Position Paper: Compounding Competencies for Pharmacy Professionals

Introduction

The combining or mixing of drug ingredients to create a final product that meets patients' unique needs, also known as compounding,[1] is an important component of providing care within pharmacy practice. While the exact prevalence of compounding in Canada is not known, the demand for sterile compounding, especially in hospitals, has increased where customized injections are necessary for patient care.[2]

Pharmacy professionals include pharmacy technicians and pharmacists. The roles of pharmacy professionals as compounders have evolved. Compounding is a significant component of Canadian pharmacy technicians' scope of practice.[3] As pharmacists' focus continues to shift to direct patient care activities, including assessment and prescribing, their involvement in the technical acts of compounding has significantly decreased.

Pharmacy technicians are recognized as sterile compounding experts. Many hospitals and other sterile compounding facilities predominantly utilize pharmacy technicians to compound pharmacy-prepared sterile products. Pharmacists still play an important role in formulation development and clinical assessment of therapies, but they fulfil the role of sterile compounder less often.

This position paper is intended to inform the direction for the education, practice and competency expectations of pharmacy professionals related to compounding.

Background

In Canada, compounding hazardous and non-hazardous, non-sterile and sterile products according to recognized guidelines has been an entry to practice competency for both pharmacy technicians and pharmacists.

Evolving practice and increased awareness of the risks associated with compounding sterile preparations led to the publication of minimum practice and quality standards. These standards are enforced by provincial pharmacy regulatory authorities to prevent patient harm related to compounding. Parenteral therapies and other treatments involving sterile preparations can be

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[1] Health Canada. Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051). https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/policy-manufacturing-compounding-drug-products.html Accessed June 30, 2023.

[2] Watson CJ, Whitledge JD, Siani AM, Burns MM. Pharmaceutical Compounding: a History, Regulatory Overview, and Systematic Review of Compounding Errors. J Med Toxicol. 2021 Apr;17(2):197-217. doi: 10.1007/s13181-020-00814-3. Epub 2020 Nov 2. PMID: 33140232; PMCID: PMC7605468.

[3] National Association of Pharmacy Regulatory Authorities. Scope of Practice for Pharmacy Technicians in Canadian Jurisdictions.https://www.napra.ca/wp-content/uploads/2023/12/NAPRA-Scope-of-Practice-Pharmacy-Technicians-EN-2023-08.pdf. Accessed December 20, 2023.

complex and pharmacy professionals must carefully adhere to these standards when sterile compounding. One of the most critical standards requires that only well-trained pharmacy professionals perform compounding.

In 2022, the National Association of Pharmacy Regulatory Authorities (NAPRA) published *Model Compounding Competencies for Pharmacists and Pharmacy Technicians in Canada.* While this document provides a high-level overview of what a compounding pharmacy professional is expected to do, the detailed description of how competencies are to be performed, and the level of performance expected, are found within NAPRA's *Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada.*

Further work by NAPRA has resulted in proposed changes to competencies that are required of pharmacy professionals at entry to practice. Draft amendments outline that pharmacy technicians and pharmacists must be able to compound non-sterile, non-hazardous products at entry to practice but only understand the general principles of sterile and hazardous compounding. This change has the potential to negatively impact the pharmacy profession and the level of care patients, and the health system, have come to expect.

Education and Training

To ensure consistent quality, pharmacy professionals' educational programs are accredited by the *Canadian Council for Accreditation of Pharmacy Programs.* The accreditation standards for pharmacy technician programs require simulation environments that enable active participation of each student in compounding activities, including non-sterile and sterile compounding.[4] Pharmacist program standards also require learning in simulated practice environments but include no specific requirements related to compounding. The simulation-based education pharmacy technicians receive from formal accredited programs builds a foundation of knowledge. Employers continue compounding training with practical real-world experiences following entry to practice. Not all compounding competencies can be adequately addressed in either formal education or employer training programs alone.

Educational programming for pharmacy professionals in Canada is routed in the concept of competency-based education. Competencies are instrumental in designing the curriculums educational programs use to educate students. If pharmacy professionals are no longer expected to be able to perform sterile and hazardous compounding at entry to practice, there is danger that curriculums will evolve, and pharmacy professionals will not be adequately prepared to sterile compound.

[4] Canadian Council for Accreditation of Pharmacy Programs. Accreditation Standards for Canadian Pharmacy Technician Programs. July 2019 (Revised 2020) https://ccapp.ca/wp-content/uploads/2020/10/2020-PT-CCAPP-PharmTech-Standards_ENG.pdf. Accessed Dec 20, 2023.

Having to seek alternative educational opportunities will create barriers for pharmacy professionals choosing practices that include sterile compounding. Additionally, there is risk that alternative programs will not meet the same standards that are currently required by accrediting organizations.

Workforce Impact

One study evaluating sterile compounding workload estimated that 1.4 pharmacist full-time equivalents (FTEs) and 2.7 pharmacy technician FTE are required to meet sterile compounding needs for a hospital with a capacity of 100 beds.[5] Assuming proportionate increases, a significant volume of the pharmacy profession is needed to provide quality and safe sterile compounding services in Canada.

Advanced or specialized pharmacy practices requiring additional formal training and/or authorization from a regulator are limited in Canada. Prescribing by initiating a prescription is one example. In Alberta, only 60% of licensed pharmacists have additional prescribing authorization.[6]

Akin to prescribing or dispensing, compounding is regulated as a restricted healthcare activity or controlled act in many Canadian jurisdictions and viewed as a pharmacy practice. Supply-demand imbalances in the pharmacy workforce already exist. Removing sterile compounding as an entry to practice competency and changing pathways to achieve authorization, could result in a significant decline in the number of pharmacy professionals qualified to practice compounding. Workforce shortages and risk of burnout among compounding pharmacy professionals is a concerning consequence. Mobilization between jurisdictions could also be impacted. Without a clear plan that considers these factors, the care provided to patients may be affected as workforce pressures increase.

Expectations for Compounding Pharmacy Professionals

Not all pharmacy professionals will perform all pharmacy activities. In some cases, this is due to scope of practice limitations. Pharmacy technicians have a different scope of practice than pharmacists. Variations are also due to professional proclivity or the nature of different practice settings. There is currently no difference in expectations for pharmacists and pharmacy technicians related to compounding despite the different levels of education and assessment provided to each group.

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[5] Ahmed Chaker, Israa Omair, Weam Hazem Mohamed, Shuaib Haroon Mahomed, Mohammad Aslam Siddiqui, Workforce planning and safe workload in sterile compounding hospital pharmacy services, *American Journal of Health-System Pharmacy*, Volume 79, Issue 3, 1 February 2022, Pages 187–192, https://doi.org/10.1093/ajhp/zxab379
NAPRA-Scope-of-Practice-Pharmacists-EN-2023-08.pdf
CCAPP Standards https://ccapp.ca/wp-content/uploads/2020/10/2020-PT-CCAPP-PharmTech-Standards_ENG.pdf. Accessed Dec 20, 2023.

[6] Alberta College of Pharmacy. 2022-23 Annual Report. https://abpharmacy.ca/wp-content/uploads/ACP_AR_2022-23.pdf. Accessed Dec 20, 2023.

Forty-three percent of the national pharmacy technician qualifying exam,[7] and only thirteen percent of the pharmacist qualifying exam,[8] is dedicated to assessing product distribution competencies, which includes those related to compounding. Regulation has enabled pharmacy technicians to assume responsibility for risk arising from compounding activities. This presents opportunities for a shift in the practice framework for pharmacy technicians to superintend the application of their foundational sterile compounding knowledge.

Recommendations

To ensure that pharmacy services will continue to meet the healthcare systems' compounding needs:

Pharmacy technicians must:

- continue to be required to safely compound quality hazardous and non-hazardous, non-sterile and sterile preparations at entry to practice.
- receive education as a student related to the preparation of hazardous and non-hazardous, non-sterile and sterile compounds within formal educational curriculums.
- be enabled to obtain additional experiential training through employer-based programs, to meet initial and ongoing practice assessment requirements as outlined in compounding standards.
- commit to continuing professional development related to compounding if these activities are part of their practices.

Educational program providers must:

- ensure the curriculums and learning formats related to hazardous and non-hazardous, non-sterile and sterile compounding prepare students with a consistent foundational knowledge that can be enhanced through post-registration training in the practice setting.

Pharmacy regulators must:

- reflect where pharmacy technician and pharmacist practices differ within the practice and regulatory frameworks while ensuring compounding remains a foundational component of the care provided by pharmacy professionals.

Questions about this paper should be directed to info@ptsa.ca

[7] Pharmacy Examining Board of Canada. Pharmacy Technician Qualifying Examination Blueprint. Qualifying Examination Blueprint - PEBC. Accessed June 30, 2023

[8] Pharmacy Examining Board of Canada. Pharmacist Qualifying Examination Blueprint. Qualifying Examination Blueprint - PEBC. Accessed June 30, 2023