Competency-based education in pharmacy and pharmaceutical sciences

A FIP handbook to support implementation of competency-based education and training
2022

Colophon

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The authors thank Aukje Mantel-Teeuwisse (Professor, Utrecht University) and Pascale Salameh (Professor, Lebanese University) for their support.

Recommended citation:
International Pharmaceutical Federation (FIP). Competency-based education in pharmacy and pharmaceutical sciences, A FIP handbook to support implementation of competency-based education and training, Version 1, The Hague, FIP, 2022

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Forewords

It is our privilege to introduce FIP Education's competency-based education implementation handbook. The move towards competency-based education (CBE) in health professional education aligns with the FIP vision to advance pharmacy worldwide through pharmacy and pharmaceutical education. Since 2010, CBE has been the core of the needs-based education model, initially set as a foundation for the FIP Pharmacy Education Action Plan by the WHO-UNESCO-FIP Pharmacy Education Taskforce. FIP has supported pharmacy leaders and educators in their endeavours to embed CBE by developing and publishing tools such as the FIP Global Competency Framework and Global Advanced Development Framework.

This handbook provides step-by-step guidance for educators to implement CBE concepts in their initial pharmacy education and training. It also supports the implementation of CBE concepts in continuing professional development, post-graduate programmes and other lifelong learning settings. The handbook helps to achieve FIP Development Goal 5 (Competency development), with major relevance to Development Goal 1 (Academic capacity). Broad collaboration across FIP constituencies addresses the One FIP vision to ensure relevance to all FIP members and member organisations. The handbook builds on evidence, including a systematic review and a global survey on CBE in pharmacy education. Contributors were sought based on their expertise, their experiences and their passion in their field. Bringing this handbook together, the team also aimed to advocate seamless transitions in the educational cycle of pharmacy and pharmaceutical education from initial education to CPD to lifelong learning. This handbook will guide educators in developing their teams and changing their curricula, and will empower them to deliver successful CBE. The ultimate goal is to help improve the workforce and thus the health of populations across the world.

We have created the vision and the tools to now be One FIP and deliver, through trust and solidarity and with actions, the changes required for the people and societies across our globe. We are convinced that if we continue our efforts towards supporting the transformation and development of pharmacy education globally, we will build a bright future for our profession and patients.

Mr Dominique Jordan, FIP president

Dr Catherine Duggan, FIP chief executive officer

Competency-based Education (CBE) is not universally understood or employed. This CBE implementation handbook provides a much-needed comprehensive resource for learning about CBE and guiding the development and delivery of quality CBE learning programmes. It is based on a few well-known education principles that underpin successful education and training programs, namely:

- The goal is learning not teaching.
- The goal of learning is to develop the ability to perform professional tasks.
- Begin with the end in mind — what outcomes must be achieved for the purpose at hand, e.g., education and training to meet societal needs from individual care to improved population-based health.
- Define the competencies needed to achieve these outcomes at various levels of education and training from initial education to early career development, advanced practice mastery and, ultimately, success at life-long learning.
- Design and implement appropriate learning methods and materials to achieve the desired outcomes
- Employ effective evaluation methods to measure success of the CBE programme.
- Use these metrics for continuous improvement.

Educators and trainers would be well-advised to keep a copy of this handbook on their virtual desktop as a go-to resource for developing and implementing a successful CBE programme at any stage of the learning process.

Ralph Altiere, FIP*Ed* chair

The pharmaceutical workforce, along with other key healthcare professions, needs to be strengthened in order to cope with an increasingly high demand of pharmaceutical health needs, and contemporary methods for professional education and training are a critical part of this solution. The challenge for the pharmaceutical workforce is that of progressing and advancing competency and flexibility as pharmaceutical healthcare delivery continues to move towards clinical roles. Provision and delivery of such roles as direct patient counselling, medicines optimisation services, adverse drug focused approaches to CPD and advanced competencies. Pharmacy will increasingly be the principal access route for the public in primary care environments to manage acute and long-term conditions.

Health care workers, particularly in a regulated profession such as ours, should have — and be able to demonstrate — the skills and abilities to cope with the public's health needs and to be better able to apply their practice to improve holistic pharmaceutical patient care.

It is clear that life-long learning and CPD are crucial for foundation and advanced pharmacists to support the workforce needs of the demographic health challenges, and the evolution of new technologies and advanced drug therapies. Our populations have high expectations from us and our training needs must be focused on ensuring we meet these expectations.

I am delighted that FIP continues to focus on needs-based education and training, as evidenced by consistent publications of transnational competency development frameworks that have proven to be invaluable in helping to reshape the global pharmacy workforce. This new handbook is a vital piece of the overall jigsaw of workforce development across our global constituencies. My thanks to the development team for pushing forward on this important document.

Prof. Ian Bates, FRPharmS, FFRPS, FFIP, FRSS, FRSPH
Director, FIP Workforce Development Hub
Director, FIP Global Observatory

The authors address a significant and important development in higher education that is critical for pharmacy and pharmaceutical sciences education. Competency-based education focuses on the skills and behaviours that learners are expected to have at the end of their training. These competencies will vary largely depending on the licensure requirements of each country or region, the specific degree being pursued (BPharm, MPharm or PharmD), and the practice area desired upon completion of the programme (manufacturing, clinical practice, public health, research etc.).

To better understand the details of how select countries around the globe are applying CBE, a strong background of the pros and cons of CBE and outcomes-based education are provided. Frameworks in the literature designed to guide the learner towards desired competencies are summarised. A systematic review was conducted to assist the reader to compare different practices and approaches to CBE. Furthermore, to help unify the language among professionals around the world, a glossary of terms is used to guide interpretation of the different papers included. To assist with application of CBE, the authors provide a guidance document that takes a stepwise approach to implementing CBE and enumerates the different components in the process that will help ensure a quality process and product. In addition, challenges identified by programmes implementing CBE are listed for potential solutions and considerations. Ultimately the reader is left with resources, tools and a roadmap to follow.

As colleges and schools contemplate the implementation of CBE, it is critical to have a unified set of criteria for countries so that quality can be maintained within the region. As minimum competencies are agreed upon by accrediting bodies, schools, colleges, and faculties can tailor their focus to ensure proper quality. Quality assurance can be obtained through evaluation and assessment of learners and subsequent accomplishment of the predetermined competencies which will eventually lead to the expression of the desired outcomes for the training programme and profession. This is an excellent addition to the body of work from FIP.

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Acknowledgements

The delivery of this project and publication would not have been possible without the contributions and expertise from the following individuals. The project team thanks the FIP staff, the FIP Academic Pharmacy Section, Academic Institutional Membership, the FIP-Hub (formerly the FIP Workforce Development Hub), and FIP Education (FIP*Ed*) for their support. The team also recognises all the respondents who participated in the global survey on CBE, which supported the development of new evidence related to CBE to advance pharmacy and pharmaceutical sciences education globally.

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Executive summary

Health systems require sufficient human resources for health, including a pharmaceutical workforce with the right competencies to meet their demands and the health needs of populations. A competent pharmaceutical workforce is vital to achieve United Nations Sustainable Development Goal 3, to ensure healthy lives and promote well-being for all at all ages through establishing universal health care across nations. This is aligned with the International Pharmaceutical Federation's (FIP) 21 Development Goals and FIP's needs-based education model, emphasising the need for the development of competencies for provision of patient care and other professional work to serve in local settings. Competency-base education (CBE) is at the core of healthcare professionals' education and training globally.

The implementation of the CBE model in initial pharmacy and pharmaceutical education and training has some challenges. These challenges are often because of the regulation and legislation surrounding the registration of a country's pharmaceutical workforce, less flexible and time-defined higher education settings and training pathways, limited resources and infrastructure and some confusion about the CBE model. It is for these reasons that this handbook has been developed.

The goal of this handbook is to help improve the health of populations across the world through supporting pharmacy leaders and educators in successful CBE implementation to develop better professional development journeys and workforce planning. The handbook is structured to support pharmacy leaders and educators to implement CBE concepts in their initial pharmacy and pharmaceutical education and training. Some examples, educational formats and assessment styles described in the handbook can also be used to support the implementation of CBE concepts in continuing professional development (CPD), postgraduate programmes and other lifelong learning settings. This handbook is a practical, step-by-step guide and a reference for readers to review when they encounter any challenges on their CBE implementation journey.

The handbook was developed based on evidence including a systematic review and a global survey on CBE use in pharmacy and pharmaceutical education. Contributors were sought based on their expertise, their experiences and their passion in the field.

Chapters in the handbook are aligned with a common journey of CBE implementation. This includes: recognition of the CBE concept and understanding of the current situation of CBE implementation in pharmacy; preparation of a competency framework as a foundation of CBE and the CBE implementation process and team; designing a CBE programme, modules and courses; delivery of the programme, and evaluation of the CBE implementation; and improving the programme. Each chapter provides some examples and references for further reading. The handbook is not intended as a rigid inflexible instruction for all settings. Rather, it can provide a first step for CBE implementation and provide a discussion point for advancement of pharmacy and pharmaceutical education globally.

Chapter 1 Background

Naoko Arakawa, Secretary of FIP Academic Pharmacy Section, Global Lead for Competency Development, FIP Workforce Development Hub, Assistant Professor in International Pharmacy, University of Nottingham (United Kingdom)

"Health is a fundamental human right." So said the World Health Organisation (WHO) director general to commemorate Human Rights Day in 2017 and his statement remains a core concept of universal health coverage.[1] Attainment of health is dependent on the quality and resilience of the health system. Health systems require sufficient human resources for health, including a pharmaceutical workforce with the right competencies to meet a health system's demands and the health needs of the population. However, there is evidence projecting an 18 million shortfall of human resources for health by 2030, primarily in low- and middle-income countries.[2] This health workforce shortage is one of the main challenges to achieving the United Nations Sustainable Development Goals (SDGs) and the WHO's commitment to universal health coverage in resource-limited countries and settings. The recent COVID-19 pandemic has left significant scars on the health care workforce and will undoubtedly worsen the shortage and well-being of the workforce. Burden and demands on the health workforce are also due to demographic changes with an increasingly ageing population and prevalence of non-communicable diseases and multi-morbidity. These challenges highlight the need for better academic capacity and high-quality transformative education to supply adaptable and flexible health professionals.

Scaling up and strengthening quality transformative education based on the health needs and demands of populations and health systems is one of key recommendations from WHO to transform the health workforce.[3] Adopting a competency-based education (CBE) approach as an instructional design in 21st century health professional education was called for in a seminal 2010 *Lancet* paper.[4]

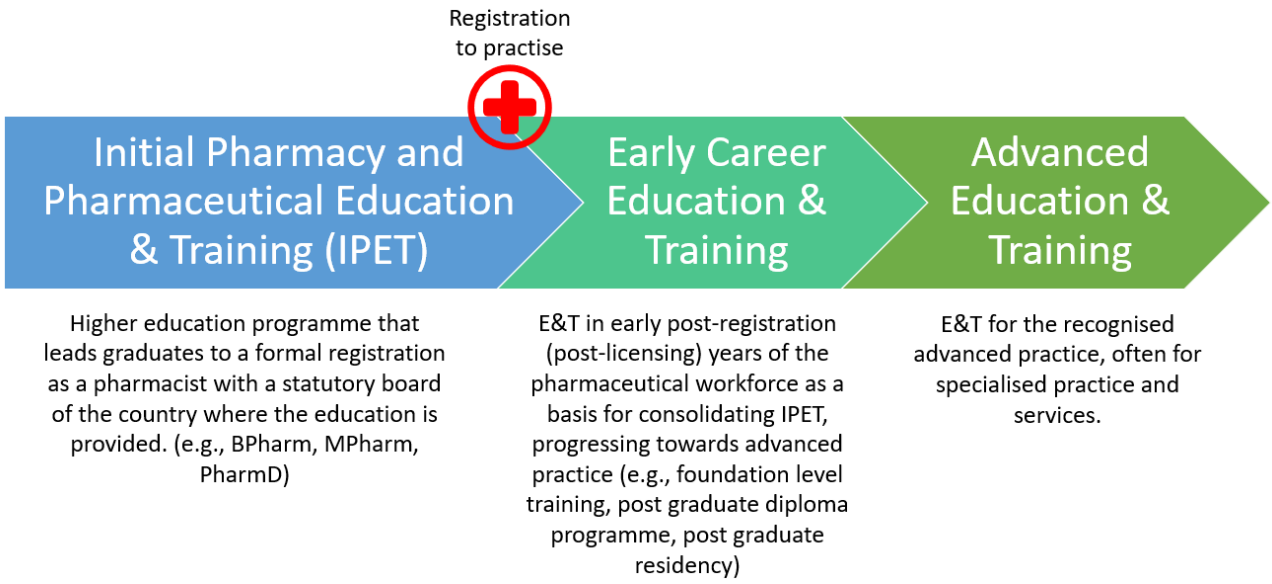
The call for and move towards CBE in health professional education also aligns with the FIP vision for pharmacy and pharmaceutical sciences education. CBE is at the core of the needs-based education cyclic model, set as a foundation for the Pharmacy Education Action Plan for 2008–2010, developed by consultation within FIP[5] and monitored by the WHO-UNESCO-FIP Pharmacy Education Taskforce.[6, 7] FIP has supported pharmacy leaders and educators in their endeavours to embed CBE by developing and publishing tools such as the FIP Global Competency Framework[8] and the Global Advanced Development Framework.[9]

Anecdotally, challenges are encountered relating to implementation of CBE concepts especially related to initial pharmacy and pharmaceutical sciences education and training (IPET). IPET refers to a pre-service higher education programme which leads a graduate to a formal registration as a pharmacist with a statutory board of the country where the education is provided.[10] This includes bachelor (e.g., BPharm), master (e.g., MPharm), and professional doctorate (e.g., PharmD) degrees, depending on the countries where the IPET is offered. These challenges faced prior to, during and after the implementation of CBE are because IPET is often determined by regulation and legislation surrounding pharmacist registration in a country, and the nature of the higher education programme with a time-defined programme and less flexible training pathways due to limited resources. Differences from traditional education and their implementation processes also require extra efforts for better application of CBE concepts in IPET.

The comments and experiences of pharmacy leaders and educators motivated the FIP team to develop this FIP*Ed* "Competency-based education implementation handbook". The handbook is structured to support pharmacy leaders and educators to implement CBE concepts in their IPET partly or wholly. Some examples, educational formats and assessment styles described in the handbook can also be used to support the implementation of CBE concepts in continuing professional development (CPD), post-graduate programmes and other lifelong learning settings. The handbook is a practical, step-by-step guide and a reference for readers to review when they encounter any challenges during their CBE implementation. The educational/ professional career structures referred to in the handbook is

illustrated in Figure 1. After the graduation from IPET, FIP considers professional careers at two levels, early career and advanced. Education and training for these levels are also described in Figure 1.

Figure 1: Educational phases in the pharmaceutical career pathway



The project to develop the handbook was primarily initiated to support achieving FIP Development Goal 5 (Competency development). However, it also has major relevance to Development Goal 1 (Academic capacity). Broad collaboration across FIP constituencies addresses the One FIP vision to ensure relevance to all FIP members and member organisations. The handbook was developed based on evidence, including a systematic review[11] and a global survey on CBE use in pharmacy education (see Chapter 3). Contributors were sought based on their expertise, their experiences and their passions in their field. Bringing this handbook together, the project team also aimed to advocate seamless transitions in the educational cycle of pharmacy and pharmaceutical sciences education from initial education to CPD to lifelong learning. We hope this handbook will support pharmacy leaders and educators in successful CBE implementation for developing better professional development journeys and workforce planning. The goal is to help improve national and global health of populations across the world.

Chapter 1 describes the background of the development and purpose of the handbook. It also aims to navigate readers to which of the following chapters they would like to focus on. Figure 2 illustrates and described the steps of CBE implementation and the structure of the Handbook.

Chapter 2 addresses the importance of CBE and describes the notion of CBE and related theoretical perspectives. It provides an overview of CBE in health professions and pharmacy education, and explains why CBE is recommended for pharmacy professional development. It sets the scene for the handbook and provides foundation information as scaffolding for later chapters.

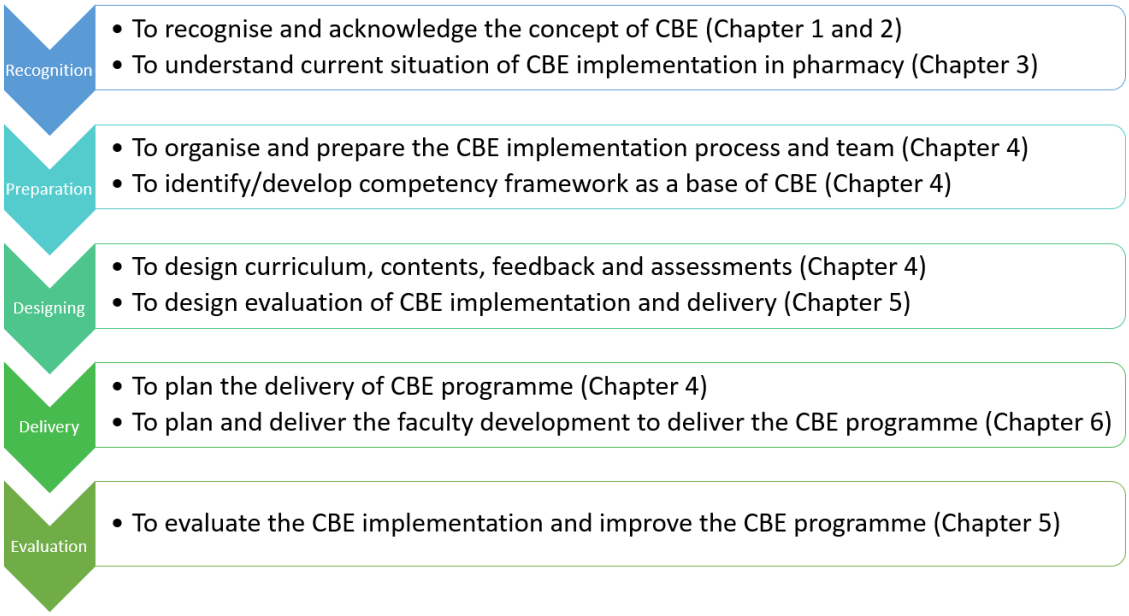
Chapter 3 summarises evidence collected from an earlier phase of the project — a systematic review and global survey. It provides existing evidence regarding CBE implementation in pharmacy across nations and describes the current situation of CBE implementation in pharmacy and pharmaceutical sciences education.

Chapter 4 provides step-by-step guidance for CBE implementation with practical examples. It describes the process of CBE implementation and important issues to be considered.

Chapter 5 addresses important issues related to evaluation where CBE is implemented. This includes short-term and long-term evaluation relating to quality assurance of CBE implemented in pharmacy education.

Chapter 6 describes necessary considerations about faculty and preceptor development prior to, during and after the CBE implementation.

Figure 2: An overview of CBE implementation and related activities and chapters of the handbook



Finally, the handbook provides a glossary of terms used as a reference point for readers.

It is hoped this handbook will inspire pharmacy education leaders and pharmacy educators to implement CBE in their programmes and support their journey of CBE implementation. It can provide a first step for CBE implementation and provide a discussion point for advancement of pharmacy education globally.

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Chapter 2 Competency-based education

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2.1 Health workforce development for the attainment of global health

Implementation of the United Nations Sustainable Development Goal 3 (SDG 3) is to ensure healthy lives and promote well-being for all persons at all ages. Achieving SDG 3 will require a strong health workforce, including a strong pharmaceutical workforce in all countries. Human resources for healthcare is the cornerstone of the health system in every country and plays a critical role in achieving universal health coverage (UHC), primary health care and the health-related targets of SDG 3. Therefore, stimulating and investing in human resources, including recruitment, management and specialised training, are essential for any health system and to reduce the projected shortage of 18 million health workers, primarily in low- and lower-middle-income countries.[1] A pharmaceutical workforce, including pharmacists, of an adequate size and skill mix is critical to the attainment of any population health goal.[2]

2.2 Needs-based and competency-based education and training

2.2.1 Competency-based education: the concept

Aligning health services with health professional education is a common discourse in the education of health professionals due to looming health challenges.[3] Competency-based education (CBE) is a topic of much interest due to the shift of education models in health professional education to address "glaring gaps and inequities in health persisting both within and between countries".[4] It is evident that having a capable workforce at the centre of health systems is essential for these systems to perform well and fulfil patient needs. This requires that health professional education systems are aligned with and prepared for local health care systems.

The concept of needs-based education is advocated by FIP and is highlighted in FIP competency frameworks including the Quality Assurance of Pharmacy Education Framework,[5] the competency framework for educators[6] and the global competency frameworks for pharmacists.[7-9] As represented in Figure 3 local, regional, national and international needs, policies and priorities will determine the services that must be provided by pharmacists, supported by other members of the pharmaceutical workforce, including technicians and pharmacy students and trainees. The services provided by pharmacists will subsequently determine what competencies must be developed by pharmacists to deliver the required services. As practice shifts from a product focus to a patient focus, pharmacists' education and training should accordingly reflect new professional competencies correlating with a country's health needs and local factors. Therefore, preparing competent pharmacy graduates to provide medication- and patient-related healthcare services in an era of evolving health care needs, systems and models is imperative.

Figure 3: Needs based education model

Competency frameworks in health professional education and training are used to help practitioners navigate and advance their careers.[10, 11] Competency frameworks are commonly structured around domains of knowledge or professional expertise and can specify defined levels of expertise, which are instrumental in designing the curriculum, teaching/learning formats and assessment formats. For example, the FIP Global Competency Framework (GbCF)[7, 8] distinguishes four competency areas (pharmaceutical public health competencies, pharmaceutical care competencies, organisation and management competencies, and professional/personal competencies) while CanMEDS[12]-based frameworks use domains and related roles as an organising principle (pharmaceutical expert, communicator, collaborator, scholar, health advocate, leader, and professional). The required levels of expertise at graduation (e.g., teacher-guided, supervised, independent) can be specified for each competency domain separately in order to reflect differentiation in required professional behaviour at the time of graduation[13] or before access to advanced pharmacy practice experiences.[14]

Definitions of competence, competency, competency-based education (CBE), and competency framework have been extracted from the recently published WHO global competency framework for universal health coverage.[15]

- **Competence:** The state of proficiency of a person to perform the required practice activities to the defined standard. This incorporates having the requisite competencies to do this in a given context. Competence is multidimensional and dynamic. It changes with time, experience and setting.
- **Competencies (singular competency)**: The abilities of a person to integrate knowledge, skills and attitudes in their performance of tasks in a given context. Competencies are durable, trainable and, through the expression of behaviours, measurable.

- **CBE:** An approach to preparing [health workers] for practice that is fundamentally oriented to outcome abilities and organised according to competencies. It de-emphasises time-based training and facilitates greater accountability, flexibility and learner-centredness.[16]
- **Competency-framework:** An organised and structured representation of a set of interrelated and purposeful competencies.[17] Each competency is accompanied by behavioural statements or indicators. These behavioural indicators describe measurable behaviours which would be observed when the individual demonstrates the associated competency.[18]

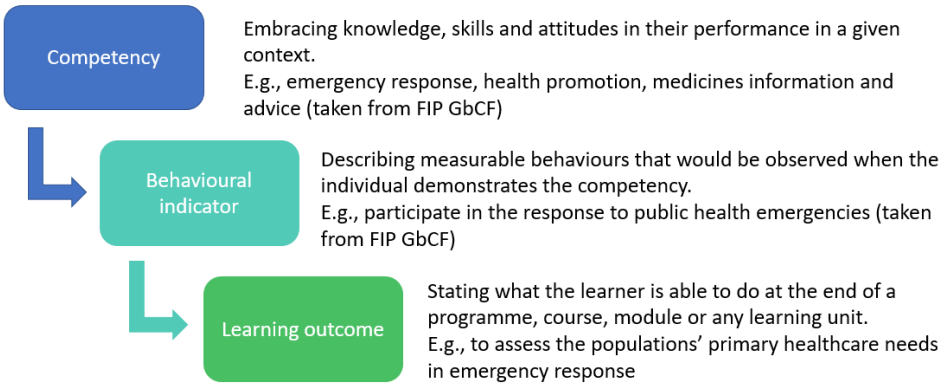
2.2.2 CBE and outcome-based education

Confusion between outcome-based education (OBE) and CBE has often made the CBE implementation process harder. While both OBE and CBE have a common focus on the results of education and training, they are not equivalent in detail.[19] Differences between OBE and CBE are related to their definitions of the endpoints. According to Spady,[20] considered the father of OBE, outcomes in the OBE model refer to "clear learning results that we want students to demonstrate at the end of significant learning experiences", and "actions and performances that embody and reflect learner competence in using content, information, ideas, and tools successfully". In OBE, the endpoint is anchored around academic performance from what has been learnt, whereas the endpoint of CBE is focused on practice-based performance. Hence, competencies emphasise performance of tasks in a given context of practice,[15] and need to be constantly developed based on health needs of populations and patients.[4, 19] The developmental feature of competencies allows for advancement, and the development of expertise and competent professional performance.[21]

Furthermore, the scopes of outcomes and competencies in education are not the same. Some argue competencies are used for professional development guiding individual learners towards achieving excellence in practice and rooted in behaviourism and mastery learning theory.[22] This scope of the concept is essential when individuals consider and identify competency-related performance and developmental gaps to master the said skills and competencies and pursue a path to excellence. On the other hand, outcomes are often considered the standards of healthcare professionals required for practice, which individual learners need to obtain at the end of educational programmes or training. Outcomes and standards are useful proxies for minimum quality assurance of health professional practice and regulation. Therefore, competencies and outcomes are not separate concepts but interlinked concepts in health professional education.

Having a competency framework describing a set of competencies and accompanied behavioural indicators, learning outcomes are may be derived from the competency framework, considering various contexts and conditions related to local health professional education and training programmes. The relationship between competency, behavioural indicator, and learning outcomes are summarised in Figure 4

Figure 4 Relationship between competency, behavioural indicator, and learning outcome

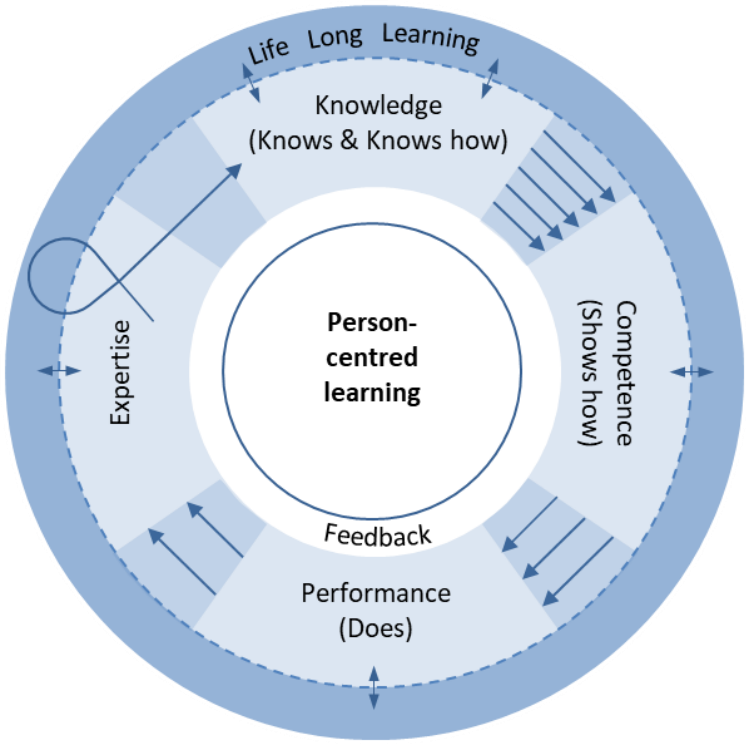


2.2.3 CBE: from initial education to professional development in the context of lifelong learning

CBE is key to supporting seamless transition from initial education to professional development. Opoku *et al* addressed the complexity and a stressful period of the transition from initial health professional education into practice for new healthcare practitioners.[23] It was highlighted that the ease or difficulty of the transition journey to professional competence is pivotal to achieving successful transition. Multiple factors were shown to impact this journey, including professional competence of health professionals upon entry to practice. CBE is therefore an important educational approach to embrace in preparing health professional students with the knowledge and skills to cope better while transitioning into practice and perform according to the needs of patients and the setting they are a part of.

Based on what has been described in Section 2.2.2, proposing CBE in a professional's development journey supports progression towards excellence in practice. Competence development therefore remains on a trajectory from knowledge acquirement to excellence in performance. Starting with initial health professional education, implementation of CBE requires application of the CBE concept to curricular content, teaching, learning and assessment methods, and educational or performance outcomes. Elaboration on the implementation of CBE in pharmacy and pharmaceutical sciences education is provided in Chapter 4. But it is noteworthy that CBE cannot be viewed in isolation of the self-initiated, ongoing pursuit of knowledge and skills throughout one's professional life, which covers a whole spectrum of formal, non-formal and informal learning in order to foster the continuous development and improvement of the knowledge and skills needed for employment and personal fulfilment.[24] The notion that CBE in pharmacy must be seen in the context of lifelong learning and continuing professional development has been described by Bajis *et al*.[25] They propose that lifelong learning practices incentivise the adoption of CBE models (discussed in this handbook) as a vehicle to support ongoing personal and professional development, which must begin in initial education and continue for life. In addition, and as far as progressing from knowledge attainment (the knowing and knowing how), to competence (the showing how), to performance (the doing) as described by Miller,[26] Bajis *et al* propose that these move in a cyclical fashion towards excellence (or expertise in a competency or skill) reflecting one's professional development goals and competency and learning gaps (Figure 5, all within the realm of lifelong learning, which enhances self-fulfilment, connection with others and professional success, and fosters innovation, to mention a few.

Figure 5: Competency-based learning and assessment cycle in the context of life-long learning. Bringing together knowledge acquirement, competence development, performance and expertise development supported by person-centred (student and professional) learning modalities and feedback. Adapted with permission[27]



In the cyclic model of competency-based learning and assessment (figure 5), firstly, four domains (knowledge, competence, and performance and expertise) are integrated in a continuous cycle of transference of knowledge to application. Secondly, building on a foundation of knowledge and skills (depicted by multiple arrows) to build competencies (depicted by fewer number of arrows) and to perform tasks. Thirdly, the dotted circular line depicts constant exchange of new knowledge from experience, practice, and research. Finally, maintaining expertise in the workplace is illustrated by a looped-arrow re-entering the learning and assessment cycle; a depiction of constant exposure to various workplace contexts in practice and need for self-reflection on continuing education needs.

2.3 Educational theories in the context of CBE

The perceptions of conceptual complexity in the CBE approach often come from the combinations of educational theories and notions in contemporary higher education.[28] These include:

- Social constructivism[29] — applying student-centred learning;
- Authentic assessment[30, 31] — connectivity from formal education to practice in the real world;
- Outcome-based education[20, 32] — allowing programmes and educators to be innovative in instructive design; and
- Self-regulation[33] and metacognition[34] — preparing students to be proactive and life-long learners.

Efforts have been made to support the implementation of CBE in health professional education by easing the complexity of CBE and the understanding of what CBE comprises. For example, a Delphi study[35] with 25 experts from the international competency-based medical education collaborators group identified five core components of competency-based medical education. These are outcome competencies, sequenced progressively, tailored learning

experiences, competency-focused instruction, and programmatic assessment. These have a strong theoretical (educational and developmental) basis, however practical implementation guidance has been lacking.

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Chapter 3 Global status of CBE in pharmacy and pharmaceutical sciences education

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3.1 Background

CBE in pharmacy, and in other healthcare professions, often follows developments in the medical field. In a review of the medical literature, Frank *et al* found a substantial level of heterogeneity in the definitions of CBE, highlighting the complexity and level of debate within the concept of CBE.[1] However, the authors defined four major CBE themes: (i) organising framework (demonstrable graduate outcomes defined as competencies and abilities); (ii) rationale (learner-centred approach based on societal needs); (iii) contrast with time; and (iv) implementing CBE (designs, components and ingredients).[1]

Nevertheless, operationalisation of competency frameworks and the implementation of CBE is a complex process.[2] As a result, rates of CBE adoption globally are low for pharmacy and many efforts fall short of a fully realised CBE curriculum. Reasons suggested for this lie among challenges in four key areas: defining the health needs of the community, defining competencies, self-regulated and flexible learning options, and assessing learners for competence.[3]

Previous literature on CBE in pharmacy addresses some of these challenges and further highlights the discrepancies between the interpretation and application of CBE.[4, 5] A variety of information is also available on different aspects of CBE, including assessment methods,[6] validity and applicability of competency frameworks,[7] and useful and practical guidance for developing a CBE programme.[2, 8]

Despite the plethora of research, tools and information supporting the implementation of CBE, it remains a significant endeavour where global uptake is inconsistent.[9] In order to understand the challenges and needs of those wishing to adapt to a CBE system it was important to examine the latest literature in the field and to perform further up-to-date research to reflect the latest developments in pharmacy. This was achieved through a systematic review of the relevant literature and a survey that was distributed to pharmacy schools globally. The aim was to collect information about CBE-related activity, in line with the core features, and to determine the current global state of CBE for pharmacy. The details of these studies and a summary of the results are presented in this chapter.

3.2 Methods

The systematic review focused on identifying the features, or prominent attributes or aspects, of CBE employed in pharmacy and pharmaceutical sciences education and training. Literature was restricted to studies published in English from 2010 to 2021. Studies relating to undergraduate (initial training or pre-registration degree depending on location e.g., MPharm, BPharm, or PharmD), postgraduate (graduate students studying for a second qualification e.g., Masters or Postgraduate Diploma, PGDip), and professionals undertaking post-qualification workplace-based training (post initial or first degree and registration as a pharmacist) were included.

Any study that fulfilled the above criteria and was related to CBE (as defined by Hodges *et al*[10]),* 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. Features of CBE from the studies were categorised into overarching themes. These features and themes were further refined, with reference to definitions of CBE from the medical field[1†] and with assistance from collaborators from around the globe with experience of competency-based education in pharmacy. A total of 20 features and 21 sub-features were identified and categorised into six overarching themes: design, teaching and learning, feedback and assessment, faculty, resources, and internal and external factors. Some of these are discussed further in this chapter, highlighting some of the key findings of the studies that may be useful when considering CBE implementation and development. Full details of the method, including the search strategy used can be found in the full published article of this review.[11]

As for the survey, it was designed to capture the current extent of CBE worldwide for pharmacy and the often-linked pharmaceutical sciences to determine the current extent of CBE utilised globally, the perceived challenges of implementing CBE in pharmacy and pharmaceutical sciences, and the characteristics of CBE-related elements incorporated within pharmacy and pharmaceutical science programmes, modules or units.

The survey was distributed online to pharmacy schools globally via FIP and the European Association of Faculties of Pharmacy, using their existing mailing lists, between November 2021 and March 2022. Personal contacts of the research team and collaborators were also emailed to further increase the distribution of the survey. The survey questions were subjected to face validation using a core team of collaborators from around the globe with experience in CBE for pharmacy and the pharmaceutical sciences (see Acknowledgements). Participants were asked to provide demographical information as well as specific details about their school or department in terms of the programmes that offered whole CBE curricula, or parts of curricula e.g., units or modules that were related to the CBE approach.

3.3 Results

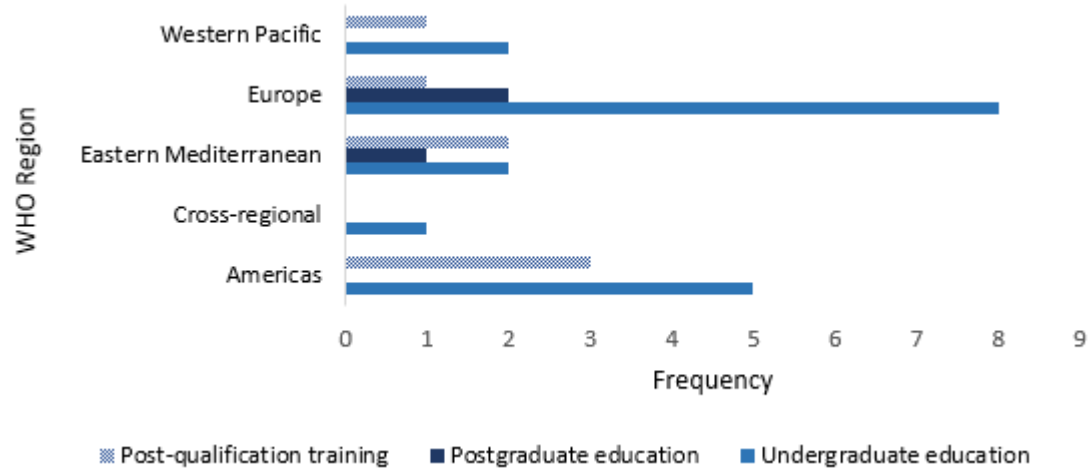
3.3.1 Systematic review

There were 28 studies included in the review. The locations of the research from the studies, according to the WHO regions, and the level of education or training referenced as the focus of the study are presented in Figure 6. Most research was based in high-income countries, none of the studies relate to CBE activity in pharmaceutical science or in the African or South-East Asian regions, and one study was cross-regional. Many of the studies focused on undergraduate education (18, 64%), followed by post-qualification training (7, 25%) and then postgraduate education (3, 11%).

* "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."

† "Competency-based education (CBE) is an approach to preparing physicians for practice that is fundamentally orientated to graduate outcome abilities and organised 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."

Figure 6 Distribution of review studies according to WHO regions and level of pharmacy education or training



Design

A patient-centred[12-17] and needs-based approach[18, 19] to CBE programme design was frequently mentioned in the studies, including the incorporation of generic skills.[16, 17, 20-23] The supporting abilities that students develop during a CBE programme are important as they align with the demands of pharmacists to work as high-standard healthcare professionals[13]. Other features were associated with the progressive process of competency development, including the sequence of competency development[24-27] and the extent to which competencies are integrated throughout the curriculum.[13, 16, 25, 28]

Systems of instruction and learning methods

A common supporting component of the CBE approach is the need to provide training on the concept of competency itself.[14, 16, 20, 22, 25, 26, 29] This is mainly to connect competencies in relation to the learning outcomes[16, 22] but also so that students can engage with a continuum of overall competence development (continuing to achieve individual competencies throughout their career) relevant to the standards of the profession and appropriate to the level at which they will be working in practice.[20, 25] Reference was made to self-directed learning helping to encourage motivation and autonomy, which could also be utilised when pharmacists advance their practice.[21] Self-directed learning is also closely linked to a learner-centred approach,[8] where students identify their own learning gaps using self-reflection and choose their own research projects or topics of interests. Learners expressed that this flexibility and opportunity to individually tailor a programme to their own needs was a benefit of the CBE approach.[21, 29]

Experiential learning strategies were perceived as important and superior for translating learning to practice and supporting acquisition of skills compared with teaching materials designed to impart knowledge.[16] However, an appropriate balance between academic content and technical skill development needs attention in the curriculum.[16] In countries where the PharmD programme is dominant, experiential learning time is a sizeable proportion of the curriculum. In Canada, the US and Australia, particular attention is dedicated to assuring the quality of experiential education, which relies on the competency of preceptors.[23, 26] In some locations there is not such a long-standing practice of experiential learning, and there is a need for more support to improve experiential learning opportunities[17] and more practice-partnerships with educational institutions.[18] Case studies, simulations and workplace-based learning can also contribute to achieving authentic and integrated teaching and learning across different contexts.[22]

Interdisciplinary learning and associated competencies are recognised as a key component of education for healthcare professionals. However, despite the inclusion of interprofessional competencies in Accreditation Council for Pharmacy Education (ACPE) standards, a recent study showed that a low proportion of US pharmacy schools (34%) indicated that these competencies were well covered by the curriculum. which suggests that this area requires improvement in the US.[27]

Feedback and assessment

A number of studies referred to providing regular feedback, particularly soon after completing assessments[13, 30, 31] and learning activities.[32] The combined use of formative and summative assessment can aid the regulation of a learner's competency development to engage in a continual learning process.[20, 22] Feedback should be specific and meaningful and come from a variety of sources, including other healthcare professionals and even patients, which contributes to objectivity.[31] In Canada most of assessments for pharmacy resident programmes (75%) were longitudinal.[31] One of the few assessment stipulations of the accreditation standards of the Canadian Pharmacy Residency Board is the requirement for longitudinal assessments.[33] Rich suggests that measuring competence in this manner as a pattern of performance overtime is more useful than measuring competencies in isolation.[22]

Portfolios were used as an assessment tool in four of the studies.[13, 20, 21, 29] Portfolios are also used in conjunction with competency frameworks, which help to structure the documentation of a learner's development.[13, 29] Development of all patient care competencies was found to be significant in a longitudinal study of community pharmacists, before and after completing a tailored education programme, which included a mandatory competency-based portfolio of the learner's contributions to patient care.[29] However, feedback on portfolios revealed they could be difficult to use. Consequently, attention to their user-friendliness is recommended to ensure they are clear and efficient to employ, thus improving their acceptance and usability.[20, 29]

Another assessment method mentioned was the Objective Structured Clinical Examination (OSCE). Recommendations for improving the experience and performance with this method include performing prior formative OSCEs in preparation for final summative OSCE assessments, which helps to allay anxieties particularly when students are new to this method.[34, 35] Kirton and Kravitz also describe only a weak correlation between performance in OSCEs and that of more traditional assessment methods, as the different formats examine different skills. Therefore, they recommend that OSCEs should be used in conjunction with a number of different assessment formats.[36] Furthermore, performance in OSCEs can be related to external factors rather than ability, and so attention should be paid to the examination environment, structure, timing and the amount of weight any assessment carries towards the final grade.[36]

Westein *et al* describe the process of a thorough evaluation of a CBE programme for community pharmacists and conclude that entrustable professional activities (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 number of EPAs to avoid administrative burden and assessment trivialisation.[13]

Learner self-assessment was a salient feature employed in pharmacy education both at undergraduate level,[25, 30] post-qualification level,[20, 21, 29, 31, 32, 38] and for the development of pharmacy education preceptors.[23] Competency frameworks provide standards which learners can assess themselves against and use to plan future learning.[20, 21, 23, 29, 31, 32, 38] Furthermore, Nash *et al* describe that asking students to self-assess on their performance using Miller's pyramid[39] can contribute to a programme's assurance of learning by providing data reflective of the actual "learnt" curriculum as experienced by students.[25] 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.[31]

Faculty — preceptors, trainers and instructors

The involvement of practice-based trainers is often fundamental.[17] 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,[16] entire programmes,[13] and significant periods of supervised practice prior to licensure as a pharmacist.[26] However, they are not necessarily trained educators and may not have much knowledge of CBE and related assessments. 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.[23] 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.[16] Different

epistemological understandings of CBE among faculty members can lead to disjointed approaches to teaching, therefore a unified approach is recommended.[16] 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 of the considerable changes needed to adapt to a CBE curriculum.[13, 16, 17]

Resources

Information technology and web-based systems are utilised in CBE to aid feedback, organisation and evaluation. Allen *et al* describe a web-based tool (individualised Skills Evaluation and Development, iSED) specifically designed for formative feedback with OSCEs that facilitates self-regulated learning.[40] Similarly, Bray *et al* 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.[41] Nash *et al* describe using a database of information from educators' and students' perspectives for curriculum mapping and the co-creation of rubrics as a useful process for highlighting issues with scaffolding of learning and the integration of professional standards.[25]

Paradis *et al* found that the differences in approaches to teaching in CBE calls for better coordination of the curriculum, which can be facilitated by specific leadership with curriculum mapping.[16] Westein *et al* describe a process of careful curriculum design, coordination and evaluation of a CBE post-graduate education programme using a programme director and a director of education responsible for overall management. On a similar note, Volmer *et al* recognise the limitations of using evaluators without expertise in curriculum development and suggest that consultation with curriculum specialists is required to progress further with CBE in Estonia.[17] Furthermore, the engagement of additional staff with expertise in CBE-related features, such as experiential education, is recognised as a strength by Walter *et al* in their approach with the design of a competency framework for preceptor development that has relevance internationally, both for pharmacy and across other health disciplines.[23]

Internal and external factors

Formal support from both inside and outside 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, Nunes-Da-Cunha and Fernandez-Limos suggest that professional regulatory bodies should work with educational bodies to support improved pairing of competencies and curricula content.[42] One of the keys to success, reported by Bray *et al* regarding the implementation and ongoing use of a competency-based assessment model, was a supportive academic leadership team understanding of the disruption necessary to enact change.[41] Similarly, Volmer *et al* recognise that considerable change requires understanding from both educational and governmental institutions.[17] Walter *et al* highlight the importance of endorsement from all stakeholders when integrating a competency framework for preceptors, as this in turn influences the support for them to complete a competency-based development programme.[23] Workplace organisational support for learning is also emphasised, as the educational environment of the learner can influence effective experiential learning[13] and a CPD approach in the workplace.[32] 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-oriented care, which is ultimately the aim of CBE for pharmacy.[19, 28, 38]

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[13, 16, 27], national[14, 19, 23, 27] and international levels.[12, 23] Stupans *et al* reported that high-income countries with similar health needs (Australia, Canada, United Kingdom and United States) displayed good alignment between their undergraduate learning outcomes and the FIP GbCF. The authors suggest that their findings support the feasibility of a common assessment tool for pharmacy education that would support transferability of skills, and thus mobilisation of the workforce across these jurisdictions.[12]

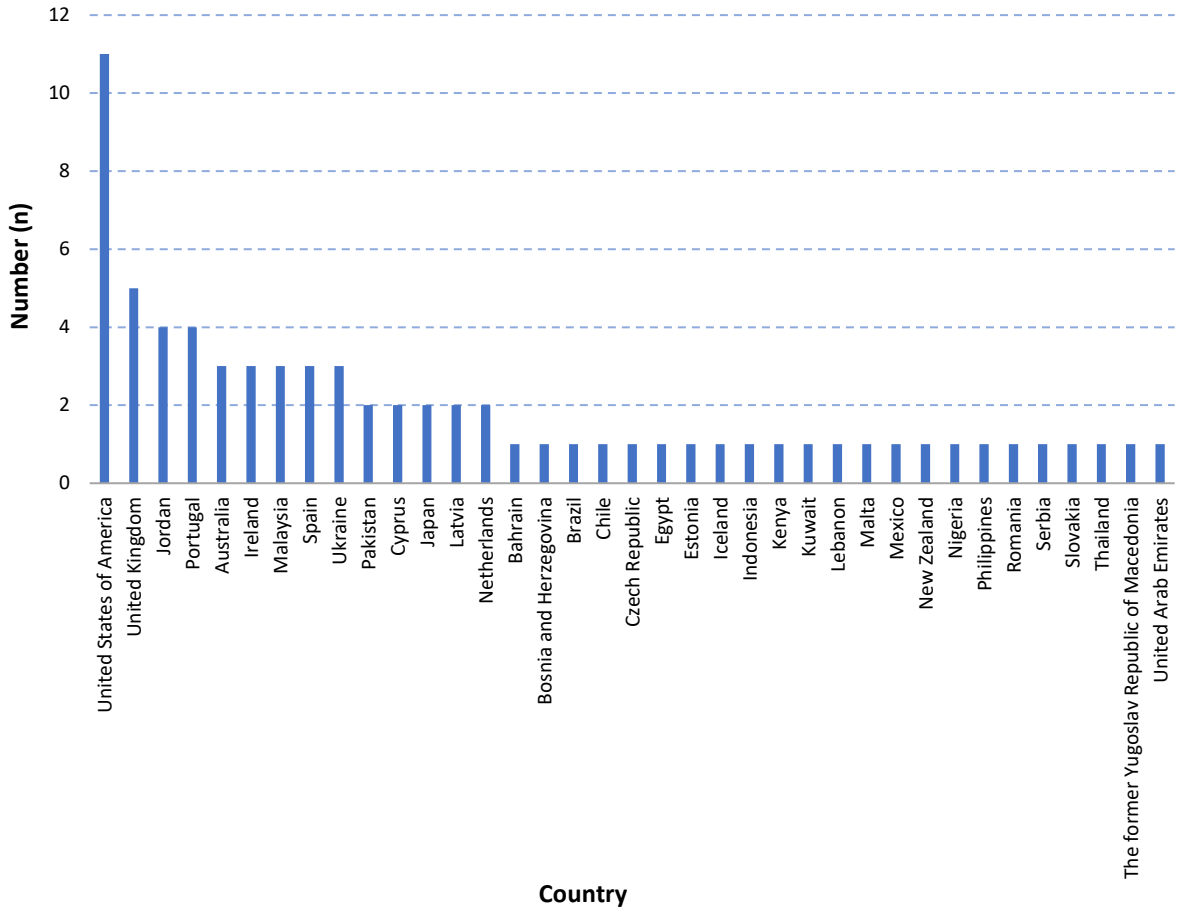
CBE for pharmacy should feature collaboration with other professions as demonstrated by the acceptability of a postgraduate programme for community pharmacists designed to align pharmacy competencies with other health

professions in the Netherlands.[13] Intrinsic competency domains (often referred to as "soft skills", i.e., communication, ethics and professionalism) are quite similar across a variety of professions. Therefore, partnerships and collaborations across institutions may be beneficial to all professions when overcoming shared challenges in related competency assessment.[22]

3.3.2 Global survey

A total of 72 responses were included in the global analysis. The distribution of responding countries is shown in Figure 7.

Figure 7: Number of survey responses from each country



Due to the issues previously mentioned with achieving a fully realised CBE curriculum, respondents were asked to provide information about whether they were using CBE throughout the whole programme, or just parts of the programme. In most cases respondents indicated that CBE was used throughout the whole programme, 41 (71.9%) for pharmacy and 15 (62.5%) for pharmaceutical sciences.

Schools or departments not using CBE

Of the 72 respondents, 62 (86.1%) indicated that they were using CBE in some format and 10 (13.9%) indicated that they were not using CBE at all. Those not using CBE were in Australia, Bosnia and Herzegovina, Japan, Malaysia, Pakistan and Nigeria (n=1), and Portugal and the US (n=2). Six of the respondents not currently using CBE indicated that they were planning to implement CBE (or elements) within the next five years at their institution or university.

Respondents that are not currently using CBE were also asked if there were any specific needs that they thought may help their institution or university to implement CBE, responses included:

- "More information on what CBE entails" (Nigeria)
- "Specific training for teachers and staff" (Portugal)
- "Technology support, instructional design, valid and reliable competency-based rubrics" (USA)
- "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." (USA)

Challenges of using or implementing CBE

Information about the challenges encountered with using CBE was gathered from the survey in relation to some of the key elements of CBE. These included health-needs underpinning, selecting competencies, drafting competency frameworks, curriculum design, systems of instruction and learning methods, feedback and assessment, and faculty involvement and readiness.

The most common challenges cited for each of these key elements were inadequate faculty training or skills to perform need analysis or assessment (health-needs underpinning), difficulty obtaining stakeholder engagement (curriculum design), inter-professional education activities (systems of instruction and learning methods), workplace or experiential learning or assessment (feedback and assessment), and formal large-scale training (faculty involvement and readiness). Selecting competencies and drafting competency frameworks were the only elements where the most common response was that "no challenge was encountered".

Aspects of CBE currently used

Finally, those indicating that CBE was being used in their pharmacy or pharmaceutical science programmes were asked to provide information on some of the key elements of CBE to gather an idea of how CBE-related activity is in use currently.

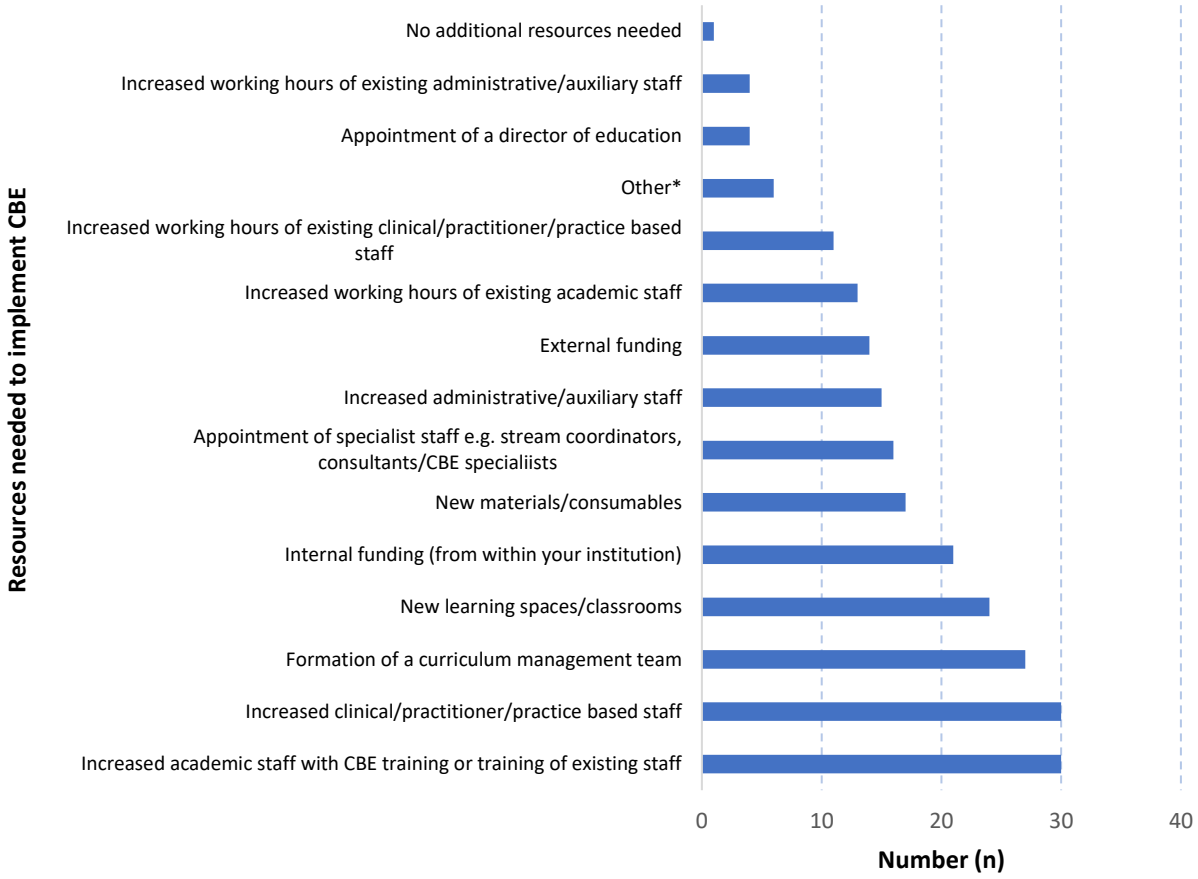
Most respondents (n=35, 56.5%) stated that they did not use a form of health needs assessment to underpin their CBE-related activity. Those that conduct a health needs assessment to inform their learning outcomes did so most commonly via the use of stakeholder meetings followed by literature review. Availability of existing local pharmacy or pharmaceutical science competency frameworks was common (n=29, 43.3%); while some institutions created their own frameworks (n=12, 17.9%) and the GbCF was the third most used competency framework (n=9, 13.4%). When asked about competencies, 35 (74.5%) of those responding indicated that these were mapped to learning objectives, and for these mapping was most usually completed in one (36.7%), two (23.3%), or three (23.3%) rounds. Mapping commonly involved school or department academic staff in combination with course coordinators but also often involved students, pharmacists, alumni, and representatives from pharmacy or pharmaceutical science quality assurance bodies.

Despite challenges that were found with interprofessional education, 27 of 48 respondents indicated that it was part of their CBE-related activity when asked about systems of instruction and learning methods. However, it was the least commonly cited educational format employed. Discussions in lectures or tutorials were the educational format used in most cases, followed by case-based learning, problem or project-based learning, self-evaluation or reflection and then simulation-based learning.

Assessment in the CBE units, module or programmes remains in line with more traditional methods such as multiple-choice questions and written examinations but in many cases both summative and formative assessment did take place at various time points rather than all at the end of the unit, module or programme. This was accompanied with an opportunity for remediation in most cases (83%). Students were provided with opportunity for regulating their own timing or pacing of learning in 68.1% of cases of CBE-related activity, commonly attributed to some version of e-learning.

In recognition of the resource requirements of implementing CBE, respondents were asked to indicate the resources involved in their own institutions. Most of these were related to increasing both clinical and academic staff. Figure 8 outlines these resource requirements in more detail. Although many organised some sort of training for their faculty to implement CBE, six respondents stated that no training was provided and 10 also stated that not all faculty members were informed of the complete CBE-related curriculum outline.

Figure 8: Resources needed to implement CBE units, modules, or programmes



3.4 Discussion

The systematic review provides some specific features to consider while using CBE and, although it is not exhaustive, it brings together the relevant research to facilitate the sharing of knowledge on CBE-related activities in pharmacy education that can be considered during all essential stages of preparation, implementation and evaluation of CBE initiatives.

It is, ultimately, the outcome, not the content, of education that is of focus in CBE — where the priority is the overall capability of the learner to perform in practice and continue to engage in life-long learning in an ever-changing environment.[43] In keeping with previous literature, this review identifies that a needs-based, integrated approach can help address many elements of CBE and avoid unnecessary overlap.[2] This review also echoes previous studies in relation to the resource intensive implementation process that CBE adoption entails.[2, 4] There were no studies from Africa or Asia eligible for inclusion in the systematic review and these regions also had the lowest amount of survey responses. Further research on CBE is called for in these regions, and especially in resource-limited settings, particularly as in these

contexts there is often the greatest need for improved educational outcomes with the potential to subsequently improve health outcomes and mitigate significant shortfalls in skilled healthcare workers.[44]

The global survey results suggest that CBE-related activity is widespread among pharmacy and pharmaceutical science educational facilities and that any lack of this activity is not necessarily related to the country within which the faculty is located. Even for respondents that replied they were not currently using CBE, the majority indicated that they were planning to in the next five years. Challenges to CBE design and execution are varied, many of which have been identified previously.[4] However, there are some promising results from this study in relation to selecting competencies and developing frameworks where there were commonly no challenges encountered. One explanation for this could be due to various recent national and international efforts to develop competency frameworks, such as the Canadian Medical Education Directive for Specialists (CanMEDS) framework, for example, which has demonstrable applicability to pharmacy practice, or the FIP GbCF which can be adapted to different contexts.[7]

The conceptualisation and associated definitions and terminology associated with CBE requires harmonisation, as illustrated by several of the studies in the systematic review 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 in CBE components has previously been noted elsewhere.[7] Similarly, previous discrepancies with the definitions, terminology and interpretations of CBE[4, 5] are worth bearing in mind when interpreting the results from the global survey. Although a broad definition of CBE was provided with the online survey (as defined by Hodges *et al*[45]), there is no guarantee that participants' understanding of this definition was homogenous, which may have influenced their responses. Furthermore, there may be some element of response bias, where those motivated to respond have a particular interest in CBE, which may have affected the results.

In addition to a shared understanding of the concept of competence, there are various other complexities and challenges to adopting the CBE approach that need to be considered. This requires a significant amount of planning and dedication of resources.[4] However, the CBE adoption process depends on the specific context which is evident from the varied experiences outlined in the review studies. Situations differ according to local support systems for development of the pharmacy profession, which may be influenced by political or socioeconomic circumstances[19] as well as the local relative novelty of the CBE approach to both pharmacy education and practice in any given setting.[17] Therefore, both internal and external factors must be taken into account when embarking on CBE development and careful consideration at all stages must be exercised.[2]

3.5 Conclusions

The list of features and supporting components identified in the systematic review is not intended to be exhaustive, but rather a reflection of just over a decade of the most recent research in this area. There are disparities in the way that CBE is conceptualised and the variations in terminology and definitions can have an impact on all features of CBE. It is therefore imperative that a consensus and shared vision for all stakeholders is reached to bridge any gaps between intended curricula and the curricula experienced by learners to enable them to engage in a life-long learning and adaptation process that is in alignment with the realities of contemporary pharmacy practice.

The survey results highlight where further development is needed to assist with CBE initiatives for pharmacy. There does seem to be some progress in terms of defining competencies and organising these into frameworks which contribute to an overall organising structure, previously identified as a key element of the CBE approach. Work is needed, however, to assist with the provision of interprofessional and experiential education. Although, not essential tenets of the CBE approach these aspects are increasingly favourable, particularly in the pharmacy curriculum, where practice is becoming more focused on clinically oriented and patient-centred services, which in turn influences the needs-based element of CBE thereby impacting the skills and abilities required from graduates. In addition to specific

changes to teaching, learning and assessment, it is also clear that further work is required to support faculties in enacting the meaningful change required to adapt to CBE.

The systematic review and survey provide a timely summary of the features of CBE in pharmacy, given the recent advancements in this area, and provides a valuable resource for those considering implementing or improving CBE by building on what has already been learnt. Advancements are not, however, uniformly distributed around the globe. Therefore, we call for further research in regions, such as Africa and South-East Asia, which can aid the application of CBE in contexts with diverse needs and limited resources.

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Chapter 4 Process of CBE implementation

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4.1 Get organised

Before starting the implementation of a CBE-curriculum an effective two-tiered organisational structure needs to be established. In order to develop and to oversee the curriculum as a whole, a curriculum committee consisting of teachers from different disciplines must be established. Ideally, also students, a staff member with managerial experience, educational specialists,[1] and an independent project manager[2] should participate in the committee. The main task is to create or design an overall curriculum structure (See section 4.3) within the boundaries of the adopted CBE framework, following guidelines from professional organisations and respecting existing governmental or university regulations. The work of the committee needs to be facilitated by the institution (faculty, department or school), and can be supported by specialised services for educational development. The main product will be a blueprint of the designed curriculum, containing at least information about the aspects mentioned in Table 1.

Table 1. Content of a blueprint for the development of a CBE curriculum

Framework	A description of the competency-framework used for the curriculum development. Depending on the local situation, an existing framework of a professional or governmental organisation can be used. Alternatively, a framework can be developed *de novo* as a preparatory step for the introduction of CBE (see Chapter 2).
Context	A description of the local context, such as related health care programmes, institutional structure, existing collaborations with professional organisations and number of incoming and outgoing students. A description is required of all those aspects that can have an impact (in terms of restrictions, limitations, opportunities or challenges) on the implementation of the intended CBE curriculum.
Educational guidelines	A description of the design principles, underlying CBE (see Chapter 2) and aiming at effective student learning. These guidelines can be used to make argued choices for teaching and learning activities, assessment of students and organisational aspects of the curriculum. If an institution (university, faculty, school) has adopted certain educational policies (e.g., problem-based or inquiry-based learning), this needs to be mentioned.
Curriculum design	A description of the courses and other curricular elements (traineeships, student mentoring, etc.), their sequence and mutual dependence. Ideally in a CBE curriculum, a certain degree of flexibility for students to follow courses at their own pace or sequence is required.
Schematic representation	A compact description of all curricular elements (courses, longitudinal aspects, traineeships) by study year and semester.
Resources	An analysis of the teaching capacity (hours, specified by discipline), facilities (classrooms, laboratories, computers, etc.) and material resources required for delivering the designed curriculum. If additional (temporary) resources are required during transition from an existing to a new curriculum, these must be specified separately.
Introduction of the programme	A description of the timeframe for the introduction of the new or modified curriculum. In particular when a traditional curriculum is to be replaced by a CBE curriculum, the use of human and other resources requires detailed and careful planning.

The blueprint will function as a reference and instruction document for the development of feedback and assessment strategies (see Section 4.5), individual courses (see Section 4.6) and use of resources (see Section 4.7) within the curriculum.

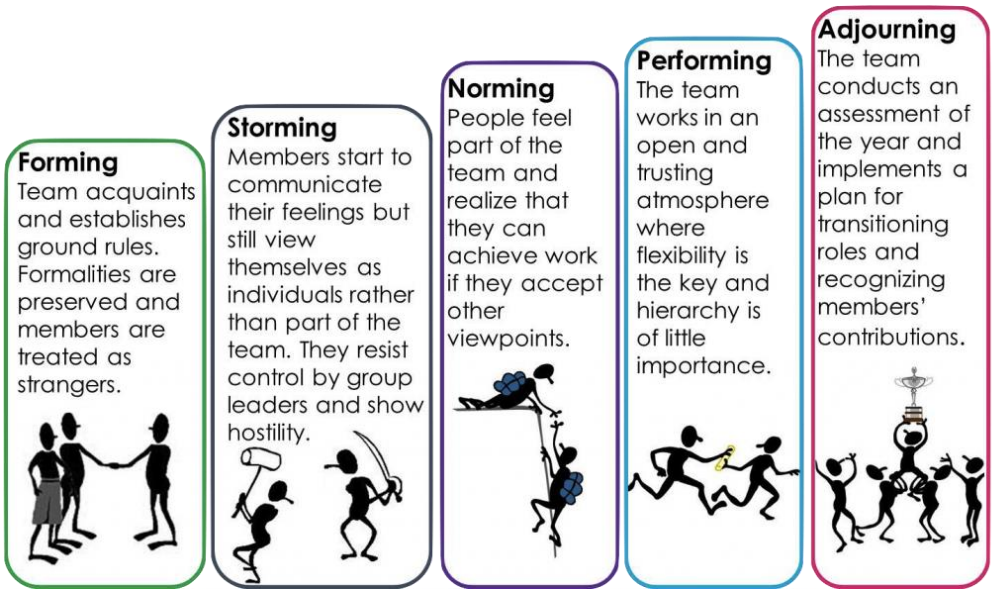
The second organisational tier consists of course development teams (CDTs) and teams for specialised functions within the curriculum (e.g., assessment, student tutoring, experiential placements, professional skills development). The composition of each team (between three and seven members) will depend on the task given; usually teachers with different disciplinary backgrounds participate but including a student and an educational specialist can be useful. Ideally, a member of the curriculum committee participates in each team to serve as a link between the curriculum committee and the various development teams. The main task of all teams is to create or design a course or other curriculum element within the boundaries of the instructions, which follows from the overall curriculum design. Explicit instructions by the curriculum committee must contain at least intended learning outcomes and an indication of the freedom and limitations of each team with respect to the use of teaching and assessment formats and resources (Table 2). The main product of each course development team will be a course specification document, where teaching and assessment formats, time schedule and available resources are described in some detail.

Table 2. Content of a course specification document

Administrative details	Course code and title, position within the curriculum, total study load, involved disciplines, responsible course coordinator, CDT composition, etc.
Course goals	Intended learning outcomes, described in terms of student knowledge and skills.
Course content	A description of the disciplinary content of the course. If a CBE curriculum is developed from an existing curriculum, suggestions for reuse of existing teaching materials, laboratory instructions and other teaching material can be given.
Context	Relations with respect to preceding, parallel and subsequent curriculum elements. Intended to frame the course content within the overall curriculum design. When longitudinal “learning lines” or “tracks” are used for structuring the curriculum, the position within and the contribution of the course to these “learning lines” or “tracks” can be specified to instruct the CDT.
Teaching formats	Suggested or prescribed teaching formats which are suitable for the course. When specific teaching and learning principles (e.g., problem-based, team-based, project-based or inquiry-based learning) are adopted within the curriculum, this needs to be specified.
Assessment formats	Suggested or prescribed assessment formats, which may depend on the position within the curriculum or other explicit educational choices, following from the adopted curricular design principles.
Boundaries	Limits on human, material and other resources. The number of participating students, the available teaching load and other restrictions, stemming from institutional or departmental structure can be specified. It can be helpful to specify the maximum percentage of contact hours, compared to the total study load (e.g., 30%).

Designing a curriculum is a creative process which requires the contribution of variously minded individuals.[3] This can be organised as a curriculum committee with a flexible structure where sub-tasks can be allocated to smaller subsets of the committee as needs arise. The composition of CDTs and other teams will depend on the content and instruction of each team (“form follows function”). Monitoring the functioning of both the curriculum committee and the development teams can be helpful in maintaining speed and goal-directedness during the change process. Most teams will necessarily go through distinct phases (forming, storming, norming, performing and adjourning) to grow, tackle problems, find solutions and deliver results (Figure 9).[4] Several examples of the organisation of a curriculum change process[5, 6] are available in the literature,[7-14] and a model for the analysis of sociodynamic processes during a radical curriculum change process has been published.[15]

Figure 9: Sociodynamic processes in project teams (after Tuckman and Jensen[4])



A CBE-curriculum requires an awareness of educational quality[16] and an effective quality management system.[17] It is advised that continuity for this process is organised at the highest possible organisational level (institute, school, faculty) and that the adopted design principles and an explicit educational model (see Sections 4.3 and 4.4) are used as an internal frame of reference to guide all discussions with the involved teachers, students and other stakeholders.[18] For efficient curriculum management it is advised that all education-related human and financial resources (further described in Section 4.7) are allocated at this level in order to avoid misappropriation of funds and other resources as a result of conflicts of interest between teaching, research and other institutional tasks at a lower organisational level.

4.2 Preparation

The main function of a framework for CBE is to give direction to the curriculum development process. Starting from a needs-based analysis, explicit descriptions of the required competencies for an entry-level pharmacist are formulated, which follow from an analysis of the professional requirements in the local context. A recent systematic review[19] identified 53 pharmacy-related frameworks, 22 of which relate to requirements for entry-level pharmacists at a nation-wide level. In addition, FIP has published a global framework,[20, 21] and many other frameworks address requirements for specific sectors or specialisations within pharmacy (see reference 19 for details).

Developing a new curriculum or adapting an existing curriculum usually begins with the adoption of a published competency-based framework as a starting point. If no nation-wide CBE framework exists, a new framework needs to be developed or an existing framework needs to be adapted to the local situation. Consultation of all stakeholders (practising pharmacists, professional organisations, health care authorities) is essential[22] to align the competences of graduated students to the local professional and healthcare needs and is essential for a framework to be accepted locally.[13, 23, 24] Developing or updating a competency framework in rare cases can be the task of a curriculum committee (see Section 4.2), but usually needs to be independently tackled by a group of professionals and stakeholders with a separate mandate.[19, 25]

An important principle in designing CBE curricula and courses is the principle of “backward design” or “reverse engineering”,[26-28] which means that thinking about the content and skills that need to be developed in the curriculum starts with the end (i.e., the desired competencies) in mind. Making choices to include (or exclude) disciplinary content and setting priorities is guided by the adopted competency framework and a critical analysis of the way the required

knowledge and skills can be learned in the available time for the programme (usually between four and six years). In this process it is unavoidable that difficult choices need to be made to prevent overburdening of the curriculum.[29] Starting from and guided by the required competencies, learning outcomes for different layers of the curriculum can explicitly be formulated (see below) and teaching/learning activities and assessments can be designed to reach the desired outcomes in an effective and efficient way.

Developing or using a competency framework for early-career level pharmacy practitioners is helpful for establishing a culture and system of seamless transition for learners from formal initial pharmacy and pharmaceutical sciences education and training (IPET) to post-registration professional development. The FIP GbCF was developed to support foundation level/early-career level practitioners (the immediate post-licensure foundational period of perhaps one to two years).[21] Using the "backward design", competencies and behavioural indicators for early-career practitioners can lead to learning outcomes for the specific IPET programme. For CDTs to define intended learning outcomes using the FIP GbCF or any other locally useful foundation/early-career level competency framework, Miller's pyramid[30] is helpful to identify the level of behaviours desired at graduation or day 1 of professional registration.

4.3 Curriculum design

CBE relies on social constructivist psychological principles (see Chapter 2), where educational methods focus on the learning of students.[31-33] Students construct meaning from what they do during their learning activities and the teaching/learning environment is designed in such a way that students cannot escape from learning (Table 3). The learning of students is not only influenced by their perception of assessment tasks, but also by the way teaching is delivered, by the teacher behaviour, and by the rules and regulations which pertain to the curriculum. The principles of constructive alignment[10, 32, 34] can be used to align all aspects of the teaching/ learning environment.

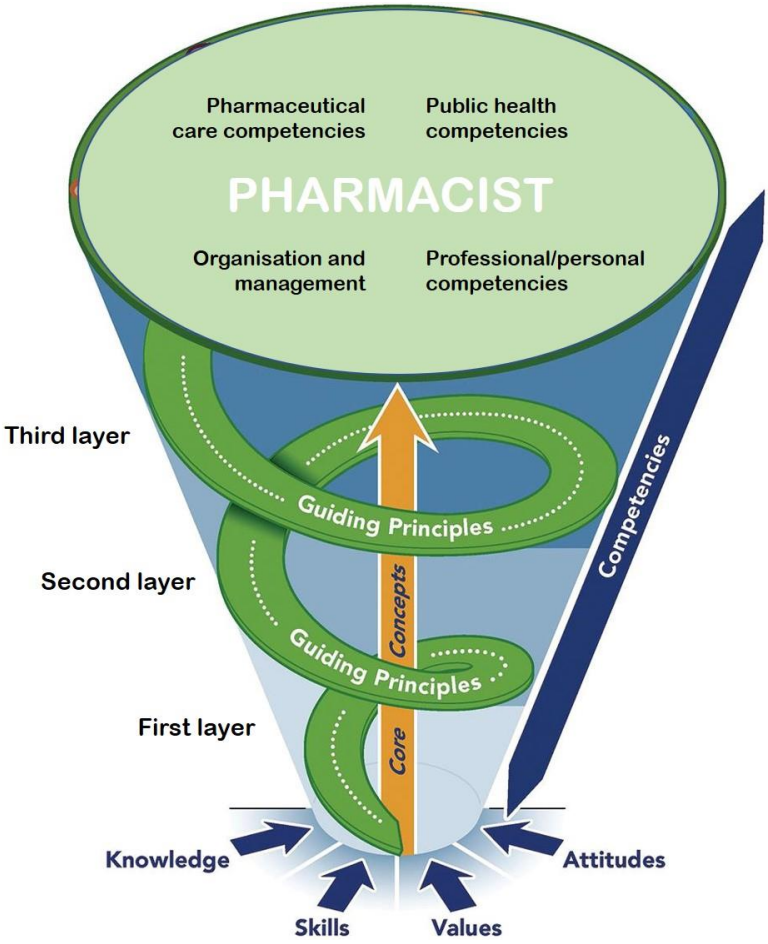
Table 3. Characteristics of a constructivist curriculum (after Alt [33])

Knowledge construction	Students are given multiple opportunities to investigate real problems, raise questions and search for possible explanations while using various methodological approaches.
In-depth learning	Students are given opportunities to deeply explore a certain subject matter, rather than engaging them in surface learning.
Authenticity	Students are given meaning to the learned concepts and addressing real-life and interesting events, which are related to the studied topic.
Multiple perspectives	Students are presented with complex ideas from several points of view.
Prior knowledge	Subject materials in individual courses are reused in subsequent courses' topics. Repetitive teaching is avoided as much as possible, but students are stimulated to reactivate earlier knowledge.
Teacher-student interaction	The teacher role is student-oriented, which includes guidance toward reflection on the learning processes.
Cooperative dialogue	Refers to dialogical activities during the lesson in which students can express opinions and original ideas.
Social interaction	Students are experiencing a variety of learning activities together with other students, not necessarily during contact hours only.

A CBE curriculum is much more than a collection of courses. Sequencing of and relationships between courses (with respect to content and educational methods) needs to be carefully designed. Frequently, the curriculum is described as a "spiral",[9, 35] where related content and skills are addressed repeatedly during each passage of a "curriculum layer" (Figure 10). The number of curriculum layers is somewhat arbitrary, but distinguishing between three or more layers (e.g., year 1, bachelor, master, postgraduate) can be used to structure a curriculum and to define developmental

milestones for students, using explicit descriptions of learning outcomes for each layer. Attainment of milestones can also be used to determine whether students will be allowed to progress to a next stage of the programme, comparable to passing formal bachelor- or master-degrees.

Figure 10: Schematic representation of a spiral curriculum (adapted, with permission, from an original of the British Columbia Institute of Technology, Bachelor of Science in Nursing programme, Burnaby, Canada[36])



As students usually enter a pharmacy curriculum directly from secondary school or from a previous bachelor's programme — where most subjects are taught by discipline — the spiral curriculum must realise a change from a discipline focus of student learning to a practice-oriented and integrated approach. This transformation can be brought about by the careful orchestration of logically sequenced courses (or modules) with increasing complexity and integration of disciplinary content and skills (*cf.* reference 36). In a CBE curriculum, a gradual approach, where students are moving from learning skills in isolation to application of skills in the context of professionally relevant tasks, is advocated.[10, 36] This can be achieved by using problem- and project-based learning methods in early phases of the curriculum, with a gradual increase in the complexity of assignments or projects as the curriculum progresses.[37-39] In later stages of the curriculum, simulations of pharmacy practice[40-42] and organising the curriculum around entrustable professional activities (see Section 4.5) can train students in real-life pharmacy practice situations under complex — but still safe and supervised — conditions.

Sequencing of content and skills in curriculum layers[39, 43] means that the main aspects and concepts of the programme are addressed repeatedly in each layer. By introducing all concepts already at the first layer in a relatively simple way, students are made familiar with the different disciplines and their mutual relationships and with a perspective on the scientific basis of their chosen profession. At the following layers, the conceptual framework is further detailed and

increasingly elaborated in a context which is relevant for the future profession. The curriculum can be structured by explicitly defining learning outcomes for each curricular layer with respect to discipline content, cognitive skills, practical skills and related assessments. Boundary crossing between formal university and informal workplace learning can be eased by considering specific design guidelines.[44, 45]

The main task of a curriculum committee is to design a curriculum structure where all longitudinal aspects of the programme (see Section 4.4) and feedback/assessment formats (see Section 4.5) are translated into building blocks (courses, modules, rotations and other activities) with increasing complexity and level of integration. At the same time, curriculum organisation is usually restrained by existing institutional scheduling (e.g., semester structure) and timetabling rules (e.g., available timeslots for contact hours). The designed curriculum, therefore, needs to be a creative solution for a multifactorial problem, compromising between an educationally desirable solution and existing practical possibilities (boundaries). Because local contexts can vary widely, it is extremely difficult to suggest a generic curriculum structure, but in the literature several examples are available from Finland,[10, 11] USA,[1, 2] Ireland,[46] Saudi Arabia,[12] the Netherlands[38, 47] and Australia.[48] An example of apparently quite different implementations of a three-year master programme, based on the same competency framework, is available in the literature.[25]

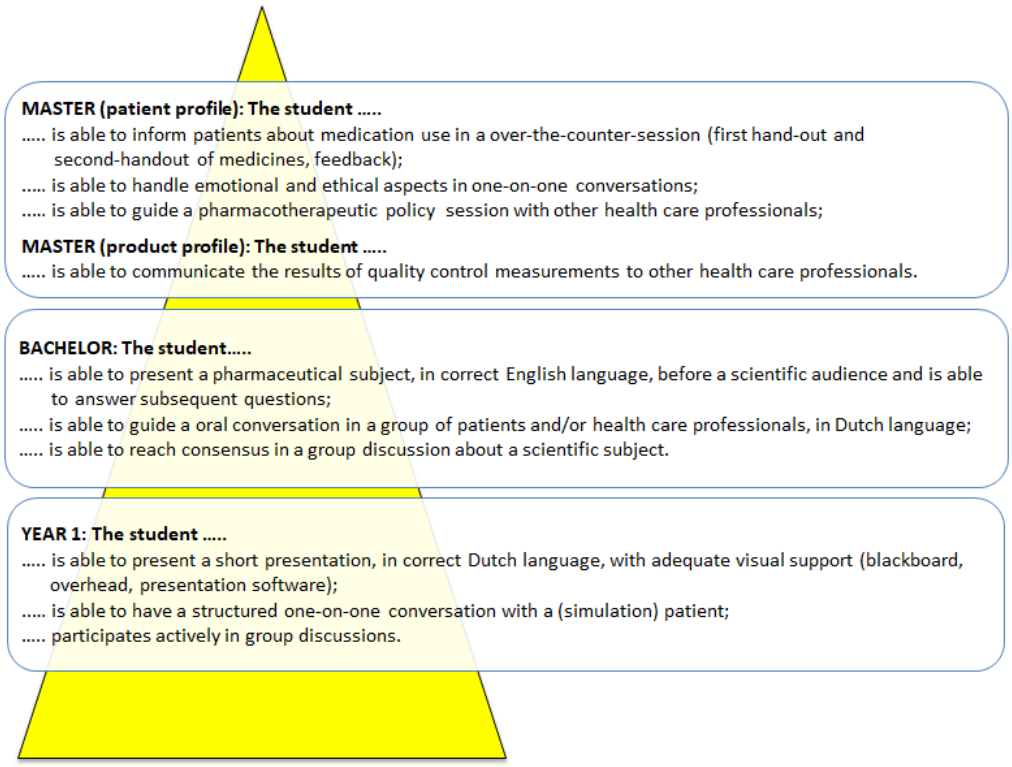
4.4 Overarching themes

Overarching themes and specialisations can be used to structure the curriculum at a higher level than the constituent courses; this can help students with mental integration of curriculum content. Related courses can be scheduled in parallel (or sequentially) and can be made recognisable for the students as “tracks”, “lines” or “strands”. Examples are the scheduling of disciplinary courses under two overarching themes, e.g., “Patients, therapeutics and safety” and “Product, quality and analysis” (Groningen University, the Netherlands),[25] or arranging individual courses under six different strands (in the bachelor programme) or two modules (in the master programme) at Helsinki University, Finland.[10, 11] At the University of British Columbia, Canada, pharmaceutical and clinical approaches are integrated as “medication management”.[39] When fixed combinations of courses are offered to students with exclusion of other courses, some form of differentiation or specialisation becomes possible. Although offering a variety of elective courses in general is encouraged in CBE to stimulate students to shape their own profiles, formal specialisations are rarely encountered in undergraduate pharmacy programmes.

The development of discipline content in the curriculum requires an explicit analysis of the way knowledge in different curricular domains can be built up. These analyses can be used to explicitly formulate learning outcomes that students are expected to have reached at intermediate milestones of the curriculum. Once these intermediate milestones are described, they can be used to define the actual course content (see Section 4.6) on distinct levels of the curriculum. Examples of explicit descriptions of curriculum layers for several content domains can be found in the literature, e.g., for pharmacokinetics[18] and pharmacovigilance.[49]

A gradual increase in the extent of integration of skills as the curriculum progresses requires also that the development of skills and their integration with the content of the curriculum is explicitly analysed and translated into teaching and learning activities which confront students with challenging tasks during the whole curriculum. This requires that awareness and knowledge about the learning of skills must be present among the teachers and that some overarching description is available of the way development of skills can be taught and how it needs to be organised, monitored and assessed. An example of a curriculum layer description for the skills domain “oral communication” is shown in Figure 11.

Figure 11. Curriculum layer outcomes for the skills domain "oral communication" in a European curriculum (Utrecht University), where the pharmacy programme is divided in a separate bachelor and master degree (reproduced from Koster *et al* 2017,[18] with permission).



An efficient way to organise monitoring of skills and content evolution in the curriculum can be realised by making teachers or committees responsible for the development of different skills and content tracks; see Malone[48] and Wolters[50] for examples related to communication skills. These teachers are stimulated to specialise in these didactic areas and can participate in local networks with teachers from other departments, faculties or universities. Within the pharmacy programme, they function as consultants to the teachers who are responsible for detailing individual courses. An example of a set of content consultants and skills consultants is given in Table 4. Other track or stream coordination functions have been described in the literature.[7, 10, 48]

Table 4. An example of curriculum content and skills consultants (Utrecht University, the Netherlands). During curriculum development individual teachers were given the task of consultant to monitor the longitudinal content and skills lines in the curriculum.

Curriculum content	**Curriculum skills**
Physiology and pathology	Information processing
Biotechnology	Written communication
Biomolecular chemistry	Oral communication
Pharmacodynamics	Methodology, statistics
Pharmacokinetics	Laboratory skills
Pharmaceutical technology	Compounding skills
Therapeutics and pharmacoepidemiology	Management
Biomedical analysis	Metacognition
Toxicology	Ethics and law

Active participation of content and skills consultants is strongly advised, in particular during initial development, evaluation and major reconstruction of a curriculum. Consultants can participate in curriculum committees and CDTs but can also advise course coordinators once a new curriculum is established. It is a matter of choice whether the function of content and skills consultants needs to be known to the students ("front office" function) or whether they serve only as advisors to curriculum committee and CDTs ("back office" function). Combining a consultant role (for communication, for example) with a role as teacher or instructor in courses and skills laboratories is desirable.

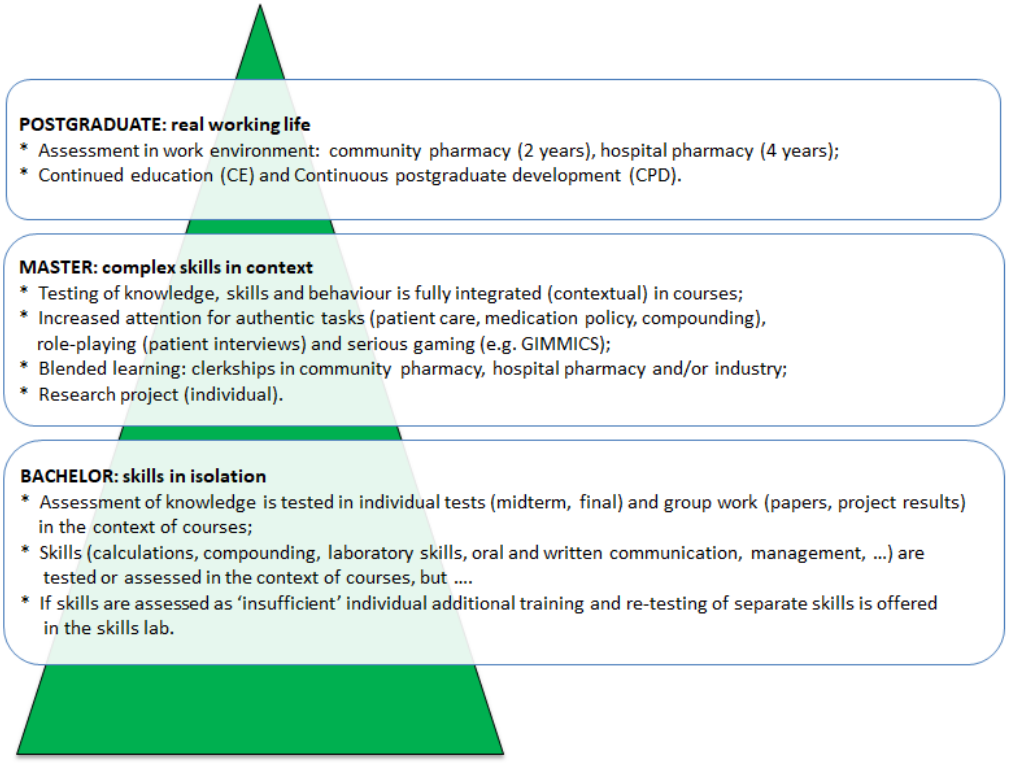
4.5 Feedback and assessment

CBE requires that knowledge and skills are assessed on a regular basis to identify existing gaps and to establish professional growth. It is required that students will frequently receive feedback on their performance in authentic assessment situations.[18, 51, 52] Preferably a wide range of assessment types is used, which are not limited to the lower levels of Miller's pyramid ("knows" and "knows how"[30]). Giving feedback on the higher levels "shows how" and "does" in authentic learning situations becomes increasingly important as the student progresses in the programme(s). Formative assessment (or assessment for learning) is intended to monitor student learning, and to inform teachers and students about progress in the learning process. Formative assessment essentially has a feedback purpose and can help students to identify their strengths and the areas that need additional attention. In contrast, the goal of summative assessment (or assessment of learning) is to evaluate and grade students at the end of a course or at predefined milestones in the curriculum by comparing their behaviour to some standard or benchmark. The overall purpose of summative assessments is to guarantee that each individual student has fulfilled the curricular requirements and that at the end of the curriculum a student can be declared competent.[53, 54]

To maintain student motivation and to prevent student burnout, overburdening the curriculum with multiple assessments should be avoided. It is better to concentrate on a limited number of well-chosen summative assessments and invest more in frequent feedback and formative assessments. Spreading assessment periods over the study year and making assessment an integral part of courses and rotations results in a system of continuous assessment, which improves study behaviour and minimises test anxiety and student burnout.[55, 56] In a full programmatic assessment system the distinction between feedback, formative assessments and summative assessments is blurred because the same assessment tasks can serve a formative and summative purpose at the same time.[52, 57-59]

In addition to conventional assessment through written or oral examinations, authentic assessment tasks have an important role in CBE. Authentic assessment tasks mimic aspects of the future professional life of the students and can greatly contribute to student motivation, but designing such assessments remains a challenging task.[60, 61] As the curriculum progresses, assessment tasks usually increase in complexity to maintain consistency with the gradual evolution of the curriculum in the direction of professional identity (illustrated in Figure 12).

Figure 12: Curriculum layers for assessment principles (skills) in a European curriculum (Utrecht University), where the pharmacy programme is divided into separate bachelor degree and master degree programmes. A pharmacy licence is obtained as a result of obtaining the master degree, and specialisations for hospital and community pharmacy are postgraduate (reproduced from Koster *et al* 2017,[18] with permission).



Recent literature reviews have analysed the validity and reliability of various assessment formats, and the authors conclude that various workplace-based assessment formats (Table 5) have great potential in competency-based education.[52, 62] Short practice observations, directly observed preparation skills, case-based discussions, critical appraisals of topics and multisource feedback, when used in real working situations, are highly authentic and have reasonable validity and reliability.[53] The use of objective structured clinical examinations (OSCE) is relatively well investigated.[63, 64]

Table 5. Examples of authentic feedback and assessment formats.[25]

Assessment tool	Description
Objective structured clinical examination (OSCE)[63, 64]	An OSCE usually comprises a circuit of short stations (usually 5–10 minutes although sometimes up to 15 minutes), in which each student or trainee is examined on a one-to-one basis with one or two examiners and either real or simulated patients.
Case-based discussion[65] Entrustment-based discussion[66]	A written report, followed by a short oral discussion with the student or trainee. Used to assess pharmacotherapy-related cases; in entrustment-based discussions, safety risks are especially important.
Critical appraisal of a topic[67, 68]	A written report, based on a critical analysis of a case, and supported by a review of the relevant literature.
Short practice observation or directly observed preparation skills[69]	Observation of work in practice (e.g., a patient consultation, compounding skills, logistic problem-solving, teaching activity), which is documented with a judgement.
Product evaluation[70]	Evaluation by the student or trainee of patient records and other written materials. The quality of the written report is assessed in a structured way.
Reflective writing[71]	A written self-reflection on a task performed, which is afterwards discussed with an assessor or supervisor.
Multisource feedback[72, 73]	Observations of trainees' competencies by other pharmacists in the working environment, by pharmacy technicians, general practitioners and patients. Data are collected by way of an electronic questionnaire, and include a self-assessment by the trainee.
Script concordance test[74]	A written test, where clinical reasoning skills are assessed by asking students to respond to a case vignette. Student responses are not scored as correct or incorrect but are compared to responses of an expert group.

A relatively recent approach to deal with the complex nature of CBE is to use entrustable professional activities (EPAs) for the operationalisation of educational outcomes at the transition of undergraduate education to professional working life.[58, 75-77] EPAs are carefully described aspects of professional performance in the workplace,[78] which are used to structure learning, training and assessment. In this context, undergraduate education, entry into professional life, further specialisation and postgraduate training become a flexible educational continuum where training and assessment are structured by using EPAs as building blocks. In this model, the required competence level at graduation for each EPA is defined as "level of entrustment" rather than "level of competence".[79]

Because EPAs are linked to daily practice, they are suited for both training and assessment purposes. Within a programme, EPAs can be mapped to the required competences and levels of entrustability.[13, 25, 58, 80, 81] For each EPA, the best type of assessment instrument (Table 5) can be selected based on the content and function of the instrument and the competencies that are measured. For example, a short practice observation can be used to assess patient counselling, and a product evaluation can be used to assess student performance in a medication review. In addition to measuring individual EPAs, multisource feedback can be used to incorporate observations of competencies.

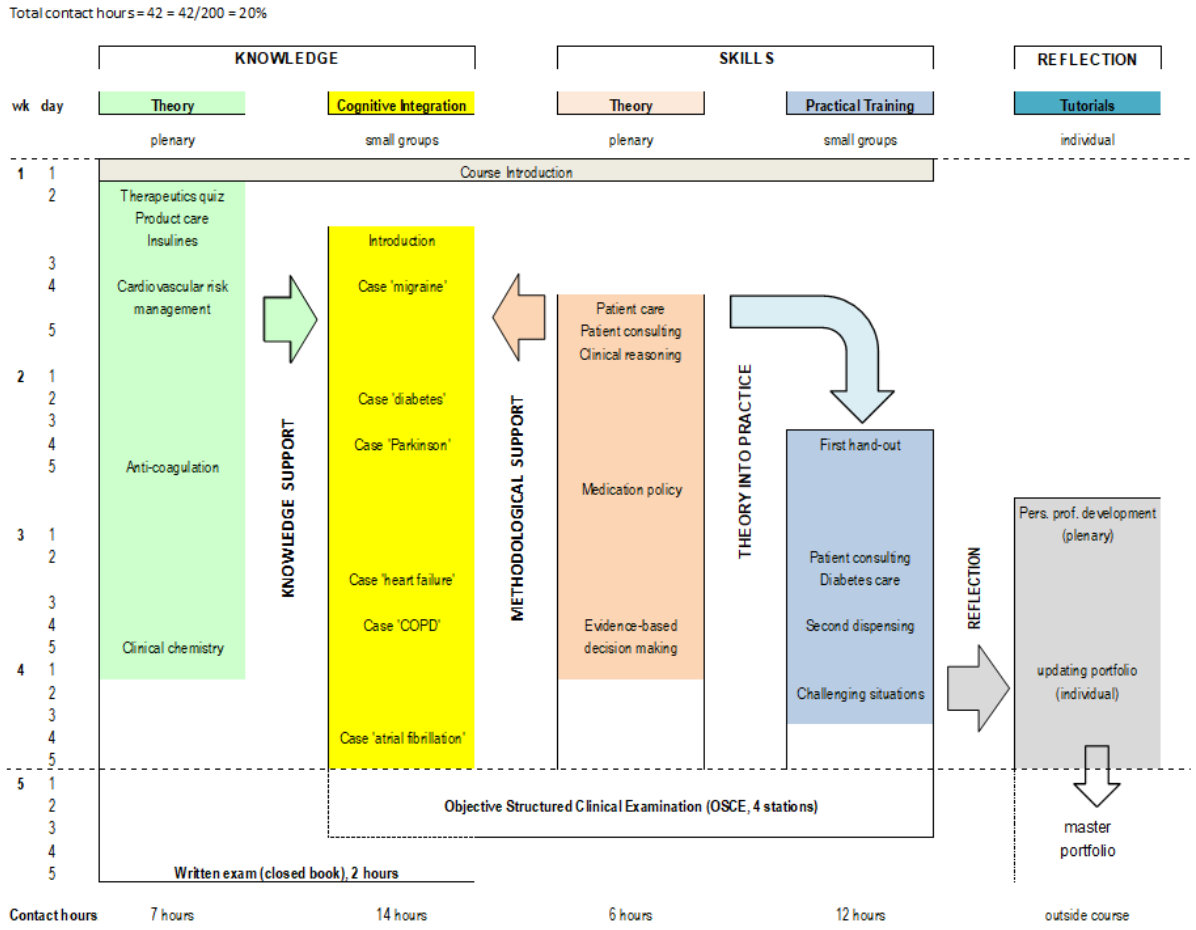
Portfolios (electronic or otherwise) can be used as monitoring instruments to track student progress.[82, 83] The results of assessments and evaluations are recorded in an organised and traceable way. In addition, the portfolio can be used to collect students' individual work, personal development plans and reflection documents.[84-86] The portfolio is primarily maintained by the student or trainee, but supervisors or assessors can be given allowance to add feedback and student evaluations. The portfolio functions as a central repository to record the competence development of the student and can be used to assess whether students have reached or passed predefined milestones in the curriculum.

4.6 Course and module design

Instructions for the design and implementation of a course are usually described by a curriculum committee and are derived from the overall curriculum design (see Section 4.3). As described above, the extent of integration of disciplinary content and skills within each course can be very different, depending on the position of the course within the curriculum structure. The main task of each course development team will be to translate the course design specifications into an optimal set of teaching/learning activities and related assessment formats. The selection of educational and assessment formats will largely depend on considerations of learning effectivity but can be restrained when a particular teaching or learning approach (e.g., problem-, project-, team-, case- or inquiry-based learning) is "prescribed" by institutional policy considerations. A CDT needs to find an optimal solution within the boundaries set by the overall educational guidelines, longitudinal curriculum themes (see Section 4.4) and assessment principles (see Section 4.5). Constructive alignment of all aspects of the teaching/learning environment can be considered as an important design principle.[32]

Integration of disciplinary content and skills is usually considered an important, but complicated aspect.[87-90] If courses are designed as "integrated", "thematic" or "methodological" , course development begins with a clear course goal (usually defined by the curriculum committee) and the selection of optimal teaching/ learning and assessment formats which are considered effective in reaching the set goal and intended learning outcomes. Within the available time frame of a course, sequencing of teaching/learning activities and timing of contact hours need to be carefully designed, and can be optimised based on iterative course evaluations (see Chapter 5). In the Appendix the "translation" of a course instruction document into a course outline is illustrated in detail. A schematic representation of a course can be helpful in clarifying the functional relationships between different course elements, teaching/learning activities and assessments (illustrated in Figure 13)

Figure 13. Schematic representation of course Ma101 “Chronic diseases”.



This thematic course is the first course of the master programme (MSc in Pharmacy, following a three-year BSc in Pharmacy programme) of Utrecht University. The course is a full-time course (five weeks, 40 h/week study load) with 20% contact time, distributed over plenary lectures (theory), case-based small group sessions, and practical training in patient communication, assessed by a written examination and a four-station OSCE. During this course, a start is made with setting up a personal professional development portfolio.

Many educational formats in small or large group format, can be used in construction of integrated courses, but a description of all possibilities is beyond the scope of this chapter. Selected inspirational examples, describing course design and evaluation in some detail, are mentioned in Table 6. Other course designs can be found in the educational literature, mainly in *Pharmacy Education*, the *American Journal of Pharmaceutical Education* and *Currents in Pharmacy Teaching and Learning*.

Table 6. Selected examples of integrated, thematic courses.

Title and description)	**Country**
Drug discovery and preclinical drug development. An inquiry-based course for pharmacy and biomedical students (BPharm, year 3, study load 200 h, 7.5 ECTS)	The Netherlands[91]
Clinical reasoning. Intended to increase the ability to think about and solve clinical problems (PharmD, year 3, study load 90 h, 2 USA-credits)	USA[92]
Mental illness and treatment in the movies. Intended to analyse portrayal of, fundamental aspects of, and attitudes to mental illnesses (PharmD, year 2/3, study load 90 h, 2 USA-credits)	USA[93]
Topics in rural health practice. A course used as a starting point for a longitudinal programme (PharmD, year 3/4)	USA[94]
Pharmaceutical care in indigenous health. Intended to fill a gap and to provide culturally safe pharmaceutical care. PharmD, year 3/4, 135 h, 3 USA-credits)	Canada[95]
Pain. An elective course for pharmacy students, open to students from other programmes (BPharm, year 3, study load 200 h, 7.5 ECTS)	the Netherlands[96]
Capstone course. Used as preparatory to participate in advanced pharmacy practice experiences (PharmD, year 3, study load 135 h, 3 USA credits)	USA[97]
Leadership, entrepreneurship and administration in pharmacy. Intended to teach concepts related to management, leadership and entrepreneurship (PharmD, year 3, 270 h, 6 USA credits)	USA[98]
Contemporary social pharmacy. Intended to enhance understanding of social pharmacy and to improve teamwork.	Denmark[99]
Research evaluation presentation skills IV. Intended to enhance scientific writing skills.	Qatar[100]

Apart from individual courses, longitudinal projects (extending over one or more years) and a specific sequence of connected courses (sometimes indicated as “concentrations”) can be used in the design of a curriculum. Examples can be found in the literature.[101-105]

4.7 Curriculum delivery

Once courses and other curricular elements are designed, the logistical consequences (in terms of contact hours, student workload, faculty/staff workload, facilities and materials budget) can be overseen. Depending on the local situation, administrative systems with various levels of detail may be available, and some constraints or boundaries may have been set already at the curriculum development stage (see Section 4.3). Within the institutional structure (university, school) individual courses will be assigned credit hours to monitor student progress and to establish exam requirements. In the European Credit Transfer System (ECTS) one credit is defined as 28 hours of study load, which includes contact hours and expected self-study and homework time. The USA-credit is defined as one hour of classroom instruction plus two hours of expected preparation and studying time, typically spread over a 15-week semester; this sums to 45 hours of total study load per USA-credit.[106] Total programme duration can vary country-by-country, e.g., five years minimum in Europe (300 ECTS, consisting of a three-year BPharm and a two-year MPharm programme), four-year MPharm in UK, four years in USA (*circa* 200 USA credits, PharmD programme, after obtaining a prior bachelor’s degree) or undivided five-year BPharm programmes in other countries.

Student workload will depend on the number of contact hours (when students are supposed to be in direct contact with teachers, supervisors, trainers or other students, and examinations) and the time needed for preparing class and laboratory meetings, home assignments, independent groupwork, self-study and examinations. When designing

courses, it is important to make an estimate of all these elements and to organise a course in such a way that study load is equally spread over the course period. The percentage of contact hours (expressed as a percentage of total course study load) should, in general, not be below 20% or above 70% to maintain student motivation and "course flow" (jeopardised by too-low percentages) and to not compromise self-study time (at higher percentages); relatively high percentages are warranted only for courses where practical training (e.g., compounding, communication) is an essential element of the course goals. A careful design of tasks and assignments, combined with regular course evaluations (see Chapter 5), can help in optimising the scheduling of contact hours within the overall course structure. It should be noted that inter-individual variation between students in real and perceived study load is extensive, which further illustrates the need for regular course evaluations. Including education specialists in CDTs and small action research projects can be helpful.

Teacher workload will depend on the number of contact hours and the time needed to prepare for student contacts (lectures, group and laboratory sessions, individual guidance and tutoring) and all other tasks related to curriculum delivery (for a detailed discussion, see McLaughlin *et al*[107] and Ujir *et al*[108]). Ideally, the institution should have an administrative system (spreadsheet or otherwise) for recording the teaching workload of individual teachers and other staff (e.g., technicians) involved. How real and perceived teaching load is experienced by individual teachers will be influenced by interest, teaching experience and other competing tasks within the organisation. An administrative system for explicit allocation of teaching tasks and some flexibility in applying it can help in maintaining transparency and prevent potential debates about teaching task expectations.

Programme workload can be calculated from the sum of teaching workload of all curricular elements (primary teaching load). In addition, estimates and task allocations must be made for other tasks and roles within the curriculum, such as track coordinators, laboratory managers, content and skills consultants, a programme coordinator or programme director, and participation in curriculum advisory committees (secondary teaching load). Such tasks are assigned best on a temporary basis to individuals who are suitable and willing to do the task-at-hand; combination with primary roles as a teacher is preferred. If the institution has an interest in quality enhancement by regular evaluations and curriculum updates, action research projects, applied educational research and teacher professionalisation (see Chapter 5), additional tasks can be assigned to interested individuals (tertiary teaching load).

The total teaching workload of a pharmacy programme will, of course, depend on the number of students, the educational and assessment formats and the standards used in assigning teaching load to the major elements of the curriculum (see previous paragraphs). Finding a transparent, simple, way of calculating teaching load that can be easily communicated to teachers and other stakeholders is preferably done by the curriculum committee or the programme director, or both. An institution will have some administrative system in place, but introduction of CBE can make adaptations or further refinements necessary. An example of calculating the teaching load of a course is given in the Box below.

Box. Calculation of course workload.

The teaching load of the pharmacy programme (Utrecht University) is calculated using the following standards:

- Group sizes (number of students during contact hours) are 100 (plenary lectures), 60 (computer-assisted sessions), 30 (workshops, laboratory sessions), 15 (small-group sessions, *e.g.* PBL, selected laboratory sessions) or 8 (selected training sessions, e.g., patient communication).
- Teaching load is estimated to be 3h (for plenary lectures) or 1.5h (for computer-assisted sessions, workshops, laboratory sessions, small-group sessions, and selected training sessions) per contact

hour per group of students. In addition, 1h of teaching load per student is assigned for all tests and examinations in a course, irrespective of the specific testing format(s) used.

Example of a calculation: The teaching load of a typical course with 180 participating students (64 contact hours, 200h study load, 32% contact time), with 14h of plenary lectures (2 groups), 25h of workshops and other group meetings (assignments, calculations, discussions; 6 groups), 16h of laboratory experiments (6 groups), and 8h of examinations (mid-course, end-of-course, and final group presentations) can be estimated as 2 x 14 x 3 (lectures) + 6 x 25 x 1.5 (workshops) + 6 x 16 x 1.5 (laboratory experiments) + 180 = 84 + 225 + 144 + 180 = 633h. This equals 633/1,600 = 0.40 full time equivalent of teaching or 633/180 = 3.52h per participating student. A full time equivalent of teaching equals 1,600h (40 weeks of 40h) per year.

The example is taken from the curriculum of Utrecht University and involves a 200h study load course for 180 students (see also the Appendix).

Facilities (lecture halls, group spaces, library, computer facilities, online resources) for a CBE programme can be different from those required for traditional forms of education. This mainly relates to the availability of spaces for small group sessions and flexible laboratory designs. Also in this case, course development teams and programme management usually need to compromise between that which is educationally desirable and that which is possible in the local circumstances. Nevertheless, full implementation of a CBE curriculum requires attention to providing optimal facilities in the long run. Regular course and curriculum updates (see Chapter 5) can be instrumental in providing the necessary information.

4.8 Setting priorities

What can you do if you want to implement aspects of CBE or develop a completely new curriculum, but have limited resources to do so? The description of the implementation process, given above, assumes that all stages of curriculum development — starting from a competency framework through a curriculum design and development of individual courses and other curriculum elements — will be followed sequentially. The following suggestions describe an effective approach.

Preferably an institutional decision to embark in principle on a CBE curriculum and a first selection of a suitable competency framework have been made. It is not necessary to have a fully developed and detailed framework initially, because first steps can be taken on the basis of CBE design principles. Ideally, existing frameworks will be guiding in curriculum development, but it is also possible that curriculum development and framework adaptations (inspired by a needs-based analysis) follow a similar timeframe. In all cases It is a good idea to continuously inform as many stakeholders as possible (within and outside the institution) about the progress of changes made and foreseen in the programme.

A general strategy could be giving priority to easing the transition of students from university to practice settings (workplace learning, authentic assessments) and working backward to earlier parts of the curriculum when time, funding and experience of organisation develops. This means that initial attention must be given to the transition from formal academic learning to practical experiential learning.[25, 45] This “boundary crossing” process is complex[109, 110] and can be eased by introducing elements of pharmacy practice into the undergraduate curriculum and by supporting and guiding pharmacy practitioners in their early career to ease the transition.[44] Introducing (introductory and advanced) pharmacy practice experiences and introduction of authentic feedback assessment formats (see Section 4.5, Table 5) must have priority. It should be noted that training and supporting teachers, instructors and preceptors in their new roles is usually required (see Chapter 6).

When the availability of human and financial resources improves, elements of CBE can be introduced into earlier parts of the curriculum. Modification of existing courses by introducing elements of CBE without disrupting the overall

curriculum structure is possible. Applying the principles of social constructivist learning (see Section 4.3, Table 3) to new or updated courses can be used as guidance. Development of skills (in particular the soft skills such as communication or development of professionalism) needs timeframes longer than a typical course and these elements are preferably organised as longitudinal lines in the curriculum. Such a process of gradual evolutionary change requires a long-term vision and continuity of curriculum management, where a programme director or coordinator, skills consultants and educational consultants can have important roles. Changes in early parts of the curriculum necessarily will have consequences for later parts, which illustrates the need for regular course and curriculum adaptations guided by regular evaluations of the course as part of a quality enhancement system (see Chapter 5).

The next step to complete implementation of a CBE curriculum could be reconsidering integration of disciplinary content and skills development in individual courses. Placing existing individual courses under overarching "lines", "track" or "themes" — without changing the actual course content and organisation itself — can be considered a relatively weak form of integration, while redesigning and developing individual courses by backward engineering can lead to higher levels of integration.[28, 90, 111]

Reconsidering course sequencing, setting milestones, defining curriculum layers (see Section 4.3) and adapting student progress administration systems accordingly can increase the freedom for students to travel through the curriculum via different routes or at different speeds, and can be considered the final stage in the development of an ideal CBE curriculum.[112-114] Introducing EPAs and a programmatic assessment system (see Section 4.5) can also be seen as a final development stage.

CBE can be introduced through an evolutionary or a revolutionary process. The final result can be the same, but the timeframe and the necessary resources can be very different. A radical change can only be successful when a specific — sometimes unique — combination of urgency, institutional commitment and leadership, stakeholder involvement, and available time and funding is present.[5, 6, 115, 116] In all other cases an evolutionary road to competency-based education will only be possible by the long-term commitment of dedicated pharmacy teachers, which have found their *ikigai* (Figure 14).

Figure 14. An illustration of the Japanese concept of *ikigai*.[117]

Ikigai is a Japanese concept that means your "reason for being". *Iki* in Japanese means "life" and *gai* describes value or worth. Your *ikigai* is your life purpose or your bliss. It is what brings you joy and inspires you to get out of bed every day.[118]

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Chapter 5 Evaluation of CBE implementation

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5.1 Introduction

Multiple stakeholders recognise the significance of the quality of pharmacy and pharmaceutical sciences education, including governments, policymakers, regulators, professional organisations, academia, practitioners, students and their families, funders of education, accreditation agencies, quality assurance organisations, and the public served by these professionals. FIP, the WHO and UNESCO also appreciate the need to build capacity and expertise in quality assurance (QA) systems of pharmacy and pharmaceutical sciences education. The QA systems must ensure that educational programmes are competency-based, meet the needs of countries and their societies, and include self-assessment as well as internal and external processes and mechanisms.

Accordingly, FIP has been developing initiatives, tools, publications and resources on QA of pharmacy and pharmaceutical sciences education. In 2008, FIP developed the Global Framework for Quality Assurance of Pharmacy Education (QA framework)[1] as a tool to facilitate the establishment of QA systems in countries where no such formal systems exist and to improve existing systems. In 2014, the QA framework was updated to version 2, which includes pillars and foundations of quality of education (namely, context, structure, process, outcomes, impact, science, practice and ethics) as well as indicators and self-assessment questions.[2]

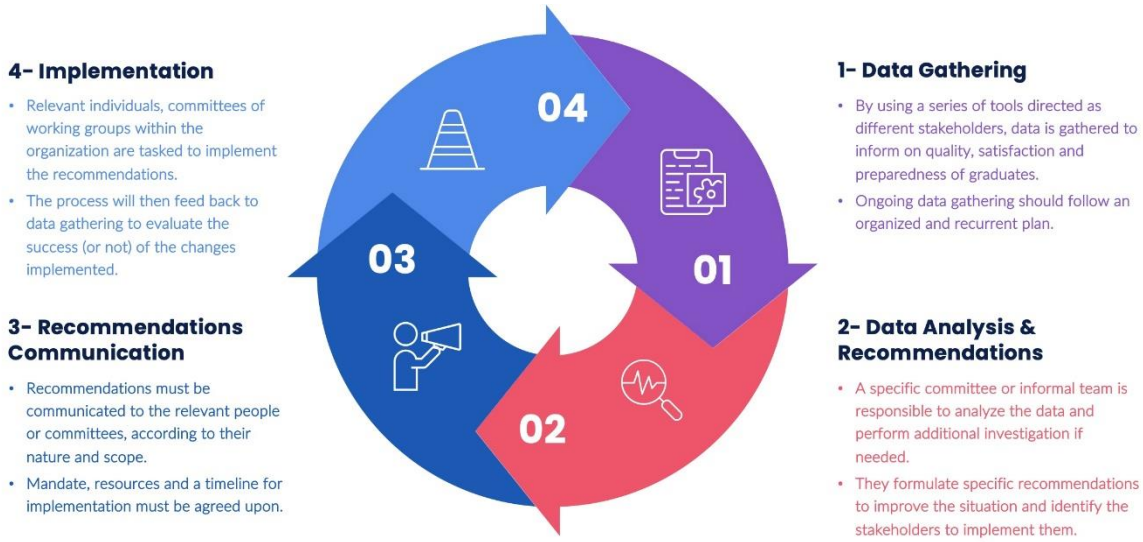
FIP developed a policy statement on quality assurance of pharmacy and pharmaceutical sciences education in 2009[3] and updated it in 2022. The policy statement on QA aims to outline the guiding principles for QA of pharmacy and pharmaceutical sciences education and to act as a foundation for QA in education, supported by FIP's existing and forthcoming tools, frameworks and publications on QA. This policy is in line with FIP Development Goal 3 (Quality assurance), which recommends that countries should have transparent, contemporary and innovative processes for the QA of needs-based education and training systems[4].In 2020, the global leads of the FIP Development Goal 3 published the FIP pharmacy education in sub-Saharan Africa report,[5] which investigated the QA and accreditation systems across seven sub-Saharan African countries, namely, Ghana, Kenya, Malawi, Namibia, Nigeria, Uganda and Zambia. The report highlighted that one of the major QA challenges is the absence of internal or external QA systems in some countries. The report suggested that complying with international or regional QA standards can potentially result in implementing suitable practices for the national context. Subsequently, they developed a QA self-assessment tool for pharmacy and pharmaceutical sciences education, which can be used to understand the status of QA of education programmes around the world, to improve existing standards of the education and training systems, and to offer recommendations at a global level to continuously improve the QA of pharmacy and pharmaceutical sciences education. By using FIP's QA policy statement, frameworks, goals and self-assessment tool, pharmacy and pharmaceutical sciences education can be continuously improved. This also applies to CBE, which is the preferred means of achieving needs-based education.[2]

5.2 Continuous quality improvement

The extent of quality improvement (QI) in education may vary among pharmacy programmes but there is no denying its importance and impact on the pharmacy profession. Pharmacists and other healthcare professionals can expect increasing levels of accountability for performance on healthcare quality metrics in today's healthcare environment.[6] In fact, the development of the FIP Education initiative (FIP*Ed*), and more specifically the International Forum for Quality Assurance of Pharmacy Education, has assisted in education development and quality improvement.[7]

Encouraging continuous quality improvement (CQI) begins with demonstrating its significance and relevance within a pharmacy student's education and career. It is about making frequent corrections along the way as you learn from experience by gathering information from different stakeholders. We propose four steps to develop a CQI strategy (Figure 15).

Figure 15. Representation of the CQI process as a framework to build quality assurance as part of an institution's activities.



5.2.1 Data gathering

Prior to collecting data for CQI of pharmacy education, there are key questions that pharmacy administrators must address:[8-10]

1. What is the purpose of the CQI data gathering step? What are the programme's desired educational outcomes?
2. What are the specific questions you want to answer through this process? How will you know if you are meeting the educational outcomes?
3. How will you design the process? What specific data will you collect? How often you will collect data and what strategy will you be using to make changes?

To foster a culture of CQI, there are essential stakeholders, both internal and external, that must be engaged in the data collection process. The internal stakeholders must include, but are not limited to, academic staff, other staff and students. Examples of external stakeholders include preceptors, residency directors, employers, licensure bodies and accreditation agencies.

Different methods can be used to gather insight into the curriculum. The tools will be tailored to the information needed and the stakeholders providing it. Surveys, interviews, focus groups, student assessment of a course and academic staff feedback can all be used to support CQI. To be effective, data collection should be organised in a system to gather the information regularly and inform on changes and adaptations to make. As an example, each academic staff member could be invited to meet with the QA unit to debrief on how their course went after they just completed it.

Also, an evaluation from the students' perspectives should be conducted during CQI data gathering. Each pharmacy programme has unique processes for admission, progression, retention, pass rates and satisfaction. Therefore, it will be beneficial to benchmark these processes with peer institutions. For instance, collecting data from current students on the quality of faculty, courses, support services and policies will be helpful to ensure their success in the pharmacy programmes and to inform on needed improvements. Gathering data from alumni's perspective of their preparedness will be beneficial for current and future students, to improve their work readiness.

Finally, an assessment of curriculum outcomes should be included in CQI data gathering.[11] Each programme must develop a list of goals and desired educational outcomes. Data collection should include an assessment of students' knowledge, skills, attitudes and competence during the programme. In addition, an evaluation of all learning experiences prior to graduation should be conducted, including feedback from the preceptors who supervise students in practice. In CBE, special attention should be paid to making sure that students are competent in the different dimensions of the competency framework in use. This can be achieved by collecting competency assessment during different learning activities (like EPAs) and using a portfolio to record and analyse students' competency development and mastering. This can be done by a competency review committee that can inform on issues arising for students and proposing remediation activities (short term) and course and curriculum adaptation to improve the issues.

Ideally, a written document that highlights the following sections will be shared with all stakeholders to ensure the success of the data gathering phase of the CQI process:

- The rationale for conducting the data collection should be shared with internal and external stakeholders to ensure engagement in the process. This background section should include the mission, vision and core values of the programme.
- The second section should include a description of the data gathering process, describing the data collection methods, which may include focus groups, online surveys and telephone calls. Using various methods to collect data may increase the reliability and validity of the information.
- The last section should include logistics of the data collection phase. Specifically, the timeline and frequency of the process should be clearly included. In addition, the roles and responsibilities of the data gathering team should be identified. Finally, a description of the data collection, analysis and communication of the results should be included to ensure a successful CQI process.

5.2.2 Data analysis and recommendations

Data analysis is a process of discovering interesting patterns and knowledge from large amounts of data. However, in CQI, data can also come from less formal or quantitative datasets and from qualitative interviews, focus groups and other methods.[12]

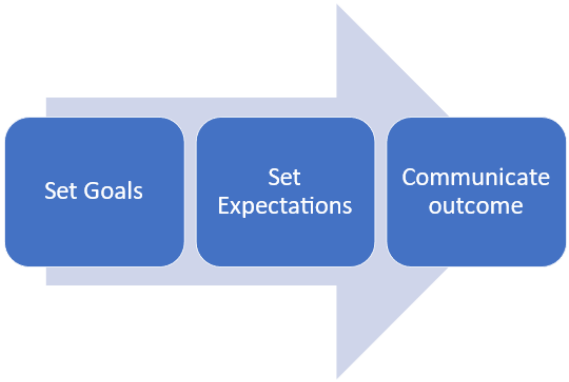
Data analysis is important in CQI because it allows one to take informed decisions on changes in specific courses or throughout the curriculum. For example, data analysis in pharmacy education leads to a better understanding of student, course, instructor and facility data, which can then be communicated to the school administration and the different layers of the educational organisation.

Data analysis can help identify strengths and weaknesses in an educational system or programme. Therefore, it can support optimisation of performance and providing resolutions to some issues. In pharmacy education, data analysis usually covers major areas of the profession related to education, practice and regulations. Leveraging data analysis to achieve these benefits begins with a solid plan of action by creating sets of goals and expectations (see Section 5.2.1).[9]

Because the volume of data has significantly increased with the digital revolution, the need for a robust data analytics programme is an absolute must if one wants to use the information in a strategic way. Using dedicated software, this will include dimensions, categories, relationships and ways to summarise the data.[13] There are many benefits of using data analytics tools, such as finding data faster, capturing results in an organised fashion, and creating a data-driven, decision-making culture.[14]

Usually, a committee or team is responsible for analysing the data and performing additional investigation and follow up if needed. Examples of these local committees or teams are a quality assurance committees or units, curriculum committees or assessment committees. In the context of CBE, data on the progression of competency development needs to be studied as well, to ensure that students are progressing according to plan. Results of performance of EPAs during rotations, for example, could be a good marker of student preparedness, as assessed by preceptors. Figure 16 illustrates the steps to take before implementing any data analysis.

Figure 16. Steps to set before implementing any data analytics QI solution



Data can also be used by national or international accreditation agency teams, government institutes of higher education, associations of colleges of pharmacy, formal or informal groups analysing data for benchmarking and educational research. Indeed, a structured CQI process can feed the research agenda of several academic staff for the purpose of scholarship of teaching and learning.[15] They formulate specific recommendations, based on data analysis, to improve the situation and identify the stakeholders to implement them. Data analysis can detect historical patterns and trends from collected data and can create models that predict future trends and patterns. When used strategically, data analysis in education has the power to transform education and empower quality improvement.

5.2.3 Recommendations communicated to

Curriculum and education developments that are aimed at improving pharmacy education can face daunting challenges, reflecting the need to align changes in delivery methods and assessment practices across multiple levels and areas of the educational organisation. However, the process of planning, testing, analysing and eventually spreading those changes does not have to be overwhelming.

Recommendations constructed from data collection and analysis should be communicated to the relevant people or committees, according to their nature and scope so that they can be implemented. It can include students themselves, educators (individual or teams), department chairs, the school's curriculum committee, or any other official institutional committee if changes to the curriculum need formal approval (like changing credit numbers of changing the sequence of courses).[2] Mandate, resources, and a timeline for implementation should be agreed upon from the beginning. Each recommendation should be documented and become part of a follow up system that will allow its proper implementation.

Information gathered should include:

- A summary of the data that triggered a recommendation;
- The recommendation to be implemented;
- The person, team or committee responsible for the recommendation;
- The timeline for implementation; and
- Success of the actual implementation (actions taken in the implementation step).

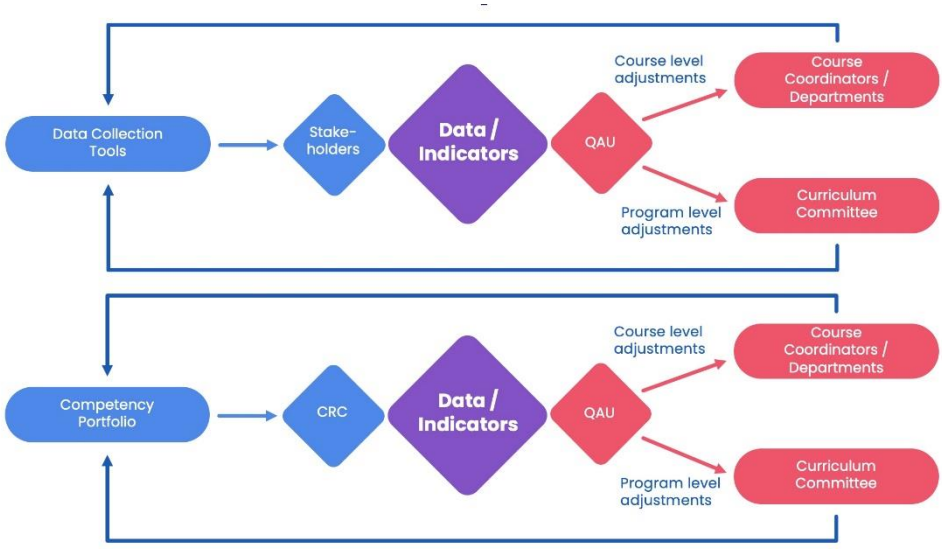
Documentation is also important to report to other stakeholders the actions that were done as problems or issues were identified, and to demonstrate that CQI is part of the institution's culture. Stakeholders to communicate with can include individual educators, students and prospective students, other schools of pharmacy, providers of continuing education, the public, patients (consumers of pharmacist services), state and federal governments (i.e., ministries of education), professional and scientific associations, accreditation agencies, employers of pharmacists, regulatory bodies and other healthcare professionals. [2]

5.2.4 Implementation of recommendations

A committee or team can be tasked to follow up with the implementation of the recommendations by the appropriate stakeholders. This is the only way to guarantee that the CQI loop will be completed (Figures 15 and 17). Expected adaptations and changes can be at a course level, or all the way to a major change in the curriculum. The amount of people involved in the implementation will thus vary. Some issues can be fixed quickly and others can take months. It is therefore important to have a follow-up mechanism.

In the future, when data are gathered again according to the CQI timeline, it will be possible to revert to the previous documented recommendations and actions and determine if they were successful, or not, in improving situations that were flagged initially, leading to continuous quality improvement.

Figure 17. Example of a decision-making process applying the CQI framework. Competency assessment (in the form or a portfolio) is illustrated as one example of data collected to inform decisions on course or curriculum changes.



Key: QAU, quality assurance unit; CRC, competency review committee.

5.3 Periodical comprehensive evaluation

In addition to CQI activities discussed in Section 5.2, each institution is in a unique quality assurance environment that will usually require a periodical comprehensive evaluation of its compliance with a set of standards or criteria. As mentioned in the introduction of this chapter, FIP has developed a survey to assess the local landscape, which is in the data collection phase at the time of the handbook publication. The standards framework used in a periodic curriculum evaluation can come from the school itself, from the university for all its schools, from the ministry of education of the country or often from government or independent national, international accreditation organisations or professional accreditation organisations.

In such instances where external accreditation is required for graduates to practise, there is a lot of pressure for schools to perform well in terms of compliance with a set of standards. A lot of attention and resources will be devoted to the self-assessment study, the site visit and the rest of the process. As such, the external accreditation process can become an exceptional leverage to improve the financial situation of a school of pharmacy. It can also be used to get exceptions from strict institutional rules and regulations that hamper the capacity to move forward with international trends, like CBE. Accreditation can also become an incentive for the school to be treated more equally with others, like medical schools, which often benefit from several exceptions and special treatment to fulfil their mission while respecting external standards.

Because CBE is not widespread yet, accreditors do not require that a CBE approach be used, and they are not setting their expectations around that educational format for programmes.[16] However, accreditors are pressured to foster innovation and accountability in education, and this provides a form of pressure to consider CBE as acceptable in terms of innovation efforts to produce a more competent workforce.[15] In this paradigm shift, accreditors need to focus on outcomes rather than inputs (class size, staff size, student-faculty ratio).[17]

In any scenario of a quality assurance environment, including where there is no formal external oversight, performing a periodic curriculum evaluation every five to eight years is a very important process to review and improve the quality of education and student services. Such a reflection can form the basis of a strategic action plan that will address deficiencies related to the curriculum, the governance or the resources available. For schools that are not submitted to any external review process, FIP has developed tools that can be used to determine their relative compliance with international expectations (see Section 5.1). For instance, the publication of the Nanjing statements, aimed at providing directives of what pharmacy education should comprise, can become a benchmark for schools to assess their position with regard to these expectations (Table 7).

Table 7. Assessment of the compliance to the 67 Nanjing statements during the transition from a 4-year BPharm to a 6-year PharmD at the College of Pharmacy of Kuwait University in 2018.

	Statements met	Statements partially met	Statements not met	Score* (%)
BPharm	28	14	25	35/67 (52)
PharmD	59	2	6	60/67 (90)

* Score out of 67: statement met = 1 point, partially met = 0.5 point, not met = 0.

FIP has also developed a revised quality assurance framework to specifically address competency-based education at its foundation.[2] The framework considers five pillars: context (external and internal to the college); structure (how the college is configured to pursue its mission); processes (activities, policies, procedures for efficient and sustainable operations); outcomes (immediate measurable results, including student competency); and impact (long-term effects on practice and society). For each pillar, a series of quality indicators is outlined to guide the self-assessment. It represents a comprehensive framework to use autonomously if there is no other external or imposed quality assurance framework.

Irrespectively of the framework or standards used, a comprehensive evaluation should include a self-assessment report and a peer-review component. Tips and tricks for each of these parts are presented below, with an emphasis on competency-based education.

5.3.1 Self-assessment

Ideally, the school already should have a structure in place, a quality assurance committee or similar, that deals with CQI (see Section 5.2) and which can be mobilised for a periodic comprehensive evaluation, such as an accreditation cycle. Furthermore, the school can create a steering committee to oversee the process. Depending on the number of dimensions to be studied, subcommittees may be formed with individuals working in those spheres. For example, there could be subcommittees working on standards related to the curriculum, governance or resources. External committee members can also be recruited to provide a complementary perspective on these subcommittees. These can include preceptors, members of higher administration, employees of the ministry of health, etc. Existing committees, such as a curriculum committee, could also provide evidence related to the curriculum, competency-based education, assessment methods and so on.

Above all, the self-assessment must be honest and transparent. This will prevent external visitors from discovering limitations that you omitted to mention. This can raise suspicion and will have a negative impact on the whole process and its outcomes. Towards that goal of transparency, the self-study report needs to outline the evidence that supports compliance with a standard, but also report any gaps or future improvements that appear to be needed. Being forthcoming will demonstrate a level of maturity and self-awareness that the reviewers will appreciate and value (Figure 18).

Figure 18. Four steps to produce a good and useful self-study report that is informative, concise and transparent.

If the accreditation body uses competence outcomes as standards (like the Canadian Council for Accreditation of Pharmacy Programs and the Accreditation Council for Pharmacy Education), it will be easy to demonstrate compliance if using a CBE model that relies on the framework used by the accreditation body. Indeed, by creating a map of the competence practice and assessment activities throughout the curriculum, compliance should be straightforward. Regrouping competency elements from the total competency framework into EPAs, simplifies the matter even more, as competence practice and assessment are integrated into meaningful professional activities that can be practised in the college and during external rotations.[18]

In contrast, in knowledge-based curricula, the link between knowledge and competence is more difficult to demonstrate. A map of the learning objectives for each course and how they relate to the competency elements of the competency framework could be created. This is a less straightforward task and often requires a leap of faith that "knowing" equals "knowing how to use the knowledge" to solve professional problems.

What can be challenging for a competency-based curriculum that includes a large proportion of integrated courses (less course structure according to disciplines), is to define the amount of each discipline included in the courses. This may be an issue if one is dealing with accreditation standards that "prescribe" a certain number of credit hours for specific pharmacy-related disciplines.

Another tip for the self-study report is to schedule a wider consultation once it is in its first draft. This will allow all stakeholders to be aware of the strengths and weaknesses identified and to comment on those. This will also help during the site visit if those stakeholders are to be met by the reviewers. A comprehensivelist of stakeholders can be seen in the FIP quality assurance framework[2] (see Figure 18).

5.3.2 Site visit

Site visitors are usually on a tight schedule and have a lot of work to do in a short amount of time. It is important to make sure that they have a comfortable meeting room that becomes their working base and that the groups they wish to meet are on time. If visits include training sites, ascertain that transportation to and from these is optimal. All people involved in the visit, internal and external to the college, should be briefed on their role and be expected to be transparent with the reviewers. Note some "visits" may now be conducted solely online, and planning, chairing and managing these meetings well is an important consideration. For example, ensuring that the internet connection is strong and stable will ease the process.

Because the accreditation process is a learning and growing activity, the visitors should be considered as consultants or collaborators.[2] It is important to get as much guidance as you can for standards that seem to be unmet or partially met. For a CBE programme, ensure that your model is thoroughly explained. CBE is still relatively new, and colleges may use very different ways of practising and assessing competence. It may be useful to use images or diagrams to demonstrate how competence acquisition is built into the curriculum. If you have measures of the outcomes (employer satisfaction surveys, qualifying examination before entering practice or others), make sure that they are available for discussion.

In conclusion, periodic curriculum evaluation of the school, with a special focus on its pharmacy curriculum, is an important endeavour to ascertain the quality of the graduates. It represents a unique opportunity for reflection, planning and growth. Having external reviewers will bring additional ideas and suggestions to further improve the school in all its dimensions. When this quality assurance activity is linked to CBE, it will strengthen the profession by preparing pharmacists to be ready to offer a wider range of services to the community.

5.4 Conclusion

A curriculum developed with competency development in mind does not escape from the necessity of both CQI and periodical comprehensive evaluation. As expressed in FIP's QA framework: "Quality assurance must be a primary focus of educational institutions and all key stakeholders."[2] By constantly monitoring the level of performance of competencies within the curriculum and its experiential learning components, the school will be informed about the capacity of the programme to achieve the goals of graduating work-ready pharmacists. Therefore, by starting with the end in mind, CBE simplifies the quality assurance process of the curriculum, if there are structures in place to gather data, analyse them, propose recommendations and implement them (Figure 16). This will ensure that accreditation visits or other instances of periodical assessment will find a healthy curriculum that addresses local needs and produces graduates who will provide all expected professional activities to contribute to a competent pharmacy workforce.

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Chapter 6 Academic capacity and faculty development

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6.1 The need for faculty and preceptor development

Health professional education, including pharmacy education, has been evolving to meet the changing needs of society and its learners.[1-3] This has become more apparent with the SARS-CoV-2 pandemic, where academic, social, technologic, economic and political drivers of educational change have allowed us to reconsider pharmacy education.[2] In particular, changes in education delivery, pharmacists' roles and learner needs have highlighted the need for pharmacy education to transition to CBE, focusing on mastery of key skills and competencies. The success of this transition is dependent on faculty members and experiential colleagues (preceptors).[1-3] Providing our colleagues with the rationale for change[2, 4, 5] and training on fundamental aspects of CBE are key to respecting and alleviating any hesitancy to adopt this new approach.[6]

6.2 Training topics

Before CBE training is embarked upon, programmes should first assure understanding of foundational education principles. FIP's Global Competency Framework for Educators and Trainers (FIP-GCFE) provides an excellent template for this training, as will professional development or education departments, if available.[7] From there, setting the stage with a common language of CBE-related terms will provide an important foundation for CBE training. For example, clearly defining "CBE", its relationship to other education terms, such as "outcomes", "milestones" or others will help learners to understand CBE. The American Association of Colleges of Pharmacy has recently defined CBE in a comprehensive white paper on this topic.[8]

CBE principles, such as learner-centredness, less time- and classroom-centred learning, flexibility to meet needs of the learner, society and profession, and a focus on skills over content, are very different from traditional education approaches. Therefore, coverage of their importance, especially that of skills and competence, is essential to any faculty or preceptor development programme on CBE.[1, 3-6, 9] Bajis *et al*'s reconsideration of traditional education models (Figure 5 in Chapter 2)[10] depicts the CBE model well, showing its components and their relation to early and later educational stages, including in the context of life-long learning.[11]

To address early-curriculum skills and competency development (i.e., the "shows how" level of educational models), exploring new methods of skills development activities, such as role plays, OSCEs and others, will be valuable to educators accustomed to educating through sharing knowledge.[6, 11] As the learner progresses, reminding educators of the importance of the individual learner and introducing the role of criterion-based milestones in skills or competency-based assessment will further explain CBE principles and learner progression.[1, 4]

Just as the learner will progress to the higher performance level (i.e., the "does" level of educational models),[11] so too should the training of faculty members and preceptors. Therefore, faculty development programmes should include

education and training on workplace-based assessments (WBAs). The Australian Pharmacy Council has defined a WBA as involving "regular observation, feedback and measurement of an individual's ability to conduct day to day tasks and duties".[12] An effective WBA requires users to be competent at the observed task, and familiar with the tools being used, further emphasising the need for faculty members and preceptors to be trained in their use.[12]

WBAs have been used extensively in medical education and include methods such as EPAs), mini-clinical evaluations and case-based discussions.[1, 3, 5, 9, 11, 13] While WBAs are used primarily in the experiential setting, their application may be a change from prior experiential education training methods.[14] For example, whereas prior experiential training methods may have relied more on role-modelling, the focus on learner-centredness of WBAs allows for customisation of the expected performance level, such as according to the learner's point in an educational programme (eg, by milestone setting) or even by prior experience. [9, 15]Sharing other benefits, such as the value of locally determined WBAs or EPAs (e.g., the US's "Core EPAs") in providing consistency among students and practitioners, can further help preceptors in appreciating their role. [9, 16] It is also possible to tie in basic science colleagues in creating and assessing WBAs or EPAs, further demonstrating their applicability to practice.[9]

Whether applying CBE through skills development in early courses or WBAs in the experiential setting, the assessment and feedback and facilitation skills of faculty members and preceptors will take on greater importance.[4, 15] As mentioned, the individual learner is central to CBE and therefore should be central in the feedback provided. Some have described the level of feedback needed as being that of a "coach", as with sports coaching, where explicit and individual feedback is provided. For success in this, training faculty members and preceptors on enhanced communication and relationship-building skills will be essential, as will training on observation skills.[4, 15] In the example of EPAs, preceptors will need guidance on changing assessment criteria from traditional grading to notes of supervision level needed or "entrustability".[9, 13]

6.3 Preceptor development

Preceptorship has been defined by Bartlett *et al* as "the formal arrangement between a practising health professional (the preceptor) and a graduate or student (the preceptee). Within a clinically-related setting, the preceptor supervises, provides guidance and facilitates the socialisation and development of the preceptee into a competent professional fit for practice."[17]

The important role played by preceptors to support work-integrated learning is well established. The nature of preceptors' role is varied depending on factors including the setting, the learner and the level and type of feedback required. Some preceptors have demonstrated expertise in use of WBA tools supporting the concept of CBE. However, it cannot be assumed that pharmacy preceptors inherently have the requisite knowledge, skills and attributes. Programmatic assessment literature supports the notion of "sharpening" the people along with the tools. The availability of tool kits, training materials, coaching, etc, is crucial to ensure assessment of competency is valid and supportive to the learner.

A set of preceptor competencies common to the health professions has been identified in the literature.[17] Although these are not specific to CBE, they should inform the necessary training for preceptors working within this learning framework. It has been proposed that these competencies could have a minimum level of performance specified, allowing for more advanced performance to be recognised.[17] This approach has been demonstrated by FIP with an entry level competency framework for pharmacists to support the development of foundation and early-career pharmacists, and the Global Advanced Development Framework to recognise and support more advanced practice.[18] A version of these frameworks adapted to support advancing practice in the education workforce has been developed and will be a useful addition to support academics and preceptors develop the necessary skills to support CBE.[7]

6.4 Implementing training

The systems-based approach of using competency frameworks and accreditation standards can provide the basis for training faculty members and preceptors, as they offer expectation setting, dissemination and guidance, and are designed to meet contemporary needs of the profession, society and learners. They can be adopted and adapted to meet local needs.[5-7, 16, 19-21]

Programmes may be designed in many ways for faculty and preceptor learners. Use of adult education theory (i.e., social constructivism) provides the need and context for training.[15, 20] Delivery can vary from live groups (small or large) to online sessions (asynchronous or synchronous). Colleagues have used peer-to-peer learning, while others have adopted the "champion" model, where full-time faculty members serve as advocates (or "champions") of CBE with each other and with practice-based colleagues.[6, 9, 20]

Challenges to any development programme can occur, because CBE means change. Providing proof of student success, a slow introduction and employment of "champions" may help.[6, 9] Evaluation of any training programme should be planned to ensure it is continuing to meet the needs of faculty members, preceptors, learners and practice.[9, 20]

6.5 Summary

Successful implementation of a CBE programme will rely on the successful training of faculty members and preceptors, with a different emphasis needed for each group. Training programmes on CBE should include topics such as educational foundations, CBE essentials and giving feedback in the workplace setting. Developers of training programmes are encouraged to refer to many available tools such as the FIP GCFE, FIP Global Advanced Development Framework and preceptor competencies.[7, 17, 18] Success and sustainability of any training programme will rely on engaging stakeholders and ongoing evaluation.

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Chapter 7 Glossary

This glossary summarises the terms and definitions used and referred to in this handbook.

Term	Definition and remarks
Authentic assessment	An assessment format requiring students to use the same competencies, or combinations of knowledge skills, and attitudes, that they need to apply in a comparable real-life situation in professional life.[1]
Case-based learning	A form of inquiry-based learning that aims to prepare students for clinical practice, through the use of authentic clinical cases.[2]
Clerkship	In healthcare education, a clerkship (or rotation) refers to students' participation in clinical practice during their final year(s) of study.
Cognitive skills	Brain-based skills (abilities, capabilities) needed in acquisition of knowledge, manipulation of information and reasoning. They have more to do with the mechanisms of how people learn, remember, solve problems and pay attention, rather than with actual knowledge.
Competence	The array of abilities across multiple domains or aspects of performance in a certain context. The recently published WHO global competency framework for universal health coverage[3] defines competence as "the state of proficiency of a person to perform the required practice activities to the defined standard. This incorporates having the requisite competencies to do this in a given context. Competence is multidimensional and dynamic. It changes with time, experience and setting." Statements about competence require descriptive qualifiers to define the relevant abilities, context and stage of training.
Competency	Competencies are preferably specified as observable abilities, integrating multiple components such as knowledge, skills, values and attitudes, and expressed as actual behaviour. Because competencies are observable, they can be measured and assessed to ensure that students have acquired them.[4] The recently published WHO global competency framework for universal health coverage[3] defines competencies as "the abilities of a person to integrate knowledge, skills and attitudes in their performance of tasks in a given context. Competencies are durable, trainable and, through the expression behaviours, measurable."
Competency-based education	An approach to preparing [health workers] for practice that is fundamentally oriented to outcome abilities and organised according to competencies. It de-emphasises time-based training and facilitates greater accountability, flexibility and learner-centredness.[5]
Competency framework	An organised and structured representation of a set of interrelated and purposeful competencies.[6] Each competency is accompanied by behavioural statements or indicators. These behavioural indicators describe measurable behaviours which would be observed when the individual demonstrates the associated competency.[7]
Constructive alignment	Constructive alignment is a design for teaching in which what students should learn, and how they should express their learning, is clearly stated before teaching takes place. Teaching is then designed to engage students in learning activities that optimise their chances of achieving those learning outcomes, and assessment tasks are designed to enable clear judgements on how well those learning outcomes have been attained.[8] CBE heavily relies on constructivist psychological principles, where students construct meaning from what they do during their learning activities. The role of teachers is to design the teaching-learning environment in such a way that students cannot escape from learning.[4]
Consultant	A professional (expert, specialist) who provides advice and other purposeful activities in an area of specialisation. In the context of CBE curriculum development, this is a teacher who specialises in a particular aspect of an educational programme, which may be related to discipline content or skills development.
Contact hours	The number of hours in a course or other curriculum element, during which students are actually meeting with other students or teachers.

Course	Building block of a curriculum. When the term "course" is used to describe the whole curriculum, the constituent parts can be indicated as "modules". A curriculum usually consists of multiple courses (in addition to other elements, such as rotations), which are offered to students in a logical, layered sequence.
Course development team	A group of teachers responsible for the construction and evaluation of a course. If desired and useful, students, educational consultants and managerial assistants can participate.
Course specification	A document, usually produced by a curriculum committee, which specifies the goals, content and organisational limitations of a course.
Curriculum committee	A group of teachers responsible for the design of a curriculum as a whole. If desired and useful, students, educational consultants and managerial assistants can participate.
Curriculum layer	A way of structuring a curriculum in (somewhat arbitrary) layers, where knowledge and skills are progressively integrated when students pass from one layer to another (see also "milestone"). The number of curriculum layers is somewhat arbitrary but can be used to structure a curriculum and to define developmental milestones for students, using explicit descriptions of learning outcomes for each layer.
Entrustable professional activity	A unit of professional practice that can be fully entrusted to a trainee, once he or she has demonstrated the necessary competence to execute this activity unsupervised.[9] Entrustable professional activities, as units of practice, constitute the description of work that operationally defines a profession. They represent a job description, not a person description.
Formative assessment	Assessment for learning, intended to monitor student learning, and to inform teachers and students about learning progress.[4] Formative assessment essentially has a feedback purpose and can help students to identify their strengths and weaknesses and to identify areas that need additional attention. The results of formative assessments can help teachers to identify areas which appear to be problematic for students, and can help them to adapt and improve their teaching.
Inquiry-based learning	A constructivist, active approach to learning driven by questions and complex problems that are open-ended and that drive the student's need for facts, procedures and guiding principles in order to investigate and find possible answers.[10]
Integration	An operational (umbrella) term used for describing different ways of combining content of different disciplines, or of combining content and skills in curricular elements and courses.[11] Integration can be described as a horizontal, vertical or spiral model. It can also be described by the themes used to integrate, such as a systems-based approach or by integrative teaching and learning approaches. The level of integration can also be described.
Internship	A period of work experience offered by an organisation for a limited period.
Learning outcome	Observable result of a course, module or other curriculum element, defined in terms of knowledge, skills, and behaviour of a student or trainee.[12] Intended learning outcomes are preferably described with action verbs, which indicate the required cognitive level. Conditions under which the concrete behaviour is expected to be demonstrated need to be specified in the intended learning outcomes.
Milestone	Intermediate stage in the acquirement of competence, used as anchor point in a curriculum and as a critical point for assessing whether students are progressing according to expectations[4] (see also "Curriculum layer").

	Progression of students through the curriculum can be guided and monitored by defining intermediate stages in the acquirement of competencies, and can be used to decide whether students are allowed to progress to a next stage of their educational programme.
Module	See “Course”.
Theme (overarching)	A way of structuring a curriculum, where aspects or content of courses are repeatedly addressed in courses. Overarching themes are used to clarify relationships between different courses at a relatively high level of abstraction. Overarching themes can be used when designing and constructing a curriculum. Sometimes longitudinal aspects (such as skills development) are communicated to students under the terms “tracks”, “lines” or “strands” to offer guidance in progression through the curriculum.
Project-based learning	Project-based learning is a model that organises learning around projects or complex tasks that involve students in design, problem-solving, decision making or investigative activities. Students have the opportunity to work relatively autonomously over extended periods, and projects culminate in realistic products or presentations.[13]
Practical skills	Manual and intellectual skills (abilities, capabilities) needed for executing professional activities in pharmacy.
Preceptor	A practising pharmacist who serves as a role model to guide a pharmacy student, preregistration trainee, or resident in the development of their professional knowledge, attitudes and practice skills.[14]
Problem-based learning	Students learn in small groups by exploring a predetermined problem. The problem is designed to trigger learning goals for individual students and subsequent group meetings permit students to monitor their learning and to set further learning goals. The tutor’s role is to offer support for learning and to help students to reach the expected outcomes. Problem-based learning enables students to develop the ability to translate knowledge into practice at an early stage of the curriculum, encourages individual participation in learning and allows the development of teamwork skills.
Programmatic assessment	An approach to assessment, where routine information about the learner’s competence and progress is continually collected, analysed and, where needed, complemented with purposively collected additional assessment information.[15] A key principle is that individual low-stake (formative) assessment are maximised for learning and feedback value, whereas high-stake (summative) decisions are based on the aggregation of the underlying low-stake assessments.
Programme workload	The total number of hours in a curriculum that are supposed to be needed for delivering an effective and efficient curriculum. Programme workload can be estimated from a teaching load allocation model (primary teaching load), supplemented with time allocated for secondary (and tertiary) teaching tasks (direction, evaluation, educational research) and professionalisation activities.
Rotation	See “Clerkship”.
Sequencing	A way of structuring a curriculum, where courses and other curricular elements are ordered in sequence in such a way that students can follow the programme in a logical way, which enables progressive development and acquirement of competence.
Simulation	An array of structured activities representing actual or potential situations in education and practice. These activities allow participants to develop or enhance their knowledge, skills and attitudes or analyse and respond to realistic situations in a simulated environment.[16]

Specialisation	A formal differentiation within, or subsequent to, a degree programme, which leads to an area of work with advanced responsibilities. In the context of entry-level pharmacy education, specialisation during the undergraduate period is uncommon. Specialisation as a hospital or community pharmacist is a postgraduate activity.
Spiral curriculum	A spiral curriculum is one in which there is an iterative revisiting of topics, subjects or themes throughout the course.[17] It is not simply the repetition of a topic taught. It requires also a deepening understanding of it, with each successive encounter building on the previous one.
Stakeholder	An individual, group or organisation that can be impacted by the outcome of a project. Stakeholders have an interest in the success of a project and can be within or outside the organisation responsible for executing the project. In the context of CBE curriculum development students, stakeholders are teachers and pharmacy professionals inside and outside the institution (school, faculty).
Student workload	The number of hours in a course or other curriculum element which students are supposed to spend on studying, including the number of contact hours. Student workload can only be estimated in the design phase of a course (based on experience) and may turn out to be highly variable between students when measured.
Summative assessment	Assessment of learning. comparing it to some standard or benchmark. The purpose of summative assessments in a curriculum is to guarantee that each individual student has fulfilled the curricular requirements.[4] In the context of CBE, the total of summative assessments is supposed to be representative for all required competencies.
Teacher workload	The number of hours in a course or other curriculum element which teachers are supposed to need for preparing, presenting and administering their teaching tasks. Teacher workload can only be estimated in the design phase of a course (based on a teaching load allocation model) and may turn out to be highly variable between students when investigated.
Teaching-learning environment	All aspects of the designed curriculum, including student tasks, assessments, organisation and teacher roles.[12] The learning of students is not only influenced by their perception of the assessment tasks, but also by the way teaching is delivered, by teacher behaviour, and by the rules and regulations which pertain to the curriculum. An effective teaching-learning environment is designed in such a way that students are motivated for deep, self-regulated learning.
Team-based learning	An active learning and small group instructional strategy that provides students with opportunities to apply conceptual knowledge through a sequence of activities that includes individual work, teamwork and immediate feedback.[18, 19] Team-based learning involves a specific sequence of individual preparation, individual and team readiness assurance tests, and team assignments.

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Appendix

Design of a course "Drug binding and action"

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This appendix illustrates the "translation" of a course specification, written by a curriculum committee, into a course design and schedule. The specification document (see Box) describes the desired content of the course and the position within the overall curriculum structure; the schematic representation below shows the course as designed by the course development team on the basis of this instruction.

Positioning: At the end of the first year of the BSc in Pharmacy curriculum (at Utrecht University) students need to learn the main concepts related to the interaction of small molecules with binding proteins. The course, entitled "Drug binding and action", is placed in the second layer of the curriculum spiral (see Section 4.3). Students have been exposed to the chemical structure and physicochemical properties of both small molecules and proteins in previous courses (first curriculum layer).

Additional information: During development of this curriculum, skills and disciplinary content were analysed, divided in different levels and described in detail in order to maintain consistency and to structure longitudinal lines within the curriculum. Specification of these longitudinal lines (skills and disciplinary content) and their relevance for this course are described in the specification (in italic type).

Example of a course development specification

<table>
<tr><td>Course title:
Study load:
Chairperson, coordinator:
Disciplines involved:</td><td>Drug binding and action
10 weeks, 50% (200 hours)
name1, name2
Medicinal chemistry, Pharmacology, Psychopharmacology</td><td>Course code Fa-200</td></tr>
<tr><td colspan="3">Course goals/outcomes
At the end of the course the student is able to:
Describe the interaction between low-molecular weight ligands and macromolecular binding sites (enzymes, receptors) in terms of the Law of Mass Action;
Describe and analyse the results of enzyme kinetic, receptor binding and pharmacological experiments using customary graphical representations;
Draw conclusions from these graphical representations with respect to affinity and activity of the ligands, distinguishing between competition/inhibition and agonism/antagonism;
Understand covalent and non-covalent interactions and enzymatic reactions in molecular detail as part of the key-lock concept; and
Use the concepts selectivity and specificity correctly.</td></tr>
<tr><td colspan="3">Content
Interaction between low-molecular weight ligands and receptors (s.l.) results from the Law of Mass Action, which describes the relationship between concentration and an "effect". The effect varies with the measuring system and the extent to which the ligand can initiate a measurable effect:
enzymatic conversion, c.q. inhibition of an enzyme (metabolism);
receptor binding, c.q. inhibition of binding (receptor binding);
pharmacological effect (agonism), c.q. antagonism (pharmacology).</td></tr>
</table>

Ligands can interact with one or more receptors (specificity, selectivity), where affinity (K_M, K_D, EC_{50}, etc) and intrinsic activity are determining whether an effect can be observed and whether an interaction between ligands can be characterised as competitive or non-competitive. Usual graphical representations (Lineweaver-Burke, Eadie-Hofstee, Scatchard, log-dose response curve) are different, while the underlying theory is similar. Students are expected to be able to recognise the similarities and to think in terms of affinity and intrinsic activity. In this course only the 1-binding site model is taken into account.

The molecular basis of reaction (chymotrypsin) and interaction (β2-receptor) are studied. Small groups of students will compile a receptor-dossier (analogous to the medicine dossier in course Fa-201). Practical experiments will be protein-binding and enzymatic conversion.

Parts of lab sessions from (existing) courses 1.4. and 2.2 can be reused. The practical experiments can be based on earlier pharmacology and medicinal chemistry courses.

Relations with other courses

In course Fa-102 (Molecular properties) the relation between structure and physicochemical properties of low molecular weight compounds has been studied; protein structure (enzymes, receptors) has been studied in course Fa-103. This course is essential as a preparation for all level-2 courses (*e.g.* biotechnology, GPCR-receptors). Course Fa-200 is also open for chemistry and biomedical sciences students.

Educational formats

Students are expected to master a difficult (threshold) concept; a relatively large part of the course needs to be dedicated to the mental construction of the concepts. This implies workshops/lab sessions, supported by calculations and simulations. Using the Four Components Instructional Design (4CID) model can be considered. The receptor dossier is organised as a small-group project.

Disciplinary content

Biomolecular chemistry, level-2: The student is able to relate the structure of a medicine to the structure of the receptor.
Pharmacodynamics, level-1: The student is knowledgeable about protein targets of medicines and understands the relationship between structure and interactions. The student has mastered quantitative aspects of receptor binding.
Biotechnology, level-1: The student becomes acquainted with protein-protein interactions and post-translational modifications.

Skills

Informatics, level-1: searching for structures and properties of proteins and ligand-receptor complexes (Protein Data Bank)
Calculations, level-1: dilutions, graphical representations, simulations.
Oral communication, level-1: At least 25% of the students will be able to give a short presentation that can be evaluated.
Laboratory skills, level-1: weighing, dilutions, interaction experiment.

Portfolio

Oral communication, level-1: Part of the students will present in this course; the evaluation will be part of their portfolio. If insufficient, additional training and re-evaluation is organised by the skills lab.

Assessment

Testing will be individual, in writing, and must be aimed at the application of concepts and methods of this course in different and new contexts. The receptor dossier is valued as a group assignment, max. 30% of the

course grade. Calculation ability can be tested using WebCT (i.e., an online testing environment) and is recorded in the portfolio.
Timeslot/contact hours Timeslot AD (i.e., a local time slot code), 30% contact time maximally.
Human resources With 200 participating students 800 teaching hours (0.5 fte) maximally. Group size 12 students maximally for small-group activities.
Financial resources 2,500 Euro budget (consumables); standard lab facilities are available.

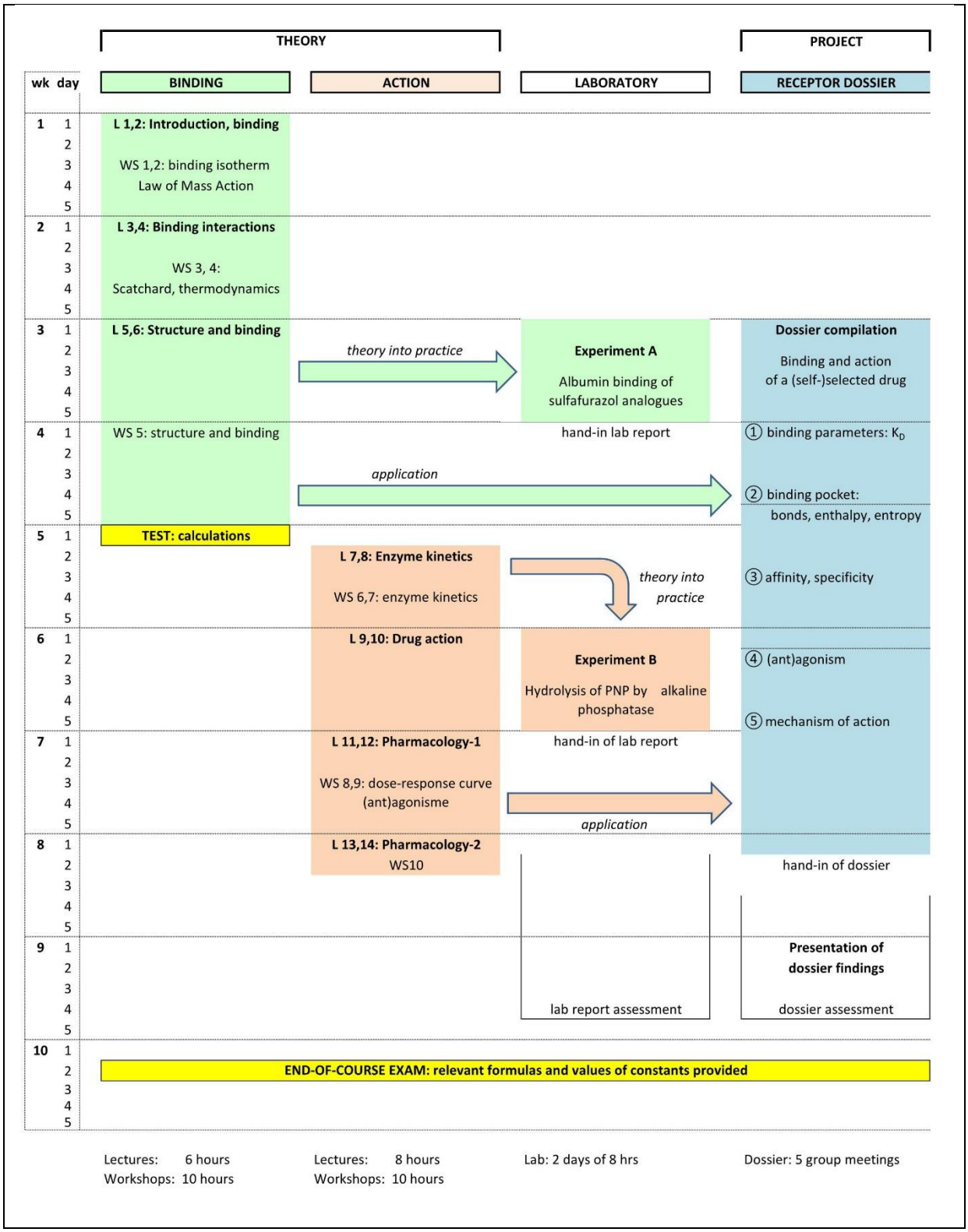
Course description: The course development team decided to structure the course along two main conceptual lines ("drug binding" and "drug action"). In weeks one to four, attention is given only to drug binding (green colour in the diagram below), where relevant theory is treated in plenary lectures and associated calculations are practised in interspersed workshops and lab sessions. This part ends with an instructional workshop on the retrieval and analysis of binding complexes from the Protein Data Bank, and a short individual test, aimed at testing students' numerical calculation abilities (mass/volume to concentration conversions, dilutions, etc). A protein binding experiment (binding of sulfafurazole analogues to Bovine Serum Albumin (BSA)) is used to integrate calculations, dilutions and interpretation of data within a laboratory experiment. The practical setup was modified from an existing "cookbook" experiment: in the new design, students have to write their own experimental protocol (based on estimated dissociation constants), including the weighing and dilution of chemicals and the listing of a pipetting schedule. The experiment is carried out as an equilibrium experiment in Eppendorf cups, where free ligand concentrations are measured at the end of the incubation period. During this full day experiment the largest part of the day is spent on preparation and calculations (dilution of stock solutions, pipetting schedule) and on converting measurement results to graphical representations (binding isotherms and Scatchard plots).

The second part of the course is dedicated to drug action (pink colour below), which follows essentially the same pattern as the first part, but now concentrates on enzyme kinetics and pharmacology. Enzymatic hydrolysis of p-nitrophenol by alkaline phosphatase is used as a practical integration tool; in this case, interaction patterns of competitive and non-competitive ligands have to be analysed by Lineweaver-Burke and Eadie-Hofstee plots.

Overall integration of the binding and action characteristics of drugs is achieved by compiling a receptor dossier (blue colour below): groups of five students collaborate in collecting and describing data of one particular drug (of their choice), starting with a description of the molecular interactions within the drug binding pocket and ending with a description of the pharmacological mechanism of action of the drug. Results are presented to other students during an oral communication session with slide presentations. The final test of the course is aimed at testing application of the relevant concepts to drugs that have not been studied during the course. A final grade is calculated from individual results in the mid-course test (5%), the end-of-course test (70%), the lab reports (group product: 5%), and the receptor dossier (group product: 20%). The result of the mid-course test (calculations) and evaluations of presentations are collected in the student's portfolio.

In this course, integration is achieved at different levels. Theory (plenary lectures) is directly used in calculations and exercises during subsequent workshop and lab sessions. In the practical experiment, the calculations and graphical presentations have to be applied in the context of designing and analysing the results of a relatively simple laboratory experiment. Cognitive integration is further enhanced by applying the concepts in compiling the data of one particular drug in the receptor dossier. Efficient guidance is realised by each group of students having the same teacher during all group activities (workshops and lab sessions, experiments and dossier meetings). Teachers for this course are recruited from the departments of medicinal chemistry, pharmacology and psychopharmacology.

Course outline of "Drug binding and action"



Integrated course for Pharmacy, Chemistry and Biomedical Sciences student, 10 weeks, 20h/week, total study load 200 hours, 64 contact hours (32%)

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