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Intern Year Blueprint Literature Review

September 2017

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Our evidence-based standards and processes ensure graduating and overseas pharmacists have the skills and knowledge to deliver effective healthcare that meets the changing needs of the community and that their skills and expertise meet public safety standards.

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Table of Contents

| | |
|--|----|
| Executive Summary | 5 |
| Introduction..... | 5 |
| Background..... | 5 |
| Literature review methodology..... | 6 |
| Competency standards/frameworks..... | 6 |
| Competency assessment..... | 7 |
| International intern assessment methods..... | 9 |
| Blueprinting..... | 10 |
| The purpose of blueprinting..... | 10 |
| Blueprinting in healthcare professional assessment..... | 10 |
| Glossary of Terms..... | 11 |
| List of tables..... | 12 |
| List of Figures..... | 12 |
| Abbreviations..... | 13 |
| Abbreviations cont..... | 14 |
| 1. Introduction..... | 15 |
| 1.1. Aims of literature review..... | 15 |
| 1.2. Background..... | 16 |
| 1.2.1. Graduate of a PharmBA approved pharmacy program of study..... | 16 |
| 1.2.2. Overseas trained pharmacists..... | 17 |
| 2. Competency standards in healthcare..... | 17 |
| 2.1. Competency standards literature review..... | 17 |
| 2.1.1. Method..... | 17 |
| 2.1.2. Results..... | 18 |
| 2.2. Definition of a competency standard..... | 18 |
| 2.3. Australian Competency Frameworks in Pharmacy..... | 18 |
| 2.4. Australian Competency Standards in other AHPRA health professions..... | 20 |
| 2.5. Potential applications for competency standards..... | 21 |
| 2.6. Potential concerns with the use of competency standards..... | 22 |
| 3. Competencies required for initial registration as a pharmacist in Australia..... | 24 |
| 4. Competency Assessment..... | 24 |
| 4.1. Competency assessment literature review..... | 24 |
| 4.1.1. Method..... | 24 |
| 4.1.2. Results..... | 26 |
| 4.2. Introduction to competency assessment..... | 26 |
| 4.3. Competency Assessment Frameworks..... | 26 |

| | | |
|--------|--|-----|
| 4.4. | Competency Assessment Methods | 30 |
| 4.4.1. | Validity and reliability | 30 |
| 4.4.2. | Multiple Choice Questions | 31 |
| 4.4.3. | Extended Matching Questions (EMQs) | 33 |
| 4.4.4. | Computer adaptive testing | 34 |
| 4.4.5. | Viva Voce/oral exams | 36 |
| 4.4.6. | The Objective Structured Clinical Examination | 38 |
| 4.4.7. | Workplace-based assessments | 41 |
| 4.4.8. | Portfolio | 47 |
| 4.4.9. | Entrustable Professional Activities | 49 |
| 4.5. | Discussion | 51 |
| 5. | International Intern Assessment Methods | 54 |
| 5.1. | United Kingdom | 54 |
| 5.1.1. | Great Britain | 54 |
| 5.1.2. | Northern Ireland | 57 |
| 5.2. | United States | 58 |
| 5.3. | Canada | 61 |
| 5.4. | New Zealand | 64 |
| 5.5. | Ireland | 65 |
| 6. | Blueprinting for assessments | 71 |
| 6.4. | Blueprinting Literature Review | 71 |
| 6.1.1. | Method | 71 |
| 6.1.2. | Results | 71 |
| 6.2. | Definition of blueprint and blueprinting | 71 |
| 6.3. | The purpose of blueprinting | 72 |
| 6.4. | The process of blueprinting | 72 |
| 6.5. | Format of a blueprint | 72 |
| 6.6. | Blueprinting in healthcare professional assessment | 73 |
| 7. | References | 73 |
| 8. | Appendices | 92 |
| | Appendix A: General Pharmaceutical Council Registration Assessment Framework | 93 |
| | Appendix B NAPLEX competency statements and weightings | 100 |
| | Appendix C: MPJE competency statements and weightings | 103 |
| | Appendix D: PEBC Pharmacist Qualifying Examination Blueprint | 110 |

Executive Summary

Introduction

The Intern Year Blueprint Project was commissioned by the Australian Pharmacy Council (APC) to inform Pharmacy Board of Australia (PharmBA) decisions regarding assessment of intern pharmacist competence in the future. The project aims to provide transparency and clarity for intern training programs (ITPs), preceptors and interns regarding how competence is measured and by whom.

The Intern Year Blueprint Project comprises three parts:

1. Literature review of intern competency assessment (including domestic and international processes and assessment methods) for International jurisdictions.
2. Documentation and analysis of the current intern year assessment structures (for PharmBA use only)
3. Development of a draft revised assessment blueprint for the intern year, mapped against the National Competency Standards Framework for Pharmacists in Australia 2016¹ (To be consulted on in September 2017)

This literature review forms the first stage of the project. Its purpose is to provide an environmental scan and evaluation of the published literature with respect to assessment blueprinting and assessment processes.

Background

The requirements for general registration as a pharmacist in Australia differ depending on the qualifications and background of the individual.

Graduate of a PharmBA approved pharmacy program of study

Following completion of an approved pharmacy program of study, all graduates must complete a period of supervised practice to be eligible for general registration as a pharmacist. This period of supervised practice, or internship, is undertaken in accordance with the PharmBA requirements, which are detailed in the Registration Standard: Supervised Practice Arrangements.²

In addition, interns must hold provisional registration with the PharmBA and undertake an accredited ITP. These training programs are accredited by the APC according to the requirements described in the Accreditation Standards for Australian Pharmacy Intern Training Programs 2010.³ There are currently six accredited ITPs in Australia.

ITPs provide opportunities for interns to integrate academic training into professional practice, and develop the competencies required for initial registration.^{1, 3} ITP providers must ensure effective and validated formative assessment measures are employed throughout the program, to ensure interns successfully complete all learning objectives.³

Before applying for general registration, an intern must also successfully complete two registration examinations. The written examination is conducted by the APC on behalf of the PharmBA, and the oral examination (practice) is conducted by the Australian Health Practitioner Regulation Agency (AHPRA) on behalf of the PharmBA. These assessment processes will be discussed in more detail in the second part of this project.

Overseas trained pharmacists

The requirements for an overseas qualified pharmacist vary depending on the country where the qualification was obtained.

Practitioners from Stream A countries (non-stream B) are required to pass the Knowledge Assessment of Pharmaceutical Sciences examination, conducted by the APC. Stream A candidates are then required to complete a full internship in accordance with the process outlined above for a graduate of an approved pharmacy program of study.

Practitioners from Stream B countries (United Kingdom (UK), the United States (US), Canada or Ireland) are required to pass the Competency Assessment of Overseas Pharmacist examination, conducted by the APC. Stream B candidates are then required to complete an assigned shorter period of supervised practice under limited registration. They are not required to undertake an accredited ITP. They are, however, required to undertake a registration assessment directed by the PharmBA, which may include an oral examination (pharmacy law and ethics) and/or oral examination (practice).

Pharmacists registered to practice in New Zealand can apply to the APC for a skills assessment under the Trans-Tasman Stream.

Literature review methodology

The literature review undertook a series of searches using the PubMed®, Embase®, Scopus® and CINAHL® healthcare databases. Grey literature searches were also conducted. The following areas were evaluated:

- Competency standards/frameworks
- Competency assessment
- Blueprint/blueprinting

Competency standards/frameworks

The latest revision of the National Competency Standards Framework for Pharmacists in Australia 2016 (National Framework), is due to be published in 2017.¹ In this version, the National Framework describes four levels of practitioner performance; general, transition, consolidation and advanced. In addition, the performance criteria applicable at initial registration are defined within each domain.

The 2011 Professional Practice Profile for Initial Registration as a Pharmacist⁴ provides guidance to both pharmacy schools and intern training providers with respect to what their individual programs should achieve. With the publication of the revised National Framework in 2017, this document becomes obsolete, and it is recommended that it be updated.

The literature review identified numerous applications for competency standards. These include:

- Ensuring standards of professional activity and maintaining patient safety⁵⁻⁷
- Practitioner self-assessment and identification of ongoing Continuing Professional Development (CPD) needs⁸⁻¹⁰
- Development of CPD activities⁹
- Student training and assessment^{5, 11}
- Development of curricula and assessment processes by education providers^{9, 12, 13}
- Accreditation of programs of study^{9, 12, 13}
- Definition and assessment of registration requirements^{5, 6, 8, 9, 12, 13}

Identified concerns with the use of competency standards included the following:

- Lack of evidence regarding the validity and reliability of using competency standards as assessment tools

- Restriction of the potential for expansion of scope of practice, and narrowing of undergraduate education curricula^{14, 15}
- Consideration of the extent and quality of practice opportunities when deciding when and how to apply competency standards for assessment purposes¹⁵
- A lack of engagement of pharmacy practitioners with the National Framework, despite it being mandated for identification of CPD needs¹⁶

Competency assessment

Miller's Pyramid has been used extensively in medical education to guide the development of assessment processes.¹⁷ At the base of the pyramid sits 'knows' (knowledge), then 'knows how' (competence), then 'shows how' (performance) with 'does' (action) at the pinnacle of the pyramid. The concept behind this framework is that assessment of a person's knowledge will not provide a true indication as to whether they can successfully perform an actual task. A practitioner must be able to know how to use the knowledge, demonstrate they can apply the knowledge to a clinical situation and ultimately perform independently within a clinical setting. Whilst several authors have suggested modifications to this model, Miller's Pyramid remains a useful benchmark against which to consider the application of various assessment methods.

The literature review evaluated the advantages, disadvantages, feasibility, validity and reliability and educational impact of commonly used assessment processes, including multiple choice questions (MCQs), viva voce/oral exams, objective structured clinical examinations (OSCEs) and workplace-based assessment (WPBA) methods.

Multiple Choice Questions

Whilst MCQs exhibit high levels of reliability and feasibility, they primarily assess knowledge, lack assessment authenticity and encourage rote learning.¹⁸⁻²¹ It is, however, possible to assess higher order cognitive processes such as interpretation, synthesis and application of knowledge with the use of well written clinical scenarios.^{20, 22, 23} Problems such as item-writing flaws can be minimised with writer training, use of writing guidelines, peer review and validation processes.^{21, 24-26}

Use of extended matching questions (EMQs) may reduce some of the disadvantages of MCQs by making it more difficult for the candidate to guess the correct answer^{27, 28} and minimising the 'cueing effect' associated with choosing the correct answer option from a supplied list.^{28, 29}

Computer adaptive testing (CAT) is a relatively new area of computer based testing, where the assessment process is customised to the candidate's ability level. There is evidence that CAT can assess a student's capability more quickly and precisely than a traditional MCQ format.³⁰⁻³³

It is, however, important to ensure adequate content coverage in high stakes assessment. CAT requires psychometric expertise, the development of an extensive calibrated item bank and technology resourcing.³⁴

Viva Voce/oral exams

Whilst the viva was once a common assessment method for undergraduate, postgraduate and professional examinations, its use has declined, and it has been increasingly replaced by other assessment methods.³⁵ Oral examinations are relatively easy to prepare, organise and run, facilitating the assessment of many candidates in a relatively quick time.

The unstructured, subjective nature of the viva, together with variations in subject matter, questioning, prompting and attitude of the assessor, may lead to poor levels of inter-rater reliability.³⁵ There is also evidence that gender, social background and ethnicity having been shown to inappropriately influence assessors.^{35, 36}

Careful selection of assessors with subsequent training, use of formal structured questions to cover pre-defined topics and a structured method of rating, have all been employed to make results more reliable.^{35, 37, 38} Increasing the number of assessors and the number of oral examinations a candidate must sit, also increases reliability.³⁹

Vivas generally test candidates at the 'knows how' level of Miller's Pyramid, and may be useful tools for assessing clinical reasoning, problem solving and decision making functions; skills that may be difficult to test by other assessment methods.

The Objective Structured Clinical Examination

OSCEs assess at the 'shows how' level of Miller's Pyramid. They provide an objective, standardised approach to assessment, and can be used to facilitate assessment across a wide range of clinical contexts.⁴⁰ They may be particularly useful for assessing performance in areas that are difficult to observe, and provide the opportunity for the candidate to be assessed in an environment that is not harmful to a patient.⁴¹ There are, however, concerns that they do not assess the candidate's ability to view the patient holistically,^{42, 43} and integrated skills assessment is more suitable at more advanced stages of training.⁴⁴

A major feasibility concern lies in the resourcing of OSCEs, with both the preparation and administration being labour intensive.^{42, 43, 45, 46}

Reliability and validity of OSCEs can be improved by increasing the number of OSCE stations, using standardised marking tools, training assessors and using standardised patients.^{42, 43, 45}

Workplace-based assessments (WPBA)

WPBA assesses at the 'does' level of Miller's Pyramid by collecting evidence of competence during normal work activities. Several tools have been developed to facilitate WBA including case-based discussion, multisource feedback and direct observation; these are discussed in full in the literature review. In the medical profession, there is increasing emphasis on ensuring performance in day to day practice, and the movement towards assessment in the work place is likely to continue.⁴⁷⁻⁴⁹ Whilst WPBA does not appear to have been widely adopted in pharmacy, some work based assessment tools such as the mini-PAT, mini-CEX, and the Global Competency Framework (GbCF) have been developed for use in the pharmacy environment.⁵⁰⁻⁵³

The advantage of all WPBAs lies in the authenticity of the assessment process and the ability to assess clinical reasoning, decision making, professional judgement, and application of knowledge and professionalism; skills that are often difficult to assess by other means. Use of multisource feedback also allows a candidate to get an overview of how others perceive them, and how they relate to other professions within the healthcare environment.

Successful use of WPBAs depends on the assessor's application of the tools, use of rating scales, engagement with the process and ability to provide constructive feedback. There are concerns that assessors may rate candidates too highly, and that both assessors and candidates may not be engaged with the process.⁵⁴⁻⁶² Reliability can be improved with assessor and candidate training and use of structured, validated assessment tools.^{59, 63-66}

Portfolio

A portfolio can be described as a collection of information that is intended to demonstrate achievement.⁶⁵ Their intention is to capture longitudinal evidence of both professional and technical development, whilst encouraging self-awareness and self-reflection.⁶⁷ Whilst portfolios have been traditionally used as a practice assessment tool in a formative setting, their use in summative and high stakes assessment is increasing.⁶⁸⁻⁷⁰

There is evidence that portfolios may improve self-awareness, self-reflection and self-confidence; increase engagement with, and responsibility for, learning; encourage student-trainer feedback and trust; improve

ability to learn independently and integrate theory into practice.^{67, 70, 71} Conversely candidates complain that completion of portfolios is time consuming, and fear that honest documentation of incidents, problem or difficulties may negatively impact assessment outcomes.^{67, 70, 72-75}

Whilst there is evidence to support portfolio review as a valid method for assessing competency,^{70, 74, 76, 77} the content will vary considerably from practitioner to practitioner. There are concerns that because portfolio contents are self-reported, this may be a threat to validity.⁷⁵

Reviews evaluating the use of portfolios for summative assessment purposes have indicated a wide range in reliability scores.^{70, 74, 78} Training of assessors, increasing the number of assessors and using evaluation tools have been shown to produce good reliability rates.^{70, 74, 76, 79}

Entrustable professional activities

A recent development in the assessment of professional competence is the introduction of entrustable professional activities (EPAs). EPAs are statements of specific task-related activities that may require the integration of multiple competencies. EPAs are a way of operationalising competencies into clinical practice, and are descriptors of work rather than descriptors of the practitioner.⁸⁰ An example of an EPA statement used in the medical setting is 'gather a history and perform a physical examination'.⁸¹

When EPAs are used for assessment purposes, an educator or supervisor assigns a level of trust to the trainee performing a specific activity. This level of trust may be absolute, where the trainee is determined to be entrustable or not. Alternatively, rating scales may be employed, where the decision about whether a trainee can perform an EPA is translated to the level of supervision that the trainee requires. These levels can be linked to specific training milestones; i.e. what level of entrustment would be expected at a specific stage of training. For example, low levels of trust would be expected and appropriate for early learners.

Discussion

Each method of assessment has its own advantages and disadvantages and no single assessment method can adequately assess all aspects of clinical competence.^{17, 19, 20, 29, 47, 82, 83} It is, therefore, important to use multiple modes of assessment to ensure that requisite knowledge, skills and attitudes are demonstrated to a pre-defined level.

Competence is contextual and not generic.⁴⁴ If a candidate exhibits competence in one area, this cannot be extrapolated to imply competence in all areas. Longitudinal assessment using varied methods in different clinical contexts will provide a more holistic approach to assessment.²⁹

The choice of assessment method will be based on a number of factors and will ultimately involve a compromise between the best evidence based method of assessment and the practicalities of implementing such methods.⁴⁷ The extent to which compromise is acceptable will depend on the context of the assessment.

Criteria for good assessment have been described as validity, reproducibility, equivalence, feasibility, educational effect, catalytic effect (i.e. driving future learning) and acceptability.⁸⁴ Formative or low stake assessment is intended to stimulate learning. Educational effects, catalytic effects and acceptability are likely to be the most important criteria in formative assessment. Summative or high stake assessment requires validated, high quality assessment material, significant content expertise, a systematic standard setting process and secure administration. Important criteria for summative assessment are, therefore, validity, reproducibility and equivalence.

International intern assessment methods

All stream B countries (UK, US, Canada and Ireland) and New Zealand employ some form of national assessment prior to registration. They all administer a written examination as part of this assessment process. The written examinations predominantly comprise a mixture of MCQ, EMQ and pharmaceutical

calculation questions. The UK, US and Canada have a written examination blueprint which is accessible by candidates.

In addition, Canada, Ireland and New Zealand use OSCEs as part of their national examination process.

Ireland also requires competence to be assessed against the national pharmacy competence framework,⁸⁵ and the trainee is required to pass a summative workplace assessment prior to registration.

The UK does not use OSCEs, but requires that tutors sign-the trainee off against a set of pre-registration performance standards.⁸⁶ This sign-off occurs at a minimum of four times a year.

Blueprinting

The purpose of blueprinting

The practice of blueprinting, which involves mapping an assessment process against program learning objectives, will establish the content validity of an assessment, by the determination of an adequate and representative sample of items to be included.⁸⁷ It will also help to ensure an assessment process is replicable, and that the assessment contents are representative of the curriculum.

The development of a blueprint should ensure there is clear link between the learning objectives, the delivered curriculum and the assessment.⁸⁸ Blueprinting can also reduce 'construct under-representation' and construct-irrelevance variance, both of which may compromise assessment validity.^{89, 90}

Blueprinting will define the content of a given assessment and hence provides a guide to assessment for trainers and assessors and, if published, for candidates.

Blueprinting in healthcare professional assessment

The concept of blueprinting in assessment is not a new one and there are numerous organisations who use this methodology. Assessment blueprinting seems to be prevalent in the medical profession.

Glossary of Terms

Where available definitions derived from Australian organisations have been used in preference to those used at an international level. Definitions utilised by pharmacy organisations have also been used in preference to those used in other healthcare professions.

| | |
|-----------------------------|--|
| Blueprint | A template used to define the content of assessment which depicts the relationship between what has to be assessed and how it is to be assessed. |
| Competence | Possession by an individual of the required knowledge, skills and attributes sufficient to successfully and consistently perform a specific task or function to the desired standard. ¹ |
| Competency standards | Describe the skills, attitudes and other attributes (including values and beliefs) attained by an individual based on knowledge and experience which together enable the individual to practise effectively as a pharmacist. ¹ |
| Curriculum | A compilation of the body of knowledge; intended learning outcomes; and learning, teaching, and assessment methods for a specified course of study. ⁹¹ |
| Intern | A graduate of a pharmacy approved program of study, who is required to complete a period of supervised practice to be eligible to apply for general registration. ⁹² For the purpose of this document the term 'intern' will refer to a pharmacy intern unless otherwise stated. |
| Internship | A period of supervised practice which occurs in accordance with the requirements set out in the Pharmacy Board of Australia's Registration standard: Supervised Practice Arrangements (1 December 2015). ² |
| Scope of practice | The professional role and services that an individual health practitioner is educated and competent to perform. ⁹³ |

List of tables

| | |
|--|----|
| Table 1: Competency standards search strategy | 18 |
| Table 2: Competency assessment search strategy | 24 |
| Table 3: Definitions of validity..... | 31 |
| Table 4: Criteria for good assessment..... | 54 |
| Table 5: Summary table of competencies examined in the Qualifying Examination Part I (MCQ) and Part II (OSCE)..... | 63 |
| Table 6: Marks Allocation for the Irish National Pharmacy Internship Program | 68 |
| Table 7: Competence standards assessment ratings used for workplace assessment | 69 |
| Table 8: Search strategy for blueprinting literature review..... | 71 |

List of Figures

| | |
|--|----|
| Figure 1: The practice continuum..... | 19 |
| Figure 2: Miller's Pyramid..... | 27 |
| Figure 3: Miller's Prism of Clinical Competence | 27 |
| Figure 4: The Cambridge Model for delineating performance and competence..... | 28 |
| Figure 5: Curve of improving performance adapted for healthcare..... | 28 |
| Figure 6: Model for the assessment of performance and examples of available assessment tools | 29 |
| Figure 7: The amended version of Miller's Pyramid with the addition of "Is" and an outline of what is to be assessed at each level..... | 30 |
| Figure 8: Model for programmatic assessment in action fit for the purpose of assessment for learning and robust decision making on learners' achievements, selection and promotion . | 53 |

Abbreviations

| | |
|----------|--|
| AHPRA | Australian Health Practitioner Regulation Agency |
| AMC | Australian Medical Council |
| APC | Australian Pharmacy Council |
| CAT | Computer adaptive testing |
| CbD | Case-based Discussion |
| CoDEG | Competency Development and Evaluation Group |
| CPD | Continuing Professional Development |
| DOPS | Direct Observation of Procedural Skills |
| EMQ | Extended Matching Question |
| EPA | Entrustable professional activity |
| GbCF | Global Competency Framework |
| GLF | General Level Framework |
| GMC | General Medical Council |
| GPhC | General Pharmaceutical Council |
| IAAC | Intern Assessment Advisory Committee |
| ITP | Intern Training Program |
| MCQ | Multiple Choice Question |
| Mini-CEX | Mini-Clinical Evaluation Exercise |
| Mini-PAT | Mini-Peer Assessment Tool |
| MPharm | Master of Pharmacy |
| MPJE | Multistate Pharmacy Jurisprudence Examination |
| MRCGP | Membership of the Royal College of General Practitioners |
| MSF | Multi-Source Feedback |

Abbreviations cont.

| | |
|--------------------|--|
| NABP | National Association of Boards of Pharmacy |
| NAPE | National Alliance for Pharmacy Education |
| NAPLEX | North American Pharmacist Licensure Examination |
| NAPRA | National Association of Pharmacy Regulatory Authorities |
| National Framework | National Competency Standards Framework for Pharmacists in Australia 2016 |
| NES | NHS Education Scotland |
| OSCE | Objective Structured Clinical Examination |
| PharmBA | Pharmacy Board of Australia |
| PCNZ | Pharmacy Council of New Zealand |
| PEBC | Pharmacy Examining Board of Canada |
| PGA | Pharmacy Guild of Australia |
| PPDC | Pharmacy Practitioner Development Committee |
| PSA | Pharmaceutical Society of Australia |
| PSI | Pharmaceutical Society of Ireland |
| PSNZ | Pharmaceutical Society of New Zealand |
| QUT | Queensland University of Technology |
| RACP | Royal Australasian College of Physicians |
| RCSI | Royal College of Surgeons in Ireland |
| SHPA | The Society of Hospital Pharmacists of Australia |
| shpaclinCAT | The Society of Hospital Pharmacists of Australia Clinical Competency Assessment Tool |
| SPRAT | Sheffield Peer Review Assessment Tool |
| UK | United Kingdom |
| US | United States (of America) |
| WPBA | Workplace-based assessment |

1. Introduction

In January 2016, the Australian Pharmacy Council (APC) submitted a proposal to the Pharmacy Board of Australia (PharmBA) to undertake a blueprint for intern pharmacist competency assessment. This proposal was prompted by the impending release of the revised National Competency Standards Framework for Pharmacists 2016. The proposed project sought to ensure intern assessments were valid, defensible and appropriate against the new competency standards.

Simultaneously, the PharmBA had commissioned, through its Registrations and Examinations Committee, the PharmBA Project 1: 'Analysis of oral examinations: processes and results' and PharmBA Project 2 'Investigating options for assessment of competence for general registration'. These projects set out to undertake a focused and comprehensive review of the PharmBA's oral examination. There was a high degree of concordance between the APC proposal and Project 2.

Following discussion between the PharmBA and APC, a small working group was formed to establish a way forward. Following a thorough review of the objectives for Project 2 and the APC blueprint proposal, a decision was made that APC should commission an Intern Year Blueprint Project. The project will inform PharmBA decisions regarding assessment of intern pharmacist competence in the future. It aims to provide transparency and clarity for intern training programs (ITPs), preceptors and interns, regarding how competence is measured and by whom.

The Intern Year Blueprint Project comprises three parts:

1. Literature review of intern competency assessment (including domestic and international processes and assessment methods)
2. Documentation and analysis of the current intern year assessment structures
3. Development of a draft revised assessment blueprint for the intern year, mapped against the National Competency Standards Framework for Pharmacists in Australia 2016¹

This literature review forms the first stage of the Intern Year Blueprint Project.

1.1. Aims of literature review

The purpose of this document is to provide an environmental scan and evaluation of the published literature with respect to assessment blueprinting and assessment processes.

The review aims to answer the following questions:

- What are the main issues and challenges around blueprinting for assessments in pharmacy/healthcare internship years in jurisdictions with competency frameworks?
- What are the main issues and challenges around competency assessment in pharmacy/healthcare internship years in jurisdictions with competency frameworks?
- What are the best ways to blueprint assessments for internships?
- What are the best forms of assessment to be employed for competency assessment in the intern year?
- What roles do stakeholders such as ITPs, preceptors and regulators/assessing authorities play in the assessment of intern competence?
- What support is needed to ensure all stakeholders can be assured of the quality and validity of assessments that are delivered in the workplace?

1.2. Background

To review the assessment processes associated with the intern training year, it is first necessary to understand the process by which an individual achieves general registration as a pharmacist in Australia. The requirements for general registration differ depending on the qualifications and background of the individual.

1.2.1. Graduate of a PharmBA approved pharmacy program of study

Following completion of an approved pharmacy program of study, it is a requirement that all graduates complete a period of supervised practice to be eligible for general registration as a pharmacist. This period of supervised practice, or internship, is undertaken in accordance with PharmBA requirements, which are detailed in the Registration Standard: Supervised Practice Arrangements.² The duration of the internship is 1,824 hours, and must be under the direction of a supervising pharmacist who holds general registration.

The intern must have a PharmBA approved preceptor, who is responsible for the overall training of the intern. The preceptor must be a pharmacist who meets the PharmBA requirements as defined in the Registration Standard: Supervised Practice Arrangements. The preceptor may personally supervise the intern, or delegate the supervision to another suitably qualified pharmacist. The preceptor should, however, be present at the approved training site on a regular basis.⁹⁴

In addition, interns must hold provisional registration with the PharmBA and undertake an accredited ITP. These training programs are accredited by the APC according to the requirements described in the Accreditation Standards for Australian Pharmacy Intern Training Programs 2010.³ There are currently six accredited ITPs in Australia as detailed below:

- Monash University
- Pharmaceutical Society of Australia (PSA)
- The Pharmacy Guild of Australia (PGA)
- The University of Queensland
- University of South Australia
- The University of Sydney

Four of the ITP providers (Monash University, the University of Queensland, University of South Australia and the University of Sydney) are members of the National Alliance for Pharmacy Education (NAPE) and offer the opportunity to obtain a Graduate Certificate in Pharmacy Practice by completing additional units of study.⁹⁵⁻⁹⁸ Interns completing the PSA's ITP will be awarded a Graduate Certificate in Applied Pharmacy Practice without undertaking additional units or assessments.⁹⁹

As well as developing generic professional attributes such as communication, teamwork, problem solving and professional and ethical conduct, the role of the ITP is to provide opportunities for interns to integrate academic training into professional practice, and develop the competencies required for initial registration.^{1,3} ITP providers must ensure effective and validated formative assessment measures are employed throughout the program, to ensure interns successfully complete all learning objectives.³

Before applying for general registration, an intern must also successfully complete two registration examinations. The written examination is conducted by the APC on behalf of the PharmBA, and the oral examination (practice) is conducted by the Australian Health Practitioner Regulation Agency (AHPRA) on behalf of the PharmBA. These assessment processes will be discussed in more detail in the second part of this project.

1.2.2. Overseas trained pharmacists

The requirements for an overseas qualified pharmacist vary depending on the country where the qualification was obtained.

Practitioners from Stream A countries (non-stream B) are required to pass the Knowledge Assessment of Pharmaceutical Sciences examination, conducted by the APC. Stream A candidates are then required to complete a full internship in accordance with the process outlined above for a graduate of an approved pharmacy program of study.

Practitioners from Stream B countries (United Kingdom (UK), the United States (US), Canada or Ireland) are required to pass the Competency Assessment of Overseas Pharmacist examination, conducted by the APC. Stream B candidates are then required to complete an assigned shorter period of supervised practice under limited registration. They are not required to undertake an accredited ITP. They are, however, required to undertake a registration assessment directed by the PharmBA, which may include an oral examination (pharmacy law and ethics) and/or oral examination (practice).

Pharmacists registered to practice in New Zealand can apply to the APC for a skills assessment under the Trans-Tasman Stream.

2. Competency standards in healthcare

To safeguard patient safety, it is necessary to ensure that any healthcare practitioner undertaking any function or task within a profession is competent to do so.

There are numerous definitions of the word competence. The definition used within this document is taken from the National Competency Standards Framework for Pharmacists in Australia 2016.¹

‘Possession by an individual of the required knowledge, skills and attributes sufficient to successfully and consistently perform a specific task or function to the desired standard’

To assess competence for any given function or task, it is necessary to have some form of measure against which to assess. Such measures can take the form of competency standards or frameworks.

2.1. Competency standards literature review

A literature review was undertaken to provide a comprehensive review of competency standards and frameworks within healthcare settings in Australia.

Whilst the authors acknowledge the existence of documents such as the GbCF,⁵³ which is discussed in section 4.4, a comprehensive review of international competency standards and frameworks is outside the scope of this document.

2.1.1. Method

Searches were carried out using the PubMed®, Embase®, Scopus® and CINAHL® healthcare databases. Keywords used in searches were: competence/competency/competencies used in combination with standard/s and framework/s. The search strategy is shown in Table 1. The search was limited to articles in English where an abstract was available to view.

A grey literature search using the Google® search engine was also conducted by combining the terms competency standard or competency framework with each of the 14 health professions that are part of the national registration and accreditation scheme.

2.1.2. Results

The search of four databases found 69,322 potentially relevant titles. Articles were reviewed for relevance by title, abstract, full-text availability through the QUT library resulting in 112 articles. In addition, 24 references were identified from grey literature.

Table 1: Competency standards search strategy

| Search number | Search term | |
|---------------|--------------|----|
| 1 | Competence | OR |
| | Competencies | |
| | Competency | |
| 2 | Standard | OR |
| | Standards | |
| | Framework | |
| | Frameworks | |
| 3 | 1 AND 2 | |

2.2. Definition of a competency standard

The definition of competency standard used in this document is taken from the draft National Competency Standards Framework for Pharmacists in Australia 2016:¹

'Competency standards describe the skills, attitudes and other attributes (including values and beliefs) attained by an individual based on knowledge and experience which together enable the individual to practice effectively as a pharmacist'

2.3. Australian Competency Frameworks in Pharmacy

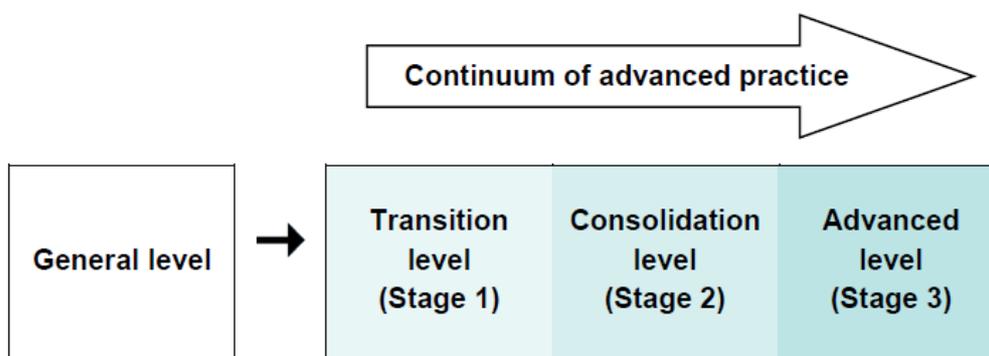
Competency standards for pharmacists in Australia were first endorsed for use in 1994, and have undergone several revisions since then. The latest version, The National Competency Standards Framework for Pharmacists in Australia 2016, is due to be published in 2017.¹ This document shall be referred to as the National Framework within this document.

The 2016 National Framework was reviewed and revised under the direction of the Pharmacy Practitioner Development Committee (PPDC), a profession-wide collaborative forum, with representatives from 11 member organisations. The most significant change from the 2010 version is the integration of the Advanced Pharmacy Practice Framework¹⁰⁰ to produce a single competency standards framework across all levels of experience.

As with previous versions of the competency standard, the framework defines the knowledge, skills and attributes that are required for a pharmacist to practice across a range of practice activities. The competencies within the standards are grouped into five domains, which represent specific areas of professional endeavour. Each domain is divided into standards which describe a specific professional activity. The standards consist of a number of enabling competencies, each of which has a number of

performance criteria that describe the observable behaviour that would be expected from a competent practitioner dependent on their level of practice. The standards describe four levels of practitioner performance; general, transition, consolidation and advanced, hence different performance criteria may be applicable to the same competency dependent on the practitioner's level of practice. General level is performance expected at initial general registration. Transition and consolidation are descriptors use to define the stages of the practice continuum from general level through to advanced level (Figure 1). Advanced level is defined as *'practice that is so significantly different from that achieved at initial registration that it warrants recognition by professional peers and the public of the expertise of the practitioner and the education, training and experience from which that capability was derived'*.¹

Figure 1: The practice continuum (adapted from the APPF)¹



Requisite competencies for individual pharmacists will vary according to the scope of practice within which the pharmacist works, and their performance level. Domains 1 and 2 and standards 4.1 and 4.2 are, however, considered universally applicable to all pharmacists. It is an expectation that individual pharmacists will review the National Framework, select the competencies relevant to their area of practice and customise them to their specific role. Such customisation can be used to create a professional practice profile which shows the competencies required for a specific role or position.

The National Framework differentiates between competency standards, professional practice/quality standards and professional guidelines. It defines professional practice standards as relating to *'the systems, procedures and information used by pharmacists to achieve a level of conformity and uniformity in their practice'*.¹ The primary function of practice standards is to facilitate self-assessment and evaluation by individual pharmacists.

Whilst this differentiation may be applicable to pharmacy standards, other health professions describe what appear to be competency standards variably as professional capabilities, practice threshold or professional practice standards (section 2.4).

2.4. Australian Competency Standards in other AHPRA health professions

Competency standards were identified for the following AHPRA registered health professions:

Chiropractors

Competency Based Professional Standards for Entry Level Chiropractors 2009 (Council on Chiropractic Education Australasia).¹⁰¹

Dental

Professional Competencies of the Newly Qualified Dentist February 2016 (Australian Dental Council).¹²

Professional Competencies of the Newly Qualified Dental Hygienist, Dental Therapist and Oral Health Therapist February 2016 (Australian Dental Council).¹⁰²

Professional Competencies of the Newly Qualified Dental Prosthetist February 2016 (Australian Dental Council).¹⁰³

Medical

Whilst there are no definitive entry level competency standards for medicine the following documents provide guidance:

The Australian Curriculum Framework for Junior Doctors 2012 (Confederation of Postgraduate Medical Education Councils). The framework is designed to support learning and training, and outlines the learning outcomes required of prevocational doctors.¹⁰⁴

The Standards for Assessment and Accreditation of Primary Medical Programs by the Australian Medical Council (AMC) 2012.¹⁰⁵ The standards contain a series of graduate outcome statements that a program graduate must achieve.

Intern Training-Intern outcome statements 2014 (AMC and Medical Board of Australia). The statements define the outcomes that medical interns should achieve by the end of their intern programs.¹⁰⁶

Medical radiation practice

Professional capabilities for medical radiation practice 2013 (Medical Radiation Practice Board of Australia).¹⁰⁷

Professional Practice Standards for the Accredited Practitioner 2013 (Australian Institute of Radiography).¹⁰⁸

Nursing

Registered nurse standards for practice 2016 (Nursing and Midwifery Board of Australia).⁷ These standards have recently replaced the national competence standards for the registered nurse.

Nurse practitioner standards for practice 2014 (Nursing and Midwifery Board of Australia).¹⁰⁹

Midwifery

National competency standards for the midwife 2010 (Nursing and Midwifery Board of Australia).⁸

Occupational Therapy

Australian minimum competency standards for new graduate occupational therapists 2010 (Occupational Therapy Australia).¹³ Note, the Occupational Therapy Board of Australia is currently developing new threshold competency standards.

Optometry

Entry-level competency standards for Optometry 2014 (Optometry Australia).¹¹⁰

Physiotherapy

Physiotherapy practice thresholds in Australia and Aotearoa New Zealand 2015 (Physiotherapy Board of Australia & Physiotherapy Board of New Zealand).¹¹¹

Podiatry

Podiatry Competency Standards for Australia and New Zealand 2015 (Australian and New Zealand Podiatry Accreditation Council).⁵

Psychology

There are no profession specific competency standards for psychology, instead the profession utilises the National practice standards for the mental health workforce 2013 (Victorian Government, Department of Health).¹⁰

The competency standards detailed above are all aimed at entry level practitioners. Some come from National Boards, some from accreditation bodies and some from professional organisations. In addition, the nursing profession has numerous special interest group developed competency standards, applicable to specific clinical areas.⁶ For example, a nurse working in the area of sexual health will be expected to comply with the competencies described in the registered nurse standards for practice as well as those described in the Competency Standards for Sexual and Reproductive Health and HIV Nurses, produced by the Australasian Sexual Health and HIV Nurse Association.¹¹²

2.5. Potential applications for competency standards

Competency standards describe specific task related criteria, which may be utilised for several purposes.

Practitioners

Practitioners can use competency standards to assess their performance or identify practice areas requiring improvement or additional training.⁸⁻¹⁰

Education providers

Education providers may use competency standards when developing curricula, and in the assessment and feedback of student performance.^{5, 6, 8, 9, 13}

Student placements

As a reference and assessment tool for both supervisors and students (i.e. for gathering evidence to demonstrate achievement of competencies).^{5, 11}

Continuing Professional Development

Competency standards may be utilised by education and training providers to develop relevant continuing professional development (CPD) activities,⁹ and by practitioners to identify professional development needs, and create individual CPD plans.¹⁰ It should be noted that the PharmBA mandates by law that pharmacists plan their CPD on an annual basis. Pharmacists are required to use the National Framework to identify competencies relevant to their role, determine their professional development needs and identify suitable CPD activities which fulfil these needs.⁹³

Employers

Employers may use competency standards to ensure appropriate standards of professional activity and care, by assessing and managing the performance of their employees.⁵⁻⁷ Gaps in performance can be identified, and appropriate education/training implemented to support improvement. In addition, competency standards may assist in the development of position descriptions and in the recruitment process.^{6, 9, 10, 13}

Accreditation bodies

Accrediting bodies may use competency standards to define program of study requirements when developing accreditation standards, and in the accreditation process.^{9, 12, 13} The APC accreditation standards for pharmacy programs in Australia and New Zealand states *'In Australia, graduates of approved programs of study are expected to achieve by the end of their internship the competencies of the National Competency Standards Framework for Pharmacists in Australia'*.¹¹³ The Accreditation Standards for Australian Pharmacy Intern Training Programs 2010 states *'The ITP must provide learning opportunities that enable interns to integrate and apply the defined functional areas, not including supplementary elements, of the current Competency Standards for Pharmacists in Australia'*.³

Registering authorities

National Boards can use competency standards to define the standards they expect from registrants, or to communicate these expectations with consumers. Other uses include the assessment of: applicants for initial registration, overseas trained practitioners, practitioners returning to work after breaks in service and practitioners involved in professional conduct or health related matters.^{5, 6, 8, 9, 12, 13}

Credentialing

Credentialing bodies may use competency standards to assist in the credentialing of practitioners.^{6, 9, 14}

Development of advanced/speciality competency standards

Entry level competency standards commonly form the basic framework for the development of advanced practice competency standards or those to be used in specific clinical specialities.¹³

2.6. Potential concerns with the use of competency standards

As can be seen above, competency standards may be used for assessment purposes both at student and graduate level. Whilst the use of professionally endorsed standards to review performance may seem a logical step, the use of competence standards as an actual assessment tool may also meet significant problems.

Validity and reliability

The review found no published evidence regarding the validity and reliability of using such standards as competency assessment tools in Australia.

Level of detail

The level of detail found in competency standards varies greatly. Whilst the midwifery, occupational therapy, pharmacy, podiatry and radiation practitioner competency standards include evidence examples or cues, which can be used by an assessor to measure performance, the recently revised registered nurse standards for practice have been significantly shortened compared to the previous version. They contain seven standards with criteria that specify how the standard is demonstrated. Explanatory notes state that these criteria are not exhaustive and *'enable rather than limit the development of individual scopes of nurse practice'*.⁷

Scope of practice

The potential to limit expansion of scope of practice using restrictive entry level competency standards is discussed by Ash et al.¹⁴ The authors point out that the competencies required to perform within a specific role are not static; competency requirements will change as work place tasks and entry level scope of practice evolves. This in turn may exert pressure on education providers to continually review and adapt courses to meet workplace competency requirements, whilst trying to ensure that quality educational outcomes are delivered. Whilst there is no published evidence in pharmacy, there are concerns that using competency standards to define program of study curricula, may result in a narrowing of undergraduate education to focus on the current capabilities of the workforce, at the expense of preparing students for the future.¹⁵

Timing of assessment processes

It is also important to determine at what stage in a practitioner's development they are expected to consistently meet competency standard requirements. Use of competency standards by education providers to assess students' performance prior to graduation may be unrealistic. Competence is achieved not only through study, but through experience gained in the workplace. Students only have limited exposure to clinical environments, and may experience only brief rotations through different clinical areas. It can be argued that competence cannot be achieved until a practitioner is working in a prolonged and stable environment.¹⁵ Gallagher et al also caution regarding the practice of 'signing off' the student against a series of individual performance competencies which may be separated in time, as these may not form a true picture of a student's competence as a whole.¹⁵

Many health profession programs of study produce entry level graduates. It is necessary to ensure they have had sufficient experiential placement exposure if entry level or threshold competencies are to be applied. Pharmacy, medicine and two of the psychology registration pathways currently have requirements for additional periods of supervised practice, which must be completed prior to eligibility for independent practice. Using competency standards within this time may be useful for training purposes, but it is important to consider the extent and quality of practice opportunities when deciding when and how to apply the competency standards for assessment purposes.

Workforce engagement

Whilst the existence of professionally endorsed competency standards may be considered essential to ensure ongoing competence, there appears to be a lack of engagement with the National Framework, despite it being mandated for identification of CPD needs. A paper by Nash, et al published in 2016, reviewed the extent of use and perceived relevance of the 2010 National Framework by general registration pharmacists, intern pharmacists, pharmacy students and pharmacy educators.¹⁶ Most respondents to an online survey self-reported as being not very familiar (46%), or not at all familiar (32%), with the National Framework. The majority of pharmacists reported that they did not use the National Framework for renewal of annual registration (57%) or for planning CPD (77%). The National Framework was perceived as relevant by 95% of students, 98% of interns and 85% of pharmacists.

3. Competencies required for initial registration as a pharmacist in Australia

Pharmacists at entry-level to the profession cannot be expected to achieve all competencies described within the National Framework. They will not have gained substantial workplace experience in all areas of practice, and can only commence independent practice upon registration. To facilitate clarity around competency requirements, the performance criteria applicable at initial registration have been defined within each domain. New terminology within the 2016 Framework has seen the term ‘entry-level’ replaced by that of ‘general level’. Within the general level performance criteria there is, however, additional differentiation between those criteria that are applicable to initial registration, and those which are likely to be achieved after registration but prior to progression into more advanced performance levels.

Graduates of approved pharmacy programs of study are not expected to be competent in all of these specified areas at graduation, but are expected to achieve these competencies by the end of their internship. In 2011 the Advanced Practice Framework Steering Committee approved release of a ‘Professional Practice Profile for Initial Registration as a Pharmacist - a customised tool of entry-level competencies incorporating guidance on Pharmacy School and Intern Training Provider contributions’.⁴ The stated purpose of this document was to assist in the preparation and assessment of pharmacy graduates and candidates for registration as a pharmacist in Australia.

The tool contains a summary of competency standards and a professional practice profile for initial registration as a pharmacist. The practice profile describes the standards, elements and performance criteria applicable to entry level practice and provides examples of program expected outcomes, indicating whether these outcomes should be achieved by a pharmacy school and/or ITP. This clarifies the respective contributions of pharmacy schools and intern training providers in achieving the requisite entry-level competencies, and can be used by intern training providers to design and develop their programs and assessment processes.

With the release of the 2016 National Framework containing revised domains and performance criteria, this document will become obsolete. It is, therefore, recommended that the tool be updated to provide both pharmacy schools and intern training providers clear objectives with respect to what their individual programs should achieve.

4. Competency Assessment

4.1. Competency assessment literature review

4.1.1. Method

Searches were carried out using the PubMed®, Embase®, Scopus® and CINAHL healthcare databases. The search strategy is shown in Table 2. Search results were limited to articles in English where an abstract was available to view.

Table 2: Competency assessment search strategy

| Search number | Search term | Combined terms |
|---------------|-------------------------------|----------------|
| 1 | “Competency assessment” | OR |
| | “Competency based assessment” | |
| | “Competency assessment tools” | |

| Search number | Search term | Combined terms |
|---------------|--|----------------|
| | "Competency assessment methods" | |
| 2 | Written exam | OR |
| | Written examination | |
| 3 | Multiple choice question | OR |
| | Multiple choice questions | |
| | Multiple choice exam | |
| | Multiple choice questionnaire | |
| | MCQ | |
| 4 | Extended matching questions | OR |
| | EMQ | |
| 5 | Certainty based marking | OR |
| | Confidence based marking | |
| 6 | "Objective structured clinical examination" | OR |
| | OSCE | |
| 7 | Viva voce | OR |
| | Viva | |
| | Oral exam | |
| | Oral exams | |
| 8 | Case based discussion | |
| 9 | Portfolio | |
| 10 | "Multi source feedback" | OR |
| | MSF | |
| | Mini-PAT | |
| 11 | "General level framework" | OR |
| | GLF | |
| | clinCAT | |
| 12 | "Workplace based assessment" | |
| 13 | 1 AND (2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12) | |

4.1.2. Results

The search of four databases found 17,925 potentially relevant titles. Articles were reviewed for relevance by title, abstract, full-text availability through the QUT library resulting in 294 articles.

4.2. Introduction to competency assessment

The development of professional competency standards brings both the opportunity, and the regulatory requirement, to ensure that practitioners are trained appropriately and are fit to practice.

Competence is contextual in that it describes a person's ability to perform a given task in a given situation. It is also developmental, with students gaining competence over time through experience and reflection.²⁹ It is, therefore, important that assessments should evaluate the expected level of achievement at defined stages in a student's training.

The goals of competency assessment may vary and include:

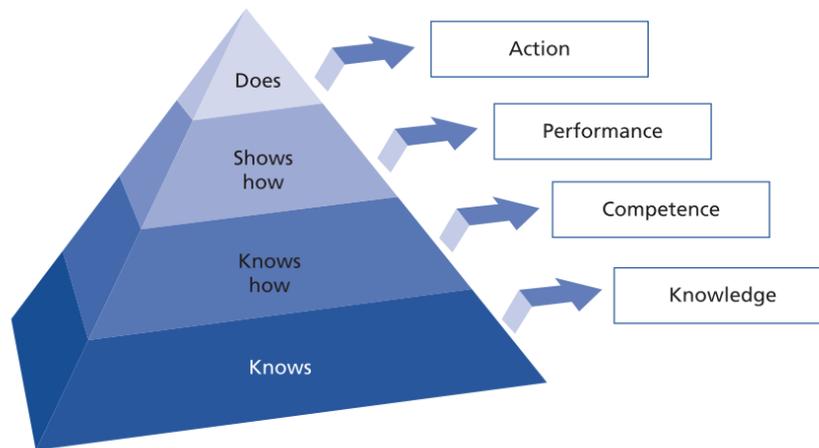
- To drive learning; optimising the capabilities of the student by providing motivation to learn and highlighting areas for improvement^{19, 29, 114}
- To identify students who require assistance to achieve the required learning outcomes¹¹⁴
- To provide information to enable decisions about a trainees advancement through a program of study¹¹⁴
- To assist in the candidate selection process for work positions or advanced training²⁹
- To protect the public by identifying practitioners who are not competent to practice for example in professional certification^{19, 29}
- To provide feedback for curriculum review as part of a continuous quality improvement process¹¹⁴

It is important to define the purpose of the assessment, as it will assist the decision as to whether a formative or summative assessment approach should be employed.

4.3. Competency Assessment Frameworks

In 1990, George Miller introduced a competency assessment framework, 'Millers Pyramid', which has been used extensively in medical education to guide the development of assessment processes.¹⁷ At the base of the pyramid sits 'knows' (knowledge), then 'knows how' (competence), then 'shows how' (performance) with 'does' (action) at the pinnacle of the pyramid (Figure 2). The concept behind this framework is that assessment of a person's knowledge will not provide a true indication as to whether they can successfully perform an actual task. A practitioner must be able to know how to use the knowledge, demonstrate they can apply the knowledge to a clinical situation and ultimately perform independently within a clinical setting.

Figure 2: Miller's Pyramid ¹⁷



The pyramid has been adapted to include suggestions for competency assessment methods that can be applied at each stage of the framework (Figure 3). In this adaption performance sits at the 'does' level of the pyramid.

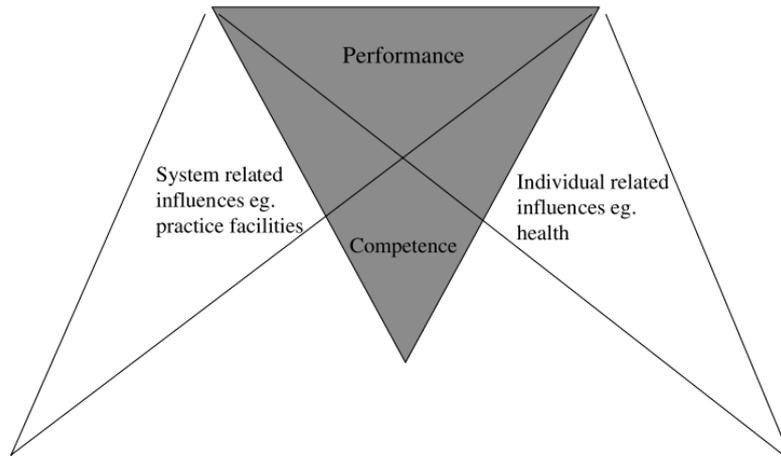
Figure 3: Miller's Prism of Clinical Competence (Adapted by R. Mehay and R. Burns) ¹¹⁵



Several authors have critiqued Miller's Pyramid and considered the relationship between competence and performance. In 2002 Rethans et al published a paper stating competence should sit at the 'shows how' level of the pyramid, whilst performance sits at the 'does' level.⁴⁸ When discussing medical training, the authors argue that competence in an examination setting does not necessarily translate into performance in the workplace. They define competency based-assessment as that which measures what doctors can do in a controlled representation of professional practice, whilst performance-based assessment measures what doctors do in actual professional practice.

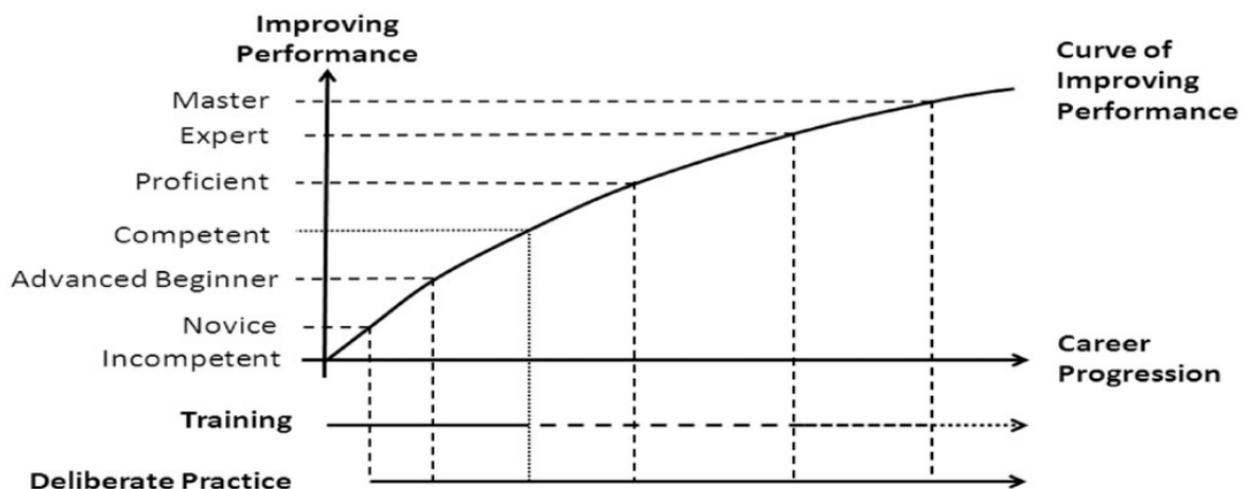
The authors state that competence is a pre-requisite for performance, but other external factors should also be considered when assessing performance. Such factors can be categorised as system related (guidelines and policies, patient expectations, time and accessibility to other health practitioners), or individual related (physical and emotional state and relationships with others). The authors propose the Cambridge Model to define the relationship between competence, performance and influences to performance (Figure 4).

Figure 4: The Cambridge Model for delineating performance and competence⁴⁸



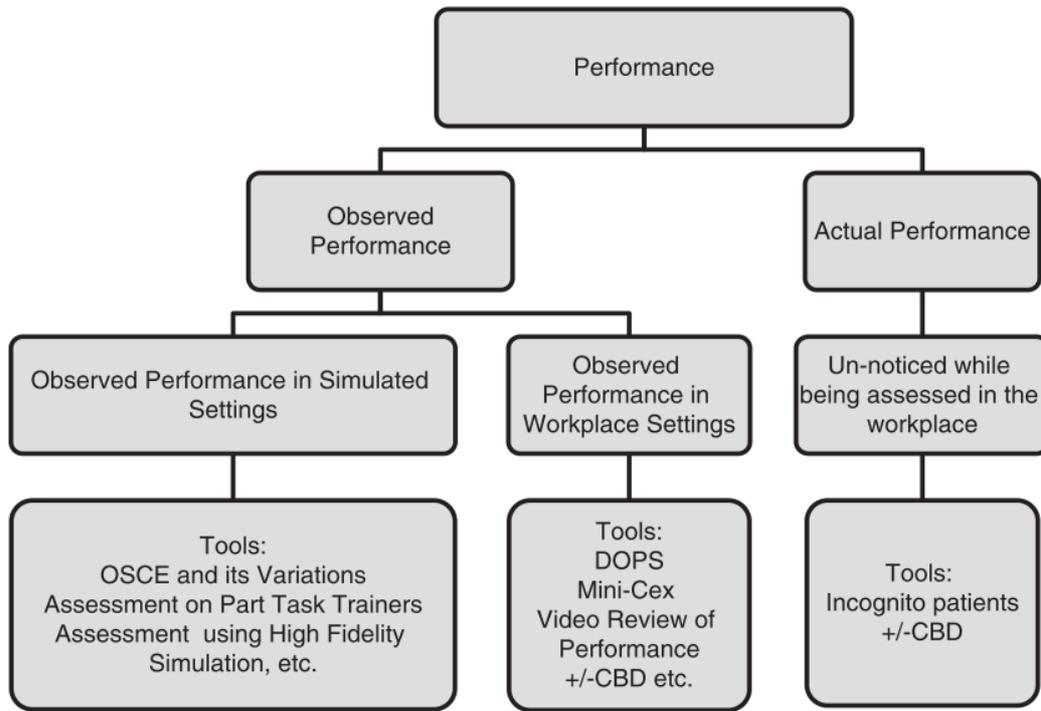
Khan et al take a different view, and describe seven steps of performance, from incompetent to master, along a continuous spectrum.⁴⁹ Competence is defined as the ability to perform at a certain level on this spectrum. The authors propose a model (adapted from work by Dreyfus and Dreyfus and ten Cate^{116, 117}) which describes the relationship between competence and performance, and indicates the roles that both training and deliberate practice play in the acquisition of skills (Figure 5).

Figure 5: Curve of improving performance adapted for healthcare – modified from Dreyfus and Dreyfus (1980) and ten Cate et al. (2010)⁴⁹



With reference to Miller's Pyramid, the authors classify both the top two levels of the pyramid as performance, with the 'does' being actual performance and 'shows how' being performance for assessment purposes, either in the workplace or in simulated settings. They also propose a model for the assessment of performance (Figure 6).

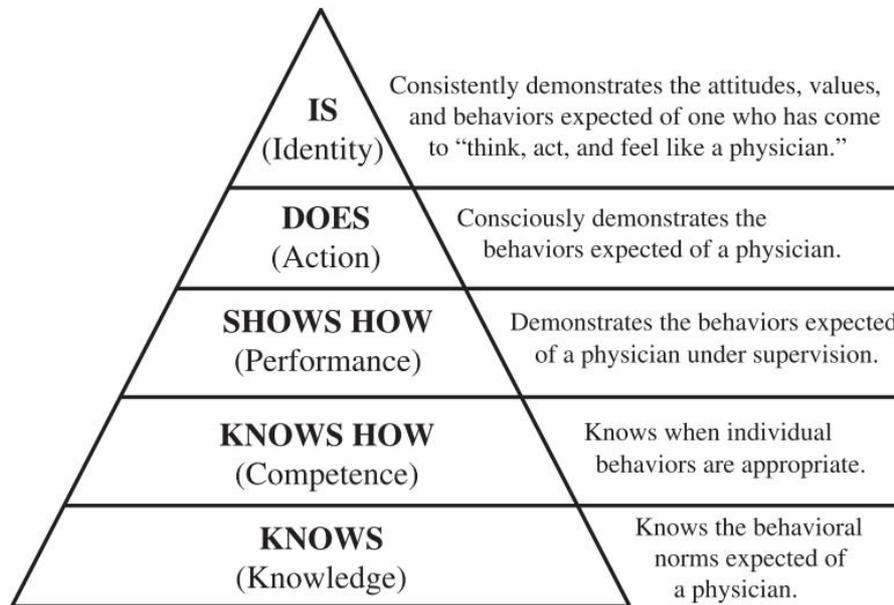
Figure 6: Model for the assessment of performance and examples of available assessment tools ⁴⁹



It is also imperative that practitioners can develop and demonstrate competence in professionalism;⁴⁷ professional values and qualities that in pharmacy are defined by such documents as the Code of Conduct for Pharmacist,¹¹⁸ PSA Code of Ethics for Pharmacists¹¹⁹ and the Society of Hospital Pharmacists of Australia (SHPA) Code of Ethics.¹²⁰

More recently, Creuss et al have recognised the importance of ensuring such competencies are captured within an assessment framework, and have proposed an amended Miller's Pyramid which incorporates the development of professional identity within a practitioner (Figure 7).¹²¹ There is an added apex level of 'Is'. This level recognises professional identity as inherent attitudes, beliefs and values that are consistently present. Although aimed at the medical profession, this pyramid is relevant to all health professions.

Figure 7: The amended version of Miller’s Pyramid with the addition of “Is” and an outline of what is to be assessed at each level ¹²¹



Creuss et al acknowledge that assessment at this level of the pyramid will be more difficult, as the attitudes, beliefs and values of professional identity are subjective in nature and difficult to assess. They suggest that observation of behaviours representative of attitudes, values and characteristics will continue to be used as surrogate markers in the assessment of professional identity.

Despite these discussions around competence, performance and professional identity, Miller’s Pyramid remains a useful benchmark against which to consider the application of various assessment methods.

4.4. Competency Assessment Methods

4.4.1. Validity and reliability

When a student successfully completes a program of study, it is important to ensure that stakeholders can be assured of the quality and validity of assessments methods. Both reliability and validity are key to quality assessment processes.

Reliability measures the reproducibility of results with repeated trials, and reflects the internal consistency of the test.¹²²

Reliability can be affected by factors such as assessor judgements, assessment content, candidate nervousness and assessment conditions.¹⁹ Inter-rater reliability measures the consistency of assessment between different assessors, whilst inter-case (or candidate) reliability measures consistency of candidate performance across the assessment. Use of multiple assessors across multiple assessments will improve inter-rater reliability by reducing the bias of the judgement that may be given by one assessor alone. Inter-case reliability can be improved by assessment across a broad number of cases or situations.¹⁹

Validity describes a test’s ability to produce results consistent with other measures of the same characteristic and requires external criteria.¹²² There are a number of individual validity descriptors which can be applied to validity measurement as shown in Table 3.¹²²

Table 3: Definitions of validity

| | |
|----------------------------|---|
| Criterion-related validity | Consistency of test results with those of a reference criterion standard |
| Construct validity | Consistency of test results with other tests or indexes purporting to measure similar characteristics |
| Content validity | Inclusion of questions representative of the qualities the test attempts to measure; appropriate domain |
| Face validity | The appearance that a test is adequate for its intended purpose (not a formal statistical term) |

Assessment processes need to be replicable, and assessment contents representative of the curriculum. If an assessment covers the specified learning objectives of a program of study, then it is considered to have content validity.¹²³

Construct validity defines how well an assessment measures what it claims to be measuring and can be compromised by both construct under-representation and construct-irrelevance variance. Construct under-representation can occur with under-sampling or bias sampling of the curriculum or program content.^{89, 124} Construct-irrelevance variance can occur with the choice of inappropriate assessment methods or assessment content that is either too hard or too easy. Rater bias, and sampling of the candidates' performance across only a limited number of aspects, can also contribute to construct-irrelevance variance.⁸⁹

4.4.2. Multiple Choice Questions

Multiple choice questions (MCQs) have been used extensively as a method of assessment in education.¹⁸⁻²⁰ There are two main formats for MCQs; true/false and single best option. The single best option, the most widely used format,^{29, 125} consists of a stem, which poses the question, followed by several possible answer options. The correct option is called the key, whilst the alternatives are called distractors. Typically, 4 or 5 option MCQs are used in health professional assessment, but there is evidence to suggest that 3 option MCQs, improve assessment efficiency, whilst maintaining validity and reliability. The reduced exam completion time with 3 option MCQs may even improve content validity, by allowing a greater number of questions per assessment.¹²⁶⁻¹²⁹ An example of single best option MCQ taken from a past APC delivered written examination is shown below.

In an intensive care ward, a chart reads: "KCl 40 mmol in 1 litre of normal saline. Infuse at 20 mmol/h."

What is the flow rate in mL/min?

- A 0.5 mL/min
- B 0.83 mL/min
- C 5 mL/min
- D 8.3 mL/min
- E 50 mL/min

Advantages

Most of the advantages associated with MCQs lie in their high degree of reliability and feasibility, and are discussed below. MCQs can assess a wide range of content area in a short period.^{20, 29, 130} Assessor bias is limited, as marking is objective.

Disadvantages

It is difficult and time consuming to write unambiguous MCQs.^{125, 131} Many considerations need to be taken into account, including grammar, formatting, number of answer options and their order, as well as the placement of distractors.^{18, 20, 132} Reviews of MCQ collections have shown high numbers of item-writing flaws.^{25, 26, 133} Item-writing training, use of standards and guidelines as well as peer review of questions, are all recommended to improve MCQ quality.^{21, 24-26}

Having the correct answer amongst alternative options may provide the candidate with a prompt; the candidate requiring only recognition rather than recall of details to pick the correct answer. This is called the 'cueing effect', and may result in the candidate choosing the correct response when, without options, they would have been unable to answer the question.^{20, 29, 125}

When faced with a question they do not know the answer to, candidates may guess an answer, working on the assumption that they have a specific probability (based on the number of options) of choosing the correct response. In the past some organisations have used negative marking to overcome this issue, where marks are deducted from the total score if an answer is incorrect. More recently certainty based marking has been employed.^{134, 135} As for traditional MCQs, the candidate is asked to choose the correct answer, they are then asked to indicate a degree of certainty that the answer will be marked as correct. The marking scheme rewards accurate reporting of certainty and good discrimination between more and less reliable answers.

Feasibility

MCQs are easy to administer, require a low level of resourcing and may be computer marked. Although difficult and time consuming to write, they are an economical form of assessment, particularly for assessing large number of candidates.¹³⁶ The same assessment may be administered in several centres simultaneously, or on-line.

It is possible to build a bank of MCQ questions for re-use, thus minimising the exam preparation time. It is important, however, to analyse questions and results after use, as questions may require revision or deletion. Reuse of questions must be done cautiously, as previous candidates may transmit questions to subsequent candidates, and it is necessary to constantly renew the MCQ bank.²⁰

Validity and reliability

It is important to test MCQs for validity and reliability prior to administration. MCQs are considered to have a high degree of reliability as they have an objective scoring process and many items can be easily tested and marked.^{18, 19}

The validity of an MCQ assessment will vary dependent upon the content of the questions that are included, the way in which these questions have been constructed, the number of answer options and the type of distractors used.

As previously mentioned 3 answer option MCQs may potential increase content validity by increasing the number of questions in the given exam time. The presence of item-writing flaws will decrease validity.

Educational impact

MCQs tend to be used for summative rather than formative assessment, with no feedback provided to the candidate. A weakness of MCQs is that they may encourage rote learning rather than understanding.²¹

Cobb et al compared the educational impact of MCQs compared to Direct Observation of Procedural Skills (DOPs) assessment in final year veterinary students. Results indicated that candidates took a surface learning approach, i.e. focussed on recall and reproduction, when studying for MCQs, whereas DOPs encouraged deeper learning.¹³⁷ This result is similar to findings in other studies.^{138, 139}

Summary

MCQs are primarily used for assessing knowledge, and assess at the 'knows' level of Miller's Pyramid. There is, however, evidence that, if constructed appropriately, they can assess higher order cognitive processes such as interpretation, synthesis and application of knowledge.^{20, 22, 23}

4.4.3. Extended Matching Questions (EMQs)

The extended matching question (EMQ) is a more recent variation of the traditional MCQ format, which is increasingly being used in medical assessment.^{28, 140, 141}

Whilst the format of EMQs may vary slightly, they are generally themed and will consist of a lead-in statement (which tells the candidate what to do), a number of answer options (which may contain distractors) and a number of questions (or stems). The candidate must select one or more answer options for each of the questions.^{21, 141}

EMQs can be used to assess knowledge and application of knowledge, as clinical scenarios are frequently employed in question setting.

The following example of an extended matching question is adapted from the Royal Australasian College of Physicians (RACP) instructions to candidates for the divisional written examination.¹⁴²

Choose the most appropriate option, from A to H

Option list:

- A. Ankylosing spondylitis
- B. Aortic dissection
- C. Prolapsed intervertebral disc
- D. Lumbar spondylosis
- E. Vertebral fracture
- F. Intervertebral disc infection
- G. Pars interarticularis defect
- H. Metastatic malignancy

For each patient with back pain, select the most likely diagnosis.

1. A 23-year-old man has a six-month history of low back pain. This is predominantly at the thoracolumbar junction and in the right buttock. His pain is worse in the morning and he has difficulty in getting out of bed. There is some improvement during the day. Examination shows restriction of lumbar spinal movement, particularly lateral flexion.

Answer: A

2. A 32-year-old woman presents with acute onset of low back pain. The pain is constant and is not significantly affected by posture. All spinal movements are painful and difficult. Three weeks earlier, she had a urinary tract infection, which had been treated with Amoxicillin.

Answer: F

Advantages

EMQs have all the advantages previously stated for MCQs, as well as several others.

EMQs have several questions with an extended option list of possible answers, this makes it more difficult for the candidate to guess the correct answer^{27, 28} and minimises cueing as a more complex understanding is required.^{28, 29}

EMQs are written as clinical scenarios, so may be considered more authentic than other test formats.²⁸ In addition, they can test diagnostic ability, clinical judgement and application of knowledge.^{21, 27}

A further advantage to EMQs is the potential flexibility that they afford to assessment writers. Numerous stems may be devised, allowing different stems to be used for the same EMQ over several different assessments. Alternatively, the lead in statement may be modified to change the intent of the question without changing the structure of the EMQ.^{27, 141}

Disadvantages

Many of the problems and concerns with question writing in MCQs also apply to EMCQs.

Feasibility

The feasibility of EMQs will be essentially the same as that for MCQs, although EMCQs may be more difficult and time consuming to write.¹⁴⁰

If EMQs are replacing MCQs, it will take time to establish new question banks, and require significant resource input with respect to developing and assessing the validity of new questions. In addition, if computer marking and statistical analysis are to be employed, investment in both hardware and software may be needed.¹⁴⁰

If EMQs are to be introduced into assessment formats candidates will need to be advised, and the concept introduced to those who may be unfamiliar with it.

Validity and reliability

The EMQ appears to have good reliability when compared with MCQs and short answer questions.^{21, 28} Whilst evidence to support reliability and validity is limited, it does appear to be supportive.²⁷

Educational impact

No specific evidence regarding the educational impact of EMQs separate to MCQ could be identified from the search results.

Summary

EMQs test at the 'knows how' level of Miller's Pyramid. They can be used to assess knowledge and clinical reasoning skills.

4.4.4. Computer adaptive testing

Computer based testing is being increasingly used to assess candidates. A relatively new area of computer based testing is the ability to use technology to customise the assessment process dependent on the candidate's ability level.

Computer (or computerized) Adaptive Test (CAT) uses ability estimation to rank candidates from lowest to highest according to their performance.

There are 5 components to a CAT:³⁴

1. Calibrated item bank
2. Starting point
3. Item selection algorithm
4. Scoring algorithm
5. Termination criterion.

Items presented to a candidate are selected from a pre-calibrated pool of questions, or item bank, according to an algorithm. The first question (starting point) is randomly selected, and is usually a question rated as having a medium level of difficulty. If the candidate answers the question correctly, they will be administered a slightly harder one. If they answer incorrectly, an easier question will be selected from the item bank.

Each time a question is answered, the question is scored, and an estimate of the candidate's ability obtained. The computer then queries the pre-defined termination criteria to see if they have been met. If they have, the assessment will end, if they haven't another question will be administered.

Termination criteria will vary according to the design of the test. Some CATs are fixed length, which means the assessment will end when a pre-determined number of questions has been delivered. Due to the adaptive nature of the assessment, however, CATs can be designed to allow for variable-length testing. This means the assessment terminates when pre-determined statistical criteria are obtained. A commonly used termination criterion is the minimum standard error criterion, which stops the assessment when a specific standard error is reached. This variable length testing means that different candidates may be presented with a varying number of questions, dependent on how quickly the termination criteria are met.

Most CATs use item response theory to calibrate assessments and facilitate item selection.^{34, 143} These are mathematical functions that calculate the probability of a specific candidate answering a particular item correctly. A widely used item response theory model is the Rasch model, which uses the single parameter of 'item difficulty' to estimate item and student characteristics.³²

A different type of variable length test is used for situations where candidates are being categorized into one or two categories (for example pass/fail). These are known as variable length computerized classification tests. Whilst these tests use computer technology, calibrated item banks and decision making algorithms to maximise information around a 'cutscore' (or pass mark), they do not take candidate ability into account and are not truly adaptive.¹⁴⁴

Advantages

CATs can assess a candidate's capability more quickly than a traditional MCQ format, and require less items to be administered; resulting in a shorter testing time.^{30, 31} Use of CAT can reduce the assessment time by 50% without compromising reliability.^{143, 145} This can have advantages in examination scheduling and adjudication resources.

There is also evidence that the CAT format assesses the capability of candidates more precisely, especially either low or high achievers.^{32, 33}

Disadvantages

Due to the way in which the CAT is administered, certain items tend to be used more frequently than others, whilst some questions (i.e. those at either extreme of difficulty) may be used minimally, if at all. This has two potential problems; firstly, the resources associated with developing questions that are rarely or never used

and secondly, the security risks that may occur with frequent exposure to certain questions. Such 'over-exposure' can result in candidates sharing question items with future candidates.^{146, 147} There are numerous CAT methodologies that can overcome such problems,¹⁴⁸ and a large pool of pre-calibrated test items will also help to maintain examination integrity.³²

There is some evidence that candidates with higher test anxiety perform less well in a CAT than in a traditional fixed item test.¹⁴⁹ This could lead to the possibility of bias in the assessment process. There is also evidence that informing candidates about the CAT assessment process may result in increased test performance.¹⁴⁹

Reliability and validity

Reliability of a CAT can be improved by ensuring candidates receive clear instructions regarding the test process, and are familiar with the CAT format.¹⁴³ Screen design with respect to control icons, readability, attention, clarity and instruction should also be considered by a CAT designer.¹⁴³ Internal consistency reliability can be measured by reviewing assessment responses to ensure item correlation between items at the same difficulty level for a given candidate.¹⁴³ Inter-rater reliability will be high as the assessment process does not rely on evaluator input. Test-retest reliability for a CAT (i.e. will a candidate receive an equivalent score if the test is administered at two different points in time), can be determined prior to implementation by pre-implementation testing.

Test security must be ensured to maintain high levels of reliability and validity, and concerns with 'over exposure', as discussed above, must be addressed. Identification of the candidate must be confirmed; this may be particularly problematic if CAT is administered over the internet, and the use of testing centres is advisable.

Although CATs may be of shorter duration than traditional MCQ assessments, it is important to ensure that all content that needs to be assessed is covered in the testing process, otherwise content and construct validity will be compromised.³² It is possible to design a CAT that delivers a fixed percentage of questions from specific domains within the pool, hence ensuring adequate content coverage. This will, however, reduce the efficiency of the adaptive algorithm as it interferes with the process of selecting the most discriminating test items.³⁴

Feasibility

Introduction of a CAT process requires significant resource investment, both in technology and labour. An organisation must have access to sufficient psychometric expertise to develop and evaluate the assessment methodology.³⁴ In addition, CAT relies on an extensive item bank of questions, which must be developed, pre-tested and calibrated with item response theory calibration software.³⁴ It is possible to use an existing item bank, but it will need to be calibrated, and new items will have to be added.

It is important to consider whether converting to a CAT is going to bring sufficient reduction to test length to justify set up costs.³⁴ As discussed previously, when using for certification purposes, it is important to ensure adequate content sampling to maintain validity, this may limit the potential reduction in items required. There are simulation models that can be employed to estimate test length, score precision, item exposure and size of the item bank that will be required to produce the desired score precision.³⁴

4.4.5. Viva Voce/oral exams

A definition of the viva voce (commonly referred to as the viva) is an '*oral examination characterised by face to face interaction between an examinee and one or more examiners*'.¹⁵⁰

Whilst the viva was once a common assessment method for undergraduate, postgraduate and professional examinations, its use has declined, and it has been increasingly replaced by other assessment methods.³⁵

Advantages

The viva may be useful for the assessment of the following characteristics; some of which are difficult to measure via alternative assessment techniques:^{35, 36, 150}

- Clinical reasoning
- Decision making
- Communication skill
- Problem solving and reasoning
- Judgement
- Ethics
- Ability to think on one's feet
- Clinical competence
- Professionalism

The viva allows the assessor flexibility to move between different subjects, and to tailor the questions to the candidate, thus making the assessment more individualised.^{35, 36}

Disadvantages

Viva examinations are often unstructured, and a wide variation may occur in the questioning of different candidates by different assessors. Assessors may direct the questioning to areas they themselves are interested or experienced in.³⁵ The viva assessment is thus subjective in nature, as the assessor may, to some extent, choose the topics that are discussed and decide how deeply they will probe areas of knowledge with different candidates.

The appearance and attitude of the candidate may also impact on the assessor's rating; gender, social background and ethnicity have been shown to inappropriately influence assessors.^{35, 36} Levels of prompting may also vary between assessors, and assessors assessing a number of candidates may subconsciously start to rank the candidates, or compare one against the other, in a subjective manner.^{35, 37}

Feasibility

Oral examinations are relatively easy to prepare, organise and run; facilitating the assessment of many candidates in a relatively quick time.

Validity and reliability

Any assessment that lacks formal structure will be prone to errors of variability. Traditional oral assessments have low reliability.³⁶ The subjective nature of the viva and variations in subject matter, questioning, prompting and attitude of the assessor may all lead to differences in the examining standards between different candidates and different assessors. Inter-rater reliability of vivas is, therefore, generally poor.³⁵

Validity of the viva is difficult to establish, as to some extent validity is dependent on the questions asked by the assessor and the content covered. As discussed earlier, these questions may vary from candidate to candidate and assessor to assessor. To some extent the flexibility of the viva and the potential to vary content matter may actually enhance some aspects of validity.³⁶

Much can be done to improve the traditional viva. Careful selection of assessors with subsequent training (as discussed below), use of formal structured questions to cover pre-defined topics and a structured method of rating, have all been employed to make results more reliable.^{35, 37, 38}

In 1995 Wakeford et al reviewed improvements to assessor training for the Membership of the Royal College of General Practitioners (MRCGP) oral examination. They concluded that correlation between pairs of examiners had increased following introduction of assessor selection, training and performance review processes.³⁷

In 2010 Cobourne published a paper which further discussed some of the modifications that the Royal College of General Practitioners in the UK had made to the oral component of the MRCGP examination.³⁵ Changes introduced to improve reliability included requirements for assessors to:

- Provide extensive references to support experience
- Attend two days of oral examinations as observers
- Sit a recent MRCGP MCQ examination
- Mark a representative section of candidate scripts
- Have their core examiner skills formally evaluated at an assessment day

If the results of any of these assessment processes caused concern, the potential examiner was not appointed.

In 2003 Wass et al evaluated changes to the MRCGP oral format that were introduced in 1998.³⁹ These included a reduction in oral length from 30 to 20 minutes, a cut in individual question length to increase the number of topics per viva and the introduction of a blueprint grid to ensure a wide spread of topics with no content overlap. (Wass 2003). In addition, the assessors, who worked in a 'two-pair quartet' (i.e. two examiners for each of the two consecutive oral assessments), met prior to the assessment session to plan the topics to be covered. Analysis of 896 candidates who took the orals indicated an inter-case reliability coefficient of 0.65 (benchmark 0.8) and pass/fail reliability of 0.85 (benchmark 0.9). It was estimated that benchmark results could be obtained by increasing the number of two-examiner orals to four, or by using five one-examiner orals. The authors concluded that oral examinations can achieve good reliability if sufficient resources are available.

It should be noted that the Royal College of General Practitioners no longer uses the viva as a method of assessment for its membership examinations. Instead it currently employs a written MCQ applied knowledge test, a clinical skills assessment and workplace based assessments.¹⁵¹

Educational impact

Oral examinations tend to be used for summative rather than formative assessment, with no feedback provided to the candidate.

There is evidence that, when preparing for an oral examination, candidates employ a deeper learning approach than that used when preparing for a MCQ.¹³⁹

Summary

Vivas generally test the candidate at the 'knows how' level of Miller's Pyramid. Whilst vivas may be unreliable, they remain useful tools for assessing clinical reason, problem solving and decision making functions; skills that may be difficult to test by other assessment methods. By using appropriate assessor training and assessment technique, some of the issues of reliability may be overcome.

4.4.6. The Objective Structured Clinical Examination

The Objective Structured Clinical Examination (OSCE) was first introduced in the 1970s as a means of objectively assessing clinical skills in medical candidates.¹⁵² The OSCE provides the ability to test multiple skill sets in a controlled environment.

Khan et al define the OSCE as *'An assessment tool based on the principles of objectivity and standardisation, in which the candidates move through a series of time-limited stations in a circuit for the purposes of assessment of professional performance in a simulated environment. At each station candidates are assessed and marked against standardised scoring rubrics by trained assessors'*.⁴⁵

The original OSCE used a series of paired stations, where the candidate would perform a task at an initial procedural station and then respond to a series of questions about the task in the second associated station. This process limited the 'cueing effect', where candidates are given cues regarding what to look for or do in the procedural station, based on the questions they must answer. The candidate may be observed at some procedural stations by assessors who use a checklist to capture information. The results from this checklist combined with the number of correct answers in the second station gives a final score. This process is then repeated at additional stations which assess other clinical skills. The original OSCEs used stations of 5-minute duration and proposed 16 stations as a convenient number.

Since development of the original OSCE, increasing numbers of medical schools across the world have taken to using this method of assessment,^{42, 153} and its use has spread to nursing and allied health professions, including pharmacy.^{42, 154}

The original format has evolved over the years, and methodology varies amongst different users.^{40-42, 46, 155, 156} Common adaptations include changes to the number of stations, combined task and assessment stations, increased station duration and increased focus on the interaction with the patient/client. The use of a longer station allows for a more complete and holistic assessment, and facilitates assessment of other professional skills such as communication and behaviour. A number of variants of the OSCE have also been developed to assess different competencies. These include the Objective, Structured Video Examination and the Objective Structured Assessment of Technical skills.⁴⁵

Marking tools have also evolved since OSCEs were first introduced. The simplest of OSCE marking tools operate like a checklist where assessors mark whether an element is achieved or not. Global rating scales, which allow differentiation of performance, may also be applied; for example, Likert scales can be used to rate performance from poor thorough to excellent. In practice, both types of rating tools may be used in an OSCE assessment to measure different aspects.^{29, 157}

The OSCE may be used as a summative or formative assessment, and is employed in undergraduate, entry to practice and postgraduate settings.^{41, 45, 153-155, 158, 159}

Advantages

OSCEs provide an objective, standardised approach to assessment, and can be used to facilitate assessment across a wide range of clinical contexts.⁴⁰ They may be particularly useful for assessing performance in areas that are difficult to observe, and provide the opportunity for the candidate to be assessed in an environment that is not harmful to a patient.⁴¹

OSCEs are predominantly viewed positively by both assessors and candidates,^{42, 160, 161} and can be used to provide immediate feedback to candidates in formative situations.

It is possible to test multiple clinical tasks in one assessment session,⁴² although Khan et al caution that effective assessment of multiple skills at a single station may be difficult due to time constraints.⁴⁵

By using standardised patients (either a 'real patient' trained to present their condition consistently or an 'actor' briefed to present their condition in a standardised way), it is possible to reduce variation in the information supplied to the candidate, and the level of co-operation that they may receive from the patient.

Disadvantages

There are concerns that whilst OSCEs facilitate assessment of individual clinical elements, they do not assess the candidate's ability to view the patient holistically.^{42, 43} In addition, actors playing standardised patients may

not be able to authentically represent complex patients. Both issues may suggest that whilst OSCEs are useful in an undergraduate setting, they may not assess the extensive knowledge, skills and attributes that are required by postgraduate students^{43, 155}.

There is evidence that candidates find OSCE assessment a stressful process,^{42, 160-162} and the simulated environment may result in candidate performance being different to that in their workplace.⁴⁵

Feasibility

A major feasibility concern lies in the resourcing of OSCEs, with both the preparation and administration being labour intensive.^{42, 43, 45, 46} OSCEs need to be run in a suitable environment with access to the necessary equipment to simulate clinical scenarios. In addition, access to medical reference information may need to be provided. Costs can be minimised by employing lower cost alternatives such as volunteer standardised patient, re-writing previous scenarios and using an office based environment rather than a simulation centre.¹⁵³

Validity and reliability

The reliability and validity of OSCEs will vary according to design and methodology, and should, ideally, be established for individual assessments. There are, however, several generalised factors which can influence the reliability and validity of the OSCE.

- **OSCE stations:**
Both reliability and validity can be improved by increasing the number of stations over which the candidate is assessed.^{42, 43, 45} Increasing the time spent on each station also increase reliability.^{41, 43}
- **Marking tools:**
Use of a standardised marking tool, to ensure that assessors are marking all candidates against the same criteria, will improve reliability.⁴⁵
- **Evaluators:**
Whilst inter-rater reliability of OSCEs is generally moderate to good, it can be improved by using two assessors per station. This is often not feasible due to resource implications, in which case random quality checks by second markers may be a compromise.⁴² Appropriate training of assessors improves reliability.^{19, 45}
- **Patients:**
Use of standardised patients will reduce variations in performance hence improving reliability.^{43, 45}

Educational impact

Boursicot et al suggest that use of OSCEs will drive learning and encourage candidates to practice clinical skills.¹⁶³ They recommend the use of rating scale marking schedules rather than checklists, to encourage students to practice skills more holistically. If OSCEs are to be used for educational purposes, time should be allowed at the end of each station for the assessor to provide the candidate with feedback, thus facilitating a learning situation. When used for summative purposes candidates should be advised of the expected competencies, so they can learn or practice the requisite skills prior to the assessment.

Khan et al state that positive educational impact is dependent on creating realistic scenarios for the OSCE stations.⁴⁵

A small qualitative study by Jay evaluated student midwives' perceptions of the OSCE. The study suggested that preparation for OSCEs encouraged deeper learning, promoted shared learning, and motivated students to learn the actual psychomotor skill, rather than just knowing how to perform it.¹⁶⁰

Summary

OSCEs can be used to test a wide range of clinical, technical and practical skills. They are also useful in the assessment of higher order skills associated with problem solving. The OSCE can also assess behavioural, interpersonal and communication skills.¹⁵³

The OSCE has the benefit over other assessment techniques in that candidates can actually demonstrate competence to an assessor; it therefore sits at the 'shows how' level of Miller's Pyramid.^{19, 40-42} It is worth noting, however, that any simulation is not going to achieve the same level of assurance as observing actual clinical practice, where the 'does' level in Miller's Pyramid can be assessed.

4.4.7. Workplace-based assessments

With a shift in the emphasis towards assessment of competence and performance rather than just knowledge, there has been a need to develop assessment tools that can be used to evaluate performance in the environment in which the practitioner works. Workplace-based assessment (WPBA) '*allows the collection of evidence during normal work activities in order to decide whether a required standard has been achieved*'.⁶³

To facilitate such assessment a range of WPBA tools have been developed. The following section reviews the evidence relating to several of these tools which have been used in the assessment of pharmacists.

Case-based Discussion

Patient cases have been used as a means of teaching in pharmacy for a long time, often by means of case presentations to peers in continuing education sessions. Case-based Discussion (CbD) is a method of formalising this process to allow assessment of the case and facilitate feedback to the student/practitioner.

CbD involves a comprehensive review of a clinical case between a student/practitioner and an assessor. The student/practitioner will typically prepare and present a case that they have been significantly involved with. Presentation may include presenting complaint, patient history (including medicines), clinical investigations and findings, management plan and follow up. The assessor will then provide feedback, using a structured tool to 'score' the student/practitioner, and suggestion for ongoing development or training needs will be identified.⁵⁶

Traditionally the CbD has been used as a training tool, and is mainly used in formative assessments.^{56, 64, 164} It is, however, potentially a useful tool for appraisal or revalidation processes.¹⁶⁵

In order to standardise assessment and feedback, CbD tools have been developed.^{166, 167} One such pharmacy specific CbD tool has been developed by the Joint Programmes Board in the UK and has ratings for pharmaceutical needs assessment, treatment recommendation, follow up/monitoring, professionalism and overall clinical judgement.⁵²

Advantages

The CbD is designed to assess clinical reasoning, decision making, professional judgement, and application of knowledge and professionalism; skills that are often difficult to assess by means of a written exam.^{56, 64, 164, 168} It has the advantage of demonstrating something that the student/practitioner has been actively involved in, whilst allowing them to explain why they acted as they did. The CbD can be considered an authentic assessment method as it uses patient cases from the student/practitioner's own workplace, and it can be used at any level of experience.¹⁶⁹

Disadvantages

In the preparation of the CbD for presentation, the student/practitioner may reflect on their case, and research information in anticipation of the questions. Whilst this is a positive outcome in terms of training and development, the CbD itself may not truly reflect the student's knowledge base and clinical decisions at the time of their involvement with the patient.

Most rating scales may ask the assessor to rate against linear gradation scales such as unsatisfactory through to superior.¹⁶⁷ Different raters may have different interpretations of these scales dependent on their experience and standards. Raters may also be disinclined to rate in negative sounding categories such as unsatisfactory or poor.⁶² Other scales are designed to assess performance in relation to the stage of training, for example, ratings such as below expectations through to exceed expectations.^{52, 166} Raters may be unsure what is actually expected for a stage of training, and may also be hesitant to rate a student/practitioner as below expectation, especially if they are reaching the end of their training period.⁶²

Feasibility

The CbD is a relatively cheap and easy to administer assessment, requiring little preparation on the part of the assessor. It is also relatively quick, with assessments taking between 20-30 minutes.^{64, 164, 170}

Trainers have expressed difficulties with providing feedback during CbD, and for these tools to be used properly it is recommended that training is offered to assessors.^{164, 171}

Validity and reliability

There is little published information about the reliability and validity of CbD, although it is considered to have face validity.^{164, 168} CbD only assesses the student/practitioner's management of one specific case at one point in time, and the number of CbDs that a student/practitioner participates in is likely to be low. This means the content validity is limited, particularly if the student/practitioner chooses cases from similar clinical areas.¹⁶⁸ Construct validity is considered high because the tool assesses actual practice in the work place.¹⁶⁸

The reliability of CbD is dependent on the assessor's ability to respond to the presentation and use rating scales appropriately.¹⁶⁸ Reliability is affected by the rater's training and experience, as well as the standardisation of the process. Reliability can be improved using standardised assessment and rating tools, which ensure the appropriate skills are tested, and reduce the risk of inter-rater variation. Instruction sheets for assessors can also be prepared with standardised questions.¹⁷²

Educational impact

Several systematic reviews on work based assessments have found there is little published evidence for the educational impact of CbD.^{59, 63, 173}

Successful use of the use of the tool is dependent on appropriate application, and feedback by the assessor or trainee. Bodgener and Tavabie reported that students/practitioners found feedback overwhelmingly useful,¹⁶⁴ whilst other studies report mixed opinions relating to feedback, with some students/practitioners expressing concerns that assessors may not be engaged with the process.^{56, 171}

Summary

The CbD assesses the candidate at the 'does' level of Miller's Pyramid.^{169, 170} It is useful for assessing clinical decision making, problem solving skills and application of knowledge. The CbD is typically employed in training and formative assessment, as it can be used to demonstrate the student/practitioner's input into patient care.

Validated tools will improve the reliability of the assessment, along with the use of structured questions for the assessor.

Multisource feedback

Multisource Feedback (MSF) is the process by which an individual receives feedback on their work performance from peers, managers and subordinates. Other descriptors include peer assessment, multi-source assessment, 360-degree feedback, 360-degree appraisal, peer review, and peer rating.¹⁷⁴

The MSF process facilitates feedback from a range of co-workers, providing insight into the way that others perceive performance, and identifying areas for change through self-reflection. In medical settings, feedback

may also be sought from patients.^{61, 174, 175} Whilst initially considered a formative assessment process, MSF is now also used in summative and high stakes assessment.^{61, 176, 177}

MSF is a useful method for assessing communication, professionalism, collaboration, leadership, decision making, judgement and clinical skills.^{176, 178}

Although MSF was originally developed by industrial organisations to improve leadership qualities, its use is becoming increasingly common at a global level to provide evidence of professional behaviours in healthcare.¹⁷⁴

Healthcare specific tools have been developed to facilitate the MSF process. These tools typically collect information in the form of rating scales, but usually allow the rater to add qualifying statements in the form of free text.

In Canada, the College of Physicians and Surgeons of Alberta introduced MSF tools as part of the Physician Achievement Review process.¹⁷⁹ This process uses separate questionnaires, for co-workers, medical colleagues and patients.

In the UK, the Sheffield Peer Review Assessment Tool (SPRAT) was developed to assess paediatricians in training.¹⁸⁰ The tool was subsequently modified to the mini-peer assessment tool (mini-PAT), which is used in postgraduate medical training.¹⁸¹ These tools use a combined assessor rating for peers and co-workers, such as nursing staff and pharmacists.

A pharmacy mini-PAT has also been developed in the UK,⁵⁰ where its application as an assessment method for general level pharmacists has been evaluated.^{51, 182}

In the UK, doctors are required to undergo a MSF assessment every five years as one component of their General Medical Council (GMC) revalidation.^{83, 183} Validated questionnaires, assessing both patient and peer assessment of the doctor's professional practice, have been developed to assist in this process.⁸³

The first process in MSF is for the candidate to nominate several assessors, who they believe would be appropriate to provide them with feedback. The typical number of assessors chosen is between 6-15. It is recommended that assessors from a range of professional backgrounds are nominated. Verbal or written consent from assessors is usually obtained by the candidate. Depending on the tool employed, the candidate may be asked to complete a self-assessment before the MSF tool is distributed to the assessors. Information may be supplied with the tool to provide guidance to assessors as to how to conduct the assessment. The tool itself may be paper based or electronic. Feedback is anonymous and the assessors usually return the completed tool to a central coordinator for collation.^{50, 174} Collated feedback to the candidate is usually then facilitated by an educator, mentor or supervisor.

Advantages

Review of MSF provides the opportunity for the assessor to get an overview of how others perceive the candidate at work, and how they relate to other professions within the healthcare environment. It facilitates comparison with other candidates, and offers the opportunity to compare self-perception with peer perception.¹⁷⁴

Review of the assessment can be used to identify strengths and weaknesses of the individual.

Davies et al concluded that the pharmacy mini-PAT was a useful tool for monitoring performance improvements in junior pharmacists who were enrolled in a postgraduate pharmacy course.⁵¹

Disadvantages

Most MSF tools rely on the candidate nominating the peer assessor. Although Ramsey et al demonstrated that peer ratings are not biased substantially by the method of selection of the peers, or the relationship between the rater and the subject,¹⁸⁴ there is concern that the candidate may nominate colleagues they

believe may provide favourable reviews.^{50, 61} This concern is substantiated by two studies which show candidate nominated assessors gave significantly higher ratings than those given by clinical supervisors or assessors nominated by the employer.^{60, 185} Candidates also acknowledged that they often chose assessors that they have a positive relationship with.⁶⁰

This can be overcome to a certain extent by the supervisor reviewing peer choices and encouraging nomination of a wide group of peer assessors.

Raters base their assessment on their perception of overall student performance. Any views offered are personal views, and may be influenced by the experience and standards of the rater. Candidates have expressed concern that feedback may not be based on direct knowledge.^{61, 186} In one study although the majority of raters stated they based their feedback on direct observation, a large minority said they used indirect evidence obtained from colleagues.¹⁸⁶ This has the potential to reduce the number of individual views and increases the risk of biased preconception.

Candidates may also have the perception that assessors are reluctant to give negative feedback, thus devaluing the MSF.^{60, 61}

Feasibility

The feasibility of MSF appears to be good.^{176, 187} Assessors and supervisors generally find the tools easy to use,^{83, 186} and the time to complete the assessment and feedback process appears acceptable.^{180, 186}

Providing feedback to the candidate is an essential component of MSF, and it is recommended that the supervisor providing the feedback is appropriately trained in feedback techniques.^{174, 188} This may limit the application of MSF in organisations that do not have access to such training.

Validity and reliability

As MSF tools vary, there is a need to demonstrate validity and reliability for each individual tool, and some such evaluations have occurred. Validity and reliability have been demonstrated in a variety of MSF tools, including SPRAT, mini-PAT, pharmacy mini-PAT GMC questionnaires and Physician Achievement Review process.^{51, 83, 179, 180, 187, 189, 190}

The number of peer assessors required to ensure reliability varies from study to study and tool to tool. Ramsey et al suggested that peer ratings from 11 physicians were needed to provide reliable ratings on a physician assessment tool.¹⁸⁴ Validity and reliability assessment of the SPRAT tool found that only four raters were required to achieve an acceptable reliability score with respect to satisfactory performance.¹⁸⁰ Validation of the questionnaires recommended by the GMC, suggest that whilst reliability and validity scores were acceptable for formative assessment, at least 34 patients and 15 colleague questionnaires per doctor are required to achieve a reliability score that is acceptable for high stakes assessment.⁸³ There is also evidence from validation of these questionnaires that feedback is biased towards the positive. In their systematic review Donnon et al concluded that across most instruments a minimum of eight medical colleagues, eight co-workers and 25 patients was required to obtain adequate reliability scores.¹⁸⁷

Different assessor groups may assess differently, and this may be an important consideration for MSF tools such as SPRAT and mini-PAT which combine assessor ratings.^{83, 191} There is also evidence that MSF is not a reliable method of identifying poor performance in doctors.^{83, 185, 186}

Educational impact

A systematic review by Miller and Archer found that most doctors felt MSF had educational value, although evidence for practice change was conflicting. The review concluded that MSF can lead to performance improvement, although factors such as feedback and facilitation can have a profound effect on the response.¹⁷³

Some papers report improvement in motivation and overall performance amongst staff undergoing 360-degree reviews.¹⁷⁴ Evidence is, however, conflicting, and some papers describe anxiety, discouragement and anger, particularly when negative feedback is received.^{61, 188, 192}

Sargent et al evaluated outcomes of MSF in family practitioners, and concluded that positive feedback resulted in few improvements to practice, whilst 'negative' feedback, suggesting a need for improvement, resulted in only selective improvements.¹⁹² Almost a half of doctors who received negative feedback did not accept it. In another study, nearly a third of trainees did not anticipate making changes to their practice as a result of MSF.¹⁸⁶ Resistance to change is greatest when the candidate perceives that feedback is coming from assessors whom have not actually observed their performance.¹⁹²

Candidates find the free text comments to be more valuable than the ratings, but there is a perception that areas of strength are documented more frequently than areas for improvement^{60, 186}

Summary

MSF is a widely used and well accepted assessment process. It assesses at the 'does' level of Miller's Pyramid. New tools will need to be validated prior to introduction. Due to concerns regarding the objectivity of rater assessment, MSF should not be used in isolation to inform decisions about a practitioner's fitness to practice.

Direct observation

Direct observation is an important element of both training and assessment of a student/practitioner, and involves the assessor observing the student/practitioner in a working environment. Numerous tools have been developed to facilitate assessment of competency by direct observation;¹⁹³ this review will focus on those commonly employed.

The mini-Clinical Evaluation Exercise (mini-CEX) was first developed in the US, and is widely used in assessment of doctors in the US¹⁹⁴ and the UK.⁵⁷ It is also used in the Basic and Advanced Training Programs for the Royal Australasian College of Physicians (RACP).¹⁹⁵ The mini-CEX has been adapted for use in the assessment of pharmacists in the UK.⁵²

The mini-CEX, as the name would suggest, is a short observational assessment, usually of a specific clinical encounter. The assessor uses rating scales to assess clinical, decision making, organisational and communication skills. Strengths and suggestions for development are usually documented, and verbal feedback is also provided by the assessor.

The Direct Observation of Procedural Skills tool was developed in the UK with the purpose of evaluating procedural skills in postgraduate trainees.⁶⁴ It is predominantly used in the formative assessment of doctors, to provide feedback on procedural technique. It has limited application within the pharmacy context and will not be discussed in detail in this review.

In Australia, professional competency tools have been implemented to support pharmacy practitioner development through a process of direct observation and feedback. Both the Queensland Health General Level Framework (GLF)¹⁹⁶ and the SHPA Clinical Competency Assessment Tool (shpaclinCAT)¹⁹⁷ were adapted from the original Competency Development and Evaluation Group (CoDEG) GLF.¹⁹⁸ These tools take considerably longer than the mini-CEX to complete, and greater emphasis is placed on feedback and the production of an education and training plan for the pharmacist. It should be emphasised that these tools were designed with professional development and training as their primary goal, rather than as a summative assessment method.

The GbCF was published by the International Pharmaceutical Federation in 2012.⁵³ It was developed through the identification of common behaviours from eight international pharmacy documents, including the Competency Standards for Pharmacist in Australia 2003 and the CoDEG GLF. The framework contains a

core set of behavioural competencies for foundation pharmacists, and is primarily considered as a mapping tool to be used for developmental purposes. The framework can, however, be attached to an assessment grid, enabling it to be used for direct observation assessments. The document guidance states that this is primarily to aid countries that do not currently have a competency assessment framework, but wish to develop one.

Advantages

Direct observation provides the opportunity to see the student/practitioner working first hand in a clinical environment. Whilst it is possible to assess a student/practitioner in a controlled environment, competence in such an environment does not predict workplace performance.¹⁹⁹

Direct observation facilitates assessment of skills such as interaction with patients and families, compassion and empathy,²⁰⁰ which would be impossible to assess otherwise. It also provides the opportunity to observe the student/practitioner's interaction with other healthcare professionals and assess the student/practitioner's place in the healthcare team.

Disadvantages

It is a well-recognised effect that once people are aware they are being observed, they intentionally or unintentionally modify their behaviour. This is called the Hawthorne effect, and means that students/practitioners undergoing observation will attempt to perform at their very best, rather than practice at their normal level.²⁰⁰

The disadvantages of rating scales, as discussed relating to clinical-based discussions, also apply to those typically used in direct observation tools.

Students/practitioners may find direct observations stressful or taxing.¹⁹⁶

Feasibility

Direct observation generally requires the assessor to complete the observation in the student/practitioner's usual workplace, and the logistics of organising this may prove difficult.

It is recommended that assessors performing observational assessments are trained to do so. Evaluators were trained in the use of the Queensland Health GLF prior to its introduction,¹⁹⁶ and SHPA has training requirements for shpaclinCAT evaluators.²⁰¹

Assessors who received comprehensive training on how to conduct a direct observation assessment feel more comfortable about conducting observations, and rate students/practitioners more stringently than those who do not receive training.²⁰²

The mini-CEX takes approximately 20 minutes to complete, this gives it the potential to be employed on multiple occasions across a year. The RACP currently require a minimum of four assessments per year in their 'Basic Training' program.²⁰³ Both the GLF and shpaclinCAT take considerably longer to complete, minimising the feasibility of using them across a large student cohort.

Brazil et al investigated the cost and feasibility of adding the mini-CEX into the existing assessment processes of 20 medical interns in the emergency department of a large teaching hospital in Queensland.²⁰⁴ They identified significant increase to costs associated with assessor time, as well as difficulties in the practicalities of arranging and conducting the assessments; a problem that has been identified in other studies.^{58, 205}

Validity and reliability

Of all the direct observation tools, the strongest validity evidence is for the mini-CEX,²⁰⁶ with several papers reporting acceptable validity.^{63, 205, 207, 208}

Reported inter-rater reliability for the mini-CEX varies. Kogan et al report variation in ratings across different levels of assessor,²⁰⁸ although there is evidence that ratings of overall clinical competence are consistent.⁶³ One study showed that 10 evaluations are necessary to ensure reliability.²⁰⁵

The GLF has been validated in the UK,²⁰⁹ Australia¹⁹⁶ and Singapore²¹⁰ as a formative tool to facilitate the evaluation of ward-based competencies of junior pharmacists, but has yet to be validated as a summative assessment tool. There is little published evidence to support the reliability of the GLF.

Educational impact

There is limited published information regarding the educational impact of the mini-CEX.⁶³ In one study medical interns felt that the mini-CEX provided timely and significant feedback and that formative impact was significant.²⁰⁴ Another study by Weston et al indicted that medical trainees did not perceive that use of the mini-CEX resulted in improvement in practice.⁵⁷ Mandated mini-CEX assessment in training programs has also been perceived as 'a hoop to jump through' by trainees.^{57, 58}

Coombes et al demonstrated that the GLF assisted in the identification of pharmacist's training needs. In addition, significant improvements in practice between baseline and repeat evaluations were seen in over half the competencies.¹⁹⁶ These findings are similar to Rutter et al,²¹⁰ who also demonstrated improvement in performance from baseline to repeat evaluation, and Antoniou et al, who demonstrated an acceleration in pharmacist practice development with use of the GLF.¹⁹⁸

Summary

Direct observation assesses at the 'does' level of Miller's Pyramid. It can be used to assess a wide skill set; including knowledge, practical skills, communication, judgement, decision making, professional relationships, workload management and professionalism. It is recommended that a validated assessment tool should be used to facilitate direct observation.

Whilst direct observation tools for pharmacists have been used for education and professional development purposes, there is no evidence regarding their use in summative assessment.

4.4.8. Portfolio

A portfolio can be described as a collection of information that is intended to demonstrate achievement.⁶⁵ Their intention is to capture longitudinal evidence of both professional and technical development, whilst encouraging self-awareness and self-reflection.⁶⁷

Portfolios can be used at any stage of education,⁶⁹ and have been introduced by numerous health professions in numerous countries.^{67, 79, 211} They are frequently used within tertiary education, but have also been used to capture evidence of continuing professional development, for registration requirements and for career progression.^{69, 71, 75, 212-214}

Whilst portfolios have been traditionally used as a practice assessment tool in a formative setting, their use in summative and high stakes assessment is increasing.⁶⁸⁻⁷⁰

Portfolios may be in paper or electronic format. The content will vary depending on the purpose of the portfolio, the requirements of the assessing body and the student/practitioner gathering the evidence for the portfolio.^{69, 212, 215}

Some key components include:^{69, 75, 79}

- Curriculum vitae
- Samples of performance evaluation (e.g. clinical placement reports)
- Action plans from direct observations

- Evidence of CPD
- Teaching presentations
- Critical incidents
- Quality improvement projects
- Evidence of research
- Written reflections on collected evidence and professional growth

Portfolios may also be used as a repository for completed WPBAs²¹⁶ (see section 4.4.7).

To successfully implement portfolio development as an assessment method, it is important to provide clear instructions to students/practitioners and assessors regarding the portfolio purpose, contents and expectations.^{68, 73, 74, 79}

Advantages

Evidence suggests that portfolios have the following benefits:^{67, 70, 71}

- Improved self-awareness and self-reflection
- Increased engagement with learning
- Increased responsibility for learning
- Identification of individual learning needs
- Improved self-confidence
- Encourage feedback between student and trainer
- Improved ability to learn independently and to integrate theory with practice
- Increased awareness of a student's needs for mentors
- Improved trust between student and tutor

Portfolios can be used to provide evidence of competencies that would otherwise be hard to assess, such as professional behaviour, practice-based improvements, creative endeavours, research activities and professional experience.⁷⁶ They are dynamic documents which capture evidence over a period of time, to demonstrate progress and provide a more complete picture of a student/practitioner's achievements, strengths, weaknesses and professional goals.

Disadvantages

Some studies indicate that use of portfolios for assessment may limit the reflective input from students/practitioners, who fear that honest documentation of incidents, problem areas, or difficulties may negatively impact the assessment outcomes.^{70, 73-75}

Feasibility

A number of studies indicate that students/practitioners find completion of portfolios time consuming, difficult to fit into their busy schedules and may even keep them away from other clinical learning.^{67, 70, 72, 73} In addition, students/practitioners perceive that the amount of paperwork required is excessive.^{68, 211, 213} The time required to review portfolios is also described as a disadvantage by assessors.²¹⁷

Many facilities have developed web based portfolios, which appear to improve flexibility of access to information for both users and assessors, motivate users and encourage reflection.⁷⁰ Some web based programs facilitate links with online peer evaluation tools and provide the ability to upload, files, videos, and

PubMed® searches.⁷⁹ Implementation of e-portfolios will, however, have resourcing implications, and requires a stable high quality information technology infrastructure.²¹⁸

Reliability and Validity

Whilst there is evidence to support portfolio review as a valid method for assessing competence,^{70, 74, 76, 77} some studies have highlighted concerns around the contradiction of encouraging original and reflective content whilst, trying to ensuring a structure that is valid.⁷⁰ Due to the nature of portfolios, the content will vary considerably from person to person, and there are also concerns that because portfolio contents are self-reported this may be a threat to validity.⁷⁵

A major concern with using portfolios in assessment is the inter-rater reliability. Individual portfolio assessors will vary in their experience and skills. Portfolio development is intended to provide evidence over a wide range of competencies and, as such, assessors will require clear and specific evaluation tools to make effective and reliable judgements.

Reviews evaluating the use of portfolios for summative assessment purposes have indicated a wide range in reliability scores.^{70, 74, 78} Training of assessors, increasing the number of assessors and using evaluation tools have been shown to produce good reliability rates.^{70, 74, 76, 79}

Educational impact

A systematic review published in 2009 specifically evaluated evidence regarding the educational effects of portfolio use.⁶⁷ The study concluded that whilst the quality of reported studies appears to be improving, the evidence surrounding educational impact remains limited. Higher quality papers identified improvements in knowledge and understanding, increased self-awareness, engagement in self-reflection and improved student-tutor relationships as the main educational benefits. Portfolio use was associated with improved ability to meet course objectives and integrate theory into practice. However, the authors note that quality of reflection cannot be assumed, and the time commitment required for portfolio use may detract from other learning.

Summary

Portfolios can be used for both learning and assessment, and can be used to assess competencies which are difficult to assess by other methods.

If they capture evidence from a range of settings, they should be able to assess at all levels of Miller's Pyramid.²¹⁹ Assessing content evidence around work place activities including work based assessment tools will assess at the 'does' level of Miller's Pyramid, whilst evidence such as case studies or teaching presentations may assess at the 'knows' or 'knows' how level.

When implementing a portfolio assessment process, the purpose of the portfolio must be clearly defined as should the content requirements and evaluation criteria.

4.4.9. Entrustable Professional Activities

A recent development in the assessment of professional competence is the introduction of EPAs. EPAs are statements of specific task-related activities that may require the integration of multiple competencies. Ten Cate describes EPAs as '*units of professional practice, defined as tasks or responsibilities to be entrusted to the unsupervised execution by a trainee once he or she has attained sufficient specific competence. EPAs are independently executable, observable, and measurable in their process and outcome, and therefore, suitable for entrustment decisions*'.⁸⁰ EPAs are, therefore, a way of operationalising competencies into clinical practice, and are descriptors of work rather than descriptors of the practitioner.⁸⁰ An example of an EPA statement used in the medical setting is 'gather a history and perform a physical examination'.⁸¹

When EPAs are used for assessment purposes, an educator or supervisor assigns a level of trust to the trainee performing a specific activity. This level of trust may be absolute, where the trainee is determined to be entrustable or not. Alternatively, rating scales may be employed, where the decision about whether a trainee can perform an EPA is translated to the level of supervision that the trainee requires. Ten Cate has defined such levels of supervision as follows:²²⁰

1. Be present and observe-trainee is present and observes what he or she will be expected to do at the next stage
2. Act with direct supervision-trainee may carry out the full activity independently. The supervisor is in the room watching and can intervene or take over at any time deemed necessary
3. Act with indirect supervision-trainee may carry out the full activity independently with a supervisor not present in the room but available within minutes
4. Act without supervision-the trainee may carry out the full activity with no supervisor available on short notice. The trainee reports post hoc the same or the next day
5. Provide supervision-a senior trainee may act in a supervisory role for more junior trainees

Stage four marks the degree of trust that would allow the learner to be entrusted with an activity. These levels can be linked to specific training milestones; i.e. what level of entrustment would be expected at a specific stage of training. For example, low levels of trust would be expected and appropriate for early learners.

To develop a EPA is generally necessary to consider the following:⁸⁰

- Whether it is possible to make and document an entrustable decision for the EPA
- Which competencies are required to perform the EPA
- How the EPA will be assessed (e.g. observation, workplace assessment tools)
- At what stage of training is unsupervised practice (or full entrustment) expected
- Basis for entrustment decisions (e.g. the number of times the activity must be performed proficiently to be entrusted)
- How will formal entrustment be recognised (e.g. documentation, certification)

Most of the experience with EPAs lies in medical education. In Australia EPAs are used in the Fellowship program of the Royal Australian and New Zealand College of Psychiatrists. Examples of EPAs within this program are shown below:²²¹

- Use of an antipsychotic medication in a patient with schizophrenia/psychosis
- Management of substance intoxication and substance withdrawal
- Demonstrating proficiency in all the expected tasks associated with prescription, administration and monitoring of ECT

The College uses EPAs as a summative assessment method, with trainees required to achieve two EPAs per 6-month full time equivalent rotation. Rating scales are not employed, and attaining an EPA shows that a supervisor can trust a trainee to perform that activity with only distant (reactive) supervision.²²² There are different EPAs for different stages of training, and attainment of specific EPAs is required to progress through the training program. To assess an EPA, supervisors use workplace assessment tools along with other evidence such as information from other staff.

In addition, the RACP is currently undertaking a renewal of its basic training curricula. The consultation report discusses the introduction of EPAs to specify the key work tasks that trainees need to be able to perform with only minimal supervision by the end of basic training.²²³ Eight EPAs have been drafted for inclusion in the basic training program, and it is proposed that Ten Cate's scale, described above, is used for assessment. Stage four has, however, been adapted to 'Act with supervision at a distance' as basic trainees do not act without some form of clinical oversight.

In 2016, Pittenger et al published an article discussing the development of EPAs to define graduations standards for a US pharmacy program of study.²²⁴ The EPA statements formed the basis of developmental milestones and provided criteria for determining pass grades. In addition, the EPA statements were used as the basis of a high stakes performance assessment required for graduation.

Summary

Whilst EPAs are a relatively new concept in medical education, their use seems to be increasing. EPAs are not meant as an alternative to professional competencies but as a means of integrating competencies from multiple domains into discrete work tasks.

4.5. Discussion

Each method of assessment has its own advantages and disadvantages, and no single assessment method can adequately assess all aspects of clinical competence.^{17, 19, 20, 29, 47, 82, 83} It is, therefore, important to use multiple modes of assessment to ensure that requisite knowledge, skills and attitudes are demonstrated to a pre-defined level.

McCoubrie et al argue that written assessments lack professional authenticity and, whilst they can be used strategically to test important course content, they should be mixed with practical assessments of clinical competence.²⁰

The concept of authenticity is also discussed by Van der Vleuten et al, who state that authenticity is essential when developing assessments.⁴⁴ The authors suggest that when assessing at the bottom three levels of Miller's Pyramid, it is not so much the response format (e.g. MCQs, essays, orals) as the stimulus format (the task presented to the candidate) that determines the validity of an assessment process. They suggest that short scenarios can provide an authentic assessment method, are relatively easy to develop and can sample widely.

Van der Vleuten et al also question the authenticity of OSCE scenarios, stating that the classic OSCE short station format does not reflect the reality of clinical practice. As discussed early in this document, short OSCE stations result in fragmented skills assessment rather than a holistic approach. The authors argue that whilst OSCEs may be useful for the early stages of training, integrated skills assessment is a more suitable stimulus format at more advanced stages.

In the medical profession, there is increasing emphasis on ensuring performance in day to day practice, and the movement towards assessment in the work place is likely to continue.⁴⁷⁻⁴⁹ The RACP and some surgical specialities within the Royal Australasian College of Surgeons use WPBA tools in training programs. In the UK, the GMC require a multi-source feedback (MSF) evaluation to be undertaken as part of the five-yearly revalidation process for licensed doctors. Whilst work based assessment does not appear to have been widely adopted in pharmacy, some WPBA tools such as the mini-PAT, mini-CEX, and the GbCF have been developed for use in the pharmacy environment.

Whilst WPBA has the advantages of authenticity and evaluation of performance in a real-life setting, these advantages rely on appropriate use of the tools, and engagement of both learner and assessor. As discussed previously, inter-rater reliability may be low and there is evidence that raters may be disinclined to rate negatively.

Several papers on WPBA tools have indicated that candidates perceive the assessment process as a 'tick box' exercise rather than a developmental experience.⁵⁴⁻⁵⁹ A study by Bindal et al, evaluating trainee doctors' views on CbD, DOPS and Mini-CEX, highlighted problems with assessor engagement in WPBA.⁵⁴ Forty percent of trainees reported that a member of medical or nursing staff had refused to conduct an assessment, citing lack of time, training, understanding of paperwork and confidence as reasons. In another study, Menon et al reported that 36% of trainers listed 'politically driven' as the main reason behind the introduction of WPBA, whilst 44% listed 'to improve training as the main reason', and only 8% 'to improve patient care'.²²⁵

In 2016 Gilberthorpe et al published the results of a retrospective audit evaluating the use of workplace assessment tools in psychiatric training.²²⁶ They found that almost a third of assessments analysed showed no divergence in assessment score across the assessment domains, raising concerns that assessors may not be actively engaged in the assessment process. Scores did not correlate well with comments provided by assessors, and there was a significantly skewed distribution in scores towards a positive rating. They concluded that WPBA is not being effectively utilised as a formative tool and that training and guidance on the use of WPBA is needed. The need for both assessor and candidate training is discussed in many other papers evaluating WPBA.^{59, 63-66}

The use of EPAs in a training program also has the advantages of authenticity and assessment of performance in a real-life setting. When part of an assessment process, they prompt the supervisor to review a trainee's performance of a specific task, and decide whether the trainee can be trusted to safely care for a patient; a decision fundamental to clinical training.²²⁰

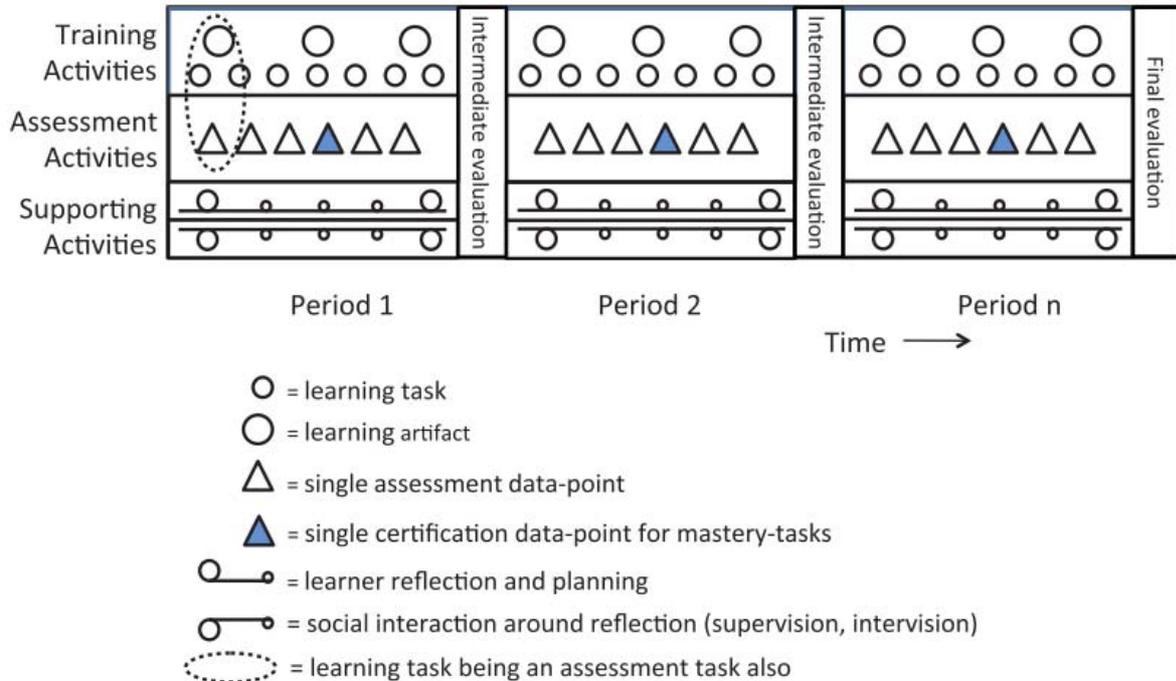
Competence is not generic.⁴⁴ It is, as previously discussed, contextual and if a candidate exhibits competence in one area, this cannot be extrapolated to imply competence in all areas. Longitudinal assessment using varied methods in different clinical contexts will provide a more holistic approach to assessment.²⁹

A more recent development has seen the movement towards the programmatic approach to assessment, which integrates assessment into a program of study curricula.^{47, 227, 228} These assessment programs align learning outcomes, program content and assessment. The assessment is longitudinal with assessment at multiple points during the program, using multiple assessment methods. The importance of feedback to a student's development is recognised, and hence assessment for learning is integral to the assessment program.

Van der Vleuten et al have developed a model for such programmatic assessment (Figure 8).²²⁷ Data from single points of assessment and supporting activities are assessed in an intermediate evaluation of progress. The authors recommend that such assessment should be by an expert committee. A high stakes final assessment by the same committee occurs at the end of the program of study.

Whilst integration of assessment into a program of study may not be an immediately feasible option, Holmboe et al provide some guidance of the direction in which we should be moving.¹¹⁴ They state that competency-based assessment needs to be continuous and frequent, criterion based and involve authentic encounters with direct observation. Assessment tools used should meet minimum standards of quality, and it is suggested that a country or region should adopt a core set of assessment tools that can be used to reduce variability in assessment.

Figure 8: Model for programmatic assessment in action fit for the purpose of assessment for learning and robust decision making on learners' achievements, selection and promotion ²²⁷



The choice of assessment method will be based on a number of factors, and will ultimately involve a compromise between the best evidence based method of assessment and the practicalities of implementing such methods.⁴⁷ The extent to which compromise is acceptable will depend on the context of the assessment. For example, the requirements of a high stakes assessment, such as those used to assess suitability for national registration, will be different from a formative assessment, where the primary goal is to facilitate feedback and learning. A conceptual model proposed by Van der Vleuten in 1996 suggests that the utility of an assessment method can be calculated by multiplying 5 criteria: reliability, validity, educational impact, cost and acceptability. Each criterion can be weighted for importance according to the context of the assessment process.²²⁹

Norcini et al list seven criteria for good assessment (Table 4), but place particular emphasis on the catalytic effect.⁸⁴

The authors state that effective formative assessment is typically low stake, informal, opportunistic and intended to stimulate learning. Educational effects, catalytic effects and acceptability are likely to be the most important criteria for examinees in formative assessment. Feasibility will also be important if recommendations for timely, ongoing assessment and feedback are followed.

Table 4: *Criteria for good assessment* adapted from Norcini J, Anderson B, Bollela V, et al⁸⁴

| | | |
|---|--------------------------------|--|
| 1 | Validity or coherence | There is a body of evidence that is coherent and that supports the use of the results of an assessment for a particular purpose. |
| 2 | Reproducibility or consistency | The results of the assessment would be the same if repeated under similar circumstances. |
| 3 | Equivalence | The same assessment yields equivalent scores or decisions when administered across different institutions or cycles of testing. |
| 4 | Feasibility | The assessment is practical, realistic, and sensible, given the circumstances and context. |
| 5 | Educational Effect | The assessment motivates those who take it to prepare in a fashion that has educational benefit. |
| 6 | Catalytic effect | The assessment provides results and feedback in a fashion that creates, enhances, and supports education; it drives future learning forward. |
| 7 | Acceptability | Stakeholders find the assessment process and results to be credible. |

Effective summative assessment is typically medium or high stake and primarily intended to facilitate accountability. It requires validated, high quality assessment material, significant content expertise, a systematic standard setting process and secure administration. Important criteria for summative assessment are, therefore, validity, reproducibility and equivalence. The authors argue that whilst feasibility, acceptability and educational effect are still important, they are not as important as the psychometric criteria.

5. International Intern Assessment Methods

The review of international intern assessment methods has been limited to New Zealand and APC Stream B countries (UK, US, Canada and Ireland). These countries are deemed to be equivalent in registration process to Australia. Regulatory organisations for each of these countries were contacted by APC to obtain information relating to intern assessment processes.

5.1. United Kingdom

5.1.1. Great Britain

The General Pharmaceutical Council (GPhC), is the regulator for pharmacy in Great Britain. Amongst other roles it is responsible for registering pharmacy professionals. The GPhC is not a training provider, but it does validate pre-registration trainees, pre-registration tutors and pre-registration training premises. Trainees are not registered with the GPhC, but the GPhC maintains a list of trainees, tutors and premises, which is updated regularly.

Pre-registration training in Great Britain

The main route to registration as a pharmacist in Great Britain is:

- Passing a four-year Master of Pharmacy (MPharm) degree; then
- Passing 52 weeks of pharmacist pre-registration training; and
- Passing a national Registration Assessment; an examination run by the GPhC. The Registration Assessment is sat towards the end of the year of pre-registration training.

During the pre-registration year, every pre-registration trainee pharmacist is assigned a pre-registration tutor, a pharmacist, who is responsible for signing them off at 13 week intervals (weeks 13, 26, 39 and 52). Trainees must be signed off positively at 39 weeks to be eligible to sit the Registration Assessment, and must be signed off positively at 52 weeks to be eligible to apply to register as a pharmacist.

The initial education and training period for pharmacists is a minimum of five years, and it must be completed in eight. A maximum of three attempts at the Registration Assessment is permitted. Note there are two other routes to registration, both incorporate 52 weeks of pre-registration training and the Registration Assessment.

There is currently no formal training scheme in England and Wales. In national health service settings, all trainees participate in a structured scheme, in which they are rotated through areas of a hospital to gain a broad understanding of hospital pharmacy services and multi-disciplinary teams. Most medium and large community pharmacy companies run their own structured scheme.

In Scotland, NHS Education Scotland (NES) is responsible for quality assurance of pre-registration training. NES administers the Pre-Registration Pharmacist Scheme. This was established to ensure that every pre-registration pharmacist funded by the NHS in Scotland receives support and a high-quality training experience, regardless of practice setting. The main components of the scheme are a centrally coordinated recruitment process, quality assurance processes and a standardised training program, which includes training days, mentorship and support. Entry to the scheme is currently capped at 170 places.

Within the Pre-Registration Pharmacist Scheme there are two formative methods of assessment:

- A full length mock assessment which runs in the April of each training year for all trainees
- A Prescribing Safety Assessment for trainees, to be piloted in 2017

A similar model is being developed in England by Health Education England, and is also being rolled out in Wales. The new scheme will include a formal application process, support for trainers and trainees, and a set method for assessing trainees.

The first phase of this model is an admissions scheme, which is being introduced in 2017-2018, and includes more than 2000 places across both the hospital and community sectors. In 2017-2018 applying through the scheme will be mandatory for hospital and community placements in the scheme, however, not all community placement providers have joined the scheme. The number of pre-registration places in Wales is capped, but the number of places in England is not.

In addition, developmental work in training and assessment is being undertaken by Health Education England; including pilots of e-portfolios, pharmacy competency panels, tutor training, and workplace-based assessment.²³⁰

Format of pre-registration assessment

There are two modes of assessment: tutor sign off and the national Registration Assessment.

Tutor sign-off

Tutors sign-off trainees on four occasions – after 13, 26, 39 and 52 weeks. At each sign-off, trainees are evaluated using an assessment summary form against a set of Pre-registration Performance Standards, all of which must be met by the end of the pre-registration training period. There are 76 performance standards in total across three units:⁸⁶

- A. Personal effectiveness
- B. Interpersonal skills
- C. Medicines and health

Guidance for tutoring is provided by the GPhC in Guidance on tutoring for pharmacists and pharmacy technicians.²³¹

The assessment of the Pre-registration Performance Standards varies between sectors and countries. The bare minimum is four tutor sign-offs, which are administered by a designated tutor. Where training is embedded in larger training structures, assessment is administered by central training functions in either companies or hospitals. The amount of feedback to individual trainees depends on the training setting – in some settings it is extensive and frequent, in other settings it is not.

Within the Scottish Pre-Registration Pharmacist Scheme there is a requirement for the tutor and trainee to meet on a weekly basis. Feedback on progress with achievement of the performance standards is provided and documented. This is in addition to the formal appraisals required by the GPhC at 13 week intervals.

Registration Assessment

The Registration Assessment is run in the final few weeks of the pre-registration training year (in June), and repeated three months later in September. There are two papers, which are sat sequentially on the same day. Paper 1 contains 40 pharmaceutical calculations questions. Paper 2 contains 120 MCQs; of which 80 are single best options format, and 40 are EMQs. Candidates may be provided with an artefact booklet containing reference material for each paper. The papers are marked by computer.

Sample questions are provided by the GPhC, along with practise material in the Pre-registration Manual and videos/webinars to help trainees prepare for a sitting. The Royal Pharmaceutical Society provides support to its pre-registration trainee members, as do providers of commercial pre-registration training schemes.

Whilst it is acknowledged that the Registration Assessment does not test aspects of pre-registration training such as communication, it does test application of clinical knowledge through clinical scenarios and pharmaceutical numeracy.

Competencies Assessed and Relative Weights

The national Registration Assessment is based on a Registration Assessment Framework,²³² which includes a set of outcomes which are weighted as being of high, medium or low importance. In addition, therapeutic areas are weighted and high risk drugs and pharmaceutical calculations types are listed. This framework can be viewed in Appendix A.

Registration Assessment Blueprint

The 'high', 'medium' and 'low' ratings in the Registration Assessment Framework determine the blueprint. Papers are constructed in accordance with the ratings, and then checked for overall balance. The number of questions dealing with high risk drugs, and the number of paediatric questions are also checked.

For each paper, a detailed spreadsheet is kept of all questions used for a fine-grained analysis of the questions.

Questions are written by question writers, all of whom are pharmacists and work in various practice roles. All questions are based on the Registration Assessment Framework, to ensure they are relevant to pharmacy practice. Once written, a group of writers review the questions in a workshop setting.

The questions are combined into draft papers by the assessment writing manager, who is a pharmacist. A template is used to make sure the questions cover all topics in the framework, and that the paper contains the correct proportion of question type. The board of assessors reviews the draft papers to confirm adequate coverage and appropriate weighting. At this stage, the board of assessors may ask for questions to be rewritten or replaced if they don't agree they are suitable.

Standard setting

A separate standard-setting panel of pharmacists assesses the standard of each question, to decide whether a borderline competent candidate would answer the question correctly. By doing this they can set a provisional pass mark. The pass mark may vary from paper to paper, depending on how difficult the questions are. The panel can ask the board of assessors to have questions rewritten or removed if they consider them inappropriate.

The board of assessors then considers the panel's comments about the questions in each paper, and decides which ones should be used. If a question is not used, it can be removed and replaced with another one, which has been reviewed by the standards-setting panel. Once the questions have been agreed, the board of assessors approves the papers.

Just before the papers are printed, the board of assessors checks that there have been no changes in practice or law that would have made any of the questions unsuitable.

5.1.2. Northern Ireland

Pre-registration training in Northern Ireland

Following completion of an MPharm, graduates are required to complete a year's pre-registration program. This is overseen by the Pre-Registration Department of the Pharmaceutical Society of Northern Ireland.

Trainees must register with the Pharmaceutical Society of Northern Ireland, and are required to demonstrate they have developed adequate competence during the pre-registration training year.²³³ Competence is demonstrated against a set of performance standards contained within an electronic portfolio (e-portfolio). Trainees must also attend mandatory training days.

Format of pre-registration assessment

E-portfolio

The trainee is required to prepare an e-portfolio of evidence to demonstrate completion of the performance standards. The trainee must achieve a satisfactory level in all performance standards to complete the pre-registration training year. The pre-registration tutor is responsible for confirming a trainee has completed all performance standards. This is achieved by direct observation of the trainee, or review of evidence collected by means of project/audit work, study days, health promotion campaigns and trainee log/diary. Appraisal forms must be completed by the tutor and submitted online to the Pharmaceutical Society of Northern Ireland at weeks 13, 26, 39 and 52.²³³

The Pharmaceutical Society of Northern Ireland continually reviews the trainee's e-portfolio, and an external examiner may request to see the e-portfolio for assessment. A selection of pre-registration trainees are requested to submit their folders of evidence for assessment purposes.

Written examination

In addition, pre-registration trainees must pass a written registration examination held by the Pharmaceutical Society of Northern Ireland twice a year. The examination is based on a detailed syllabus for the pre-registration training year, produced by the Pharmaceutical Society of Northern Ireland and accessible to trainees.²³³

The written examination is in two parts. The first, an open book examination, lasts three hours, and is divided into two sections; calculation questions and open book questions. The second examination lasts two hours, and is closed book. The closed book examination consists of MCQs in true/false format. A mock examination is available for trainees on the pre-registration training website.

All MCQs in the written examination are tested by item analysis; those MCQ stems achieving a correct score of less than 15% are reviewed.

Purpose of the examinations

The aim of the open book examination is *'to test the ability of the pharmacist' to use his/her knowledge and skills in conjunction with the main references sources that are readily accessible to be able to interpret data and answer questions that are within the broad remit of the professional responsibilities of a pharmacist'*.²³³

The aim of the closed book examination is *'to test day-to-day knowledge that a pharmacist should have without consulting additional sources of information on'*.²³³

- Practice issues, including responding to symptoms
- Knowledge of disease pathology and management
- Knowledge of drugs including therapeutic issues, side-effects, drug interactions and contraindications
- Professional and Ethical issues
- Legislation for pharmacists

5.2. United States

The definition and assessment of interns and internship programs are defined by each of the US state boards of pharmacy, and varies across the boards. To satisfy the experiential components of the pharmacy education program, all pharmacy students must complete a Pre-Advanced Pharmacy Practice Experience in their first year, and an Advanced Pharmacy Practice Experience in their third or fourth year. The experiential components of pharmacy education programs are accepted by some states as satisfying internship requirements.

Although some states have mechanisms to assess the competency of interns, it is not universal across the states, and there is no national standard or uniform assessment tool. It is outside the scope of this document to review the individual registration requirements of all US states.

The National Association of Boards of Pharmacy (NABP) is an independent, international association whose members comprise the US state boards of pharmacy, as well as international associate member boards from Canada, New Zealand and Australia. One of its roles is to develop the North American Pharmacist Licensure Examination (NAPLEX). This examination measures a candidate's knowledge of the practice of pharmacy, and is used by the US state boards of pharmacy as part of their assessment of a candidate's competence to practice as a pharmacist.

In addition, numerous state boards of pharmacy also require interns to pass a pharmacy law exam, the Multistate Pharmacy Jurisprudence Examination (MPJE). This examination combines federal and state-

specific questions to test the legislative knowledge of prospective pharmacists. The MPJE is also developed by NABP, and both examinations are administered by a computer-based testing company on behalf of NABP.

Purpose of the examinations

The goal of the NAPLEX test design is to measure a candidate's knowledge and ability as accurately and efficiently as possible.

The MPJE serves as the pharmacy legislation examination in participating jurisdictions, and tests a candidate's mastery of pharmacy law.

Format of the examination

NAPLEX

The examination is held over 6 hours at designated test centres. As of November 2016, the examination consists of 250 items delivered in a computerised, fixed-form rather than using adaptive technology.²³⁴

The examination requires that all questions are answered in the order in which they are presented. Candidates are not able to skip a question, or return to a previous question to review the answer. Once candidates have confirmed an answer choice and moved on to the next question, they cannot return to the previous question to change the answer.

Of the 250 delivered questions, 200 are used to calculate a test score. The remaining 50 pre-test questions are administered to evaluate their appropriateness for possible inclusion in future examinations. The pre-test questions are dispersed throughout the examination and cannot be identified by the candidate.

Most of the questions on the NAPLEX are asked in a scenario-based format (i.e. patient profiles/medical records with accompanying test questions). Interspersed among these profile-based questions are 'stand-alone questions' whose answers are drawn solely from the information provided in the question.

Questions are a mixture of formats as follows:

- MCQ - candidate chooses the single best option
- Multiple response format - candidate selects all answer choices that apply, from several options
- Constructed-response format - candidate produces the answer without choices
- Ordered-response question format - candidate is required to place the answers in a specific order
- Hot spot question format - candidate is required to identify a 'hot spot' or specific area on a graphic image by clicking on the correct area with the mouse

Candidates have the option to sit a pre-NAPLEX examination to prepare for NAPLEX. This examination is delivered by NABP, accessed via the internet and consists of 100 questions.

MPJE

The examination is held over two and a half hours at designated test centres, and consists of 120 items delivered using adaptive technology to deliver selected response test questions.²³⁴

Of the 120 delivered questions, 100 are used to calculate a test score. The remaining 20 pre-test questions are administered to evaluate their appropriateness for possible inclusion in future examinations. The pre-test questions, are dispersed throughout the examination and cannot be identified by the candidate.

Questions are a mixture of formats as follows:

- MCQ - candidate chooses the single best option
- Multiple response format - candidate selects all answer choices that apply, from several options
- Ordered-response question format - candidate is required to place the answers in a specific order

Competencies assessed and weightings

NAPLEX

The NAPLEX competency statements provide a blueprint of the topics covered in the examination, and the weightings given to each of the two assessed areas. They are freely available to candidates.²³⁴ The statements are listed in Appendix B.

MPJE

The MPJE competency statements provide a blueprint of the topics covered on the examination and the weightings given to each of the three assessed areas. They are freely available to candidates.²³⁴ The statements are listed in Appendix C.

Registration Assessment Blueprint

NAPLEX

The NAPLEX is presented as a fixed-form examination in compliance with the content specifications, blueprint, and other statistical and psychometric targets.

MPJE

The MPJE is developed, administered and scored in cooperation with participating state boards of pharmacy under policies and procedures developed by NABP. The content of the examination is approved by MPJE Review Committee members. Each participating state board of pharmacy approves those questions that are specific to the federal and state laws of the jurisdictions in which candidates are seeking licensure. Candidates must take a separate examination for each state or jurisdiction in which they are seeking licensure.

Standard Setting

NAPLEX

The passing score on the NAPLEX scale is 75, which is not a percentage value. NABP uses a mathematically based weighted scoring model to calculate an ability measure for each examinee. The ability measure is transformed to a reporting scaled score that ranges from 0 to 150.

The NAPLEX passing standard is established by a panel of pharmacy experts, and the ability level that defines the passing standard is the same for all NAPLEX administrations.

Official score reports for candidates who receive a failing score on the NAPLEX includes a section which indicates their relative performance in each of the two major competency areas. No review of the test questions is allowed.

MPJE

To receive an MPJE test score, candidates must complete at least 107 questions on the examination. Candidates completing fewer than 107 questions will not have their scores reported. Candidates who complete at least 107 questions, but fewer than 120 questions, will have a penalty applied and their scores adjusted to reflect the number of questions that remained unanswered.

The same methodology is used for MPJE as NAPLEX, with a passing score of 75 on a scale ranging from 0-100.

The score is calculated by first determining the candidate's ability level on the MPJE, and then determining whether the score has met the MPJE passing standard. The passing standard is established by a panel of pharmacy experts and is the same for all candidates for licensure.

5.3. Canada

The Pharmacy Examining Board of Canada (PEBC) is the national certification body for pharmacists in Canada. It was established to assess the qualifications of pharmacists on behalf of the provincial pharmacy regulatory authorities, by providing fair and equitable examinations. To achieve a national standardised process, the PEBC develops and administers a national Qualifying Examination, and awards a Certificate of Qualification to those who pass. This certificate is a requirement for licensure by provincial and territorial regulatory authorities (except Quebec). It is important to note that different provinces and territories have different additional requirements for registration, and the Certification of Qualification alone does not confer a right to practice. These additional requirements may include practice-based training and assessment, and legislation training and/or assessment. It is outside the scope of this document to review the individual registration requirements of the 13 provinces and territories.

Purpose of the examination

The purpose of the Qualifying Examination is to ensure that successful candidates have met the standard of competence required for entry to practice. The assessment standard of the Qualifying Examination serves as the final summative evaluation before candidates become licensed, and may identify borderline unqualified graduates who have been granted a degree. The examination is designed to assess the competencies required for safe and effective practice as defined in the National Association of Pharmacy Regulatory Authorities (NAPRA) document: Professional Competencies for Canadian Pharmacists at Entry to Practice 2014.²³⁵

Format of the qualifying examination

The qualifying examination consists of two separate components, and is available in both official languages (English and French). Parts I and II are administered, scored and reported separately, but both parts must be completed successfully by the candidate to be certified as ready for entry-to-practice.

Part I is a written examination in single best option MCQ format. It consists of 200 questions, with additional pre-test questions, administered in two 3¼ hour sittings over two consecutive days. Questions are designed to assess the understanding and application of knowledge to problems, as well as the ability to make judgments and problem-solve. A wide range of higher-order cognitive questions are included, requiring candidates to use skills such as application, analysis, synthesis and evaluation. The examination incorporates many case questions, which are related to patient scenarios. These cases require candidates to apply their knowledge and problem-solving skills to written descriptions of clinical situations. For example, candidates apply specific drug, disease and patient information to select the most appropriate responses to a series of questions, such as the most appropriate choice of therapy and most appropriate monitoring parameters.

Recognition of the need to test important skills and abilities that cannot be measured well solely with traditional MCQs, led the PEBC to develop a second assessment component. Part II is designed in OSCE format and consists of a series of 12 scored seven-minute stations, and one pre-test (unscored) station, which are based on common and/or critical practical situations. These stations primarily involve interactions with a 'standardised' patient, client or physician. Each station task or interaction is designed to assess one or two specific competencies. A trained assessor observes, records and assesses how the candidate interacts

and completes the task. The assessor uses specific, standardised assessment criteria, check lists and rating scales.

To solve the clinical and practice problems presented in the OSCE stations, candidates may be required to integrate several cognitive processes and professional skills. Such skills include: application, evaluation, synthesis and analysis of knowledge and information; ethical and professional judgement; clinical decision-making; and communication skills. All stations are developed based on practice experience, and relate to the application of pharmaceutical care, communication skills and other abilities necessary for safe and effective practice.

Competencies Assessed and Relative Weights

The content of both parts of the Qualifying Examination are based on the nine broad competency statements detailed in NAPRA's Professional Competencies for Canadian Pharmacists at Entry to Practice, 2014.²³⁵

The competency elements tested in each examination, and the approximate percentage of each part of the examination that relates to each of the nine major competency areas, are summarised in Table 5. Additional detail is provided in the examination blueprint (Appendix D). This blueprint is available on the PEBC website and is, therefore, accessible to candidates.²³⁶ Two competency areas, 'patient care' and 'communication and education,' together account for the majority of competencies tested in both parts of the Qualifying Examination.

The Qualifying Examination-Part II (OSCE) provides an assessment of communication skills, including demonstration of effective interviewing techniques, and educational strategies needed by pharmacists.

Qualifying Examination Blueprint

In 2015, the PEBC conducted a national practice review survey based on NAPRA's Professional Competencies for Canadian Pharmacists at Entry to Practice 2014. This survey of approximately 2000 pharmacists from across Canada, was used to assess the relative importance of the competencies to be tested through the Qualifying Examination, and thus represented a validation of the competency statements.

Criticality and frequency ratings analyses, performed by a psychometrician, were used to determine the relative importance of the NAPRA competency elements. A PEBC Blueprint Task Group reviewed the analysis data, and developed a blueprint for both Part I and Part II of the Qualifying Examination (Appendix D). The Committee on Examinations reviewed the overall blueprint.

Each Part of the Qualifying Examination is constructed in accordance with the required weighting for each competency area in the examination blueprint.

Table 5: Summary table of competencies examined in the Qualifying Examination Part I (MCQ) and Part II (OSCE). Source PEBC

| Competency | MCQ | OSCE | Overall % |
|--|-----|------|-----------|
| 1: Ethical, legal and professional responsibilities | ✓ | ✓✓ | 8% |
| 2: Patient care | ✓✓✓ | ✓✓✓ | 42% |
| 3: Product distribution | ✓✓ | ✓ | 13% |
| 4: Practice setting | ✓ | ✓ | 3% |
| 5: Health promotion | ✓ | ✓✓ | 3% |
| 6: Knowledge and research application | ✓✓ | ✓✓ | 6% |
| 7: Communication and education | ✓ | ✓✓✓ | 14% |
| 8: Intra and inter-professional collaboration | ✓ | ✓✓ | 6% |
| 9: Quality and safety | ✓✓ | ✓✓ | 5% |

Standard Setting

A criterion-referenced pass/fail standard is established for both parts of the PEBC Qualifying Examination. This standard is performance-based, and represents the level of performance appropriate to enter practice, as determined by a panel of practitioner experts.

This approach ensures that the same pass/fail standard is applied each year, and that only candidates who meet or surpass that standard pass the examination. It is a candidate's level of ability compared to the standard that determines whether the candidate passes or fails, rather than their ability compared to others. There is no built-in passing or failure rate with a criterion-referenced pass/fail standard.

Part I (MCQ)

In June 2016, a representative group of practitioner experts (Panel of Examiners) conducted a thorough review of the content of the examination, determining the minimum number of questions that must be answered correctly by a borderline competent practitioner to pass. The ability level that corresponded to that minimum passing score has been adopted as the pass/fail standard for Part I.

To maintain the same pass/fail standard from one examination to the next, whilst considering the difficulty of the examination, an equating process has been implemented. The equating process is a statistical procedure, that determines the minimum number of questions that must be answered correctly on a new examination to meet the established pass/fail standard. Although the specific number of questions that must be answered correctly to pass varies with the difficulty of the examination, the underlying estimate of ability that represents the pass/fail standard remains the same each time.

Part II (OSCE)

Following a thorough review of the examination, a panel of practitioner experts from across Canada determined the minimum score for each station (the score that would be achieved by a 'borderline qualified candidate'). The sum of these scores across all stations in the examination becomes the passing score for that examination. This process is repeated for each examination, thus taking into consideration the variations

in difficulty that may occur from one examination to the next. Candidates who do not perform at this level (i.e. do not pass the examination) are deemed to be less than borderline qualified, as they have not demonstrated that they can practice safely and effectively in situations simulating practice.

5.4. New Zealand

The Pharmacy Council of New Zealand (PCNZ) is responsible for the regulation of pharmacists (including registration) in New Zealand. The APC provides accreditation evaluation services to the PCNZ, these include assessment against accreditation standards and monitoring activities.

Intern Training in New Zealand

All New Zealand (or Australian) Bachelor of Pharmacy graduates wishing to register in New Zealand must complete a minimum of 44 weeks practical training in an approved pharmacy training site.²³⁷ They are also required to undertake the EVOLVE intern training program provided by the Pharmaceutical Society of New Zealand (PSNZ). This program is accredited by PCNZ, and is designed to help interns reach the required level of competency for registration. Interns are assessed against the PCNZ Competence Standards For the Pharmacy Profession,²³⁸ based on assessments such as on-the-job appraisals, written assignment and portfolios.

Intern preceptors are required to undertake a one day training course on workplace based assessment. Training is provided by the PSNZ and is valid for three years, after which a preceptor is required to take a refresher course. If a preceptor trains an intern every year they need only complete a refresher course every six years.²³⁹

In addition to any the EVOLVE assessments, the interns are required to pass two summative PCNZ assessments: The Intern Written Examination and the Assessment Centre.

Purpose of the Examinations

The Intern Written Examination is used to assess the intern's clinical knowledge and the application of that clinical knowledge.²⁴⁰

Format of the PCNZ intern assessments

Intern Written Examination

The written examination may be taken once the intern has completed 50% of their supervised practice hours. It is an open-book, computer-delivered examination held over three hours, and contains 125 single best option MCQs. The examination is delivered in three locations across New Zealand, three times a year.

The written examination is administered by APC on behalf the PCNZ. APC writes and develops questions, which are then validated in New Zealand to ensure content is appropriate to the New Zealand context. APC maintains a database specifically for items to be used in the New Zealand written exams. Due to the inherent risks associated with an external body developing legal, ethical and professional questions, PCNZ writes the eight questions for each paper which cover domain M1 (Practise Professionalism in Pharmacy).

The PCNZ directs interns to the APC written examination online modules and sample questions to prepare for the examination.

Interns must receive an overall mark of 65% to pass the examination, as well as the specified minimum pass mark in the following four domains:

- Domain M1: Practise Professionalism in Pharmacy (minimum pass mark 63%)
- Domain O1: Health and medicine management. May include some of O2.2 Health promotion (minimum pass mark 50%)

- Domain O3: Supply and administration of medicines (minimum pass mark 50%)
- Pharmaceutical Calculations: (minimum pass mark 63%)

The Assessment Centre

Interns may only attend the Assessment Centre if they have passed the written examination. This OSCE type assessment is run twice a year in May and November and is administered by PSNZ. It consists of ten scored seven-minute stations with standardised patients.

Assessment Centre Blueprint

The blueprinting for the OSCE is conducted via a pharmacy specific focus group.

The blueprint itself is an integrated assessment of the 10 stations, with each station referencing the competence framework and each checklist item within each station reflecting a competence standard.

The focus group concentrates on two key aspects:

1. What are the core competence standards required of an entry level pharmacist?
2. Does the competence standard fit within the parameters of the assessment tool, i.e. can the competence standard be assessed fairly and robustly in an OSCE format?

The proposed blueprint is then reviewed by a subcommittee, the Intern Assessment Advisory Committee (IAAC), whom provide expertise, guidance and sign off the blueprint on behalf of the PCNZ.

Standard Setting for the Assessment Centre

The PCNZ facilitates the standard setting group, which use a rubric to weigh/score the checklists items of each OSCE station. This then informs a pass score that an intern must achieve to be deemed competent.

Borderline candidates sitting either side of this pass mark are reviewed by the IAAC. The IAAC benchmark each borderline candidate against set criteria to determine whether they are safe to practise, and therefore safe to register. Any interns who do not meet the requirements of the OSCE, or are deemed not yet competent by the IAAC, receive feedback in the areas where they scored less than 70 percent. Interns who are successful in the OSCE do not receive any further feedback.

5.5. Ireland

The pharmacy regulator in Ireland is the Pharmaceutical Society of Ireland (PSI). It is responsible for accreditation of pharmacy degree programs, as well as CPD education and training for registered pharmacists. In addition, the PSI registers pharmacists, pharmaceutical assistants and pharmacies.

Intern training in Ireland

Integrated Master's Degree Program

In 2008, the PSI undertook a review of its education and training for pharmacists, which culminated in the Pharmacy Education and Accreditation Reviews report.²⁴¹ One of the main recommendations of this report was the introduction of an integrated five year Master's level program to replace the existing route to pharmacist registration, which consisted of a four-year Bachelor degree plus one year in-service practical training program (known as the National Pharmacy Internship Program).

The integrated Master's degree program in pharmacy commenced in September 2015. There are currently two years remaining of the '4+1' structure and the final year of the National Pharmacy Internship Program will commence for the last time in August 2018.

Under the new five-year integrated Master's degree program, students undertake experiential learning throughout the five years, starting in the second year with shadow placements. At the start of their fourth

year, students are required to undertake a statutory four-month practical training placement. This training can be undertaken in either a community pharmacy, a hospital pharmacy department or in industry. In the final year, students are required to undertake a statutory eight-month placement, and this takes place in the latter half of the year. This placement must be undertaken in a clinical setting and under the direct supervision of a tutor pharmacist.

National Pharmacy Internship Program

Following an outsourcing of the internship year in 2009, the current 'National Pharmacy Internship Program' is managed and delivered by the Royal College of Surgeons in Ireland (RCSI). This program is accredited by the PSI. Upon successful completion of this program students are awarded a Master's qualification. The program consists of two components:

- 12-month in-service practical training
- Professional Registration Examination

The 12-month practice placement occurs in an approved training establishment, under the supervision of a tutor pharmacist and the supporting academic program. Training is provided to tutor pharmacists through compulsory attendance at a one-day tutor training workshop.

Supervised practice can be completed either as one 12-month block or two 6-month blocks, with a minimum of six months spent in a clinical training establishment (community/hospital). The intern must complete the equivalent of 'full-time' supervised practice per week, with a minimum of three days per week with their designated tutor. The academic program is designed to support learning in the training establishment. It consists of one orientation module, six taught modules and one research module.

The Professional Registration Examination is developed and delivered by the RCSI on behalf of the PSI. It is delivered at the end of the 12-month in-service practical training program. A student must have successfully completed their 12 months training, and be signed off by their tutor, to be eligible to apply to sit the examination.

Purpose of assessment

The aim of assessment is to ensure that graduates have obtained the designated learning and competencies appropriate for professional practice as a pharmacist, and that graduates will be able to practice pharmacy competently ensuring patient safety.

Format of assessment

12-month in-service practical training

Assessments during the 12-month practice placement include:

- Continuous summative online assessment of the six taught modules

Assessments include a mixture of guided reading activities, case based assessments and CPD activities. Students receive individual feedback for each assessment component.

- Workplace-based assessment

Each student is appraised against competence standards relevant to each of the six taught modules.

Feedback is provided to the student by the intern tutor. The student is appraised a specified number of times (minimum three) based on the placement structure. Students also attend a one-to-one Competence Assessment and Performance Appraisal session, with a RCSI academic, on one occasion over the course of the training year.

A final clinical summative appraisal is completed near the end of the period of supervised practical training. The tutor assesses the intern against the PSI's Core Competency Framework for

Pharmacists.⁸⁵ Only this final appraisal will form part of the summative assessment of the student's competence.

- Research dissertation

The student is required to produce an 8,000 to 10,000-word dissertation as assessment for the research module. Students attend a training workshop to support them undertaking their research project.

Professional Registration Examination

The Professional Registration Examination consists of two parts, which must be passed independently.

Part 1 is MCQ format; it is held over two hours and contains 40 pharmaceutical calculation MCQ questions. The examination is delivered twice a year.

Students are provided with a full 40 MCQ sample paper to support their preparation for Part 1. Students are advised to complete the sample paper under simulated exam conditions in their own time. Sample paper answers are subsequently released to the students.

Part 2 consists of 18 OSCE stations of five minutes' duration each. The stations align to the modules that are taught during the academic program of the National Pharmacy Internship Program (three stations for each of the six modules). The stations are a blend of interactive and non-interactive scenarios.

RSCI provides a mock OSCE session for interns during the training year, following which global feedback is provided to all students. Students also complete a training workshop on effective communication skills to support their individual practice and their preparation for the OSCE.

Competencies Assessed and Relative Weights

Competence is assessed against the Core Competency Framework for Pharmacists.⁸⁵ Each of the six taught modules in the academic program correlates to one of the six domains within the framework.

Assessment is across all seven modules in the National Pharmacy Internship Program and the marks allocation is shown in Table 6.²⁴²

Table 6: Marks Allocation for the Irish National Pharmacy Internship Program

| Module | Workplace Assessment | Online Assessment | First Aid | Terminal (MCQ) | Terminal (OSCE) | Total | Credits | Marks |
|---|----------------------|-------------------|-----------|----------------|-----------------|-------------------------------|---------|-------|
| MP1 Professional Practice | Pass/Fail | 40% | N/A | N/A | 60% | 100% | 15 | 100 |
| MP2 Personal Skills | Pass/Fail | 40% | N/A | N/A | 60% | 100% | 15 | 100 |
| MP3 Supply of Medicines | Pass/Fail | 30% | N/A | 10% | 60% | 100% | 15 | 100 |
| MP4 Safe and Rational Use of Medicines | Pass/Fail | 40% | Pass/Fail | N/A | 60% | 100% | 15 | 100 |
| MP5 Public Health | Pass/Fail | 40% | N/A | N/A | 60% | 100% | 15 | 100 |
| MP6 Organisational and Management Skills | Pass/Fail | 40% | N/A | N/A | 60% | 100% | 15 | 100 |
| MP7 Research | N/A | N/A | N/A | N/A | N/A | 100% research dissertation | 30 | 200 |
| Total marks | | | | | | | | 800 |

As discussed previously, the summative workplace assessment of the intern's competency is completed near the end of the period of supervised practical training. Assessment is conducted by the tutor against the PSI's Core Competency Framework for Pharmacists in Ireland. For the intern to pass this assessment they must achieve a 'Level 4' rating in all behaviours of the framework. If a student is not awarded the required Level 4 rating in any behaviour of the framework (other than N/A), they will not be eligible to sit the Professional Registration Examination and will normally have to complete a further period of supervised practical training. The rating scale applied by the tutor has five levels and is shown in Table 7 below.

Table 7: Competence standards assessment ratings used for workplace assessment

| Level | Rating | Definition | Percentage Expression |
|-------|--------------|--|-----------------------|
| N/A | Cannot | Intern not exposed to this standard in the training establishment | N/A |
| 1 | Rarely | Very rarely meets the standard expected. No logical thought process appears to apply | 0-20% |
| 2 | Sometimes | Much more haphazard than mostly | 21-50% |
| 3 | Mostly | Implies standard practice with occasional lapses | 51-84% |
| 4 | Consistently | Demonstrates the expected practice with very rare lapses | 85-100% |

Professional Registration Examination Blueprint

Blueprinting is an integral part of the assessment strategy for the Professional Registration Examination. The assessment blueprint ensures the Professional Registration Examination assesses the program's curriculum, sampling proportionately across all the relevant components, and uses appropriate test modalities. Validity and reliability are considered as part of the blueprinting process. Validity requires that all aspects of the curriculum content, relevant to the specific module being assessed, are covered by the assessment. Reliability depends upon the choice of appropriate test modalities.

Blueprinting for the Professional Registration Examination is carried out under the direction and supervision of the program's Director of Assessment, who is an experienced academic in assessment.

Part 1 of the Professional Registration Examination (MCQ) is blueprinted to include questions that proportionately address the eight areas of pharmaceutical calculations taught in the program: systems of units, concentrations, dilutions, formulations, calculation of doses, density, displacement volumes and displacement values. Calculations involving molecular weights, parenteral solutions and isotonicity.

Part 2 of the Professional Registration Examination (OSCE) is blueprinted so that there are three OSCE stations mapped to the learning outcomes for each of the six taught modules.

Module co-ordinators collectively develop the blueprint for the examination by constructing a document (typically a spreadsheet) that incorporates module components to be tested, and their respective weighting and test modalities for each OSCE station. This ensures assessment validity by avoiding 'construct under-representation'. The key feature of the blueprint is that it sets out explicitly the structure and content-coverage of the examination and allows clear mapping to the relevant module learning outcomes and the program's overall Teaching and Learning strategy.

Standard setting

Part 1 of the Professional Registration Examination

The cut score for Part 1 is determined using statistical methods approved by the external examiners.

Part 2 of the Professional Registration Examination

Standard setting for the interactive stations is performed using statistical methods agreed by the appointed external examiners. Non-interactive stations have a predetermined pass mark of 50%. The overall pass mark for the OSCE is determined by calculating the arithmetic mean of the cut scores for all 18 OSCE stations, to which one standard error of measurement is added.

6. Blueprinting for assessments

6.4. Blueprinting Literature Review

6.1.1. Method

Searches were carried out using PubMed®, Embase®, Scopus® and CINAHL® healthcare databases.

Keywords used in searches were blueprint, blueprinting. These were used alone and in combination with assessment as shown in Table 8.

A grey literature search was also carried out with the same keywords using the Google® search engine.

Table 8: Search strategy for blueprinting literature review

| Search number | Search term | |
|---------------|--------------|----|
| 1 | Blueprint | OR |
| | Blueprinting | |
| 2 | Assessment | |
| 3 | 1 AND 2 | |

6.1.2. Results

The search of four databases found 954 potentially relevant titles. Articles were reviewed for relevance by title, abstract, full-text availability through the QUT library resulting in the identification of 35 articles. In addition, 27 references were identified from the grey literature.

6.2. Definition of blueprint and blueprinting

The term blueprint, originally used in architecture to define a plan or design of how something is to be achieved, has been adapted for use in the education environment and is being increasingly used in the development of assessment processes.

An Australian Medical Council (AMC) document regarding WPBA states that a *'blueprint depicts the relationship between what has to be assessed and how it is to be assessed'*.²⁴³

Patil describes a blueprint as *'a map and a specification for an assessment program which ensures that all aspects of the curriculum and educational domains are covered by assessment programs over period of time'*.²⁴⁴ An examination blueprint has been defined as a template used to define the content of an examination.⁹⁰

For the purpose of this document the definition of an assessment blueprint shall be taken as

'A template used to define the content of assessment which depicts the relationship between what has to be assessed and how it is to be assessed'.

Blueprinting is the creation of such a template, and involves the mapping of the assessment content against the program learning objectives to ensure adequate and representative content.^{19, 33, 87, 89, 123}

6.3. The purpose of blueprinting

The practice of blueprinting, which involves mapping an assessment process against program learning objectives, will establish the content validity of an assessment by the determination of an adequate and representative sample of items to be included.⁸⁷ It will also help to ensure an assessment process is replicable, and that the assessment contents are representative of the curriculum.

The development of a blueprint should ensure there is clear link between the learning objectives, the delivered curriculum and the assessment.⁸⁸ Blueprinting can also reduce ‘construct under-representation’ and construct-irrelevance variance, both of which may compromise assessment validity.^{89, 90}

Blueprinting will define the content of a given assessment and hence provides a guide to assessment for trainers and assessors and, if published, for candidates. McLaughlin et al discuss whether an assessment blueprint should be made available to candidates.⁸⁸ Publication of an assessment blueprint may lead to candidates only learning what they know they are going to be tested on, and studying solely for the purpose of passing assessments. It has, however, been argued that assessment drives learning^{17, 19} and that blueprinting an assessment against learning objectives will result in the candidate learning core material and achieving curriculum objectives.^{19, 88}

A study into the effect of the publication of a program assessment blueprint found that whilst publication did not significantly affect students’ performance, it did affect students’ perception of the assessment. Following publication of the blueprint a significantly greater proportion of students perceived the course assessment to be fair and reflective of both important subject matter and the curriculum.⁸⁸

Another study by Ahmad et al found that introduction of an assessment blueprint led to improvements in student performance and assessment satisfaction ratings.²⁴⁵

6.4. The process of blueprinting

A review of the literature has identified several common process steps that can be followed when designing an assessment blueprint:^{90, 245-250}

- 1. Define the scope and purpose of the assessment**
- 2. Define and tabulate the learning objectives or competencies that are to be assessed**

This establishes the content of the assessment.
- 3. Assign a weighting to the learning objectives or competencies**

This establishes the relative ‘importance’ of the content areas to ensure appropriate coverage in an assessment. In practice, content importance can be difficult to attribute.
- 4. Identify specific activities associated with each learning objective or competency that can be assessed**

This involves the identification of individual problems/tasks to be assessed and should take into consideration the level of competency at which the student is expected to perform.
- 5. Assign each activity to the most appropriate assessment method/s**

6.5. Format of a blueprint

Whilst there are many forms of assessment blueprint, it usually takes the form of a table, grid, matrix or spreadsheet. The learning objectives or competencies are typically listed down the vertical axis, with exam content, weightings and assessment type across the horizontal axis.

6.6. Blueprinting in healthcare professional assessment

The concept of blueprinting in assessment is not a new one and there are numerous organisations who use this methodology. Assessment blueprinting seems to be prevalent in the medical profession:

The Australian Medical Council (AMC) accreditation standards for both primary medical programs in Australia and Specialist Medical Programs and Professional Development Programs specify that education providers have a blueprint to guide assessments at each stage of the program of study.^{105, 251}

The UK General Medical Council (GMC) standards for curricula and assessment systems states '*The blueprint detailing assessments in the workplace and national examinations will be referenced to the approved curriculum and Good Medical Practice and must be available to trainees and trainers in addition to assessors/examiners*'.²⁵²

The Medical Council of Canada initiated a blueprint project in 2011 to review the content covered in their examinations. An examination blueprint was approved in 2014 and the new qualifying examinations based on the blueprint will begin in 2018.²⁵³

In 2012 Health Workforce Australia funded Medical Deans Australia and New Zealand to conduct a project to develop a National Assessment Blueprint for Clinical Competencies for the medical graduate. The report, published in 2014, details the development of clinical assessment blueprints following consultation with all the medical schools in Australia and New Zealand.²⁵⁴ Five clinical assessment blueprints were developed, which can be used as templates by medical schools and modified to suit individual needs.

With respect to non-medical AHPRA professions, the 2016 Optometry Council of Australia and New Zealand accreditation standards state that '*an assessment matrix/blueprint which details assessment methods and weightings and demonstrates alignment of assessment to learning outcomes and OCANZ endorsed professional competencies can be used as evidence for the assessment standard*'.²⁵⁵ The Australian and New Zealand Podiatry Accreditation Council 2015 accreditation standards also lists assessment matrices or blueprints as possible examples of evidence for the assessment of learning outcomes.²⁵⁶ Whilst other non-medical AHPRA professions including Chinese medicine,²⁵⁷ chiropractic,²⁵⁸ dental practitioners,²⁵⁹ medical radiation practice,²⁶⁰ nursing and midwifery,²⁶¹⁻²⁶³ occupational therapy,²⁶⁴ pharmacy,¹¹³ physiotherapy²⁶⁵ and psychology²⁶⁶ recognise the importance of the relationship between learning outcomes and assessment strategies, blueprinting methodology is not suggested or mandated.

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8. Appendices

Appendix A: General Pharmaceutical Council Registration Assessment Framework²³²

Outcome weightings

| | Proportion of questions |
|------------------|-------------------------|
| high weighting | 60% to 70% |
| medium weighting | 25% to 35% |
| low weighting | up to 10% |

Registration assessment outcomes

| 10.1 Expectations of a pharmacy professional | | |
|--|---|---|
| Future pharmacists outcome | | Indicative assessment topics |
| Low | Recognise the duty to take action if a colleague's health, performance or conduct is putting patients or the public at risk | <ul style="list-style-type: none"> GPhC standards and guidance documents Action to take if a colleague's conduct has the potential to affect patient or public health |
| Low | Apply the principles of clinical governance in practice | <ul style="list-style-type: none"> Purpose and principles of clinical governance Risk management in pharmacy and other healthcare contexts Systems to reduce medication errors |
| Low | Demonstrate how the science of pharmacy is applied in designing and developing medicines and devices | <ul style="list-style-type: none"> Factors affecting the stability of medicinal products Procedures for the dilution of solid, semi-solid and liquid dosage forms |
| Medium | Respond appropriately to medical emergencies, including providing first aid | <ul style="list-style-type: none"> Appropriate responses to medical emergencies |

| | | |
|---------------|---|--|
| 10.2 | The skills required in practice | |
| 10.2.1 | Implementing health policy | |
| | Future pharmacists outcome | Indicative assessment topics |
| Medium | Access and critically evaluate evidence to support the safe, rational and cost-effective use of medicines | <ul style="list-style-type: none"> Principles of obtaining and applying evidence for use in current practice Interpreting and applying information to improve patient care |
| Medium | Apply knowledge of current pharmacy-related policy to improve health outcomes | <ul style="list-style-type: none"> Principles of promoting healthy lifestyles including current pharmacy-related policy Collaboration across the healthcare professions to improve patient outcomes Purpose of prescribing guidelines |
| 10.2.2 | Validating therapeutic approaches and supplying prescribed and over-the-counter medicines | |
| | Future pharmacists outcome | Indicative assessment topics |
| High | Identify and employ the appropriate diagnostic or physiological testing techniques in order to promote health | <ul style="list-style-type: none"> Selecting appropriate diagnostic or physiological testing techniques for use in clinical decision-making and to promote health Normal ranges for test results, and actions to take when results are out of the normal range |
| High | Identify inappropriate health behaviours and recommend suitable approaches to interventions | <ul style="list-style-type: none"> Concepts of health promotion, health education and health improvement programmes, based on national and local health priorities and parameters Role of pharmacists and pharmacy support staff in promoting health and preventing disease Behavioural change as a tool to support health promotion Social, environmental and dietary factors that influence health |

| Future pharmacists outcome | | Indicative assessment topics |
|----------------------------|--|--|
| High | Instruct patients in the safe and effective use of their medicines and devices | <ul style="list-style-type: none"> Identifying appropriate advice on the use of medicines |
| Medium | Analyse prescriptions for validity and clarity | <ul style="list-style-type: none"> Legal and professional requirements for prescriptions, to enable the safe and legal supply of medicines |
| High | Clinically evaluate the appropriateness of prescribed medicines | <ul style="list-style-type: none"> Appropriateness of prescribed medicines, for example in the context of presenting conditions, associated diseases, and test results Circumstances in which prescribed medicines are contra-indicated Interactions that occur between medicines (either prescribed or purchased), and between these medicines and food or other substances Use of licensed, off-label and unlicensed medicines including providing information to patients |
| High | Provide, monitor and modify prescribed treatment to maximise health outcomes | <ul style="list-style-type: none"> Principles of medicines management, medicines optimisation and pharmaceutical care Dosages and dose adjustments, especially for people with particular needs due to, for example, age or health conditions Reasons for treatment failures Recognising and managing adverse effects of medicines Mechanism of action, administration, absorption, distribution, metabolism and excretion of medicines |
| Low | Record, maintain and store patient data | <ul style="list-style-type: none"> Maintaining confidentiality, and disclosing information both with and without the subject's consent Information governance Requirements for recording, maintaining and storing data |

| Future pharmacists outcome | | Indicative assessment topics |
|----------------------------|--|---|
| Med | Supply medicines safely and efficiently, consistently within legal requirements and best professional practice. NB: This should be demonstrated for both human and veterinary medicines | <ul style="list-style-type: none"> • Statutory regulations and professional requirements for the supply of human and veterinary medicines |
| 10.2.3 | Ensuring that safe and effective systems are in place to manage the risk inherent in the practice of pharmacy and the delivery of pharmaceutical services | |
| Future pharmacists outcome | | Indicative assessment topics |
| Low | Ensure the quality of ingredients to produce medicines and products | <ul style="list-style-type: none"> • Quality assurance processes for medicines and ingredients • Storage requirements for medicines and ingredients |
| Medium | Apply pharmaceutical principles to the formulation, preparation and packaging of products | <ul style="list-style-type: none"> • Formulation, preparation and packaging of products |
| High (Part 1) | Use pharmaceutical calculations to verify the safety of doses and administration rates | <ul style="list-style-type: none"> • Accurately perform calculations affecting patient care |
| Low | Procure and store medicines and other pharmaceutical products working within a quality assurance framework | <ul style="list-style-type: none"> • Procurement and storage of medicines • Additional precautions necessary for particular formulations |
| Low | Dispose of medicines safely, legally and effectively | <ul style="list-style-type: none"> • Statutory regulations covering the safe, legal and effective disposal of medicines • Procedures for the disposal of special and controlled waste from the pharmacy |

| Future pharmacists outcome | | Indicative assessment topics |
|----------------------------|--|---|
| Low | Identify, report and prevent errors and unsafe practice | <ul style="list-style-type: none"> • Supervising others involved in service delivery • Identifying, reporting and preventing errors and unsafe practices • Responding to complaints and concerns |
| Low | Procure, store, dispense and supply veterinary medicines safely and legally | <ul style="list-style-type: none"> • Regulations and professional requirements governing the procurement, storage, dispensing and supply of veterinary medicines |
| 10.2.4 | Working with patients and the public | |
| Future pharmacists outcome | | Indicative assessment topics |
| High | Identify and employ the appropriate diagnostic or physiological testing techniques to use in clinical decision-making | <ul style="list-style-type: none"> • Identifying appropriate diagnostic or physiological testing techniques, and interpreting results • Identifying conditions that need referring to another healthcare professional • Identifying conditions that may be treated by non-prescription medicines |
| 10.2.5 | Maintaining and improving professional performance | |
| Future pharmacists outcome | | Indicative assessment topics |
| Low | Demonstrate the characteristics of a prospective professional pharmacist as set out in relevant codes of conduct and behaviour | <ul style="list-style-type: none"> • Characteristics of a pharmacist as set out in the relevant standards and guidance • Principles of the NHS complaints procedures |
| Low | Participate in audit and in implementing recommendations | <ul style="list-style-type: none"> • Purpose of audit and principles of audit procedures • Principles of change management |
| Low | Contribute to the development and support of individuals and teams | <ul style="list-style-type: none"> • Principles of identifying, and responding to, the learning and development needs of professional team members • Principles of CPD and regulatory requirements |

Therapeutic areas

| Therapeutic area | Weighting |
|-----------------------------|-----------|
| Cardiovascular system | High |
| Nervous system | High |
| Endocrine system | High |
| Infection | High |
| Genito-urinary tract system | Medium |
| Gastro-intestinal system | Medium |
| Respiratory system | Medium |
| Malignant disease | Medium |
| Blood and nutrition | Medium |
| Musculoskeletal system | Low |
| Eye | Low |
| Ear, nose, and oropharynx | Low |
| Skin | Low |
| Vaccines | Low |
| Anaesthesia | Low |

High-risk drugs

Each assessment is likely to include at least one question on each of the following drugs or drug groups:

- antibiotics
- anticoagulants
- antihypertensives
- chemotherapy
- insulins
- antidiabetic drugs
- drugs with a narrow therapeutic index
- non-steroidal anti-inflammatory drugs
- methotrexate
- opiates
- parenteral drugs

Paediatrics

Around 20 per cent of questions in the assessment will relate to paediatric patients.

Calculations

Each assessment is likely to include at least one calculation question involving each of the following in part 1:

- doses and dose regimens
- dosage and unit conversions
- estimations of kidney function
- displacement volumes and values
- concentrations (e.g. expressed as w/v, % or 1 in x)
- dilutions
- molecular weight
- using provided formulae
- infusion rates
- pharmacokinetics
- health economics
- quantities to supply

Up to 10 questions in part 2 will require some calculation.

Appendix B NAPLEX competency statements and weightings²³⁴

| | Competency statement | | Weighting |
|---------------|--|---|--------------------------|
| Area 1 | Ensure Safe and Effective Pharmacotherapy and Health Outcomes | | Approximately 67% |
| 1.10 | Obtain, Interpret, Assess, and/or Evaluate: | | |
| | 1.1.1 | Information from patient interviews | |
| | 1.1.2 | Patient medical records | |
| | 1.1.3 | Results from instruments and screening strategies used to assess patients | |
| | 1.1.4 | Laboratory and diagnostic findings | |
| | 1.1.5 | Signs and symptoms associated with diseases and medical conditions | |
| | 1.1.6 | Patients' need for medical referral | |
| | 1.1.7 | Risk factors relevant to the prevention of a disease or medical condition and the maintenance of wellness | |
| | 1.1.8 | Information from interdisciplinary health care providers | |
| 1.2.0 | Develop and Implement Individualized Treatment Plans, Taking into Consideration: | | |
| | 1.2.1 | Specific uses and indications and dosing for drugs | |
| | 1.2.2 | Purported uses and indications for dietary supplements and complementary and alternative medicine | |
| | 1.2.3 | Lifestyle and self-care therapy | |
| | 1.2.4 | Pharmacologic classes and characteristics of drugs | |
| | 1.2.5 | Actions and mechanisms of actions of drugs | |
| | 1.2.6 | The presence of pharmacotherapeutic duplications and/or omissions | |
| | 1.2.7 | Drug interactions | |
| | 1.2.8 | Contraindications, warnings, and precautions | |
| | 1.2.9 | Allergies | |
| | 1.2.10 | Adverse effects and drug-induced illness | |
| | 1.2.11 | Pharmacodynamic, pharmacokinetic, and pharmacogenomic principles | |

| Competency statement | | Weighting |
|----------------------|---|--|
| | 1.2.12 | Pharmacokinetic data to determine equivalence among drug products |
| | 1.2.13 | Pharmacoeconomic factors |
| | 1.2.14 | Routes and methods of administration, dosage forms, and delivery systems |
| 1.3.0 | Assess and Modify Individualized Treatment Plans, Considering: | |
| | 1.3.1 | Therapeutic goals and outcomes |
| | 1.3.2 | Safety of therapy |
| | 1.3.3 | Efficacy of therapy |
| | 1.3.4 | Medication non-adherence or misuse |
| 1.4.0 | Techniques for Effective Communication/Documentation of the Development, Implementation, and Assessment of Individualized Treatment Plans to: | |
| | 1.4.1 | Patients and/or patients' agents |
| | 1.4.2 | Interdisciplinary health care providers |
| 1.5.0 | Advocate Individual and Population-Based Health and Safety, Considering: | |
| | 1.5.1 | Best practices, scientific literature evaluation, and health-related resources |
| | 1.5.2 | Quality improvement strategies in medication-use systems |
| | 1.5.3 | Processes, evaluation of, and responses regarding medication errors |
| | 1.5.4 | Role of automated systems and technology in medication distribution processes |
| | 1.5.5 | Emergency preparedness protocols |
| Area 2 | Safe and Accurate Preparation, Compounding, Dispensing, and Administration of Medications and Provision of Health Care Products | Approximately 33% |
| 2.1.0 | Employ Various Techniques to Calculate: | |
| | 2.1.1 | Patients' nutritional needs and the content of nutrient sources |
| | 2.1.2 | Drug concentrations, ratio strengths, and/or extent of ionization |
| | 2.1.3 | Quantities of medication to be compounded, dispensed, or administered |
| | 2.1.4 | Quantities of ingredients needed to compound preparations |

| Competency statement | | Weighting |
|----------------------|---|-----------|
| 2.1.5 | Rates of administration | |
| 2.2.0 | Compound Sterile and Nonsterile Products, Considering: | |
| 2.2.1 | Techniques, procedures, and equipment for drug preparation, compounding, and administration of sterile products | |
| 2.2.2 | Techniques, procedures, and equipment for drug preparation, compounding, and administration of nonsterile products | |
| 2.2.3 | Physicochemical properties of active and inactive ingredients | |
| 2.2.4 | Identifying the presence of, and the cause of, product incompatibilities or degradation and methods for achieving stability | |
| 2.2.5 | Physicochemical properties of drugs that affect solubility and stability | |
| 2.3.0 | Review, Dispense, and Administer Drugs and Drug Products, Considering: | |
| 2.3.1 | Packaging, labelling, storage, handling, and disposal of medications | |
| 2.3.2 | Commercial availability, identification, and ingredients of prescription and non-prescription drugs | |
| 2.3.3 | Physical attributes of drug products | |
| 2.3.4 | Specific instructions and techniques for administration | |

Appendix C: MPJE competency statements and weightings²³⁴

| | Competency statement | | Weighting |
|---------------|---|---|--------------------------|
| Area 1 | Pharmacy Practice | | Approximately 83% |
| 1.1 | Legal responsibilities of the pharmacist and other pharmacy personnel | | |
| | 1.1.1 | <p>Unique legal responsibilities of the pharmacist-in-charge (or equivalent), pharmacists, interns, and pharmacy owners</p> <ul style="list-style-type: none"> Responsibilities for inventory, loss and/or theft of prescription drugs, the destruction/disposal of prescription drugs and the precedence of Local, State, or Federal requirements | |
| | 1.1.2 | <p>Qualifications, scope of duties, and conditions for practice relating to pharmacy technicians and all other non-pharmacist personnel</p> <ul style="list-style-type: none"> Personnel ratios, duties, tasks, roles, and functions of non-pharmacist personnel | |
| 1.2. | Requirements for the acquisition and distribution of pharmaceutical products, including samples | | |
| | 1.2.1 | <p>Requirements and record keeping in relation to the ordering, acquiring, and maintenance of all pharmaceutical products and bulk drug substances/excipients</p> <ul style="list-style-type: none"> Legitimate suppliers, pedigrees and the maintenance of acquisition records | |
| | 1.2.2 | <p>Requirements for distributing pharmaceutical products and preparations, including the content and maintenance of distribution records</p> <ul style="list-style-type: none"> Legal possession of pharmaceutical products (including drug samples), labelling, packaging, repackaging, compounding, and sales to practitioners | |
| 1.3 | Legal requirements that must be observed in the issuance of a prescription/drug order | | |
| | 1.3.1 | <p>Prescription/order requirements for pharmaceutical products and the limitations on their respective therapeutic uses</p> <ul style="list-style-type: none"> Products, preparations, their uses and limitations applicable to all prescribed orders for both human and veterinary uses | |
| | 1.3.2 | <p>Scope of authority, scope of practice, and valid registration of all practitioners who are authorized under law to prescribe, dispense, or administer pharmaceutical products, including controlled substances</p> <ul style="list-style-type: none"> Federal and State registrations, methadone programs, office-based opioid treatment programs, regulations related to retired or deceased prescribers, Internet prescribing, limits on jurisdictional prescribing | |

| Competency statement | | Weighting |
|----------------------|--|-----------|
| 1.3.3 | <p>Conditions under which the pharmacist participates in the administration of pharmaceutical products, or in the management of patients' drug therapy</p> <ul style="list-style-type: none"> • Prescriptive authority, collaborative practice, consulting, counseling, medication administration (including immunization, vaccines), ordering labs, medication therapy management, and disease state management | |
| 1.3.4 | <p>Requirements for issuing a prescription/order</p> <ul style="list-style-type: none"> • Content and format for written, telephonic voice transmission, electronic facsimile, computer and Internet, during emergency conditions, and tamper-resistant prescription forms. | |
| 1.3.5 | <p>Requirements for the issuance of controlled substance prescriptions/orders</p> <ul style="list-style-type: none"> • Content and format for written, telephonic voice transmission, electronic facsimile, computerized and Internet, during emergency conditions, conditions for changing a prescription, time limits for dispensing initial prescriptions/drug orders, and requirements for multiple Schedule II orders | |
| 1.3.6 | <p>Limits of a practitioner's authority to authorize refills of a pharmaceutical product, including controlled substances</p> | |
| 1.4 | <p>Procedures necessary to properly dispense a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order</p> | |
| 1.4.1 | <p>Responsibilities for determining whether prescriptions/orders were issued for a legitimate medical purpose and within all applicable legal restrictions</p> <ul style="list-style-type: none"> • Corresponding responsibility, maximum quantities, restricted distribution systems, red flags/ automated alerts, controlled substances, valid patient / prescriber relationship, and due diligence to ensure validity of the order | |
| 1.4.2 | <p>Requirements for the transfer of existing prescription/order information from one pharmacist to another</p> | |
| 1.4.3 | <p>Conditions under which a prescription/order may be filled or refilled</p> <ul style="list-style-type: none"> • Emergency fills or refills, partial dispensing of a controlled substance, disaster or emergency protocol, patient identification, requirement for death with dignity, medical marijuana, and conscience /moral circumstances | |
| 1.4.4 | <p>Conditions under which prospective drug use review is conducted prior to dispensing</p> <ul style="list-style-type: none"> • Patient-specific therapy and requirements for patient-specific documentation | |

| Competency statement | | Weighting |
|----------------------|---|-----------|
| 1.4.5 | <p>Conditions under which product selection is permitted or mandated</p> <ul style="list-style-type: none"> • Consent of the patient and/or prescriber, passing-on of cost savings, and appropriate documentation | |
| 1.4.6 | <p>Requirements for the labeling of pharmaceutical products and preparations dispensed pursuant to a prescription/order</p> <ul style="list-style-type: none"> • Generic and therapeutic equivalency, formulary use, auxiliary labels, patient package inserts, FDA medication guides, and written drug information | |
| 1.4.7 | <p>Packaging requirements of pharmaceutical products, preparations, and devices to be dispensed pursuant to a prescription/order</p> <ul style="list-style-type: none"> • Child-resistant and customized patient medication packaging | |
| 1.4.8 | <p>Conditions under which a pharmaceutical product, preparation, or device may not be dispensed</p> <ul style="list-style-type: none"> • Adulteration, misbranding, and dating | |
| 1.4.9 | <p>Requirements for compounding pharmaceutical products</p> <ul style="list-style-type: none"> • Environmental controls, release checks and testing, beyond use date (BUD), initial and ongoing training | |
| 1.4.10 | <p>Requirements for emergency kits</p> <ul style="list-style-type: none"> • Supplying, maintenance, access, security, and inventory | |
| 1.4.11 | <p>Conditions regarding the return and/or reuse of pharmaceutical products, preparations, bulk drug substances/excipients, and devices</p> <ul style="list-style-type: none"> • Charitable programs, cancer or other repository programs, previously dispensed, and from “will call” areas of pharmacies | |
| 1.4.12 | <p>Procedures and requirements for systems or processes whereby a non-pharmacist may obtain pharmaceutical products, preparations, bulk drug substances/excipients, and devices</p> <ul style="list-style-type: none"> • Pyxis (vending), after hour’s access, telepharmacies, and secure automated patient drug retrieval centers | |
| 1.4.13 | <p>Procedures and requirements for establishing and operating central processing and central fill pharmacies</p> <ul style="list-style-type: none"> • Remote order verification | |
| 1.4.14 | <p>Requirements for reporting to PMP, accessing information in a PMP and the maintenance of security and confidentiality of information accessed in PMPs</p> | |

| Competency statement | | Weighting |
|----------------------|---|--|
| | 1.4.15 | Requirements when informed consent must be obtained from the patient and/or a duty to warn must be executed <ul style="list-style-type: none"> • Collaborative practice and investigational drug therapy |
| 1.5 | Conditions for making an offer to counsel or counselling appropriate patients, including the requirements for documentation | |
| | 1.5.1 | Requirements to counsel or to make an offer to counsel |
| | 1.5.2 | Required documentation necessary for counselling |
| 1.6 | Requirements for the distribution and/or dispensing of non-prescription pharmaceutical products, including controlled substances | |
| | 1.6.1 | Requirements for the labelling of non-prescription pharmaceutical products and devices |
| | 1.6.2 | Requirements for the packaging and repackaging of non-prescription pharmaceutical products and devices |
| | 1.6.3 | Requirements for the distribution and/or dispensing of poisons, restricted, non-prescription pharmaceutical products, and other restricted materials or devices <ul style="list-style-type: none"> • Pseudoephedrine, dextromethorphan, emergency contraception, and behind the counter products as appropriate |
| 1.7 | Procedures for keeping records of information related to pharmacy practice, pharmaceutical products and patients, including requirements for protecting patient confidentiality | |
| | 1.7.1 | Requirements pertaining to controlled substance inventories |
| | 1.7.2 | Content, maintenance, storage, and reporting requirements for records required in the operation of a pharmacy <ul style="list-style-type: none"> • Prescription filing systems, computer systems and backups, and prescription monitoring programs |
| | 1.7.3 | Requirements for protecting patient confidentiality and confidential health records <ul style="list-style-type: none"> • HIPAA requirements and conditions for access and use of information |

| | Competency statement | | Weighting |
|---------------|---|---|--------------------------|
| 1.8 | Requirements for handling hazardous materials such as described in USP | | |
| | 1.8.1 | Requirements for appropriate disposal of hazardous materials | |
| | 1.8.2 | Requirements for training regarding hazardous materials <ul style="list-style-type: none"> Reverse distributors, quarantine procedures, comprehensive safety programs, Material Safety Data Sheets | |
| | 1.8.3 | Environmental controls addressing the proper storage, handling, and disposal of hazardous materials <ul style="list-style-type: none"> Ventilation controls, personal protective equipment, work practices, and reporting | |
| | 1.8.4 | Methods for the compounding, dispensing and administration of hazardous materials <ul style="list-style-type: none"> All hazardous materials including sterile and non-sterile compounding | |
| Area 2 | Licensure, Registration, Certification, and Operational Requirements | | Approximately 15% |
| 2.1 | Qualifications, application procedure, necessary examinations, and internship for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing of pharmaceutical products (prescription and non-prescription) | | |
| | 2.1.1 | Requirements for special or restricted licenses, registration, authorization, or certificates <ul style="list-style-type: none"> Pharmacists, pharmacist preceptors, pharmacy interns, pharmacy technicians, controlled substance registrants, and under specialty pharmacist licenses (Nuclear, Consultant etc.) | |
| | 2.1.2 | Standards of practice related to the practice of pharmacy <ul style="list-style-type: none"> Quality assurance programs (including peer review), changing dosage forms, therapeutic substitution, error reporting, public health reporting requirements (such as notification of potential terrorist event, physical abuse, and treatment for tuberculosis), and issues of conscience and maintaining competency | |
| | 2.1.3 | Requirements for classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted individual | |

| Competency statement | | Weighting |
|----------------------|---|-----------|
| 2.1.4 | <p>Requirements for reporting to, and participating in, programs addressing the inability of an individual licensed, registered, or certified by the Board to engage in the practice of pharmacy with reasonable skill and safety</p> <ul style="list-style-type: none"> • Impairment caused by the use of alcohol, drugs, chemicals, or other materials, or mental, physical, or psychological conditions | |
| 2.2 | Requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity | |
| 2.2.1 | <p>Requirements for registration, license, certification, or permitting of a practice setting</p> <ul style="list-style-type: none"> • In-state pharmacies, out-of-state pharmacies, specialty pharmacies, controlled substance registrants, wholesalers, distributors, manufacturers/repackagers, computer services providers, and internet pharmacies | |
| 2.2.2 | Requirements for an inspection of a licensed, registered, certified, or permitted practice setting | |
| 2.2.3 | Requirements for the renewal or reinstatement of a license, registration, certificate, or permit of a practice setting | |
| 2.2.4 | Classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted practice setting | |
| 2.3 | Operational requirements for a registered, licensed, certified, or permitted practice setting | |
| 2.3.1 | <p>Requirements for the operation of a pharmacy or practice setting that is not directly related to the dispensing of pharmaceutical products</p> <ul style="list-style-type: none"> • Issues related to space, equipment, advertising and signage, security (including temporary absences of the pharmacist), policies and procedures, libraries and references (including veterinary), and the display of licenses | |
| 2.3.2 | <p>Requirements for the possession, storage, and handling of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances</p> <ul style="list-style-type: none"> • Investigational new drugs, repackaged or resold drugs, sample pharmaceuticals, recalls, and outdated pharmaceutical products | |
| 2.3.3 | Requirements for delivery of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances | |

| Competency statement | | Weighting |
|----------------------|---|-------------------------|
| | <ul style="list-style-type: none"> Issues related to identification of the person accepting delivery of a drug, use of the mail, contract delivery, use of couriers, use of pharmacy employees, use of kiosks, secure mail boxes, script centers, use of vacuum tubes, and use of drive-up windows | |
| Area 3 | General Regulatory Processes | Approximately 2% |
| 3.1 | Application of regulations | |
| | 3.1.1 Laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, (prescription and non-prescription), including controlled substances <ul style="list-style-type: none"> Food, Drug, and Cosmetic Act(s) and Regulations, the Controlled Substances Act(s) and Regulations, OBRA 90's Title IV Requirements, Practice Acts and Rules, other statutes and regulations, including but not limited to, dispensing of methadone, child-resistant packaging, tamper resistant packaging, drug paraphernalia, drug samples, pharmacist responsibilities in Medicare-certified skilled-nursing facilities, NDC numbers, and schedules of controlled substances | |

Appendix D: PEBC Pharmacist Qualifying Examination Blueprint²³⁶

Note: a double tick indicates the competency has a higher weighting in one part of the exam than the other.

| Part I (MCQ) | Part II (OSCE) | COMPETENCIES | Parts I and II Overall |
|--------------|----------------|---|------------------------|
| √ | √ | Competency 1: Ethical, Legal and Professional Responsibilities Pharmacists practise within legal requirements, demonstrate professionalism and uphold professional standards of practice, codes of ethics and policies. | 8% |
| √ | √ | 1.1 Practise within legal requirements. <ul style="list-style-type: none"> Apply legal requirements to practice, including federal and provincial/territorial¹ legislation, policies, by-laws, and standards. Apply federal and provincial/territorial¹ privacy legislation to the collection, use, storage, disclosure and destruction of personal health information. | |
| √ | √ | 1.2 Uphold ethical principles. <ul style="list-style-type: none"> Apply the principles of professional codes of ethics. Apply ethical principles in the decision-making process. | |
| √ | √ | 1.3 Manage actual and potential illegal, unethical, or unprofessional actions or situations in practice. <ul style="list-style-type: none"> Identify illegal, unethical or unprofessional actions or situations. Conduct appropriate intervention to address illegal, unethical or unprofessional actions or situations. | |
| √ | √ | 1.4 Apply principles of professionalism. <ul style="list-style-type: none"> Apply principles of self-regulation. Accept responsibility and accountability for own actions and decisions. Seek guidance when uncertain about own knowledge, skills, abilities, and scope of practice. Maintain appropriate professional boundaries. Protect the privacy and confidentiality of the patient. Manage situations of actual and perceived conflict of interest. Describe the Canadian health care system and the role of health professionals within it. | |
| √ | √ | 1.5 Document activities of practice in compliance with federal and provincial/territorial legislation¹, standards and policies. <ul style="list-style-type: none"> Maintain complete, accurate and secure patient records. Identify situations in which documentation should and should not be shared with other health professionals or third parties. Select appropriate methods to share documentation within the circle of care and facilitate patient care. | |

¹ Provincial/territorial legislation is **not** tested in the PEBC Qualifying Examination.

| Part I (MCQ) | Part II (OSCE) | COMPETENCIES | Parts I and II Overall |
|-----------------|-------------------|--|------------------------------|
| √ | √ | <p>Competency 2: Patient Care</p> <p>Pharmacists, in partnership with the patient and in collaboration with other health professionals, meet the patient's health and drug-related needs to achieve the patient's health goals.</p> | 42% |
| | √ | <p>2.1 Develop a professional relationship with the patient.</p> <ul style="list-style-type: none"> Establish and maintain rapport by using effective communication skills. Demonstrate a caring, empathetic, and professional attitude. Determine and acknowledge the patient's needs, values, desired level of care and health goals. Identify and respect the roles and responsibilities of each party in the relationship. | |
| √ | √ | <p>2.2 Obtain information about the patient.</p> <ul style="list-style-type: none"> Gather information from the patient using appropriate interview techniques, including active listening. Gather information from the patient's health records and from other health care team members. Perform, order and/or retrieve relevant laboratory tests and other diagnostic assessments. Perform physical assessments. Organize, reconcile and record the patient's information. | |
| √ | √ | <p>2.3 Assess the patient's health status and concerns.</p> <ul style="list-style-type: none"> Assess the patient's health and drug-related needs, as expressed by the patient, considering the impact of factors such as culture, language, demographic and physical characteristics. Assess the relevance, accuracy, currency and completeness of the information in relation to the patient's needs. Interpret relevant laboratory tests and other diagnostic assessments. Interpret findings of relevant physical assessments. Perform medication reconciliation. Assess the patient's ability to access and use his or her medication. | |
| √ | √ | <p>2.4 Determine the patient's actual and potential drug therapy problems.</p> <ul style="list-style-type: none"> Identify actual and potential drug therapy problems. Prioritize drug therapy problems in collaboration with other members of the patient's circle of care. | |

| Part I (MCQ) | Part II (OSCE) | COMPETENCIES |
|-----------------|-------------------|--|
| √ | √ | <p>2.5 Develop the patient's care plan, in partnership with the patient and in collaboration with other health professionals.</p> <ul style="list-style-type: none"> • Determine the patient's health goals and optimal therapeutic outcomes, specifying measurable endpoints, target values and timeframes. • Assess possible treatment options, including drug and other therapeutic methods, using an evidence-informed approach. • Outline the potential benefits and risks of the treatment options. • Recommend the optimal treatment for the patient. • Provide education to support the patient in making informed decisions about their care plan. • Determine the actions required, and person responsible for each action, to achieve the patient's health goals. • Consult other health professionals as appropriate and adjust the proposed care plan accordingly. • Determine the monitoring parameters, including the clinical indicators, techniques and timelines. • Communicate the rationale for the care plan within the circle of care. |
| √ | √ | <p>2.6 Implement the patient's care plan.</p> <ul style="list-style-type: none"> • Provide consultation and education to support the patient in successfully implementing the care plan • Undertake the actions and interventions outlined in the care plan including prescribing drugs, adapting prescriptions, and collaborating within the circle of care. |
| √ | | <p>2.7 Administer drugs to the patient by injection² using the necessary technical skills and applying the appropriate clinical knowledge.</p> |
| √ | √ | <p>2.8 Monitor the patient's progress and assess therapeutic outcomes.</p> <ul style="list-style-type: none"> • Review monitoring parameters, end points and timelines outlined in the patient's care plan. • Discuss with the patient the ongoing monitoring and information sharing responsibilities of the pharmacist, patient and other health professionals. • Follow-up with the patient to evaluate the effectiveness of care plan activities. • Assess the patient's adherence and tolerance to drug therapy. • Assess the effectiveness and safety of the drug therapy. • Undertake appropriate intervention based on the patient's progress towards their health goals and revise the care plan accordingly. |

² Detailed competencies required of pharmacists providing injections are outlined in the document entitled *Supplemental Competencies on Injection for Canadian Pharmacists*.

| Part I (MCQ) | Part II (OSCE) | COMPETENCIES | Parts I and II Overall |
|-----------------|-------------------|---|------------------------------|
| √√ | √ | Competency 3: Product Distribution Pharmacists ensure accurate product distribution that is safe and appropriate for the patient. | 13% |
| √ | √ | 3.1 Dispense a product safely and accurately that is appropriate for the patient. <ul style="list-style-type: none"> • Address concerns related to the validity, clarity, completeness or authenticity of the prescription. • Assess the therapeutic appropriateness of the prescription for the patient. • Select appropriate products and ingredients using knowledge of bio-equivalency, therapeutic equivalency, interchangeability, quality, integrity and stability of drugs. • Perform pharmaceutical, compounding and patient-specific calculations, including pharmacokinetic and other therapeutic calculations. • Develop master compounding formulas. • Prepare and compound non-sterile and sterile products according to recognized guidelines and standards of practice. • Identify and address patterns of unusual drug prescribing and usage including possible diversion or drug misuse. • Check the product and its prescription label against the prescription using a systematic approach, including an independent double check. | |
| √√ | | Competency 4: Practice Setting Pharmacists oversee the practice setting with the goal of ensuring safe, effective and efficient patient care. | 3% |
| √ | | 4.1 Optimize the safety, efficacy and efficiency of operations in the practice setting. <ul style="list-style-type: none"> • Demonstrate the organizational and time management skills necessary to effectively prioritize, organize and manage patient care. • Manage support personnel such that assigned functions are carried out to meet accepted standards. | |
| √ | | 4.2 Oversee pharmacy inventory to ensure safe, effective and efficient patient care. <ul style="list-style-type: none"> • Address issues with the drug supply chain, including drug shortages and drug recalls. • Develop procedures to ensure the return or proper disposal of recalled, expired and unusable products. | |
| √ | √ | Competency 5: Health Promotion Pharmacists use their expertise to advance the health and wellness of patients, communities and populations. | 3% |

| Part I (MCQ) | Part II (OSCE) | COMPETENCIES | Parts I and II Overall |
|-----------------|-------------------|---|------------------------------|
| √ | √ | 5.1 Engage in health promotion activities with the patient. <ul style="list-style-type: none"> Assess the primary health needs of the patient, considering the socio-economic, cultural, environmental and other factors that are barriers to, or facilitators of, health and wellness for the patient. Collaborate with the patient and other health professionals in the development and implementation of patient-specific health promotion strategies, including smoking cessation and immunization. Facilitate the patient's access to and interaction with support agencies and health services within the healthcare system. | |
| √ | √ | 5.3 Contribute to the maintenance of a healthy environment for the public. <ul style="list-style-type: none"> Promote the proper handling and disposal of drugs and hazardous materials with the patient, self and others. Identify and minimize the risk of disease transmission from the pharmacy environment. | |
| √ | √ | Competency 6: Knowledge and Research Application Pharmacists access, retrieve, critically analyze and apply relevant information to make evidence -informed decisions within their practice with the goal of ensuring safe and effective patient care. | 6% |
| √ | √ | 6.1 Apply knowledge, research skills and professional judgment to the decision-making process. <ul style="list-style-type: none"> Critically analyze and develop solutions to problems in pharmacy practice. Make decisions using an evidence-informed approach. Rationalize recommendations and decisions with critically analyzed evidence and accurate explanations. | |
| √ | √ | 6.2 Respond to questions using appropriate strategies. <ul style="list-style-type: none"> Use a variety of retrieval techniques to access reliable sources of relevant information, including evidence-based information when possible. Evaluate and interpret the information. Apply critical appraisal techniques to scientific and research information. Analyze the information to determine the appropriate response. | |
| √ | √ | 6.3 Apply relevant information to practice. <ul style="list-style-type: none"> Gather new information, including evidence-based information when possible, that may be applicable to practice. Evaluate and interpret the information using critical analysis techniques. Use current, relevant and reliable information to improve practice. | |
| √ | √√ | Competency 7: Communication and Education Pharmacists communicate effectively with patients, the pharmacy team, other health professionals and the public, providing education when required. | 14% |

| Part I (MCQ) | Part II (OSCE) | COMPETENCIES | Parts I and II Overall |
|-----------------|-------------------|--|------------------------------|
| √ | √ | 7.1 Establish and maintain effective communication skills. <ul style="list-style-type: none"> • Demonstrate proficiency in written and verbal English or French. • Demonstrate appropriate verbal and non-verbal communication skills, including listening skills. • Demonstrate appropriate interview techniques. • Select appropriate communication and education techniques for use with the patient and other health professionals. • Conduct interpersonal interactions, including conflict management, in a professional manner. • Communicate with sensitivity, respect and empathy. | |
| √ | √ | 7.2 Implement safe, effective and consistent communication systems. <ul style="list-style-type: none"> • Use communication techniques that maximize safety and understanding, including repeating back verbal orders, using recognized terminology and avoiding unnecessary or unsafe abbreviations. | |
| √ | √√ | Competency 8: Intra- and Inter-Professional Collaboration Pharmacists work in collaboration with the pharmacy team and other health professionals to deliver comprehensive services, make best use of resources and ensure continuity of care in order to achieve the patient's health goals. | 6% |
| . | √ | 8.1 Create and maintain collaborative professional relationships. <ul style="list-style-type: none"> • Identify potential collaborators with whom to initiate ongoing professional relationships. • Collaborate with other parties in the relationship to define the roles and responsibilities of each party. | |
| . | .√ | 8.2 Contribute to the effectiveness of working relationships in collaborative teams. <ul style="list-style-type: none"> • Interact respectfully with other members of the team by accepting accountability for themselves and managing disagreements and conflict. • Share decision-making activities with other members of the team. | |
| | √ | 8.3 Participate in the delivery of collaborative health services. <ul style="list-style-type: none"> • Participate in the formation and functioning of a collaborative team. • Collaborate with team members to ensure appropriate utilization of resources. • Collaborate with team members to determine and achieve team goals and objectives. • Participate in the assessment of the patient and development of the care plan in collaboration with other members of the team. • Facilitate continuity of care. | |

| Part I (MCQ) | Part II (OSCE) | COMPETENCIES | Parts I and II Overall |
|-----------------|-------------------|---|------------------------------|
| √ | √ | 8.4 Accept and make referrals for specific services. <ul style="list-style-type: none"> Recognize signs, symptoms and risk factors indicative of health needs that fall beyond the scope of practice of pharmacy. Select the most appropriate health professional or health agency for the referral. Accept responsibility for referrals from other health professionals | |
| √ | √ | Competency 9: Quality and Safety Pharmacists collaborate in developing, implementing, and evaluating policies, procedures and activities that promote quality and safety. | 5% |
| √ | √ | 9.1 Contribute to a culture of patient safety. <ul style="list-style-type: none"> Apply principles of patient safety to improve practice. Employ best practices when informing the patient of the occurrence of a medication incident or adverse drug event. | |
| √ | √ | 9.2 Contribute to continuous quality improvement and risk management activities related to pharmacy practice. <ul style="list-style-type: none"> Apply principles of continuous quality improvement to practice. Apply principles of risk management to practice by anticipating, recognizing and managing situations that place the patient at risk. Identify the occurrence of a medication incident, adverse drug event or close call and respond effectively to mitigate harm and prevent reoccurrence. Identify high-alert drugs and high-risk processes in order to respond effectively. | |
| √ | √ | 9.3 Ensure the quality, safety and integrity of products. <ul style="list-style-type: none"> Ensure that products are stored and transported under the conditions required to maintain product quality, safety and integrity, including cold chain management. | |
| √ | √ | 9.4 Create and maintain a working environment that promotes safety. <ul style="list-style-type: none"> Handle hazardous products safely by minimizing personal exposure and reducing environmental contamination. | |

