcare professionals) (Q44_3)	○	○	○	○
Behaviour 4.7.4 Comply with patient privacy legislation including documentation of information (Q44_4)	○	○	○	○
Behaviour 4.7.5 Consider available evidence and support the patient to make informed choices about medicine use (Q44_5)	○	○	○	○
Behaviour 4.7.6 Obtain patient consent (it can be implicit on occasion) (Q44_6)	○	○	○	○
Behaviour 4.7.7 Recognise professional limitations of self and others in the team (Q44_7)	○	○	○	○

Behaviour 4.7.8 Demonstrate professional responsibility for all decisions made and actions taken (Q44_8)	○	○	○	○
Behaviour 4.7.9 Demonstrate awareness of socially accountable practice (including cultural and social needs; cultural safety, respect, and responsiveness; diversity, equity and inclusiveness) (Q44_9)	○	○	○	○

X→

Q45 4.8 Quality assurance and research in the workplace

	Highly Relevant (4)	Relevant (3)	Low Relevance (2)	Not Relevant (1)
Behaviour 4.8.1 Apply research findings and understand risk-benefit analyses (e.g. pre-clinical, clinical trials, experimental clinical pharmacological research, and risk management) (Q45_1)	○	○	○	○
Behaviour 4.8.2 Audit quality of service (meet local and national standards and specifications) (Q45_2)	○	○	○	○
Behaviour 4.8.3 Develop and implement Standard Operating Procedures (SOPs) (Q45_3)	○	○	○	○
Behaviour 4.8.4 Ensure appropriate quality control tests are performed and managed appropriately (Q45_4)	○	○	○	○
Behaviour 4.8.5 Ensure medicines are not counterfeit and adhere to quality standards (Q45_5)	○	○	○	○
Behaviour 4.8.6 Identify and evaluate evidence-base to improve the use of medicines and services (Q45_6)	○	○	○	○

Behaviour 4.8.7 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice) (Q45_7)	○	○	○	○
Behaviour 4.8.8 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions) (Q45_8)	○	○	○	○
Behaviour 4.8.9 Initiate and implement audit research activities (Q45_9)	○	○	○	○

Q46 Please feel free to add any comment and additional behaviours that you would consider useful for this cluster

_____

End of Block: FIP Global Competency Framework

Start of Block: Random ID

Q49 Here is your ID:

When you have copied this ID, **please click the next button to submit your survey.**

End of Block: Random ID

Appendix 6 Information Sheet - Competency Framework Consensus Development Stakeholders Workshop

Competency-Framework for Pharmacists in Kenya Consensus Development Panel

Information Sheet

Principal Researcher: Jessica McMullen
Supervisors: Claire Anderson, Naoko Arakawa, Simon McGrath
Collaborators: Dr Lucas Nyabero, PSK

On behalf of the University of Nottingham, and in collaboration with the Pharmaceutical Society of Kenya (PSK), we would like to invite you to take part in our research study. In order for you to understand the research before you decide whether or not to participate please read the following information. We will go through this information sheet before you consent to participate in the study and there will be an opportunity for you to ask any questions or to discuss any concerns or anything that you think is not clear.

What is the purpose of this research?

The trend in pharmacy practice, both in Kenya and internationally, has been evolving from a manufacture and supply orientated role to a more patient-centred clinical role. In order to contribute to healthcare development and keep up with these transformations, pharmacy education and training also needs to adapt to equip pharmacists with the skills necessary for contemporary practice. The use of competency frameworks is an approach that is advocated for in healthcare professional workforce development across the globe. However, there is no national-level competency framework in place for pharmacists of all sectors in Kenya.

The International Pharmaceutical Federation (FIP) developed a Global Competency Framework (GbCF) in 2012 for foundation level pharmacy practice, which has subsequently been updated with version 2 having been released in 2020. Many countries have now adapted the GbCF to their own settings. The FIP defines competencies as a set of skills, attitudes, knowledge and behaviours necessary to practice safely and effectively which are acquired by pharmacists through education and training that is expected to be a continuous processes throughout their career.

The purpose of this research is to identify necessary competencies and associated behaviours for effective performance of foundation-level (the first 1000 days of registered practice) pharmacists across all sectors in Kenya.

Do I have to take part?

No, it is completely up to you to decide whether or not you want to take part in this research. If you do decide to take part you will be asked to give your consent to participate.

What will happen during the research?

The research will consist of an online survey and two short face-to-face workshops (no longer than 3 hours each) involving stakeholders in pharmacy practice and education in Kenya. These stakeholders will form a consensus development panel. The aim is to reach a consensus from all stakeholders on what the competencies for pharmacy practice in Kenya should be. If you are happy for the discussion to be recorded, we will make an electronic audio recording which will only be available to the members of the project team to prepare typed notes. These recordings and any other documentation will stored securely on the university's OneDrive (Microsoft).

The structure of the research will be as follows:

Step 1 – Survey (30 mins): All participants will be required to complete an online survey asking them to rate the applicability of the behavioural statements of the FIP GbCF (version 2) to pharmacy practice in Kenya.

Step 2 – Workshop (3 hours): Participants will be asked to meet in a face-to-face workshop in Nairobi to discuss their responses, together with the results gathered from nation-wide distribution of the same online survey to practicing pharmacists in Kenya between February and March 2022. Amendments to the behavioural statements will then be made to adapt them to the Kenyan context.

Step 3 – Survey (30 mins): The amended behavioural statements will be then be distributed in another online survey where you will then be asked again to rate their applicability to pharmacy practice in Kenya before the next workshop.

Step 4 – Workshop (3 hours): Participants will be asked to attend another face-to-face workshop in Nairobi to discuss your responses to the amended behavioural statements. Any discrepancies will be discussed and resolved to develop a consensus on what the final behavioural statements should be to create a bespoke competency framework for pharmacy in Kenya. The final behavioural statements will be distributed again via an online survey to ask you to rate their applicability and ensure that the panel has reached a consensus on the final framework.

Why have I been invited to participate?

You have been invited to take part because you have experience with pharmacy practice, education, or policy in Kenya.

What are the possible benefits of taking part?

There may not be any direct benefit to you from taking part in this research but it is hoped that the information gathered can help to have a beneficial impact on pharmacy education in Kenya. The results will be published in peer-reviewed journals and shared with policy makers and pharmacy practitioners to inform educational planning and professional work. You will not be identified in any report or publication.

Expenses and payments

Participants will receive £90 each after completion of both workshops. Payment will be made electronically by the university.

What if there is a problem?

Should you have any concerns about anything to do with this research, contact details are provided at the bottom of this form. If, despite talking to the principal researcher, you still have concerns you can contact the project lead, Claire Anderson at: claire.anderson@nottingham.ac.uk

Will my information be kept confidential?

The study will be conducted in accordance with research guidelines approved by the University of Nottingham Ethics Committee.

All information provided by you and collected during the course of the study will be kept strictly confidential and will be stored in a secure locked location at the University of Nottingham. Any digital information will be stored on a password protected and secure online database. No personal information will be shared with any other parties. Any names and addresses or other personal information will only be accessible to the principle researcher and research team. Personal information will be removed from the research documents prior to analysis and you will not be personally identifiable in any of the findings released.

We will keep any written information for a minimum of 7 years but may keep it for longer up to a maximum of 25 years. During this time there will be a designated team member responsible for ensuring that your information is kept secure and access is restricted at all times.

The University of Nottingham is registered as a Data controller under the Data Protection act 1998 (registration No. Z5654762 https://ico.org.uk/ESDWebPages/Entry/Z5654762) in the United Kingdom.

The University will process your personal data in accordance with the General Data Protection Regulation (GDPR) of the European Union and the Data Protection Act 2018 in the United Kingdom. For information about the University's obligations with respect to your data, who you can get in touch with and your rights as a data subject, please visit: https://www.nottingham.ac.uk/utilities/privacy.aspx.

If you are concerned about how your personal data is being processed, please contact the University's Data Protection Officer at:

Data Protection Officer
Legal services
A5 Trent Building
University of Nottingham
dpo@nottingham.ac.uk

What will happen if I want to leave the study?

You are free to decide to leave the study at any time without any affect to your legal rights. The information collected during your participation so far in the study however cannot be erased and may still be including in the study analysis. All information will still be treated with the strictest confidence as per national data protection and university guidelines if you choose to withdraw at any time.

Who is organising the research?

The research is organised and funded by the University of Nottingham, UK.

Who has reviewed the research?

This research has been reviewed and given ethical approval by the University of Nottingham School of Pharmacy Research Ethics Committee (Ref:012-2020) and has been granted a Kenyan research license by the National Commission for Science, Technology & Innovation (license number NACOSTI/P/21/12536).

Contact details for further information

Miss Jessica McMullen
Pharmacy School Building
University Park
Nottingham
NG7 2RD
jessica.mcmullen@nottingham.ac.uk

Thank you for your time and for your interest in this research study.

Appendix 7 Consent Form - Competency Framework for Pharmacists in Kenya Consensus Development Panel

Consent form
Competency Framework for Pharmacists in Kenya Consensus Development Panel

Principal Researcher: Jessica McMullen
Supervisors: Claire Anderson, Naoko Arakawa, Simon McGrath
Collaborators: Dr Lucas Nyabero, PSK

Name of Participant: **Please initial box**

1. I understand the purpose of the research project and my involvement in it. I confirm that I have read and understand the participant information sheet version 1.0 dated 14/03/22 for the above study and have had the opportunity to ask questions	
2. I understand that I may contact the researcher or supervisors if I require further information about the research, and that I may contact the Research Ethics Committee of the School of Pharmacy, University of Nottingham, if I wish to make a complaint relating to my involvement in the research	
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.	
4. I understand that relevant sections of my data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group, and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.	
5. I understand that the workshop will be audio-recorded using a digital device and that anonymous direct quotes from the transcripts may be used in the study reports.	
6. I understand that while information gained during the study will be included in a report, I will not be identified, and my personal results will remain confidential.	
7. I understand that data will be securely stored both digitally, and physically in a locked draw only accessible by myself. All data will be stored securely for 7 years at which point it will be securely destroyed	
8. I agree to take part in the above study.	

Name of Participant Date Signature

_____ _____ _____

Person taking consent Date Signature

_____ _____ _____

Appendix 8 FIP GbCFv2 Behavioural Statements from the National Applicability Survey Ranked as Not-Relevant by more than 20% of the Respondents

Competency	FIP GbcFv2 Behavioural Statement	Percentage (%) of national survey respondents indicating low relevance of the behavioural statement to their own pharmacy practice
Cluster 1 Pharmaceutical Public Health		
1.3 Medicines Advice	1.3.3 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	21.5
Cluster 2 Pharmaceutical Care		
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	22.3
	2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines	23.1
2.3 Prescription processing and dispensing	2.3.6* Implement and maintain a dispensing error reporting system and a 'near misses' reporting system	21.5
2.6 Patient consultation and diagnosis	2.6.1 Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care	21.5
Cluster 3 Organisation and Management		
3.1 Budget and reimbursement	3.1.3* Manage appropriate claims for reimbursements	27.7
	3.1.5* Ensure proper reference sources for service reimbursement	26.2
3.4 Procurement	3.4.5* Identify and select reliable supplier(s)	20.8
	3.4.7* Supervise procurement activities	22.3
	3.4.8* Understand the tendering methods and evaluation of tender bids	25.4
Cluster 4 Professional/Personal		
4.8 Quality assurance and research in the workplace	4.8.4* Ensure appropriate quality control tests are performed and managed appropriately	20.8

**statements that showed both disagreement in the Chapter 3 consensus development panel, and low relevance (received a 'relevant' rating from less than 80% of the respondent's) in the Chapter 5 FIP GbcFv2 national applicability survey*

Appendix 9 Example Consensus Development Panel Personalised Panelist Rating Sheet

Competency-Framework for Pharmacists in Kenya

Consensus Development Panel Personalised Panelist Rating Sheet

Principal Researcher: Jessica McMullen

Supervisors: Claire Anderson, Naoko Arakawa, Simon McGrath

Collaborators: Dr Lucas Nyabero, CEO PSK

Participant Name: Panelist 1

Cluster 1. Pharmaceutical Public Health

	Agreement on the applicability of the behavioural statement with pharmacy practice in Kenya				
	National Survey Median (4-point Likert*)	Your response (9-point Likert)	Group Median (9-point Likert)	Group Interquartile Range (IQR)	Additional comments
1.1 Emergency response					
1.1.1 Participate in the response to public health emergencies	4	1	9	3	
1.1.2 Assist the multidisciplinary healthcare teams in emergency situation	4	1	9	3	
1.2 Health Promotion					
1.2.1 Assess the patient's/population's primary healthcare need (taking into account the cultural and social setting of the patient/populations)	4	8	8	1.5	
1.2.2 Advise and provide services related to health promotion; disease prevention and control (e.g. vaccination); and healthy lifestyle	4	8	9	1	

Panelist 1

1.2.3 Identify and support national and local health priorities and initiatives	4	9	9	1	
1.3 Medicines information and advice					
1.3.1 Counsel population on the safe and rational use of medicines and devices (including the selection, use, contraindications, storage, and side effects of non-prescription and prescription medicines)	4	8	9	0	
1.3.2 Identify sources, retrieve, evaluate, organise, assess and provide relevant medicines information according to the needs of patients and clients	4	8	9	0	
1.3.3 Support the patient's use of health information technologies and digital communication (including IT driven health solutions)	3	9	9	1.5	Support and advise clinical teams on appropriate use of health technologies

*1= no relevance, 2 = low relevance, 3= relevant, 4= highly relevant

Panelist 1 Cluster 2. Pharmaceutical Care

	Agreement on the appropriateness of the behavioural statement with current and future pharmacy practice				
	National Survey Median(4-point Likert*)	Your response (9-point Likert)	Group Median (9-point Likert)	Group Interquartile Range (IQR)	Additional Comments
2.1 Assessment of medicines					
2.1.1 Gather, analyse, research, and interpret information about the patient and patient's medicines-related needs (e.g. indication, effectiveness, safety and adherence)	4	9	9	2	
2.1.2 Retrieve relevant patient information (including drug history, or immunisation status for example) and record of allergies to medicines and Adverse Drug Reactions (ADR) in medication record.	4	9	9	0.5	
2.1.3 Identify, prioritise, resolve and follow up on medicine-medicine interactions; medicine-disease interactions; medicine-patient interactions; medicines-food interactions	4	9	9	0.5	
2.1.4 Appropriately select medicines (e.g. according to the patient, hospital, government policy, etc.)	4	8	9	0	
2.2 Compounding medicines					
2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)	4	9	9	1.5	

Panelist 1

2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines	4	9	9	0.5	
2.3 Dispensing					
2.3.1 Accurately dispense medicines for prescribed and/or minor ailments, including an embedded checking process	4	9	9	1	
2.3.2 Accurately report defective or substandard medicines to the appropriate authorities.	4	9	9	1	
2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal	4	9	9	1	
2.3.4 Dispense devices (e.g. inhaler or a blood glucose meter)	4	9	9	1	
2.3.5 Document and act upon dispensing errors	4	9	9	0.5	
2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system	4	9	8	1.5	
2.3.7 Label the medicines (with the required and appropriate information)	4	9	9	1	
2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors'	4	9	9	1.5	
2.4 Medicines					
2.4.1 Advise patients on proper storage conditions of the medicines and ensure that medicines are stored appropriately (e.g. humidity, temperature, expiry date, etc.)	4	9	9	0	

Panelist 1

2.4.2 Appropriately select medicine formulation and concentration for minor ailments (e.g. diarrhoea, constipation, cough, hay fever, insect bites, etc.)	4	9	9	0.5	
2.4.3 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients	4	9	9	0	
2.4.4 Package medicines to optimise safety (ensuring appropriate re-packaging and labelling of the medicines)	4	9	9	0	
2.5 Monitor medicines therapy					
2.5.1 Apply guidelines, medicines formulary system, protocols and treatment pathways	4	8	9	0	
2.5.2 Apply therapeutic medicines monitoring, impact and outcomes (including objective and subjective measures)	4	8	9	0.5	
2.5.3 Identify, prioritise and resolve medicines management problems (including errors)	4	9	9	0.5	
2.6 Patient consultation and diagnosis					
2.6.1 Support urgent care needs (physical and mental) of patient and others and act upon arranging follow-up care	3	9	9	1.5	
2.6.2 Appropriately refer the patient or carer	4	9	9	1	
2.6.3 Assess and diagnose based on objective and subjective measures (where applicable)	3	7	8	2	
2.6.4 Evaluate, assess, and develop health literacy education and counselling on medicines and healthcare needs	4	8	9	0.5	

Panelist 1

2.6.5 Discuss and agree with the patient on the appropriate use of medicines, taking into account patients' preferences	4	9	9	0	
2.6.6 Document any intervention (e.g. document allergies, medicines and nutrition, in patient medicines history)	4	9	9	0.5	
2.6.7 Obtain, reconcile, review, maintain and update relevant patient medication and disease history	4	9	9	1.5	Prioritize acquisition and application of appropriate Health Information Technology skills

*1= no relevance, 2 = low relevance, 3= relevant, 4= highly relevant

Panelist 1 Cluster 3. Organisation and Management

	Agreement on the appropriateness of the behavioural statement with current and future pharmacy practice				
	National survey median (4-point Likert*)	Your response (9-point Likert)	Group Median (9-point Likert)	Group Interquartile Range (IQR)	Additional Comments
3.1 Budget and reimbursement					
3.1.1 Acknowledge the organisational structure	4	9	9	2	
3.1.2 Effectively set and apply budgets	4	9	8	2	
3.1.3 Manage appropriate claims for reimbursements	3	9	8	4	Be resource persons for reimbursement of medicines claims. To be prepared for roles in insurance claims and reimbursements related to purchase of drugs
3.1.4 Ensure financial transparency	4	9	9	1.5	
3.1.5 Ensure proper reference sources for service reimbursement	3	9	9	3.5	
3.2 Human Resources management					
3.2.1 Demonstrate organisational and management skills (e.g. plan, organise and lead on medicines management, risk management, self-management, time management, people management, project management, policy management)	4	9	9	1.5	
3.2.2 Identify and manage human resources and staffing issues	4	8	8	2	
3.2.3. Recognise and manage the potential of each member of the staff and utilise systems for performance management (e.g. conduct staff appraisals)	4	8	9	2	

Panelist 1

3.2.4. Recognise the value of the pharmacy team and of a multidisciplinary team	4	9	9	1	
3.2.5 Support and facilitate staff training and continuing professional development	4	9	9	2	
3.3 Improvement of service					
3.3.1 Identify and implement new services (according to local needs)	4	9	9	1.5	
3.3.2 Resolve, follow up and prevent medicines related problems	4	9	9	0	
3.4 Procurement					
3.4.1 Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality	4	9	9	1	
3.4.2 Develop and implement contingency plans for shortages	4	9	9	1	
3.4.3 Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms	4	9	9	1	
3.4.4 Ensure there is no conflict of interest	4	9	9	2	
3.4.5 Identify and select reliable supplier(s)	4	9	8	1.5	
3.4.6 Select reliable supply of high-quality products (including appropriate selection and procurement processes, cost effectiveness, timely delivery)	4	9	9	1.5	
3.4.7 Supervise procurement activities	4	9	7	2	
3.4.8 Understand the tendering methods and evaluation of tender bids	4	9	8	1.5	
3.5 Supply chain and management					

Panelist 1

3.5.1 Demonstrate knowledge in store medicines to minimise errors and maximise accuracy	4	9	9	1	
3.5.2 Verify the accuracy of rolling stocks	4	9	9	1.5	
3.5.3 Ensure effective stock management and running of service with the dispensary	4	9	9	1	
3.5.4 Ensure logistics of delivery and storage	4	9	9	1.5	
3.5.5 Implement a system for documentation and record keeping	4	9	9	1	
3.5.6 Take responsibility for quantification and supply chain forecasting	4	9	9	1.5	
3.6 Workplace management					
3.6.1 Address and manage day to day management issues	4	8	9	1.5	
3.6.2 Demonstrate the ability to take accurate and timely decisions and make appropriate judgements	4	8	9	1	
3.6.3 Ensure the production schedules are appropriately planned and managed	4	9	8	1.5	
3.6.4 Ensure the work time is appropriately planned and managed	4	9	9	1.5	
3.6.5 Improve and manage the provision of pharmaceutical services	4	9	9	1	
3.6.6 Recognise and manage pharmacy resources (e.g. financial, infrastructure)	4	9	9	1.5	

*1= no relevance, 2 = low relevance, 3= relevant, 4= highly relevant

Panelist 1 Cluster 4. Professional/personal

	Agreement on the appropriateness of the behavioural statement with current and future pharmacy practice				
	National survey median (4-point Likert*)	Your response (9-point Likert)	Group Median (9-point Likert)	Group Interquartile Range (IQR)	Additional Comments
4.1 Communication skills					
4.1.1 Communicate clearly, precisely and appropriately while being a mentor or tutor	4	9	9	0	
4.1.2 Communicate effectively with health and social care staff, support staff, patients, carer, family relatives and clients/customers, using lay terms and checking understanding	4	9	9	0	
4.1.3 Tailor communication that is appropriate to the patient's needs (including health literacy, cultural or language barriers, social needs, and emotional status).	4	9	9	0.5	
4.1.4 Use appropriate communication skills (e.g. verbal and non-verbal) to establish and maintain rapport with the patient and others including when communicating through digital and electronic platforms	4	9	9	1	
4.2 Continuing professional development (CPD)					
4.2.1 Document CPD activities	4	9	9	1.5	
4.2.2 Engage with students/interns/residents	4	9	9	0.5	
4.2.3 Evaluate accuracy of knowledge and skills	4	9	9	1	
4.2.4 Identify learning and development needs	4	9	9	1.5	
4.2.5 Evaluate learning and development progress	4	8	9	1.5	
4.2.6 Identify if expertise is needed outside current scope of knowledge	4	8	9	1.5	

Panelist 1

4.2.7 Recognise own limitations and act upon them	4	9	9	1	
4.2.8 Reflect on performance	4	8	9	1.5	
4.2.9 Demonstrate engagement/participation in professional development and lifelong learning activities	4	9	9	1	
4.3 Digital literacy					
4.3.1 Identify, manage, organise, store, and share digital information	4	9	8	2.5	
4.3.2 Critically appraise, analyse, evaluate, and/or interpret digital information and their sources	4	9	8	1.5	
4.3.3 Where applicable, participate in digital health services that promote health outcomes and engage with digital technologies (e.g. social media platforms & mobile applications) to facilitate discussion with the patient and others	3	9	9	1	
4.3.4 Maintain patient privacy and security of digital information related to the patient and workplace	4	9	9	2	
4.4 Interprofessional collaboration					
4.4.1 Respect and acknowledge the expertise, roles and responsibilities of colleagues and other health professionals	4	9	9	1	
4.4.2 Participate, collaborate, advise in therapeutic decision-making, and use appropriate referral in a multi-disciplinary team	4	9	9	0	
4.4.3 Engage in collaborative practice, research and service provision to optimise patient health outcomes	4	9	9	0	

Panelist 1

4.4.4 Engage in relationship-building with health professionals allowing conflict resolution, teamwork, communication, and consultation	4	8	9	0	
4.4.5 Demonstrate mutual respect and adopt shared values of the workplace and toward patient care	4	9	9	0	
4.5 Leadership and self-regulation					
4.5.1 Apply assertiveness skills (inspire confidence)	4	8	9	0.5	
4.5.2 Demonstrate leadership and practice management skills, initiative and efficiency	4	8	9	1	
4.5.3 Document risk management (critical incidents)	4	8	9	1.5	
4.5.4 Prioritise work practice punctuality and time management	4	9	9	1	
4.5.5 Develop, implement and monitor innovative ideas	4	9	9	2	
4.5.6 Recognise and describe emotional information about self and others (e.g. self-awareness, self-regulation, motivation, social skills and empathy)	4	8	9	1	
4.5.7 Demonstrate flexibility and adaptability to a variety of conditions and circumstances	4	8	9	1	
4.5.8 Recognise when affected by setback or stress and manage with effective coping strategies (resilience)	4	8	9	1	
4.6 Legal and regulatory practice					
4.6.1 Apply regulatory affairs and the key aspects of pharmaceutical registration and legislation	4	9	9	1	
4.6.2 Apply the principles of business economics and intellectual property rights including the basics of patent interpretation	4	8	8	2	

Panelist 1

4.6.3 Be aware of and identify the new medicines coming to the market	4	8	9	1.5	
4.6.4 Comply with legislation for drugs with the potential for abuse	4	9	9	0.5	
4.6.5 Apply the principles of marketing and sales	3	9	8	2	
4.6.6 Engage with health and medicines policies	4	9	9	1.5	
4.6.7 Recognise the steps needed to bring a medical device or medicine to the market including the safety, quality, efficacy and pharmacoeconomic assessments of the product	4	9	9	1.5	
4.7.1 Demonstrate awareness and employment of local/national codes of ethics	4	9	9	1	
4.7.2 Fulfil duty of care to the patient and the public	4	9	9	0	
4.7.3 Maintain privacy and confidentiality (with the patient and other healthcare professionals)	4	9	9	1	
4.7.4 Comply with patient privacy legislation including documentation of information	4	9	9	1	
4.7.5 Consider available evidence and support the patient to make informed choices about medicine use	4	8	9	0	
4.7.6 Obtain patient consent (it can be implicit on occasion)	4	9	9	0.5	
4.7.7 Recognise professional limitations of self and other in the team	4	9	9	1	
4.7.8 Demonstrate professional responsibility for all decisions made and actions taken	4	9	9	0.5	

Panelist 1

4.7.9 Demonstrate awareness of socially accountable practice (including cultural and social needs; cultural safety, respect, and responsiveness; diversity, equity and inclusiveness)	4	8	9	1	
4.8.1 apply research findings and understand risk-benefit analyses (e.g. pre-clinical, clinical trials, experimental clinical pharmacological research, and risk management)	4	7	9	2	
4.8.2 Audit quality of service (meet local and national standards and specifications)	4	8	8	1	
4.8.3 Develop and implement Standard Operating Procedures (SOPs)	4	8	8	2	
4.8.4 Ensure appropriate quality control tests are performed and managed appropriately	4	8	8	2.5	
4.8.5 Ensure medicines are not counterfeit and adhere to quality standards	4	9	9	1	Move towards coding of health technologies to reduce incidences of counterfeits and low standards
4.8.6 Identify and evaluate evidence-base to improve the use of medicines and services	4	9	9	1	
4.8.7 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice)	4	8	9	2	
4.8.8 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)	4	9	9	1	

Panelist 1

4.8.9 Initiate and implement audit research activities	3	8	8	2	

*1= no relevance, 2 = low relevance, 3= relevant, 4= highly relevant