

**Simulated professional pharmacy techniques for training and
assessment of professional competence in the review and
supply of prescribed medicines in community pharmacy**

Hayley Alison Croft

BPharm (*Sydney*), BInformationTech (Hons) (*Newcastle*) GradCertDiabetes (*Curtin*),
AACPA, MPS

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Statement of originality

I hereby declare that the work embodied in this thesis is my own work, conducted under normal supervision. The thesis contains no material which has been accepted, or is being examined, for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968 and any approved embargo.

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Thesis by publication

I hereby certify that this thesis is in the form of a series of papers. I have included as part of the thesis a written declaration from each co-author, endorsed in writing by the Faculty Assistant Dean (Research Training), attesting to my contribution to any jointly authored papers.

This declaration is included in Appendix 1.

Hayley A Croft

Thesis organisation

This thesis by publication consists of eight chapters. Six chapters (Chapter 2, 3, 4, 5, 6 and 7) are the final accepted version of manuscripts authored by the candidate. All six manuscripts have been published, or are *In Press*, having been accepted for publication.

Unpublished, original work comprises the entirety of Chapter 1 (the Introduction to the study) and Chapter 8 (the Discussions and Conclusions chapter).

Original work is also interspersed between article-based chapters, which explain to the reader the purpose of incorporating individual papers and provide a link successive chapters and their themes.

A diagram representing an overall view of thesis structure is shown in Figure 1.1, Chapter 1.

A list of all abbreviations used in this thesis is included in Appendix 2. A glossary of commonly used terms throughout this thesis is included on Pages x-xiv.

Publications arising from PhD research thesis

This thesis is presented with the inclusion of six peer-reviewed papers. At the time of submission, five of these were published and a further one accepted for publication. I am the lead author on all papers.

Manuscripts in peer-reviewed journals: Published

1. **Croft, H.**, Nesbitt, K., Rasiah R., Levett-Jones, T., & Gilligan, C. (2017). Safe dispensing in community pharmacies: How to apply the SHELL model for catching errors. *Clinical Pharmacist* 7(9), 215-224.
2. **Croft, H.**, Gilligan C., Rasiah R., Levett-Jones T., Schneider J. (2019). Current Trends and Opportunities for Competency Assessment in Pharmacy Education – A Literature Review. *Pharmacy* 7(2); 67. <https://doi.org/10.3390/pharmacy7020067>
3. **Croft, H.**, Gilligan C., Rasiah R., Levett-Jones T., Glass B., Schneider J. (2019). Integrated simulation-based skills assessment for evaluating pharmacist competence – A scoping review. *Pharmacy Education*. 19(1), 381-396.
4. **Croft, H.**, Gilligan C., Rasiah R., Levett-Jones T., Schneider J. (2017). Thinking in Pharmacy Practice: A Study of Community Pharmacists' Clinical Reasoning in Medication Supply Using the Think-Aloud Method. *Pharmacy* 6(1), 1-14. <https://doi.org/10.3390/pharmacy6010001>
5. **Croft, H.**, Gilligan C., Rasiah R., Levett-Jones T., Schneider J. (2020). Development and inclusion of an Entrustable Professional Activity (EPA) scale in a simulation-based medicine dispensing assessment. *Currents in Pharmacy Teaching and Learning* 12(2) 203-212. <https://doi.org/10.1016/j.cptl.2019.11.015>

**Manuscripts in peer-reviewed journals: Accepted for publication:
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6. **Croft, H.,** Gilligan C., Rasiah R., Levett-Jones T., Schneider J. (2020). Developing a validity argument for a simulation-based Model of Entrustment in Dispensing Skills (MEDS) assessment framework. *Currents in Pharmacy Teaching and Learning* 12(9) *[In Press]*

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Croft, H., Gilligan, C., Rasiah, R., Levett-Jones, T., Schneider, J. *Developing a validity argument for a simulation-based assessment framework in medicine dispensing activities.* Australian & New Zealand Association for Health Professional Educators (ANZAHPE) Conference. July 2019. Canberra, Australia (Oral presentation)

Croft, H., Gilligan, C., Rasiah, R., Levett-Jones, T., Schneider, J. *Validation of a simulation-based assessment framework for pharmacy students in medication supply.* MEU Forum: Faculty of Health and Medicine, School of Medicine and Public Health. November 2018. Newcastle, NSW (Oral presentation)

Croft, H., Gilligan, C., Rasiah, R., Levett-Jones, T., Schneider, J. *Inclusion of EPAs in a validated assessment framework for medicine dispensing.* Western Australian Centre for Rural Health Learning Lunch: University of Western Australia. October 2018. Newcastle, NSW (Oral presentation via Video Conference)

Croft, H., Gilligan, C., Rasiah, R., Levett-Jones, T., Schneider, J. *Validation of a simulation-based assessment framework for pharmacy students in medication supply.* International Pharmaceutical Federation World Congress. September 2018. Glasgow, Scotland (Oral presentation)

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Croft, H., Gilligan, C., Rasiah, R., Levett-Jones, T., Schneider, J. *Development and validation of a framework for evaluating competency in medication supply.* Australian & New Zealand

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Croft, H., Gilligan, C., Rasiah, R., Levett-Jones, T., Schneider, J. *Does simulation have the potential for training and assessment of professional competence for pharmacists in the review and supply of prescribed medicines in community pharmacy?* Hunter New England Simulation Centre Research Group, March 2017. Newcastle, Australia. (Oral presentation)

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Statement of ethical clearances

The research presented and reported in this thesis was conducted within the guidelines for research ethics. Ethical clearances were obtained for qualitative and quantitative research presented in Chapters 5, 6 and 7 of this thesis by formal application to the University of Newcastle Human Research Ethics Committee (HREC).

The research presented in Chapter 5 has been approved by the University's Human Research Ethics Committee, Approval No H-2017-0058. The statement of ethics approval is included in Appendix 3.

The research presented in Chapters 6 and 7 has been approved by the University's Human Research Ethics Committee, Approval No H-2018-0083. The statement of ethics approval is included in Appendix 4.

Glossary of terms

This section defines and describes common terms used throughout the thesis and describes the context in which they have been used within this doctoral research.

Assessment	The process of gathering and discussing information from multiple and diverse sources in order to develop a deep understanding of what students know, understand, and can do with their knowledge as a result of their educational experiences; the process culminates when assessment results are used to improve subsequent learning (Huba & Freed, 2000).
Authentic assessments	Performance assessments deployed under realistic conditions in which students are asked to perform real-world tasks that demonstrate meaningful application of essential knowledge and skills. Authentic assessments emphasise the need to apply the knowledge and skills in practical contexts and settings (Benedict et al., 2017).
Clinical Reasoning	A systematic and cyclical process by which health professionals collect cues, process the information and come to an understanding of a patient problem or situation, plan and implement interventions, evaluate outcomes, and reflect on and learn from the process (Levett-Jones et al., 2009)
Community Pharmacies	Shops distributed throughout metropolitan, suburban, rural and remote regions that provide medicines and health services to community residents, and play a role in public and preventative health

Competence	Competence is an objective term defined as a generic quality referring to a person's overall capacity, and represents potential to perform, rather than actual performance (Sears et al., 2014). The full repertoire of competencies representing the degree that an individual can use the knowledge, skills and judgement associated with the specialty to perform effectively in the domain of possible encounters defining the scope of professional practice (Jouriles, Burdick, & Hobgood, 2002; Nash, Chalmers, Brown, Jackson, & Peterson, 2015). Measures of competence often include subjective evaluations.
Competency	A single item of knowledge, skill or professional value (Nash et al., 2015).
Competency Standards	The National Competency Standards Framework for Pharmacists in Australia describes, in generic terms, clear competencies that are central to pharmacists performing effectively in contemporary professional practice. The 2016 framework contains Performance Criteria (PC) that can support professional development along a practice continuum from initial registration level through to advanced practice level (Pharmacy Practitioner Development Committee, 2016).
Entry-level pharmacists	Describes the transition between mandatory training (usually undergraduate or post-graduate training) to workplace practice
Integration	The ability to apply basic science concepts, knowledge, skills and communications during each step of clinical practice (Panzarella & Manyon, 2007).

Integrated assessment	The collection of evidence and judgement of competency that is not based narrowly on tasks but embraces all aspects of workplace performance using an integrated, holistic approach. Integrated assessment covers multiple dimensions of competence including: 1) performance of individual tasks; 2) managing multiple tasks within the one job; 3) management skills, including responding to problems; and 4) environment skills, including dealing with responsibilities and expectations in the workplace (Australian National Training Authority, 2007).
Medicine dispensing	A core skill and key competency for pharmacists that describes the integrated application of knowledge, functional and behavioural competence, and judgement in the provision of medicines to the public by a pharmacist, directed from a prescription, in a timely, convenient, affordable and equitable manner; and underpinned by appropriate ethics and values. Medicine dispensing is a major focus of pharmacy education in Australia and many other countries (McDowell et al., 2016). A holistic process underpinned by multiple, parallel steps that include interpreting and evaluating a prescription, retrieval and review of a medication history, selection, preparation, packaging, labelling, record-keeping, and transfer of the prescribed medicine to the patient, including counselling as appropriate. The dispensing process may also incorporate other associated tasks such as communication with the prescriber, and provision of more complex advice to the patient (Pharmaceutical Society of Australia, 2017; World Health Organisation, 2012).
Non-Technical Skills (NTS)	Interpersonal skills including communication skills; leadership skills; team-work skills; decision-making skills; and situation-awareness skills
Professional competency	Multidimensional construct. Defined as “the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning,

	emotions, values and reflection in daily practice for the benefit of the individual and the community being served” (Epstein & Hundert, 2002). As a professional competency, medicine dispensing blends specialist knowledge, functional and behavioural competence, and judgment, and is underpinned by appropriate ethics and values (McDowell et al., 2016). The process of developing such competence occurs progressively by increasingly integrating separate dimensions during professional activities and decision making (Cheetham and Chivers, 2005).
Reflexivity	An attitude of attending systematically to the context of knowledge construction, especially to the effect of the researcher, at every step of the research process, thus acknowledging the subjective nature of the research (Nestel et al., 2019).
Simulation	Simulation is “the imitation or representation of one act or system by another” (“Society for Simulation in Healthcare,” 2016). The term simulation can adopt different meanings when applied across different domains. Simulation includes a wide variety of educational techniques that are used throughout health education and training, and there are several interpretations that exist in the literature. One that is applicable to undergraduate healthcare training defines simulated learning technologies as “activities that provide students with an opportunity to rehearse skills or elements of practice that they will be required to perform as part of their future professional roles. This includes activities that use simple to complex technologies and low to high fidelity and that may take place in learning, simulated or real clinical settings (Nestel, Krogh, Harlim, Smith, & Bearman, 2014).
Technical Skills	The core skills of a task or an activity including ability to identify pharmaceutical products such as identifying packaging, interpreting dense information displayed on product packaging and within drug information systems; performing calculations; use of pharmaceutical

	equipment (e.g. medical devices, monitoring equipment) and software (e.g. dispensing programs and medical records).
Validity	A construct used to ‘attest’ to the quality of tools and to justify the use of assessments in health professions education using a collection of evidence (Marceau, Gallagher, Young, & St-Onge, 2018).
Validation	The process of collecting validity evidence to evaluate the appropriateness of the interpretations, uses, and decisions based on assessment results (Cook & Hatala, 2016).

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Abstract

Safe and effective patient-centred medicine dispensing is central to the role of community pharmacists. There is increasing demands for graduate pharmacists to be competent across all areas of professional practice, a requirement given momentum by health regulators, public interest and educational institutions. Consequently, it is necessary for student assessment models to evolve to track progress towards competence and ensure preparedness of entry level pharmacists for practice. The research in this thesis is underpinned by current trends identified in a thorough review of the literature related to competency-based entry level pharmacy education and assessment. This review highlighted key opportunities that have become the focus of this research including; 1) integrated assessment models which evaluate multiple competencies simultaneously and provide a suitable focus to expand the range of practice-based assessment of pharmacists in medicine dispensing and; 2) entrustment decisions about learners using Entrustable Professional Activity (EPA) descriptions that provide an opportunity to reframe our approach to assessment of pharmacy practice skills.

Aspects of the community pharmacy work system that are vulnerable to medication-related errors were identified using a comprehensive literature review and structured using a human factors framework. Analysed according to the dimensions of the human factors SHELL model, the findings of this review identified key areas of focus for competency-based interventions and assessment in simulation-based training activities. This research is focused on the assessment of pharmacist's clinical reasoning processes in the supply of prescribed medicines in a community pharmacy. These processes are not routinely captured in simulation-based assessments, despite being crucial elements of the dispensing process and given their potential to impact patient safety.

Undertaking a qualitative think-aloud study with community pharmacists revealed seven core cognitive processes used by pharmacists when making decisions about the appropriateness and safety of a prescribed medicine before supplying to a patient. These findings were used to inform the development of an assessment model focused on the evaluation of competency in medicine dispensing, and identifying the complex and dynamic cognitive skills required in this area of practice.

The resulting *Model of Entrustment in Dispensing Skills* (MEDS) assessment framework utilises seven domains representing key competency areas in medicine dispensing; complimented by a global rating using an entrustment scale. Evidence for validity of the assessment framework was ensured through both the collection and interpretation of evidence. The framework was used in a pilot study conducted with expert assessors (n=10) who provided assessment ratings of final year undergraduate pharmacy students (n=21) in two simulated medicine dispensing tasks. The study demonstrated that entrustment decisions can be incorporated successfully to evaluate student performance and provide feedback on performance, with psychometric analysis of the framework producing high reliability coefficients and good correlation between total score and EPA ratings.

This thesis contributes valuable knowledge to current developments in health professional assessment. In particular, this work furthers the discussion concerning the challenging nature of evaluating competence by demonstrating a framework that creates evidence to support the validity of assessment decisions. The developed EPA-based assessment evaluates medicine dispensing skills in an integrated manner, informing reliable decisions about the level of supervision required for students when supplying medicines. The framework represents promising progress towards development of a validated holistic assessment of competency in medicine dispensing, and may be adopted into entry level training programs nationally and internationally.