

# CJHP

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Athabasca River, Alberta

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Directrice générale  
ext. / poste 225  
email: [jciuffo@cshp.ca](mailto:jciuffo@cshp.ca)

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Peggy Robinson  
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Hélène Roulston  
email: [hroulston@sympatico.ca](mailto:hroulston@sympatico.ca)

**TRANSLATION / TRADUCTION**

Sigma Translations  
email: [info@sigmatranslations.ca](mailto:info@sigmatranslations.ca)

**PRODUCTION**

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# Pharmacy First

Christine M Bond

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As of January 1, 2023, pharmacists in Ontario are allowed to prescribe medication for 13 minor common ailments.<sup>1</sup> Similar changes are planned in British Columbia.<sup>2</sup> The move is intended to empower pharmacists to use their skills, improve patients' access to care, and reduce the workload of primary care physicians and emergency departments. These objectives are admirable, but why has it taken so long?

Across the 13 Canadian provinces and territories, the variation in pharmacists' scope of practice is striking,<sup>2</sup> especially so for prescribing. Although all jurisdictions but one (Nunavut) allow pharmacists to renew or extend prescriptions for continuity of care, only Alberta allows a pharmacist to initiate independently a prescription for any schedule I drug. The number of conditions for which Ontario pharmacists can prescribe ( $n = 13$ ) is modest compared with those in Alberta, who can prescribe for 58 of the 59 conditions listed in a comparative chart prepared by the Canadian Pharmacists Association.<sup>3</sup> Why is there such a difference?

Pharmacy practice in Canada is evolving from a technical supply function to a more clinical cognitive role. This parallels practice changes across many other countries, especially in the developed world. The variability in the extent of these changes across countries may reflect differences in pharmacy training, but this is not the case for variations within a single country such as Canada.

Until recently, the general separation of prescribing and dispensing functions was hailed as an important safety net for patients, removing potential conflicts of interest and also the potential for prescribing errors to reach the patient. However, a shift toward a greater prescribing role has been occurring incrementally. Although the word "prescribe" is often understood to mean "write a prescription for a schedule I drug to be dispensed by a pharmacist", pharmacists have for many years been prescribing over-the-counter (OTC) medications. The first step to increase their prescriptive authority came with the deregulation of many previously schedule I drugs to OTC availability. Evaluations demonstrated that this steady increase in the number of often-potent OTC medications that pharmacists can prescribe or recommend was both safe and well accepted by the public. This expanded role has resulted in greater public awareness of pharmacists' expertise in medicines.

For a fundamental paradigm shift in role to occur, three things must be in place: governmental need, societal acceptability, and evidence of benefit,<sup>4</sup> all underpinned by professional aspiration and expertise. It is therefore interesting to speculate whether existing jurisdictional variation is due to differing needs across provinces or inconsistent interpretation of research evidence. Is it right that in some provinces the public does not have such easy access to care provided by prescribing pharmacists?

Other questions come to mind, presenting a fascinating research agenda. Does the hypothesis outlined above hold true for Canada? To what extent are these new roles actually being used in practice? Is the public now more dependent on medicines, given their increased availability through pharmacists? Research from the United Kingdom has demonstrated the efficiency and effectiveness of minor ailment schemes,<sup>5</sup> but is there similar evidence from Canada? If not, should there be, or can evidence from other, arguably similar, jurisdictions be used as the basis of new provincial policies?<sup>6</sup> Furthermore, to what extent are these new authorizations being implemented in the hospital sector, and what is the benefit? Pharmacists are highly trained experts in medicine, and it is right that their skills should be utilized for the benefit of all patients. As leaders in our profession, we should be lobbying for all pharmacists to practise to their full scope of practice.<sup>6</sup>

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**Christine M Bond**, BPharm, PhD, MEd, is Emeritus Professor, Division of Applied Health Sciences, University of Aberdeen, Foresterhill, Aberdeen, Scotland. She is also an Associate Editor with the *Canadian Journal of Hospital Pharmacy*.

**Competing interests:** None declared.

**Address correspondence to:**

Professor Christine M Bond  
University of Aberdeen  
Polwarth Building West Block, Room 1.123  
Foresterhill, Aberdeen AB25 2ZD  
Scotland

**email:** c.m.bond@abdn.ac.uk

## ON THE FRONT COVER



### **Athabasca River, Alberta**

This photograph was taken by pharmacist and CSHP member Arden Barry while he was on vacation in 2012. The image, taken with a Canon PowerShot SD600 digital camera, depicts the Athabasca River just outside of Jasper in Jasper National Park.

Arden is a Clinical Pharmacy and Research Specialist with Lower Mainland Pharmacy Services at the Jim Pattison Out-patient Care and Surgery Centre in Surrey, British Columbia, and is also an Associate Professor (Partner) with the Faculty of Pharmaceutical Sciences at the University of British Columbia in Vancouver. Outside of work, he enjoys running, travelling, and spending time with his kids.

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# La pharmacie d'abord

par Christine M. Bond

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Depuis le 1<sup>er</sup> janvier 2023, les pharmaciens de l'Ontario sont autorisés à prescrire des médicaments pour 13 affections mineures courantes<sup>1</sup>. Des changements similaires sont prévus en Colombie-Britannique<sup>2</sup>. Cette décision vise à donner aux pharmaciens les moyens d'utiliser leurs compétences, à améliorer l'accès des patients aux soins et à réduire la charge de travail des médecins de soins primaires et des services d'urgence. Ces objectifs sont admirables, mais pourquoi a-t-il fallu si longtemps?

La variation du champ de pratique des pharmaciens dans les 13 provinces et territoires canadiens est frappante<sup>2</sup>, particulièrement en ce qui concerne la prescription. Bien que toutes les régions sauf le Nunavut autorisent les pharmaciens à renouveler ou à prolonger les ordonnances pour la continuité des soins, seule l'Alberta permet à un pharmacien d'initier indépendamment une ordonnance pour tout médicament de l'annexe I. Le nombre de problèmes de santé pour lesquels les pharmaciens ontariens peuvent prescrire des médicaments ( $n = 13$ ) est modeste par rapport à celui de l'Alberta, où ils peuvent le faire pour 58 des 59 problèmes répertoriés dans un tableau comparatif préparé par l'Association des pharmaciens du Canada<sup>3</sup>. Pourquoi une telle différence?

La pratique de la pharmacie au Canada passe d'une fonction d'approvisionnement technique à un rôle cognitif plus clinique. Cela correspond aux changements de pratiques dans de nombreux autres pays, en particulier dans les pays développés. La variabilité de l'ampleur de ces changements d'un pays à l'autre peut refléter des différences dans la formation en pharmacie, mais ce n'est pas le cas des variations au sein d'un même pays comme le Canada.

Jusqu'à récemment, la séparation générale des fonctions de prescription et de distribution était saluée comme un filet de sécurité important pour les patients, supprimant les conflits d'intérêts potentiels ainsi que la possibilité que des erreurs de prescription ne touchent le patient. Cependant, une évolution vers un plus grand rôle de prescripteur s'est produite progressivement. Bien que le mot « prescrire » soit souvent compris comme « rédiger une ordonnance pour un médicament de l'annexe I devant être délivré par un pharmacien », ces derniers prescrivent depuis de nombreuses années des médicaments en vente libre. La première étape pour accroître leur autorité prescriptive est venue avec la déréglementation de nombreux médicaments auparavant

de l'annexe I à la disponibilité en vente libre. Les évaluations ont démontré que cette augmentation constante du nombre de médicaments en vente libre souvent puissants que les pharmaciens peuvent prescrire ou recommander était à la fois sûre et bien acceptée par le public. Ce rôle élargi a entraîné une plus grande sensibilisation du public à l'expertise des pharmaciens en matière de médicaments.

Pour qu'un changement de paradigme fondamental dans le rôle se produise, trois éléments doivent être en place : le besoin du gouvernement, l'acceptabilité de la société et la preuve des bienfaits<sup>4</sup>, le tout étayé par une aspiration et une expertise professionnelles. Il est donc intéressant de spéculer si la variation existante entre les régions relève des besoins différents d'une province à l'autre ou à une interprétation incohérente des données de recherche. Est-il juste que dans certaines provinces, la population n'ait pas un accès aussi facile aux soins prodigués par les pharmaciens prescripteurs?

D'autres questions viennent à l'esprit, et présentent un programme de recherche passionnant. L'hypothèse décrite ci-dessus est-elle vraie pour le Canada? Dans quelle mesure ces nouveaux rôles sont-ils réellement utilisés dans la pratique? Le public dépend-il désormais plus des médicaments, compte tenu de leur disponibilité accrue auprès des pharmaciens? Des recherches menées au Royaume-Uni ont démontré l'efficacité et l'efficacité des régimes d'affections mineures<sup>5</sup>, mais existe-t-il des éléments probants similaires au Canada? Si non, devrait-il y en avoir, ou peut-on utiliser des éléments probants d'autres juridictions, sans doute similaires, comme point de départ pour adopter de nouvelles politiques provinciales?<sup>6</sup> De plus, dans quelle mesure ces nouvelles autorisations sont-elles mises en œuvre dans le secteur hospitalier et quels en sont les avantages? Les pharmaciens sont des experts hautement qualifiés en médecine, et il est juste que leurs compétences soient utilisées au profit de tous les patients. En tant que chefs de file de notre profession, nous devrions exercer des pressions pour que tous les pharmaciens exercent leur plein champ d'exercice<sup>6</sup>.

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**Christine M. Bond**, B. Pharm., Ph. D., M. Ed., est professeur émérite, Division des sciences appliquées de la santé, Université d'Aberdeen, Foresterhill, Aberdeen, Écosse. Elle est également rédactrice adjointe du *Journal canadien de la pharmacie hospitalière*.

**Conflits d'intérêts** : Aucune déclaration.

**Adresse de correspondance** :

Professor Christine M Bond  
University of Aberdeen  
Polwarth Building West Block, Room 1.123  
Foresterhill, Aberdeen AB25 2ZD  
Écosse

**Courriel** : c.m.bond@abdn.ac.uk



# Side-by-Side Comparison of Methods for Environmental Monitoring for Hazardous Drug Contamination

Chun-Yip Hon

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## ABSTRACT

**Background:** Exposure to hazardous drugs is known to have deleterious effects on health care workers. To assess risk, environmental monitoring is conducted to ascertain drug contamination on surfaces, as dermal contact is the main route of exposure. Conventional monitoring employs wipe sampling whereby the wipe must be sent to a laboratory for analysis. This means that quantitative results are not available for some time, during which the risk remains unknown. A new device, the HD Check system, developed by BD, which uses lateral-flow immunoassay technology, allows for near real-time qualitative assessment of contamination (positive or negative); however, its sensitivity relative to the traditional method is unknown.

**Objective:** To evaluate the ability of this novel device to detect drug contamination relative to the conventional method.

**Methods:** Five sets of different known drug concentrations were compared between the conventional wipe sampling method and the HD Check systems for methotrexate (MTX) and cyclophosphamide (CP). Stainless steel surfaces were tested, and the drug concentrations ranged from 0 ng/cm<sup>2</sup> to twice the limit of detection (LOD) of each HD Check system.

**Results:** For MTX, positive results were obtained in every test trial at all drug concentrations examined with the HD Check system (LOD = 0.93 ng/cm<sup>2</sup>). For CP, test results with the HD Check system (LOD = 4.65 ng/cm<sup>2</sup>) were all positive at the LOD and twice the LOD; however, at 50% and 75% of the LOD, the result was positive in only 90% (9/10) of the trials. The conventional method was able to quantify the test drug concentrations with a high level of accuracy and reproducibility.

**Conclusions:** These results suggest the potential utility of the novel device as a screening tool for higher levels of drug contamination with MTX and CP, but additional research is needed to determine its suitability for lower concentrations, especially of CP.

**Keywords:** hazardous drugs, wipe sampling, surface contamination, HD Check system, risk assessment

## RÉSUMÉ

**Contexte :** L'exposition à des médicaments dangereux est connue pour avoir des effets délétères sur les travailleurs de la santé. Pour évaluer les risques, une surveillance environnementale est menée pour vérifier la contamination des surfaces par les médicaments, car le contact cutané est la principale voie d'exposition. La surveillance conventionnelle utilise un échantillonnage par frottis, lequel doit être envoyé à un laboratoire pour analyse. Cela signifie que les résultats quantitatifs ne sont pas disponibles pendant un certain temps – temps pendant lequel le risque reste inconnu. Un nouvel appareil, le système HD Check de BD, qui utilise la technologie d'immunodosage à flux latéral, permet une évaluation qualitative en temps quasi réel de la contamination (positive ou négative); cependant, sa sensibilité par rapport à la méthode traditionnelle est inconnue.

**Objectif :** Évaluer la capacité de ce nouveau dispositif pour détecter la contamination médicamenteuse par rapport à la méthode conventionnelle.

**Méthodes :** Cinq ensembles de différentes concentrations connues de médicaments ont été utilisés pour comparer la méthode conventionnelle d'échantillonnage par frottis et les systèmes HD Check pour la méthotrexate (MTX) et la cyclophosphamide (CP). Des surfaces en acier inoxydable ont été testées et les concentrations de médicament variaient de 0 ng/cm<sup>2</sup> à deux fois la limite de détection (LD) de chaque système HD Check.

**Résultats :** Pour la MTX, des résultats positifs ont été obtenus dans chaque essai à toutes les concentrations de médicament examinées avec le système HD Check (LD = 0,93 ng/cm<sup>2</sup>). Pour la CP, les résultats des tests avec le système HD Check (LD = 4,65 ng/cm<sup>2</sup>) étaient tous positifs à la LD et au double de la LD; cependant, à 50 % et 75 % de la LD, le résultat n'était positif que dans 90 % (9/10) des essais. La méthode conventionnelle a été en mesure de quantifier les concentrations de médicament à l'essai avec un niveau élevé de précision et de reproductibilité.

**Conclusions :** Ces résultats suggèrent l'utilité potentielle du nouveau dispositif comme outil de dépistage pour des niveaux plus élevés de contamination médicamenteuse par la MTX et la CP, mais des recherches supplémentaires sont nécessaires pour déterminer son adéquation à des concentrations plus faibles, en particulier de CP.

**Mots-clés :** médicaments dangereux, prélèvement par frottis, contamination de surface, système BD HD Check, évaluation

## INTRODUCTION

The risk of occupational exposure to hazardous drugs, also known as cytotoxic or antineoplastic drugs, has been documented since the 1970s.<sup>1,2</sup> The adverse health effects associated with occupational exposure to hazardous drugs include reproductive toxicities and genotoxic effects, as well as a higher risk for certain cancers.<sup>3-5</sup> According to CAREX Canada (a multi-institution team of experts providing knowledge about exposure to carcinogens), approximately 75 000 Canadians are exposed to hazardous drugs in the course of their work.<sup>6</sup> One of the most common means to assess the risk of health care workers' exposure to hazardous drugs is environmental monitoring or surface wipe sampling.<sup>7</sup> This is because the route of exposure to hazardous drugs for health care workers is believed to be dermal uptake or skin contact.<sup>8,9</sup> Essentially, workers can be exposed if they touch a drug-contaminated surface. As such, environmental monitoring is recommended in many best practice documents, including the US Pharmacopeial Convention's General Chapter <800>,<sup>10</sup> the International Society of Oncology Pharmacy Practitioners' standards of practice for the safe handling of cytotoxics,<sup>11</sup> and the National Association of Pharmacy Regulatory Authorities' *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*.<sup>12</sup>

At present, environmental monitoring typically involves using a moistened wipe material to wipe a surface in a pre-determined pattern. The surface area that is commonly sampled is 10 cm × 10 cm (or 100 cm<sup>2</sup>).<sup>13</sup> After sample collection, the wipe material is placed into a container such as a vial, which is then sealed, labelled, and sent to a laboratory for analysis. The gold standard laboratory analytical method is liquid chromatography with tandem mass spectrometry (LC-MS/MS) and the results are usually reported in units of nanograms per square centimetre (ng/cm<sup>2</sup>).<sup>13</sup> Because the wipes must be sent to a laboratory, the results are typically not available until days or weeks after the sample collection date. Surface contamination levels may change during this lag period, and, in turn, the level of risk may also evolve.<sup>14</sup>

Recently, monitors based on lateral flow immunoassay (LFIA) have been developed to allow for near real-time detection of hazardous drugs on surfaces.<sup>15,16</sup> These monitors consist of a test line and a control line. The colour of the test line changes in intensity based on the concentration of the drug, while the control line serves to indicate that the monitor is working properly (i.e., a form of quality control). The user then inserts the monitor into a digital reader, which indicates whether drug is present (i.e., the result is either positive or negative). The advantage of this novel technology is that analysis in a laboratory is not required, and therefore the results indicate the presence of drug contamination within a few minutes after sampling. However, to the author's knowledge, this novel technology has

never been evaluated in terms of its ability to detect surface contamination relative to the conventional wipe method described above.

This study aimed to compare the novel LFIA technology with an established surface wipe sampling and analysis method to assess the suitability of LFIA monitors to screen for hazardous drug contamination on work surfaces in health care settings. In other words, the goal was to ascertain whether the sensitivity of an LFIA monitor is suitable for employment of such devices as a substitute for conventional wipe sampling, to allow for near real-time detection of hazardous drugs on work surfaces. If deemed adequate, LFIA monitors could be considered for routine use in Canada and other jurisdictions for the purposes of environmental monitoring, assessment of exposure risk, and training, to name a few applications that would aid in reducing hazardous drug exposure among health care workers.

## METHODS

In this controlled laboratory study, 2 methods—LFIA monitoring and conventional wipe sampling and analysis—were tested side by side with various known concentrations of hazardous drugs on stainless steel surfaces. This method of comparison has been used previously in the occupational hygiene domain for assessing direct-reading instruments relative to an established sampling method for chemical hazards.<sup>17-22</sup> The LFIA monitors evaluated were from the HD Check system line of products, which are manufactured by BD and are currently the only lateral flow devices commercially available.<sup>23</sup> Specifically, the HD Check assays for methotrexate (MTX) and cyclophosphamide (CP) were evaluated. The conventional wipe sampling method employed was developed by members of the author's team and is suitable for analyzing both MTX and CP.<sup>24</sup>

### Test Surface

Stainless steel plates were chosen as the test surface, because stainless steel is the material used for biological safety cabinets, the typical location of drug preparation within health care facilities. Because 100 cm<sup>2</sup> is the typical surface area for wipe samples,<sup>16</sup> each stainless steel plate had dimensions of 10 cm × 10 cm.

### Drug Concentrations

For both MTX and CP, the following 5 concentrations were assessed: 0 ng/cm<sup>2</sup> (control/blank), 50% of the limit of detection (LOD) of the corresponding HD Check system, 75% of the LOD of the HD Check system, the LOD of the HD Check system, and twice (200%) the LOD of the HD Check system. The manufacturer's LOD was 0.93 ng/cm<sup>2</sup> for the MTX HD Check system and 4.65 ng/cm<sup>2</sup> for the CP HD Check system.

## Replicate Samples

For each drug (MTX and CP), 10 replicate samples of each of the aforementioned concentrations were evaluated by the 2 methods. This resulted in 20 samples (10 for the HD Check system and 10 for the conventional method) for each of the 5 drug concentrations tested. Overall, 100 test plates were examined for each drug, 50 for the HD Check system and 50 for the conventional wipe method. The total number of pairs of samples is consistent with other side-by-side tests<sup>17,18,20</sup> and allows for an understanding of the variability within each method.

## Sample Collection

Two sets of plates were set up for each sampling round per test drug concentration (20 altogether). One set of samples ( $n = 10$ ) was collected using conventional wipe sampling for laboratory analysis, and the other set of samples ( $n = 10$ ) was collected using the HD Check system. A small volume (50  $\mu$ l) of known drug concentration (as detailed above) was placed on each test of the plates. After the surface was allowed to dry naturally (for about 15 min), the residual drug was wiped by a single individual (C.Y.H.) using the conventional method.<sup>24</sup> Briefly, this method involved use of a Whatman filter moistened with a solution of water/methyl alcohol 20:80 with 0.1% formic acid. Subsequently, the wipe samples were analyzed by high-performance liquid chromatography tandem mass spectroscopy (HPLC-MS/MS), as described by Colombo and others,<sup>24</sup> at the Occupational and Environmental Hygiene laboratory, University of British Columbia, Vancouver, British Columbia.

After the first 10 plates were wiped via conventional testing, the same individual (C.Y.H.) sampled the remaining 10 plates with the HD Check system (to minimize the likelihood of inter-individual variability). Subsequently, the HD Check results were read using the system's digital reader, according to the manufacturer's instructions, and the findings, either positive or negative, were documented.

The wiping pattern for both conventional wipe sampling and HD Check sampling involved a back-and-forth motion in the vertical direction, followed by a back-and-forth motion in the horizontal direction. For the conventional wipe method, the wipe material was folded over to reveal a "fresh" side before wiping in the horizontal direction.

The sample collection procedure was repeated for every test drug concentration for each of the 2 HD Check assays (for MTX and CP). Between test drug concentrations, each set of plates was cleaned as described by Jeronimo and others.<sup>25</sup>

## RESULTS

With the HD Check assay for MTX, positive results were obtained in every test trial at all drug concentrations examined. In other words, the assay was able to detect positive contamination at concentrations less than its LOD (specifically,

50% and 75% of 0.93 ng/cm<sup>2</sup>). The corresponding average MTX concentrations detected by conventional wipe sampling and analysis were as follows: 0.457 ng/cm<sup>2</sup> at 50% of the LOD, 0.690 ng/cm<sup>2</sup> at 75% of the LOD, 0.919 ng/cm<sup>2</sup> at 100% of the LOD, and 1.854 ng/cm<sup>2</sup> at 200% of the LOD (Table 1).

With the HD Check assay for CP, test results were all positive at 100% and 200% of the assay LOD (where LOD = 4.65 ng/cm<sup>2</sup>). The corresponding average CP concentrations determined by conventional wipe sampling were 4.542 ng/cm<sup>2</sup> at 100% of the LOD and 9.224 ng/cm<sup>2</sup> at 200% of the LOD. However, at 50% and 75% of the LOD, the HD Check results were positive in only 9 of the 10 test trials. At these 2 concentrations, the corresponding average CP concentrations detected by the conventional wipe sampling method were 2.235 ng/cm<sup>2</sup> and 3.374 ng/cm<sup>2</sup>, respectively (Table 2).

## DISCUSSION

The objective of this study was to ascertain whether a novel direct-reading device based on LFIA technology, the HD Check system, can detect hazardous drug contamination levels to the same extent as the conventional wipe sampling method. By conducting side-by-side comparisons of the 2 methods, the investigator found that the MTX assay was capable of detecting drug contamination from stainless steel surfaces at all (100%) concentrations tested, including at 50% of the LOD of 0.93 ng/cm<sup>2</sup>. However, the CP assay was able to detect the presence of drug concentration in all instances only for contamination with solutions at 100% and 200% of the LOD of 4.65 ng/cm<sup>2</sup>; at 50% and 75% of the LOD, the assay detected the drug on the surface in only 90% of the test trials.

Relatively speaking, the LODs of the HD Check assays are higher than average or median concentrations found in previous surface contamination studies conducted in Canada. Hon and others<sup>26</sup> evaluated surface contamination levels on more than 400 surfaces and objects found throughout the hospital medical system in health care facilities in British Columbia and reported an average CP concentration of 0.201 ng/cm<sup>2</sup>. In their study of Quebec hospitals, Bussi eres and others<sup>27</sup> reported median concentrations of 0.0035 ng/cm<sup>2</sup> for CP and less than 0.0060 ng/cm<sup>2</sup> for MTX. In a more recent Canadian study involving 83 centres,<sup>28</sup> the same author group found that the 75th percentile concentration for CP was 0.004 ng/cm<sup>2</sup>, whereas the 75th percentile concentration for MTX was less than 0.0020 ng/cm<sup>2</sup>. Moreover, surface contamination levels in Canadian facilities are showing a downward trend over time.<sup>29</sup>

Of note, the US Pharmacopeial Convention's General Chapter <800>,<sup>10</sup> a best practice document that is widely referenced for use by hospital pharmacies in North America, has indicated a maximum threshold level of 1 ng/cm<sup>2</sup> for CP to reduce the risk of uptake among exposed individuals. Therefore, the promising results offered by the HD

**TABLE 1. Side-by-Side Comparison of Results for Methotrexate**

Concentration <sup>a</sup>	Sample ID	Wipe Sampling Result (ng/cm <sup>2</sup> ) <sup>b</sup>	HD Check Result
50% of device LOD	BD-T-M-50-1	0.472	Positive
	BD-T-M-50-2	0.460	Positive
	BD-T-M-50-3	0.594	Positive
	BD-T-M-50-4	0.495	Positive
	BD-T-M-50-5	0.360	Positive
	BD-T-M-50-6	0.414	Positive
	BD-T-M-50-7	0.422	Positive
	BD-T-M-50-8	0.483	Positive
	BD-T-M-50-9	0.402	Positive
	BD-T-M-50-10	0.468	Positive
	Overall <sup>c</sup>	0.457 (0.064)	100%
75% of device LOD	BD-T-M-75-1	0.517	Positive
	BD-T-M-75-2	0.888	Positive
	BD-T-M-75-3	1.014	Positive
	BD-T-M-75-4	0.085	Positive
	BD-T-M-75-5	0.626	Positive
	BD-T-M-75-6	0.701	Positive
	BD-T-M-75-7	0.978	Positive
	BD-T-M-75-8	0.575	Positive
	BD-T-M-75-9	0.784	Positive
	BD-T-M-75-10	0.733	Positive
	Overall <sup>c</sup>	0.690 (0.269)	100%
100% of device LOD	BD-T-M-100-1	1.152	Positive
	BD-T-M-100-2	0.399	Positive
	BD-T-M-100-3	0.072	Positive
	BD-T-M-100-4	0.658	Positive
	BD-T-M-100-5	0.478	Positive
	BD-T-M-100-6	0.889	Positive
	BD-T-M-100-7	0.896	Positive
	BD-T-M-100-8	1.615	Positive
	BD-T-M-100-9	1.133	Positive
	BD-T-M-100-10	1.899	Positive
	Overall <sup>c</sup>	0.919 (0.558)	100%
200% of device LOD	BD-T-M-200-1	1.609	Positive
	BD-T-M-200-2	1.275	Positive
	BD-T-M-200-3	2.135	Positive
	BD-T-M-200-4	1.919	Positive
	BD-T-M-200-5	2.009	Positive
	BD-T-M-200-6	1.983	Positive
	BD-T-M-200-7	1.978	Positive
	BD-T-M-200-8	1.902	Positive
	BD-T-M-200-9	1.540	Positive
	BD-T-M-200-10	2.188	Positive
	Overall <sup>c</sup>	1.854 (0.288)	100%

<sup>a</sup>LOD = limit of detection of the BD HD Check system. For methotrexate, LOD = 0.93 ng/cm<sup>2</sup>.

<sup>b</sup>All wipe sampling results have been corrected for the blank.

<sup>c</sup>Overall results presented as average (standard deviation) for conventional wipe sampling and as percent positive for HD Check system.

**TABLE 2. Side-by-Side Comparison of Results for Cyclophosphamide**

Concentration <sup>a</sup>	Sample ID	Wipe Sampling Result (ng/cm <sup>2</sup> ) <sup>b</sup>	HD Check Result
50% of device LOD	BD-T-C-50-1	2.181	Positive
	BD-T-C-50-2	2.434	Positive
	BD-T-C-50-3	1.405	Positive
	BD-T-C-50-4	2.587	Positive
	BD-T-C-50-5	2.416	Positive
	BD-T-C-50-6	2.512	Positive
	BD-T-C-50-7	2.208	Negative
	BD-T-C-50-8	2.341	Positive
	BD-T-C-50-9	2.134	Positive
	BD-T-C-50-10	2.131	Positive
	Overall <sup>c</sup>	2.235 (0.333)	90%
75% of device LOD	BD-T-C-75-1	3.814	Positive
	BD-T-C-75-2	2.778	Positive
	BD-T-C-75-3	3.187	Negative
	BD-T-C-75-4	4.114	Positive
	BD-T-C-75-5	3.519	Positive
	BD-T-C-75-6	3.263	Positive
	BD-T-C-75-7	3.153	Positive
	BD-T-C-75-8	3.402	Positive
	BD-T-C-75-9	2.889	Positive
	BD-T-C-75-10	3.625	Positive
	Overall <sup>c</sup>	3.374 (0.410)	90%
100% of device LOD	BD-T-C-100-1	4.217	Positive
	BD-T-C-100-2	3.949	Positive
	BD-T-C-100-3	4.541	Positive
	BD-T-C-100-4	4.625	Positive
	BD-T-C-100-5	4.757	Positive
	BD-T-C-100-6	5.096	Positive
	BD-T-C-100-7	3.954	Positive
	BD-T-C-100-8	4.535	Positive
	BD-T-C-100-9	5.284	Positive
	BD-T-C-100-10	4.463	Positive
	Overall <sup>c</sup>	4.542 (0.437)	100%
200% of device LOD	BD-T-C-200-1	9.381	Positive
	BD-T-C-200-2	9.266	Positive
	BD-T-C-200-3	9.439	Positive
	BD-T-C-200-4	7.394	Positive
	BD-T-C-200-5	10.407	Positive
	BD-T-C-200-6	10.199	Positive
	BD-T-C-200-7	9.837	Positive
	BD-T-C-200-8	8.250	Positive
	BD-T-C-200-9	8.313	Positive
	BD-T-C-200-10	9.752	Positive
	Overall <sup>c</sup>	9.224 (0.955)	100%

<sup>a</sup>LOD = limit of detection of the BD HD Check system. For cyclophosphamide, LOD = 4.65 ng/cm<sup>2</sup>.

<sup>b</sup>All wipe sampling results have been corrected for the blank.

<sup>c</sup>Overall results presented as average (standard deviation) for convention wipe sampling and as percent positive for HD Check system.

Check system must be tempered by the recognition that even though the device yielded positive findings at 50% of the LOD, that value is still higher than the drug concentrations typically found on hospital surfaces.

That being said, all of the maximum values reported in the aforementioned surface contamination studies were greater than 0.93 ng/cm<sup>2</sup> and 4.65 ng/cm<sup>2</sup>, the LODs of the MTX and CP HD Check assays, respectively. As such, HD Check systems could be of value to screen for those surfaces likely to be highly contaminated, such as biological safety cabinets after drug preparation or after a spill or leak of drugs. If the HD Check system yields a positive result, then cleaning of the surfaces would be needed, or it might be necessary to sample the surface with a conventional wipe method to quantify the amount of contamination. In fact, this scheme was proposed following the 2020 Safe to Touch Conference, composed of experts with experience in hazardous drug handling, monitoring, and research. The consensus statement issued by conference attendees included the recommendation to “employ both qualitative and quantitative tests for ongoing surface contamination monitoring”.<sup>30</sup>

Some limitations of this study should be noted. The results are applicable only to the 2 assay systems evaluated (for MTX and CP). Other assays that are commercially available were not evaluated, and their results may differ from those reported here. The LODs listed in product materials of the HD Check systems are actually 0.1 ng/cm<sup>2</sup> for MTX and 0.5 ng/cm<sup>2</sup> for CP; however, these values are based on a sampling area of 1 ft<sup>2</sup> or 930 cm<sup>2</sup> (Product Manager, BD, written personal communication, July 27, 2021). Had this larger wipe sampling area been tested, rather than the typical 100 cm<sup>2</sup> employed in the current study, the findings might have been different. Finally, only stainless steel surfaces were examined, and the results might differ for other types of surfaces found in health care facilities (e.g., laminate, metal, plastic).

## CONCLUSION

Despite its limitations, this study showed that the HD Check system was able to positively identify hazardous drug contamination at concentrations below the listed LODs with a fair degree of repeatability, relative to a conventional wipe sampling method. To confirm these findings, it is suggested that future studies examine the HD Check system to detect drug contamination at lower gradients of the LOD (i.e., less than 50% of the LOD). It would also be important to test the ability to detect drug contamination on other types of surfaces, as well as uneven surfaces such as keyboards and calculators, which have been found to have drug contamination in prior studies.<sup>14</sup> If the HD Check system is able to reliably detect positive drug contamination at lower concentrations (i.e., closer to the average reported in surface contamination studies), as well as from different types of

surface materials, it could be considered an extremely useful tool for health care facilities to qualitatively assess drug contamination through environmental monitoring and, in turn, minimize the risk (though actual quantification of exposure levels will still not be possible with this device).

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**Chun-Yip Hon**, PhD, CRSP, CIH, is with the School of Occupational and Public Health, Toronto Metropolitan University, Toronto, Ontario.

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**Address correspondence to:**

Chun-Yip Hon  
School of Occupational and Public Health  
Toronto Metropolitan University  
350 Victoria Street, DCC318  
Toronto ON M5B 2K3

**email:** cyhon@torontomu.ca

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# Ferric Derisomaltose Evaluation in Patients with Non–Dialysis-Dependent Chronic Kidney Disease or Peritoneal Dialysis

Emma England, Maneka Sheffield, Penelope Poyah, David Clark, and Jo-Anne Wilson

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## ABSTRACT

**Background:** Iron deficiency anemia is common in patients with advanced chronic kidney disease (CKD). Ferric derisomaltose (FDI) enables iron repletion in a single dose, unlike other forms of iron for IV administration, which require multiple doses. Protocols are commonly used with other IV irons, but there are limited Canadian data for FDI, and no protocol exists.

**Objectives:** To evaluate the efficacy and safety of FDI for patients with CKD and to ascertain information related to its use in Canadian provinces.

**Methods:** This retrospective cohort study involved patients with non-dialysis-dependent CKD (NDD-CKD) and patients undergoing peritoneal dialysis (PD) who received FDI in a tertiary hospital in Nova Scotia between June 2020 and May 2021. Each patient was followed for a minimum of 6 months. The efficacy outcomes were the changes from baseline in hemoglobin, transferrin saturation (TSAT), and ferritin after the first dose of FDI and at 3 and 6 months. The safety outcomes were the frequency and types of adverse reactions to FDI. Electronic surveys were sent to 33 Canadian renal pharmacists to gather information about FDI use, dosing, administration, monitoring, funding, and safety in their respective organizations.

**Results:** A total of 52 infusions were administered to 35 patients during the study period. The median times between doses 1 and 2 and between doses 2 and 3 were 19.1 and 6.6 weeks, respectively. The median change from baseline to first post-FDI follow-up blood work was significant for hemoglobin (9.0 g/L,  $p = 0.023$ ), TSAT (11 percentage points,  $p < 0.001$ ), and ferritin (271.4 µg/L,  $p < 0.001$ ). Median darbepoetin doses decreased from baseline to 6 months ( $p < 0.001$ ). Three adverse reactions occurred. At least 15 (65%) of the 23 survey respondents reported that FDI was funded by their province or was listed on their hospital drug formulary.

**Conclusion:** This study provides evidence that FDI is an effective and safe treatment for anemia in NDD-CKD and PD patients.

**Keywords:** ferric derisomaltose, iron isomaltoside, IV iron, anemia, chronic kidney disease, peritoneal dialysis

## RÉSUMÉ

**Contexte :** L'anémie ferriprive est fréquente chez les patients atteints d'insuffisance rénale chronique avancée (IRC). Une seule dose de dérisomaltose ferrique (FDI) permet au niveau de fer de se rétablir, contrairement à d'autres formes de fer administrées par IV qui nécessitent, elles, plusieurs doses. Des protocoles sont couramment utilisés avec d'autres fers administrés par IV, mais les données canadiennes sur le FDI sont limitées et il n'existe aucun protocole.

**Objectifs :** Évaluer l'efficacité et l'innocuité du FDI chez les patients atteints d'IRC et vérifier les informations relatives à son utilisation dans les provinces du Canada.

**Méthodes :** Cette étude de cohorte rétrospective comprenait des patients atteints d'IRC sans dialyse (NDD-IRC) et des patients sous dialyse péritonéale (DP) ayant reçu du FDI dans un hôpital de soins tertiaires de la Nouvelle-Écosse entre juin 2020 et mai 2021. Chaque patient a fait l'objet d'un suivi pendant au moins 6 mois. Les résultats d'efficacité étaient les changements par rapport à la base de trois mesures après la première dose de FDI et à 3 et 6 mois, soit l'hémoglobine, la saturation de la transferrine (TSAT) et la ferritine. Les résultats d'innocuité étaient la fréquence et les types de réactions indésirables au FDI. Des sondages ont été envoyés par voie électronique à 33 pharmaciens canadiens spécialisés en néphrologie afin de recueillir des renseignements sur l'utilisation, le dosage, l'administration, la surveillance, le financement et l'innocuité du FDI dans leurs organismes respectifs.

**Résultats :** Au total, 52 perfusions ont été administrées à 35 patients au cours de la période d'étude. Les délais médians entre les doses 1 et 2, et entre les doses 2 et 3 étaient respectivement de 19,1 et 6,6 semaines. Le changement médian entre la base et le premier bilan sanguin de suivi post-FDI était important pour l'hémoglobine (9,0 g/L,  $p = 0,023$ ), le TSAT (11 points de pourcentage,  $p < 0,001$ ) et la ferritine (271,4 µg/L,  $p < 0,001$ ). Les doses médianes de darbépoéine ont diminué par rapport à la base à 6 mois ( $p < 0,001$ ). Trois effets indésirables se sont produits. Au moins 15 des 23 répondants au sondage (65 %) ont déclaré que le FDI était financé par leur province ou figurait sur les listes de médicaments des hôpitaux.

**Conclusion :** Cette étude fournit des preuves que le FDI est un traitement efficace et sûr de l'anémie chez les patients NDD-IRC et PD.

**Mots-clés :** dérisomaltose ferrique, isomaltoside de fer, fer IV, anémie, maladie rénale chronique, dialyse péritonéale



## INTRODUCTION

Iron deficiency anemia is a common complication associated with chronic kidney disease (CKD), and its prevalence increases with advancing stages of CKD.<sup>1,2</sup> Factors associated with iron deficiency in CKD include reduced gastrointestinal absorption of iron, blood loss, use of erythropoiesis-stimulating agents (ESAs), which increase the demand for iron, and inefficient utilization of iron stores due to chronic inflammation and increased hepcidin levels.<sup>3</sup> Iron deficiency, combined with inadequate production of erythropoietin by the kidneys, results in decreased erythropoiesis leading to anemia. Untreated anemia in patients with CKD has been associated with reduced quality of life, progression of kidney disease, and adverse clinical and economic outcomes.<sup>4,5</sup>

Iron supplementation is an established therapy to treat iron deficiency and enhance the efficacy of ESAs in those with CKD.<sup>6-8</sup> International and Canadian anemia guidelines advocate for the use of iron by adult CKD patients who have anemia, irrespective of their use of ESAs. These guidelines recommend treatment with IV iron or alternatively 1–3 months of oral iron in patients with non-dialysis-dependent chronic kidney disease (NDD-CKD) if an increase in hemoglobin without starting ESA or a decrease in ESA dose is desired.<sup>7</sup>

Although oral iron is more accessible, IV iron may be necessary to treat anemia in patients with NDD-CKD and those receiving peritoneal dialysis (PD), particularly if oral iron is not tolerated or does not yield the desired hematological response. Moreover, oral iron has been reported to be less efficacious than parenteral iron in patients with stage 4 or 5 CKD and in PD patients.<sup>6,9,10</sup>

Ferric derisomaltose (FDI), previously known as iron isomaltoside 1000 (produced by Pharmacosmos A/S, Denmark; imported/distributed by Pfizer Canada ULC, Quebec), is the newest IV iron agent to be marketed in Canada; in this country, it is branded as Monoferric. It is a high-dose formulation that can be administered in a single infusion of up to 20 mg/kg body weight (maximum single dose of 1500 mg).<sup>11</sup> FDI is an iron carbohydrate complex with a matrix structure composed of alternating layers of ferric hydroxide and the carbohydrate derisomaltose.<sup>11</sup> This strongly bound complex enables a slow, controlled release of bioavailable iron to iron-binding proteins with minimal risk of toxic effects from labile iron. This allows for single-dose iron repletion in patients with CKD, whereas traditional IV iron preparations require between 3 and 10 doses for repletion. More rapid iron repletion has benefits for both patients and hospitals, such as quicker improvements in anemia-related symptoms, avoidance or minimization of more expensive ESA therapy or blood transfusions, preservation of venous access, reduced chair time resulting in less time lost from work, and greater capacity for hospitals to administer IV iron.

Data from clinical and observational trials outside Canada have reported good efficacy and safety of FDI in CKD patients with anemia.<sup>12-22</sup> Given Health Canada safety warnings and subsequent market withdrawal of the first large-dose IV iron preparation, ferumoxytol, in 2014,<sup>23</sup> clinicians have been cautious in prescribing FDI, and real-world experience with this formulation is therefore limited.

Standardized anemia protocols for ESA and traditional IV iron therapies are frequently used in Canada for maintenance anemia management in patients with CKD.<sup>24-27</sup> However, there is currently no FDI protocol available to aid clinicians in the maintenance management of iron deficiency anemia in CKD patients. We evaluated the real-world efficacy and safety of FDI in NDD-CKD and PD patients and endeavoured to better understand its use in Canada through a survey of renal pharmacists.

## METHODS

### Efficacy and Safety Evaluation

This retrospective cohort study involved consecutive NDD-CKD and PD patients who received an initial dose of IV FDI in our hospital's medical day unit from June 1, 2020, to May 31, 2021. The research protocol was approved by, and received a waiver exemption from, the hospital research ethics board, as the study was deemed to be a quality assurance study. Individual patient consent was not required. The study was conducted in accordance with STROBE guidelines.<sup>28</sup>

The Nova Scotia Health Renal Program provides anemia management to approximately 250 NDD-CKD (stage 4 or stage 5) and PD patients within the largest zone of the provincial health authority. Twenty-five percent of these patients require IV iron periodically or for long-term maintenance therapy to treat iron deficiency anemia. Prescriptions for IV iron are based on a hospital order set. Anemia in NDD-CKD and PD patients is comanaged by a nephrologist and a nurse, including routine blood work performed every 4–6 weeks according to standardized protocols, with targets for hemoglobin (Hgb) and iron indices being based on best practice for ESAs, oral iron, and IV iron sucrose.<sup>7</sup> No protocol is available for IV administration of FDI.

For purposes of this study, the medical day unit assistant notified the renal pharmacist (M.S.) when patients were booked for FDI infusion. Eligible patients with the conditions of interest were those who received an initial dose of IV FDI 1000 mg (or 2 doses of 500 mg separated by 1 week) for transferrin saturation (TSAT) less than 20% and/or ferritin less than 100 µg/L during the study period. Each FDI dose was diluted in 100 mL sodium chloride 0.9% and administered as an infusion over 20 minutes, as per the Canadian product monograph.<sup>11</sup> Each patient was followed for a minimum of 6 months and up to 18 months after the initial infusion. Patients were excluded if another form of

IV iron (i.e., iron sucrose, sodium ferric gluconate) was administered during the study period.

Hospital electronic medical records and the provincial drug information system were used to retrieve the following baseline clinical and demographic characteristics: age, sex, weight, estimated glomerular filtration rate, modality (stage 4 or 5 CKD or PD), comorbidities, cumulative monthly dose of darbepoetin alfa and of iron sucrose, daily dose of elemental oral iron, and laboratory parameters (specifically Hgb, TSAT, and ferritin). Electronic medical records were also used to obtain timing and values for Hgb, TSAT, and ferritin after the initial FDI infusion and at 3 and 6 months, as well as the timing of subsequent FDI infusions. Laboratory values within 45 days of the 3- and 6-month evaluation time points after FDI infusion were included. Electronic drug databases were used to collect data for oral iron and darbepoetin alfa doses at the 3- and 6-month assessment time points. Adverse effects related to FDI during and up to 60 minutes after the infusion were collected from nursing progress notes in the electronic medical records and patient incident reports.

The primary efficacy objectives were to evaluate (1) the changes in Hgb, TSAT, and ferritin from baseline to next routine blood work after the FDI infusion and (2) overall effectiveness, as determined by the changes in Hgb, TSAT, and ferritin from baseline to 3 and 6 months after FDI infusion. The primary safety objective was to determine the types and frequencies of adverse reactions to FDI (i.e., anaphylaxis, Fishbane reaction, isolated reaction), as assessed by 2 independent investigators (renal pharmacists J.W. and M.S.) using previously described criteria.<sup>29</sup> The secondary objective was to evaluate, at 3 and 6 months, the change from baseline in concomitant anemia medications (i.e., darbepoetin alfa and oral elemental iron).

Descriptive statistics (mean and standard deviation [SD]) were used for continuous data and percentages for categorical data in reporting patients' demographic, clinical, and laboratory characteristics. Changes in laboratory parameters (i.e., Hgb, TSAT, ferritin) were presented as means with SDs and medians with interquartile ranges (IQRs); these data were analyzed using the Wilcoxon signed-rank test. A *p* value less than 0.05 was considered statistically significant.

## Survey

The survey rationale and an electronic link to the survey were sent by email to 33 Canadian renal pharmacists on July 20, 2021, and the survey remained open for 3 weeks. Responses were anonymous, except that participants were asked to specify the province in which they were practising and whether their organization had an FDI order set or protocol that they were willing to share by email with the research assistant (E.E.). The survey, which took 5–10 minutes to complete, consisted of 18 closed-ended questions

with an option for free-text responses to gather information related to FDI use, dosing, administration, monitoring, funding, and safety.

Ordinal data from the closed-ended survey questions were reported as percentages. Qualitative data from the free-text fields were coded and analyzed for themes.

## RESULTS

### Efficacy and Safety Evaluation

During the 18-month study period, a total of 40 patients (28 with stage 4 or 5 NDD-CKD and 12 receiving PD) received at least 1 infusion of FDI (Table 1). The mean patient age

**TABLE 1. Baseline Demographic and Clinical Characteristics of Participants**

Characteristic	No. (%) of Participants <sup>a</sup> ( <i>n</i> = 40)
<b>Demographic</b>	
Sex	
Male	24 (60)
Female	16 (40)
Age (years) (mean ± SD)	65.6 ± 12.0
Weight (kg) (mean ± SD)	85.2 ± 22.9
Comorbidities	
Diabetes	23 (58)
Hypertension	35 (88)
Cardiac disorders	21 (52)
Subgroups	
Non-dialysis-dependent CKD	28 (70)
eGFR 15–29 mL/min/1.73 m <sup>2</sup> (stage 4)	12 (30)
eGFR < 15 mL/min/1.73 m <sup>2</sup> (stage 5)	16 (40)
Peritoneal dialysis	12 (30)
<b>Clinical</b>	
Hemoglobin (g/L) (mean ± SD)	94.7 ± 15.2
Transferrin saturation <sup>b</sup> (%) (mean ± SD)	14.8 ± 3.8
Ferritin <sup>c</sup> (µg/L) (mean ± SD)	326.8 ± 573.6
Receiving darbepoetin alfa	
Cumulative monthly dose <sup>d</sup> (µg) (mean ± SD)	103.2 ± 72.5
Receiving oral iron	
Daily dose of elemental iron (mg) (mean ± SD)	233.7 ± 132.0
Receiving IV iron sucrose	
Cumulative monthly dose <sup>d</sup> (mg) (mean ± SD)	342.9 ± 378.0

CKD = chronic kidney disease, eGFR = estimated glomerular filtration rate, SD = standard deviation.

<sup>a</sup>Except where indicated otherwise.

<sup>b</sup>Recorded within 3 months before infusion.

<sup>c</sup>Recorded within 6 months before infusion (*n* = 33).

<sup>d</sup>Dose calculated in the month before initial infusion of ferric derisomaltose.

was 65.6 (SD 12.0) years, and 24 (60%) of the patients were male. At baseline, mean Hgb was 94.7 (SD 15.2) g/L (with 19 patients having Hgb < 95 g/L) and mean TSAT was 14.8% (SD 3.8%). Concomitant medications for treatment of anemia at baseline included oral iron (26 [65%] of the patients) and darbepoetin alfa (25 [63%] of the patients), and 7 patients (17%) were receiving IV iron sucrose during the month before FDI infusion. Additional baseline clinical and demographic characteristics are presented in Table 1.

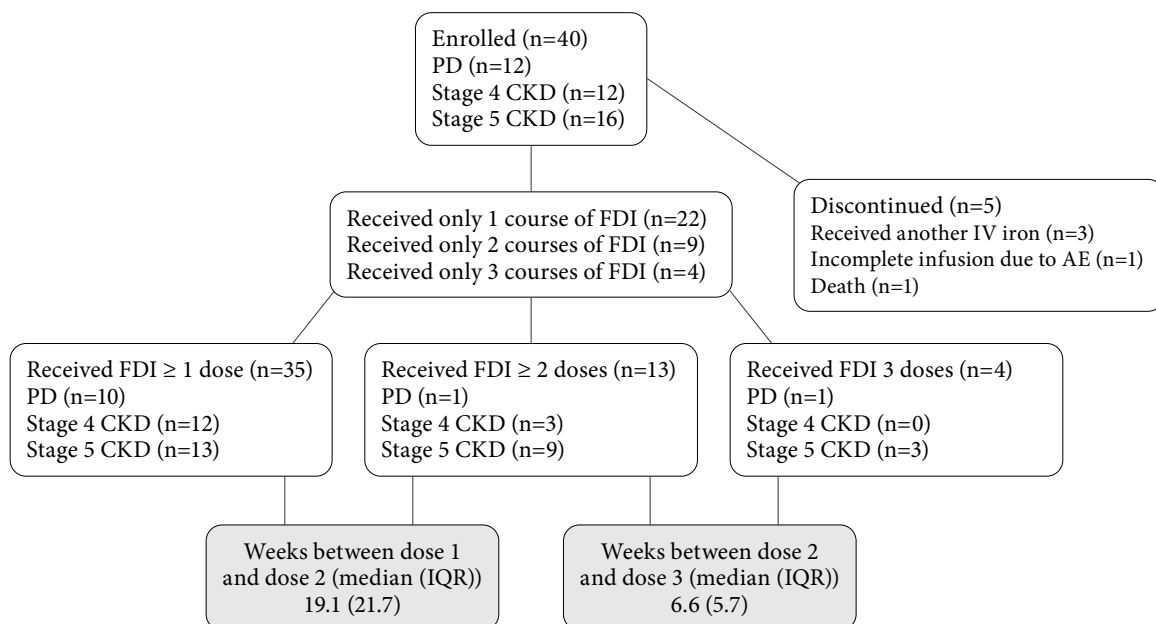
Thirty-five patients, all of whom received at least 1 FDI infusion, were included in the efficacy analysis. Of the 5 patients who were excluded, 3 had received another form of IV iron during the study period, 1 died for reasons unrelated to the FDI infusion (with no pertinent data available for analysis), and 1 experienced a Fishbane reaction after a partial FDI infusion (Figure 1). A total of 52 infusions of FDI were administered to the 35 included patients over the study period. Forty-eight of the FDI infusions were administered as a single fixed dose of 1000 mg, and the remaining 4 infusions were administered as 2 doses of 500 mg separated by 1 week. Thirteen patients required a second dose of FDI, and 4 patients required a third dose. The median time between the first and second doses was 19.1 (IQR 21.7) weeks and between the second and third doses was 6.6 (IQR 5.7) weeks (Figure 1). Second and third doses were administered to 9 (69%) and 3 (23%) of the 13 patients with stage 5 CKD, respectively. The median duration of study participation was 12.1 (IQR 4.8) months.

Table 2 displays changes from baseline in Hgb, TSAT, and ferritin measured 5.6 to 9.2 weeks after the first FDI infusion for CKD subgroups and all patients combined. For

all patients combined, the changes from baseline to first blood work after FDI infusion (the primary efficacy end points) were significant for Hgb (median 9.0 [IQR 13.0] g/L,  $p = 0.023$ ), TSAT (median 11.0 [IQR 11.0] percentage points,  $p < 0.001$ ), and ferritin (271.4 [IQR 272.8]  $\mu\text{g/L}$ ,  $p < 0.001$ ). The median values for Hgb, TSAT, and ferritin at first blood work after FDI infusion were 104.0 (IQR 19.5) g/L, 25.0% (IQR 10.0%), and 351.4 (IQR 526.6)  $\mu\text{g/L}$ , respectively.

The overall effectiveness, as determined by changes from baseline to 3 and 6 months after FDI infusion in Hgb, TSAT, and ferritin for 44 infusions, is outlined in Table 3. Median Hgb increased from 96 g/L at baseline to 106 g/L at 3 months ( $p = 0.020$ ) and returned to 96 g/L at 6 months. There were significant median increases from baseline to the 3-month evaluation in TSAT (from 15% to 23%;  $p < 0.001$ ) and ferritin (from 132.9  $\mu\text{g/L}$  to 294.5  $\mu\text{g/L}$ ;  $p = 0.027$ ). Median TSAT remained significantly elevated at 6 months, at 24% ( $p < 0.001$ ). From baseline to 6 months, the median monthly dose of darbepoetin alfa decreased from 80 (IQR 60)  $\mu\text{g}$  to 80 (IQR 40)  $\mu\text{g}$  ( $p < 0.001$ ), and the median daily dose of oral elemental iron remained relatively unchanged (180 [IQR 161.1] mg versus 300 [IQR 158] mg). The number of patients who required darbepoetin alfa and oral iron declined by 5 and 4, respectively, from baseline to 6 months.

Five patients (mean Hgb 65 g/L, minimum 55 g/L, maximum 72 g/L) received a total of 6 blood transfusions due to gastrointestinal bleeding ( $n = 3$  transfusions), post-operative orthopedic complication ( $n = 2$  transfusions), or malignancy ( $n = 1$  transfusion). Blood transfusion occurred at a median of 60 days after the FDI infusion.



**FIGURE 1.** Flow diagram for administration of ferric derisomaltose (FDI) to study participants. AE = adverse effect, CKD = chronic kidney disease, PD = peritoneal dialysis. Dosing: FDI 1000 mg ( $n = 48$  infusions) or FDI 500 mg  $\times$  2, separated by 1 week ( $n = 4$  infusions). The median duration of individuals' participation in the study was 12.1 (interquartile range 4.8) months.

**TABLE 2. Analysis of Laboratory Parameters after First Ferric Derisomaltose Treatment**

Parameter	Patient Group; Median (IQR)			
	CKD Stage 4	CKD Stage 5	Peritoneal Dialysis	Total
Hemoglobin	<i>n</i> = 12	<i>n</i> = 13	<i>n</i> = 10	<i>n</i> = 35
Change from baseline to post-treatment (g/L)	5.5 (11.5) <i>p</i> = 0.45	9.0 (17.0) <i>p</i> = 0.05	13.0 (8.0) <i>p</i> = 0.12	9.0 (13.0) <i>p</i> = 0.023
Time of evaluation (weeks)	5.8 (2.4)	5.9 (3.1)	4.9 (3.2)	5.6 (3.1)
Post-treatment level (g/L)	105.5 (31)	103.0 (11.0)	113.0 (19.4)	104.0 (19.5)
Transferrin saturation	<i>n</i> = 12	<i>n</i> = 13	<i>n</i> = 10	<i>n</i> = 35
Change from baseline to post-treatment (percentage points)	10.5 (9.5) <i>p</i> = 0.003	9.0 (14.0) <i>p</i> = 0.002	14.0 (9.5) <i>p</i> < 0.001	11.0 (11.0) <i>p</i> < 0.001
Time of evaluation (weeks)	6.8 (3.6)	7.1 (3.6)	7.7 (2.1)	7.1 (3.6)
Post-treatment level (%)	24.5 (12.5)	24.0 (9.0)	28.5 (8.2)	25.0 (10.0)
Ferritin	<i>n</i> = 11	<i>n</i> = 8	<i>n</i> = 9	<i>n</i> = 28
Change from baseline to post-treatment (µg/L)	273.6 (333.7) <i>p</i> < 0.001	242.2 (165.7) <i>p</i> = 0.38	298.1 (177.9) <i>p</i> = 0.032	271.4 (272.8) <i>p</i> < 0.001
Time of evaluation (weeks)	8.9 (3.2)	11.0 (3.2)	9.1 (2.9)	9.2 (3.8)
Post-treatment level (µg/L)	387.5 (374.5)	475.8 (593.2)	330.3 (328.8)	351.4 (526.6)

CKD = chronic kidney disease, IQR = interquartile range.

**TABLE 3. Overview of Effectiveness of Ferric Derisomaltose during 6-Month Follow-Up Period<sup>a</sup>**

Parameter and Visit <sup>b</sup>	<i>n</i>	Mean ± SD	Minimum	Median (IQR)	Maximum
Hemoglobin (g/L)					
Baseline	35	95.5 ± 14.8	59	96 (19)	127
Midpoint	32	103.7 ± 17.4	54	106 (19) <sup>c</sup>	137
Final	30	97.8 ± 15.3	65	96 (18.3)	148
Difference	NA	2.3 ± 0.5	6	0 (17)	21
Transferrin saturation (%)					
Baseline	35	14.9 ± 3.8	8	15 (4)	24
Midpoint	30	25.3 ± 10.5	9	23 (11) <sup>c</sup>	51
Final	30	23.4 ± 11.0	11	24 (11.8) <sup>c</sup>	61
Difference	NA	8.5 ± 7.2	3	7 (15)	37
Ferritin (µg/L)					
Baseline	31	358.0 ± 586.9	15.1	132.9 (337.5)	2469.5
Midpoint	24	622.4 ± 924.0	7.1	294.5 (621.1) <sup>c</sup>	4018.5
Final	20	407.8 ± 442.0	9.8	270.9 (321.8) <sup>d</sup>	1985.2
Difference	NA	120.1 ± 14.2	-5.3	174.7 (131.4)	-484.3
Monthly darbepoetin alfa dose (µg)					
Baseline	20	108.0 ± 80.4	40	80 (60)	400
Midpoint	16	93.8 ± 49.4	20	80 (45) <sup>c</sup>	200
Final	15	94.7 ± 60.2	40	80 (40) <sup>c</sup>	240
Difference	NA	-13.3 ± 20.2	0	0 (20)	-160
Daily oral elemental iron dose (mg)					
Baseline	24	232.6 ± 137.9	60	180 (161.1)	600
Midpoint	19	237.7 ± 124.1	60	300 (150.3)	600
Final	20	236.7 ± 125.3	60	300 (158)	600
Difference	NA	4.1 ± 12.6	0	0 (0)	0

IQR = interquartile range, NA = not applicable.

<sup>a</sup>Includes data related to 44 infusions of ferric derisomaltose (35 at baseline, 39 by the midpoint, 44 by final), with all but 1 infusion completed more than 30 days before the blood work.

<sup>b</sup>Midpoint = 3 months, final = 6 months; difference refers to change from baseline to 6 months.

<sup>c</sup>Statistically significant difference from baseline to midpoint or final evaluation, *p* < 0.05.

<sup>d</sup>*p* = 0.08.

Three patients, all of whom received a fixed dose of 1000 mg infused over 20 minutes, experienced nonsevere adverse reactions to FDI. Two of the reactions were classified as isolated, and one was deemed to be a Fishbane reaction; the rates of these types of reactions were 5% and 3%, respectively. There were no anaphylactic reactions. The management of adverse reactions and subsequent rechallenge with IV iron are outlined in Table 4.

### Survey

Twenty-three (70%) of the 33 Canadian renal pharmacists participated in the electronic survey, with at least 1 participant from each province. FDI was funded by the province (17 respondents [74%]) or listed on the hospital drug formulary (15 respondents [65%]). The most commonly reported patient populations for whom funding was approved by the province or the hospital were patients with NDD-CKD (15/19 [79%] and 13/17 [76%] respondents, respectively), patients receiving PD (14/19 [74%] and 12/17 [71%] respondents, respectively), and patients undergoing home hemodialysis (12/19 [63%] and 8/17 [47%] respondents, respectively). Most respondents (16/20 [80%]) reported that FDI is administered in a hospital outpatient unit, clinic, or facility, with administration in a private infusion clinic or renal program clinic reported by 2/20 respondents (10%). No respondents reported self-administration of FDI by patients undergoing home hemodialysis. The most commonly reported FDI dose was 1000 mg IV infusion (15/19 [79%]), followed by 500 mg (12/19 [63%]) and 1500 mg (7/19 [37%]). The reported administration time for FDI infusion ranged from 20 to 65 minutes. Only 1 respondent reported administering FDI 500 mg as an IV bolus over 2 minutes.

Eleven (52%) of the 21 respondents reported using an FDI order set. Participants reported that subsequent doses of FDI were based on iron indices obtained either 4 weeks after infusion (15/21 respondents [71%]) or before the next clinic visit (i.e., at 2–3 months) (6/21 respondents [29%]). No participants reported using an FDI protocol for subsequent dosing, because of limited experience or because no

data were available. Of the 16 participants who described their management of a Fishbane reaction with FDI, 7 (44%) reported waiting 30 minutes and restarting the FDI infusion at a slower rate, 8 (50%) reported switching to a different IV iron preparation for the next dose, and 1 (6%) reporting rechallenge with FDI at a later date.

### DISCUSSION

This study demonstrated significant improvements in median Hgb, TSAT, and ferritin measured a mean of 7.3 weeks from baseline in NDD-CKD (stage 4 or stage 5) and PD patients who received 1 course of FDI 1000 mg. In terms of the overall effectiveness by 3 months after FDI infusion, median increases in Hgb, TSAT, and ferritin were statistically significant. Although Hgb peaked at 3 months and returned to near-baseline levels by 6 months, TSAT and ferritin remained elevated at 6 months and were within their respective guideline targets. The FERWON-EXT trial similarly reported a peak effect for Hgb at 3 months after FDI treatment.<sup>19</sup> European NDD-CKD and PD trials evaluating FDI showed comparable significant improvements in Hgb, TSAT, and ferritin from baseline to various post-FDI time points (between 4 and  $\geq 52$  weeks).<sup>14-17,19,20</sup>

Our study revealed a significant and clinically relevant reduction in the median monthly dose of darbepoetin alfa, as well as a reduction in the number of patients requiring ESA treatment, from baseline to 3 and 6 months. A significant mean reduction in the use of ESA (specifically epoetin alfa) was also reported in a 9-month FDI study.<sup>14</sup> An ESA-sparing effect has potential benefits, including lowering the ESA-associated risk for stroke or cardiovascular events, as well as reducing the economic burden of ESA therapy.<sup>30</sup> Although we did not evaluate the cost-effectiveness of FDI relative to other IV irons, a reduction in the number of FDI infusions per patient has been shown to translate into economic savings in the United Kingdom.<sup>31</sup>

The median interval between FDI infusions was 19.1 weeks between doses 1 and 2 and 6.6 weeks between doses 2

**TABLE 4. Summary of Adverse Effects<sup>a</sup> after Infusion of Ferric Derisomaltose and Management**

Reaction Type	Symptoms	Time of Symptom Onset (min) <sup>b</sup>	Reaction Management	IV Iron Rechallenge
Isolated <sup>c</sup> (n = 1 patient)	Nausea and retching	30	Administered dimenhydrinate 50 mg IV	No
Isolated <sup>c</sup> (n = 1 patient)	Nausea and vomiting	60	Administered dimenhydrinate 25 mg IV	No
Fishbane <sup>d</sup> (n = 1 patient)	Abdominal pain	15–30	Stopped infusion, administered acetaminophen 650 mg PO	Yes, iron sucrose

<sup>a</sup>All reactions occurred with ferric derisomaltose 1000 mg IV infusion over 20 minutes (administered to a total of 40 patients).

<sup>b</sup>Time in minutes after infusion was started.

<sup>c</sup>Non-life-threatening symptoms affecting 1 organ system, excluding the respiratory system.<sup>29</sup>

<sup>d</sup>The Fishbane reaction can consist of transient flushing, truncal myalgia, and tightness or pain in the chest and back.<sup>29</sup>

and 3. For those needing a second dose, these findings suggest that retreatment correlates with infusion of FDI 1000 mg IV every 5 months. The NIMO-CKD-UK trial reported that the probability of FDI retreatment was higher among those who received FDI doses at or below 1000 mg (mean 814.4 mg; group 1) than among those who received FDI doses above 1000 mg (mean 1537 mg; group 2).<sup>17</sup> Although the mean FDI dose was lower in group 1 of the earlier study than in our study (814.4 mg versus 1000 mg, respectively), the proportions of participants requiring 1 dose (75%) or 2 doses (25%) were similar to our findings (22/35 [63%] and 9/35 [26%], respectively).

In our study, the follow-up period was variable, and for some it was intentionally longer than 12 months, in order to include more infusions for determination of adverse effects. Three (8%) of the 40 patients had mild reactions, which resolved a median of 30 minutes after the infusion. The safety profile of FDI observed in our study was consistent with the findings of other clinical trials.<sup>14-20</sup> In a recently conducted evaluation of severe hypersensitivity reactions in 21 randomized controlled trials of IV irons, a mean odds ratio of 0.51 was reported for FDI compared with iron sucrose, indicating a 49% lower risk of experiencing a serious reaction with FDI.<sup>22</sup>

In the survey of renal pharmacists, at least 65% of respondents reported that their province and/or hospital provided funding to use FDI primarily in NDD-CKD, PD, and home hemodialysis populations. Given that the most commonly administered FDI dose is 1000 mg IV infusion, the retreatment interval observed in our study provides a useful guide for clinicians. None of the survey respondents reported using an FDI protocol similar to the protocols commonly used for iron sucrose or sodium ferric gluconate.<sup>24-27</sup>

This study had several strengths. It provides real-world Canadian evidence of the efficacy and safety of FDI in NDD-CKD and PD patients, as well as useful information for clinicians about the timing of subsequent doses of FDI and initial data to support the development of an FDI protocol. To the authors' knowledge, this is the first Canadian study providing initial retreatment information that may aid in the development of an FDI protocol.

Despite these strengths, there were some limitations. First, we were dependent on patients completing blood work during a period when the availability of laboratory testing was limited by the COVID-19 pandemic; this resulted in a delay in laboratory evaluations to a median of 5.6 to 9.2 weeks after the FDI injection (whereas the usual standard is 4 to 6 weeks). To accommodate this limited testing availability, we included values within 45 days on either side of the 3- and 6-month evaluation points. Second, we emulated the actual clinical setting with participants representative of typical NDD-CKD and PD populations and did not exclude patients who had received a blood transfusion. Given that these patients had mean Hgb of 65 g/L, it is likely

that their inclusion resulted in less favourable laboratory values after FDI. Third, ferritin data were available for only 20 patients at the 6-month evaluation, because our program relies mainly on TSAT. Fourth, the FDI dosing interval was influenced by availability of the infusion chair, not only the prescribed dosing interval. Fifth, a small number of patients had a follow-up period that was substantially shorter than the intended 18 months (as indicated by the overall median of 12.1 months). If all of these patients had been followed for 18 months, there likely would have been more FDI infusions to evaluate for effectiveness and safety. Finally, we did not determine whether FDI reduces the cost of care relative to IV iron formulations currently in use for these populations; this issue requires further study.

## CONCLUSION

This study provides supportive evidence that FDI is an effective and safe treatment for anemia in patients with NDD-CKD and those undergoing PD. Our findings could be used to inform the development and evaluation of FDI dosing protocols in the future.

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**Emma England**, BScPharm, was, at the time of this study, a student with the College of Pharmacy, Faculty of Health, Dalhousie University, Halifax, Nova Scotia. She is now a Pharmacy Resident with the Kingston Health Sciences Centre, Kingston, Ontario, and is a candidate for the ACPR credential.

**Maneka Sheffield**, BScPharm, is a Clinical Pharmacist with the Renal Program of Nova Scotia Health, Halifax, Nova Scotia.

**Penelope Poyah**, MD, FRCPC, is a Clinical Nephrologist and Medical Director of the nephrology clinic within the Division of Nephrology, Department of Medicine, Nova Scotia Health, and an Associate Professor with the Faculty of Medicine, Dalhousie University, Halifax, Nova Scotia.

**David Clark**, MD, FRCPC, is a Clinical Nephrologist and Medical Site Director of home hemodialysis and peritoneal dialysis within the Division of Nephrology, Department of Medicine, Nova Scotia Health, and an Assistant Professor with the Faculty of Medicine, Dalhousie University, Halifax, Nova Scotia.

**Jo-Anne Wilson**, BScPharm, ACPR, PharmD, is an Associate Professor with the College of Pharmacy, Faculty of Health, Dalhousie University, and a Clinical Pharmacy Specialist with the Renal Program of Nova Scotia Health. She is also a Master of Education candidate with St Francis Xavier University.

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**Address correspondence to:**

Dr Jo-Anne Wilson  
College of Pharmacy, Faculty of Health  
Dalhousie University  
Room 535, 5th Floor Bethune Building  
5920 University Avenue  
Halifax NS B3H 2Y9

**email:** jo-anne.wilson@nshealth.ca

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# Effects of a Computerized Prescriber Order Entry System on Pharmacist Prescribing

Stephanie Metzger, Christopher Evernden, Tammy J Bungard, Gordon Bell, and Mohamed A Omar

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## ABSTRACT

**Background:** In Alberta, pharmacists are eligible to obtain additional prescribing authority (APA). At the University of Alberta Hospital, a transition was made from a paper-based prescriber order entry system to a computerized prescriber order entry (CPOE) system.

**Objectives:** The primary objective was to quantify any change in pharmacist prescribing after CPOE implementation. The secondary objective was to compare the paper-based and CPOE systems in terms of drug schedule, order type, medication class, and the pharmacist's area of clinical practice.

**Methods:** A retrospective comparative review of pharmacist orders was completed using 2-week periods of data from each of the paper-based order entry system and the CPOE system, spaced 1 year apart (in January 2019 and January 2020).

**Results:** Pharmacists prescribed a mean of 3.76 (95% confidence interval 1.97–5.96) more orders per day within the CPOE system than in the paper-based system ( $p < 0.001$ ). Schedule I medications accounted for a higher proportion of pharmacists' prescriptions in the CPOE system than in the paper-based system (77.7% versus 70.5%,  $p < 0.001$ ). In terms of order type, discontinuation orders accounted for a much higher proportion of pharmacists' orders in the CPOE system than in the paper-based order entry system (58.0% versus 19.8%,  $p < 0.001$ ).

**Conclusions:** This study showed that a CPOE system resulted in more use of APA by pharmacists, with schedule I medications accounting for a higher proportion of pharmacists' prescriptions. With the CPOE system, pharmacists used their prescribing privileges to discontinue a higher proportion of orders than was the case with the paper-based system. Therefore, the CPOE system is a potential facilitator of pharmacist prescribing.

**Keywords:** pharmacist, prescribing, computer, medical order entry systems

## RÉSUMÉ

**Contexte :** En Alberta, les pharmaciens peuvent obtenir des pouvoirs de prescription supplémentaires (PPS). À l'hôpital de l'Université de l'Alberta, le système de saisie des ordonnances est passé d'un système sur papier à un système de saisie électronique des ordonnances (SSEO) par les prescripteurs.

**Objectifs :** L'objectif principal consistait à quantifier tout changement dans la prescription des pharmaciens après la mise en place du SSEO. L'objectif secondaire visait à comparer le système sur papier et le SSEO en matière d'annexe des médicaments, de type d'ordonnance, de catégorie de médicament et de domaine de pratique clinique du pharmacien.

**Méthodes :** Un examen comparatif rétrospectif des ordonnances des pharmaciens a été réalisé à l'aide de périodes de données de 2 semaines provenant de chacun des systèmes (papier et électronique), avec un intervalle d'un an (janvier 2019 et janvier 2020).

**Résultats :** Les pharmaciens prescrivaient en moyenne 3,76 (intervalle de confiance à 95 % 1,97–5,96) ordonnances de plus par jour avec le SSEO qu'avec le système sur papier ( $p < 0,001$ ). La part des ordonnances de médicaments de l'annexe I était plus importante avec le SSEO qu'avec le système sur papier (77,7 % contre 70,5 %,  $p < 0,001$ ). En ce qui concerne le type d'ordonnance, la part des ordonnances de cessation était beaucoup plus élevée avec le SSEO qu'avec le système de saisie sur papier (58,0 % contre 19,8 %,  $p < 0,001$ ).

**Conclusions :** Cette étude a démontré un plus grand recours au PPS lorsque les pharmaciens utilisaient un SSEO et les médicaments de l'annexe I représentant une proportion plus élevée des ordonnances. Avec le SSEO, les pharmaciens ont utilisé leur pouvoir de prescription pour interrompre une part plus élevée d'ordonnances que ce n'était le cas avec le système sur papier. Le SSEO est donc un facilitateur potentiel de la prescription par les pharmaciens.

**Mots-clés :** pharmacien, prescription, informatique, systèmes d'entrée des ordonnances par les

## INTRODUCTION

Since 2007, pharmacists in Alberta have been able to obtain additional prescribing authorization (APA), which allows them to prescribe nearly all provincially regulated drugs that require a prescription (i.e., schedule I drugs), on the basis of their own assessments. Use of APA in the hospital

practice setting differs from APA use in the community, as a hospital pharmacist must have APA to order any medication independently, including medications that could be dispensed by a community pharmacist without a prescription.<sup>1</sup> Without APA, a hospital pharmacist would require authorization or a cosignature from an authorized prescriber to order any medication, regardless of the medication schedule.



In Alberta hospitals, most pharmacists have obtained APA.<sup>2</sup> A 2015 survey determined that hospital-based pharmacists who were working in oncology and had APA prescribed for about half of the patients under their care. Most of these prescriptions were for antibiotics or anticoagulant drugs, and pharmacists were most often adjusting medication doses based on renal function or clinical assessment.<sup>3</sup> A cross-sectional study of electronic orders placed by hospital pharmacists in Calgary, Alberta, conducted in 2017, showed that 90% of hospital pharmacists used their prescribing authority, and they averaged 11.3 initial access prescriptions per pharmacist monthly.<sup>2</sup> Fully half of the orders they placed were for discontinuation of medications.<sup>2</sup>

Since 2007, a number of Canadian studies have demonstrated the benefits of APA in community settings. Having patients see a prescribing pharmacist allowed for better control of risk factors in stroke patients,<sup>4</sup> better control of blood glucose levels and hemoglobin A1C in patients with diabetes,<sup>5</sup> better blood pressure control,<sup>6</sup> a higher rate of cure for urinary tract infection,<sup>7</sup> and a reduction in cardiovascular events.<sup>8</sup> In contrast, there is a lack of evidence for the benefit of pharmacists prescribing in hospital settings.

In 2019, the University of Alberta Hospital in Edmonton implemented a computerized prescriber order entry (CPOE) system called Connect Care (Epic Systems Corporation). This new system drastically changed the process of prescribing from a written order entry system to a computerized system. To date, there are no data on how CPOE systems may influence pharmacist prescribing. The transition to Connect Care at the University of Alberta Hospital presented an opportunity to analyze the correlation between CPOE and pharmacist prescribing. It has also provided insight for pharmacy and interdisciplinary teams that are considering CPOE implementation into how CPOE systems and pharmacist prescribing may be related. As such, the purpose of this study was to determine whether pharmacist prescribing practices changed after the implementation of CPOE.

The primary objective of this study was to compare pharmacist prescribing rates before and after implementation of the CPOE system. The secondary objectives were to compare various aspects of prescribing before and after implementation of CPOE, specifically, therapeutic class and schedule of prescribed medications, clinical care area of prescribing pharmacists, and type of order.

## METHODS

### Study Design and Time Frame

The study was a retrospective comparative review of medication orders prescribed by pharmacists with APA in a tertiary care hospital. All paper-based orders from January 15 to 28, 2019 (scanned to the BD Pyxis Connect system, Becton, Dickinson and Company), and pharmacist-prescribed

CPOE orders from January 15 to 28, 2020 (processed in the Connect Care system), at the University of Alberta Hospital were reviewed. The period January 15–28 was chosen to balance pharmacist vacation scheduling and seasonal factors. The data collection start date of January 2020 for the CPOE group of prescriptions was 3 months after the CPOE system was launched, and was chosen to ensure that pharmacists had sufficient time to develop proficiency with the system. This period was also before the COVID-19 pandemic had affected hospital bed occupancy rates in Alberta, where elective surgeries were cancelled beginning March 18, 2020.<sup>9</sup>

Ethics approval was obtained from the Research Ethics Board (Pro00104379). The need for informed consent was waived.

### Data Sources and Extraction

Three data sources were used for this study. The first data source was BD Pyxis Connect, the system in which medication orders were scanned and stored at the University of Alberta Hospital before implementation of the CPOE system; this system was used to collect data for the paper-based order entry period of the study. In this system, prescribers wrote the prescriptions on order sheets, which were scanned and stored for pharmacy order verification. The scanned orders remained in the system after pharmacy order verification and dispensing of the medication. All scanned orders within the study time frame that met the inclusion criteria were entered into the data collection form for the study, which was prepared using Research Electronic Data Capture (REDCap) data collection software.

The second data source was the health care charting system Connect Care, introduced at the University of Alberta Hospital in November 2019. Connect Care contains all elements of the patient chart, including medication orders. Data for the CPOE group of prescriptions were obtained from Connect Care reports. More specifically, one of the authors (S.M.) used Connect Care to run separate reports for all medication orders prescribed, held, and discontinued by University of Alberta Hospital pharmacists. These data were entered into the same REDCap data collection tool as used for the paper-based order entry period.

The third data source was archived pharmacist schedules, which were used to determine the clinical practice area of each pharmacist.

### Inclusion and Exclusion Criteria

Any medication order prescribed by a University of Alberta Hospital pharmacist for an inpatient during either of the specified study periods was included. Orders were excluded if they were verbal orders received from a nonpharmacist prescriber or pharmacist suggestion orders with a cosignature from a nonpharmacist prescriber. Orders made by pharmacists in the dispensary and pharmacists in training

were also excluded, as were orders for laboratory investigations and nonmedicinal products.

## Outcomes

The primary outcome was the relative numbers of pharmacist orders per clinical pharmacist shift (7.75 h) over the 2 study periods (data from Pyxis Connect, January 15–28, 2019, for paper-based order entry; data from Connect Care, January 15–28, 2020, for CPOE), overall and categorized according to weekdays and weekends.

Four secondary outcomes were used to determine differences in proportionate pharmacist prescribing patterns before and after CPOE implementation. First, each medication order in the 2 study periods was classified by medication schedule (schedule I, schedule II, schedule III, or unscheduled), which determines whether a prescription or pharmacist assessment is required for a drug to be sold in a community pharmacy. Schedule I medications must have a prescription to be dispensed. Schedule II and III medications can be sold only when a pharmacist is present, and schedule II medications must be kept behind the counter. “Unscheduled” medications can be sold at any store with or without a pharmacist present. Drug schedules are determined by the National Association of Pharmacy Regulatory Authorities<sup>10</sup> and the Alberta College of Pharmacy.<sup>11</sup> Second, we reported proportionate differences in the order type (new order, order modification, or immediate order discontinuation). Modified orders were subsequently sorted according to the type of order modification: change to administration instructions, change in duration of therapy, change in dose, or “other”. Third, we sorted medications by medication class (e.g., gastrointestinal, antibiotics), as per the First Data Bank Therapeutic Classification System, the classification criteria used by the Connect Care system. Fourth, the orders were proportionally analyzed by the prescribing pharmacist’s clinical care area (e.g., internal medicine, surgery). These clinical care areas were adapted from those used by Saunders and others<sup>2</sup> and were intentionally kept broad to preserve the confidentiality of pharmacists at the research location.

## Sample Size Considerations

Saunders and others<sup>2</sup> reported that 64 293 orders were placed by 172 pharmacists in 1 year, which corresponded to 17 new orders per pharmacist per month and about 31 total orders per pharmacist per month. There are approximately 25 full-time clinical pharmacists working at the University of Alberta Hospital each day, accounting for differences in weekday and weekend staffing. Therefore, we expected to collect 775 orders in each period of the study. With a standard deviation of 5 orders, collecting data from 775 orders in each period would provide 95% power to detect a difference between the groups. Data collection was stopped after 2 weeks because more than the predicted sample size was obtained.

## Data Analysis

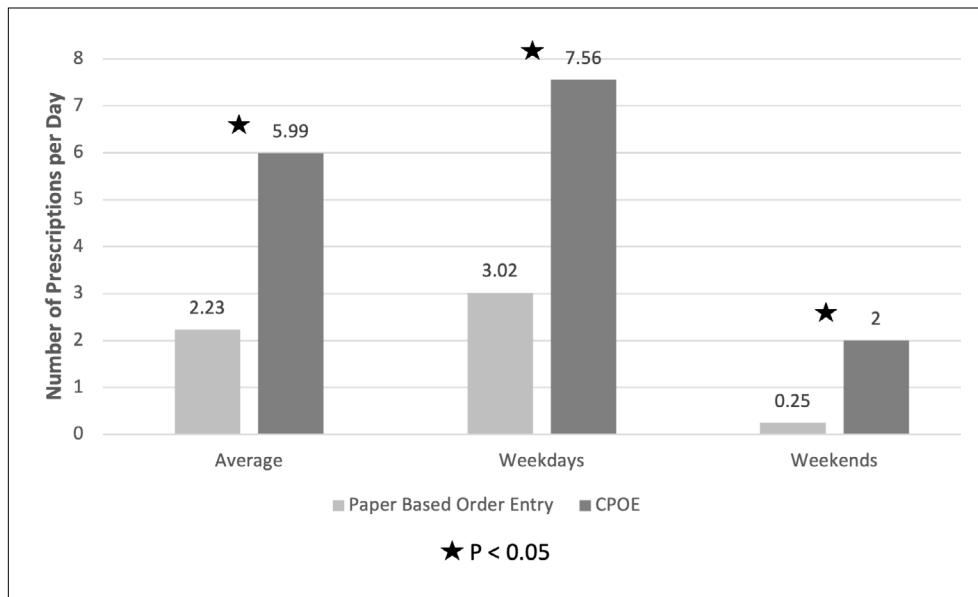
The analysis included *t* tests to determine whether there was a significant difference in mean number of total orders prescribed per clinical pharmacist before and after CPOE implementation. For all secondary outcomes, a *Z* test was performed to determine whether there was a significant difference in proportion of orders placed in each group before and after CPOE implementation. Statistical significance was determined by *p* values less than 0.05.

## RESULTS

A total of 1049 orders screened for the period January 15 to 28, 2019, met the inclusion criteria for the paper-based order entry group of prescriptions. In this period, pharmacists prescribed 2.23 orders per clinical pharmacist shift (standard deviation [SD] 1.35). The number of prescriptions per clinical pharmacist shift was higher on weekdays than on weekends (3.02 [SD 0.42] and 0.25 [SD 0.29], respectively) (Figure 1). A total of 2522 orders screened for the period January 15 to 28, 2020, met the inclusion criteria for the CPOE group of prescriptions. In this period, pharmacists prescribed 5.99 orders per clinical pharmacist shift (SD 2.98). This group also had more prescriptions per clinical pharmacist shift on weekdays than on weekends (7.56 [SD 1.03] and 2.00 [SD 2.35], respectively). Pharmacists prescribed a mean of 3.76 more orders per shift after implementation of the CPOE system than with the paper-based order entry system (95% confidence interval 1.97–5.96, *p* < 0.001).

Pharmacists prescribed a higher proportion of schedule I drugs after implementation of CPOE (70.5% with paper-based system versus 77.7% with CPOE system, *p* < 0.001) and lower proportions of schedule III drugs (5.1% with paper-based system versus 3.1% with CPOE system, *p* = 0.030) and unscheduled drugs (18.1% with paper-based system versus 14.1% with CPOE system, *p* = 0.003) (Table 1).

There were notable differences in the types of orders prescribed (Table 2). Pharmacists prescribed lower proportions of new and modified orders after CPOE implementation and a higher proportion of immediate discontinuation orders. The largest category of orders in the paper-based order entry period consisted of new orders (47.3%), whereas the majority of orders in the CPOE period were discontinuation orders (58.0%). The proportion of modified orders was higher with the paper-based order entry system than the CPOE system (27.3% versus 11.8%, *p* < 0.001). Modified orders were further analyzed by modification type (Figure 2). There was a significantly higher proportion of dose changes in the paper-based order entry period (77.7% with the paper-based system versus 74.7% with the CPOE system, *p* < 0.001), and a higher proportion of duration changes in the CPOE period (2.5% with the paper-based system versus 11.1% with the CPOE system, *p* < 0.001). Differences



**FIGURE 1.** Mean number of prescriptions per clinical pharmacist per day in paper-based order entry and computerized prescriber order entry (CPOE) periods, according to days of the week.

in the proportions of administration instruction modifications and “other” modifications were not statistically significant (Figure 2).

There were significant differences in proportionate prescribing patterns for many of the medication classes before and after CPOE implementation (Table 3). The 3 medication classes with the highest proportion of prescriptions in the paper-based order entry period were gastrointestinal drugs, antibiotics, and vitamins. Gastrointestinal drugs and antibiotics remained among the top 3 in the CPOE period, with the third being cardiovascular drugs. There were also differences in the proportions of orders placed by pharmacists in various clinical care areas before and after CPOE implementation (Table 3). Despite the statistically significant differences between the CPOE and paper-based periods, internal medicine and cardiology pharmacists represented the top 2 categories of prescribers both before and after CPOE implementation, whereas critical care

pharmacists represented the lowest category of prescribers in both periods.

## DISCUSSION

To our knowledge, this is the first study comparing pharmacist prescribing between a paper-based order entry system and a CPOE system. According to data for the primary outcome, pharmacists used their prescribing privileges significantly more often after the Connect Care CPOE system was implemented. Pharmacists also prescribed a higher proportion of schedule I medications within the CPOE system than the paper-based order entry system. Pharmacists used their prescribing authority to discontinue a higher proportion of orders using the CPOE system than

**TABLE 1. Proportional Differences in Orders by Drug Schedule in Paper-Based and CPOE Study Periods**

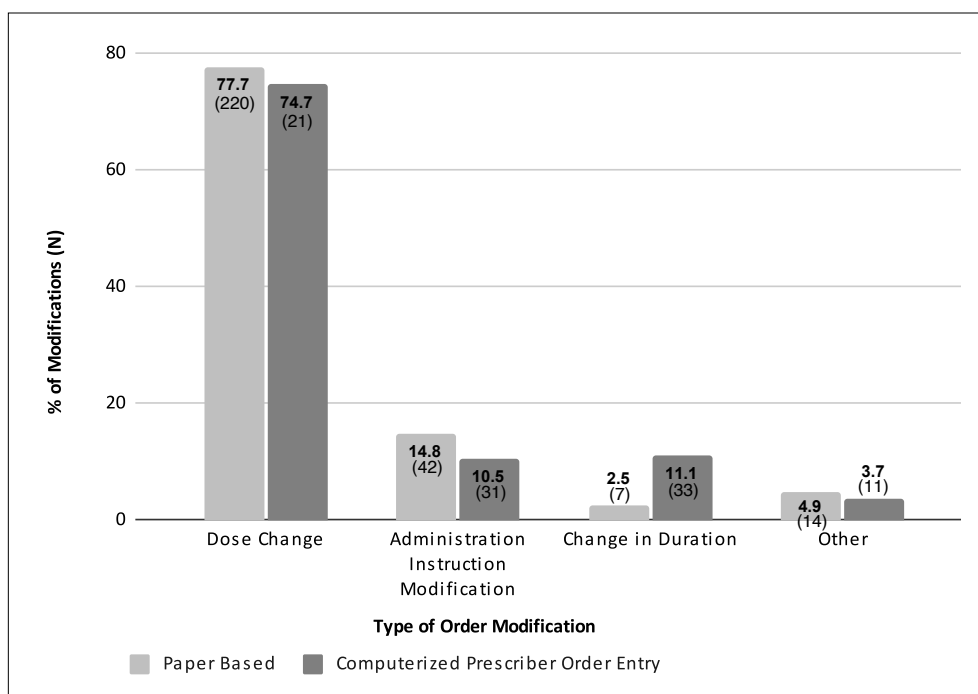
Schedule	Study Period; No. (%) of Orders		p Value
	Paper-Based (n = 1049)	CPOE (n = 2522)	
Schedule I	740 (70.5)	1959 (77.7)	< 0.001
Schedule II	65 (6.2)	128 (5.1)	0.18
Schedule III	54 (5.1)	79 (3.1)	0.030
Unscheduled	190 (18.1)	356 (14.1)	0.003

CPOE = computerized prescriber order entry.

**TABLE 2. Proportional Differences in Type of Order in Paper-Based and CPOE Study Periods**

Type of Order	Study Period; No. (%) of Orders		
	Paper-Based (n = 1048)	CPOE (n = 2520)	p Value
New	496 (47.3)	709 (28.1)	< 0.001
Discontinue	208 (19.8)	1461 (58.0)	< 0.001
Modify	286 (27.3)	297 (11.8)	< 0.001
Hold	24 (2.3)	46 (1.8)	0.36
Unhold	6 (0.6)	7 (0.3)	0.19
Reorder	28 (2.7)	0 (0)	< 0.001

CPOE = computerized prescriber order entry.



**FIGURE 2.** Modification types in paper-based and computerized prescriber order entry periods, expressed as proportion of all modifications.

in the paper-based order entry system and prescribed a lower proportion of new orders in the CPOE system. There were some proportional differences in therapeutic classification of medications and clinical care area before and after CPOE implementation, but these findings were less clinically significant.

Overall, these findings suggest that CPOE may be a facilitator of pharmacist prescribing to full scope. There are a number of potential reasons for this result. First, the convenience of placing orders in a computerized system rather than writing out orders by hand may have contributed. Second, many pharmacists have computer access on their clinical unit, which means the CPOE and all of the patient information that it contains are more readily available to inform pharmacist prescribing and to facilitate convenient order entry than is the case with a paper chart being used by many team members. Third, Connect Care includes a secure chat feature that allows members of the care team to contact each other directly. This feature allows pharmacists to easily communicate with the interprofessional team when prescribing, which is a requirement for pharmacist prescribing, according to the Alberta College of Pharmacy Standards of Practice.<sup>11</sup> Finally, Connect Care was a relatively new system at the time of study, and practitioners may have made mistakes when ordering medications. Pharmacists may be prescribing more in the CPOE system because of the need to amend these errors.

The main reason for the difference in numbers of orders before and after CPOE implementation was the

drastic increase in discontinuation orders during the CPOE period of the study. Pharmacists may have been responsible for more discontinuation orders in the CPOE period because Connect Care has a best possible medication history (BPMH) feature that autopopulates medications from the patient's electronic health record and previous hospital visits. However, the information in the system does not always accurately reflect the patient's home medication list, and pharmacists are likely the providers who will reconcile these discrepancies, which presumably involves the use of discontinuation orders. A high proportion of discontinuation orders was also noted by Saunders and others,<sup>2</sup> who collected data on pharmacist prescribing habits in a CPOE system and noted that 50% of the orders placed were for discontinuation of medications. Despite the lower proportion of new orders in the CPOE system, due to the increased proportion of discontinuation orders, there was a higher total number of new orders in the CPOE period (709 versus 496), which further supports the idea that the CPOE system facilitates pharmacist prescribing.

In terms of medication classification, gastrointestinal medications and antibiotics were among the most frequently prescribed medication classes in both periods, which is consistent with data from previous studies.<sup>2</sup> Findings regarding clinical care practice area were somewhat consistent with data from the previous study,<sup>2</sup> in which internal medicine and surgical pharmacists had the most prescriptions and intensive care pharmacists the least.

This study had some limitations. First, pharmacist

**TABLE 3. Proportional Differences in Therapeutic Classification and Clinical Care Area**

Class or Clinical Area	Study Period; No. (%) of Orders		p Value
	Paper-Based (n = 1049)	CPOE (n = 2522)	
<b>Therapeutic classification</b>			
Gastrointestinal drugs	130 (12.4)	321 (12.7)	0.79
Antibiotics	129 (12.3)	287 (11.4)	0.44
Vitamins	100 (9.5)	170 (6.7)	0.004
Cardiac drugs	91 (8.7)	297 (11.8)	0.010
Anticoagulants	79 (7.5)	113 (4.5)	0.010
Antihyperglycemics	70 (6.7)	164 (6.5)	0.85
Antiasthmatics	65 (6.2)	96 (3.8)	0.002
Electrolytes and miscellaneous nutrients	55 (5.2)	156 (6.2)	0.79
Eye, ear, nose, throat preparations	52 (5.0)	45 (1.8)	< 0.001
Analgesics	51 (4.9)	136 (5.4)	0.52
Hormones	24 (2.3)	88 (3.5)	0.06
Unclassified drug products	23 (2.2)	53 (2.1)	0.87
Diuretics	23 (2.2)	81 (3.2)	0.10
Antiplatelet agents	19 (1.8)	82 (3.3)	0.18
Psychotherapeutic drugs	13 (1.2)	55 (2.2)	0.06
Immunosuppressants	8 (0.8)	42 (1.7)	0.040
Other	117 (11.2)	336 (13.3)	0.80
<b>Clinical care area</b>			
Internal medicine	556 (53.0)	1107 (43.9)	< 0.001
Cardiology	284 (27.1)	810 (32.1)	< 0.001
Surgery	127 (12.1)	208 (8.2)	< 0.001
Pediatrics	66 (6.3)	233 (9.2)	0.003
Other	8 (0.8)	102 (4.0)	< 0.001
Critical care	8 (0.8)	62 (2.5)	< 0.001

CPOE = computerized prescriber order entry.

documentation was not accessed, so details supporting the medication orders could not be obtained. A chart review would have allowed us to analyze whether new medications ordered by pharmacists represented continuation of home medications or initial prescriptions. It also would have provided the rationale for modifications made by pharmacists (e.g., renal dose adjustments, correction of errors). Second, this study was a single-centre evaluation and consequently may lack generalizability to other centres. However, Epic Systems software has been implemented at many other hospitals in Canada, and these results may be of use to those centres.

## CONCLUSION

In this study, pharmacists generated more prescriptions in a CPOE system than a paper-based order entry system at the University of Alberta Hospital, with a higher proportion of schedule I medications prescribed. This finding could be due to convenience and easy access to the CPOE system, as well as the CPOE system's ability to facilitate interprofessional collaboration. More data are needed to determine

whether increased pharmacist prescribing in the CPOE system correlates with improved patient outcomes.

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**Stephanie Metzger**, PharmD, ACPR, is with Pharmacy Services, Alberta Health Services, Edmonton, Alberta.

**Christopher Evernden**, BSc, BScPharm, ACPR, is with Pharmacy Services, Alberta Health Services, Edmonton, Alberta.

**Tammy J Bungard**, BScPharm, PharmD, is with the Department of Medicine and Dentistry, University of Alberta, Edmonton, Alberta.

**Gordon Bell**, BScPharm, is with Pharmacy Services, Alberta Health Services, Edmonton, Alberta.

**Mohamed A Omar**, BScPharm, PhD, is with Pharmacy Services, Alberta Health Services, Edmonton, Alberta.

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**Address correspondence to:**

Dr Stephanie Metzger  
Department of Pharmacy  
University of Alberta Hospital  
8840 112 Street NW  
Edmonton AB T6G 2B7

**email:** [Stephanie.metzger@albertahealthservices.ca](mailto:Stephanie.metzger@albertahealthservices.ca)

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**APOTEX**



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# A Framework for Evaluating the Implementation of Biosimilar Drugs

Lisa Milgram, Sarah Wheeler, Andrea Adamic, Mirhad Loncar, Micheal Guirguis, and Betty Jo McCabe

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## ABSTRACT

**Background:** The introduction of biosimilar drugs has significant effects on health care systems, and a variety of approaches are required to support acceptance, adoption, and use of these drugs. Literature exists on the enablers of, and barriers to, biosimilar implementation, but frameworks that support the evaluation of biosimilar implementation strategies are currently lacking.

**Objective:** To develop an evaluation framework for assessing the effects of biosimilar implementation strategies on patients, clinicians, and publicly funded drug programs.

**Methods:** The scope of the evaluation was determined by a pan-Canadian working group through the creation of a logic model of activities and expected outcomes associated with biosimilar implementation. Each component of the logic model was considered under the RE-AIM framework, which led to a set of evaluation questions and indicators. Feedback to inform the final framework was sought from stakeholders through focus group sessions and written responses.

**Results:** An evaluation framework was created that articulates evaluation questions and indicators across 5 priority areas: stakeholder engagement, patient experience, patient outcomes, clinician experience, and system sustainability and affordability. Stakeholder feedback was obtained through 9 focus group sessions with a total of 87 participants. Feedback was used to refine the framework on the basis of stakeholder priorities and feasibility.

**Conclusions:** Through extensive stakeholder consultation, an evaluation framework was developed to measure and monitor the effects of biosimilar implementation on the 5 identified priority areas, as well as to inform future biosimilar implementations. This framework can be used as a starting point for evaluating the implementation of biosimilars across health care systems.

**Keywords:** biosimilar drugs, evaluation framework, biosimilar implementation, indicators

## RÉSUMÉ

**Contexte :** L'apparition de médicaments biosimilaires a eu et continue d'avoir des effets importants sur les systèmes de soins de santé et diverses approches doivent être mises en place pour qu'ils soient acceptés, adoptés et utilisés. Il existe de la documentation sur les catalyseurs et les obstacles à leur mise en œuvre, mais les cadres entourant l'évaluation des stratégies de mise en œuvre des médicaments biosimilaires font actuellement défaut.

**Objectif :** Développer un cadre d'évaluation pour estimer les retombées des stratégies de mise en œuvre des biosimilaires sur les patients, les cliniciens et les programmes de médicaments financés par les deniers publics.

**Méthodes :** Un groupe de travail pancanadien a déterminé la portée de l'évaluation à l'aide d'un modèle logique des activités et des résultats attendus associés à la mise en œuvre des biosimilaires. Chaque composante du modèle logique a été examinée dans le cadre RE-AIM, ce qui a donné lieu à un ensemble de questions d'évaluation et des indicateurs d'évaluation. Des commentaires pour éclairer le cadre final ont été sollicités auprès des parties prenantes au moyen de groupes de discussion et de réponses écrites.

**Résultats :** Un cadre d'évaluation a été défini. Il articule les questions d'évaluation et des indicateurs d'évaluation dans 5 domaines prioritaires : l'engagement des intervenants, l'expérience des patients, les résultats des patients, l'expérience des cliniciens et la durabilité et l'abordabilité du système. Les commentaires des intervenants ont été obtenus au cours de 9 séances de groupes de discussion avec un total de 87 participants. Les commentaires ont été utilisés pour affiner le cadre sur la base des priorités des parties prenantes et de la faisabilité.

**Conclusions :** Une vaste consultation des parties prenantes a permis de définir un cadre d'évaluation pour mesurer et surveiller les effets de la mise en œuvre des biosimilaires sur les 5 domaines prioritaires identifiés, ainsi que pour éclairer les futures mises en œuvre des biosimilaires. Ce cadre peut être utilisé comme point de départ pour évaluer la mise en œuvre des biosimilaires dans les systèmes de soins de santé.

**Mots-clés :** médicaments biosimilaires, cadre d'évaluation, mise en œuvre des biosimilaires, indicateurs

## INTRODUCTION

Biologic drugs are expensive and represent a growing segment of the pharmaceutical market. Global biologics sales increased by 70% between 2011 and 2016.<sup>1</sup> Canada has the second-highest per capita spending on biologics within the member countries of the Organisation for Economic

Co-operation and Development, not accounting for confidential price rebates resulting from product listing agreements.<sup>2</sup> In 2018, Canadian sales of biologics reached \$7.7 billion, representing 30.1% of the country's total pharmaceutical sales.<sup>2</sup> However, the biologic shares of claims in Canadian public and private plans were much lower, at 1.5% and 1.9%, respectively.<sup>2</sup> Health care payers are looking for

ways to contain costs in light of limited budgets and the need for health care system sustainability. Biosimilars represent lower-cost alternatives to existing biologic drugs. A biosimilar is a biologic drug that is highly similar to a biologic drug already authorized for sale (commonly referred to as the reference biologic), with no expected clinically meaningful differences in efficacy or safety.<sup>3</sup> Biosimilars offer an opportunity for significant cost savings, because they enter the market after the reference biologic drug's patents and data protection have expired.<sup>4</sup>

Canada has a mixed system of private and public drug coverage. Each of the 10 provinces and 3 territories has its own drug funding policies for nonhospitalized patients, which differ between oncology and non-oncology therapeutic areas. Oncology biologic drugs are primarily publicly funded and are usually administered in a hospital outpatient setting, whereas non-oncology biologic drugs are funded through a mix of public insurance, private insurance, manufacturer-sponsored patient support programs, and out-of-pocket payment, and they are typically administered in private clinics. The pan-Canadian Pharmaceutical Alliance, a network of representatives from the provincial, territorial, and federal governments, guides and defines the process of how prices for biologic and biosimilar products are negotiated for public drug plans. Federal, provincial, and territorial drug plan managers make independent decisions on funding policies and coverage. Since 2018, a variety of approaches stemming from the action plan for oncology biosimilar implementation<sup>5</sup> have been implemented across Canadian jurisdictions and therapeutic areas to support the appropriate use of biosimilars and related reference biologics and to enhance patients' access to clinically relevant and cost-effective treatment options. These approaches have included engagement with stakeholders throughout implementation efforts,<sup>6,7</sup> development and dissemination of educational resources for patients and providers,<sup>8,9</sup> identification and development of funding policies<sup>10-15</sup> to promote uptake of biosimilars, and development of recommendations to support changes to the practices of health care providers.<sup>16</sup>

Extant literature on the enablers of, and barriers to, biosimilar implementation<sup>17-21</sup> focuses largely on clinician perspectives and features the need for clinician-directed education about biosimilars and facilitation of administrative processes related to prescribing them. Literature was also found on patient perspectives before, during, and after the implementation of nonmedical switching policies; this literature highlights patient concerns, enablers of and barriers to implementation, and impacts of policy changes on affected patients.<sup>22-24</sup> However, no comprehensive evaluation framework was found in the literature to assess the effects of enablers, barriers, and implementation strategies on biosimilar implementation. As such, this study was undertaken to develop, through extensive stakeholder consultation, an evaluation framework for effectively and

objectively evaluating the impacts of implementation approaches on drug utilization and uptake, cost savings, patient experiences and outcomes, clinician experiences, and education and resource needs.

## METHODS

A pan-Canadian Evaluation Working Group (EWG) was established to help with this initiative. EWG participants represented ministries of health and cancer agencies from across Canada, health technology assessment organizations, a provincial health authority, Health Canada, and the Canadian Association of Provincial Cancer Agencies. EWG participants were nominated through jurisdictional representatives of the pan-Canadian Pharmaceutical Alliance and included a mix of pharmacists, physicians, nurses, health economists, policy advisors, and drug formulary managers. At monthly teleconferences, the project team presented on the progress of their work and facilitated generative discussion for the EWG to identify priorities for evaluation and to provide input on the feasibility of data collection and analysis. The EWG determined the scope of the evaluation by developing a logic model showing the activities and expected outcomes associated with the various approaches to biosimilar implementation across Canada. Box 1 shows a summary of the Biosimilars Implementation Logic Model.

### Evaluation Framework

The RE-AIM framework is a tool that helps program planners, evaluators, funders, and policy-makers develop effective, sustainable health programs and interventions.<sup>25</sup> When applied for purposes of evaluation, the framework proposes that different perspectives be used to evaluate the success of a program or intervention. Each activity and expected outcome identified within the Biosimilars Implementation Logic Model was considered from the 5 perspectives of the RE-AIM framework—Reach, Effectiveness, Adoption, Implementation, and Maintenance—as facilitated by the RE-AIM planning and evaluation tool.<sup>26</sup> This process generated an extensive list of evaluation questions and indicators that formed the first draft of the evaluation framework. The draft framework was reviewed by the EWG, who provided feedback on its alignment with jurisdictional evaluation priorities and on the feasibility of data collection and analysis. EWG feedback also ensured that the framework was comprehensive and that irrelevant or infeasible questions and indicators were excluded.

### Stakeholder Consultations

To ensure that the framework reflected the priorities and perspectives of the stakeholders most affected by changes in biosimilar policy, consultations on the draft framework were conducted through focus group sessions and requests for written comments from key stakeholder groups.



Invitations were extended to 26 patient groups and 13 clinician groups across disease areas where biosimilars were approved for use (oncology, rheumatology, dermatology, gastroenterology, endocrinology, ophthalmology, and rare

disorders), 4 pharmaceutical industry groups, 3 providers of patient support programs with private infusion clinics, 1 organization representing private health insurers, and 13 Canadian drug plan managers representing federal, provincial, and territorial ministries of health and cancer agencies. Organizations were identified by reviewing lists of participation in prior pan-Canadian biosimilar consultation sessions and through an online search of additional Canadian national organizations with an overt interest in biosimilar implementation. Invitations were sent to the leaders of the organizations, with a request to identify 1 or 2 representatives to participate in the focus group sessions.

Nine focus group sessions involving a total of 87 participants were conducted via Microsoft Teams videoconferencing software (Microsoft Corporation) in November 2020, 4 with patient groups (grouped by therapeutic area) and 1 each with clinician groups, the pharmaceutical industry, providers of patient support programs, private health insurance representatives, and public drug plan managers. Box 2 lists the participating organizations. Participants were not compensated for their time. Each session was facilitated by 2 of the authors (L.M., a program manager, and S.W., a methodologist) from the core project team, who had no known conflicts of interest. Meetings were recorded to facilitate transcription and subsequent analysis of the discussion.

To ensure efficient use of time during focus group sessions, evaluation questions and indicators that were most aligned with the perspectives of the various groups were prioritized for discussion. Clinician sessions prioritized themes of local implementation and education; patient group sessions focused on funding policies, local implementation, and education; industry sessions prioritized funding policies and education; and payer sessions focused on funding policies. All groups were given time to discuss questions and indicators related to stakeholder engagement. Time was reserved at the end of each session for discussion on any of the other evaluation questions or indicators, so that all stakeholders could comment on any aspect in the draft framework. Following the focus group sessions, stakeholders had the opportunity to provide additional feedback on the draft framework through the electronic platform Microsoft Forms (Microsoft Corporation). This ensured that all focus group participants had the opportunity to be heard on all issues.

## Analysis

Transcripts from the focus group sessions were analyzed using NVivo qualitative data analysis software (QSR International Pty Ltd; version 11, 2015) to identify areas of importance for each stakeholder group. All feedback, including focus group discussions and written responses, was synthesized and thematically analyzed to inform the final list of indicators and evaluation questions. The final evaluation plan was developed from the draft plan by first

<b>BOX 1. Summary of Biosimilars Implementation Logic Model</b>	
<b>Inputs</b>	<ul style="list-style-type: none"> <li>• Perspectives from patients, pharmaceutical industry, and clinicians</li> <li>• Existing funding policies and implementation strategies</li> <li>• Biosimilar implementation experiences at treatment settings</li> <li>• Existing resources for patients and physicians</li> </ul>
<b>Activities</b>	<ul style="list-style-type: none"> <li>• Development of action plan for pan-Canadian biosimilar implementation</li> <li>• Consultations with stakeholders on implementation strategies and funding policies</li> <li>• Development, publication, and dissemination of educational resources</li> <li>• Implementation of biosimilars</li> </ul>
<b>Outputs</b>	<ul style="list-style-type: none"> <li>• Number and type of stakeholders consulted</li> <li>• Number of engagements</li> <li>• Stakeholder perceptions</li> <li>• Themes and insights generated by consultations</li> <li>• Number of brands funded in each jurisdiction</li> <li>• Biosimilar funding policies</li> <li>• Cost savings</li> <li>• Utilization (new patients, switched patients)</li> <li>• Exception requests and approvals</li> <li>• Time from jurisdiction funding announcement to local implementation (i.e., at hospitals/clinics and other care settings)</li> <li>• Effort/resources to implement a biosimilar in the treatment setting</li> <li>• Operational changes at the treatment setting</li> <li>• Patient experiences switching to biosimilars</li> <li>• Number and types of educational resources developed</li> <li>• Views/downloads of educational resources</li> </ul>
<b>Outcomes</b>	<ul style="list-style-type: none"> <li>• Increased awareness, acceptance, and understanding of biologics and biosimilars</li> <li>• Increased confidence in biosimilars (reduced uncertainty around safety and efficacy)</li> <li>• Increased transparency and awareness of biosimilar implementations and funding policies among stakeholders</li> <li>• Sustainable market for multiple products</li> <li>• Improved access to treatment options and reduced risk of supply shortages</li> <li>• Increased readiness to implement biosimilars at the treatment setting</li> <li>• Alignment and awareness of practices across treatment settings</li> <li>• Increased awareness of policy options, including facilitators and barriers</li> <li>• Plan for monitoring outcomes of biosimilar implementation</li> <li>• Achieve target biosimilar uptake and cost savings</li> <li>• Reinvestments of cost savings into patient care</li> <li>• Sustainable provincial/territorial drug budgets</li> <li>• Enhanced information systems that allow effective pharmacovigilance</li> </ul>

## BOX 2. Organizations that Participated in Focus Groups

### Patient organizations

- Arthritis Consumer Experts
- Arthritis Society Canada
- Canadian Arthritis Patient Alliance
- Canadian Breast Cancer Network
- Canadian Cancer Society
- Canadian CML Network
- Canadian Council of the Blind
- Canadian Digestive Health Foundation
- Canadian Organization for Rare Disorders
- Canadian Skin Patient Alliance
- Canadian Society of Intestinal Research
- Canadian Spondylitis Association
- Colorectal Cancer Canada
- Diabetes Canada
- Fighting Blindness Canada
- Gastrointestinal Society
- Lymphoma Canada

### Clinician groups

- Arthritis Health Professions Association
- Canadian Association of Gastroenterology
- Canadian Association of Pharmacy in Oncology
- Canadian Dermatology Association
- Canadian IBD Nurses
- Canadian Ophthalmological Society
- Canadian Pharmacists Association
- Canadian Rheumatology Association
- Canadian Society of Hospital Pharmacists

### Industry

- Biosimilars Canada
- Canadian Biosimilars Forum

### Private payer

- Canadian Life and Health Insurance Association

### Private infusion clinics

- Bayshore HealthCare
- Innomar Strategies

removing evaluation questions and indicators that were not important to any stakeholder group and then expanding and clarifying the questions and indicators in the areas that stakeholder groups felt were most relevant to understanding the implementation of biosimilars. Priorities emerging from each stakeholder perspective were equally weighted, and thus emergent themes with high priority for any particular stakeholder group were included, even if other stakeholder groups did not consider the area to be a priority. For example, if patient support programs and private health insurance representatives prioritized different areas, both sets of priorities were included in the framework.

## RESULTS

Through the process of considering the activities and outcomes of biosimilar implementation under the RE-AIM framework and incorporating the EWG's feedback

regarding relevance and feasibility, a draft framework was developed that contained the evaluation questions and indicators pertinent to assessing the effects of biosimilar implementation. In this framework, evaluation questions and indicators were thematically grouped into 5 priority areas: stakeholder engagement, patient experience, patient outcomes, clinician experience, and system sustainability and affordability.

Feedback received during the focus group sessions and through written feedback mechanisms highlighted the evaluation and implementation priorities for the various stakeholders and clarified which aspects were most relevant to measure. Feedback on the priority areas is summarized below.

### Feedback on Stakeholder Engagement

All participants described the importance of collaborative engagement and consultation with stakeholders for the successful implementation of biosimilars. The following are key aspects that were identified to help measure the scope and effect of stakeholder engagement:

- Awareness of which stakeholders were involved in the development of funding policies
- Times and frequency of engagement
- Methods used for stakeholder engagement
- Stakeholder perceptions of the engagement process
- Intended recipients of communicated funding policies
- Inputs used in the development of funding policies

### Feedback on Patient Experience

Patient groups indicated that clear and objective information on biosimilars was helpful to support acceptance and comfort with biosimilar therapy. However, in some jurisdictions and therapeutic areas, patients were faced with changes in out-of-pocket expenses and changes in treatment location. The following key aspects were identified to help measure the effects of patient experiences:

- Patient knowledge of biosimilars
- Available educational supports for patients
- Change in travel distance to treatment site
- Change in patient out-of-pocket expenses

### Feedback on Patient Outcomes

Some patient groups and clinicians expressed a lack of confidence in the safety and effectiveness of biosimilar drugs when a patient was switched from a reference biologic to a biosimilar. These concerns may stem from limited evidence in support of switching. Participants suggested that real-world data be collected to measure and monitor patient outcomes compared with historical cohorts (i.e., patients on the reference biologic), such as the following:

- Number of physician visits, hospitalizations, and emergency department visits

- Drug discontinuation rates
- Use of concomitant drugs

### Feedback on Clinician Experience

Clinicians (physicians, pharmacists, nurses) indicated that policy and process changes resulted in increased workload when they were prescribing or administering biosimilars to patients. They wanted to examine these changes in early phases of biosimilar implementation to improve the efficiency of future implementations. Clinicians also indicated that the quantity, quality, and availability of credible, objective, evidence-based information on biosimilars differed across diseases and that it is important to understand where knowledge gaps exist. The key aspects that were identified to help measure the effects on clinician experiences included the following:

- Changes in clinician and administrator time to support patients switching to a biosimilar
- Activities associated with implementing biosimilars on the front line (e.g., information system upgrades, education delivery, revisions to policies and procedures)
- Resources needed to implement biosimilars on the front line (e.g., time, money, human resources)
- Readiness of existing information systems to enable data collection and clinical operations with biosimilars
- Clinician knowledge of biosimilars
- Access to educational materials regarding biosimilars (e.g., who has access, what materials are available, how they are incorporated into practice)
- Changes in prescribing patterns (e.g., switching patients to a new therapeutic class instead of switching to a biosimilar)

### Feedback on System Sustainability and Affordability

Some stakeholders identified cost savings as a driving force for biosimilar implementation. Other stakeholders cautioned that a focus on costs alone does not align with the goals of better patient care and increased treatment options. A focus on driving down drug costs may also lead to decreased manufacturer profit margins and a disincentive for manufacturers to remain in the biosimilars market, resulting in potential drug shortages, supply interruptions, or fluctuations in pricing. The following key aspects were identified to help measure the effects on market and financial sustainability in a publicly funded system:

- Biosimilar utilization
- Cost savings
- Market share distribution
- Use and effect of exception policies to remain on or switch back to the reference biologic (including number of requests and approval rate)
- Time to drug funding availability

### Biosimilars Implementation Evaluation Framework

The stakeholder feedback received through the focus groups and written contributions, summarized above, was used to refine and develop the Biosimilars Implementation Evaluation Framework presented in Appendix 1 (available from <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>). Data to support these indicators may come from a variety of sources, including existing administrative data sets (information routinely collected about program operations that is used for performance management, funding, or reporting), new organizational data sources (information about how a program is constructed and operates, which is used to understand how a program is implemented), and qualitative methods (information about context that is used to understand why a program worked or did not work well) such as informational interviews, focus groups, or surveys. The evaluation framework also includes supporting questions to further explore perspectives related to the qualitative indicators (Box 3). Because of differences in drug funding policies and the delivery of care across Canada, stakeholders recommended stratifying analysis of the indicators across therapeutic areas, jurisdictions, and care settings, when necessary, to demonstrate different effects and outcomes.

### DISCUSSION

The Biosimilars Implementation Evaluation Framework consists of evaluation questions and indicators to measure and monitor the effects of biosimilar funding policies and implementation strategies on patients, clinicians, and drug programs. Stakeholders who are most strongly affected by biosimilar policy changes helped to refine the indicators and improve the robustness and relevance of the evaluation framework. The EWG's input on the feasibility of data collection and reporting helped support jurisdictional buy-in from those who may be responsible for executing components of the framework. Most stakeholders were interested in participating in the process, as they were given an opportunity to share their feedback on what would be most important to measure.

Similar to what has been reported in the literature,<sup>17-21</sup> stakeholders identified the need for more education, such as a centralized source of accredited, evidence-informed, objective educational material for physicians. They also identified the need for patient information, purposeful stakeholder engagement, and clear and timely communication to support the use and acceptance of biosimilars. In addition, stakeholders identified the need for clear and transparent policies for switching and substitution of biologic drugs.

Through the inclusion of diverse stakeholder perspectives, such as patient and industry groups, additional areas for evaluation were articulated. System sustainability and affordability were of particular importance to policy- and decision-makers, given the nature of public drug funding in

### BOX 3. Qualitative Questions and Probes

#### Assessing perspectives on stakeholder engagement

- How were stakeholders engaged throughout the continuum of biosimilar implementation?
  - What were the time points at which stakeholders were engaged?
- Do stakeholders believe their contribution was valued, making them champions of the work?
  - Were the methods, timeliness, and frequency of engagement appropriate for the intended outcomes and the stakeholder groups that were engaged?
- Are stakeholders interested in engaging in future discussions?
  - What are the stakeholder preferences for continued engagement and why?
- Who was engaged in developing the funding policies, and to which stakeholder groups were these policies communicated?
  - What method(s) were used in communicating funding policies to stakeholders?
  - What method(s) were used to engage with each stakeholder group?
  - Were the methods of engagement and communication with each stakeholder group appropriate?
  - Was the timing and frequency of engagement with each stakeholder group appropriate?
  - What are the preferences for future engagement (e.g., earlier or later, frequency) with each stakeholder group?

#### Assessing perspectives on local implementation (e.g., hospitals, clinics)

- Which individuals and groups of people (e.g., roles/positions) were engaged in preparing for the implementation of biosimilars at your site? How were they engaged? What were their roles?
  - What types of techniques were used to implement biosimilars (e.g., technical upgrades, education, policies, and procedures)?
  - What resources were required for implementation of biosimilars (e.g., time, money, human resources)?
- What intended outcomes or targets were monitored at the local level?
  - What types of indicators, targets, or metrics were collected at the local level?
  - What worked, what did not work, and what were the reasons why?
- Were the targets reached and after how long?
  - To what extent were the desired outcomes and/or targets achieved?
  - What was the length of time to reach the intended outcomes?
  - What contextual information is available to understand met or unmet targets?
- What enablers or barriers affected biosimilar implementation at the local level?
  - What are the known enablers and barriers encountered in local implementation (e.g., stakeholders, existing information systems, existing practices/operations, available staff)?
  - What gaps were identified during implementation?
- What changes were made at the local level to implement biosimilars?
  - How was education delivered to clinicians and to patients?
  - What system upgrades and/or revisions to policies and procedures were made?
  - What were the changes in clinician (physician, nursing, pharmacist) and administrative time (in full-time equivalents or number of extra visits) for each patient switched to a biosimilar?
- What supports are in place to ensure the ease of ongoing use of biosimilars?
  - What gaps were identified or additional supports needed?
  - What types of resources were in place to support new biosimilar implementations?
  - How are supports for biosimilars embedded into standard practice?

Canada and the increasing cost of biologic drugs. Patient and industry groups acknowledged the importance of the future sustainability of the health care system and also highlighted the need for a sustainable market where multiple biosimilar brands can coexist. Patient groups expressed interest in additional safety and effectiveness data on switching (from reference biologic to biosimilar and from one biosimilar to another), psychological supports, and genuine collaboration and transparency to improve patients' and clinicians' experiences. More information about these consultations in Canada, as well as a Canadian-specific evaluation framework, is available by contacting the corresponding author.

There were some limitations in the development of the Biosimilars Implementation Evaluation Framework.

First, although a concerted effort was made to consult with a diverse set of stakeholders, it is recognized that some perspectives may not have been captured. Although all stakeholders had prior knowledge of biosimilars and were engaged in various consultations and activities in preparation for the introduction of biosimilars and funding policies in Canada, only a few stakeholders had lived experienced with mandated switching. However, given the diversity of organizations that were invited for engagement, a wide range of perspectives was included. Second, although all participants had the opportunity to comment on the entire draft framework, participants may not have discussed every indicator directly, as a subset of indicators were prioritized for discussion at each focus group

session. In addition, new indicators that were suggested at focus group sessions or through written feedback were not subsequently reviewed by all focus group participants. Therefore, the EWG had to decide whether to include those new indicators in the final evaluation framework without additional consultation. Decisions were based on expected value of the indicator, importance to stakeholders, and feasibility of data collection. Lastly, no prioritization exercise was conducted to reduce the number of indicators included in the framework. Some stakeholders expressed concern that the draft evaluation framework would be expensive and time-consuming to execute, given the large number of indicators. The framework, however, can be used as a toolkit, which can be customized or narrowed in scope, to align with the specific considerations of an individual jurisdiction or organization.

## CONCLUSION

The introduction of biosimilar drugs has significant effects on health care systems. Jurisdictions across Canada have taken a variety of approaches to funding policies and implementation strategies, which will affect patients, clinicians, and drug programs. The Biosimilars Implementation Evaluation Framework contains evaluation questions and indicators to measure and monitor the introduction of biosimilar drugs. This framework may be used as a starting point for jurisdictions evaluating the implementation of biosimilars in their health care systems.

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**Lisa Milgram**, MBA, is with the Provincial Drug Reimbursement Programs, Ontario Health (Cancer Care Ontario), Toronto, Ontario.

**Sarah Wheeler**, PhD, is with Quality Measurement and Evaluation, Ontario Health (Cancer Care Ontario), Toronto, Ontario.

**Andrea Adamic**, BA, is with the Provincial Drug Reimbursement Programs, Ontario Health (Cancer Care Ontario), Toronto, Ontario.

**Mirhad Loncar**, MSc, is with Pharmaceutical Reviews, CADTH, Ottawa, Ontario.

**Micheal Guirguis**, BSc(Pharm), PhD, is with the University of Alberta Hospital, Alberta Health Services, Edmonton, Alberta.

**Betty Jo McCabe**, MEd, is with Quality Measurement and Evaluation, Ontario Health (Cancer Care Ontario), Toronto, Ontario.

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**Address correspondence to:**

Andrea Adamic  
Provincial Drug Reimbursement Programs  
Ontario Health (Cancer Care Ontario)  
525 University Avenue  
Toronto ON M5G 2L3

**email:** andrea.adamic@ontariohealth.ca

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# Pharmacy Students' and Pharmacist Preceptors' Perceptions of the Hospital Rotation Experience during the COVID-19 Pandemic

Monica Lee and Jenny Chiu

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## ABSTRACT

**Background:** The COVID-19 pandemic brought significant disruptions to pharmacy experiential education. To ensure the safety of students and staff, university and rotation site educators needed to make changes rapidly to adapt to the dynamic environment.

**Objectives:** To explore the impact of the COVID-19 pandemic on pharmacy students and their preceptors during experiential rotations and to identify any barriers to learning that arose and opportunities for improvement.

**Methods:** Two online questionnaires were developed to explore the perceptions of pharmacy students and preceptors during experiential rotations. The following topics were examined: support for rotations by the hospital and the university, perceived safety, accessibility of resources, interpersonal interactions, professional development, assessment and evaluation, and overall impressions. All Advanced Pharmacy Practice Experience students from the University of Toronto who completed 1 or more rotations at North York General Hospital during the 2020/21 academic year and their preceptors were invited to participate.

**Results:** Sixteen and 25 questionnaires were completed by students and preceptors, respectively. Both groups agreed that they were adequately prepared for the rotations and felt safe. There was a decrease in interpersonal interactions, while the use of virtual communication tools increased. Lessons learned included the need for timely communications and access to resources for learners and preceptors, contingency plans for staff shortages and outbreaks, and workspace assessments.

**Conclusions:** During the COVID-19 pandemic, implementation of experiential rotations was associated with many challenges, but pharmacy learners and preceptors believed the overall experience was not significantly affected.

**Keywords:** experiential education, COVID-19, pharmacy education, pharmacy preceptor, pandemic, pharmacy students

## RÉSUMÉ

**Contexte :** La pandémie de COVID-19 s'est accompagnée de perturbations importantes dans le domaine de la formation pratique en pharmacie. Les éducateurs de l'université et du lieu de stage ont dû rapidement apporter des changements pour s'adapter à l'environnement dynamique et assurer la sécurité des étudiants et du personnel.

**Objectifs :** Étudier les effets de la pandémie de COVID-19 sur les étudiants en pharmacie et leurs précepteurs pendant les stages pratiques et identifier les obstacles qui se sont présentés ainsi que les améliorations possibles.

**Méthodes :** Deux questionnaires en ligne ont été préparés pour étudier les perceptions des étudiants en pharmacie et des précepteurs pendant les stages pratiques. Les sujets suivants ont été examinés : le soutien de l'hôpital et de l'université pour les stages, la perception de la sécurité, l'accessibilité des ressources, les interactions interpersonnelles, le perfectionnement professionnel, l'évaluation et les impressions générales. Tous les étudiants du programme Advanced Pharmacy Practice Experience de l'Université de Toronto qui ont effectué un ou plusieurs stages à l'Hôpital général de North York au cours de l'année universitaire 2020-2021 et leurs précepteurs ont été invités à participer.

**Résultats :** Les étudiants et les précepteurs ont répondu à 16 et 25 questionnaires, respectivement. Les deux groupes ont convenu qu'ils étaient bien préparés aux stages et qu'ils se sentaient en sécurité. On a observé une diminution des interactions interpersonnelles, tandis que l'utilisation d'outils de communication virtuels a augmenté. Les leçons tirées comprennent : la nécessité de communiquer en temps opportun et l'accès aux ressources pour les apprenants et les précepteurs; les plans d'urgence en cas de pénurie de personnel et d'épidémies; et les évaluations de l'espace de travail.

**Conclusions :** Pendant la pandémie de COVID-19, la mise en œuvre des stages pratiques a été associée à de nombreux défis, mais les apprenants en pharmacie et les précepteurs ont estimé que l'expérience globale n'a pas été touchée de manière significative.

**Mots-clés :** formation pratique, COVID-19, formation en pharmacie, précepteur en pharmacie, pandémie, étudiants en pharmacie

## INTRODUCTION

The World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic on March 11, 2020.<sup>1</sup> Since then, this disease has transformed many aspects of

our lives. To limit transmission of SARS-CoV-2, various measures were taken, including the closure of nonessential services, the implementation of restrictions on entry into Canada, and the practice of social or physical distancing.<sup>2</sup>

Regional decisions to implement “lockdowns” resulted in the closure of in-person classes, including those at the university level.<sup>3</sup> Although pharmacy learners could gain valuable experience during a global health crisis, numerous issues made it challenging for institutions to continue clinical placements. First, hospital pharmacies diverted their resources to managing drug shortages,<sup>4</sup> exploring alternative methods of medication administration,<sup>5</sup> and redesigning staffing models to accommodate potential staff shortages. Second, the methods to ensure the safety and well-being of staff and learners were uncertain while information about the coronavirus continued to evolve. Third, conservation of personal protective equipment (PPE) was thought to be crucial, because inventory was scarce and supply chains were unpredictable.<sup>6</sup> Pharmacy educators and hospital pharmacy administrators were suddenly faced with the challenges of implementing experiential rotations during this unprecedented time.

The entry-to-practice Doctor of Pharmacy and post-baccalaureate PharmD programs in the Leslie Dan Faculty of Pharmacy (LDFP) at the University of Toronto (U of T) require candidates to complete Advanced Pharmacy Practice Experience (APPE) rotations in various settings.<sup>7</sup> With a strong commitment to teaching and learning, the Pharmacy Department at North York General Hospital (NYGH) has historically offered an average of 40 APPE placements per academic year. Following the WHO’s declaration of the COVID-19 pandemic, all nonpaid, prelicensure rotations (including those for pharmacy) at NYGH were halted on March 16, 2020, and U of T cancelled all experiential rotations for the remainder of the academic year. At NYGH, all pharmacy rotations resumed on July 13, 2020. When on-site placements were permitted, U of T and NYGH made plans for the safe reintegration of learners during a period when there were still many unknowns.

The NYGH Centre for Education provided the hospital’s education leads with planning tools to assess the feasibility of resuming in-person rotations. Considerations included assessment of the number of learners on site, space limitations, and COVID-19 resources. Supports implemented by the hospital included training for donning and doffing of PPE, making the medical library available for use exclusively by learners, and resources outlining what to expect when on placement during the pandemic, as well as new communication platforms such as Microsoft Teams (Microsoft Corporation). The university developed student guidelines in the event of exposure to COVID-19, as well as procedures outlining provision of care for patients with COVID-19. The university also developed a COVID-19 curriculum, which learners in all health disciplines had to complete before their return to on-site rotations.

The goals of this study were to explore how these modifications affected pharmacy students during their experiential rotations and to identify barriers to learning and

opportunities for improvement. The results of this study may help to inform pharmacy educators and on-site education coordinators about modifications needed to improve future rotations when faced with similar circumstances.

## METHODS

### Development of Questionnaires

A literature search was conducted to determine whether a validated survey existed to help address the research questions. No prior studies on this topic were found, so the authors developed 2 questionnaires through consensus. The questionnaire for students (available by request to the corresponding author) consisted of 29 items, divided into a section for demographic characteristics and the following 7 domains to evaluate the impact of the pandemic on the students’ experience during their rotations:

- support for rotation by the hospital and university (e.g., COVID-19 protocols)
- perceived safety (e.g., infection control protocols and PPE)
- accessibility of resources (e.g., physical workspace; hardware and software; remote access to electronic health records, drug information resources, and hospital intranet)
- interpersonal interactions (e.g., with patients, families, health care providers)
- professional development (e.g., rounds, education sessions)
- assessment and evaluation
- overall impression

These 7 domains reflect the components and key requirements for learner preparedness for a hospital-based rotation.<sup>8</sup>

The questionnaire for pharmacist preceptors (also available by request to the corresponding author) was developed from the student questionnaire, with modifications to elicit pharmacists’ perceptions of how the students felt regarding some domains. Two former pharmacy students and 2 pharmacists tested the preliminary questionnaires to evaluate readability and clarity of the questions and to estimate the time required to complete the survey. Feedback was incorporated to improve the readability of the questions. The final versions of the questionnaires were created using SurveyMonkey (Momentive).

### Participant Selection

All LDFP Doctor of Pharmacy students who completed an APPE placement at NYGH between July 13, 2020, and April 30, 2021, as well as their pharmacist preceptors, were invited, on the last day of their respective rotations, to participate in the study. Preceptors were invited to provide consent and complete a questionnaire for each student on their rotation. Some preceptors taught more than 1 rotation



block and provided consent for each block. The pharmacy education coordinator identified eligible participants from the placement schedule provided by the LDFFP. For students who had multiple rotations at NYGH, the invitation to participate was extended at the end of their last NYGH rotation. Students who did not complete their APPE rotations and Doctor of Pharmacy students from institutions other than U of T, as well as their preceptors, were not eligible to participate.

### Data Collection

For each potential participant who provided written informed consent, one of the study investigators sent the survey link by email (through SurveyMonkey) after completion of the rotation, with 2 weekly follow-up emails sent to increase response rates. Data were collected anonymously.

The data from each response were extracted into a spreadsheet (Excel 2016, Microsoft Corporation) by a single investigator (J.C.). The second investigator (M.L.) verified the data entry for accuracy. Quantitative data were analyzed using descriptive statistics. Qualitative data were reviewed and common themes extracted under each domain upon agreement between the 2 authors.

### Ethics Approval

The research protocol was reviewed and approved by the NYGH Research Ethics Board in July 2020.

## RESULTS

### Participant Characteristics

There were 29 rotation blocks at NYGH during the 2020/21 academic year: 26 involving direct patient care and 3 involving non-direct patient care. Of the 18 eligible APPE students, 17 (94%) consented to participate in the study, but only 16 completed the questionnaire. Five (31%) of these 16 student participants had completed an early practice experience rotation in a hospital setting before their APPE rotations at NYGH. Eleven (69%) of the student participants completed more than 1 rotation at NYGH. Twenty-one pharmacist preceptors and copreceptors were eligible to participate in the study. Given that some preceptors had multiple students, the total number of potential consents (and hence the potential number of preceptor questionnaires) was 30. However, only 25 questionnaire responses were available for analysis, because invitations to 3 preceptors were missed, and 2 preceptors did not submit any response. Of the 25 preceptor responses submitted, 1 was incomplete; any data available from this questionnaire were included in the analysis. With respect to teaching experience, the pharmacist preceptors had supervised a median of 4 students (range 1 to 7) per preceptor over the past 2 academic years. The areas where rotations were held are listed in Table 1.

**TABLE 1. Characteristics of Student Participants and Rotation Types at North York General Hospital**

Characteristic	Number
Student's program	<i>n</i> = 16 participants
Entry-level PharmD	14
Postbaccalaureate PharmD	2
Student's prior experiential practice experience	<i>n</i> = 16 participants
Early practice experience in a hospital setting	5
Rotation type	<i>n</i> = 27 rotations
Direct patient care ( <i>n</i> = 24)	
General medicine and geriatrics	9
Cardiology	5
Outpatient clinics	2
Oncology	2
Antimicrobial Stewardship Program	1
Pediatrics/neonatal intensive care unit	2
Surgery	2
Critical care	1
Non-direct patient care ( <i>n</i> = 3)	
Drug utilization/informatics	1
Oncology: project	1
Antimicrobial Stewardship Program: project	1

### Preparation and Support for Rotation

Fourteen (88%) of the 16 student respondents agreed that they were adequately prepared to start the rotation with the resources provided by NYGH, whereas 12 (75%) felt this way about the resources provided by U of T (Figure 1). Five student participants believed that the university could have done more to prepare them for their rotations during the pandemic. From the pharmacist preceptors' point of view, 20 (80%) and 23 (92%) of 25 responses indicated that the university and the hospital, respectively, had adequately prepared students to start the rotation with COVID-19 resources and support. Similarly, 21 (84%) and 24 (96%) of the 25 preceptor responses indicated a belief that the preceptors themselves were adequately prepared for the rotations with the resources provided by the university and the hospital, respectively. Ideas from students and preceptors on how to improve their preparedness are summarized in Table 2.

### Safety

All but 1 of the student participants felt safe working in the hospital environment during the pandemic. Twenty-three (92%) of 25 preceptor responses indicated a belief that their students felt safe. The reasons for students feeling safe or unsafe are listed in Box 1.

### Resources

Participants were asked to indicate the amount of time they were able to access computer terminals on site, applications

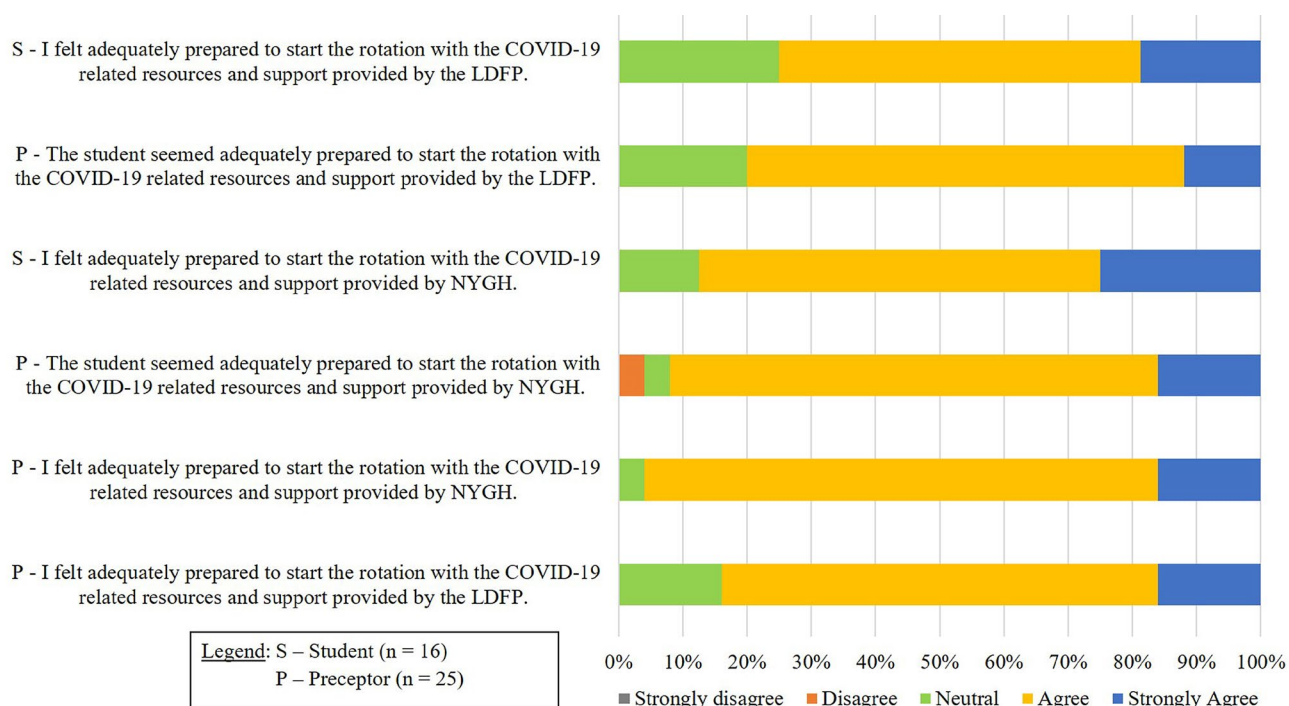
such as Microsoft Teams, and online resources by remote access. The results are illustrated in Figure 2. With respect to workspace and computer terminal access in the hospital, preceptors consistently perceived these resources to be less accessible than did students. All student respondents indicated that they were able to reliably access Microsoft Teams, the NYGH email system, and virtual care resources (where applicable) the majority of the time. A few participants reported problems with remote access. One person was able to use remote access only some of the time, whereas 2 indicated they had access about half the time. Specific problems with electronic tools were delays in registration or initial set-up, a delay in resolving a particular problem, inconsistency in remote access, and connectivity problems when using a particular tool. Positive feedback and suggested

improvements from students and preceptors are summarized in Table 3.

### Interpersonal Interactions

Perceptions of how interactions with patients and families, other health care providers and interprofessional collaborators, preceptors and other pharmacy personnel, and peers differed during the pandemic were elicited in this part of the questionnaire. Table 4 summarizes the themes identified and their respective frequencies, based on comments from student and preceptor respondents.

Although some of the students and preceptors reported no differences, others felt that there were fewer face-to-face interactions, which resulted in increased use of telephones to interact with patients and families and increased use



**FIGURE 1.** Perceptions of students and preceptors regarding preparation for the rotations. LDFP = Leslie Dan Faculty of Pharmacy (University of Toronto), NYGH = North York General Hospital.

**TABLE 2. Additional Ideas Suggested by Participants to Help Prepare for the Rotations**

Source of Needed Resource	Suggestions from Students	Suggestions from Preceptors
University of Toronto	<ul style="list-style-type: none"> <li>• Provide information related to what a student should expect in the event they contract COVID-19 during the rotation</li> <li>• Adjust the evaluation description to account for limitations related to COVID-19</li> <li>• Provide COVID-19–related clinical resources, such as treatment guidelines and vaccination information for patients</li> <li>• Describe safety measures implemented</li> </ul>	<ul style="list-style-type: none"> <li>• Share information on how students were prepared for their rotation in terms of managing COVID-19–related issues</li> <li>• Outline expectations of students with respect to caring for patients with COVID-19 or working on a unit dedicated to caring for patients with COVID-19</li> </ul>
North York General Hospital	<ul style="list-style-type: none"> <li>• Discuss the changes to workflow and student expectations related to COVID-19 during the hospital orientation, to help students feel safer</li> </ul>	<ul style="list-style-type: none"> <li>• Review donning and doffing of personal protective equipment before the start of each rotation</li> </ul>

of Microsoft Teams to interact with health care providers. There was also less engagement with patients' families because of visitor restrictions.

The need for physical distancing, the use of PPE, and the lack of face-to-face opportunities all contributed to challenges with communication. One student expressed concerns about a higher risk of medication errors as a result of these barriers.

**BOX 1. Factors that Made Students Feel Safe or Unsafe during Rotations<sup>a</sup>**

Factors that made students feel safe
<ul style="list-style-type: none"> <li>• Adequate amount of personal protective equipment and safety protocols in place (<i>n</i> = 24)</li> <li>• Limited physical contact with staff and patients (<i>n</i> = 8)</li> <li>• Availability of alternative modes of communication (<i>n</i> = 8)</li> <li>• Adequate amount of space for physical distancing (<i>n</i> = 5)</li> <li>• Preceptor ensured student's safety (<i>n</i> = 5)</li> </ul>
Factors that made students feel unsafe
<ul style="list-style-type: none"> <li>• Testing was not provided to individuals who worked on units with COVID-19–positive cases unless an outbreak had been declared (<i>n</i> = 1)</li> <li>• Being asked to assess patients whose COVID-19 swab results were still pending (<i>n</i> = 1)</li> <li>• Surgical masks provided did not fit well (<i>n</i> = 1)</li> <li>• Space did not always allow for proper physical distancing (<i>n</i> = 1)</li> </ul>
<p><sup>a</sup>Factors were identified by students themselves and also by preceptors (describing factors that the preceptors perceived as making students feel safe or unsafe).</p>

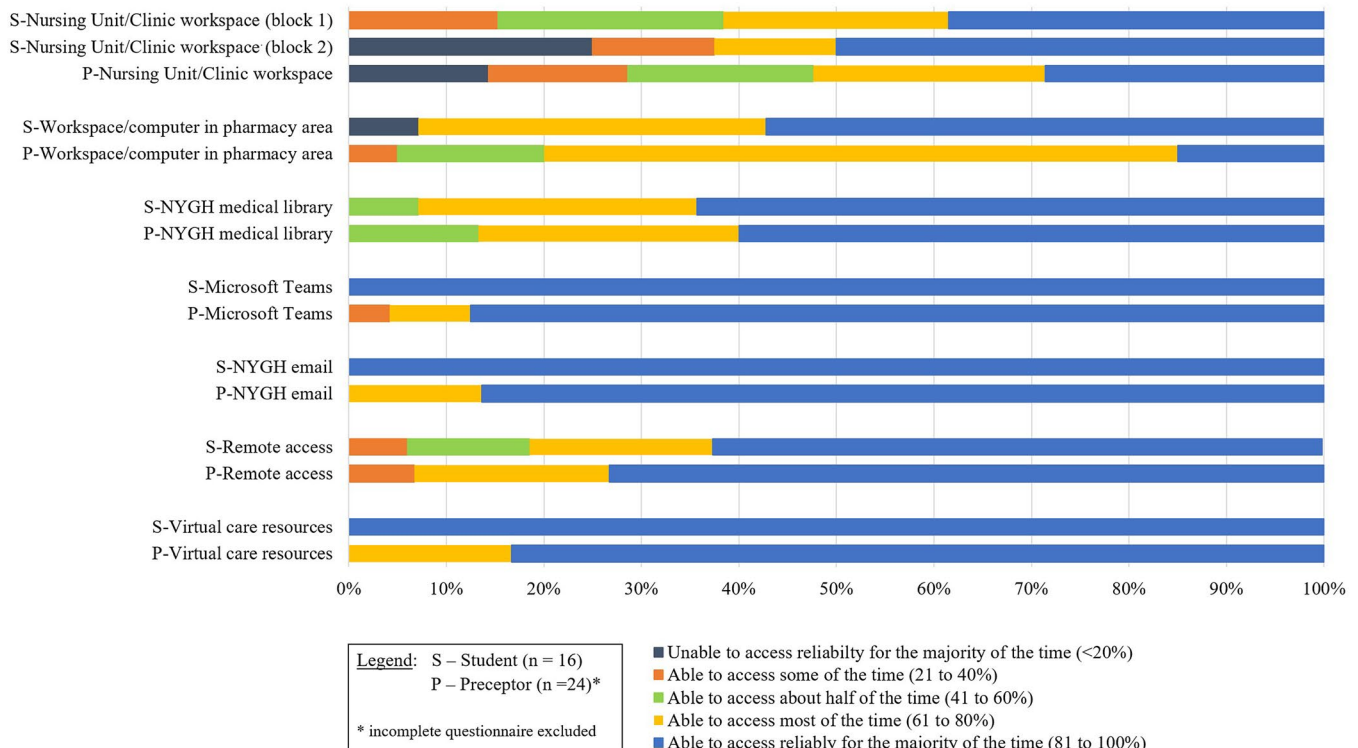
**Professional Development**

Compared with experiential rotations in previous academic years, 6 students believed there were fewer opportunities for professional development at NYGH during the pandemic, whereas 4 students expressed the opposite perception. Most students commented on having to learn to use virtual platforms to communicate, attend rounds, and participate in presentations. They were able to find workarounds when they encountered barriers (e.g., performing medication histories over the phone rather than in person, finding ways to accommodate language barriers). Working remotely was a new experience for some. These students learned to create a stringent work-from-home routine to ensure work–life balance. One student suggested that alternative activities be arranged so that they could continue to have learning opportunities outside their assigned clinical areas, when shadowing of other pharmacists was not feasible.

Among preceptor respondents, the top themes were recognition of students' development of virtual presentation skills and their provision of virtual care. Other themes mentioned were skills in working and learning remotely, which increased students' independence, and students' roles and responsibilities in infection control and prevention.

**Assessment and Evaluation**

Most students did not think that they were assessed or evaluated differently by their preceptors during the pandemic. Similarly, most students did not think there were any challenges



**FIGURE 2.** Perceptions of students and preceptors regarding accessibility of resources for students. NYGH = North York General Hospital.

**TABLE 3. Positive Feedback and Suggested Improvements Regarding Resources and Their Accessibility**

Resource	Positive Feedback	Suggested Improvement
Workspace/computer on nursing unit or clinic or in the pharmacy	<ul style="list-style-type: none"> <li>Some preceptors felt that there was adequate space for the students both on the nursing units and in the pharmacy</li> </ul>	<ul style="list-style-type: none"> <li>Provide students with mobile technology, such as tablet devices and mobile workstations</li> <li>Increase the amount of space (or provide dedicated space for students) and number of workstations</li> <li>Ensure computers at workstations work properly</li> </ul>
Microsoft Teams application	<ul style="list-style-type: none"> <li>Preceptors found it more convenient to communicate with students using Microsoft Teams, compared with traditional pagers, although screen time was increased</li> </ul>	<ul style="list-style-type: none"> <li>Ensure that Microsoft Teams can be accessed on all computer terminals and that it functions properly</li> </ul>
Remote access (to electronic health records, intranet, etc.)	NA	<ul style="list-style-type: none"> <li>Ensure there are no compatibility issues when students use their personal computers and that online resources are accessible from these devices</li> <li>Ensure that remote access functions properly and consistently</li> <li>Ensure that remote access has been set up and tested ahead of the rotation, to avoid delays in accessing resources</li> </ul>
North York General Hospital email system	NA	<ul style="list-style-type: none"> <li>Ensure that email time zone has been set correctly</li> </ul>
Telephones	<ul style="list-style-type: none"> <li>On-site shared telephones could be accessed most of the time; conferencing features worked well</li> </ul>	NA
Teaching room	<ul style="list-style-type: none"> <li>This was a useful, quiet space for virtual rounds, reviewing care plans, and therapeutic discussions</li> </ul>	NA

NA = not applicable.

in performing self-assessment during the pandemic. However, some respondents pointed out that patient interaction was evaluated on the basis of a smaller sample size because of restrictions in place during the pandemic. In addition, it was more difficult to find interprofessional team members to complete the interprofessional competency assessment, given that the interaction between students and these team members was reduced. Informal assessments were performed less often, with the focus on the midpoint and final evaluations. Some preceptors found it more challenging to evaluate their students because speaker phones were not always available and therefore they could not listen to the other side of students' telephone conversations (e.g., with patients or colleagues). Students were less frequently present on the unit to interact with patients, families, and other health care professionals, which resulted in fewer opportunities for assessments. Space limitations made it more challenging to find private areas for conducting evaluations and feedback.

## DISCUSSION

Most participants felt that the COVID-19 resources and supports provided by U of T and NYGH adequately prepared them for their rotations and made them feel safe. However, 1 participant commented that a discussion of workflow changes and expectations during orientation would have been helpful. Some preceptors were unaware of the COVID-19-specific resources that were available to students. Given the

ever-changing information and protocols, timely development, implementation, and dissemination of information was a challenge. Ideally, a central internet site for both NYGH and U of T, dedicated to COVID-19-related questions and resources, might have been beneficial, especially at the start of learner reintegration. However, during the latter part of the academic year, both the university and the hospital had developed separate learner-dedicated websites with COVID-19-related rotation information.

With respect to the challenges in communication, providing students with tips on how to communicate effectively while wearing PPE may help them to build better rapport with the individuals with whom they interact. With the increased use of telephones, it was soon realized that conferencing telephones were not readily accessible on the units. Consequently, a conferencing telephone was added in the pharmacy, which also enabled preceptors to assess interactions between students and families. The use of other technologies, such as tablets for videoconferencing, could also be considered. Using a platform such as Microsoft Teams helped with communications when staff were working off-unit, since this platform offered secure, real-time communication and videoconferencing.

Students and preceptors spent less time together in person, which led to missed opportunities for spontaneous teaching. Remote teaching and virtual care posed their own set of problems, such as a reduced variety of patients, problems with online access, and the need to develop online

**TABLE 4. Themes Related to Students' Interpersonal Interactions during the COVID-19 Pandemic**

Theme <sup>a</sup>	Group; No. of Participants Reporting the Theme	
	Students	Preceptors
<b>Students communicating with patients/families</b>		
Increased use of telephone/virtual opportunities	8	13
Fewer face-to-face interactions with patients	3	5
Less engagement with families because of visitor restrictions	3	3
No difference/minimal impact	0	5
Personal protective equipment and physical distancing made it more difficult to communicate	2	2
Difficulty with performing tasks or communicating without being face-to-face	3	0
Difficulties reaching patients/families	1	1
Exposure of students to different patient populations	0	2
Need for greater physical distancing from patient	1	0
Added risk of medication errors because of communication issues	1	0
<b>Students communicating with other health care professionals</b>		
Increased use of telephone/virtual opportunities	6	10
No difference/minimal impact	6	6
Fewer face-to-face interactions	3	10
Fewer opportunities to collaborate in person	4	6
Communication difficulties when using virtual communication tools	0	2
Dynamic situation, given the changes in coverage	0	1
<b>Students communicating with preceptors or other pharmacy personnel</b>		
No difference/minimal impact	9	9
Increased use of virtual communication tools	5	11
Less in-person time with preceptor /less time for preceptor to teach	4	3
Reduced interaction with other pharmacy personnel	1	2
<b>Students communicating with peers at the same site</b>		
No difference/minimal impact	6	10
Reduced interaction with peers	6	3
More interaction with peers	3	3

<sup>a</sup>Themes in each section are listed in descending order of frequency.

communication skills. Although team rounds took place virtually in many units, these did not universally include students. Ensuring that participants have access to meeting links or quick status updates for patients would have been beneficial. Workspace issues could have been alleviated by providing laptops to students, which would have allowed for more flexibility in where work could be done.

Assessments and evaluations were not overly affected. However, consideration should be given to modifying evaluation criteria to accommodate limitations, for example, prolonged absences (e.g., because of quarantine) or reduced interprofessional collaboration or patient interactions (e.g., use of role playing).

Despite the challenges, the pandemic did provide an opportunity for new and innovative experiential practices, such as leveraging the use of technology for secure remote access to electronic health records and provision of virtual care. These technologies enabled students to work from home, which helped foster learner independence. Other organizations have adopted similar strategies.<sup>9-12</sup> Some of the changes implemented in our setting will continue in

postpandemic rotations, such as permanently using Microsoft Teams to replace pagers as a communication tool. Working from home will also remain an option if a student is unable to come on site. The use of virtual platforms will likely remain as an option for assessing patients and providing clinical services in the future.

Overall, participants in our study thought that students had a positive learning experience at NYGH. For example, they developed several new skills that would not have been likely if not for the pandemic. With continued evolution of the pandemic and variability in each wave of infection, it would be useful to develop a “playbook” for future pandemics or disaster preparedness, incorporating lessons learned in this study.<sup>13,14</sup> As well, teaching hospitals and pharmacy schools could work in partnership to develop a collaborative curriculum that would include patient cases, specific topic discussions,<sup>15</sup> or alternative experiential opportunities such as simulation or virtual computer-based cases.<sup>11-13,16,17</sup> These approaches could also be useful when there is a significant staff shortage. Communication among learners, preceptors, the university, and the hospital could

be optimized by providing regular updates and actively seeking feedback from preceptors and learners to alleviate anxieties associated with constant changes.<sup>14</sup>

Our study had a few limitations. First, it was a single-site study limited to students from 1 teaching institution, which limits the generalizability of the results. Preparation of students to cope with COVID-19, as well as the resources available, might have differed from those at other sites or institutions. Second, NYGH is a technologically advanced organization, with availability of electronic health records and the ability to provide students with remote access to various resources. Although other facilities may not have similar technologies, some of the themes identified in this study could help to generate ideas for other sites to consider. Third, because the study was designed as an online, self-administered questionnaire, respondents could not be questioned further to elaborate on their responses, which limited the utility of some of the feedback received. Focus group sessions could have enabled the collection of more detailed information. Fourth, because of competing priorities during the pandemic, the researchers missed inviting 3 preceptors to participate in the study; this oversight might not have affected the results significantly, given that themes reached saturation. Fifth, given the perpetual changes occurring throughout the pandemic and the constant pivoting of practices and resources, some themes identified in this study may no longer be pertinent. Lastly, our study did not explore the emotional impacts of COVID-19 on students and preceptors or how they felt, which were found to be important lessons learned in other studies.<sup>9,18,19</sup>

## CONCLUSION

The pandemic introduced challenges in experiential rotations that have never been encountered before. The ongoing evolution in safety practices and availability of resources demanded adaptability and flexibility from both pharmacy learners and preceptors. Despite these problems, learners considered their overall learning experience to be well supported and safe. Although conventional learning activities might have been limited, innovative ways to meet the rotation objectives resulted in the development of new skills. For future pandemic planning, key points to consider are timely communication, provision of adequate pandemic-related resources to learners and preceptors, development of contingency plans in the event of staff shortages and outbreaks, and assessment and arrangement of alternate workspaces.

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**Monica Lee**, BScPhm, MSc, PharmD, RPh, is an Elder Care Pharmacy Practitioner with North York General Hospital and an Adjunct Lecturer with the Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario.

**Jenny Chiu**, BScPhm, PharmD, ACPR, RPh, is the Clinical Coordinator and an Acute Care Pharmacy Practitioner with North York General Hospital and an Adjunct Lecturer with the Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario.

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**Address correspondence to:**

Dr Monica Lee  
North York General Hospital  
4001 Leslie Street  
Toronto ON M2K 1E1

**email:** monica.lee@nygh.on.ca

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# Anticoagulation Interventions by Pharmacists in Acute Care

Taylor McVannel, Kirsten Tangedal, Aleina Haines, and William M Semchuk

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## ABSTRACT

**Background:** Clinical pharmacy key performance indicators (cpKPIs) relate to activities performed by pharmacists that have been shown to improve patient outcomes. Within Saskatchewan Health Authority (SHA) Regina, most cpKPIs are incorporated into the organization's clinical practice standards, which provide guidance in prioritizing care, especially for high-risk medications, including anticoagulants. To track pharmacists' interventions associated with clinical practice standards, a locally developed electronic data-capture system (known as AIM High) was implemented.

**Objectives:** To quantify and describe pharmacists' anticoagulation interventions on 16 wards with dedicated ward-based clinical pharmacists and to compare intervention rates between the cardiology and internal medicine wards to further evolve the organization's practice model.

**Methods:** Data from the electronic data-capture system were retrospectively analyzed for a 5-year period (January 2016 to December 2020).

**Results:** A total of 94 201 interventions were recorded in the AIM High system (average 362 interventions per week or 26 interventions per pharmacist per week). Of these, 15 661 (16.6%) cited the anticoagulation standard (average 60 anticoagulation interventions per week or 4 anticoagulant interventions per pharmacist per week). For the cardiology and internal medicine wards, 4183 of 11 888 (35.2%) and 9034 of 54 843 (16.5%) interventions cited the anticoagulation standard, respectively. The top 4 types of anticoagulation interventions were dose changed ( $n = 4372$  or 27.9%), drug started or restarted ( $n = 3867$  or 24.7%), patient education ( $n = 3094$  or 19.8%), and drug discontinued ( $n = 2944$  or 18.8%).

**Conclusion:** Dedicated ward-based clinical pharmacists were following clinical practice standards incorporating the majority of cpKPIs to complete anticoagulation interventions. The types of anticoagulation interventions evolved over time and were influenced by the patient population.

**Keywords:** anticoagulation, pharmacist interventions, clinical pharmacy, clinical pharmacy key performance indicators

## RÉSUMÉ

**Contexte :** Les indicateurs clés de performance en pharmacie clinique (ICPEPC) se rapportent à des activités exécutées par des pharmaciens qui ont fait leurs preuves dans l'amélioration des résultats pour les patients. À la Saskatchewan Health Authority (SHA) Regina, la plupart des ICPEPC sont intégrés aux normes de pratique clinique de l'organisme. Celles-ci fournissent des conseils pour hiérarchiser les soins liés aux médicaments, en particulier ceux associés aux médicaments à haut risque, notamment les anticoagulants. Un système électronique de saisie de données développé localement, le « AIM High », a été mis en place afin de suivre les interventions des pharmaciens associées aux normes de pratique clinique.

**Objectifs :** Quantifier et décrire les interventions des pharmaciens en matière d'anticoagulation dans 16 services avec des pharmaciens cliniciens dédiés et comparer les taux d'intervention entre les services de cardiologie et de médecine interne en vue de faire évoluer davantage le modèle de pratique de l'organisation.

**Méthodes :** Les données du système électronique de saisie des données ont été analysées rétrospectivement sur une période de 5 ans (de janvier 2016 à décembre 2020).

**Résultats :** Au total, 94 201 interventions ont été enregistrées dans le système (moyenne de 362 interventions par semaine ou 26 interventions par pharmacien par semaine). Parmi celles-ci, 15 661 (16,6 %) citent la norme d'anticoagulation (moyenne de 60 interventions d'anticoagulation par semaine – soit 4 interventions d'anticoagulation par pharmacien par semaine). Pour les services de cardiologie et de médecine interne, 4183 (35,2%) des 11 888 et 9034 (16,5 %) des 54 843 interventions citent respectivement la norme d'anticoagulation. Les 4 principaux types d'interventions d'anticoagulation étaient le changement de dose ( $n = 4372$  ou 27,9 %), le traitement commencé ou redémarré ( $n = 3867$  ou 24,7 %), l'éducation du patient ( $n = 3094$  ou 19,8 %) et l'arrêt du médicament ( $n = 2944$  ou 18,8 %).

**Conclusion :** Les pharmaciens cliniques dédiés au service suivaient les normes de pratique clinique incorporant la majorité des ICPEPC pour mener à bien les interventions d'anticoagulation. Les types d'interventions d'anticoagulation ont évolué au fil du temps et ont été influencés par la population de patients.

**Mots-clés :** anticoagulation, interventions du pharmacien, pharmacie clinique, indicateurs clés de performance de la pharmacie clinique



## INTRODUCTION

Hospital pharmacists strive to provide high-quality pharmaceutical care, and clinical pharmacy key performance indicators (cpKPIs) can be used to quantify the quality of care.<sup>1</sup> The cpKPIs are 8 activities that, when performed by pharmacists, have been demonstrated to improve patient outcomes by decreasing morbidity and hospital readmissions.<sup>2</sup> These activities include medication reconciliation, patient education, attendance at interprofessional rounds, and resolution of drug therapy problems.<sup>2</sup>

The cpKPIs can be used to guide pharmacists in prioritizing care activities, elevate professional accountability by informing patients and their care team about activities that pharmacists will reliably perform, and permit benchmarking within and between organizations.<sup>2</sup> Within Saskatchewan Health Authority (SHA) Regina, not all 8 cpKPIs are routinely captured, but the majority of cpKPIs have been operationalized into clinical practice standards that guide patient care expectations. The local practice model includes dedicated ward-based clinical pharmacists providing interdisciplinary care, with an average patient to pharmacist ratio of 30:1, and dispensary-based patient care, provided by centralized pharmacists working primarily in the main pharmacy department, with higher patient to pharmacist ratios. Clinical practice standards used by the dedicated ward-based clinical pharmacists target prevalent disease states requiring complex regimens and high-risk medications, including antimicrobials, heart failure medications, and anticoagulants.

Anticoagulants are deemed to be high-alert medications because of their risk of causing significant harm when used in error.<sup>3</sup> In 2016, harm from oral anticoagulants ranked as one of the highest-priority drug safety problems, and anticoagulants were shown to account for 14.9% of all emergency room visits for adverse drug events, more than any other class of medication.<sup>4,5</sup> Previous studies showed that the most common anticoagulation-related events included not starting drugs, inappropriate drug choice, and use of wrong strength,<sup>6</sup> and patients exposed to incorrect anticoagulation dosing had double the risk of bleeding.<sup>7</sup>

As pharmacists routinely focus on optimizing medication therapy, involvement of a pharmacist may improve anticoagulant-related outcomes. In 2014, pharmacists in Regina collaborated with physicians and allied health providers to develop the anticoagulation clinical practice standard for use in the Regina area, which outlines activities intended to improve the use of anticoagulants (Appendix 1, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>). SHA Regina continues to assess both the practice model and the various clinical practice standards as we strive to consistently improve the care provided by pharmacists.

In 2015, an electronic, stand-alone data-capture system (AIM High) was developed and implemented in SHA

Regina utilizing Google Forms, as a means to collect completed pharmacist interventions. Within this system, pharmacists self-report and manually input their interventions daily, including the specific intervention performed, the clinical practice standard followed, the time of day, the location, and whether documentation was completed in the patient's medical record (Appendix 2, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>). AIM High, the data-capture tool, has not been tested by a third party but has been modified on the basis of feedback from end-users, and version 2 is currently in use (AIM High [version 2])

The primary objective of this study was to quantify pharmacist interventions that followed the anticoagulation clinical practice standard for adult inpatients on all wards with dedicated ward-based clinical pharmacists. We further sought to determine if the frequency and types of anticoagulation interventions performed were similar or different in the subgroups of cardiology and internal medicine. The secondary objective was to describe the types of pharmacist anticoagulation interventions occurring on these wards.

## METHODS

A retrospective analysis of 5 years of data (January 2016 to December 2020) from the AIM High system was performed using Microsoft Excel (version 14.0); the timeframe was chosen to include all data since the inception of the AIM High system. The data were reported using a descriptive analysis of counts and proportions. Ethics approval and consent were not obtained because of the quality improvement nature of this project; also, the AIM High system reports only aggregated, de-identified information. The data analyzed described interventions completed for adult patients on 16 wards with dedicated clinical pharmacists (including 3 cardiology wards and 6 internal medicine wards; the remaining 7 wards were for critical care, general surgery, palliative care, and oncology populations) at the Regina General Hospital (a 437-bed tertiary care hospital) and the Pasqua Hospital (a 250-bed tertiary care hospital) during clinically staffed hours in Regina, Saskatchewan. Care on these wards is provided by 14 dedicated clinical pharmacists from Monday to Friday, 0730 to 1600. Outpatients, pediatric patients, and patients on wards receiving services from centralized, dispensary-based pharmacists were excluded.

## RESULTS

A total of 94 201 pharmacist interventions were recorded over 5 years, equivalent to an average of 362 interventions per week (or about 26 interventions per pharmacist per week). Interventions related to the anticoagulation clinical practice standard accounted for 16.6% ( $n = 15\ 661$ ) of these interventions, for an average of 60 interventions per week (or

about 4 interventions per pharmacist per week) (Table 1). The number of anticoagulation interventions remained largely consistent at about 3000 interventions per year over the period of analysis. With further categorization, anticoagulation interventions accounted for 35.2% ( $n = 4183$ ) of all interventions on the 3 cardiology wards and 16.5% ( $n = 9034$ ) of all interventions on the 6 internal medicine wards.

Pharmacists' anticoagulation interventions included changing the dose (27.9%;  $n = 4372$ ), starting or restarting a drug (24.7%;  $n = 3867$ ), providing patient education (19.8%,  $n = 3094$ ), and discontinuing a drug (18.8%,  $n = 2944$ ). On cardiology wards, pharmacists most commonly provided patient education (39.5% of anticoagulation interventions), whereas on internal medicine wards, pharmacists most commonly changed doses (30.3% of anticoagulation interventions). Figure 1 indicates a shift in interventions over time, with declines in the proportions of education and re-initiation interventions and an increase in the proportion

of interventions that involved discontinuing medications. Examination of the data specific to anticoagulation interventions on the cardiology and internal medicine wards showed that patient education interventions decreased both numerically and proportionally.

## DISCUSSION

Within SHA Regina, pharmacists performed anticoagulation interventions 15 661 times over 5 years, accounting for approximately 1 in 6 of all pharmacist interventions (average of 60 times per week or 4 interventions per pharmacist per week). The main types of interventions were resolving drug therapy problems and providing patient education, which also correlate with 2 of the 8 cpKPIs. Our aim was to use these pharmacist intervention data to describe current practice and then, as part of the evolution of our clinical practice model, to develop a quality improvement strategy in patient

**TABLE 1. Frequency of Interventions for Adult Inpatients, Performed by Pharmacists in Accordance with Clinical Practice Standards**

Intervention <sup>a</sup>	Year; No. (%) of Interventions					
	All Years	2016	2017	2018	2019	2020
Wards with dedicated ward-based clinical pharmacists ( $n = 16$ )						
All interventions	94 201	15 742	15 074	16 995	22 847	23 543
Drug discontinued	26 763 (28.4)	4 820 (30.6)	4 401 (29.2)	4 752 (28.0)	6 333 (27.7)	6 457 (27.4)
Drug started/restarted	26 019 (27.6)	4 045 (25.7)	4 274 (28.4)	4 999 (29.4)	6 242 (27.3)	6 459 (27.4)
Dose changed (including interval)	20 103 (21.3)	3 064 (19.5)	2 922 (19.4)	3 505 (20.6)	5 433 (23.8)	5 179 (22.0)
Patient education	7 110 (7.5)	1 467 (9.3)	1 315 (8.7)	1 279 (7.5)	1 521 (6.7)	1 528 (6.5)
Anticoagulation interventions	15 661 (16.6) <sup>b</sup>	3 240 (20.6) <sup>b</sup>	3 159 (21.0) <sup>b</sup>	2 890 (17.0) <sup>b</sup>	3 265 (14.3) <sup>b</sup>	3 107 (13.2) <sup>b</sup>
Drug discontinued	2 944 (18.8)	567 (17.5)	576 (18.2)	551 (19.1)	633 (19.4)	617 (19.9)
Drug started/restarted	3 867 (24.7)	827 (25.5)	829 (26.2)	763 (26.4)	746 (22.8)	702 (22.6)
Dose changed (including interval)	4 372 (27.9)	823 (25.4)	795 (25.2)	836 (28.9)	1 034 (31.7)	884 (28.5)
Patient education	3 094 (19.8)	759 (23.4)	717 (22.7)	520 (18.0)	565 (17.3)	533 (17.2)
Cardiology wards ( $n = 3$ )						
All interventions	11 888	2 531	2 217	2 090	2 397	2 653
Anticoagulation interventions	4 183 (35.2) <sup>c</sup>	1 060 (41.9) <sup>c</sup>	950 (42.9) <sup>c</sup>	758 (36.3) <sup>c</sup>	724 (30.2) <sup>c</sup>	691 (26.0) <sup>c</sup>
Drug discontinued	689 (16.5)	172 (16.2)	165 (17.4)	138 (18.2)	130 (18.0)	84 (12.2)
Drug started/restarted	802 (19.2)	201 (19.0)	163 (17.2)	161 (21.2)	125 (17.3)	152 (22.0)
Dose changed (including interval)	742 (17.7)	152 (14.3)	154 (16.2)	132 (17.4)	166 (22.9)	138 (20.0)
Patient education	1 652 (39.5)	468 (44.2)	404 (42.5)	291 (38.4)	244 (33.7)	245 (35.5)
Internal medicine wards ( $n = 6$ )						
All interventions	54 843	6 653	7 612	10 369	15 059	15 150
Anticoagulation interventions	9 034 (16.5) <sup>d</sup>	1 693 (25.4) <sup>d</sup>	1 783 (23.4) <sup>d</sup>	1 593 (15.4) <sup>d</sup>	2 008 (13.3) <sup>d</sup>	1 957 (12.9) <sup>d</sup>
Drug discontinued	1 924 (21.3)	319 (18.8)	343 (19.2)	356 (22.3)	428 (21.3)	478 (24.4)
Drug started/restarted	2 310 (25.6)	447 (26.4)	532 (29.8)	430 (27.0)	469 (23.4)	432 (22.1)
Dose changed (including interval)	2 736 (30.3)	513 (30.3)	497 (27.9)	487 (30.6)	662 (33.0)	577 (29.5)
Patient education	1 283 (14.2)	260 (15.4)	274 (15.4)	205 (12.9)	275 (13.7)	269 (13.7)

<sup>a</sup>Subentries in this column represent only the 4 most common types of pharmacist interventions, not an inclusive list of all pharmacist interventions completed.

<sup>b</sup>Percentages for anticoagulation interventions are relative to all interventions on wards with dedicated ward-based clinical pharmacists

<sup>c</sup>Percentages for anticoagulation interventions are relative to all interventions on cardiology wards.

<sup>d</sup>Percentages for anticoagulation interventions are relative to all interventions on internal medicine wards.

care by ensuring that pharmacists focus on cpKPI-related activities. National registry data for cpKPIs are being collected in hospitals across Canada, but to date, few of these data (if any) have been published, and a Canadian benchmark has not been established.<sup>8</sup> Similarly, existing studies have measured different activities completed by pharmacists, and we found no consensus on productivity measures for pharmacists in the literature.

The number of anticoagulation interventions on wards with dedicated ward-based clinical pharmacists remained consistent over time in our practice setting; however, the proportion of anticoagulation interventions relative to total interventions is decreasing, which suggests an evolution toward a broader range of clinical pharmacist interventions in SHA Regina. One possible explanation for the proportional decline in anticoagulation interventions is that prescribers may be adapting their prescribing habits after collaborating with pharmacists to rectify incorrect anticoagulation orders. In such a situation, a pharmacist may interact with a prescriber only once, but the impact of that interaction on patient care may be repeated multiple times and thus is difficult to quantify.<sup>9</sup> Another possible explanation is the continued growth of prescribing supports such as standardized order sets.<sup>10</sup>

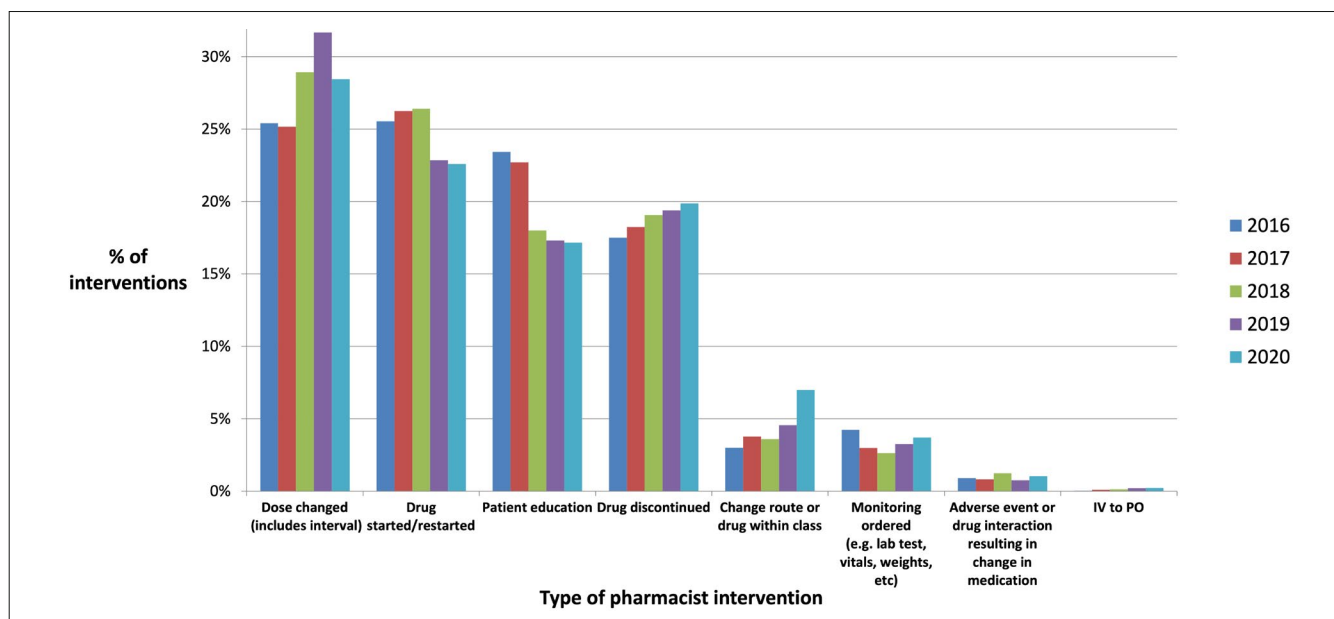
Pharmacists on cardiology wards completed a higher proportion of anticoagulation interventions than those on internal medicine wards, which highlights heterogeneity in patients' demographic characteristics and diagnoses, as well as variation in use of the anticoagulation clinical practice standard. For example, patients on cardiology wards frequently have more indications for treatment doses of anticoagulants, as well as indications for antiplatelet agents, than

patients on internal medicine wards, who may receive prophylactic doses of anticoagulants to prevent venous thromboembolism. Thus, pharmacists practising in different specialities have different opportunities for interventions.

In 2018, additional funding was obtained to improve patient to pharmacist ratios for clinically staffed hours through development of an "Accountable Care Unit" philosophy, which was instituted on 3 internal medicine wards (change in patient to pharmacist ratio from 30:1 to about 17:1). As a result, pharmacist interventions increased overall, and clinical services expanded beyond the high-priority clinical practice standards such as anticoagulation. Extrapolating the findings from this experience, we anticipate that improving patient to pharmacist ratios across all wards with dedicated ward-based clinical pharmacists could increase medication optimization and improve quality of care.

In terms of the types of anticoagulation interventions performed by pharmacists, the proportions of interventions related to patient education and restarting medications are declining while the proportion related to discontinuing medications is increasing. This may be explained by departmental prioritization of optimizing medications before discharge and relying on our well-positioned community pharmacy colleagues to provide education once patients' medication therapy has been optimized.<sup>11,12</sup>

The Canadian Cardiovascular Society Atrial Fibrillation Guidelines 2010 recommended a transition in practice from warfarin to direct oral anticoagulants (DOACs) as preferred first-line therapy,<sup>13</sup> which may have affected pharmacists' anticoagulant interventions during the study period. However, given that the AIM High system was



**FIGURE 1.** Types of interventions (and their frequency) performed by dedicated ward-based clinical pharmacists, according to the anticoagulation clinical practice standard.

implemented in 2015 and DOACs have been the standard of care in Regina (according to the anticoagulant clinical practice standard) since 2014, the effect of the 2010 guidelines on local data is thought to be minimal. Also, no collaborative prescribing agreement existed for pharmacists to independently manage inpatients' warfarin therapy in Regina. Therefore, pharmacists likely intervened similarly on both warfarin and DOAC therapy.

This study provides a unique description of pharmacist interventions with respect to anticoagulation and is strengthened by the collection and presentation of several years of cumulative data. Limitations include dependence on pharmacists self-reporting interventions into the AIM High system and the variability in reporting among the pharmacists, which may have led to misrepresentation of the actual numbers and types of interventions. The AIM High system quantifies only the number of interventions accepted, not the number recommended. The COVID-19 pandemic that began in 2020 may have had a multifaceted impact, with pharmacists having only limited contact with isolated patients and workload increasing because of higher patient loads and changing demographic characteristics.

## CONCLUSION

Over the study period, dedicated ward-based clinical pharmacists were following clinical practice standards that incorporate the majority of cpKPIs to complete anticoagulation interventions. The types of anticoagulation interventions evolved over time and were influenced by patient population.

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**Taylor McVannel**, BScPharm, ACPR, was, at the time of this study, a Pharmacy Resident with the Department of Pharmacy Services, Saskatchewan Health Authority, Regina, Saskatchewan. She is now with the Department of Pharmacy Services, Brandon Regional Health Centre – Prairie Mountain Health, Brandon, Manitoba.

**Kirsten Tangedal**, BSP, ACPR, is with the Department of Pharmacy Services, Saskatchewan Health Authority, Regina, Saskatchewan.

**Aleina Haines**, BSP, ACPR, is with the Department of Pharmacy Services, Saskatchewan Health Authority, Regina, Saskatchewan.

**William M Semchuk**, BSP, MSc, ACPR, PharmD, FCSHP, is with the Department of Pharmacy Services, Saskatchewan Health Authority, Regina, Saskatchewan.

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**Address correspondence to:**

Taylor McVannel  
Brandon Regional Health Centre – Prairie Mountain Health  
150 McTavish Avenue E  
Brandon MB R7A 2B3

**email:** [Tmcvannel@pmh-mb.ca](mailto:Tmcvannel@pmh-mb.ca)

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# Critical Appraisal Tools to Aid Pharmacists in Evidence-Based Practice: A Narrative Review

Ariane Blanc, Vivian Ho, and Jameason Cameron

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## ABSTRACT

**Background:** Pharmacists and allied health researchers need to ensure that their practice is supported by current, evidence-based information. Critical appraisal tools have been developed to aid in this process.

**Objectives:** To analyze the current landscape of critical appraisal tools and to create an aid for pharmacists and other allied health researchers to use in comparing various tools and choosing the best one for each particular study design.

**Data Sources:** A literature search of the PubMed, University of Toronto Libraries, and Cochrane Library databases was conducted in December 2021, to generate an up-to-date list of critical appraisal tools. The tools were then summarized in a descriptive table.

**Study Selection and Data Extraction:** Review articles, original manuscripts, and tool webpages were examined to develop a comparison chart based on the user-friendliness, efficiency, comprehensiveness, and reliability of each tool.

**Results:** Fourteen tools were found through the literature search. These tools were compared using the findings of included review articles, and a comparison chart was created to aid pharmacists and allied health researchers in selecting the appropriate tool for their practice.

**Conclusions:** There are many standardized critical appraisal tools that can help in assessing the quality of evidence, and the summary list of tools developed and reported here can help health care researchers to compare among them and choose the best one. No tools were found that have been specifically adapted to serve the needs of pharmacists when assessing scientific articles. Future research should examine how existing critical appraisal tools can better identify common data elements that are essential to evidence-based decision-making in pharmacy practice.

**Keywords:** critical appraisal tools, risk-of-bias 2 (RoB 2) tool, pharmacist, evidence-based practice, validity

## RÉSUMÉ

**Contexte :** Les pharmaciens et les chercheurs en soins de la santé doivent faire en sorte que leur pratique soit étayée par des informations actualisées et fondées sur des données probantes. Des outils d'évaluation critique ont été développés pour faciliter ce processus.

**Objectifs :** Analyser le paysage actuel des outils d'évaluation critique et créer une aide que les pharmaciens et les autres chercheurs paramédicaux peuvent utiliser pour comparer divers outils et choisir le meilleur pour chaque conception d'étude particulière.

**Sources des données :** Une recherche documentaire dans trois bases de données (PubMed, les University of Toronto Libraries et la Cochrane Library) a été menée en décembre 2021 afin de générer une liste actualisée d'outils d'évaluation critique qui ont ensuite été résumés dans un tableau descriptif.

**Sélection des études et extraction des données :** Des articles de synthèse, des manuscrits originaux et des pages Internet d'outils ont été examinés pour dresser un tableau comparatif basé sur la convivialité, l'efficacité, l'exhaustivité et la fiabilité de chaque outil.

**Résultats :** Quatorze outils ont été trouvés grâce à la recherche documentaire. Ils ont été comparés à l'aide des résultats des articles de synthèse inclus, et un tableau comparatif a été créé pour aider les pharmaciens et les chercheurs en soins de la santé à sélectionner l'outil approprié pour leur pratique.

**Conclusions :** De nombreux outils d'évaluation critique normalisés peuvent aider à évaluer la qualité des données probantes, et la liste récapitulative des outils développés et rapportés ici peut aider les chercheurs en soins de santé à les comparer et à choisir le meilleur. Aucun outil spécifiquement adapté pour répondre aux besoins des pharmaciens lors de l'évaluation d'articles scientifiques n'a été trouvé. Les recherches futures devraient se pencher sur la manière dont les outils d'évaluation critique existants peuvent mieux identifier les éléments de données communs qui sont essentiels à la prise de décision fondée sur des données probantes dans la pratique de la pharmacie.

**Mots-clés :** outils d'évaluation critique, outil Risque de biais 2 (RoB 2), pharmacien, pratique fondée sur des données probantes, validité

## INTRODUCTION

Pharmacists regularly use their knowledge and skills to provide patient care, to support decision-making by the health care team, and to conduct research. These activities must be supported by current, evidence-based information, and

pharmacists must develop their critical appraisal skills and become experts at synthesizing and interpreting relevant information. National campaigns like Choosing Wisely Canada,<sup>1</sup> which aim to reduce unnecessary tests and treatments, encourage clinicians to follow recommendations

that have been developed following review of scientific evidence to make informed choices with their patients. Similarly, the National Association of Pharmacy Regulatory Authorities (NAPRA)<sup>2</sup> lists expertise in medications and medication use as a requirement for licensed pharmacists practising in Canada. As part of modelling this standard, NAPRA highlights the importance of evidence-based medicine and critical appraisal of the source of information when providing care to patient.<sup>2</sup> Critical appraisal is not only a skill important to pharmacy practice, but also part of pharmacy practice standards in Canada.

Critical appraisal is a systematic process that is used to identify credible and relevant evidence to support clinical practice and policy.<sup>3</sup> When pharmacists and health care workers read a scientific article, they apply their critical appraisal skills to determine whether the article supports or changes their recommendations and practice. They may look at evidence from randomized controlled trials (RCTs) to understand the efficacy, safety, and appropriateness of new or innovative drugs, disease treatments, and pharmacy interventions.<sup>4</sup> Observational studies can be read for evidence of an association of drug exposure or pharmaceutical interventions with unintended effects or other outcomes of interest.<sup>4,5</sup> Systematic reviews attempt to uncover “all” of the evidence relevant to a specific question, focusing on research that reports data rather than concepts or theory.<sup>6</sup> Systematic reviews are rich resources to gain rapid insight into specific health-related questions in a single document, and they are the pinnacle of evidence synthesis used to create and update guidelines for clinical pharmacists.<sup>7</sup>

Critical appraisal involves interpreting information in a systematic and objective manner. Critical appraisal tools for all types of research methodologies (e.g., case-control studies, observational studies, RCTs) have been developed for quality appraisal of the literature in a formal and systematic process, each with study-specific applicability.<sup>3</sup> As described by Twells,<sup>8</sup> the traditional critical appraisal process for scientific articles involves 3 main questions: Are the results of the study valid (internal validity)? What are the results? Are the results applicable or generalizable to my patient population? In terms of the specific lens of pharmacy practice, in addition to these 3 questions, the pharmacist is also concerned with questions for evaluating appropriate drug use in practice, such as the following: What are the study limitations, and will they affect my recommendation in this situation? Will I make this recommendation (i.e., do the benefits outweigh the risks)? Will this study change my practice? With so much research available, pharmacists and allied health workers need to use the appropriate critical appraisal tools to select the highest-quality evidence and to determine if the quality of the research is applicable to their objectives and practice.

Although other health care professionals, such as nurses, have produced guidance on the use of critical appraisal tools,<sup>9</sup> to our knowledge there are no similar

guidance documents comparing current critical appraisal tools that are specifically directed at pharmacists. Therefore, the goal of this narrative review is to analyze the current landscape of critical appraisal tools and to create an aid for pharmacists and other allied health researchers to use in comparing various tools and choosing the best one for a particular study design.

## METHODS

A literature search was conducted in December 2021 using the PubMed, University of Toronto Libraries, and Cochrane Library databases. The databases were searched for articles compiling and/or reviewing critical appraisal tools. The keywords used in the search were “critical appraisal”, “tools”, “risk of bias”, and “validated”, and the results were restricted to articles published between 2011 and 2021. Relevant articles and their reference lists were examined to obtain a preliminary list of potential critical appraisal tools. Tools that were described for use in critical appraisal, assessments of quality or methodology, and analysis of risk of bias were included. Tools described primarily as reporting guidelines, guides developed with the goal of helping authors know what to include in research reports, and tools described as classifying recommendations or assessing only animal studies were excluded from the preliminary list. The same databases were searched with the additional keywords “pharmacy” and/or “pharmacist” to determine if there were any critical appraisal tool recommendations specific to pharmacy. This initial search process yielded a final list of appraisal tools and where to access them (see Appendix 1, available from <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>), at which point the literature was reviewed to determine whether the tools had been validated and compared, and to gauge the frequency of their use in literature reviews.

For each identified tool, the original tool-development manuscript or webpage was reviewed for information. PubMed was also searched with a combination of keywords, including the name of the tool, “critical appraisal”, “reliability”, and “validation or validated”. No publication date filters were applied for this stage of searching, because some of the critical appraisal tools that we identified were developed before 2011.

The final list of appraisal tools was additionally formatted as a comparison chart that could serve as a convenient visual selection aid for pharmacists and allied health researchers. The comparison categories—user-friendliness, efficiency, comprehensiveness, and reliability—were determined through discussion among the authors, and the rating system, from 1 star (lowest rating) to 5 stars (highest rating), was established on the basis of information from the literature search results and an analysis of how the critical appraisal tools compared with each other.

More specifically, user-friendliness was compared to indicate how easy it would be to understand and use the tool without additional training. Tools that reviewers described as requiring extra training, being more complex, and/or being more appropriate for experienced methodologists were given lower ratings. Efficiency was compared to indicate how much time would be required to complete the assessment. Tools with fewer items to complete and those described with words like “convenient” were given higher ratings, whereas tools with many items to complete and those described by reviewers as being “more demanding” or requiring more time than other tools were given lower ratings. Efficiency ratings were also influenced by findings from articles comparing tools, if available. Comprehensiveness was compared to indicate how “complete” the tool was in terms of fulfilling the requirements for the critical appraisal process for scientific articles.

If a tool could be used to assess the 3 main components—internal validity, results, and relevance—and additionally included questions similar to what pharmacists would ask when appraising scientific articles, it was given a rating of 5 stars. Tools allowing assessment of only internal validity were given a rating of 1 star, since all tools included in the review assessed internal validity.

For the last category, reliability, tools with inter-rater reliability testing or other forms of validation were given higher ratings. Tools with criticisms of reliability or limited testing were given lower scores. Tools with unclear results on reliability testing or no reliability testing were given a rating of 1 star.

## RESULTS

From the literature search, 5 review articles on critical appraisal tools were identified and examined<sup>3,8-11</sup> (for the PRISMA diagram, see Appendix 2, available from <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>). One of the 5 articles was written as a resource for registered nurses,<sup>9</sup> whereas the other 4 articles were general reviews of the available critical appraisal tools. None of the 5 articles provided recommendations specific to pharmacy, and no pharmacy-specific reviews came up during the database searches. Certain universities, including the University of Waterloo,<sup>12</sup> provided links to some critical appraisal resources for pharmacy students. Bashir and Dziemidowicz<sup>13</sup> also published an online article discussing the theory of critical appraisal to assist pharmacists in evaluating research, providing links to selected user-friendly critical appraisal tools. In addition, the Canadian Society of Hospital Pharmacists provides a list of critical appraisal resources, but it was last updated in 2011,<sup>14</sup> and new tools have been developed since then.

From the 5 review articles and the online article by Bashir and Dziemidowicz,<sup>13</sup> a preliminary list of 21 critical appraisal tools was obtained. The National Institutes of

Health (US) Study Quality Assessment Tool was excluded because the developer did not consider it to be standardized.<sup>15</sup> Three tools—the revised Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2), for diagnostic studies; the Evidence-Based Practice Process Quality Assessment (EPQA), for evidence-based projects that guide nursing practice; and the Physiotherapy Evidence Database (PEDro) scale, for physiotherapy intervention studies—were excluded because they have limited applicability to pharmacy practice. Three additional tools—the Jadad Scale and the Delphi List for RCTs and the Reisch Tool for non-randomized intervention studies—were excluded because they are no longer commonly used or recommended,<sup>11</sup> likely because of development of newer tools for their respective study designs. The Reisch Tool was also criticized as being too complex and specific for general use.<sup>10</sup> Finally the JAMA user guide was excluded because another, more recent set of tools, the CASP checklists, was developed using its recommendations. The remaining 14 critical appraisal tools and their strengths and limitations are summarized in Table 1 (where each tool abbreviation is also defined), and the selected tools are compared by category in Table 2.

## DISCUSSION

In this narrative review, we have summarized the current landscape of critical appraisal tools that can be used to assess scientific articles, with a specific focus on the unique needs of pharmacists. This review can serve as an aid for pharmacists and other health care practitioners, helping them to quickly choose an optimal critical appraisal tool for the study design in question. Of the 14 tools listed in Table 1, all contain components that assess internal validity, answering the question “Are the results of the study valid?” Furthermore, 5 of the 14 tools include other components of the critical appraisal process for scientific articles (i.e., answering the questions “What are the results?” and/or “Are the results applicable or generalizable to my patient population?”). None of the tools analyzed in this narrative review included questions specific to pharmacy per se, although the CASP checklists came the closest, including components that assess internal validity, results, risks and benefits, and relevance. The 14 tools may still be incorporated into the critical appraisal process that pharmacists and allied health researchers apply for scientific articles, given that they do provide value for learning to identify and select high-quality scientific articles to support evidence-based practice.<sup>11</sup>

We have also created an up-to-date comparison chart (Table 2) that will serve as a guide to pharmacists and allied health researchers in selecting the appropriate critical appraisal tool, while acknowledging that these tools do not answer all questions in the critical appraisal process for scientific articles used by these practitioners. More

**TABLE 1 (Part 1 of 3). Summary of Critical Appraisal Tools Useful for Pharmacists**

Critical Appraisal Tool	Applicability / Study Design	Description	Components Assessed	Strengths	Limitations	Notes
RoB (Cochrane Risk of Bias tool) <sup>16 a</sup>	RCTs	<ul style="list-style-type: none"> <li>• Tool to assess risk of bias within 6 bias domains</li> <li>• For each item, the assessor provides a risk-of-bias rating (high, low, or unclear risk) and supporting evidence from the article</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity only</li> <li>• Risk-of-bias assessment</li> <li>• Summary table + overall risk of bias</li> </ul>	<ul style="list-style-type: none"> <li>• Assesses important threats to internal validity and is practical to use</li> <li>• Results can be presented in a 2- or 3-column table, useful for journal club presentation</li> <li>• Has been widely accepted and recommended</li> <li>• About 8.8 minutes per assessment, according to Cochrane Collaboration<sup>16</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Requires judgment from the assessor to summarize overall risk of bias</li> <li>• Bias domains (i.e., incomplete outcome data and selective reporting of outcomes) may be confusing or difficult to assess; training may be required<sup>16</sup></li> <li>• More likely to rate studies as high risk if unblinded</li> </ul>	<ul style="list-style-type: none"> <li>• Commonly recommended for RCTs<sup>11</sup> and was standard for Cochrane reviews (now replaced by RoB 2)</li> <li>• Domains developed using empirical evidence and theoretical considerations, and the tool has been evaluated</li> </ul>
RoB 2 (Cochrane Risk of Bias tool 2) <sup>17 a</sup>	RCTs	<ul style="list-style-type: none"> <li>• Tool to assess risk of bias within 5 domains (22 signalling questions, including conditional questions)</li> <li>• For each domain, the assessor answers signalling questions (total of 22, including conditional) that lead to a risk-of-bias rating (low, high, or some concerns)</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity only</li> <li>• Risk-of-bias assessment</li> <li>• Overall risk of bias</li> </ul>	<ul style="list-style-type: none"> <li>• Understandable labelling of domains (using descriptions) and bias judgments (“some concerns” instead of “unclear risk”)</li> <li>• Signalling questions elicit information required for assessment</li> <li>• Available as Excel spreadsheet file (Microsoft), with macros for automation</li> </ul>	<ul style="list-style-type: none"> <li>• More complex and demanding (about 28 minutes per assessment), even for experienced reviewers<sup>30</sup></li> <li>• Organization of response options may be confusing/less intuitive (Yes/Probably; Yes = lower risk for some questions but higher risk for others)</li> <li>• Sufficient training required for reliable results</li> </ul>	<ul style="list-style-type: none"> <li>• Revised Cochrane RoB tool based on literature, feedback, and recent developments in understanding of bias</li> <li>• Recommended by Cochrane Collaboration for RCT reviews</li> </ul>
NOS (Newcastle-Ottawa Scale) <sup>18</sup>	Nonrandomized studies (cohort studies, case-control studies)	<ul style="list-style-type: none"> <li>• Tool to assess quality of studies using a “star rating system” to judge quality of selection, comparability, and outcome/exposure</li> <li>• 8 items in each scale</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity only</li> <li>• Study components</li> <li>• Star-based scoring of components</li> </ul>	<ul style="list-style-type: none"> <li>• User-friendly and convenient to use</li> <li>• Star system provides a quick visual reference of study quality</li> <li>• Established validity and inter-rater reliability, available as just the scale or as a version with short explanations</li> </ul>	<ul style="list-style-type: none"> <li>• Not as comprehensive as other scales</li> <li>• Not intended to generate an overall appraisal score, only individual star ratings for each component</li> </ul>	<ul style="list-style-type: none"> <li>• More widely used in assessments of observational studies than for other types of studies<sup>31</sup></li> </ul>
ROBINS-I (Risk Of Bias In Non-randomised Studies – of Interventions) <sup>19 a</sup>	Nonrandomized studies of interventions	<ul style="list-style-type: none"> <li>• Tool to assess risk of bias</li> <li>• Risk of bias assessed within 7 domains using signalling questions (total of 34, including conditional)</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity and results</li> <li>• Review question + study summary</li> <li>• Preliminary consideration of confounders and co-interventions</li> <li>• Risk-of-bias assessment (confounding, selection, classification, deviations, missing data, measurement of outcomes, reporting, overall)</li> <li>• Can use “study summary” with “review question” to determine relevance, separate from tool</li> </ul>	<ul style="list-style-type: none"> <li>• Structured and comprehensive assessment process</li> <li>• Signalling questions elicit information required for assessment</li> <li>• Clear approach for summarizing overall risk of bias</li> <li>• Reliability similar to that of NOS<sup>31</sup></li> <li>• Refined through expert review, piloting, and user feedback</li> </ul>	<ul style="list-style-type: none"> <li>• Complex and demanding appraisal process, requires methodological expertise</li> <li>• “Too comprehensive to provide a concise critical appraisal”<sup>31</sup></li> <li>• Took reviewers 3 hours versus 30 minutes for NOS<sup>31</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Designed primarily for use in developing systematic reviews</li> <li>• Based on popular Cochrane RoB tool and builds on signalling questions used in QUADAS-2<sup>19</sup></li> </ul>



**TABLE 1 (Part 2 of 3). Summary of Critical Appraisal Tools Useful for Pharmacists**

Critical Appraisal Tool	Applicability / Study Design	Description	Components Assessed	Strengths	Limitations	Notes
MINORS (Methodological Index for Non-randomized Studies) <sup>20</sup>	Nonrandomized studies of interventions	<ul style="list-style-type: none"> <li>• Tool for assessing methodological quality</li> <li>• Contains 12 items scored from 0 to 2</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity only</li> <li>• Study components</li> <li>• Scoring of components</li> </ul>	<ul style="list-style-type: none"> <li>• Simple scoring system, user-friendly and convenient to use for readers and researchers</li> <li>• Total score thresholds for overall quality scores</li> </ul>	<ul style="list-style-type: none"> <li>• Only tested by 2 reviewers (junior surgeon and senior surgeon)</li> </ul>	<ul style="list-style-type: none"> <li>• Originally developed for assessing surgical studies, with goal of expanding applicability</li> </ul>
AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews) <sup>21</sup>	Systematic reviews (randomized studies, nonrandomized studies, or both)	<ul style="list-style-type: none"> <li>• Tool for assessing methodological quality (based on 16 items) in a checklist format</li> <li>• Questions framed so that Yes = positive result, No = negative result</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity only</li> <li>• Study components in checklist format</li> </ul>	<ul style="list-style-type: none"> <li>• Uses simple response categories that are convenient, quick, and easy to use; user only needs to understand study design</li> <li>• Designed for health professionals and policy-makers</li> <li>• Intended for reviews of health care interventions<sup>21</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Not intended to generate an overall appraisal score<sup>21</sup></li> <li>• Limited binary response options</li> </ul>	<ul style="list-style-type: none"> <li>• Revision of widely used AMSTAR tool based on critiques and feedback</li> </ul>
ROBIS (Risk of Bias in Systematic Reviews) <sup>22, a</sup>	Systematic reviews	<ul style="list-style-type: none"> <li>• Tool for assessing risk of bias</li> <li>• Use of signalling questions to help judge concerns and risk of bias</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity, relevance</li> <li>• Assessing relevance (optional)</li> <li>• Identifying concerns with review process</li> <li>• Judging risk of bias</li> <li>• Overall risk of bias</li> </ul>	<ul style="list-style-type: none"> <li>• In-depth tool to assess risk of bias</li> <li>• Designed to evaluate reviews applicable to health care settings</li> <li>• Rigorously developed, with reliability similar to that of AMSTAR<sup>22</sup></li> </ul>	<ul style="list-style-type: none"> <li>• More complex and requires more consideration to complete<sup>22</sup></li> <li>• Developers designed the tool for use by experienced reviewers/methodologists</li> </ul>	
AGREE II (Appraisal of Guidelines for Research & Evaluation Instrument 2) <sup>23</sup>	Clinical practice guidelines	<ul style="list-style-type: none"> <li>• Framework to assess quality of guidelines; also provides strategy for guideline development</li> <li>• 6 domains (23 items), followed by 2 global rating items rated on a 7-point scale</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity only</li> <li>• Scope and purpose of guideline</li> <li>• Stakeholder involvement</li> <li>• Rigour of development</li> <li>• Clarity of presentation</li> <li>• Applicability</li> <li>• Editorial independence</li> <li>• Overall assessment</li> </ul>	<ul style="list-style-type: none"> <li>• Intended for health care providers, guideline developers, policy-makers, and educators</li> <li>• User manual contains definitions, examples, and tips to help standardize use of the tool</li> </ul>	<ul style="list-style-type: none"> <li>• Recommended that multiple reviewers use the tool to improve reliability</li> <li>• Tool provides only overall scores for each domain, not an overall score</li> </ul>	<ul style="list-style-type: none"> <li>• Refined version of the original AGREE tool</li> </ul>
GRACE (Good Research for Comparative Effectiveness checklist) <sup>24</sup>	Comparative effectiveness research	<ul style="list-style-type: none"> <li>• 11-item checklist about the key attributes of high-quality noninterventonal comparative effectiveness studies</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity only</li> <li>• Study components</li> <li>• Scoring of components</li> </ul>	<ul style="list-style-type: none"> <li>• Tested on articles comparing treatment effectiveness and/or safety of drugs, medical devices, and medical procedures<sup>24</sup></li> </ul>	<ul style="list-style-type: none"> <li>• No scoring system</li> <li>• Use limited to noninterventonal studies that assess comparative effectiveness</li> <li>• No inter-rater reliability study</li> </ul>	<ul style="list-style-type: none"> <li>• Rigorously developed, with validation testing by multiple reviewers</li> </ul>
CASP checklists (Critical Appraisal Programme) <sup>25</sup>	RCTs, cohort studies, case-control studies, qualitative studies, systematic reviews	<ul style="list-style-type: none"> <li>• Checklists to be used when reading and assessing research</li> <li>• Three sections: Are the results of the study valid? What are the results? Will the results help locally?</li> </ul>	<ul style="list-style-type: none"> <li>• Internal validity, results (including risk versus benefit), relevance</li> <li>• Validity of study design</li> <li>• Results (reporting, precision, benefits outweigh risks)</li> <li>• Will the results help locally?</li> <li>• Summary of appraisal</li> </ul>	<ul style="list-style-type: none"> <li>• Simple, quick, and easy to use</li> <li>• Designed for health care professionals</li> <li>• Good resource for framing journal club sessions</li> </ul>	<ul style="list-style-type: none"> <li>• Possibly less sensitive than other tools; unclear if validated</li> <li>• Designed for education workshops, primarily as a pedagogic tool (not validated as an appraisal tool)</li> </ul>	<ul style="list-style-type: none"> <li>• Developed using JAMA user guide (1994) and updated using CONSORT<sup>25</sup></li> <li>• Developed for educational use</li> </ul>

**TABLE 1 (Part 3 of 3). Summary of Critical Appraisal Tools Useful for Pharmacists**

Critical Appraisal Tool	Applicability / Study Design	Description	Components Assessed	Strengths	Limitations	Notes
CEBM guides (Centre for Evidence Based Medicine) <sup>26</sup>	RCTs, qualitative studies, systematic reviews	<ul style="list-style-type: none"> <li>List of questions asking if the study is valid and if the results are important and applicable</li> </ul>	<ul style="list-style-type: none"> <li>Internal validity, results, relevance</li> <li>Validity of results</li> <li>What were the results?</li> <li>Will the results help in caring for my patient?</li> </ul>	<ul style="list-style-type: none"> <li>Simple and easy to use, especially for beginners in critical appraisal</li> <li>Has questions and explanations for steps in the critical appraisal process</li> </ul>	<ul style="list-style-type: none"> <li>More introductory and less elaborate than other tools</li> <li>Less frequent use in literature reviews (based on PubMed keyword search)</li> <li>Unclear if it has been validated</li> </ul>	<ul style="list-style-type: none"> <li>Available in multiple languages</li> <li>Developed for educational use</li> </ul>
JBI critical appraisal tools (Joanna Briggs Institute, University of Adelaide) <sup>27</sup>	RCTs, cross-sectional studies, case-control studies, case reports, case series, cohort studies, qualitative research, quasi-experimental studies, systematic reviews	<ul style="list-style-type: none"> <li>Checklists for critical appraisals</li> <li>Includes explanations for each question to guide assessor</li> </ul>	<ul style="list-style-type: none"> <li>Internal validity only</li> <li>Study components in checklist format</li> </ul>	<ul style="list-style-type: none"> <li>Easy-to-use checklists with explanations</li> <li>Checklists available for many different study designs</li> <li>Relatively frequent use in literature reviews (based on PubMed keyword search)</li> </ul>	<ul style="list-style-type: none"> <li>Checklists for additional study designs primarily used for qualitative research in field of nursing<sup>10</sup></li> <li>Unclear if it has been validated tool</li> <li>Developed using JBI's standards for articles</li> </ul>	<ul style="list-style-type: none"> <li>Designed for systematic reviews but can also be used in selecting critically appraised topics, journal clubs, and as an educational tool</li> </ul>
SIGN (Scottish Intercollegiate Guidelines Network) <sup>28</sup>	RCTs, cohort studies, case-control studies, systematic reviews, meta-analyses	<ul style="list-style-type: none"> <li>Checklists for methodology assessments</li> <li>Two files for each checklist: the checklist tool and notes with explanations for the components/questions</li> </ul>	<ul style="list-style-type: none"> <li>Internal validity, relevance</li> <li>Study components in checklist format</li> <li>Overall assessment (includes section for relevance + additional comments)</li> </ul>	<ul style="list-style-type: none"> <li>Easy-to-use checklists with explanations</li> <li>Checklists available for many study designs</li> </ul>	<ul style="list-style-type: none"> <li>Less frequent use in literature reviews (based on PubMed keyword search)</li> <li>No scoring system</li> <li>Described as meeting SIGN's requirements, but method of evaluation was not described, and unclear if it has been validated</li> </ul>	<ul style="list-style-type: none"> <li>Developed using SIGN's standards for articles</li> </ul>
CCAT (Crowe Critical Appraisal Tool) <sup>29</sup>	General, "designed to assess health research across all research designs" <sup>33</sup>	<ul style="list-style-type: none"> <li>Fillable form that must be used together with detailed user guide</li> <li>8 categories scored from 0 to 5, with checklist used as a guide</li> </ul>	<ul style="list-style-type: none"> <li>Internal validity, results, relevance</li> <li>Research design</li> <li>Scores (summary)</li> <li>General notes</li> <li>Scored categories assessing study components</li> </ul>	<ul style="list-style-type: none"> <li>Not specific to a particular research design; can be applied to any type of evidence</li> <li>Tool tested for reliability using papers encompassing 6 research designs<sup>34</sup></li> </ul>	<ul style="list-style-type: none"> <li>Developer described tool as demanding<sup>29</sup></li> <li>Requires knowledge or references on research methodology to appropriately score categories</li> <li>Less frequent use in literature reviews (based on PubMed keyword search)</li> </ul>	<ul style="list-style-type: none"> <li>Developed following analysis of 44 critical appraisal tools available in 2010</li> </ul>

RCT = randomized controlled trial.

<sup>a</sup>See Appendix 3 (available from <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>) for risk-of-bias domains assessed by these tools.

**TABLE 2. Comparison of Critical Appraisal Tools to Help Pharmacists with Evidence-Based Practice<sup>a</sup>**

Critical Appraisal Tool and Elements	Applicability	User-Friendliness	Efficiency	Comprehensiveness	Reliability	Notes
RoB: table (various formats)	RCTs	★★★★☆	★★★★☆	★★☆☆☆	★★★★☆	Developed for Cochrane reviews
RoB 2: table and signalling questions (pdf + Excel templates)	RCTs	★★★★☆	★★☆☆☆	★★☆☆☆	★★★★☆	Developed for Cochrane reviews
NOS: list rated with "star" scale (pdf)	Nonrandomized studies (cohort studies, case-control studies)	★★★★★	★★★★★	★★☆☆☆	★★★★★	
ROBINS-I: table and signalling questions (pdf template)	Nonrandomized studies of interventions	★★☆☆☆	★★☆☆☆	★★★★☆	★★★★★	Developed for Cochrane reviews; intended for experienced methodologists
MINORS: scored list (pdf)	Nonrandomized studies of interventions	★★★★★	★★★★★	★★☆☆☆	★★☆☆☆	Originally developed for surgical studies
AMSTAR 2: checklist (pdf)	Systematic reviews (randomized studies, nonrandomized studies, or both)	★★★★☆	★★★★☆	★★☆☆☆	★★★★★	Developed for clinicians and policy-makers
ROBIS: table and signalling questions (pdf)	Systematic reviews	★★☆☆☆	★★☆☆☆	★★★★☆	★★★★★	
AGREE II: list rated with 7-point scale (pdf)	Clinical practice guidelines	★★★★☆	★★☆☆☆	★★☆☆☆	★★★★☆	Developed for clinicians and guideline developers; available in multiple languages
GRACE: checklist (pdf)	Comparative effectiveness research	★★★★☆	★★★★☆	★★☆☆☆	★★☆☆☆	Developed for clinicians
CASP: checklists (pdf)	RCTs, cohort studies, case-control studies, qualitative studies, systematic reviews	★★★★★	★★★★☆	★★★★★	★★☆☆☆	Developed for educators and clinicians
CEBM guides: checklist (pdf)	RCTs, qualitative studies, systematic reviews	★★★★★	★★★★★	★★★★☆	★★☆☆☆	Developed for educators and clinicians; available in multiple languages
JB critical appraisal tools: checklist (pdf)	RCTs, cross-sectional studies, case-control studies, case reports, case series, cohort studies, qualitative research, quasi-experimental studies, systematic reviews	★★★★★	★★★★★	★★☆☆☆	★★☆☆☆	More commonly used in nursing than in other fields <sup>9,10</sup> ; developed to meet JBI's standards
SIGN: checklist (pdf)	RCTs, cohort studies, case-control studies, systematic reviews and meta-analyses	★★★★★	★★★★★	★★☆☆☆	★★☆☆☆	Developed for clinicians; designed to meet SIGN's standards
CCAT (Crowe Critical Appraisal Tool): checklist	General, "designed to assess health research across all research designs" <sup>33</sup>	★★☆☆☆	★★☆☆☆	★★★★☆	★★★★★	Intended for those familiar with research designs and methodology; developer suggests having a general research methods textbook available when appraising papers <sup>29</sup>

RCT = randomized controlled trial.

<sup>a</sup>Ratings are based on findings from literature search and analysis by the authors.

specifically, Table 2 summarizes comparisons among the 14 tools covered in this narrative review based on user-friendliness, efficiency, comprehensiveness, and reliability. Some of the tools are user-friendly, including the NOS scale, which, according to Wells and others,<sup>18</sup> was developed as “an easy and convenient tool for quality assessment” and is available in the form of a brief manual that walks the reviewer through each item in the scale. The MINORS tool<sup>20</sup> is also user-friendly, formatted as a list with a simple scoring system. The CASP, CEBM, SIGN, JBI, AMSTAR 2, and GRACE tools are all formatted as checklists (Table 2), which makes them easy to understand and would make the appraisal process efficient, allowing users to check off the study criteria as they read a research article. In addition, the CEBM tool, while not allowing in-depth assessment and not frequently used in literature reviews (Table 1), has clear explanations that would make it a good introductory tool for beginners, such as pharmacy students.

The Cochrane Collaboration’s risk-of-bias (RoB) tool requires training to interpret the bias domains<sup>16</sup> but can be efficient and easy to present once the reviewer has gained some familiarity. The RoB 2 tool<sup>30</sup> is an updated tool that is more comprehensive than the original RoB tool but, as a result, can require more consideration and understanding of the training materials to obtain reliable results. The ROBINS-I and ROBIS tools are the most in-depth tools and are best used by experienced methodologists.<sup>31,32</sup> In a study comparing the NOS with the ROBINS-I, both intended for assessing non-RCTs, Zhang and others<sup>31</sup> found that the ROBINS-I took more time to complete (3 h versus 30 min to assess a single study), which would limit its use in practice. The AMSTAR 2 and ROBIS tools, which are used for assessing systematic reviews, were compared in another study. According to Perry and others,<sup>32</sup> “raters felt AMSTAR-2 was more straightforward and user-friendly than ROBIS” possibly because “it does not require expertise in systematic reviewing ... just knowledge of trial design.” Thus, pharmacists may find the AMSTAR 2 tool more practical to use.

In terms of reliability, the NOS, ROBINS-I, AMSTAR 2, and ROBIS tools have demonstrated good inter-rater reliability.<sup>18,21,31,32</sup> The Cochrane Collaboration’s RoB tool, while widely accepted (Table 1), has only modest inter-rater reliability because of its emphasis on assessor judgment, nonstandard implementation, and the need for training to interpret the bias domains.<sup>16,17</sup> The RoB 2 tool is an improvement over its predecessor, but given its greater complexity, training would still be beneficial to improve reliability in application.<sup>17,30</sup> The AGREE II tool is a refinement of the original AGREE tool, intended to improve validity and reliability, but it still requires multiple assessors to achieve the increased reliability.<sup>23</sup> The MINORS tool also had limited reliability testing, with only 2 surgeons as reviewers.<sup>20</sup> The GRACE checklist was piloted with comparative efficacy studies on drugs, medical devices, and medical procedures,

which resulted in good specificity and sensitivity scores relative to other quality assessment methods.<sup>35</sup> However, no inter-rater reliability studies have been completed (Table 1). The CASP, CEBM, JBI, and SIGN tools also had no inter-rater reliability testing completed or validation method specified, so they would be less appropriate for use in literature reviews.

Most of the tools identified were developed for conducting research, primarily research to support systematic reviews or clinical guidelines, although tools such as the MINORS, GRACE, JBI, and SIGN tools were developed with clinicians or health care decision-makers as additional end-users (Table 1). The AGREE II tool was developed for health care providers, guideline developers, policy-makers, and educators.<sup>23</sup> The AMSTAR 2, CASP, and CEBM tools were developed for educational purposes or for use by consumers of research, such as clinicians (Table 1). The MINORS tool was initially developed for surgical studies,<sup>20</sup> whereas the JBI tools are mainly used in nursing.<sup>10</sup> None of the tools were developed specifically for pharmacy, although the GRACE checklist was successfully applied to comparative effectiveness studies of drugs.<sup>24</sup>

As for possible bias and conflicts of interest, it should be noted that the RoB, RoB 2, and ROBINS-I tools were developed by the Cochrane Collaboration, and their criteria are specifically applicable to the development of Cochrane reviews (Table 1). The JBI and SIGN tools were also described as meeting the standards of their respective organizations (Table 1), but these standards were not specified and may not be applicable to other practice settings. The Critical Appraisal Skills Programme<sup>25</sup> and the Centre for Evidence-Based Medicine<sup>26</sup> provide critical appraisal workshops, so their tools may be adapted to suit an educational setting, which may in turn make the tools more appropriate for students or as introductions to critical appraisal.

Two of the tools have been translated into other languages. The AGREE II tool is available in multiple languages, with more translations in progress and available on request,<sup>23</sup> and the CEBM checklists are also available in several languages (Table 2). In terms of formats, all tools are available as printable pdfs, with the exception of the RoB tool, for which the documentation only provides examples of how to format the tool, and the RoB 2 tool, which is available as both a pdf and an Excel (Microsoft) template. High-reliability tools such as RoB 2 (see Table 2) are available for pharmacists to evaluate RCTs for quality of evidence. Although RCTs represent the “gold standard” for experimental design, a trial’s execution and the resulting article’s analysis and reporting can influence the quality of the evidence. By selecting the appropriate tools, pharmacists working in different settings can support their evidence-based practice. Pharmacists who work in a hospital setting often have opportunities to work on collaborative projects spanning all types of evidence-based research (e.g., case-control

study, cohort study, RCT, cross-sectional study, meta-analysis). The applicability column of Table 2 shows that the Critical Appraisal Skills Programme and the Joanna Briggs Institute offer tools for several study types based on the same checklist formats, which can be efficient, since pharmacists need to learn how to use only one type of tool.

A pharmacist serving on an internal interprofessional committee may be involved in developing local drug therapy manuals for their organization and would need to examine systematic reviews to find evidence for recommendations. Table 2 includes 2 tools for systematic reviews, AMSTAR 2 and ROBIS. A tool like AMSTAR 2, which was developed for health professionals and policy-makers, would be ideal for this purpose. Alternatively, if the interprofessional team has an experienced methodologist available for consultation, the pharmacist could use the ROBIS tool, and then compare tool outcomes and reach a consensus with the methodologist. In contrast, a pharmacist working in a pediatric neonatal care unit might be caring for a unique patient whose condition has only been described in case reports. In this situation, the pharmacist could review the applicability column of Table 2 and would find that the Joanna Briggs Institute has a checklist for case reports, which can be used to assess the quality of each case report identified.

Pharmacists involved in education initiatives such as journal clubs present and critique new research articles to other pharmacists. For journal club presentations, a pharmacist would likely want to employ a user-friendly and efficient tool. If presenting findings from a novel and timely RCT, for example, the pharmacist could use the RoB assessment tool to easily translate the RCT data into tables or figures for succinct presentation. If presenting findings on a cohort study or case-control study, the pharmacist could use the NOS tool to create pleasing visuals based on a star rating system.

Of the many validated tools available, most address only internal validity, with few asking questions that would provoke judgments of study applicability, limitations, and practice-changing outcomes. Moreover, no tools have been developed specifically for pharmacists, and no literature was found indicating how pharmacists could apply critical appraisal skills in practice or commenting on whether a standardized approach would be beneficial. A potential future project could take an approach similar to that used in the development of the MINORS tool,<sup>20</sup> with involvement of pharmacists and pharmacy leaders in the development and piloting of a critical appraisal tool specific to the literature on drugs and pharmacy interventions. In addition, many current tools are available only as pdf files that must be printed for use. Newer tools such as the RoB 2 allow creation of Excel spreadsheet files,<sup>17</sup> which can be more efficient but are still not as accessible as applications developed for other uses, such as MDCalc for medical calculations (www.mdcalc.com). It would be interesting to see the development of an accessible application for critical appraisals.

This narrative review had some structural limitations. In particular, it was not a systematic review and did not generate an exhaustive list of all critical appraisal tools currently available. A limitation of the comparison chart (Table 2) is that the rating score was based on findings from the included review articles rather than being determined systematically through expert consensus. The scoring system would benefit from incorporating a survey or results from a study piloting these tools with pharmacists and allied health researchers.

## CONCLUSION

Critical appraisal is an essential skill for pharmacists and health care practitioners alike. Many standardized critical appraisal tools are available that can help in systematically assessing various aspects of the quality of evidence, and the current narrative review summarizes 14 tools useful for pharmacists and allied health care researchers. In examining the current landscape of critical appraisal tools, we found that no tools that have been specifically modified to serve the needs of pharmacists when assessing scientific articles. As such, future research should examine how critical appraisal tools could be improved to better identify common data elements that are essential to evidence-based decision-making in pharmacy practice.

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**Ariane Blanc**, BPharm, MSc, RPEBC, MBA, is Director of Pharmacy and Chief Clinical Pharmacist at the Children's Hospital of Eastern Ontario, Ottawa, Ontario.

**Jameason Cameron**, PhD, MSc, is the Pharmacy Project Coordinator at the Children's Hospital of Eastern Ontario, Ottawa, Ontario.

**Vivian Ho**, PharmD, was, at the time this article was prepared, a pharmacy student in the University of Toronto Leslie Dean Faculty of Pharmacy, on rotation at the Children's Hospital of Eastern Ontario, Ottawa, Ontario. She has now graduated from the program.

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**Address correspondence to:**

Ariane Blanc  
Department of Pharmacy  
The Children's Hospital of Eastern Ontario  
401 Smyth Road  
Ottawa ON K1H 8L1

**email:** ABlanc@cheo.on.ca

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## TRIBUTE TO THE REVIEWERS OF THE CANADIAN JOURNAL OF HOSPITAL PHARMACY

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## 2023 CSHP NATIONAL AWARDS PROGRAM WINNERS / PROGRAMME NATIONAL DES PRIX 2023 DE LA SCPH : LAURÉATS ET LAURÉATES

<https://doi.org/10.4212/cjhp.3455>

The winner of the **Distinguished Service Award** (sponsored by Pharmascience Inc.) is **Blair W Seifert** (Saskatoon, SK).

The winner of the **Hospital Pharmacy Student Award** (co-sponsored by the Canadian Society of Hospital Pharmacists [CSHP] and the Canadian Association of Pharmacy Students and Interns [CAPSI]) is **Randilynne Ursiak** (Oxford Mills, ON).

### **Excellence in Pharmacy Practice — Interprofessional Collaboration Award**

Sponsored by **Teva Canada Limited**

IInvestigation of the impact of a Pharmacist in a Hospital At home Care Team (IN PHACT)  
(completed at Island Health, Victoria, BC)

*Morgan E Patrick, Curtis K Harder, Sean P Spina*

### **Excellence in Pharmacy Practice — Leadership Award**

Sponsored by **HealthPRO Procurement Services Inc.**

Eco-Friendly Pharmacy Practices to Support a Sustainable Green Transition in Hospital Pharmacy  
(completed at Children's Hospital of Eastern Ontario and Telfer School of Management,  
University of Ottawa, Ottawa, ON)

*Ariane Blanc, Nisha Varughese*

### **Excellence in Pharmacy Practice — Patient Care Award**

Sponsored by **SteriMax Inc.**

The Sunnybrook Odette Cancer Centre Oral Anticancer Medication (OAM) Program  
(completed at Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON)

*Christine Peragine, Victoria Bugaj*

*The award-winning abstracts are published exactly as submitted by the authors  
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à une révision linguistique et les publie ici tels que remis par les auteurs.*

### **IInvestigation of the impact of a Pharmacist in a Hospital At home Care Team (IN PHACT)**

*Excellence in Pharmacy Practice – Interprofessional Collaboration Award  
Sponsored by Teva Canada Limited*

*Patrick ME<sup>1,2</sup>, Harder CK<sup>1,2</sup>, Spina SP<sup>1,2,3</sup>*

<sup>1</sup>Island Health Authority, Victoria, BC

<sup>2</sup>UBC Faculty of Pharmaceutical Sciences, Vancouver, BC

<sup>3</sup>University of Victoria Health Information Sciences, Victoria, BC

**Background:** In November 2020, Island Health, with the support of the British Columbia Ministry of Health, introduced Hospital at Home (HaH) at Victoria General Hospital in Victoria, BC, Canada. Given the acuity of the patients anticipated to receive care through this model, questions arose about how the delivery of clinical pharmacy services that inpatients rely on could be included in the model. With limited supporting evidence for the inclusion of a clinical pharmacist, Island Health launched the HaH program with a clinical pharmacist who provides services 7 days a week during day-time hours.

**Objective:** To assess the impact of the HaH pharmacist on patient care, from the perspective of the pharmacists serving in this role, patients, caregivers and program stakeholders.

**Methods:** This prospective, observational mixed methods study was conducted from December 2021 to March 2022. Data collection involved the HaH pharmacist documenting daily clinical activities and resolved drug therapy problems, patients and caregivers completing a 4-question post-discharge phone survey, and program stakeholders completing a 9-question online survey and an optional 7-question interview.

**Results:** It was found that one of the most significant roles the pharmacist plays is in identifying indications for medication therapy and making recommendations to initiate therapy where there is an absence. There was high congruence between patient, caregiver, and stakeholder perceptions that the HaH pharmacist positively impacts patient care within the Island Health model.

**Conclusions:** This study provides support for the integration of a dedicated clinical pharmacist in the HaH care model.

**Keywords:** hospital staffing, integrated healthcare, patient centered care, program evaluation, qualitative research



## Eco-Friendly Pharmacy Practices to Support a Sustainable Green Transition in Hospital Pharmacy

*Excellence in Pharmacy Practice – Leadership Award*

*Sponsored by HealthPRO Procurement Services Inc.*

*Blanc A<sup>1</sup>, Cameron J<sup>1</sup>, Varughese N<sup>1</sup>, McKeague R<sup>2</sup>, Lin S<sup>2</sup>, Zebrowski J<sup>2</sup>, Pourziaei Manesh R<sup>2</sup>, Hoyte C<sup>2</sup>, Ballinger B<sup>2</sup>, Kronick M<sup>2</sup>*

<sup>1</sup>*Department of Pharmacy, Children's Hospital of Eastern Ontario, Ottawa, ON*

<sup>2</sup>*MBA Purple Consulting Team, Telfer School of Management, University of Ottawa, Ottawa, ON*

**Background:** The Children's Hospital of Eastern Ontario (CHEO) launched its "Kick the Carbon" strategy in 2021, aiming at reducing Green House Gases by 30% by 2025.

**Objectives:** In 2021, CHEO pharmacy collaborated with the University of Ottawa's Telfer School of Management Consulting team to develop its own eco-initiative plan aligned with CHEO's eco-responsible strategy.

**Methods:** The project included internal and external survey methods conducted in spring 2022. The former focused on operations of CHEO's pharmacy including interviews of interdisciplinary stakeholders and a sustainability engagement survey. The latter employed a literature search, an external key stakeholders' interviews and an Ontario hospital pharmacy survey on eco-initiatives. Data analysis used various management tools such as Input/Output Workflow, SWOT, Force Field Analysis.

**Results:** The internal survey showed the main barriers to implementing green practices in hospital pharmacy were cost, complexity, and time, and that the three largest areas of waste were single use plastic, lack of awareness of green practices, and lights left on. The external survey showed that 94% of respondents had implemented fewer than 3 green practices in their workplace, with 64% implemented >2 years ago. Twenty-eight percent indicated these initiatives saved money, 26% had considered implementing eco-practices, and for 30% unevaluated programs was the main challenge. Seven pillars were identified as key for sustainability with implementing at least 3 for "green labelling".

**Conclusion:** This interdisciplinary project highlights the need to further describe the Canadian hospital pharmacy landscape of eco-practices and to assess barriers and metrics for carbon footprint reduction. As such, our CHEO pharmacy team will conduct a REB approved National survey in winter 2023 to identify and evaluate hospital pharmacy past, current and future eco-initiatives, to assess knowledge and interest in this field, to develop a roadmap and to raise awareness for a better green transition of Canadian Hospital Pharmacies.

**Keywords:** eco-initiatives, green hospital pharmacy, pharmacy carbon footprint, sustainability, zero-waste, management

See related poster abstract, page 158.

## The Sunnybrook Odette Cancer Centre Oral Anticancer Medication (OAM) Program

*Excellence in Pharmacy Practice – Patient Care Award*

*Sponsored by SteriMax Inc.*

*Peragine C<sup>1</sup>, Bugaj V<sup>1</sup>, Singh S<sup>1</sup>, Sun C<sup>1</sup>, Choi G<sup>1</sup>, Chu J<sup>1</sup>, Mychaskiw C<sup>1</sup>, Lipman B<sup>1</sup>, Inaganti O<sup>1</sup>, Malladi S<sup>1</sup>, Nusrat N<sup>1</sup>, Jegatheswaran T<sup>1</sup>, Zhong B<sup>1</sup>, Liu B<sup>1</sup>*

<sup>1</sup>*Odette Cancer Centre Department of Pharmacy, Sunnybrook Health Sciences Centre, Toronto, ON*

**Background:** Increased availability of oral anticancer medications (OAMs) created a paradigm shift in oncology that introduced new challenges to treatment access, placed additional burden on the patient and prescriber to coordinate care, and increased risk for medication non-adherence and severe toxicity. Recognizing the emergent issues associated with OAM therapies, the Sunnybrook Odette Cancer Centre Pharmacy created an innovative program to optimize the clinical, and technical, medication-related support needed by OAM patients and prescribers.

**Objective:** OAM Program goals include: (1) coordinating timely and continuous OAM access; (2) improving OAM safety and effectiveness; (3) providing OAM information and education to patients, staff, and trainees; and (4) creating new knowledge on OAM-related practices, processes, and outcomes.

**Methods:** Dedicated pharmacy technicians liaise with prescribers, drug access navigators, and patient support programs to proactively resolve funding issues and facilitate timely medication access. Oncology pharmacists clinically verify each OAM order, perform drug-interaction analyses, and provide tailored education to optimize drug safety and adherence. The OAM Team has developed a variety of clinical tools to guide OAM management and ensures protocolized telephone follow-up for over 60 OAM agents.

**Results:** The OAM Team has enhanced the care of 3007 Oncology patients since 2015 (1108 currently active). Patients of the OAM Program report high rates of satisfaction, excellent rates of medication adherence and reduced rates of grade 3-4 drug toxicities. OAM Program services optimize OAM distribution efficiency, improve patients' ability to self-manage OAMs, and reduce the risk of severe side effects and unplanned breaks in therapy.

**Conclusions:** The OAM Program minimizes time-to-access OAM therapy, maximizes time on OAM therapy, and optimizes patient and prescriber convenience. The Program was identified as a *Leading Practice in Cancer Care* by Accreditation Canada in 2017 and is considered the gold standard / best-practice for OAM care among local oncology professionals.

**Keywords or Terms:** Oral chemotherap\*, oral anticancer\*, pharmaceutical care, clinical pharmacy services, telepharmacy\*, remote pharmacy service\*, e-pharmacy\*, oncology, pharmacy

## TOGETHER: CANADA'S HOSPITAL PHARMACY CONFERENCE 2023 / ENSEMBLE : CONGRÈS DES PHARMACIENS D'HÔPITAUX DU CANADA 2023

<https://doi.org/10.4212/cjhp.3448>

*Facilitated Poster Sessions: Discussions of original research, pharmacy practice projects, and case reports.*

*Séance animée de présentations par affiches : Discussions sur des projets de recherche originale des projets dans le domaine de la pratique pharmaceutique et les observations cliniques.*

### ORIGINAL RESEARCH / RECHERCHE ORIGINALE

1. What Types of Clinical Pharmacy Key Performance Indicators (cpKPI) Care Are Patients Receiving Across Canada? A 4-Year National cpKPI Patient Care Registry Trending with Clinical Specialty Analysis
2. A Cross-Sectional Analysis of Equity, Diversity, Inclusion and Accessibility within Pharmacy Residency Programs in Canada
3. Telepharmacist-Led Opioid Stewardship Program for Patients With Chronic Non-cancer Pain in a Remote and Rural Family Health Team
4. Adherence to Recommendations from Antimicrobial Stewardship Audit and Feedback Rounds in Academic Intensive Care Units
5. An Analysis of Imipenem-Cilastatin Usage and the Potential for Carbapenem De-escalation at London Health Sciences Centre
6. Antibiotic Stewardship and Route of Administration - Evolution of the Share of Oral and Parenteral Days of Therapy in a Teaching Hospital
7. Assessing the Use of IV Fosfomycin in the Setting of Multi-Drug Resistant (MDR) Infections: Real World Experience
8. Assessment of the Compliance of Our Drug Circuit Audit Process with a Selection of 42 Effectiveness Criteria
9. Calgary Acute Care Pharmacists: Changes in Prescribing and Lab Ordering Over Time
10. Comparing Outcomes and Characteristics Associated with Treatment Strategies in Critically Ill COVID-19 Patients
11. Demand for Exceptional Access Drugs and Projected Impact of Exceptional Access Drug Applications on Pharmacy Workload at the Odette Cancer Centre
12. Effect of Clozapine Treatment on Relapse to Methamphetamine Use among Inpatients with Co-occurring Treatment-Resistant Schizophrenia Spectrum and Methamphetamine Use Disorders: A Retrospective Cohort Study
13. Evaluating the Incidence of Hypoglycemia among Hyperkalemic Patients Treated with Insulin in the Emergency Department at Trillium Health Partners (THP)
14. Evaluation of Guideline Directed Medical Therapy Use in Outpatients Living with Heart Failure with Reduced Ejection Fraction
15. Evolution of the Conformity of the Drug Use Circuit on Healthcare Units and Outpatient Clinics of a Mother-Child University Healthcare Center
16. Evolution of the Speed of Reading and Summarizing Articles on the Roles and Impacts of Pharmacists
17. Exploring Key Elements of User Experience in Gamification of Health Profession Education: What We Learned from the Literature
18. How Patient-Centred Are Inhaler Device Choices? A Survey of Canadian Prescribers
19. Improving Precision of Vancomycin Dosing in Neonates Based on Clinical Outcome Evaluation and Population Pharmacokinetics
20. In-Use Variability of Tacrolimus Concentration in Compounded Suspension for Transplanted Pediatric Patients
21. Patients' Beliefs About Their Cardiovascular Medications After Acute Coronary Syndrome
22. Phenobarbital Alone or as Adjunct vs Benzodiazepine Therapy for Alcohol Withdrawal Syndrome in Critical Care – A Retrospective Cohort Study
23. Podcast on Quality Improvement and Leadership for Early Career Healthcare Professionals
24. Postsurgical Discharge Prescriptions for Opioid-Naïve Patients in University Teaching Hospitals in Quebec: A Descriptive Analysis
25. Prescribing Patterns and Cardioversion Before and After the Introduction of Vernakalant for Recent-Onset Atrial Fibrillation in an Emergency Room
26. Prescribing Trends for Antiestrogens, Bicalutamide, Traditional Oral Cytotoxic Agents, and Oral Immunosuppressants at the Odette Cancer Centre between 2018 to 2022
27. Prevalence and Patterns of Cannabis Use in Cancer Patients Receiving Systemic Anticancer Treatment: A Prospective Survey Study
28. Prioritizing Quality Over Quantity: Defining Optimal Pharmacist to Patient Ratios to Ensure Comprehensive Direct Patient Care in a Medical or Surgical Unit
29. Profile of Antimicrobial Use in a Teaching Hospital

## TOGETHER CONFERENCE 2023 POSTER ABSTRACTS / RÉSUMÉS DES AFFICHES DU CONGRÈS ENSEMBLE 2023

30. Profile of the Data Available on Impactpharmacie Relating to the Roles and Impacts of Pharmacists
31. SGLT2 Inhibitors, the Blockbuster Drug of the Early 21st Century
32. Stability and Compatibility of Bupivacaine and Hydromorphone in PVC and Non-DEHP Bags for 30 Days at 4°C and 25°C
33. Stability of 5-Fluorouracil at 4°C, 25°C and 33°C Stored in Nipro SureFuser+ Ambulatory Balloon Infusers
34. Status of Reporting of Adverse Events Occurring in a Tertiary Cardiopulmonary and Metabolic Healthcare Center: Preliminary Results
35. Surgical Antimicrobial Prophylaxis (SAP) Decision-Making and Disagreement in the Operating Room: A Thematic Analysis
36. Survey of CHEO Staff on the Use of Epinephrine and the End-User Experience with Removal of Ratios from Epinephrine Products: A Quality Improvement Pilot
37. Sustainability in Hospital Pharmacy: A Quality Improvement Pilot to Assess Awareness to “Go Green” (see related award abstract, page 143)
38. Trends in New and Total Prescriptions for Oral Anticancer Medications at the Odette Cancer Centre: A 51-Month Retrospective Study
39. Use of Podcasts in Healthcare: A Literature Review
40. Venous Thromboembolism Prophylaxis Across the Prairie Provinces: Description of Definitions and Unique Populations
6. Implementation of Neonatal and Paediatric Medication Calculators
7. Incorporating the Principles of Equity, Diversity, and Inclusion in Canadian Pharmacy Residency Admissions Using a Holistic Review Framework
8. Listen to Your Clinicians: Collecting User Input after Smart Pump Implementation to Drive Continuous Quality Improvement
9. Pharmacist Led Cardiac Amyloid Clinic
10. Reconciling Wisely: Pharmacist-Led Medication Reconciliation Quality Improvement Initiative
11. Reviewing Medications for Hazardous Classification
12. The New Brunswick Pharmacy Assessment Clinic: A Novel, Hospital Pharmacist-Led Collaborative Practice Hub
13. Twenty Years of Pharmacy Practice Research: Evaluation of Internship Satisfaction
14. Using Pharmacy Students to Prioritize Inpatient Care
15. Utilization of Smart Pump Technology to Effect Practice Change
16. We’re in This Together: How Our Outpatient Pain Clinic’s Fluoroscopy Suite Survived the Global Iohexol Shortage Without Limiting Patient Care Services
17. Workflow Analysis of Daily Tasks Performed by Pharmacy Technicians at CHEO: A Pilot Project Using the Lean Six Sigma Approach

### PHARMACY PRACTICE / PRATIQUE PHARMACEUTIQUE

1. A Virtual Interactive Case System Innovation to Support Pharmacist Prescribing for Minor Ailments
2. Assessment of Sedative-Hypnotic Drug Use to Reduce Risk of Falls in Selected Inpatient Areas of Nova Scotia Health: Results of a Pilot Project
3. Developing a Non-formulary Drug Usage Report for the Pharmaceuticals and Therapeutics (P&T) Committee
4. Development and Evaluation of an Online Pocket Guide to Quality Improvement
5. Health Care Workers’ Perceptions of a Pharmacist-Led Collaborative Practice Agreement for the Prescribing of Nirmatrelvir/Ritonavir to Eligible COVID-19 Patients

### CASE REPORTS / OBSERVATIONS CLINIQUES

1. Appearance of Lanthanum Tablets on Abdominal X-Ray
2. Elexacaftor/Tezacaftor/Ivacaftor Induced Rash and Subsequent Desensitization in a Paediatric Patient with Cystic Fibrosis
3. Piperacillin-Tazobactam Induced Thrombocytopenia in the Setting of Diabetic Foot Infection and End-Stage Renal Disease in Peritoneal Dialysis: A Case Report
4. Vascular Mycobacterium Infection 3 Years Following Intravesical Live Attenuated *Mycobacterium bovis* Therapy

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ORIGINAL RESEARCH / RECHERCHE ORIGINALE

**What Types of Clinical Pharmacy Key Performance Indicators (cpKPI) Care Are Patients Receiving Across Canada? A 4-Year National cpKPI Patient Care Registry Trending with Clinical Specialty Analysis**

Zhou Y<sup>1</sup>, Fernandes O<sup>1,2</sup>, Carroccia A<sup>1</sup>, Saragosa J<sup>2</sup>, Lowe D<sup>1</sup>, Toombs K<sup>3</sup>, Gorman SK<sup>4</sup>, Spina SP<sup>5</sup>, Semchuk WM<sup>6</sup>, Meade A<sup>3</sup>, Hamandi B<sup>1,2</sup>, Lui P<sup>1</sup>, Andriets A<sup>7</sup>, Bayoud T<sup>7</sup>, Bucci C<sup>8</sup>, Bussièrès JF<sup>9</sup>, Chant C<sup>2,10</sup>, Doucette D<sup>11</sup>, Dumont Z<sup>6</sup>, LeBlanc M<sup>11</sup>, Latariya G<sup>3</sup>, Leung J<sup>10</sup>, Macdonald E<sup>12</sup>, MacLean B<sup>12</sup>, Mikhail G<sup>13</sup>, Rolko E<sup>13</sup>, Seto W<sup>14</sup>, Shalansky S<sup>15</sup>, Slavik RS<sup>4</sup>, Szabolcs N<sup>16</sup>, Yamashita S<sup>2,8</sup>

<sup>1</sup>University Health Network, Toronto, ON

<sup>2</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

<sup>3</sup>Nova Scotia Health Authority, Halifax, NS

<sup>4</sup>Interior Health Authority, Kelowna, BC

<sup>5</sup>Vancouver Island Health Authority, Victoria, BC

<sup>6</sup>Saskatchewan Health Authority, Regina, SK

<sup>7</sup>St. Joseph's Health Care London, London, ON

<sup>8</sup>Sunnybrook Health Sciences Centre, Toronto, ON

<sup>9</sup>CHU Sainte-Justine, Montréal, QC

<sup>10</sup>Unity Health Toronto, Toronto, ON

<sup>11</sup>Horizon Health Network, Moncton, NB

<sup>12</sup>The Ottawa Hospital, Ottawa, ON

<sup>13</sup>North York General Hospital, Toronto, ON

<sup>14</sup>The Hospital for Sick Children, Toronto, ON

<sup>15</sup>Providence Health Care, Vancouver, BC

<sup>16</sup>London Health Sciences Centre, London, ON

**Background:** Clinical pharmacy key performance indicator (cpKPI) care delivery is associated with improved patient outcomes. In 2018, the Canadian National cpKPI Patient Registry was created with an inaugural 1-year pilot. Since then, multi-year comparative trending and clinical specialty specific data analysis have not been conducted.

**Objective:** To expand cpKPI registry by generating pooled national summaries and comparative trending for 2018-2021 (including COVID impact), and enhance the registry by focusing on comparisons across pharmacy clinical specialties.

**Methods:** In this prospective, national, multi-center, multi-year, quality improvement study, participating hospitals submitted annual aggregate and clinical specialty cpKPI care data for 2018-2021. The patient-level cpKPI data were analyzed to generate multi-year trends and clinical specialty comparisons.

**Results:** Overall, the cpKPI Registry enrolled 43 unique hospitals and 1,027,701 patients from 2018-2021. Core analysis included 25 unique acute care institutions (that measured cpKPI patient proportion data continuously). Trending revealed that the three most delivered cpKPIs remained as admission medication reconciliation, interprofessional rounding, and pharmaceutical care plans. Discharge medication reconciliation and patient education (hospital stay/ discharge) remained the most common national cpKPI care gaps. The top cpKPI care types delivered varied among pharmacy cpKPI practice profiles generated for each clinical specialty, including: Adult General Internal Medicine, Adult Medical Surgical Intensive Care Unit, Adult Surgery, Adult Inpatient Oncology, Rehabilitation, and General Pediatrics (for 11 hospitals, n=162,849). There appeared to be a slight decrease (6%) in cpKPI care delivery during COVID-impacted years (2020-2021) compared to pre-COVID years (2018-2019) for hospitals that submitted for all 4 years.

**Conclusions:** National cpKPI registry data were trended for 2018-2021. The registry data was enhanced with aggregate data from clinical specialty areas to enable more meaningful comparisons. The study results track national progress, benchmark cpKPI practice profiles across hospitals, and can inform pharmacy practice advancement to improve patient outcomes.

**A Cross-Sectional Analysis of Equity, Diversity, Inclusion and Accessibility within Pharmacy Residency Programs in Canada**

Burgess SV<sup>1,2</sup>, Smith M<sup>2</sup>

<sup>1</sup>Pharmacy Department, QEII Health Sciences Centre, Nova Scotia Health, Halifax, NS

<sup>2</sup>College of Pharmacy, Dalhousie University, Halifax, NS

**Background:** Equity, Diversity, Inclusion and Accessibility (EDIA) is a broad concept encompassing the principles, ideologies and practices related to fostering cultures that aim to minimize bias, address systemic inequities, and promote belonging and inclusion, particularly for members of equity-deserving groups.

**Objective(s):** To determine if and how EDIA has been incorporated into pharmacy residency programs in Canada and to identify challenges and opportunities.

**Methods:** A cross-sectional survey was created and electronically distributed to 44 pharmacy residency programs in Canada over a 4-week period (August 12 to September 9, 2022). The survey was to be anonymously completed by either a program director or program coordinator and included 28 questions that used a 4-point Likert scale to measure how EDIA was considered or incorporated into various aspects of the program. Additional open-ended questions were included to capture response details and identify challenges.

**Results:** Surveys were completed for 28 of 44 (63.6%) pharmacy residency programs in Canada; the majority by a program coordinator (21/28, 75%). Participants agreed (12/28, 42.9%) or strongly agreed (16/28, 57.1%) that EDIA is important to incorporate into residency programs and 6 (6/28, 21.4%) had or were developing formal policies. Some responded that their programs currently do or are developing ways to incorporate EDIA into applicant screening (8/25, 32%), resident education and training (16/25, 64%), and preceptor education and training (11/25, 44%). A diverse team of applicant reviewers and residency preceptors was reported in 52% (13/25) and 80% (20/25) of programs, respectively. Challenges with incorporation of EDIA were identified and included knowledge and training gaps, staffing and resource challenges, and limitations of the applicant matching system.

**Conclusion(s):** Incorporating EDIA into pharmacy residency programs in Canada is perceived to be important however, only a few programs are developing or currently have EDIA policies in place. Challenges to incorporating EDIA should be addressed.

**Telepharmacist-Led Opioid Stewardship Program for Patients With Chronic Non-cancer Pain in a Remote and Rural Family Health Team**

Newman P<sup>1</sup>, Chang F<sup>2</sup>, Dhaliwall S<sup>1</sup>, Chan D<sup>1</sup>, McDonald K<sup>1</sup>

<sup>1</sup>Northwest Telepharmacy Solutions, Winnipeg, MB

<sup>2</sup>University of Waterloo, Waterloo, ON

**Background:** In Canada, opioid-related hospitalizations increased by 27% in 2017, and 4034 lost their lives in 2019. Pharmacists can lead opioid stewardship programs (OSP) to coordinate interventions designed to improve, monitor, and evaluate the use of opioids to support and protect human health. Specialized clinicians in non-cancer chronic pain (NCCP) management in rural communities is often non-existent, including the care of a pharmacist.

**Objective:** To evaluate the feasibility and effect of a pharmacist-led OSP for CNNP, utilizing videoconference in a rural community family health team.

**Methods:** A mixed method pilot study including surveys and/or semi-structured interviews conducted with patients, clinicians, pharmacists and administrative staff involved in the OSP to understand their experiences

and/or satisfaction with the program. Retrospective chart review was undertaken to collect data on patient's opioid dose changes, and pharmacist recommendations. Adults with CCNP taking at least 50 morphine equivalent dose (MED) for at least 30 days, or less than 50 MED with persistent problematic pain and/or adverse effects were scheduled to attend 5 video-conference sessions over 10 weeks. Patient, physician and pharmacist surveys were web-based and semi-structured interviews with clinicians and family health team staff conducted by telephone. Descriptive statistics were generated from numeric variables, and change in patient's daily MED will be analyzed with either paired t-test or non-parametric testing.

**Results:** Nineteen participants were enrolled, most with upper body (53%) or back pain (29%). The OSP pharmacist made 35 recommendations, 63% accepted and implemented. Interviews conducted with service providers and program surveys showed the OSP had a positive impact and an interest in continuing to implement elements of the program into existing patient care practices.

**Conclusions:** Results generated from this study may add new evidence on the feasibility and effectiveness of clinical model in this kind on managing high dose opioid prescriptions in remote communities.

### Adherence to Recommendations from Antimicrobial Stewardship Audit and Feedback Rounds in Academic Intensive Care Units

Griffiore K<sup>1</sup>, Selvakumar K<sup>1</sup>, Wan M<sup>2</sup>, Taggart LR<sup>3,4</sup>, Leung E<sup>4,5,6</sup>

<sup>1</sup>University of Toronto, Toronto, ON

<sup>2</sup>Unity Health Toronto/St. Joseph's Health Centre, Toronto, ON

<sup>3</sup>Division of Infectious Diseases, Department of Medicine, University of Toronto, Toronto, ON

<sup>4</sup>Unity Health Toronto/St. Michaels Hospital, Toronto, ON

<sup>5</sup>University of Toronto, Leslie Dan Faculty of Pharmacy, Toronto, ON

<sup>6</sup>Li Ka Shing Knowledge Institute, Interprofessional Practice Based Research, Toronto, ON

**Background:** Antimicrobial stewardship programs (ASPs) can improve patient outcomes and decrease emergence of antimicrobial resistance. ASP guidelines recommend prospective audit and feedback (PAF) as it has been shown to reduce inappropriate antimicrobial use.

**Objective:** Factors associated with variable PAF acceptance rates are not well studied. Identifying predictors of successful recommendations may help optimize PAF processes.

**Methods:** The setting was a large, academic teaching hospital in Toronto, Canada. Data were recorded from verbal recommendations made during selected ASP rounds conducted in 3 intensive care units (ICUs) between April 2013 and September 2022. ASP recommendations were categorized using standardized definitions (Table 1). The primary outcome was acceptance of ASP recommendations.

**Results:** Overall, 85.7% of ASP recommendations were accepted. Interventions aimed at promoting appropriate antimicrobial coverage were less likely to be accepted in comparison to all other recommendations combined (OR 0.47, 95% CI 0.27-0.82). Recommendations within the "promote appropriate coverage" category were further classified to demonstrate that recommendations to expand antimicrobial coverage were more likely to be accepted than recommendations to narrow coverage (OR 2.37, 95% CI 1.08 - 5.19). There were no statistically significant differences in acceptance rates between ICUs or other intervention categories.

**Conclusions:** Most of the recommendations made during ASP rounds were accepted by the ICU teams. Recommendations that suggested expanding antimicrobial coverage were more likely to be accepted than those that suggested de-escalation. This finding is consistent with studies that looked at predictors of ASP intervention success in similar institutions. These results

highlight important considerations for optimizing PAF process measures within institutional ASPs.

#### Encore Presentation

For the table that goes with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>

### An Analysis of Imipenem-Cilastatin Usage and the Potential for Carbapenem De-escalation at London Health Sciences Centre

Abaza R<sup>1,3</sup>, Dhama R<sup>1,2,4</sup>, Elsayed S<sup>1,2</sup>, Almousa A<sup>1</sup>

<sup>1</sup>London Health Sciences Centre, London, ON

<sup>2</sup>University of Western Ontario, London, ON

<sup>3</sup>The Ottawa Hospital, Ottawa, ON

<sup>4</sup>University of Waterloo, Waterloo, ON

**Background:** London Health Sciences Centre currently uses imipenem-cilastatin as the primary formulary carbapenem agent. Carbapenem de-escalation studies have shown ertapenem can provide reliable activity against extended spectrum beta-lactamase (ESBL) organisms while alleviating selective pressure off drug resistant pathogens such as *Pseudomonas spp.* and *Acinetobacter spp.*

**Objectives:** The primary objective was to quantify empiric versus targeted use and how much could have been de-escalated to ertapenem. The secondary objectives were to characterize prescribing services, sources of infection, and pathogens detected.

**Methods:** This study was a retrospective chart review of adult inpatient imipenem-cilastatin orders from January 2021 to December 2021. 1298 orders were included, and 501 random orders were analyzed in the interim analysis and assessed for eligibility of de-escalation to ertapenem. Empiric therapy was defined as a culture negative infection, and was not eligible for de-escalation. Targeted therapy was defined as the presence of a positive culture with an isolated pathogen. Pathogens not eligible for de-escalation were *Acinetobacter spp.*, *Pseudomonas spp.*, and *Enterococcus spp.*

**Results:** Among the 501 orders included in the interim analysis, 53.5% (n=268) were identified as empiric therapy and 46.5% (n=233) were targeted therapy. Among the targeted therapy, 72.9% (n=170) were eligible for de-escalation to ertapenem based on study criteria. The most common prescribing services were Medicine (30.5%), Oncology (28.3%), Critical Care (15.6%) and General Surgery (7%). The most common sources of infection were urinary (19.5%), bloodstream (18.6%), respiratory (18%), and febrile neutropenia (17.6%). The most commonly isolated pathogens were *Enterobacter spp.* (n=57), *E. coli* (n=41) *Pseudomonas spp.* (n= 37), *E. coli* ESBL (n= 34) and *Klebsiella spp.* (n= 34).

**Conclusion:** This study demonstrates approximately 73% of targeted imipenem-cilastatin usage was eligible for de-escalation to ertapenem. These findings suggest an opportunity for optimization of carbapenem use and de-escalation to ertapenem for certain commonly isolated pathogens.

### Antibiotic Stewardship and Route of Administration – Evolution of the Share of Oral and Parenteral Days of Therapy in a Teaching Hospital

Monnier A<sup>1</sup>, Roy H<sup>1</sup>, Bussi eres JF<sup>1,2</sup>

<sup>1</sup>Unit  de Recherche en Pratique Pharmaceutique, D partement de pharmacie, CHU Sainte-Justine, Montr al, QC

<sup>2</sup>Facult  de pharmacie, Universit  de Montr al, Montr al, QC

**Background:** Antimicrobial stewardship ensures monitoring of the proper use of antimicrobials. The conversion from intravenous to oral route is encouraged rapidly because it reduces some inherent risks and facilitates patient discharge.

**Objectives:** To evaluate the share of parenteral days of therapy (DOT) in a teaching hospital from 2005-2006 to 2021-2022.

**Methods:** Descriptive study. The study was taking place in a mother-child university hospital center with 500 beds. Using antimicrobial consumption data, the total number of DOT/1000 patient days for all oral and parenteral drugs was calculated by fiscal year from 2005-2006 to 2021-2022. The proportion of the number of parenteral DOTs to the total number of DOTs per fiscal year was calculated. In addition, the number of DOT/1000 patient days for pairs of antimicrobials available for the oral and parenteral routes was also calculated by fiscal year.

**Results:** The total number of DOT/patient days was reduced from 710 (2005-2006) to 609 (2021-2022). The proportion of DOT/1000 patient days for the parenteral route fell from 77% in 2005-2006 to 62% in 2021-2022. The proportion of DOT/1000 patient days for the parenteral route also decreased from 2005-2006 to 2021-2022 for the following antimicrobial pairs: acyclovir (97% c. 32%), azythromycin (12% c. 5%), ciprofloxacin (58% c. 31%), fluconazole (69% c.64%), levofloxacin (49% c.24%), metronidazole (71% c.16%), voriconazole (68% c.43%). However, this proportion increased for linezolid (0% c.38%). Other pairs of different pharmaceutical ingredient were also explored.

**Conclusion:** We observed a global reduction in the share of DOT by parenteral route in favor of the enteral route from 2005-2006 to 2021-2022. This reduction may be linked to the increased availability of some oral forms of antimicrobials overtime and to the interventions of our antibiotic stewardship program that contributes to the good use of antimicrobials within our hospital.

### Assessing the Use of IV Fosfomycin in the Setting of Multi-Drug Resistant (MDR) Infections: Real World Experience

Kwok A<sup>1</sup>, Dhami R<sup>1,2,3</sup>

<sup>1</sup>London Health Sciences Centre, London, ON

<sup>2</sup>University of Waterloo, Waterloo, ON

<sup>3</sup>Western University, London ON

**Background:** Intravenous (IV) fosfomycin is approved for the treatment of a variety of conditions including nosocomial lower respiratory tract infections (nLRTI) and complicated urinary tract infections (cUTI). IV fosfomycin has moderate activity against certain strains of *Pseudomonas aeruginosa* (*P.aeruginosa*) and *Klebsiella pneumoniae* (*K.pneumoniae*) which makes it a unique alternative when facing the increasing rates of antimicrobial resistance.

**Objectives:** The purpose of this study is to describe a real-world experience of IV fosfomycin treatment as adjunct salvage therapy for multi-drug resistant (MDR) infections and evaluate the incidence of clinical cure and microbiologic eradication at a tertiary care hospital.

**Methods:** A retrospective chart review was completed on patients who received IV fosfomycin in the setting of MDR infections from July 2021 until November 2022. A systematic data collection sheet was used to gather patient characteristics, clinical information, and outcomes. MDR was defined as resistance to at least one antibiotic in two or more antimicrobial classes. Descriptive statistics were used to analyze the collected data. Clinical cure was defined as resolution of signs or symptoms of infection.

**Results:** Over the study period, 4 patients received IV fosfomycin. Most patients (75%) were male with a mean age of 57.25. The most commonly isolated pathogens were MDR *P.aeruginosa* (75%) and *K.pneumoniae* (50%). Among the 2 nLRTI patients, both achieved short-term clinical cure but not microbiologic eradication. One later died from unrelated complications during a stay in critical care. Among the 2 cUTI patients, both accomplished clinical cure and microbiologic eradication. The adverse effects experienced were hypernatremia (50%) and hypokalemia (75%).

**Conclusions:** This real-world experience demonstrated the potential role of IV fosfomycin as add-on salvage therapy in MDR respiratory and urinary infections. Randomized controlled trials are required to further clarify the role of IV fosfomycin as monotherapy versus add-on therapy for MDR infections.

### Assessment of the Compliance of Our Drug Circuit Audit Process with a Selection of 42 Effectiveness Criteria

Monnier A<sup>1</sup>, Jacolin C<sup>1</sup>, Atkinson S<sup>1</sup>, Bussièrès JF<sup>1,2</sup>

<sup>1</sup>Unité de Recherche en Pratique Pharmaceutique, Département de pharmacie, CHU Sainte-Justine, Montréal, QC

<sup>2</sup>Faculté de pharmacie, Université de Montréal, Montréal, QC

**Background:** A new theory for the design, implementation and evaluation of feedback in healthcare has been published. It includes a selection of high-confidence hypotheses that influence the effectiveness of feedback cycle.

**Objectives:** To assess the compliance of our drug circuit audit process with a selection of 42 effectiveness criteria.

**Methods:** This is a descriptive study. In our mother-child university hospital center, we conduct an annual audit on drug circuit targeting drug preparation and administration by nursing staff. Using the Clinical Performance Feedback Intervention Theory and its 42 hypotheses (compliance criteria), we assessed the compliance of that annual audit process. The hypotheses are categorised in three group of variables (feedback, recipient, and context) and 10 sub-group (goals, data collection and analysis method, feedback display, feedback delivery, health professional characteristics, behavioural response, organisation or team characteristics, patient population, co-interventions, implementation process). Two research assistants rated each criterion, along with supporting comments. Each criterion was rated as conform, not conform or not applicable. Two pharmacists independently reviewed the grid to confirm the ratings. Differences were resolved by consensus.

**Results:** The compliance of our drug circuit audit process was 70.7% (29/41) and one criteria were non applicable. Per sub-group of variables, it was: 100% (3/3) for goals, 75.0% (3/4) for data collection and analysis method, 71.4% (5/7) for feedback display, 75.0% (3/4) for feedback delivery, 66.7% (2/3) for health professional characteristics, 0% (0/1) for behavioural response, 100% (2/2) for patient population, 62.5% (5/8) for organisation or team characteristics, 75% (3/4) for co-interventions and 60.0% (3/5) for implementation process. Areas for improvement have been identified: computerize the collection of information in real time, increase data sharing with other hospitals.

**Conclusion:** Our drug circuit audit process complies with most of the criteria of an external standard. This evaluation made it possible to identify areas for improvement.

### Calgary Acute Care Pharmacists: Changes in Prescribing and Lab Ordering Over Time

Erpilla E<sup>1</sup>, Charlton A<sup>2</sup>, Hill C<sup>2</sup>, Zuk D<sup>2</sup>, Dersch-Mills D<sup>2</sup>, Saunders S<sup>3</sup>, Savin A<sup>2</sup>

<sup>1</sup>Department of Pharmacy, Island Health, Nanaimo, BC

<sup>2</sup>Department of Pharmacy, Alberta Health Services, Calgary, AB

<sup>3</sup>Department of Pharmacy, Northern Health, Dawson Creek, BC

**Background:** In Alberta, pharmacists can obtain Advanced Prescribing Authority and laboratory test ordering authority. While independent prescribing was mandated for Calgary inpatient pharmacists by 2018, lab ordering has been available since 2009.

**Objectives:** To describe the annual changes in frequencies and types of inpatient pharmacist prescribing and lab ordering from 2018 to 2021 in order to detect increased use of expanded scope of practice across Calgary, sites, and clinical pharmacy teams. Proportions of verbal orders were compared as indirect indicators of independent prescribing use.

**Methods:** A retrospective, descriptive review of pharmacist orders was completed using data from a computerized order entry system used across Calgary hospitals. Chi-square tests were used to determine differences in prescribing and lab ordering rates in 2018 compared to 2021. Z-scores were determined to identify differences in proportional outcomes between 2018 and 2021. For secondary outcomes, the study adjusted for multiple comparisons using Bonferroni tests.

**Results:** From 2018 to 2021, pharmacist prescribing and lab ordering rates rose by 67% and 5.5% respectively. All hospitals increased their prescribing rates (7%-176%). *Cardiology, ICU, and Mental Health* teams increased most in prescribing, while *Mental Health, Hospitalist, and ICU* teams increased most in lab ordering. The top ordered medication and lab test each year was vancomycin and vancomycin pre level. Verbal orders decreased from 60.0% to 47.4%.

**Conclusions:** Calgary acute care pharmacists have increased their use of expanded scope of practice over time with a greater change in prescribing than lab ordering. Pharmacist prescribing and lab ordering are complementary activities because the medications and labs they order support each other. Pharmacy leadership could address the high proportion of verbal orders and the minority of pharmacists who do not prescribe. These results can fuel individual change, practice review, or further research.

### Comparing Outcomes and Characteristics Associated with Treatment Strategies in Critically Ill COVID-19 Patients

Lo L<sup>1</sup>, Jeong E<sup>2</sup>, Cen R<sup>2</sup>, Bagri H<sup>1,2</sup>, Gellatly R<sup>1,2</sup>

<sup>1</sup>Pharmacy Department at Surrey Memorial Hospital, Surrey, BC

<sup>2</sup>Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC

**Background:** A Fraser Health study identified a similar mortality rate with the use of interleukin-6 receptor antagonists (IL-6 RAs) in critically ill patients with COVID-19 to what was reported early in the pandemic before IL-6 RAs were standard of care.

**Objectives:** The primary objective was to compare in-hospital mortality for critically ill COVID-19 patients at Surrey Memorial Hospital (SMH) in the following groups: oxygen only, dexamethasone only, and IL-6 RAs. The key secondary objectives were to compare hospital length of stay (LOS), presence of secondary microbial infection and patient characteristics.

**Methods:** This retrospective, cohort study evaluated consecutive patients with COVID-19 in the critical care unit between March 2020 to May 2021 who received 1 of the 3 treatments described above. Descriptive statistics were used for baseline characteristics. For group differences, chi-squared and ANOVA analyses were used for nominal and continuous data respectively. Logistic regression was performed to analyze the relationship between mortality and treatment arms.

**Results:** Of the 379 included patients, 65.4% were males and median age was 63 years (IQR 52,72). Ten percent (N=38) received oxygen, 31.7% (N=120) received dexamethasone, and 58.3% (N=221) received IL-6 RAs. The respective mortality was: 10.5% vs 27.5% vs 21.3% (P=0.079). Compared to the IL-6 RAs and after controlling for baseline differences, the odds of mortality were lower in the oxygen group (OR= 0.10, P=0.001); however, there was no significant association with dexamethasone. The dexamethasone group had a shorter hospital LOS compared to IL-6 RAs (P=0.005). There was no difference in microbial infections (P=0.740).

**Conclusion:** Although a lower mortality rate was observed in the oxygen only group, the small sample size may be a limitation to these results. Despite administration of immunomodulators, no difference in infections was observed. Future studies may consider using a larger patient database to better elucidate mortality differences between treatments.

### Demand for Exceptional Access Drugs and Projected Impact of Exceptional Access Drug Applications on Pharmacy Workload at the Odette Cancer Centre

Sun C<sup>1</sup>, Bugaj V<sup>1</sup>, Peragine C<sup>1</sup>

<sup>1</sup>Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON

**Background:** The Exceptional Access Program (EAP) facilitates access to high-cost drugs which are not funded under the provincial drug formulary. Preparing EAP applications is a laborious process which takes time away from prescribers' clinical duties. As such, medical oncologists at the Odette Cancer Centre (OCC) have requested the Pharmacy team assume this task as medication experts.

**Objective:** To quantify the demand for EAP submissions and estimate the number of staffing hours required to completely take over EAP management for all eligible patients of the OCC Pharmacy.

**Methods:** OCC Pharmacy records were used to identify active and pending EAP cases, which were organized and described as frequency counts by drug and prescriber. To estimate the anticipated workload associated with the EAP cases identified, an initial application was assigned a workload of 0.5h to complete, renewals were assigned a workload of 0.25h to complete, and 2 EAP renewals were assumed per year. Total projected workload for EAP submissions was reported in terms of FTE equivalents.

**Results:** A total of 910 active/pending EAP cases were identified for 42 unique drugs requested by 45 different prescribers. The 5 most commonly requested drugs were osimertinib (n=99), enzalutamide (n=91), abiraterone (n=76), palbociclib (n=74), and ibrutinib (n=53). One genitourinary (GU) oncologist was identified as an EAP super-user with 117 active/pending EAP submissions. The second, third, and fourth highest EAP users were another GU oncologist (68 submissions), a lung oncologist (61 submissions), and a hematologist (57 submissions). It would require 24.3 weeks of an FTE(37.5hrs/week) to prepare and submit 910 initial EAP applications and two renewals. Using these estimations, 0.5FTE would be required to meet the administrative workload demand.

**Conclusion:** This data demonstrates the time intensive nature of EAP applications and the need for a 0.5 FTE equivalent to completely assume the administrative burden for OCC Pharmacy patrons.

### Effect of Clozapine Treatment on Relapse to Methamphetamine Use among Inpatients with Co-occurring Treatment-Resistant Schizophrenia Spectrum and Methamphetamine Use Disorders: A Retrospective Cohort Study

Mahmood H<sup>1</sup>, Frankow L<sup>1</sup>, Poonia S<sup>1,2</sup>, Rafizadeh R<sup>1,2</sup>

<sup>1</sup>Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC

<sup>2</sup>Lower Mainland Pharmacy Services, Vancouver, BC

**Background:** There are high rates of concurrent substance use disorders (SUD) in patients with schizophrenia spectrum disorders (SSD). Substance use relapse results in poorer outcomes in SSD and may be a risk factor for developing treatment-resistance. According to some preliminary evidence, clozapine may have a favorable impact on SUD outcomes versus other antipsychotics. However, there is paucity of evidence on its impact on concurrent methamphetamine use disorder (MAUD) outcomes.

**Objective(s):** We hypothesized that clozapine treatment would be associated with significantly lower rates of relapse to methamphetamine use and a higher likelihood of remaining abstinent compared to other antipsychotics.

**Methods:** A retrospective review of electronic health records was conducted on inpatients at the Burnaby Centre for Mental Health and Addiction between December 8, 2019 to October 8, 2021. Included patients had

concurrent treatment-resistant SSD and MAUD. Medication exposure was categorized as “on clozapine” or “on other antipsychotic(s)”. Data extracted included demographics, diagnoses, substance use history, medications on admission/discharge, and urine drug screen results (methamphetamines/amphetamines, opiates, fentanyl, THC) during stay. Relapse rates were calculated as relapse-to-length of stay ratio; and were confirmed by positive urine drug screens and as-needed confirmatory testing. The Mann-Whitney U test and binomial logistic regression were utilized for hypothesis testing.

**Results:** Majority of 87 included patients were male. Indigenous ancestry had the highest prevalence in both cohorts. Methamphetamine use relapse rates were 71% higher in the other antipsychotic cohort compared to the clozapine users cohort ( $p=0.008$ ). The odds ratio for complete abstinence for ‘clozapine’ versus ‘other antipsychotic(s)’ was 2.80 (1.03-7.63,  $p=0.04$ ).

**Conclusion(s):** Clozapine treatment was associated with significant reduction in relapse rates to methamphetamine use and higher odds of remaining abstinent in treatment-resistant SSD-SUD versus other antipsychotic medications.

### Evaluating the Incidence of Hypoglycemia among Hyperkalemic Patients Treated with Insulin in the Emergency Department at Trillium Health Partners (THP)

Naccarato S<sup>1</sup>, Beaman A<sup>1</sup>, Hammond E<sup>1</sup>

<sup>1</sup>Pharmacy Department, Trillium Health Partners, Mississauga, ON

**Background:** Management of hyperkalemia with IV insulin is associated with a 5-28% risk of hypoglycemia (blood glucose (BG) < 4 mmol/L) in admitted patients and 17-19% risk in Emergency Department (ED) patients. Untreated hypoglycemia can extend a patient’s hospital stay and increase morbidity and mortality.

**Objectives:** We aimed to determine the incidence of hypoglycemia in hyperkalemic patients receiving 10 units IV insulin using the THP Adult ED Hyperkalemia Order Set (OS), as well as evaluate factors associated with hypoglycemia, and assess the 3-hour BG monitoring requirements from the OS.

**Methods:** A retrospective chart review of eligible patients administered insulin via the OS from January 1 to December 31, 2021 were identified through an electronic medical record report. Administrations were categorized into three cohorts (none, moderate (BG 2.8 to 3.9 mmol/L) or severe (BG < 2.8 mmol/L) hypoglycemia) to allow for comparison of outcomes by group.

**Results:** 197 insulin administrations in 181 adult patients were evaluated. The overall incidence of hypoglycemia was 24% (48/197) with 15 administrations (7.6%) resulting in a severe event. The proportion of hypoglycemic events that occurred more than 3 hours after insulin administration was 31%. Factors associated with hypoglycemia identified for future study included female sex, lower body weight, chronic kidney disease and lack of pre-existing diabetes.

**Conclusions:** Hypoglycemia incidence in THP ED was slightly higher than literature expectations. These findings will inform OS improvements such as extended BG monitoring. Future studies may identify high-risk patients who would benefit from alternative dosing and perform subgroup analysis to determine the statistical relationship between specific variables and hypoglycemia.

For the table that goes with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>

### Evaluation of Guideline Directed Medical Therapy Use in Outpatients Living with Heart Failure with Reduced Ejection Fraction

Siddiqui M<sup>1</sup>, Yeung C<sup>1</sup>, Baran A<sup>1</sup>, Reid B<sup>1</sup>, Kosar L<sup>2</sup>, Albers L<sup>1</sup>, McVannel T<sup>1</sup>

<sup>1</sup>Saskatchewan Health Authority, Regina Area, SK

<sup>2</sup>Saskatchewan Health Authority, Saskatoon Area, SK

**Background:** Pharmacotherapy is the cornerstone of treatment of heart failure with reduced ejection fraction (HFrEF) and major cardiac societies define guideline directed medical therapy (GDMT) as four foundational medications: renin angiotensin inhibitor (RASi), a beta blocker (BB), a mineralocorticoid receptor antagonist (MRA), and a sodium glucose transport 2 inhibitor (SGLT2i). Despite strong recommendations for use of GDMT in HFrEF, current practice alignment is unknown.

**Objectives:** Determine the proportion of patients prescribed GDMT for HFrEF, describe doses achieved, documented rationale limiting the optimization of GDMT, documented pharmacist activities between multidisciplinary heart function clinic (HFC) visits, and heart failure hospitalizations and emergency department(ED) visits in 2021.

**Methods:** Retrospective review of medical records for 270 patients of the Regina HFC with HFrEF as of December 31, 2021.

**Results:** Of the 129 patients included, 61 (47.3%) were on optimized GDMT, accounting for documentation of appropriate utilization of foundational therapies at target or maximally tolerated doses. Specifically, 82.2% (106/129), 80.6% (104/29), 79.1% (102/129), 74.4% (96/129) were optimized on RASi, MRA, BB, and SGLT2i, respectively. Documented rationale was not available in 35% (38/106) of instances of suboptimal utilization and 42% (60/144) of instances of suboptimal dosing. When documented, the most common rationale included intolerance to medication (33%, 35/106) and dose increases (56.6%, 83/144). A total of 553 pharmacist activities outside multidisciplinary clinic visits were documented in 58.9% (76/129) of patients. In total, 16 patients (12.4%, 16/129) were admitted to hospital and/or ED 31 times for HFrEF-related events in 2021.

**Conclusion:** Although many patients are receiving the benefits of multidisciplinary care at the Regina HFC, there remains a treatment gap in the utilization of GDMT for HFrEF. These findings inform strategies to improve clinic processes, including efficient identification of patients requiring optimization of GDMT, who would benefit the most from multidisciplinary care.

### Evolution of the Conformity of the Drug Use Circuit on Healthcare Units and Outpatient Clinics of a Mother-Child University Healthcare Center

Monnier A<sup>1</sup>, Jacolin C<sup>1</sup>, Atkinson S<sup>1</sup>, Bussi eres JF<sup>1,2</sup>

<sup>1</sup>Unit  de Recherche en Pratique Pharmaceutique, D partement de pharmacie, CHU Sainte-Justine, Montr al, QC

<sup>2</sup>Facult  de pharmacie, Universit  de Montr al, Montr al, QC

**Background:** The drug use circuit is complex and encompasses many steps. Pharmacy departments are responsible for maintaining a safe drug use circuit that allows for quality patient care.

**Objectives:** To assess the conformity of the drug use circuit on patient care units and outpatient clinics and to compare it for 2019 and 2022.

**Methods:** This descriptive, observational, and cross-sectional study was conducted in a mother-child university healthcare center from 07/15/2019-07/24/2019 and 09/09/2022-10/13/2022. A standardized electronic tool comprising 8 themes and 25 criteria was used for patient care units and 7 themes and 19 criteria for outpatient clinics. Two pharmacy residents scored criteria by direct observation as: conform with/without recommendations, not conform or non-applicable. A Chi-2 was used to compare both years.



**Results:** Respectively, in 2019 and 2022, 17 and 21 patient care units and 30 and 33 clinics were audited. The conformity varied from 23.5%-100% per criteria. The overall conformity was respectively 82.5±17.4 in 2019 and 74.0±18.5% in 2022 on patient care units and 84.3±14.2 and 82.6±19.6% in outpatient care units. On patient care units and in outpatient clinics, respectively, 76.0% (19/25) and 85.7% (12/14) of criteria had a conformity rate superior to 75% in 2019, compared with 52.0% (13/25) and 72.2% (13/18) in 2022. The conformity was significantly reduced between 2019 and 2022 for two criteria: 88.9% (16/18) of patient care units did not have expired drugs in 2019, versus 52.6% (5/11) in 2022 ( $p=0.029$ ); 75.0% (18/24) of outpatient clinics had a container for pharmaceutical waste in 2019 compared with 35.7% (9/24) in 2022 ( $p=0.019$ ).

**Conclusion:** A reduction in conformity of the drug use circuit was observed between 2019 and 2022. The results of this repeated audit was used as an opportunity to provide feedback to the teams in order to maintain a safe drug circuit.

### Evolution of the Speed of Reading and Summarizing Articles on the Roles and Impacts of Pharmacists

Martel-Côté N<sup>1</sup>, Monnier A<sup>1</sup>, Jacolin C<sup>1</sup>, Côté-Sergerie C<sup>1</sup>, Bussi eres JF<sup>1,2</sup>  
<sup>1</sup>Pharmacy Practice Research Unit, Pharmacy Department, CHU Sainte-Justine, Montr eal, QC

<sup>2</sup>Faculty of Pharmacy, Universit e de Montr eal, Montr eal, QC

**Background:** Healthcare professionals are exposed to a steady stream of new knowledge and articles. Good fast and efficient reading skills can help to better process this information. We hypothesized that reading time decreases with exposure to an article type.

**Objectives:** Evaluate the speed of reading and summarizing articles on the roles and impacts of pharmacists.

**Methods:** Descriptive and prospective study. Four research assistants updated the Impactpharmacie platform which summarizes articles describing the role and impact of pharmacists. In addition, they noted the number of pages and the time for reading and entering each article in the platform. We calculated the average reading time (h:min:sec) by page per type of article (i.e. article vs systematic reviews/meta-analysis), the average reading time per page per quartile and the slope describing the evolution of reading and typing speed over the articles read.

**Results:** A total of 186 articles were read and entered; only 164 had exploitable data for reading time (159 articles, 25 meta-analyses or systematic reviews) in the summer of 2022. The average reading time was 1h27±24min per article (min 30 min, max 3h30). The reading time per page was lower for systematic reviews/meta-analysis (10min58±4min42 vs 4min22±1min58). For studies, the average reading time per page per quartile decreased from 12min37±5min39 (1st quartile) to 11min56±4min42 (2nd quartile) to 10min9±3min55 (3rd quartile) to 9min19±3min20 (4th quartile). A plot of all reading times per page in reading order demonstrates a progressive reduction in reading time for studies ( $y = -9E-05x + 0.0094$ ) and for systematic reviews/meta-analysis ( $y = -9E-05x + 0.0072$ ).

**Conclusion:** Approximately 1h30 per article needs to be planned to maintain the impactpharmacy platform. Other factors such as ease of finding information and the clarity of the study design influenced the reading speed. Our study demonstrates a reduction in reading/summarizing time associated with experience.

### Exploring Key Elements of User Experience in Gamification of Health Profession Education: What We Learned from the Literature

Ezekwemba V<sup>1,2</sup>, Wei W<sup>1,2</sup>, Chen AQH<sup>1</sup>, Garg A<sup>1</sup>, Lau S<sup>1</sup>, Ma E<sup>1,2</sup>, Ho C<sup>1,2</sup>  
<sup>1</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON  
<sup>2</sup>Temerty Faculty of Medicine, University of Toronto, Toronto, ON

**Background:** Serious games (or gamification) in health profession education aims to improve knowledge retention in a more engaging format than traditional teaching and learning methods. Elements of user experience (UX) in game design impact the effectiveness and satisfaction of educational games.

**Objective(s):** The goal of this project is to identify key UX elements in health education gamification to help design educational games related to patient or medication safety topics for pharmacy students and pharmacy professionals.

**Methods:** We completed the first 3 steps of Kern's six-step approach to curriculum development of a patient safety curriculum for health professionals in a previous study. This project is Step 4 of Kern's: Educational Strategies. A structured search on MEDLINE, Science Direct, JSTOR, Web of Science, and IEEE Xplore was performed to locate relevant papers discussing UX elements of games and applications in medical and health profession education. Article titles and abstracts were screened and cross-analyzed by two independent analysts, followed by a thematic and content analysis.

**Results:** We identified 76 articles. Upon screening, 9 articles were included in our subsequent thematic analysis. Key elements of UX in gamification that enhanced game effectiveness and satisfaction included ease of use, clarity, and affordance; realism and authenticity; feedback mechanism; competition and points system; and complexity and challenge.

**Conclusion(s):** Our study identified a series of UX elements that must be considered by educators to design engaging games for health profession students and health practitioners. Patient safety education is an aspect of health education that deserves further interprofessional collaboration and innovations from all health professions, and gamification can be an effective education strategy.

### How Patient-Centred Are Inhaler Device Choices? A Survey of Canadian Prescribers

Frank IR<sup>1</sup>, Falk J<sup>2,3</sup>, Korownyk C<sup>4</sup>, Kolber M<sup>4</sup>, Tejani AM<sup>5</sup>  
<sup>1</sup>Department of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC  
<sup>2</sup>College of Pharmacy, University of Manitoba, Winnipeg, MB  
<sup>3</sup>Department of Family Medicine, University of Manitoba, Winnipeg, MB  
<sup>4</sup>Department of Family Medicine, University of Alberta, Edmonton, AB  
<sup>5</sup>Therapeutics Initiative at the University of British Columbia, Vancouver, BC

**Background:** The choice of inhaler device type is an important consideration in the management of asthma and chronic obstructive pulmonary disease (COPD). There are various devices available in Canada, with differences in how each device needs to be used which may lead to confusion for both prescribers and patients.

**Objectives:** The primary objective was to identify the factors prescribers consider when selecting an inhaler device for patients with asthma and COPD. The secondary objective was to evaluate the ranking of these factors.

**Methods:** An online 10-question survey was developed and distributed to prescribers through email and online platforms. This study included prescribers in a primary care or outpatient setting within Western Canada. Prescribers were free to use their own words when describing the factors they considered important in the two scenarios provided in the survey. The first scenario included an 83-year-old woman with COPD. Whereas the second scenario included a 21-year-old male with asthma. Results were examined in a qualitative and quantitative manner.

**Results:** 148 participants interacted with the survey link. Of these, 82 respondents completed the survey and met the eligibility criteria (estimated response rate was 55%). The most frequently mentioned factor was prescriber experience (51%), cost (41%), ease of use (36%) and patient considerations (30%). In scenario 1, the factor most frequently mentioned was prescriber experience and ease of use. Whereas, in scenario 2, the factor most frequently mentioned was cost. In both scenarios, prescriber experience was ranked highest.

**Conclusion:** Prescriber experience was mentioned most frequently within both scenarios and ranked first by many prescribers. There was less emphasis on patient considerations which may indicate that device choices are not entirely driven by patient-centred factors.

### Improving Precision of Vancomycin Dosing in Neonates Based on Clinical Outcome Evaluation and Population Pharmacokinetics

Chung E<sup>1,2</sup>, Pelle B<sup>2</sup>, Seto W<sup>1,2,3</sup>

<sup>1</sup>The Hospital for Sick Children, Toronto, ON

<sup>2</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

<sup>3</sup>Child Health Evaluative Services, The SickKids Research Institute, Toronto, ON

**Background:** Neonatal sepsis is commonly treated with vancomycin in the neonatal intensive care unit (NICU). Vancomycin dosing remains a challenge due to significant pharmacokinetic variability and unclear vancomycin target range in neonates.

**Objectives:** The main objectives were to determine vancomycin target range associated with clinical outcomes and develop a better dosing strategy to increase probability to reach study-derived target range in the NICU.

**Methods:** This retrospective cohort study included neonates admitted to NICU receiving intravenous vancomycin. A population pharmacokinetic (popPK) model was derived and validated using nonlinear mixed effects modelling. The associations between vancomycin trough concentrations and persistent/recurrent infections and mortality or acute kidney injury were assessed using logistic regression and classification and regression tree (CART) analyses. Monte Carlo simulations (MCS) were performed to derive optimal dosing regimens.

**Results:** A one-compartment popPK model best described the observed data from 655 vancomycin courses in 448 neonates. A strong association between time to reach target range and composite outcomes was demonstrated ( $p=0.005$ ). A vancomycin trough concentration of  $>10$  mg/L was associated with lower odds of persistent/recurrent infections (adjusted odds ratio: 0.3, 95% confidence interval (CI): 0.09-0.86,  $p=0.023$ ) and  $>15$  mg/L was associated with increased risk of acute kidney injury (adjusted hazard ratio of 2.94, 95% CI: 1.10-7.90,  $p=0.003$ ). A linear relationship between trough and area under the concentration-time curve over 24 hours ( $AUC_{24h}$ ) was observed ( $p<0.0001$ ). CART-derived  $AUC_{24h}$  of 420-650 mg<sup>\*</sup>h/L appeared to be associated with lowest risk of outcomes ( $p=0.025$ ). MCS-derived vancomycin doses showed significant improvement in target attainment.

**Conclusion:** A vancomycin trough target range of 10-15 mg/L was associated with most optimal outcomes in treating neonatal sepsis, which supports using vancomycin trough concentrations for therapeutic drug monitoring in neonates. A vancomycin dosing guideline using loading dose was derived to increase probability of target attainment and time at target in neonates.

#### Encore Presentation

### In-Use Variability of Tacrolimus Concentration in Compounded Suspension for Transplanted Pediatric Patients

Landry ÉK<sup>1</sup>, Djebbar F<sup>1</sup>, Autmizguine J<sup>1,3,4</sup>, Bérubé S<sup>1</sup>, Lebel D<sup>1,2</sup>, Litalien C<sup>1,4</sup>

<sup>1</sup>The Rosalind & Morris Goodman Family Pediatric Formulations Centre, CHU Sainte-Justine, Montréal, QC

<sup>2</sup>Pharmacy Department, CHU Sainte-Justine, Montréal, QC

<sup>3</sup>Department of Pharmacology and Physiology, Université de Montréal, QC

<sup>4</sup>Department of Pediatrics, Université de Montréal, QC

**Background:** Variations of drug concentrations of oral compounded preparations may affect drug safety and efficacy. This is especially significant with drugs known to have a narrow therapeutic index like tacrolimus, an immunosuppressive agent widely used in solid organ transplantation. Stability studies provide guidance on the storage condition of drugs. We suspect that real life use may affect the quality of the formulation.

**Objectives:** To measure tacrolimus concentrations in bottles of compounded suspension stored and handled according to various scenarios mimicking real-world use, and to compare with the expected concentration (0.5 mg/mL  $\pm$  10%). To evaluate presence of microbial contamination over time.

**Methods:** Nine bottles of tacrolimus suspension (150 mL – 0.5 mg/mL) were prepared by the hospital pharmacy and subjected to the conditions and analyses shown in Table 1. We simulated patient use and measured some aliquots using a validated ultraviolet high-performance liquid chromatography assay. Samples for microbial analysis were inoculated on agar allowing bacterial and fungal growth for 14 days.

**Results:** Two (22%) of the 9 bottles prepared had concentration less than 0.45 mg/mL. Of the 6 bottles sampled twice daily over 28 days, 4 (67%) were below 0.45 mg/mL on day 7 and 5 (83%) on days 14, 21 and 28. No microbial growth was detected up to day 56.

**Conclusion:** Oral drug compounding has many limitations over commercially available products. The concentration of a compounded formulation of tacrolimus can be further affected by real life use. This should be considered by clinicians in their evaluation of patients with a suboptimal response to a compounded medication.

For the table that goes with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>

### Patients' Beliefs About Their Cardiovascular Medications After Acute Coronary Syndrome

Zhou L<sup>1</sup>, Wang EHZ<sup>1,2</sup>, Chua D<sup>1,2</sup>, Loewen P<sup>1</sup>, Barry A<sup>1,3</sup>

<sup>1</sup>Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC

<sup>2</sup>Lower Mainland Pharmacy Services, St. Paul's Hospital, Vancouver, BC

<sup>3</sup>Lower Mainland Pharmacy Services, Jim Pattison Outpatient Care and Surgery Centre, Surrey, BC

**Background:** Adherence to secondary preventive pharmacotherapy after an acute coronary syndrome (ACS) is generally poor and associated with increased risk of recurrent cardiovascular events and mortality. Patients' beliefs about their medications are a strong predictor of intentional medication nonadherence. The Beliefs About Medicines Questionnaire (BMQ) is a validated tool that has been correlated with adherence.

**Objective:** To assess patients' beliefs about their cardiovascular prevention medications post-ACS using the BMQ and self-reported adherence using the Medication Adherence Report Scale-5 (MARS-5) during their hospitalization and 4 weeks after discharge.

**Methods:** This was a prospective observational study of adult patients admitted with ACS to St. Paul's Hospital in Vancouver, BC from May-August 2022. The BMQ and MARS-5 were administered in hospital and 4 weeks after discharge. Patients with a type II myocardial infarction or

those unable to communicate in English were excluded. The primary outcome was change in BMQ post-discharge compared to in-hospital.

**Results:** In total, 43 participants completed the in-hospital questionnaires and 25 completed the 4-week follow-up. Mean age was 66 years, 74% were male, and 74% were white. Most presented with a non-ST-segment elevation ACS (67%) and reported taking all five post-ACS medications at 4 weeks (76%). There was no significant difference in the BMQ Necessity-Concerns Differential (5.5 vs 4.5,  $p=0.27$ ) or MARS-5 (23.3 vs 23.7,  $p=0.17$ ) from discharge to 4 weeks, or the BMQ General-Harm, General-Overuse, and Specific-Concern subscales. However, the BMQ Specific-Necessity subscale decreased significantly from discharge to 4 weeks (19.3 vs 18.1,  $p=0.02$ ).

**Conclusions:** Participants held favourable beliefs about their post-ACS medications with high self-reported adherence, which were largely unchanged from hospitalization to 1 month after discharge; however, beliefs about the necessity of these medications declined significantly. Follow-up education about the benefits of secondary prevention medications may be necessary to reduce the risk of nonadherence in ACS patients.

### Phenobarbital Alone or as Adjunct vs Benzodiazepine Therapy for Alcohol Withdrawal Syndrome in Critical Care – A Retrospective Cohort Study

Su K<sup>1</sup>, Shah K<sup>2,3</sup>, Stabler S<sup>2,3</sup>, Crowe S<sup>3</sup>, Mitra A<sup>3,4</sup>

<sup>1</sup>Department of Pharmacy, Royal Columbian Hospital, Vancouver, BC

<sup>2</sup>Department of Pharmacy, Surrey Memorial Hospital, Surrey, BC

<sup>3</sup>Department of Critical Care, Surrey Memorial Hospital, Surrey, BC

<sup>4</sup>Division of Critical Care Medicine, Department of Medicine, University of British Columbia, Vancouver, BC

**Background:** Benzodiazepines based protocols have long been the mainstay of managing alcohol withdrawal (AWS). There has been increased interest in using phenobarbital in AWS given its unique pharmacological properties.

**Objectives:** The objectives of this study were to evaluate efficacy and safety of phenobarbital use for AWS compared to standard benzodiazepine therapy and to characterize the prescribing pattern for phenobarbital at Surrey Memorial Hospital.

**Methods:** This is a retrospective cohort study of adult patients admitted to Critical Care Units with a primary diagnosis of AWS, between January 1st, 2017 and January 31st, 2022. The exposure group included patients who received at least one dose of phenobarbital as monotherapy or adjunct therapy and the controlled group included patients who received benzodiazepine therapy. The primary outcome was Critical Care length of stay (LOS). The secondary outcomes were hospital LOS, mechanical ventilation, adverse events, and characterization of phenobarbital prescribing pattern.

**Results:** A total of 36 patients were included in the phenobarbital group and 59 patients in the benzodiazepine group. No statistically significant difference was found for Critical Care LOS (2.5 vs. 2.0 days,  $p=0.73$ ). No difference was found in secondary outcomes of hospital LOS (7.7 vs. 7.0 days,  $p=0.65$ ) or mechanical ventilation (6% vs. 14%,  $p=0.22$ ). No statistically significant difference was observed in safety parameters, albeit more patients in the benzodiazepine group experienced at least one episode of reduced heart rate (34% vs. 19%) and decreased respiratory rate (20% vs. 8%). In the phenobarbital group, cumulative dose was 573mg, 25% of patients received only one dose, and 39% of patients received a loading dose ranging from 240 to 260mg.

**Conclusions:** Phenobarbital adjunctive therapy in the management of AWS in Critical Care was not associated with a reduction of Critical Care LOS. No significant difference was observed in adverse events compared to benzodiazepine treatment.

### Podcast on Quality Improvement and Leadership for Early Career Healthcare Professionals

Ho C<sup>1</sup>, Chan S<sup>1</sup>, Yao A<sup>1</sup>, Amirabadi V<sup>1</sup>, Zhang C<sup>1</sup>, Tabassum N<sup>1</sup>, Chen A<sup>1</sup>

<sup>1</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

**Background:** Podcasts have grown rapidly as a platform for providing engaging and entertaining educational content to healthcare professionals and health profession learners. They can be considered as a resource to complement traditional didactic-based continuing professional development (CPD) on quality improvement and leadership.

**Objective(s):** The objective of the “Leading with Quality” Podcast was to create a virtual resource for early career healthcare practitioners to learn about quality improvement (QI), medication safety, leadership, and business management.

**Methods:** We developed 6 podcast episodes where 7 guest speakers, ranging from faculty members to clinical directors, shared their QI and leadership experiences in higher education, hospital administration, pharmaceutical industry, provincial regulatory authority, and experiential learning. An interview format, along with a 30-minute podcast episode, was maintained to optimize audience engagement. The podcast content included real-life examples and lived experiences from the presenters. We released the episodes on SoundCloud and administered a 10-item online questionnaire to obtain feedback from listeners.

**Results:** A total of 20 responses were collected within a month of dissemination of the online questionnaire. Respondents perceived the podcast episodes to be valuable and relevant and they improved their knowledge about leadership and QI. They would listen to more episodes and recommend existing episodes to other healthcare professionals and learners. A few respondents mentioned that concepts and jargon should be explained at the beginning of the episode to improve clarity, and that some episodes might benefit from dividing into two sessions to allow for more elaboration on the subject matter.

**Conclusion(s):** The “Leading with Quality” Podcast is an accessible educational resource for healthcare professionals who wish to learn more about QI and leadership. The “Leading with Quality” Podcast will serve as a self-directed and easy-to-access CPD resource to support early career healthcare professionals in learning about QI and lived experiences from healthcare leaders.

### Postsurgical Discharge Prescriptions for Opioid-Naïve Patients in University Teaching Hospitals in Quebec: A Descriptive Analysis

Varin F<sup>1,6</sup>, Marcotte S<sup>1</sup>, Guévremont C<sup>2,6</sup>, Bérard G<sup>3,6</sup>, Marcotte N<sup>4,6</sup>, Michel MC<sup>4,6</sup>, Pelletier E<sup>5,6</sup>, Bally M<sup>1</sup>, Deschênes L<sup>4,6</sup>, Froment D<sup>1,6</sup>, Ovetchkine P<sup>5,6</sup>, Rajan R<sup>2,6</sup>, Farand P<sup>5,6</sup>

<sup>1</sup>Centre hospitalier de l'Université de Montréal, Montréal, QC

<sup>2</sup>Centre Universitaire de Santé McGill, Montréal, QC

<sup>3</sup>Centre intégré universitaire de soins et services sociaux de l'Estrie – Centre hospitalier universitaire de Sherbrooke (CIUSSS de l'Estrie - CHUS), Sherbrooke, QC

<sup>4</sup>CHU de Québec - Université Laval, Québec, QC

<sup>5</sup>CHU Sainte-Justine, Montréal, QC

<sup>6</sup>Programme de gestion thérapeutique des médicaments (PGTM)

**Background:** Opioid overprescription at discharge from surgery could predispose to misuse, addiction and mortality. In some situations, naloxone co-prescription could help reduce mortality. The PGTM performed an assessment of opioid prescriptions provided to patient at discharge after four selected surgeries in Québec's university hospitals.

**Objectives:** Describe prescriptions characteristics (quantity to be issued, nonopioid coanalgesics, partial-fill orders with dispensing interval and

naloxone prescription), assess oral morphine equivalents (OME) to be dispensed and compare it to opioid use during hospital stay.

**Methods:** Retrospective analysis of prescriptions in opioid-naïve adults following one of four selected surgeries (cholecystectomy, pulmonary lobectomy, total knee replacement or intestinal resection) between July 1<sup>st</sup> and December 31<sup>st</sup>, 2019.

**Results:** There was a wide variation of prescribing patterns based on the surgery performed in the 689 identified prescriptions. Quantity to be dispensed was indicated on 98% of prescriptions. Only 34% of prescriptions for more than 30 tablets were divided into partial-fills; 43% of those had a specified dispensing interval between refills. At least one nonopioid co-analgesic was present on most prescriptions (89%) and 34% had two. OME per 24 hours (OME/24h) was 50 mg or more in 39% of prescriptions; none included naloxone. More than one third of prescriptions at discharge was for opioids exceeding 200 OME. Many patients hospitalized for more than two days received a prescription where OME/24h did not correlate with OME from the last 24 hours prior to discharge. For some, it exceeded by two to three-fold what was received in the last 24-hours of hospitalization.

**Conclusions:** Some prescribing characteristics do correspond to good practice principles while others need to be optimized: many patients could have had fewer opioid prescribed, the excess of 200 OME was too frequent and naloxone is not routinely prescribed. Recommendations to improve opioid prescriptions were shared with the surgical units involved.

### Prescribing Patterns and Cardioversion Before and After the Introduction of Vernakalant for Recent-Onset Atrial Fibrillation in an Emergency Room

Poitras R<sup>1,2</sup>, Oros S<sup>2,3</sup>, Lemay M<sup>2,3</sup>, Bellissimo V<sup>1,2</sup>, Germain M<sup>1,4</sup>, Sarrazin JF<sup>2,3</sup>, Méthot J<sup>1,2,4</sup>

<sup>1</sup>Faculté de Pharmacie, Université Laval, Québec, QC

<sup>2</sup>Centre de recherche de l'Institut universitaire de cardiologie et de pneumologie de Québec-Université Laval, Québec, QC

<sup>3</sup>Faculté de Médecine, Université Laval, Québec, QC

<sup>4</sup>Département de pharmacie, Institut universitaire de cardiologie et de pneumologie de Québec-Université Laval, Québec, QC

**Background:** Atrial fibrillation (AF) is an arrhythmia frequently encountered in the emergency department (ED). Vernakalant, an antiarrhythmic with preferential action on the atria and shorter cardioversion time compared to other pharmacological agents, was introduced at our ED in autumn 2019.

**Objective(s):** The objective of this study was to describe the prescribing patterns and cardioversion of recent-onset AF in the ED before and after the introduction of vernakalant as a pharmacological option.

**Methods:** This descriptive, retrospective study was conducted using the electronic records of patients who consulted with recent-onset AF in the ED of the Institut universitaire de cardiologie et de pneumologie de Québec-Université Laval (IUCPQ-UL). Rates of successful cardioversion, defined as the return to sinus rhythm within 90 minutes of the start of drug administration, were compared between time periods before (n=110) and after (n=99) the introduction of vernakalant.

**Results:** Of 209 patients overall, 159 had electrical cardioversion (conversion rate: 96%), 26 received intravenous (IV) procainamide (conversion rate: 35%), 1 received propafenone orally successfully, 6 received flecainide orally (conversion rate: 17%), 21 received amiodarone IV (conversion rate: 24%) and 26 received vernakalant IV (conversion rate: 69%). With the introduction of vernakalant, there was a drop in the prescription of procainamide (19% vs 5%) and a decrease in electrical cardioversion (66% vs 57%). Of all drugs, vernakalant had the shortest time to cardioversion (median: 9

minutes vs. 46-129 minutes) and its use was associated with shorter stay in the ED (7 hours vs. 11-17 hours), both p<0.05.

**Conclusions:** This study has demonstrated different cardioversion prescription patterns following the introduction of vernakalant in this ED. The superior conversion rate as well as the reduction in both cardioversion time and length of stay with vernakalant support its clinical use.

### Prescribing Trends for Antiestrogens, Bicalutamide, Traditional Oral Cytotoxic Agents, and Oral Immunosuppressants at the Odette Cancer Centre between 2018 to 2022

Jain B<sup>1,2</sup>, Sun C<sup>1</sup>, Singh S<sup>1</sup>, Bugaj V<sup>1</sup>, DeAngelis C<sup>1</sup>, Peragine C<sup>1</sup>

<sup>1</sup>Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON

<sup>2</sup>School of Pharmacy, University of Waterloo, Kitchener, ON

**Background:** Our initial report found a decrease in the number of patients started on traditional oral anticancer medications (OAMs) and immunosuppressants each quarter.

**Objective:** This retrospective study describes prescribing rates for traditional OAMs and immunosuppressants, including anastrozole, exemestane, letrozole, tamoxifen, bicalutamide, capecitabine, chlorambucil, cyclophosphamide, cyclosporine, etoposide, fludarabine, hydroxyurea, isotretinoin, lomustine, mercaptopurine, methotrexate, midostaurin, mycophenolate, procarbazine, tacrolimus, temozolomide, and tretinoin.

**Methods:** Data for prescriptions dispensed between 01 January 2018 and 31 March 2022 were extracted from the Odette Pharmacy's Kroll database. Data was organized to identify new starts (patients starting a new OAM), unique prescriptions, and total prescriptions for antiestrogen agents, bicalutamide, traditional cytotoxics and immunosuppressants. Descriptive statistics and quarterly trends (p<0.05) were calculated for the total sample and each OAM subgroup.

**Results:** Findings are summarized in Table 1. Cytotoxics and/or immunosuppressants were the most frequently started (52%, 2132/4132) and prescribed (63%, 14961/22119). Although a decrease in the number of new starts was found for these agents over time (-1.4 new starts/quarter, p=0.04), the total number of prescriptions processed continued to increase (+7.9 prescriptions/quarter, p=0.03). Bicalutamide was the most frequently started single agent across all OAMs, but the total number of bicalutamide prescriptions and new starts decreased across the study period (-2.3 new starts/quarter, p=0.01; -2.7 prescriptions/quarter, p=0.01). No statistically significant changes in total or new antiestrogen prescriptions were found.

**Conclusion:** All traditional OAMs exhibited a decrease in new starts per quarter, but only bicalutamide and cytotoxics/immunosuppressants trends were statistically significant. Total number of bicalutamide prescriptions processed per quarter decreased over time, whereas other traditional OAMs exhibited static or increasing trends.

For the table that goes with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>

## Prevalence and Patterns of Cannabis Use in Cancer Patients Receiving Systemic Anticancer Treatment: A Prospective Survey Study

Danchuk-Lauzon M<sup>1</sup>, Ha S<sup>1</sup>, Kiss A<sup>2,3</sup>, Park J<sup>1</sup>, DeAngelis C<sup>1,4</sup>

<sup>1</sup>Sunnybrook Odette Cancer Centre, Toronto, ON

<sup>2</sup>Department of Research Design and Biostatistics, Sunnybrook Research Institute, Toronto, ON

<sup>3</sup>Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, ON

<sup>4</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

**Background:** Cannabis is commonly used by cancer patients. There is a need for healthcare providers (HCPs) to engage patients and have open dialogue to ensure safe and effective use of cannabis for medical purposes.

**Objective(s):** Determine the prevalence and patterns of medical cannabis (MC) use among cancer patients.

**Methods:** Participants were adults  $\geq 18$ , able to speak, read and understand English and currently receiving systemic anticancer treatment (SAT) at the Sunnybrook Odette Cancer Centre. There were 2 survey versions, one for patients who had used MC since their cancer diagnosis, and one for those who had not. Survey themes included: demographics/clinical characteristics, attitudes (assessed through a validated survey), prevalence/dosage forms, reasons for use, efficacy, concerns/side effects, access/availability, support, and MC information. Statistical analysis was completed using descriptive statistics, bivariate analyses, and multivariable models.

**Results:** The survey was completed by 234 patients (61% were female). Mean age was 60.2 (SD $\pm$ 13.3; range 22 – 89). The rate of MC use was 19% (95%CI 14%-24%). Of patients who had not used MC (n=190), 35% were interested in trying MC and 72% would consider using MC if recommended by their oncologist/family doctor. Of patients who had used MC (n=44), only 18% were being followed by a clinic/consult service. Eighty percent of patients who had used MC believed it should be more readily available to cancer patients compared to 60% of patients who had not used. Age and sex were not statistically significant predictors of MC use. Patients treated for advanced/metastatic disease were significantly more likely to use MC than patients treated for early/non-metastatic disease (p=0.0007).

**Conclusion(s):** Most cancer patients would trial MC. Disease status may predict decision to use. Few patients who use MC are followed by HCPs. We highlight the need for open dialogue between cancer patients and HCPs regarding MC use.

## Prioritizing Quality Over Quantity: Defining Optimal Pharmacist to Patient Ratios to Ensure Comprehensive Direct Patient Care in a Medical or Surgical Unit

Damji S<sup>1,2</sup>, Dahri K<sup>1,2</sup>, Partovi N<sup>1,2</sup>, Shalansky S<sup>1,3</sup>, Legal M<sup>1,3</sup>

<sup>1</sup>Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC

<sup>2</sup>Department of Pharmaceutical Sciences, Vancouver General Hospital, Vancouver, BC

<sup>3</sup>Department of Pharmaceutical Sciences, Providence Healthcare, Vancouver BC

**Background:** The expanding scope of hospital pharmacists has led to improvements in patient care at the expense of increased workloads. Currently, pharmacist staffing ratios for medical and surgical units have not yet been established in Canada.

**Objectives:** To determine the pharmacist to patient ratio which allows pharmacists to provide comprehensive care to each patient on a medical or surgical unit. To determine which comprehensive care tasks are deliverable in settings where staffing resources are limited.

**Methods:** A multi-phase study was conducted within six hospitals in British Columbia. First, a modified Delphi study was conducted to define and

prioritize the elements of comprehensive pharmaceutical care. Next, a work sampling study was conducted to characterize the pharmacist workflow and to establish the time required and frequency associated with completing each task. Lastly, a validated workforce calculator was used to determine pharmacist to patient ratios.

**Results:** Ten pharmacists participated in the modified Delphi study, finalizing a list of 15 comprehensive pharmaceutical care tasks. Thirty-one pharmacists participated in the work sampling study. The optimal patient care ratio was found to be 1 pharmacist to 13 patients within Internal Medicine Clinical Teaching Units (CTU), 1 pharmacist to 26 patients in Hospitalist or non-CTU units, and 1 pharmacist to 14 patients in surgical units.

**Conclusions:** Ratios of 1 pharmacist to 13 patients in CTU units, 26 patients in Hospitalist or non-CTU units, and 14 patients in surgical units would enable pharmacists to provide comprehensive pharmaceutical care to each patient. Implementing these staffing ratios will serve to increase the consistency of hospital pharmacy services, improve patient outcomes, and improve pharmacist job satisfaction, but could increase healthcare system costs. Further research is needed to validate these staffing ratios in subspecialty units.

## Profile of Antimicrobial Use in a Teaching Hospital

Monnier A<sup>1</sup>, Roy H<sup>1</sup>, Bussi eres JF<sup>1,2</sup>

<sup>1</sup>Unit  de Recherche en Pratique Pharmaceutique, D partement de pharmacie, CHU Sainte-Justine, Montr al, QC

<sup>2</sup>Facult  de pharmacie, Universit  de Montr al, Montr al, QC

**Background:** In its Required Organizational Practices, Accreditation Canada requires the presence of an antimicrobial stewardship program to ensure the optimal use of medications. Testing for compliance includes the need to periodically verify usage and share this data with clinicians.

**Objectives:** Describe the profile of antimicrobial use in a teaching hospital.

**Methods:** This is a descriptive study. All antimicrobial consumption data from April 1<sup>st</sup>, 2021 to March 31<sup>st</sup>, 2022 were extracted from the electronic health record. From these data, the number of days of therapy (DOT) was calculated globally and by antimicrobial (n=95). Subsequently, ratios of DOT/1000 patient days were calculated globally, by class (i.e. antibiotics, antivirals, antifungals, others) and by care unit. Were also calculated the share of DOT according to the three groups of the World Health Organization AWaRe classification.

**Results:** A total of 70527.0 DOT and 672.5 DOT/1000 patient days were calculated in 2021-2022, compared to 67578.0 DOT and 696.6 DOT/1000 patient days in 2020-2021. The number of DOT/1000 patient days was 550.8 for all antibiotics, 46.5 for all antivirals, 67.9 for all antifungals and 7.3 for all others. The ratio varied by antimicrobial used (e.g., 0.02 as minimum value (ribavirine) to 77.5 as maximum value (piperacillin-tazobactam)). It also varied by care unit (e.g. 2.30 as minimum value in psychiatry and 336.9 as maximum value in oncology). According to the AWaRe classification applicable to 52 of our antimicrobials, 34.6% (18/52) of the DOTs referred to Access group, 53.8% (28/52) to Watch group and 11.5% (6/52) to Reserve group.

**Conclusion:** There are relatively few pediatric published data from hospitals on the use of antimicrobials. Antimicrobial stewardship is based on an individual activity targeted by prescription as part of the care provided to the patient as well as global surveillance to comment on the evolution of practices within a setting.

## Profile of the Data Available on Impactpharmacie Relating to the Roles and Impacts of Pharmacists

Monnier A<sup>1</sup>, Jacolin C<sup>1</sup>, Martel-Côté N<sup>1</sup>, Côté-Sergerie C<sup>1</sup>, Bussi eres JF<sup>1,2</sup>  
<sup>1</sup>Pharmacy Practice Research Unit, Pharmacy Department, CHU Sainte-Justine, Montr al, QC

<sup>2</sup>Faculty of Pharmacy, Universit  de Montr al, Montr al, QC

**Background:** There are a growing number of published studies on the roles and impacts of community and hospital pharmacists in the literature. Our research team has been maintaining a platform that showcases these studies for a decade.

**Objectives:** Describe the profile of the data available on Impactpharmacie relating to the roles and impacts of pharmacists.

**Methods:** Descriptive study. Based on the data from the platform and the injection of 186 new articles in the summer of 2022, we extracted a profile of the summary sheets available. These articles were categorized according to 40 pharmaceutical activities, 29 diseases/clinical conditions and 28 patient care programs.

**Results:** As of November 2022, the Impact Pharmacy platform included 3,250 study summaries describing the roles and impacts of pharmacists, published from 1990 to the present day. The studies were cross-sectional (44%,1443/3250 studies), retrospective (38%,1248/3250), prospective (17%,543/3250). These studies came from work conducted in the United States (44%, 1436/3250), in more than one country (9%, 306/3250), Canada (7%,222/3250), France (6%,184/3250), and in several other countries. The studies were conducted in a hospital setting (43%,1398/3250), a community pharmacy (19%,611/3250), an outpatient clinic (17%,561/3250) or in a mixed setting or otherwise (21%,680/3250). A minority of studies had a control group (35%,1130/3250), randomized (18%,587/3250) or blinding (8%,249/3250). The top-3 pharmaceutical activities were: evaluating pharmacotherapy, individual patient counseling, therapeutic education; the top-3 diseases/clinical conditions were: diabetes, infections, hypertension; the top-3 patient care programs were: cardiology, infectious diseases and diabetes/endocrinology. The studies assessed outcome/impact indicators (54%,8392/15580 indicators) and descriptive indicators (46%,7188/15580 indicators).

**Conclusion:** In 30 years, more than 3200 studies have been published describing the roles and impacts of pharmacists. There is a need for more controlled studies to better demonstrate their impact. Updating a platform like Impactpharmacie.org makes it possible to share this data in an educational or professional setting.

## SGLT2 Inhibitors, the Blockbuster Drug of the Early 21st Century

Chan J<sup>1,2</sup>, Chan M<sup>1</sup>

<sup>1</sup>Department of Medicine, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, AB

<sup>2</sup>Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta, Edmonton, AB

**Background:** Sodium Glucose Cotransporter 2 inhibitor (SGLT2i) is a class of drug which were originally intended for decreasing blood glucose in patients with diabetes. However, SGLT2i have recently been shown to offer other impressive clinical benefits.

**Objective(s):** The objective of this review is to summarize the results and clinical benefits from recent diabetes, heart failure, and kidney disease SGLT2i trials.

**Methods:** Major clinical trials involving SGLT2i medications from 2015 to 2022 were reviewed.

**Results:** Recent major SGLT2i landmark trial have demonstrated cardio-renal benefits regardless of diabetes.

**Conclusion(s):** The consistent cardio-renal benefits observed in major landmark trials have led to the rapid adoption of SGLT2i therapy in not only diabetes guidelines but also cardiovascular and renal guidelines.

### Encore Presentation

For the tables that go with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>

## Stability and Compatibility of Bupivacaine and Hydromorphone in PVC and Non-DEHP Bags for 30 Days at 4°C and 25°C

Shead K<sup>1</sup>, Derrick H<sup>1</sup>, Lyons D<sup>1</sup>, Law S<sup>2</sup>, Ma NH<sup>2</sup>

<sup>1</sup>Department of Pharmacy, Alberta Health Services, Edmonton, AB

<sup>2</sup>Department of Pharmacy, Sunnybrook Health Sciences Centre, Toronto, ON

**Background:** Studies have demonstrated stability and compatibility of hydromorphone and bupivacaine, but none at hydromorphone concentrations  $\leq 20$ mcg/mL or in non-DEHP bags.

**Objective:** The objective was to evaluate the stability and compatibility of bupivacaine and hydromorphone diluted in 0.9% sodium chloride (NS) and stored in PVC bags and non-DEHP bags for 30 days at 4°C and 25°C.

**Methods:** On day 0, eight PVC and eight non-DEHP bags were prepared with hydromorphone and bupivacaine diluted in NS: bupivacaine 0.5mg/mL and hydromorphone 1.5mcg/mL; bupivacaine 0.5mg/mL and hydromorphone 30mcg/mL; bupivacaine 2.5mg/mL and hydromorphone 1.5mcg/mL; bupivacaine 2.5mg/mL and hydromorphone 30mcg/mL. Four bags of each were stored at 4°C and 25°C. Concentration and physical inspection were completed on days 0,2,7,9,14,21,30. Drug concentrations were determined using a validated stability-indicating liquid chromatographic method with UV detection. Chemical stability was calculated from lower limit of the 95% confidence interval of the degradation rate and time to achieve 90% of the initial concentration.

**Results:** The analytical method measured bupivacaine and hydromorphone specifically, accurately (deviations from known averaged 1.03% and 2.72%), and reproducibly (replicate error within days averaged 0.21% and 0.28%, and between days averaged 0.67% and 1.22%). Bupivacaine and hydromorphone retained  $\geq 96\%$  of their initial concentrations for all concentration combinations, temperatures and container. The calculated chemical stability exceeded the 30 day study duration for all concentration combinations. Analysis of variation revealed day ( $p < 0.01$ ), temperature ( $p = 0.02$ ), and initial concentration ( $p < 0.01$ ) affected percent remaining of bupivacaine but container did not ( $p = 0.91$ ). For hydromorphone, day ( $p < 0.01$ ) and initial concentration ( $p < 0.01$ ) affected percent remaining while temperature ( $p = 0.19$ ) and container ( $p = 0.12$ ) did not. The study was capable of detecting a 1.05% difference in percent remaining due to the variables.

**Conclusion:** The concentration combinations of bupivacaine and hydromorphone were stable and compatible for 30 days when stored in PVC or non-DEHP bags at 4°C and 25°C.

## Stability of 5-Fluorouracil at 4°C, 25°C and 33°C Stored in Nipro SureFuser+ Ambulatory Balloon Infusers

Ma NH<sup>1</sup>, Charbonneau LF<sup>1</sup>, Law S<sup>1</sup>, Walker SE<sup>1,2</sup>

<sup>1</sup>Department of Pharmacy, Sunnybrook Health Sciences Centre, Toronto, ON

<sup>2</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

**Background:** Elastomeric infusion devices can facilitate home infusions but require stability studies to ensure the stability of the drug during storage and administration.

**Objective:** To evaluate the stability of 5-fluorouracil undiluted (50mg/mL) or prepared with 5% dextrose (D5W) to concentrations of 5 and 30mg/mL and stored in Nipro SureFuser+ Ambulatory Balloon Infusers for 60 days at 4°C and 25°C and 7 days at 33°C.

**Methods:** On day 0, 250mL infusers were each filled with undiluted 5-fluorouracil, 5mg/mL 5-fluorouracil in D5W, or 30mg/mL 5-fluorouracil in D5W. Four infusers of each concentration were stored at 4°C, 25°C, and 33°C. Physical inspection and concentration analysis were completed on days 0,2,4,7,14,21,28,42,49,60 for infusers stored at 4°C and 25°C; and days 0,1,2,3,4,7 for infusers stored at 33°C. 5-fluorouracil concentrations were determined using a validated, stability-indicating liquid chromatographic method with UV detection. Chemical stability was determined using the intersection of the lower limit of the 95% confidence interval of the observed degradation rate and time to achieve 90% of the initial concentration.

**Results:** The analytic method separated degradation products from 5-fluorouracil such that the concentration was measured specifically, accurately (deviations from known averaged 1.15%), and reproducibly (within day replicate error averaged 0.34%, between day error averaged 0.88%). Solutions retained ≥97% of their initial concentration for all concentrations and temperatures and no degradation products were seen. Infusers with undiluted 5-fluorouracil stored at 4C had precipitation on day 60, but were resolubilized after storage at room temperature. Multiple linear regression identified differences in percent remaining due to day (p<0.01), concentration (p=0.01) but not temperature (p=0.35). The study was capable of detecting a <1% difference in percent remaining due to the variables.

**Conclusion:** 5-fluorouracil stored in Nipro SureFuser+ Ambulatory Balloon Infusers is stable for ≥60 days when stored at 4°C and 25°C, and ≥7 days when stored at 33°C.

## Status of Reporting of Adverse Events Occurring in a Tertiary Cardiopulmonary and Metabolic Healthcare Center: Preliminary Results

Lavallée M<sup>1,2</sup>, Corbin S<sup>1,2</sup>, Pradhan P<sup>3</sup>, Blonde Gueffack L<sup>3</sup>, Thibault M<sup>2</sup>, Méthot J<sup>1,2</sup>, Bérard A<sup>4,5</sup>, Piché ME<sup>2,6</sup>, Escobar Gimenes FR<sup>2</sup>, Leclerc J<sup>1,2</sup>

<sup>1</sup>Faculty of Pharmacy, Université Laval, Québec, QC

<sup>2</sup>Centre de recherche, Institut universitaire de cardiologie et de pneumologie de Québec-Université Laval, Québec, QC

<sup>3</sup>Anatomy department, Université du Québec à Trois-Rivières, Trois-Rivières, QC

<sup>4</sup>Centre de recherche du Centre Hospitalier Universitaire Ste-Justine, Montréal, QC

<sup>5</sup>Faculty of Pharmacy, Université de Montréal, Montréal, QC

<sup>6</sup>Faculty of Medicine, Université Laval, Québec, QC

<sup>7</sup>Faculty of Nursing, University of São Paulo, São Paulo, Brazil

**Background:** Drug-related adverse events (AEs) reporting is essential to ensure continuous commercialized drug safety assessment. For Health Canada to assess the risk-benefit ratio of drugs available to the population, AEs potentially associated with a drug must be reported to health authorities. The proportion of AEs is currently reported to Health Canada remains unknown. However, since December 2019, Vanessa's Law requires the declaration of all serious AEs occurring in hospitals.

**Objective:** Quantify serious AEs that have been or should have been reported to Health Canada.

**Methods:** A descriptive cohort study is underway at the Quebec Heart and Lung Institute, a tertiary academic cardiopulmonary and metabolic healthcare center. The study includes 1,000 randomly selected patients (250 patients/year) who have been hospitalized between January 1, 2018 and December 31, 2021. Descriptive analyzes (median [minimum-maximum]; proportions) were used to characterize the sample (sex, age, etc.) and the drug-related AEs that occurred.

**Results:** Among the 301 files identified (125: 2018, 139: 2019 and 27: 2020), the median age of patients is 70 years old [minimum: 21-maximum: 93] and 44% were female. During their hospitalization, the patients consumed between 1 and 48 different drugs (median: 13). In addition, the median number of AEs per patient is 5 [0-40]. Among the 2,043 AEs identified, 86 are considered serious. During the studied period, no AEs (serious or not) (0%) have been reported to Health Canada.

**Conclusion:** According to our preliminary data, AEs that occurred in our academic healthcare center mainly from 2018 to 2019 were largely under-reported. Data extraction continues for the following cohorts. If the Vanessa's Law is not an effective solution for improving AE reporting in our jurisdiction, other possible solutions will have to be thought and developed to improve commercialized drug safety for the Canadian population.

## Surgical Antimicrobial Prophylaxis (SAP) Decision-Making and Disagreement in the Operating Room: A Thematic Analysis

Ghataura J<sup>1</sup>, Jeffs L<sup>2,3,4,5</sup>, McIntyre M<sup>1,2</sup>

<sup>1</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

<sup>2</sup>Antimicrobial Stewardship Program, Sinai Health/University Health Network, Toronto, ON

<sup>3</sup>Lunenfeld-Tanenbaum Research Institute, Sinai Health, Toronto, ON

<sup>4</sup>Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, ON

<sup>5</sup>Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON

**Background:** Antimicrobial prophylaxis decision-making in the operating room relies on joint decision-making by anesthesiologists and surgeons. Although team-based decisions are common in medical care, joint responsibility for the same decision shared concurrently between disciplines is fairly unique and may lead to areas of indecision or conflict and ultimately less appropriate prophylaxis.

**Objective:** The purpose of this study was to evaluate drivers of decision-making and conflict around SAP between surgeons and anesthesiologists.

**Methods:** Semi-structured interviews were conducted with anesthesiologists and surgeons practicing at Mount Sinai Hospital in Toronto, Ontario. Thematic analysis was applied in an effort to reach saturation.

**Results:** Three themes were extracted from the six semi-structured interviews conducted. **Theme 1:** There is frequent conflict in terms of the assessment and management of penicillin allergies prior to surgery. The conversation surrounding the cross-reactivity of penicillin and cefazolin persistently results in antimicrobial prophylaxis discussions between both clinicians. **Theme 2:** There is a lack of awareness of local resources and guidelines surrounding emergent surgeries, SAP weight-based dosing and redosing intervals, resulting in uncertainty and heterogeneity in practice. **Theme 3:** There is variability in SAP recommendations across institutions and between clinicians. Discussions show that although policies and guidelines are situated in the operating rooms, unique experiences and preferences result in poor adherence to SAP policy.

**Conclusion:** Surgical antimicrobial prophylaxis decision-making is more than following the algorithm. Understanding the multiple unique and complex drivers of prophylaxis decision-making behaviour is vital to improving the delivery of optimal patient care.

## Survey of CHEO Staff on the Use of Epinephrine and the End-User Experience with Removal of Ratios from Epinephrine Products: A Quality Improvement Pilot

Blanc A<sup>1</sup>, Varughese N<sup>1</sup>, Cameron J<sup>1</sup>

<sup>1</sup>Department of Pharmacy, Children's Hospital of Eastern Ontario, Ottawa, ON

**Background:** In 2016, Pharmaceutical companies have removed ratios from the labelling of single-entity injection drug products like epinephrine. This follows reports of multiple incidents report related to the potential confusion with ratios expression by ISMP. However, hospital pharmacies have been requested by clinical staff to add ratios back on labelling.

**Objective:** The objective of this survey conducted from November 16<sup>TH</sup> 2021 to December 6<sup>th</sup> 2021 was to find out how healthcare professionals at CHEO who are front-line users of epinephrine feel with respect to their current habits when they need to use epinephrine.

**Methods:** Healthcare workers who work in any area of the hospital were surveyed anonymously via REDCap on their use of epinephrine in emergency settings. Questions assessed the training received on epinephrine use, the issues encountered when administering epinephrine, and the overall acceptance of the current standard of no-ratio epinephrine use.

**Results:** 67 employees responded to the survey (28% physicians, 52% nurses, 18% pharmacists, and 2% respiratory therapists). 36% of respondents indicated they had PALS/ACLS training with ratios (74% of physicians, 27% of nurses, and 8% of pharmacists). There were 22.4% of respondents who did not have training on ratios. A total of 28.4% of respondents indicated they would like ratios adding back to labelling (17.2% did not want ratios added back and 22.3% did not have an opinion). Physicians were the most likely to want ratios added back (50%), followed by nurses (36%), then pharmacists (14%). A total of 12% of respondents indicated they have had at least 1 medication administration problem with current labelling (75% physicians, 13% care facilitators, and 12% pharmacists).

**Conclusion(s):** This survey highlights the challenges of implementing new regulations without a global strategy to engage all key stakeholders in enacting changes and safe practices in a sustainable way.

## Sustainability in Hospital Pharmacy: A Quality Improvement Pilot to Assess Awareness to "Go Green"

Blanc A<sup>1</sup>, Varughese N<sup>1</sup>, Cameron J<sup>1</sup>

<sup>1</sup>Department of Pharmacy, Children's Hospital of Eastern Ontario, Ottawa, ON

**Background:** A new strategy titled 'Kick the Carbon' was initiated in the 2021 Children's Hospital of Eastern Ontario (CHEO) organizational strategy plan with a goal of reducing greenhouse gas (GHG) emissions by 30% from 2019 to 2025.

**Objectives:** Determine awareness of and describe Eco-initiatives that the department of pharmacy can implement to aim to reduce the carbon footprint in hospital pharmacy and contribute to CHEO's organizational strategy.

**Methods:** In a quality improvement initiative, CHEO pharmacy employees (i.e. pharmacists and pharmacy technicians) were invited to complete a cross-sectional survey which was designed to gauge willingness to 'go green' at work, to identify actionable areas of waste, and to assess commuting practices.

**Results:** A total of 15 respondents completed the internal pharmacy survey conducted between March 14<sup>th</sup> -April 7<sup>th</sup>, 2022. Most respondents (73%) were willing to engage in more sustainable practices at work. Approximately 25% indicated they have biked at least once to work and 1 respondent (~5%) indicated biking as a primary commuting method. Respondents indicated the main barriers to implementing green practices at work were cost (26%), complexity (33%), and time (33%). The three largest areas of waste in

hospital pharmacy cited by respondents were single use plastic (36%), lack of awareness of green practices (15%), and lights left on in empty rooms (12%).

**Conclusions:** There was a very high willingness to be part of more sustainable 'go green' practices in hospital pharmacy. There is a need to describe and measure how hospitals can contribute in measurable ways to strategically implement Eco-initiatives.

## Trends in New and Total Prescriptions for Oral Anticancer Medications at the Odette Cancer Centre: A 51-Month Retrospective Study

Jain B<sup>1,2</sup>, Sun C<sup>1</sup>, Singh S<sup>1</sup>, Bugaj V<sup>1</sup>, DeAngelis C<sup>1</sup>, Peragine C<sup>1</sup>

<sup>1</sup>Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON

<sup>2</sup>School of Pharmacy, University of Waterloo, Kitchener, ON

**Background:** The Odette Cancer Centre is the second largest cancer centre in Canada. Although various publications discuss trends in intravenous chemotherapy use, little data describing use of oral anticancer medications (OAMs) is available.

**Objective:** Describe use of OAMs at the Odette Cancer Centre from the first quarter of 2018 to the first quarter of 2022.

**Methods:** Data for dispensing events between 01 January 2018 and 31 March 2022 were extracted from the Odette Pharmacy's Kroll database. Data was organized to identify new starts (patients starting a new OAM), unique prescriptions, and total prescriptions for all OAMs, traditional OAMs (anti-estrogens, bicalutamide, traditional cytotoxic agents, and immunosuppressants), and modern OAMs (non-traditional OAMs). Descriptive statistics and quarterly trends (significance level of <0.05) were generated for each OAM group.

**Results:** Findings are summarized in Table 1. Over 60 thousand OAM prescriptions were processed across the study period. Although the majority of prescriptions dispensed were for modern OAMs (63%), the majority of new starts were for traditional agents (59%). The number of OAM prescriptions processed increased by 79.6 each quarter (p<0.001), driven by prescriptions for modern OAM agents (+76.4 prescriptions/quarter, p<0.001). The number of new OAM starts decreased by 5.2 each quarter (p=0.03), driven by a reduction in traditional OAM starts (-5.3 new starts/quarter, p=0.02). No change in the number of new starts per quarter was found for modern OAMs.

**Conclusion:** Although fewer patients are started on OAMs each quarter, the total number of OAM prescriptions dispensed each quarter is on the rise and driven by modern OAMs.

For the table that goes with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>

## Use of Podcasts in Healthcare: A Literature Review

Bertrand L<sup>1</sup>, Bourdeau K<sup>1</sup>, Gagnon-Lépine S<sup>1</sup>, Karamé C<sup>1</sup>, Lebel D<sup>1</sup>, Bussièrès JF<sup>1,2</sup>

<sup>1</sup>Pharmacy Practice Research Unit, Pharmacy Department, CHU Sainte-Justine, Montréal, QC

<sup>2</sup>Faculty of Pharmacy, Université de Montréal, Montréal, QC

**Background:** There are different dissemination tools used in academic or continuing education. The podcast can be used as a broadcasting tool.

**Objectives:** To describe the use of podcasts in healthcare.

**Methods:** Literature review. From Pubmed, the following strategies were used: term "podcast" alone, the combination "podcast AND medicine", "podcast AND healthcare" as well as "podcast AND pharmacy". From Embase, the following strategies have been used: term "podcast" alone, the combination "podcast.mp. or podcast/ AND medicine.mp. or medicine/", the combination "podcast.mp. or podcast/ AND healthcare.mp. or



healthcare/” and the combination “podcast.mp. or podcast/ AND pharmacy.mp. “. Were included articles published in English or French, dealing with the design and/or use of podcasting in the field of health. Articles citing podcasts without describing or evaluating their impact were excluded.

**Results:** Of the 19 articles retained, 12 came from the United States, two from Australia and one respectively from Canada, the United Kingdom, Ireland, Germany or several countries. Types of studies included surveys (n=3), literature reviews (n=7), and studies involving an intervention or evaluation (n=9). Six articles related to drug-related content or target pharmacy students or pharmacists. Podcasts were used as training tools but also as an evaluation tool (e.g. the format of the work to be submitted by students is a podcast). Several studies commented on the quality indicators surrounding the design, choice of content, credibility and dissemination of podcasts. Some studies offered a list of relevant podcasts (eg *Cursiders*, *Flip the script*, the *clinical problem solvers*, *2 Docs talk*). The included studies described the use of podcasts in oncology, obstetrics-gynecology, dermatology and rheumatology.

**Conclusion:** There is little data on the use of podcasts in the field of health including pharmacy. Further work is needed to confirm the usefulness and impact of health podcasts.

## Venous Thromboembolism Prophylaxis Across the Prairie Provinces: Description of Definitions and Unique Populations

Bungard TJ<sup>1</sup>, Lamb DA<sup>2</sup>, Semchuk W<sup>3</sup>, Lowerison J<sup>4</sup>, Thomson P<sup>5</sup> on behalf of the Collaborative Learning on Thrombosis (CLOT) group

<sup>1</sup>Department of Medicine, University of Alberta, Edmonton, AB

<sup>2</sup>Pharmacy Services, Saskatchewan Health Authority, Saskatoon, SK

<sup>3</sup>Pharmacy Services, Saskatchewan Health Authority, Regina, SK

<sup>4</sup>Pharmacy Services, Alberta Health Services, Calgary, AB

<sup>5</sup>Pharmacy Services, Winnipeg Regional Health Authority, Winnipeg, MN

**Background:** Venous thromboembolism (VTE) is the most common preventable cause of hospitalization death, and requires institutional accreditation. Despite this, practices vary related to order sets, unique populations, and clinical bias.

**Objective(s):** To describe VTE prophylactic strategies across varying patient demographics (weights/renal function) and awareness of institutional policies used across prairie provinces.

**Methods:** Electronic survey of pharmacists having general/family medicine institutional practices within Alberta, Saskatchewan and Manitoba in late 2017.

**Results:** Amongst 88 (24.2%) respondents, the majority (60.2%) had practiced >5 years, were working in full time positions (81.8%) as staff pharmacists (94.3%). Most (77.1%) reported that prophylaxis was provided for >75% of patients, with therapy being discontinued at discharge (58.0%) or once mobile (37.5%). The majority (55.7%) lacked a definition for mobility, while activities at home (20.5%) and up to bathroom with walking a defined distance (13.6%) was defined. For normal weight and renal function, agents used were: dalteparin (36.4%), enoxaparin (31.1%), unfractionated heparin (UFH) (15.4%) and tinzaparin (11.3%). For upper body weight cut offs, 50% used kilograms (median 100Kg [range 100-150]), 29.5% used BMIs (median 40 [30-40]) with 86.7% escalating doses with obesity. For lower weight cut offs, 63.6% used Kgs (median 40Kg [30-50]) with 72.3% lowering the dose. For those with CrCl <30mL/min or hemodialysis, most common agents were UFH (55.7% and 65.2%) and enoxaparin (23.5% and 26.3%). The majority (80.7%) used institutional order sets with 56.8% aware of an institutional audit. Medicine and surgery units were most commonly audited with pharmacists most often responsible for the audit.

**Conclusion(s):** Most patients were prophylaxed with enoxaparin or dalteparin unless CrCl <30mL/min or undergoing hemodialysis wherein UFH was used. Despite 80.7% having institutional order sets, mobility was not defined for the majority and some pharmacists identified not having weight cut offs for obese (29.5%) or emaciated (35.2%) patients.

## PHARMACY PRACTICE / PRATIQUE PHARMACEUTIQUE

### A Virtual Interactive Case System Innovation to Support Pharmacist Prescribing for Minor Ailments

Ho C<sup>1,2</sup>, Chen A<sup>2</sup>, Lin W<sup>2</sup>, Lau S<sup>2</sup>, Thakrar S<sup>2</sup>, Tabassum N<sup>2</sup>, Yao A<sup>2</sup>, Tait G<sup>1</sup>

<sup>1</sup>Temerty Faculty of Medicine, University of Toronto, Toronto, ON

<sup>2</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

**Background:** Virtual interactive cases (VICs) have been used as an educational resource for differential diagnosis training in medical students, but they have not been explored in pharmacist prescribing for minor ailments.

**Description:** We aimed to share our experience in the development of 3 VICs to support pharmacist prescribing for minor ailments.

**Action:** We created VICs on minor ailment prescribing for allergic rhinitis, conjunctivitis, and cold sores. Through iterative case writing, reviewing, transcribing, and standard setting to the VIC online environment, we recognized the benefits and challenges when attempting to fully utilize the built-in functionalities of the platform, assuming that a patient may not always be able to explicitly inform the pharmacist the type of minor ailment consultation that is being sought.

**Evaluation:** When developing the patient assessment component of VICs, we embedded 10% relevant or essential questions that a VIC user should ask to rule in or out a differential diagnosis. We included one correct and 6-10 incorrect diagnosis statements to challenge the user on differential diagnosis of the minor ailment. When managing the minor ailment, the user was presented with only 30% appropriate interventions, including pharmacologic and self-care options. A user would be able to solve the case scenario with the correct minor ailment diagnosis if all statements and questions were inspected during patient assessment, but costs and time associated with irrelevant actions taken would be reflected in the VIC final debriefing, informing the user that such clinical encounter was not practically and logistically feasible.

**Implications:** We recognized the core benefits of the VICs are to support and challenge pharmacist knowledge and skills in providing minor ailment prescribing service. The VICs are not meant for educating nor training pharmacists in minor ailment prescribing. VIC is a safe and user-friendly platform to support pharmacist prescribing for minor ailments.

**Encore Presentation**

### Assessment of Sedative-Hypnotic Drug Use to Reduce Risk of Falls in Selected Inpatient Areas of Nova Scotia Health: Results of a Pilot Project

Shaw J<sup>1,2</sup>, VanDerstine C<sup>1,2</sup>, Veinott C<sup>2</sup>, McDonald J<sup>3</sup>, Smith S<sup>3</sup>, Bowles S<sup>1,2</sup>,

Burgess S<sup>1</sup>, Connolly J<sup>1</sup>, Dearing M<sup>1</sup>, Isenor P<sup>2</sup>, Toombs K<sup>1</sup>, Neville H<sup>1</sup>

<sup>1</sup>Pharmacy Department, QEII Health Sciences Centre, Nova Scotia Health, Halifax, NS

<sup>2</sup>College of Pharmacy, Dalhousie University, Halifax, NS

<sup>3</sup>Pharmacy Department, Valley Regional Hospital, Nova Scotia Health, Kentville, NS

**Background:** Sedative-hypnotic drugs (SHDs) are commonly prescribed in hospitalized patients to manage sleep disturbances and anxiety. Older adults are particularly vulnerable to adverse effects of SHDs such as impaired coordination, increasing their risk for falls and fractures.

**Description of Service:** The objective of this project was to assess the feasibility of conducting a structured medication assessment in hospitalized patients to reduce SHD use, and thus falls risk.

**Action:** A standardized medication assessment form evaluating SHD use and fall risk was developed and incorporated into clinical pharmacy practice on 4 pilot units within Nova Scotia Health. For patients prescribed SHDs, the assessment form was completed by a pharmacy student or pharmacist, which gathered patient demographics, fall history and risk factors, SHD use and other fall risk increasing drugs (FRIDs). For each assessment, recommendations were made to the care team and discussed with the patient when possible.

**Evaluation:** Acceptance of recommendations were documented on the assessment form for data collection. A total of 32 patients (mean age 77.5 years) were assessed during the pilot period of August 4 to September 28, 2022. Each pilot unit completed 6 to 10 assessments. Excluding SHDs, patients were prescribed a mean 4.9 concurrent FRIDs, and 59.4% had a history of falls. Twenty-four assessments (75%) resulted in recommendations to stop or reduce the dose of an SHD, of which 20 (83.3%) were accepted. Nineteen of 32 patients (59.4%) had SHDs initiated during their hospital stay. After assessment, 14 recommendations to stop or reduce the dose of the SHD were made and 13 were accepted.

**Implications:** Results indicate that incorporating a structured medication assessment to reduce SHD use and fall risk was feasible and acceptable to inpatient care teams. Pharmacists' attitudes toward the tool and ability to incorporate into clinical practice will be assessed.

#### Encore Presentation

### Developing a Non-formulary Drug Usage Report for the Pharmaceuticals and Therapeutics (P&T) Committee

Ma E<sup>1</sup>, Beaman A<sup>2</sup>

<sup>1</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON  
<sup>2</sup>Trillium Health Partners, Mississauga, ON

**Background:** An often-overlooked tool in formulary management is monitoring and reporting on patterns of non-formulary drug (NFD) usage to the Pharmaceuticals and Therapeutics (P&T) committee, allowing for evaluation of appropriate NFD use and identification of potential targets for formulary review or assessment of best practices. In an environmental scan of hospitals within the Greater Toronto Area, 1 out of 6 hospitals reports NFD usage metrics to the P&T committee, indicating that NFD usage is an area with challenges and opportunity for standardization.

**Description:** As supported by literature, metrics such as the number of NFD therapy initiations or instances of overridden therapeutic-interchange alerts can be reported semi-annually or annually at P&T committee meetings. Additionally, the recent implementation of computerized provider order entry (CPOE) at Trillium Health Partners (THP) improves access to data surrounding medication orders and NFD usage.

**Action:** A report corresponding with metrics from the literature was designed for orders placed from May 1-31, 2022 using data extracted from the CPOE. Successes and challenges were noted for the future implementation of an NFD report relevant to the P&T committee.

**Evaluation:** NFDs comprised 0.54% (1624/303,385) of all orders in the evaluation period. The therapeutic classes with the most NFD orders were blood products and skin preparations. Across THP sites, the emergency departments ordered the greatest number of NFDs, which is expected. We experienced challenges in data quality that required correction, such as the misclassification of formulary status and confusing therapeutic class labeling. Data corrections and further analysis are required to report on the metrics we sought as supported by literature.

**Implications:** This project provides a starting point and lessons learned for THP as well as other CPOE-enabled institutions in developing an evidence-based NFD usage report, which will ultimately aid P&T committees in optimizing safe and effective care.

### Development and Evaluation of an Online Pocket Guide to Quality Improvement

Ho C<sup>1,2</sup>, Chan C<sup>2</sup>, Ma E<sup>1,2</sup>, Wei W<sup>1,2</sup>, Yao A<sup>2</sup>

<sup>1</sup>Temerty Faculty of Medicine, University of Toronto, Toronto, ON

<sup>2</sup>Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON

**Background:** Continuous quality improvement empowers healthcare professionals to optimize patient safety and quality care. A virtual community of practice will facilitate knowledge exchange of quality improvement (QI) initiatives among pharmacy professionals.

**Objective(s):** Our project is aimed to develop and evaluate an infographic-based online Pocket Guide to Quality Improvement (PGQI), which will serve as a preliminary step to build a QI community of practice for pharmacy professionals.

**Methods:** We consulted national and international resources for training healthcare professionals on QI and consolidated into an infographic-based online pocket guide. We pilot tested the PGQI to a convenience sample of pharmacists and pharmacy students in Canada and administered a 14-item online survey to gather their user experience in October 2021.

**Results:** We developed an infographic-based online PGQI, which outlines key concepts in QI. The PGQI is a resource to educate pharmacists and pharmacy students on QI. A total of 20 responses were collected from our user experience online survey. The respondents' primary practice was diversely located in community, hospital, administrative, and regulatory authorities, with representation from six provinces. The length of time to review the PGQI ranged from 5-15 minutes. Users found the materials relevant and easy to understand. Notably, 70% respondents perceived a significant increase in their QI knowledge; 90% would recommend the PGQI to other healthcare professionals; and 65% were interested in planning a QI project in the next 12 months. Many respondents appreciated the effective use of graphics, charts, and visuals to explain and illustrate QI concepts.

**Conclusion(s):** The online PGQI presented QI concepts in an easy-to-read format. It can be easily accessible by pharmacists and pharmacy students who wish to learn more about defining, planning, and conducting a QI project. The PGQI serves as a foundational resource to support a virtual QI community of practice for pharmacy professionals.

#### Encore Presentation

### Health Care Workers' Perceptions of a Pharmacist-Led Collaborative Practice Agreement for the Prescribing of Nirmatrelvir/Ritonavir to Eligible COVID-19 Patients

Sansom B<sup>1</sup>, Adams B<sup>2</sup>, Canales D<sup>3</sup>, Doucette D<sup>4</sup>, Gagnon J<sup>5</sup>, LeBlanc M<sup>6</sup>, Levesque J<sup>4</sup>, Louis F<sup>5</sup>, MacLaggan T<sup>1</sup>, Naylor H<sup>6</sup>, Nurse B<sup>1</sup>

<sup>1</sup>Department of Pharmacy, The Moncton Hospital, Horizon Health Network, Moncton, NB

<sup>2</sup>Department of Pharmacy, Dr. Georges-L.-Dumont University Hospital Centre, Vitalité Health Network, Moncton, NB

<sup>3</sup>Research Services, Horizon Health Network, Saint John, NB

<sup>4</sup>Department of Pharmacy, Horizon Health Network, Moncton, NB

<sup>5</sup>Department of Pharmacy, Horizon Health Network, Fredericton, NB

<sup>6</sup>Department of Pharmacy, Saint John Regional Hospital, Horizon Health Network, Saint John, NB

**Background:** Health Canada approved nirmatrelvir/ritonavir in January 2022 as the first oral treatment of mild-to-moderate COVID-19. Due to

an initial limited supply and the complex nature of prescribing, an innovative approach was required to ensure safe and efficient prescribing, patient access, and reduced healthcare burden. The New Brunswick Pharmacy Assessment Clinic (PAC) was subsequently developed.

**Description:** Sixteen hospital pharmacists joined the PAC utilizing a pharmacist-led collaborative practice agreement (CPA). This entirely virtually-run clinic allowed for remote care provision from any location. Referrals were submitted electronically by government-designated sources and processed entirely by PAC pharmacists, the initial sole prescribers of nirmatrelvir/ritonavir in the province.

**Action:** An online survey study was designed to determine how health care workers involved with PAC perceived the implementation and impact of the innovative care model. Surveys were distributed to PAC pharmacists, CPA physicians, initial community pharmacists eligible to dispense nirmatrelvir/ritonavir, and the Public Health pre-screeners.

**Evaluation:** There were a total of 23 survey participants. Using 5-point Likert scales, 87% of participants felt PAC pharmacist contributions to patient care were significantly valuable, with 82.6% perceiving a very positive impact on safe prescribing. Eighty three percent of participants felt either a good or very good satisfaction level with the PAC model. Prescriptions by PAC pharmacists versus primary care providers were identified as taking significantly less time to review by community pharmacists (90%). The majority of participants (66.6%) felt that virtual care improved patient accessibility, with no change (80%) to perceived job satisfaction. Interviews with a subset of participants are currently underway. These qualitative data will be evaluated by means of thematic analysis upon completion.

**Implications:** The broad pattern of results suggests that PAC was generally well-received and may be a potential model to expand into other areas of clinical pharmacy practice.

## Implementation of Neonatal and Paediatric Medication Calculators

Tsang J<sup>1</sup>, Bowmeister M<sup>2</sup>, Hahn-Ebrahim E<sup>3</sup>

<sup>1</sup>Department of Pharmacy, Oak Valley Health, Markham, ON

<sup>2</sup>Paediatrics Program, Lakeridge Health, Oshawa, ON

<sup>3</sup>Professional Practice Program, Oak Valley Health, Markham, ON

**Background:** Electronic medication calculating tools are useful in these patient populations and have shown to minimize calculation errors, decrease time to treatment, reduce stress and increase confidence of those involved. With significant process changes to emergency response due to COVID coupled with recommendations from paediatric and neonatal case reviews at Oak Valley Health, an automatic medication calculation tool was needed. Absence of an automatic calculation tool increases the risk for errors and increases the emotional burden of staff involved in resuscitation events.

**Action:** Calculation tool was created by the Department of Pharmacy in collaboration with the Professional Practice Program and Paediatric Program. The calculator contained information on medication weight based dosing, dose, volume, preparation comments and supplied strength information. Medications in the calculator included those used for resuscitation, seizure, rapid sequence intubation and high-alert medication infusion. Resuscitation and airway equipment specification with Broselow colour coding was integrated into the calculator in collaboration with the Respiratory Therapists. Education and process was implemented quickly once approval of the calculator was completed.

**Evaluation:** The use of the tool was validated and compliance was audited a year after implementation, showing a compliance rate of 100% in the Paediatric unit and Neonatal Intensive Care Unit. A quality survey was also released with results showing that the tool is useful and valuable for the nurses involving in paediatric emergencies.

**Implications:** As it is well-established that a calculation tool will reduce dosing errors and increase efficiency, the creation and implementation of the neonatal calculator was deemed necessary at Oak Valley Health. This also opens up future opportunities for interdisciplinary collaboration in quality and safety improvement projects.

## Incorporating the Principles of Equity, Diversity, and Inclusion in Canadian Pharmacy Residency Admissions Using a Holistic Review Framework

Kennedy Z<sup>1,2</sup>, MacInnis M<sup>1,2</sup>

<sup>1</sup>IWK Health Centre, Halifax, NS

<sup>2</sup>College of Pharmacy, Dalhousie University, Halifax, NS

**Background:** Pharmacists are responsible for providing inclusive and affirmative care to underserved populations. Creating diverse learning environments and workforces has been demonstrated to improve health outcomes for these populations, yet there remains a lack of diversity and representation in pharmacy residency training. Despite this knowledge, there is currently no guidance regarding incorporating principles of equity, diversity, and inclusion in pharmacy residency admissions in Canada.

**Description:** We completed a holistic review with the purpose of revising application screening tools to incorporate the effects of historical and current marginalization of certain groups on their abilities to demonstrate their skills on paper. A review of the current literature guided mathematical adjustments to our scoring rubric to incorporate diversity as a metric to mitigate existing structural bias.

**Action:** All applicants were given the opportunity to provide confidential self-identification information. Our holistic review yielded the implementation of changes to our application process, which included requiring reviewers and interviewers to take a minimum of one implicit bias test, blinding reviewers to applicants' names, and reweighting our existing scoring rubric to value non-academic skills.

**Evaluation:** Feedback was collected from reviewers and interviewers and included an overall easier experience and positive reactions to implicit bias test reflections. Logistic challenges included obtaining self-identification information from applicants and blinding reviewers to their demographic information. From 2021 to 2022, there was a 24% increase in applicants who self-identified as belonging to an underrepresented group, and the proportion of interviewed candidates belonging to an underrepresented group increased by 20%.

**Implications:** Adopting a holistic review of pharmacy residency admissions process will enable programs to create a diversity mission and shift scoring rubrics toward emphasizing valuable non-academic predictors of success in pharmacy residency programs. This has the potential to increase access to residency positions for underrepresented individuals, ultimately improving health outcomes for underserved populations.

## Listen to Your Clinicians: Collecting User Input after Smart Pump Implementation to Drive Continuous Quality Improvement

Mourad M<sup>1</sup>, Bertoldo L<sup>2</sup>, Vinet J<sup>3</sup>

<sup>1</sup>Medical Affairs, Baxter Healthcare, Mississauga, ON

<sup>2</sup>Pharmacy Department, Thunder Bay Regional Health Sciences Centre, Thunder Bay, ON

<sup>3</sup>Nursing Professional Practice Department, Thunder Bay Regional Health Sciences Centre, Thunder Bay, ON

**Background:** A robust drug library is crucial to the successful implementation of smart pumps. This initiative sought to collect feedback on the use of the pump drug library from frontline clinicians after pump implementation in a 400-bed hospital in Ontario.

**Description:** The pump implementation process involves a pharmacy workflow where the drug library build is vetted with a limited number of clinical representatives. After implementation, it becomes challenging to fully understand the end-user experience and the opportunities for improvement of the drug library.

**Action:** This initiative sought to collect feedback on the drug library in actual clinical practice at the end-user level.

**Evaluation:** We designed an online survey which was made available within three months of pump go-live to all front-line nurses. A total of 232 respondents completed the survey (26% response rate); the results are presented in the two tables below [for the tables that go with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>].

**Implications:** The data collected will be leveraged to implement strategies at the pharmacy and clinical levels within the hospital to optimize the clinicians' experience and enhance patient safety. Pump design-related input will be examined by the pump manufacturer to support its efforts in improving the technology.

## Pharmacist Led Cardiac Amyloid Clinic

Martin S<sup>1</sup>, Davey R<sup>1</sup>

<sup>1</sup>University Hospital, London Health Sciences Centre, London, ON

**Background:** Cardiac amyloidosis is a progressive disease which is caused by the deposition of misfolded proteins in the myocardium impacting heart function leading to heart failure and functional decline. Recent interest in this field has prompted improved awareness and diagnostic techniques. Therefore, there are an influx of patients identified with disease who require specialized care. To manage these patients' and coordinate novel medication therapies a pharmacist led outpatient clinic structure has been developed.

**Description:** Extensive multidisciplinary resources are required to facilitate care for cardiac amyloid patients. The Pharmacist Clinical Navigator works closely with the medical secretary to review new referrals and organize diagnostics testing. They also work the cardiologist to triage patient concerns, facilitate medication coverage and conduct in person clinic assessments.

**Action:** A pharmacist is well suited to serve as a Clinical Navigator with their therapeutic knowledge and understanding of the drug funding system. They act as a liaison by between procedural tasks and clinical decision making.

**Evaluation:** To date the London Cardiac Amyloid Clinic serves over 100 patients and is growing. Referrals from across the region range from assessment of AL amyloid cardiac involvement and suitability for stem cell transplant to evaluating the risk of being a carrier of a gene linked to cardiac amyloid. The majority of the patients are diagnosed with wild type transthyretin cardiac amyloid and are initiated on tafamidis, a disease stabilizer. Since inception of this role, there has been a notable increase in patients gaining access to therapy and a decrease in time to initiation.

**Implications:** The deposition of amyloid is progressive and time sensitive. Therefore, by improving clinic workflow through the addition of a Pharmacist Clinical Navigator, it will improve patient outcomes. This model can also be applied to other clinical areas where a pharmacist can help seamlessly navigate complex patient care.

## Reconciling Wisely: Pharmacist-Led Medication Reconciliation Quality Improvement Initiative

Tsang J<sup>1</sup>, Chan A<sup>1</sup>

<sup>1</sup>Department of Pharmacy, Oak Valley Health, Markham, ON

**Background:** Medication Reconciliation (MedRec) is a powerful and provider strategy to reduce medication errors at transition points. From quarterly audits, it was identified that the Inpatient Mental Health (IMH) unit,

at Oak Valley Health, required streamlining of processes and improvement in completion of MedRec on admission. IMH Best Possible Medication Histories (BPMHs) are often not reconciled in a timely manner, resulting in confusion and potential for error when pharmacist identified discrepancies are no longer accurate.

**Action:** In order to create a new process for pharmacist-led MedRec, criteria and process for these low-risk MedRecs were drafted and shared with the stakeholders for approval: Department of Pharmacy and Department of Psychiatry. Mental Health (MH) Pharmacists would reconcile BPMHs when: (1) patients are on no home medications, (2) all patients' home medications have been ordered correctly and (3) patients' home medications are intentionally changed and changes are documented. Trial was implemented and data was collected and analyzed. Feedback from psychiatrists and MH pharmacists were collected.

**Evaluation:** MH MedRec on admission completion rates has increased substantially since the implementation of pharmacist-led MedRec, with an increase from 57% to 82%. Pharmacists completed 29% of the MedRecs. Feedback from psychiatrists show that there is perceived improvements to efficiency and patient safety and that this service should be continued. Pharmacists reported positive downstream effects: decrease in need for clarification when BPMHs are not signed in a timely manner and this initiative allows complex BPMHs prioritization for psychiatrists to review.

**Implications:** Pharmacist-led MedRec has been shown to reduce unintended discrepancies and improve medication safety and patient outcomes. The expansion of the pharmacist role in MedRec at Oak Valley Health will open up future opportunities for pharmacists to drive quality and safety improvement initiatives.

## Reviewing Medications for Hazardous Classification

Eckel L<sup>1</sup>

<sup>1</sup>Provincial Pharmacy Services Medication Quality and Safety Team (MQST), Alberta Health Services, Edmonton, AB

**Background:** The National Institute for Occupational Safety and Health (NIOSH) published the most recent NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings in 2016. Drugs that were marketed as of December 2013 were reviewed at that time. An average of 55 new medications have been approved for market in Canada each year since publication.

**Description:** To be effective, a hazardous medication list must include medications that are new to market. To accomplish this, an algorithm was developed to align with NIOSH's classification of hazardous medications.

**Action:** A review of NIOSH "Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings" (draft) determined how the organization established classification levels. Building on previous work, an algorithm was created that aligns with the criteria that NIOSH now uses (based on the NIOSH 2020 draft list). To be consistent in the approach to classifications, data was collected from multiple sources and an Assessment of Risk (AoR) was developed. Once an AoR is complete, the algorithm was used to classify the medication.

**Evaluation:** After processing the medication through the algorithm, documentation of the classification and rationale was included on the AoR. The medical director, Workplace Health and Safety (WHS) reviewed the AoR, and then the classification was brought to the overarching committee for approval. If approved, updates were made to the hazardous medication list.

**Implications:** The algorithm allows our organization to maintain a current list of hazardous medications. We have committed to align with NIOSH. Once they publish again, our organization may have to revise our classifications and algorithm.

## The New Brunswick Pharmacy Assessment Clinic: A Novel, Hospital Pharmacist-Led Collaborative Practice Hub

Adams B<sup>1</sup>, Sansom B<sup>2</sup>, Doiron N<sup>1</sup>, Doucette D<sup>2</sup>, Gagnon J<sup>1</sup>, Landry D<sup>1</sup>, LeBlanc M<sup>2</sup>,  
Levesque J<sup>3</sup>, Louis F<sup>4</sup>, MacLagan T<sup>2</sup>, Naylor H<sup>5</sup>

<sup>1</sup>Department of Pharmacy, Dr. Georges-L.-Dumont University Hospital Centre,  
Vitalité Health Network, Moncton, NB

<sup>2</sup>Department of Pharmacy, The Moncton Hospital, Horizon Health Network,  
Moncton, NB

<sup>3</sup>Department of Pharmacy, Horizon Health Network, Moncton, NB

<sup>4</sup>Department of Pharmacy, Horizon Health Network, Fredericton, NB

<sup>5</sup>Department of Pharmacy, Saint John Regional Hospital, Horizon Health Network,  
Saint John, NB

**Background:** Collaborative practice agreements (CPA) are effective clinical service arrangements which remain underutilized. The rapid authorization of nirmatrelvir/ritonavir by Health Canada in January 2022 for mild-moderate COVID-19, in combination with a limited supply, required innovative approaches to assessment and distribution. The New Brunswick Pharmacy Assessment Clinic (PAC) was subsequently developed.

**Description:** Sixteen hospital pharmacists staffed within two regional health authorities in New Brunswick were re-assigned from regular patient care duties or temporarily hired to work in the PAC. This entirely virtual clinic allowed for remote, bilingual, care provision from any location. Referrals were submitted electronically by government-designated sources and processed entirely by pharmacists, with clinic processes outlined in Figure 1.

**Action:** Referrals were triaged based on government criteria and evidence-based factors. Pharmacists obtained consent from patients or substitute decision makers, analyzed detailed patient histories from direct consultation and EHRs, and subsequently made therapeutic decisions regarding the use of nirmatrelvir/ritonavir. Education was provided to patients at the time of assessment, with standardized communications provided to community pharmacies and primary care providers.

**Evaluation:** From January 24<sup>th</sup> to April 11<sup>th</sup>, 2022, over 1,100 referrals were submitted to the PAC for further assessment, resulting in over 400 prescriptions. After April 11<sup>th</sup>, 2022, all primary care providers were given authority to assess patients and prescribe nirmatrelvir/ritonavir.

**Implications:** This innovative pharmacist-led model of assessment and prescribing involving a CPA could be replicated in multiple areas of clinical pharmacy practice.

For the figure that goes with this abstract, please see Abstract Appendix, available at <https://www.cjhp-online.ca/index.php/cjhp/issue/view/214>

## Twenty Years of Pharmacy Practice Research: Evaluation of Internship Satisfaction

Tanguay C<sup>1</sup>, Atkinson S<sup>1</sup>, Lebel D<sup>1</sup>, Bussières JF<sup>1,2</sup>

<sup>1</sup>Pharmacy Practice Research Unit, Pharmacy Department, CHU Sainte-Justine,  
Montreal, QC

<sup>2</sup>Faculty of Pharmacy, Université de Montréal, Montreal, QC

**Background:** Pharmacist-led research is necessary to better understand the impact of pharmacists in diverse areas and to obtain “real-life” data on their practice and activities.

**Description:** The Pharmacy Practice Research Unit was created in 2002. It includes pharmacists, a research coordinator, local and international students. The research unit facilitated the creation of evaluative projects in the pharmacy department of a mother-child healthcare center.

**Action:** In addition to contributing to the student's respective internships projects, we hypothesized that their involvement in the research unit would benefit their future careers. The 20-year anniversary of the research unit was used as an opportunity to survey former students.

**Evaluations:** 275/383 former interns were contacted by email or LinkedIn and were requested to fill an online survey describing their satisfaction and perceived impact of their internship. 186/275 (68%) answered the survey. 145 (78%) did an internship of 1 year or less, 32 (17%) of more than 2 years. 118 (63%) now work in a hospital setting, 20 (11%) in community pharmacy and 18 (10%) in the pharmaceutical industry. 95 (51%) live in Canada, 72 (39%) in France and 19 (10%) in other countries. Interns reported that their internship had a moderate (72, 38%) or determining (108, 58%) impact on their scientific curiosity. They also reported a moderate (64, 34%) or determining (110, 59%) impact on their knowledge transfer competencies. 92 (49%) reported presenting at least one poster after their internship (average 7.3±9.4 poster) and 90 (48%) at least one manuscript (5.3±7.8 articles).

**Implications:** Although hospital pharmacists spend most of their time providing pharmaceutical services and direct patient care, evaluative research is important to provide an optimal environment, in line with patient needs, regulatory requirements and changing technologies. Former interns reported the usefulness of participating in evaluative research and many used these skills in their careers.

## Using Pharmacy Students to Prioritize Inpatient Care

Goodine C<sup>1</sup>, Whiteway G<sup>1</sup>, Canales DD<sup>2</sup>, Naylor H<sup>3</sup>, Demmings P<sup>4</sup>, Noseworthy K<sup>5</sup>  
<sup>1</sup>Pharmacy Services, Doctor Everett Chalmers Regional Hospital, Horizon Health  
Network, Fredericton, NB

<sup>2</sup>Research Services, Horizon Health Network, Saint John, NB

<sup>3</sup>Pharmacy Research and Education, Horizon Health Network, Saint John, NB

<sup>4</sup>Patient Experience Advisor, Horizon Health Network

<sup>5</sup>Pharmacy Services, Miramichi Regional Hospital, Horizon Health Network,  
Miramichi, NB

**Background:** Patient acuity is increasing and there is an increased demand for clinical pharmacy services in Fredericton area hospitals. At the same time, a significant influx of pharmacy students requiring structured clinical placements is anticipated due to Doctor of Pharmacy programs in Canada. In 2020, a Pharmacy Patient Screening Tool (PPST) was developed and piloted by a pharmacy student. Pilot study results suggested that the PPST had potential to integrate students in clinical pharmacy activities and aid in patient prioritization. Limitations included reliance on chart review; the patient's perspective - an important element to consider when identifying potential medication-related problems was not investigated. Thus, we sought to improve our patient prioritization process by developing and testing the addition of a Medication Experience Interview (MEI) to elicit patient views regarding medication use.

**Action:** We modified and expanded the previous student-led patient screening project to a second site. Pharmacy students were trained to conduct a Best Possible Medication History and MEI in addition to using the PPST. Our goal was to determine the most effective method for students to identify which patients would benefit most from clinical pharmacy services.

**Evaluation:** Semi-structured interviews were conducted with the 2 student and 4 pharmacist participants. Facilitators, challenges, impact on pharmacist activities, impact on student learning and overall impression of the process were explored. Thematic analysis was completed, and six themes emerged: Ambivalence Toward MEI, PPST Valued over MEI, Barriers, Facilitators, Positive Pharmacy Student Experience, and Student Impact on Workflow and Patient Care.

**Implications:** Patient screening using an MEI and PPST was a feasible and valuable learning experience for pharmacy students. Pharmacy students assisted pharmacists with patient care, however, pharmacists did not find the MEI useful for prioritizing pharmacist activities. Further study is required to determine the most effective method for prioritizing pharmacist inpatient care.

## Utilization of Smart Pump Technology to Effect Practice Change

Bertoldo L<sup>1</sup>, Mourad M<sup>2</sup>

<sup>1</sup>Department of Pharmacy, Thunder Bay Regional Health Sciences Centre, Thunder Bay, ON

<sup>2</sup>Medication Affairs, Baxter Healthcare, Mississauga, ON

**Background:** Thunder Bay Regional Health Sciences Centre was the first institution worldwide to utilize Baxter's newest Novum IQ large volume intravenous (IV) infusion pumps. This represented a large practice change for the users. Programming was performed using the new Dose IQ software, while its monitoring software, Enterprise IQ, was used to compile data on pump usage. Being the first to utilize this technology, we explored the options to utilize the data collected to identify usage trends and develop strategies to promote compliance with the pump drug safety programming.

**Description:** To develop a strategy to communicate requested adjustments and new medications to the pump programmer. To develop a strategy to utilize the data from the IV pump usage to improve compliance.

**Action:** A communication form was developed to inform the pump programmer of adjustments required for pump programming, as well as new medications to add to the pump library. Each month, utilizing Enterprise IQ, usage data is compiled, including areas of non compliance with the pump drug error reduction software (DERS), as well as reported hard and soft limit trends with medications. Data is collected and reported monthly at the hospital's Medication Safety Committee. The Oncology area was the pilot unit to evaluate the efficacy of the process.

**Evaluation:** From November 2021 until July 2022, DERS compliance for the Oncology area was 95.2%. Utilizing the results of the communication form as well as hard and soft limit data from the Enterprise IQ software, adjustments were made to the pump drug library. Compliance with DERS increased in September 2022 to 98.2% (3.15% increase in compliance).

**Implications:** Compliance with DERS increases patient safety. The process implemented has allowed improved compliance with DERS for the IV pumps. We plan to utilize the same process with other care areas in order to improve safety compliance.

## We're in This Together: How Our Outpatient Pain Clinic's Fluoroscopy Suite Survived the Global Iohexol Shortage Without Limiting Patient Care Services

Kreutzwiser D<sup>1,2</sup>, Deaconu A<sup>1</sup>, Lee B<sup>1</sup>, Andriets A<sup>1</sup>, Bellingham G<sup>2,3</sup>, Rumford M<sup>2</sup>, Hansford H<sup>4</sup>

<sup>1</sup>Pharmacy Department, St. Joseph's Health Care London, London, ON

<sup>2</sup>Pain Management Program, St. Joseph's Health Care London, London, ON

<sup>3</sup>Department of Anesthesiology and Perioperative Medicine, Schulich School of Medicine & Dentistry, Western University, London, ON

<sup>4</sup>Diagnostic Imaging, St. Joseph's Health Care London, London, ON

**Background:** A global shortage of the iodinated contrast media (ICM) iohexol commenced in May 2022 after the main manufacturing site in China experienced reduced production and distribution capabilities related to COVID-19 lockdowns. On May 31, Ontario Health asked all health-care facilities to immediately institute ICM conservation strategies and patient triage.

**Description:** Interventionalists in the fluoroscopy suite at our outpatient pain clinic administer iohexol 240 via the epidural, perineural, and intra-articular routes to guide select injections. Prior to this shortage, iohexol supply management was only through our hospital's general healthcare materials department; the pharmacy department was not involved.

**Action:** Our inpatient pharmacy technicians began repackaging, in a sterile compounding environment, iohexol 240 from a single-use container (either a 20 mL vial or 100 mL bottle) into 4mL aliquots and storing it in a glass vial with a beyond-use-date (BUD) of 9 days refrigerated or 30 hours room temperature. A standard operating procedure was created to delineate roles of the pain clinic nurses, medical radiation technologists, and interventionists in obtaining the aliquot supply from a medication fridge, administering the aliquot, and recording administration on a traceability log. The pain clinic pharmacist coordinated the day-to-day aliquot supply management by factoring in the BUDs with anticipated demand based on the interventionists' procedure schedules.

**Evaluation:** Between June 13 and October 20, 9 x 100mL bottles and 15 x 20mL vials of iohexol 240 were repackaged to give a total of 305 aliquot vials for which 235 aliquot vials were administered; facilitating completion of 226 procedures. Seventy aliquot vials were wasted when the BUD was reached.

**Implications:** An iohexol 240 supply that would normally have provided for 102 procedures has been/will be repackaged to facilitate completion of approximately 700 procedures. The need to cancel any procedures due to the global ICM shortage was averted.

## Workflow Analysis of Daily Tasks Performed by Pharmacy Technicians at CHEO: A Pilot Project Using the Lean Six Sigma Approach

Varughese N<sup>1</sup>, Blanc A<sup>1</sup>, Osman D<sup>1</sup>, Cameron J<sup>1</sup>

<sup>1</sup>Department of Pharmacy, Children's Hospital of Eastern Ontario, Ottawa, ON

**Background:** Quality improvement methodologies, including Six Sigma Lean, are used across workplaces with the goals of improving efficiency, quality and reducing costs. Originally developed by car manufacturers, Six Sigma Lean is used in healthcare settings to improve workflow efficiency.

**Objective(s):** The primary objectives of this pilot project at CHEO pharmacy were to operationalize pharmacy technician workflow and track interruptions by frequency and time. The secondary objectives were to assess differences of interruptions related to technician experience.

**Methods:** A modified Six Sigma Lean methodology was employed to describe, measure, and analyze workflow of pharmacy technicians by assessing interruptions in a typical shift. The main dispensary technician workflow was assessed over the course of 12 shifts.

**Results:** Communication interruptions occurred in the highest frequency, accounting for 40% of all interruptions, while sending Rx interruptions had the highest mean interruption time (126 seconds). Pareto charts for subcategories of interruptions revealed that communicating with other technicians was responsible for 67% of communication interruptions and that technicians personally delivering was responsible for 79% of Sending Rx interruptions. Analyzing differences between SR and JR technicians, SR technicians experienced more interruptions in 75% of categories.

**Conclusion(s):** Modified Six Sigma Lean methodology revealed that communication and Sending Rx were the main causes of interruption in the dispensary. The Pareto principle revealed that communicating with other technicians (communication) and personally delivering (sending Rx) were the most common interruptions. Overall, interruptions are targetable and future studies should address the "improve" and "control" stages of the Six Sigma Lean process to implement and measure the impact of future changes.

## CASE REPORTS / OBSERVATIONS CLINIQUES

### Appearance of Lanthanum Tablets on Abdominal X-Ray

Zekic F<sup>1</sup>, Suarez A<sup>1</sup>, Druken R<sup>2</sup>

<sup>1</sup>London Health Sciences Centre, London, ON

<sup>2</sup>Foothills Medical Centre, Calgary, AB

**Background:** Lanthanum is a phosphate binder indicated for the treatment of hyperphosphatemia in chronic kidney disease. Lanthanum tablets should be chewed or crushed to maximize phosphate binding and reduce gastrointestinal complications. As a rare earth metal, lanthanum can also appear radiopaque on x-ray imaging, potentially contributing to inappropriate diagnoses, investigations and treatments.

**Case Description:** An 80-year-old female with end-stage renal disease was hospitalized with shortness of breath and delirium. During investigations, an abdominal x-ray was completed showing multiple circular radiopaque densities throughout the abdomen. Differential diagnoses for the densities included renal obstruction, constipation and foreign object ingestion. This led to further imaging, as well as a urology consultation and initiation of laxatives. The densities were later concluded to be lanthanum tablets, with the patient confirming she was swallowing the tablets whole instead of chewing them.

**Assessment of Causality:** An abdominal x-ray taken prior to the patient starting lanthanum did not show circular radiopacities. The radiopacities were the same relative shape and size of lanthanum tablets. Imaging from previous case reports looks almost identical to that of this patient. This case received a score of 4 on the Naranjo Probability Scale, indicating a possible adverse drug reaction.

**Literature Review:** Several case reports have documented lanthanum radiopacities on x-ray imaging. Attempts to identify the radiopacities have led to increased utilization of healthcare resources, including additional imaging, endoscopy, pharmacotherapy and consultations. Guidelines do not discuss approaches to lanthanum radiopacities, leaving the ideal management unclear.

**Importance to Practitioners:** Lanthanum precipitates may lead to incorrect interpretations of x-ray findings, which can impede diagnostic and therapeutic decision making. Awareness of this phenomenon can mitigate healthcare resource utilization and improve appropriate medication use.

### Elexacaftor/Tezacaftor/Ivacaftor Induced Rash and Subsequent Desensitization in a Paediatric Patient with Cystic Fibrosis

Renwick C<sup>1</sup>, Xing C<sup>1</sup>, Harris V<sup>1,2</sup>, Price A<sup>1,2</sup>, St. Pierre K<sup>1</sup>, Fleischer E<sup>1</sup>, Rieder M<sup>1,2</sup>, Del Pozzo-Magana B<sup>1,2</sup>

<sup>1</sup>Children's Hospital at London Health Sciences Centre, London, ON

<sup>2</sup>Department of Paediatrics, Western University, London, ON

**Background:** Elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) is a cystic fibrosis (CF) transmembrane conductance regulator (CFTR) modulator approved for CF patients carrying the F508del mutation. CFTR modulators are the first class of CF medications that target the underlying genetic mutation and have shown promising benefits. Unfortunately, a documented adverse effect of ELX/TEZ/IVA is wide spread skin rash.

**Case Description:** A 16-year-old male with pancreatic insufficient CF was admitted to hospital for a CF exacerbation. A complex course of antibiotics was completed including 6 days IV piperacillin/tazobactam, 7 days IV tobramycin, 8 days IV ceftazidime, and was discharged on IV meropenem and oral sulfamethoxazole/trimethoprim to complete treatment. ELX/TEZ/IVA was started on discharge. Four days after initiating ELX/TEZ/IVA, the

patient developed a fever of 40°C and a maculopapular rash tending toward confluence with reticular pattern and blotchy areas. The sulfamethoxazole/trimethoprim was stopped with some improvement, but the rash returned shortly after and persisted until ELX/TEZ/IVA was discontinued. A desensitization protocol with slow dose titration over 2 months was initiated, allowing for successful resumption of ELX/TEZ/IVA without recurrence of skin rash.

**Assessment of Causality:** This case of ELX/TEZ/IVA-induced drug reaction received a 4 on the Naranjo scale indicating a possible association. The patient received multiple antibiotics concomitantly throughout his admission and while he had documented tolerance to many, they cannot be definitively ruled out as possible contributors.

**Literature Review:** ELX/TEZ/IVA is reported to cause dermatologic adverse events including diffuse skin rash in approximately 10% of users. Available case reports document desensitization protocols with reported success in resuming the medication without inducing a rash.

**Importance to Practitioners:** ELX/TEZ/IVA is a promising new CF medication which is being used with increasing frequency. With a known risk of rash, it is encouraging to see results of successful desensitization protocols to promote effective CF treatment for those who would derive benefit.

### Piperacillin-Tazobactam Induced Thrombocytopenia in the Setting of Diabetic Foot Infection and End-Stage Renal Disease in Peritoneal Dialysis: A Case Report

Ko J<sup>1</sup>, Suarez A<sup>1</sup>

<sup>1</sup>London Health Sciences Centre, London, ON

**Background:** Piperacillin-tazobactam is an ureidopenicillin combined with a beta-lactamase inhibitor. Its broad spectrum of activity makes it a regularly utilized agent in the hospital setting. However, use of piperacillin-tazobactam is not without risk; adverse effects include risk of *Clostridioides difficile* infection, nephrotoxicity and hematologic effects. Rarely, drug-induced immune thrombocytopenia can occur which is believed to occur through the production of drug-dependent antibodies that bind to platelets and lead to their depletion.

**Case Description:** A 71-year-old male was treated with piperacillin-tazobactam for a diabetic foot ulcer and possible osteomyelitis. He had a complex medical history that included end-stage renal disease secondary to diabetic nephropathy and was undergoing nightly peritoneal dialysis. After 11 days of therapy, he presented with generalised petechial rash, mucosal bleeding, melena, bruising, and bright red blood per rectum. He was found to be thrombocytopenic with platelets measured to be  $17 \times 10^9/L$ . Approximately 1 week after stopping piperacillin-tazobactam, his platelets returned to normal.

**Assessment of Causality:** The patient's thrombocytopenia occurred after administration of piperacillin-tazobactam and resolved after drug withdrawal. It also occurred within a similar timeframe as other reported cases within the literature. The Naranjo score was 5, indicating a probable adverse drug reaction.

**Literature Review:** Many medications have been reported to cause drug-induced thrombocytopenia. Case reports of thrombocytopenia associated with beta-lactams, including piperacillin-tazobactam, have been published; however, the frequency has not been well defined.

**Importance to Practitioners:** Though thrombocytopenia is a rare side effect of piperacillin-tazobactam, its outcomes can be severe. Piperacillin-tazobactam is a frequently used anti-infective agent and practitioners must be diligent in monitoring patients to ensure that adverse drug reactions are detected quickly and appropriately managed.

### Vascular *Mycobacterium* Infection 3 Years Following Intravesical Live Attenuated *Mycobacterium bovis* Therapy

Hopkins M<sup>1</sup>, Dhami R<sup>1,2,3</sup>

<sup>1</sup>London Health Sciences Centre, London, ON

<sup>2</sup>University of Waterloo, Waterloo, ON

<sup>3</sup>Western University, London, ON

**Background:** Therapy with intravesical live attenuated *Mycobacterium bovis* (BCG) irrigation to prevent recurrence of non-muscle invasive urothelial bladder cancer is a generally well-tolerated treatment. This case describes a rare infectious complication of treatment.

**Case Description:** A 68-year-old man presented to a tertiary academic hospital following treatment for bladder cancer. He received intravesical BCG to prevent recurrence. On his last course in 2018, there was difficulty with instrumentation. In July 2021, he presented to hospital with hip pain and infectious signs. A CT found a perforated abdominal aorta with concern for mycotic infection. It was noted that he drank unpasteurized dairy products as a child. Initial cultures were negative. In August 2021, the culture

returned positive for *Mycobacterium bovis*. He started rifampin, isoniazid, ethambutol, and moxifloxacin therapy for 2 months, followed by triple therapy for 11 months and dual therapy for 9 months. He is being considered for lifelong rifampin due to chronic leukocytosis.

**Assessment of Causality:** BCG may have entered systemic circulation through a cut in the urethra during the patient's last treatment, where instrumentation was difficult. The consumption of unpasteurized dairy products as a child is also a plausible cause; however, unlikely given the mycobacterium would have remained dormant for 60 or more years in this scenario.

**Literature Review:** Three case studies involving 3 patients from 1988 to 2000 depict ruptured abdominal aortic repairs 1-3 years after intravesical BCG. All tissue cultures returned positive for *Mycobacterium bovis*. Outcomes following 12-20 months of antimycobacterial therapy consisted of complete remission, graft infection and removal and death.

**Importance to Practitioners:** Infectious complications of intravesical BCG can lead to significant morbidity and mortality. This case demonstrates the importance of considering mycotic infection as a part of the differential diagnosis years after receipt of intravesical BCG.



# CSHP Hospital Pharmacy in Canada Report 2020/21: Expertise and Evidence

Jody Ciuffo

<https://doi.org/10.4212/cjhp.3451>

In late 2022, the Canadian Society of Hospital Pharmacists published the *Hospital Pharmacy in Canada Survey Report 2020/21*, the 22nd edition of this monumental resource and the second edition published under the auspices of CSHP.

“Monumental” certainly describes the level of effort, resources, and volunteer time dedicated to this project. It also reflects the obstacles encountered in putting it together, most particularly the COVID-19 pandemic, which the hospital pharmacy community and the Hospital Pharmacy in Canada Survey Board overcame to make this happen. Still not behind us at the end of 2022, the pandemic was responsible for a four-year gap between editions, instead of the usual two-year timeframe. For the first year of the pandemic, asking Canadian hospital pharmacies to shift their focus from managing the unprecedented crisis to completing a complex survey, no matter how important the work, was simply unthinkable.

By 15 months into the pandemic, hospital pharmacies had found ways to negotiate the crisis, and nearly 150 managed to complete the survey, despite surging and receding COVID-19 waves. We are extremely grateful to these hospital pharmacy teams for their commitment to providing the information that underpins the immense longitudinal value of the survey. And because their participation fell in the midst of the crisis, professional pharmacy staff captured real-time data that translates into the solid evidence documented in this report and upon which hospitals and healthcare systems will rely as we navigate the next crisis, whatever form it takes.

Beyond the hospital pharmacy teams, CSHP is indebted to each of the Hospital Pharmacy in Canada Survey Board members, whose volunteer commitment made this massive report possible, in spite of the effects of the pandemic on their professional and personal obligations. Sincere thanks are due to Executive Editor Richard Jones for his steady leadership in this, his third and final edition of the survey report and to the organizational mastery of Managing Editor Carolyn Dittmar. The Survey Board members, who are the authors and editors of the report, are second to

none: André Bonnici, Jean-François Bussi eres, Bal Dhillon, Douglas Doucette, Kyle MacNair, Debra Merrill, Allan Mills, and R egis Vaillancourt.

The importance of our sponsors cannot be overstated. The resources of Pfizer Canada, Pendopharm/Pharmascience Canada Inc., and Baxter Canada supported both the survey and the resulting report. Primary research like this is expensive, despite the hundreds of thousands of volunteer hours. This generous external funding made possible the complex survey programming, scientific editing, translation, and final publication. As always, editorial direction from our corporate partners was neither sought nor offered. They and we simply share a dedication to the overriding quality of the survey and its findings.

The newest edition of the *Hospital Pharmacy in Canada Survey Report* is a permanent record of the status of hospital pharmacy in Canada’s healthcare systems in 2020/21. As we all know, advocacy is one of CSHP’s main pillars. Even as it serves the profession, this advocacy is ultimately targeted to improving patient outcomes in a systemic way. Such advances can only be achieved with expertise and evidence. This report does not advocate in and of itself, but it puts the reported data into many hands in many organizations: hospitals, universities, colleges, other healthcare professions, patient groups, industry, legislators, regulators, and government agencies.

Indeed, over the past four decades, pharmacy directors have used the survey’s staffing ratios to build the case for increasing human resources, its drug distribution findings to support adoption of robotic automation in the pharmacy, and its data about pharmacy technician practice to reconfigure teams for optimal clinical practice. Furthermore, the survey provides trending information that allows leaders to make decisions about the evolution of their departments’ practice and to determine whether they are leading or trailing behind regional or national rates of technology adoption. And let’s not forget the many times that survey reports have been cited in these very pages over the years since the project was initiated, when it was known as the “Lilly Hospital Survey”.

The *Hospital Pharmacy in Canada Survey Report 2020/21*, realized through the collective work of pharmacy teams, CSHP volunteers, and supporters, gives us the means to create optimal outcomes for our patients, to support excellence in the profession, and to achieve meaningful, lasting change in Canada's healthcare systems.



**Jody Ciufo, MBA**, is Chief Executive Officer of the Canadian Society of Hospital Pharmacists.

# Rapport sur les pharmacies hospitalières canadiennes de la SCPH 2020-2021 : Expertise et données probantes

par Jody Ciuffo

<https://doi.org/10.4212/cjhp.3457>

Vers la fin de 2022, la Société canadienne des pharmaciens d'hôpitaux a publié le *Rapport du Sondage sur les pharmacies hospitalières canadiennes 2020-2021*, la 22<sup>e</sup> édition de cette ressource monumentale et la deuxième édition publiée sous les auspices de la SCPH.

Le terme « monumental » décrit avec justesse le niveau d'efforts, de ressources et de temps bénévole consacré à ce projet. Il reflète également les obstacles qui se sont présentés lors de l'élaboration du rapport – en particulier la pandémie de COVID-19 – que le milieu de la pharmacie hospitalière et le Comité du Sondage sur les pharmacies hospitalières canadiennes ont dû surmonter. La pandémie, qui n'est toujours pas terminée à la fin de 2022, est responsable d'un intervalle de quatre ans, plutôt que deux, entre les éditions. Au cours de la première année de la pandémie, il était tout simplement impensable de demander aux pharmacies hospitalières canadiennes de détourner leur attention de la gestion de la crise sans précédent pour réaliser un sondage complexe, même s'il s'agissait d'un travail important.

Quinze mois après le début de la pandémie, les pharmacies des hôpitaux avaient trouvé des moyens de manœuvrer face à la crise, et près de 150 d'entre elles ont réussi à répondre au sondage, malgré le va-et-vient des vagues de COVID-19. Nous sommes extrêmement reconnaissants envers ces équipes de pharmacie hospitalière pour leur engagement à fournir les renseignements qui sous-tendent l'immense valeur longitudinale du sondage. Et parce que leur taux de participation a chuté en pleine crise, les membres du personnel de pharmacie professionnel ont saisi des données en temps réel qui se traduisent par de solides données probantes documentées dans ce rapport, sur lesquelles les hôpitaux et les systèmes de soins de santé s'appuieront lors de la prochaine crise, quelle qu'en soit la forme.

Au-delà des équipes de pharmacie des hôpitaux, la SCPH est redevable à chacun des membres du Comité du Sondage sur les pharmacies hospitalières canadiennes dont l'engagement bénévole a rendu possible ce rapport massif, malgré l'incidence de la pandémie sur leurs obligations

professionnelles et personnelles. Nous tenons à remercier sincèrement Richard Jones, directeur de la rédaction, pour le leadership dont il a fait preuve dans sa troisième et dernière édition du Rapport du Sondage, ainsi que Carolyn Dittmar, rédactrice en chef, pour sa maîtrise organisationnelle. Les membres du Comité du Sondage, qui sont les auteurs et les rédacteurs du rapport, sont sans égaux : André Bonnici, Jean-François Bussières, Bal Dhillon, Douglas Doucette, Kyle MacNair, Debra Merrill, Allan Mills et Régis Vaillancourt.

On ne saurait surestimer l'importance de nos commanditaires. Les ressources de Pfizer Canada, de Pendopharm/Pharmascience Canada Inc. et de Baxter Canada ont contribué à ce sondage et au rapport qui en a découlé. Malgré les centaines de milliers d'heures de bénévolat, la recherche originale comme celle qui a été menée coûte cher. Ce généreux financement externe a permis la programmation complexe du sondage, la révision scientifique, la traduction et la publication finale. Comme toujours, aucune orientation rédactionnelle de la part de nos entreprises partenaires n'a été sollicitée ou offerte. Comme eux, nous soulignons simplement le dévouement envers la qualité remarquable du sondage et de ses conclusions.

La nouvelle édition du *Rapport du Sondage sur les pharmacies hospitalières canadiennes* est un registre permanent de l'état des pharmacies hospitalières dans les systèmes de soins de santé du Canada en 2020-2021. Nous savons tous que la défense des intérêts est l'un des principaux piliers de la SCPH. Même si elle sert la profession, elle vise ultimement à améliorer les résultats pour les patients de façon systémique. De telles avancées ne peuvent être réalisées qu'au moyen d'expertise et de données probantes. Le présent rapport ne défend pas d'intérêts en soi, mais il met les données déclarées entre de nombreuses mains, dans de nombreuses organisations : hôpitaux, universités, collèges, autres professions de la santé, groupes de patients, industrie, législateurs, organismes de réglementation et organismes gouvernementaux.

En effet, les directeurs de pharmacie se sont fondés sur les ratios de dotation du sondage pour justifier

l'augmentation des ressources humaines, sur ses conclusions sur la distribution de médicaments pour appuyer l'adoption de systèmes robotisés dans les pharmacies, et sur ses données sur la pratique du technicien en pharmacie afin de reconfigurer les équipes pour assurer une pratique clinique optimale. De plus, le sondage fournit des renseignements sur les tendances qui permettent aux dirigeants de prendre des décisions sur l'évolution des pratiques de leurs services et de déterminer s'ils sont en avance ou accusent un retard par rapport aux taux régionaux ou nationaux d'adoption de la technologie. N'oublions pas non plus les nombreuses fois où les rapports de sondage ont été cités dans ces mêmes pages, au fil des ans, depuis le lancement du projet sous le nom de « sondage Lilly ».

Le *Rapport du Sondage sur les pharmacies hospitalières canadiennes 2020-2021*, réalisé grâce au travail collectif d'équipes de pharmacie, de bénévoles de la SCPH et de partisans, nous donne les moyens de créer des résultats optimaux pour nos patients, d'appuyer l'excellence dans la profession et d'apporter des changements significatifs et durables dans les systèmes de santé du Canada.

**Jody Ciuffo**, M.B.A., est directrice générale de la Société canadienne des pharmaciens d'hôpitaux.

## APPENDIX 1 (Part 1 of 3). Biosimilars Implementation Evaluation Framework.

RE-AIM Element	Evaluation Questions	Indicators	Data Collection <sup>a</sup>
<b>Stakeholder engagement</b>			
Reach	Which stakeholders were invited to participate, and were they representative of the affected parties?	Number and list of invited stakeholders	Organizational
	Who was engaged in developing the funding policies, and to which groups were these policies communicated?	Number and types of stakeholders involved in the development of funding policies Intended recipients of communicated funding policies	Organizational Organizational
Effectiveness	Do stakeholders believe their contributions were valued, making them champions of the work?	How and when stakeholders were engaged	Qualitative
		How stakeholder input was used	Qualitative
		Stakeholders' perceptions of their contributions	Qualitative
Adoption	What influenced the development of the funding policies (e.g., evidence, rationale, other jurisdictions' experience, effect of private sector policies)?	Resources, evidence, reports, and stakeholder feedback used to develop funding policies	Qualitative
Maintenance	What changes were made to funding policies after initial implementation?	Changes made to the funding policy after its initial release	Qualitative
<b>Patient experience</b>			
Reach	Who was targeted for biosimilar education?	Types of individuals targeted for biosimilar education	Organizational
		Patient groups not targeted or missed for biosimilar education	Qualitative
Effectiveness	Were there unintended outcomes of the funding policies?	Change in travel distance to treatment site after switching to a biosimilar	Qualitative
		Change in patient out-of-pocket expenses after switching to a biosimilar	Qualitative
		Did educational resources increase knowledge and acceptance of biosimilars?	Percent of individuals who indicated increased knowledge after receiving education about biosimilars
Adoption	How were educational resources accessed and used (by format and by stakeholder group)?	Number of individuals who accessed each type of educational resource	Organizational
<b>Patient outcomes</b>			
Effectiveness	Were there unintended outcomes of the funding policies?	Number of outpatient physician visits compared with historical cohorts	Administrative
		Number of hospitalizations compared with historical cohorts	Administrative
		Number of emergency department visits compared with historical cohorts	Administrative
		Use of concomitant drug products after a switch to a biosimilar, compared with historical cohorts	Administrative
		Discontinuation rates of a biosimilar, compared with historical cohorts on the reference biologic	Administrative
		Number of patients switching back to the reference biologic after switching to the biosimilar	Administrative

Appendix to: Milgram L, Wheeler S, Adamic A, Loncar M, Guirguis M, McCabe BJ. A framework for evaluating the implementation of biosimilar drugs. *Can J Hosp Pharm.* 2023;76(2):109-16.

## APPENDIX 1 (Part 2 of 3). Biosimilars Implementation Evaluation Framework.

RE-AIM Element	Evaluation Questions	Indicators	Data Collection <sup>a</sup>
Clinician experience			
Reach	Which individuals (roles, groups) were targeted in preparation for local implementation (i.e., at hospitals/clinics and other care settings) of biosimilars? How?	Activities used to implement biosimilars on the front lines of care (e.g., information system upgrades, education delivery, revisions to policies and procedures)	Qualitative
		Resources required for implementation of biosimilars (e.g., time, money, human resources)	Qualitative
Effectiveness	Did educational materials increase knowledge and acceptance of biosimilars?	Percent of clinicians who indicated increased knowledge after receiving education about biosimilars	Qualitative
		Patients who were switched to a new therapeutic class instead of being switched to a biosimilar	Administrative
Adoption	What enablers or barriers affected biosimilar implementation at the local level (e.g., stakeholders, existing information systems, existing practices/operations, available staff)?	Enablers and barriers to local implementation	Qualitative
		Gaps that were identified and supports that were needed during implementation	Qualitative
		Who was targeted for biosimilar education?	Types of clinicians targeted for biosimilar education Clinicians not targeted or missed for biosimilar education
	How were educational resources accessed and used (by format and by stakeholder group)?	Number of clinicians who accessed the educational resources	Organizational
Implementation	What changes were made at the local level to integrate biosimilars?	Changes in physician time for each patient switched to a biosimilar	Qualitative
		Changes in nursing time for each patient switched to a biosimilar	Qualitative
		Changes in pharmacist time for each patient switched to a biosimilar	Qualitative
		Changes in administrative time for each patient switched to a biosimilar	Qualitative
		Work effort for initial and subsequent biosimilar drug implementations by type of activity (e.g., clinician education, system upgrades, policy and procedure revisions, patient education, administrative requirements for switching a patient to a biosimilar)	Qualitative
		Number of new and existing FTE resources dedicated to initial and subsequent biosimilar drug implementations	Qualitative
		Timelines for initial and subsequent biosimilar drug implementation	Qualitative
		Readiness of data collection systems to collect biosimilar data	Qualitative
		Changes that were made to existing systems to support data collection with respect to biosimilars	Qualitative
		How were educational materials incorporated into clinical practice?	Ways in which materials were incorporated into practice (e.g., protocols updated, links to materials on website, placement of printed materials in clinics, training requirements)
Maintenance	What administrative and clinical supports are in place to ensure the ease of ongoing use of biosimilars?	Types of resources in place to support new biosimilar implementations at treatment facilities	Qualitative

Appendix to: Milgram L, Wheeler S, Adamic A, Loncar M, Guirguis M, McCabe BJ. A framework for evaluating the implementation of biosimilar drugs. *Can J Hosp Pharm.* 2023;76(2):109-16.

## APPENDIX 1 (Part 3 of 3). Biosimilars Implementation Evaluation Framework.

RE-AIM Element	Evaluation Questions	Indicators	Data Collection <sup>a</sup>
System sustainability and affordability			
Effectiveness	What were the intended outcomes or targets of the funding policies?	Utilization of biosimilars	Administrative
		The extent to which utilization targets were achieved	Administrative
	Were they reached, and after how long?	Utilization of related drugs (e.g., concomitant drugs, different therapeutic classes)	Administrative
		Did different funding policies lead to different outcomes in the uptake of biosimilars?	Number of jurisdictions that have an exception policy or process
		Number of exception requests received	Administrative
		Approval rate of exception requests	Administrative
		Cost savings within a defined time period after implementation	Administrative
		Market distribution of brands for a drug	Administrative
		Administrative resources required for multiple brand negotiations and contracting	Qualitative
		Number of amendments to product listing agreements	Organizational
	Timing of jurisdictional funding of new biosimilar drugs after regulatory approval or price negotiation	Organizational	
	Change in utilization of health care resources	Qualitative	

FTE = full-time equivalent.

<sup>a</sup>Organizational data consist of information about how a program is constructed and operates, which is used to understand how a program is implemented.

Qualitative data consist of information about context, which is used to understand why a program worked well or did not work well. Administrative data consist of information routinely collected about program operations, which is used for performance management, funding, or reporting.

Appendix to: Milgram L, Wheeler S, Adamic A, Loncar M, Guirguis M, McCabe BJ. A framework for evaluating the implementation of biosimilar drugs. *Can J Hosp Pharm.* 2023;76(2):109-16.

**APPENDIX 1: Clinical practice standards for anticoagulation. © 2014 Saskatchewan Health Authority Regina. Reproduced by permission.**



**Appendix 1: Anticoagulation Clinical Practice Standard**

**Goal:** The pharmacist will provide evidence-based pharmaceutical care to patients receiving anticoagulation therapy to achieve desired outcomes and minimize risk of negative outcomes

**Standard #1:** The pharmacist will assess thromboembolic risk and recommend evidence-based anticoagulation for all patients receiving injectable or oral anticoagulants.

**Standard #2:** The pharmacist will assess bleeding risk for all patients receiving therapeutic anticoagulation therapy and intervene where possible to reduce bleeding risk.

**Standard #3:** The pharmacist will assess and provide practical recommendations for management of drug interactions with warfarin and other oral anticoagulants.

**Standard #4:** The pharmacist will educate patients on therapeutic anticoagulation therapy initiated during the hospital stay.

**Standard #5:** The pharmacist will review discharge medications/prescription for completeness and accuracy of anticoagulation orders.

	Activity	Descriptor of Expectation	AIM-HIGH
<b>Patient Identification</b>	Admission and prescriber orders	Identify anticoagulant medications (rivaroxaban, dabigatran, apixaban, edoxaban, LMWH, UFH, fondaparinux, warfarin, argatroban, bivalirudin), admitting diagnoses (VTE, Afib, etc) and tests to identify patients requiring anticoagulation therapy  Identify patient risk factors increasing risk for VTE to identify patients requiring assessment for VTE prophylaxis (medical patients, orthopedic surgery patients, other surgical patients)	n/a
	Auto generated Centricity Report of Clinical Interventions	Review report of dabigatran, rivaroxaban, apixaban, edoxaban and "warfarin daily" orders on applicable wards	n/a
	Unit Patient Rosters	Identify admitting diagnoses that require anticoagulation (e.g DVT, PE, VTE, Afib, cardiac valve surgery, ACS)	n/a
	Consults	Patients may also be identified through other healthcare professional consults as this clinical priority becomes a known expectation	n/a

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	Activity	Descriptor of Expectation	AIM HIGH
<b>Evidence Based Therapies</b>	Pharmaceutical Care/Medication Management: <ul style="list-style-type: none"> <li>• Profile Review</li> <li>• Chart Review</li> <li>• Patient Interview</li> </ul>	Review all orders for anticoagulation therapy to confirm and assess: <ul style="list-style-type: none"> <li>• Indication</li> <li>• Drug</li> <li>• Dose - Confirm weight, calculate mg/kg dose, and CrCl when required</li> <li>• Frequency</li> <li>• Route</li> <li>• Duration</li> <li>• No cautions or contraindications ☺Pay close attention to the peri-procedural period (eg. surgery bleed risk, hemostasis post op, epidural use)</li> </ul> <p>Follow and complete the “Dabigatran/Rivaroxaban/Apixaban Orders Checklist”</p> <p>Conduct patient interviews as required to ensure medication regimens are accurate; consult with community pharmacists, review refill history, etc.</p> <p>Decrease patient’s bleed risk by:</p> <ul style="list-style-type: none"> <li>• Confirm need for antiplatelet agents (ASA/NSAIDs/clopidogrel/ticagrelor, etc)</li> <li>• Minimize duration of dual or triple therapy to what’s necessary based on current evidence (e.g. post cardiac stent placement, recent ACS)</li> <li>• Assess need for PPI when high risk for GI bleed</li> <li>• Ensuring blood pressure controlled</li> <li>• If receiving warfarin, minimize labile INRs. Strategies to minimize labile INRs:               <ul style="list-style-type: none"> <li>• address drug interactions, if present</li> <li>• provide patient education</li> <li>• Refer to RQHR AMS</li> <li>• convert to other oral anticoagulant, if appropriate</li> </ul> </li> </ul> <p><b>Possible References:</b>            CLOT checklists:            Dabigatran; Rivaroxaban; Apixaban            Canadian Cardiovascular Society            Antithrombotic Therapy &amp; Prevention of Thrombosis. 9<sup>th</sup> ed: American College of Chest Physicians            Thrombosis Canada</p>	Pharmaceutical care Medication management: if not a full pharmaceutical care plan of the patient <ul style="list-style-type: none"> <li>• Cardiovascular subgrouping</li> <li>• Input action taken</li> </ul>
	Drug-Drug Interactions	Assess for actual and potential warfarin drug interactions using the following tool as a guide: Bungard T et al. Drug interactions involving warfarin	Discuss practical and specific management recommendations with the attending or, if less

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	urgent, document in the progress notes of medical chart	subgrouping
	Ensure progress notes are followed up in a timely manner	<ul style="list-style-type: none"> <li>Input action taken</li> </ul>

	Activity	Descriptor of Expectation	AIM HIGH
<b>Patient Education</b>	Warfarin	<p>Prior to discharge for patients newly initiated on warfarin, or in whom further education is warranted (e.g. mechanical valve patients, non-compliance)</p> <p>Follow the warfarin education checklist and use RQHR patient information sheet, or manufacturer's patient booklet. Include:</p> <ul style="list-style-type: none"> <li>Intended benefit / Indication</li> <li>Dose – multiple tablet strengths of warfarin usually required to manage dose adjustments</li> <li>Target INR &amp; monitoring</li> <li>Duration</li> <li>Potential drug and food interactions &amp; management</li> <li>Side effects and management</li> <li>Importance of carrying ID indicating on warfarin</li> <li>Warfarin dosing until follow up INR and INR date post discharge</li> </ul>	<p>Pharmaceutical care Medication management: if not a full pharmaceutical care plan of the patient</p> <ul style="list-style-type: none"> <li>Cardiovascular subgrouping</li> <li>Input action taken - Patient Education</li> </ul>
	LMWH	<p>For those requiring long-term treatment (i.e. VTE and active cancer), or short-term for cross-coverage/bridging, ensure ability to administer in community ☺Facilitate patient education &amp; administration teaching via nursing staff prior to discharge, or via Home Care/Treatment Centre referral</p> <p><b>Dalteparin:</b> <a href="http://www.fragmin.ca">www.fragmin.ca</a> To enter the site, type in an 8-digit DIN for Fragmin.</p> <p><b>Enoxaparin:</b> <a href="http://www.lovenox.com/default.aspx">http://www.lovenox.com/default.aspx</a></p> <p>Tinzaparin: <a href="https://www.leo-pharm.ca/Home/patient-resources.aspx">https://www.leo-pharm.ca/Home/patient-resources.aspx</a> (to enter the site, type in a DIN for tinzaparin)</p> <p>Patient information: LMWH</p> <p>Medication cost and ability to pay - Make patient aware of potential costs and assist with drug coverage if required ☺(e.g. SK drug plan coverage/EDS, NIHB, special support application); ☺if barriers, discuss with attending</p> <p>For bridging send at least a 5 day supply of LMWH prior to discharge ☺Refer to RQHR Pharmacy Procedure for LMWH-Provision for Outpatients</p>	<p>Pharmaceutical care Medication management: if not a full pharmaceutical care plan of the patient</p> <ul style="list-style-type: none"> <li>Cardiovascular subgrouping</li> <li>Input action taken - Patient Education</li> </ul>

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	Activity	Descriptor of Expectation	AIM HIGH
	Novel oral anticoagulants (Factor Xa, IIa/Thrombin Inhibitors)	<p>All patients being initiated on novel oral agents for Afib or VTE</p> <p>Patient information: Rivaroxaban, Apixaban, Dabigatran, Edoxaban</p> <ul style="list-style-type: none"> <li>• Explain benefit/Indication</li> <li>• Dose and duration</li> <li>• Importance of adherence</li> <li>• Potential drug interactions &amp; management</li> <li>• Side effects and management</li> <li>• Importance of carrying ID indicating on anticoagulation</li> </ul> <p>Medication cost and ability to pay – Make patient aware of potential costs and assist with drug coverage if required ☺(e.g. SK drug plan coverage/EDS, NIHB, special support application); ☹If barriers, discuss with attending</p>	<p>Pharmaceutical care Medication management: if not a full pharmaceutical care plan of the patient</p> <ul style="list-style-type: none"> <li>• Cardiovascular subgrouping</li> <li>• Input action taken - Patient Education</li> </ul>

	Activity	Descriptor of Expectation	AIM HIGH
<b>Seamless Care</b>	Discharge Prescriptions	<p>Review prescription to ensure:</p> <ul style="list-style-type: none"> <li>• Anticoagulation medication and doses are correct</li> <li>• If warfarin, ensure patient aware of warfarin dosing until follow up INR</li> <li>• Adequate LMWH or newer oral anticoagulant supply to avoid missed doses</li> <li>• Discontinued medications are not resumed ☺Write stopped orders on outpatient Rx</li> </ul>	<p>Pharmaceutical care Medication management: if not a full pharmaceutical care plan of the patient</p> <ul style="list-style-type: none"> <li>• Cardiovascular subgrouping</li> <li>• Input action taken</li> </ul>
	Transfers	<p>For transfers to another enhanced/targeted unit, or facility, ensure:</p> <ul style="list-style-type: none"> <li>• Monitoring forms are shared</li> <li>• Outstanding issues are resolved where possible; if not, communicate follow up plans</li> </ul> <p>For patients referred to RQHR AMS:</p> <ul style="list-style-type: none"> <li>• the AMS pharmacist will contact the ward pharmacist prior to patient discharge if assistance is required</li> </ul>	<p>Pharmaceutical care Medication management: if not a full pharmaceutical care plan of the patient</p> <ul style="list-style-type: none"> <li>• Cardiovascular subgrouping</li> <li>• Input action taken</li> </ul>

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<b>Documen tation</b>	Medical Chart	<p>Document the following in the Progress Notes:</p> <ul style="list-style-type: none"> <li>• Suggestions for changes in medication</li> <li>• Summary of patient education provided</li> <li>• Supply of LMWH upon discharge has been provided ☺If outpatient Rx, ensure available at community pharmacy to ensure no missed doses</li> </ul> <p>For patients initiated on an oral anticoagulant other than warfarin, indicate:</p> <ul style="list-style-type: none"> <li>• Patient aware to NOT resume warfarin (if on prior)</li> <li>• EDS has been completed, and/or patient is aware of cost and able to pay</li> </ul> <p>For CSU/ST/3F, document on cardiac teaching document (if available): initials, medication, and date of education</p>	
	Centricity and New Orders Checklist	<p>Complete the “Dabigatran/Rivaroxaban/Apixaban/Edoxaban Orders Checklist” and attach to corresponding medication order in Centricity for each agent. Discard in confidential recycling once attached</p>	
	Centricity Clinical Interventions	<p>Ensure interventions and outstanding clinical activities documented</p>	
	RQHR Patient Monitoring Form	<p>Complete for more complex patients</p>	

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## APPENDIX 2: Captured metrics in AIM High, version 2 (collected in Google Forms).

- 1) Work hours
  - a. Regular: 0730 to 1600 Monday to Friday
  - b. Other: any time after 1600 and before 0730 on weekdays, as well as all hours on weekends and stat holidays
- 2) Select pharmacist team (from drop-down menu)
- 3) Pharmacist name
- 4) Ward (including if it has a ward based clinical pharmacist)
- 5) Type of clinical activity/issue
  - a. Multidisciplinary care rounds
  - b. Medication management
  - c. Transition in care: on admission
  - d. Transition in care: on transfer
  - e. Transition in care: on discharge
- 6) Action: Types of pharmacist interventions
  - a. Adverse event or drug interaction resulting in change in medication
  - b. Change route or drug within class
  - c. Drug discontinued
  - d. Drug started/restarted
  - e. Dose changed (includes interval)
  - f. IV to PO
  - g. Monitoring ordered (e.g., laboratory test, vital signs, weights)
  - h. Patient education
- 7) Action involved direct patient/caregiver interaction with pharmacist
  - a. Yes
  - b. No
- 8) Action documented in patient medical record by pharmacist
  - a. Physician order
  - b. Progress note
  - c. Both physician order and progress note
  - d. None
- 9) Was prescriptive authority used for intervention?
  - a. Yes
  - b. No
- 10) High-risk drug?
  - a. Yes
  - b. No
- 11) From drop-down list, select clinical practice standard followed (e.g., Anticoagulation)

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## APPENDIX 1. Search strategy for critical appraisal tool manuscripts and webpages.

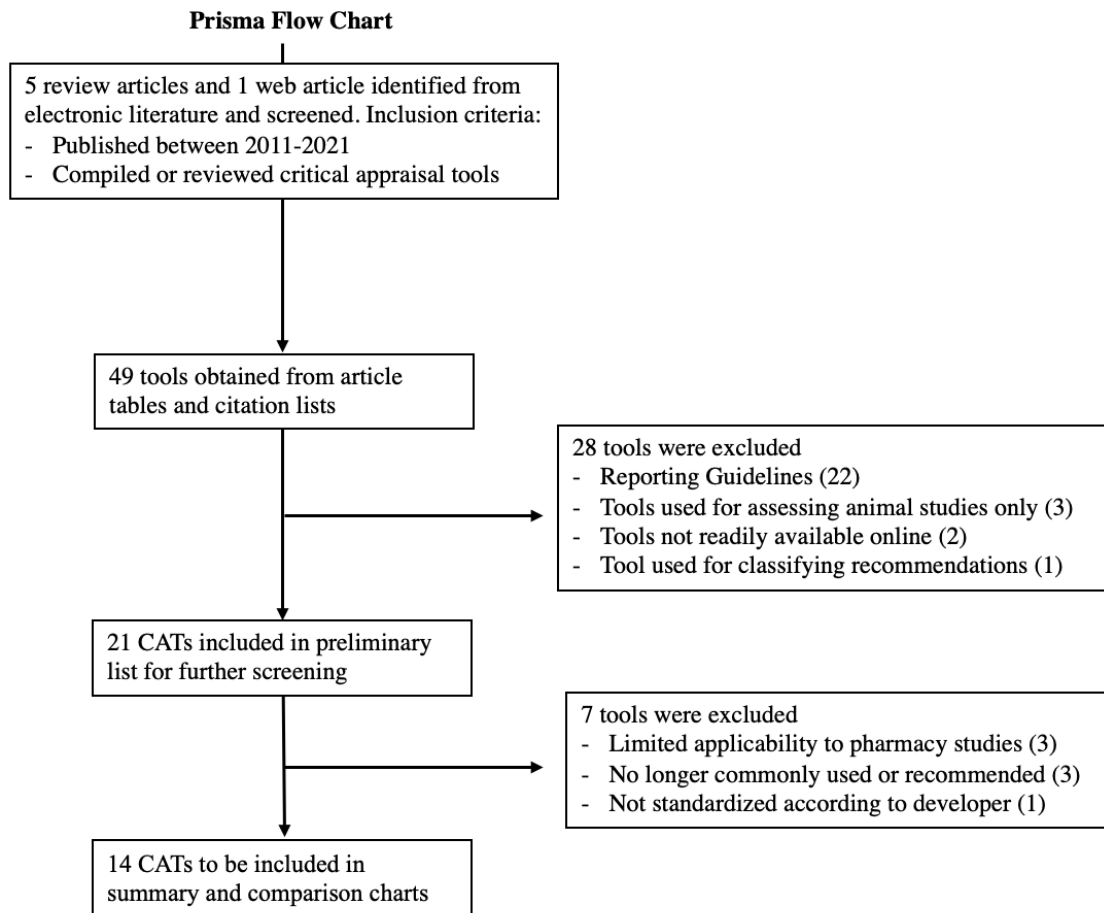
Tool <sup>a</sup>	Search Strategy
RoB	Original manuscript obtained from citation list of Zeng et al. <sup>1</sup> Tool obtained from Tables 1 and 2 of original manuscript. Link for tool: <a href="https://www.bmj.com/content/343/bmj.d5928">https://www.bmj.com/content/343/bmj.d5928</a>
RoB 2	Original manuscript obtained from citation list of Haile. <sup>2</sup> Tool obtained through Google search using "ROB 2 Tool"; a link to the tool on the Cochrane Collaboration's risk-of-bias Google site was available on the first page of results. Link for tool: <a href="https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool?authuser=0">https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool?authuser=0</a>
NOS	Tool webpage obtained from citation list of Zeng et al. <sup>1</sup> Link for tool: <a href="http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp">http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp</a>
ROBINS-I	Original manuscript obtained from citation list of Ma et al. <sup>3</sup> Tool obtained through Google search using "ROBINS-I Tool"; a link to the tool on the Cochrane Collaboration's risk-of-bias Google site was available on the first page of results. Link for tool: <a href="https://www.riskofbias.info/welcome/home/current-version-of-robins-i">https://www.riskofbias.info/welcome/home/current-version-of-robins-i</a>
MINORS	Original manuscript obtained from citation list of Zeng et al. <sup>1</sup> Tool obtained from Table 2 of original manuscript. Link for tool: <a href="https://www.unisa.edu.au/contentassets/72bf75606a2b4abcaf7f17404af374ad/6f--minors1.pdf">https://www.unisa.edu.au/contentassets/72bf75606a2b4abcaf7f17404af374ad/6f--minors1.pdf</a>
AMSTAR 2	Original manuscript obtained from citation list of Haile. <sup>2</sup> Tool obtained from manuscript "Data Supplement". Link for tool: <a href="https://www.bmj.com/content/358/bmj.j4008/related">https://www.bmj.com/content/358/bmj.j4008/related</a>
ROBIS	Original manuscript obtained from citation list of Ma et al. <sup>3</sup> Tool obtained through Google search using "ROBIS Tool"; a link to the tool on University of Bristol's webpage was available on the first page of results. Link for tool: <a href="https://www.bristol.ac.uk/population-health-sciences/projects/robis/robis-tool/">https://www.bristol.ac.uk/population-health-sciences/projects/robis/robis-tool/</a>
AGREE II	Tool webpage obtained from citation list of Zeng et al. <sup>1</sup> Link for tool: <a href="https://www.agreetrust.org/resource-centre/agree-ii/">https://www.agreetrust.org/resource-centre/agree-ii/</a>
GRACE	Original manuscript obtained from citation list of Ma et al. <sup>3</sup> Tool obtained through Google search using "GRACE Checklist"; a link to the tool on the Grace Principles website was available on the first page of results. Link: <a href="https://www.graceprinciples.org/doc/GRACE-Checklist-031114-v5.pdf">https://www.graceprinciples.org/doc/GRACE-Checklist-031114-v5.pdf</a>
CASP checklists	Tool webpage obtained from citation list of Zeng et al. <sup>1</sup> Link for tool: <a href="https://casp-uk.net/casp-tools-checklists/">https://casp-uk.net/casp-tools-checklists/</a>
CEBM guides	Tool webpage obtained from citation list of Twells. <sup>4</sup> Link for tool: <a href="https://www.cebm.ox.ac.uk/resources/ebm-tools/critical-appraisal-tools">https://www.cebm.ox.ac.uk/resources/ebm-tools/critical-appraisal-tools</a>
JBI critical appraisal tools	Tool webpage obtained from citation list of Buccheri and Sharifi. <sup>5</sup> Link for tool: <a href="https://jbi.global/critical-appraisal-tools">https://jbi.global/critical-appraisal-tools</a>
SIGN	Tool webpage obtained from citation list of Zeng et al. <sup>1</sup> Link for tool: <a href="https://www.sign.ac.uk/what-we-do/methodology/checklists/">https://www.sign.ac.uk/what-we-do/methodology/checklists/</a>
CCAT	Tool obtained from Table 3 of Bashir and Dziemidowicz <sup>6</sup> Link: <a href="https://conchra.com.au/2015/12/08/crowe-critical-appraisal-tool-v1-4/">https://conchra.com.au/2015/12/08/crowe-critical-appraisal-tool-v1-4/</a>

<sup>a</sup>The full name of each tool is provided in Table 1 of the main article.

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Appendix to: Blanc A, Ho V, Cameron J. Critical appraisal tools to aid pharmacists in evidence-based practice: a narrative review. *Can J Hosp Pharm*. 2023;76(2):131-40.



Appendix to: Blanc A, Ho V, Cameron J. Critical appraisal tools to aid pharmacists in evidence-based practice: a narrative review. *Can J Hosp Pharm.* 2023;76(2):131-40.

## APPENDIX 3. Risk-of-bias (RoB) domains assessed by tools.

### Cochrane RoB<sup>1</sup>

- Selection bias (random sequence generation, allocation concealment)
- Performance bias (blinding of participants and personnel)
- Detection bias (blinding of outcome assessment)
- Attrition bias (incomplete outcome data)
- Reporting bias (selective reporting)
- Other bias (anything else, ideally prespecified)
- Overall RoB

### Cochrane RoB 2<sup>2</sup>

- RoB arising from the randomization process
- RoB due to deviations from the intended interventions (effect of assignment to intervention and effect of adhering to intervention)
- Missing outcome data
- RoB in measurement of the outcome
- RoB in selection of the reported result
- Overall RoB

### Cochrane ROBINS-I<sup>3</sup>

- Bias due to confounding
- Bias in selection of participants into the study
- Bias in classification of interventions
- Bias due to deviations from intended interventions
- Bias due to missing data
- Bias in measurement of outcomes
- Bias in selection of the reported result
- Overall bias

### ROBIS<sup>4</sup>

- Concerns regarding specification of study eligibility criteria
- Concerns regarding methods used to identify and/or select studies
- Concerns regarding methods used to collect data and appraise studies
- Concerns regarding the synthesis and findings

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Appendix to: Blanc A, Ho V, Cameron J. Critical appraisal tools to aid pharmacists in evidence-based practice: a narrative review. *Can J Hosp Pharm*. 2023;76(2):131-40.



## APPENDIX FOR 2023 POSTER ABSTRACTS / ANNEXE POUR LES RÉSUMÉS DES AFFICHES 2023

Appendix to: Griffore K, Selvakumar K, Wan M, Taggart LR, Leung E. Adherence to recommendations from antimicrobial stewardship audit and feedback rounds in academic intensive care units [abstract]. *Can J Hosp Pharm.* 2023;76(2):147.

TABLE 1: Rates of recommendation acceptance collected from PAF during selected ASP rounds								
	Trauma and Neurosurgery ICU		Medical Surgical ICU		Cardiovascular ICU		ICUs combined	
	recommendation (n)	accepted	recommendation (n)	accepted	recommendation (n)	accepted	recommendation (n)	accepted
total	134	86.6%	280	85.7%	33	81.8%	447	85.7%
promote appropriate antimicrobial coverage	24	66.7%	52	75%	6	83.3%	82	73.2%
a. expand empiric coverage	9	66.7%	18	77.8%	4	100%	31	77.4%
b. initiate therapy to cover a positive culture not currently being treated	0	NA	3	100%	1	100%	4	100%
c. change agent given positive culture resistant to current therapy	2	100%	1	100%	0	NA	3	100%
d. change regimen to further optimize therapy	13	61.5%	30	70%	1	0%	44	65.9%
reduce selective pressure	86	77.9%	191	85.3%	22	81.8%	299	82.9%
e. shorten duration of therapy	25	80%	49	87.8%	8	75%	82	84%
f. discontinue agent	24	79.2%	64	79.7%	7	85.7%	95	80%
g. discontinue agent given unnecessary double coverage	1	100%	5	100%	7	85.7%	13	83.6%
h. narrow spectrum	36	75%	73	87.7%	0	NA	109	100%
dose adjustment	11	90.9%	20	85%	4	75%	35	85.7%
Infectious diseases consult	14	100%	32	90.6%	3	100%	49	93.9%

Appendix to: Naccarato S, Beaman A, Hammond E. Evaluating the incidence of hypoglycemia among hyperkalemic patients treated with insulin in the emergency department at Trillium Health Partners (THP) [abstract]. *Can J Hosp Pharm.* 2023; 76(2):150.

**Table 1. Treatment-Related Variables <sup>a</sup>**

Parameter	All insulin administrations (n=197)	Hypoglycemia groups		
		No hypoglycemia (BG ≥ 4 mmol/L) (n = 149)	Moderate hypoglycemia (BG 2.8 to 3.9 mmol/L) (n = 33)	Severe hypoglycemia (BG < 2.8 mmol/L) (n = 15)
<b>Dextrose dose administered, n (%)</b>				
None	4 (2)	3 (2)	0 (0)	1 (6.7)
25 g	189 (96)	143 (96)	33 (100)	13 (86.7)
50 g	4 (2)	3 (2)	0 (0)	1 (6.7)
<b>Other hyperkalemia treatment given, n (%)</b>				
Diuretics	64 (32.5)	48 (32.2)	13 (39.4)	3 (20)
Cation exchange resins	79 (40.1)	63 (42.3)	10 (30.3)	6 (40)
Inhaled β <sub>2</sub> agonists	63 (32)	56 (37.6)	3 (9.2)	4 (26.7)
<b>Concomitant medications that ↓ BG, n (%)</b>				
Other insulins	16 (8.1)	16 (10.7)	0 (0)	0 (0)
Secretagogues	1 (0.5)	1 (0.7)	0 (0)	0 (0)
<b>Concomitant medications that ↑ BG</b>				
Dextrose (from IV drugs), n (%)	55 (27.9)	42 (28.2)	9 (27.3)	4 (26.7)
Total dextrose (from IV drugs), g (median, IQR)	12.5 (7.5-22.5)	16.9 (9.3 -22.5)	7.5 (4.2 – 21.3)	7 (4-9.3)
Dextrose (for hypoglycemia), n (%)	25 (12.7)	1 (0.7)	13 (39.4)	11 (73.3)
Dextrose (for hypoglycemia), g (mean, ± SD)	26.5 ± 8	12.5 ± 0	25 ± 3.9	29.5 ± 10.5
<b>Blood Glucose</b>				
Hypoglycemic event, n (%)	48 (24.4)		33 (16.8 <sup>b</sup> )	15 (7.6 <sup>b</sup> )
Lowest value recorded, mmol/L (median, IQR)	5.8 (4-8.7)	6.8 (5.3-10.8)	3.1 (2.8-3.6)	2.1 (1.6-2.4)
Time of lowest value, hours (median, IQR)	2.7 (1.8-3.73)	2.8 (2-3.8)	2.6 (1.8-2.9)	2.2 (1.6-3.2)
Hypoglycemic events that occurred > 3 hours post-insulin <sup>c</sup> , n (%)	15/48 (31)	10 (30.3)	5 (33.3)	
<b>Potassium</b>				
K+ ≤ 5 mmol/L, n (%)	71 (36)	50 (33.6)	14 (42.4)	7 (46.7)

<sup>a</sup> All treatment-related variables were only included if they were given (drugs) or recorded (lab values) within 6-hours post-insulin administration

<sup>b</sup> Percentage out of the entire project sample (n = 197)

<sup>c</sup> Includes 48 administrations where hypoglycemia (BG < 4 mmol/L) occurred

**TABLE 1: Handling of bottles of tacrolimus 0,5 mg/mL compounded suspension<sup>1</sup> and analyses carried over time**

Scenario/ Bottle (A)umber (C)lear	Storage and handling conditions				Time Points of Analyses		
	Temp. (°C)	Daylight Exposure	Vigorous agitation of bottle for 30 seconds	2 mL sampling <sup>2</sup>	Amlodipine <sup>3</sup> Contamination	Microbial (3 mL sampling) <sup>4</sup>	Tacrolimus HPLC Assay (2 mL sampling) <sup>5</sup>
1 <sup>6</sup> /A	2-8		x	D0, D56, D63, D70, D77, D84		D0, D56, D84	D0, D56, D63, D70, D77, D84
2/A	2-8		x	BID <sup>7</sup> from D0 to D28		D0, D28	D0,D7,D14,D21,D28
3/A	2-8			BID from D0 to D28		D0, D28	D0,D7,D14,D21,D28
4/A	2-8		x	BID from D0 to D28	x	D0, D28	D0,D7,D14,D21,D28
5/A	2-8			BID from D0 to D28	x	D0, D28	D0,D7,D14,D21,D28
6/A	20-25	x	x	BID from D0 to D28		D0, D28	D0,D7,D14,D21,D28
7/C	20-25	x	x	BID from D0 to D28		D0, D28	D0,D7,D14,D21,D28
8/A	-20			D0,D1			D0, D1
9/A	20-25		x <sup>8</sup>	14 times on D0, D1, D2, D3 <sup>9</sup>			D0, D1, D2, D3 <sub>1</sub> , D3 <sub>2</sub>

D= Day, BID=twice daily, HPLC=High Performance Liquid Chromatography

<sup>1</sup>150 mL in plastic bottles

<sup>2</sup>Samples taken from each bottle by first pouring the amount into a 30 mL measuring cup and then withdrawing 2 mL using a 3 mL syringe. Any remaining amount in the measuring cup was poured back in the bottle. The 2 mL sample was either used for the assay on pre-determined days or was safely discarded.

<sup>3</sup>1 mL of amlodipine withdrawn in the syringe and put back in its bottle prior to tacrolimus sampling with the contaminated syringe.

<sup>4</sup>3 mL transferred into sterile container stored in refrigerator and analysed within 24 hours

<sup>5</sup>Two 1 mL aliquots transferred into two 5 mL cryovials and stored in a freezer at -80°C until analysis.

<sup>6</sup>Control bottle: Agitation twice daily, every day up to day 84

<sup>7</sup>One sample on D0, two samples from D1 to D28 taken less than 4 but no more than 12 hours apart;

<sup>8</sup>Bottle shaken 30 seconds on first sampling

<sup>9</sup>Until the bottom of the bottle is reached

Appendix to: Jain B, Sun C, Singh S, Bugaj V, DeAngelis C, Peragine C. Prescribing trends for antiestrogens, bicalutamide, traditional oral cytotoxic agents, and oral immunosuppressants at the Odette Cancer Centre between 2018 to 2022 [abstract]. *Can J Hosp Pharm.* 2023;76(2):154.

**TABLE 1. Descriptive statistics and trends for new, unique, and total prescriptions for traditional oral anticancer medications**

	Total for study period (count)	Average per quarter (count)	Average per month (count)	Average per day (count)	Quarterly trend	
					( $\Delta$ count/quarter)	P-value
<b>TOTAL PRESCRIPTIONS</b>						
Antiestrogens*	5715	336	112	3.7	-2.0	0.57
Bicalutamide	1443	85	28	0.9	-2.7	<b>0.01</b>
Traditional cytotoxics and/or immunosuppressants**	14 961	880	293	9.7	+7.9	<b>0.03</b>
<b>UNIQUE PRESCRIPTIONS</b>						
Antiestrogens*	5697	335	112	3.7	-2.0	0.58
Bicalutamide	1443	85	28	0.9	-2.7	<b>0.01</b>
Traditional cytotoxics and/or immunosuppressants**	10 487	617	206	6.8	+3.7	0.08
<b>NEW STARTS</b>						
Antiestrogens*	974	57	19	0.6	-1.6	0.24
Bicalutamide	1 026	60	20	0.7	-2.3	<b>0.01</b>
Traditional cytotoxics and/or immunosuppressants**	2 132	125	42	1.4	-1.4	<b>0.04</b>

\*Antiestrogen OAMs include anastrozole, exemestane, letrozole, and tamoxifen

\*\* Traditional cytotoxics and/or immunosuppressants include capecitabine, chlorambucil, cyclophosphamide, cyclosporine, etoposide, fludarabine, hydroxyurea, isotretinoin, lomustine, mercaptopurine, methotrexate, midostaurin, mycophenolate, procarbazine, tacrolimus, temozolomide, and tretinoin

**TABLE 1. SGLT2i trials in type 2 diabetes**

Trial (Medication)	Primary Outcome HR (95% CI) (P-value)	Key Summary
EMPA-REG OUTCOME (empagliflozin 10 or 25 mg)	↓ MACE 0.86 (0.74 – 0.99) (P=0.04)	This was the first SGLT2i trial showing reduction of CV events.
CANVAS Program (canagliflozin 100 or 300 mg)	↓ MACE 0.86 (0.75 – 0.97) (P=0.02)	Canagliflozin reduced CV events and HHF.
DECLARE-TIMI 58 (dapagliflozin 10 mg)	↓ CV death or HHF 0.83 (0.73 – 0.95) (P=0.005)	Dapagliflozin lowers rate of CV death or HHF, but not MACE.
VERTIS CV (ertugliflozin 5 or 15 mg)	MACE 0.97 (0.75 – 1.03) (P<0.001 for noninferiority)	Ertugliflozin is non-inferior to placebo in reducing MACE.

CV = cardiovascular; eGFR = estimated glomerular filtration rate; HHF = heart failure hospitalization; MACE = major adverse cardiovascular event

**TABLE 2. SGLT2i trials in cardiovascular disease**

Trial (Medication)	Primary Outcome HR (95% CI) (P-value)	Key Summary
DAPA-HF (dapagliflozin 10 mg)	↓ worsening HF or CV death 0.74 (0.65 – 0.85) (P<0.001)	Dapagliflozin lowered the risk of worsening HF or CV death in HFrEF patients, regardless of diabetic status
EMPEROR-Reduced (empagliflozin 10 mg)	↓ composite of CV death and HHF 0.75 (0.65 – 0.86) (P<0.001)	Empagliflozin shown to reduce CV death and HHF in HFrEF, regardless of diabetic status
EMPEROR-Preserved (empagliflozin 10 mg)	↓ CV death or HHF 0.79 (0.69 – 0.90) (P<0.001)	Empagliflozin reduced CV death or HHF in HFpEF patients
SOLOIST-WHF (sotagliflozin 200 or 400 mg)	↓ CV death and HHF 0.67 (0.52 – 0.85) (P<0.001)	This was the first large trial of SGLT1/SGLT2 inhibitor in hospitalized patients
DELIVER (dapagliflozin 10 mg)	↓ CV death or worsening HF 0.82 (0.73 – 0.92) (P<0.001)	Patients with HF with mildly reduced or preserved ejection fraction. Dapagliflozin benefits extend to all HF patients.

CV = cardiovascular; HF = heart failure; HHF = hospitalization heart failure; HFrEF = heart failure reduced ejection fraction; HFpEF = heart failure preserved ejection fraction

**TABLE 3. SGLT2i trials in renal disease**

Trial (Medication)	Primary Outcome HR (95% CI) (P-value)	Key Summary
CREDENCE (canagliflozin 100 mg)	↓ ESRD, doubling of sCr, renal death, or CV death 0.70 (0.59 – 0.82) (P=0.00001)	CREDENCE was the first trial showing GLD in improving kidney endpoints.
DAPA-CKD (dapagliflozin 10 mg)	↓ Decline in eGFR, new ESRD, renal death, or CV death 0.61 (0.51 – 0.72) (P<0.001)	Dapagliflozin reduced the risk of eGFR decline, ESRD, and renal or CV death in CKD patients, regardless of diabetic status.

CKD = chronic kidney disease; CV = cardiovascular; eGFR = estimated glomerular filtration rate; ESRD = end stage renal disease; GLD = glucose lowering drug; sCr = serum creatinine

**TABLE 1. Descriptive statistics and trends for new, unique, and total prescriptions for oral anticancer medications**

	Total for study period (count)	Average per quarter (count)	Average per month (count)	Average per day (count)	Quarterly trend	
					(Δ count/quarter)	P-value
<b>TOTAL PRESCRIPTIONS</b>						
All OAM	60 387	3 552	1 184	39	<b>+79.6</b>	<b>&lt;0.001</b>
Traditional * OAM	22 119	1 301	434	14	+3.2	0.3
Modern** OAM	38 268	2 251	750	25	<b>+76.4</b>	<b>&lt;0.001</b>
<b>UNIQUE PRESCRIPTIONS</b>						
All OAM	46 644	2 744	915	30	<b>+40.5</b>	<b>&lt;0.001</b>
Traditional * OAM	17 627	1 037	346	11	-1.0	0.75
Modern** OAM	29 017	1 707	569	19	<b>+41.5</b>	<b>&lt;0.001</b>
<b>NEW STARTS</b>						
All OAM	6 978	410	137	5	<b>-5.2</b>	<b>0.03</b>
Traditional * OAM	4 132	243	81	3	<b>-5.3</b>	<b>0.02</b>
Modern** OAM	2 846	167	56	2	+0.2	0.82

\*Traditional OAMs include Anastrozole, exemestane, letrozole, tamoxifen, bicalutamide, capecitabine, chlorambucil, cyclophosphamide, cyclosporine, etoposide, fludarabine, hydroxyurea, isotretinoin, lomustine, mercaptopurine, methotrexate, midostaurin, mycophenolate, procarbazine, tacrolimus, temozolomide, tretinoin.

\*\*Modern OAMs include abemaciclib, abiraterone, acalabrutinib, afatinib, alectinib, alpelisib, apalutamide, axitinib, binimetinib, brigatinib, cabozantinib, capmatinib, cedazuridine/decitabine, cobimetinib, crizotinib, dabrafenib, darolutamide, dasatinib, eltrombopag, enasidenib, encorafenib, enzalutamide, erdafitinib, erlotinib, everolimus, gefitinib, gilteritinib, glasdegib, ibrutinib, idelalisib, imatinib, ixazomib, lapatinib, larotrectinib, lenalidomide, lenvatinib, lorlatinib, mobocertinib, neratinib, nilotinib, niraparib, olaparib, osimertinib, palbociclib, pazopanib, pomalidomide, pralsetinib, regorafenib, ribociclib, ruxolitinib, selinexor, selpercatinib, sorafenib, sotorasib, sunitinib, telotristat ethyl, trametinib, trifluridine/tipiracil, tucatinib, veliparib, vemurafenib, venetoclax, vismodegib, vorinostat, zanubrutinib

Appendix to: Mourad M, Bertoldo L, Vinet J. Listen to your clinicians: collecting user input after smart pump implementation to drive continuous quality improvement [abstract]. *Can J Hosp Pharm.* 2023;76(2):161-2.

**TABLE 1. Clinician Responses to Survey Questions**

Question*	Average Rating out of 5 before implementation (% agreement with the statement)	Average Rating out of 5 after implementation (% agreement with the statement)	Percent Difference
I always use the pump drug library for IV infusions.	2.81 (56.2%)	4.10 (82%)	+25.8%
It is easy for me to find the drugs I need in the pump drug library	3.15 (63%)	3.61 (72.2%)	+9.2%
The pump's drug library supports safe patient infusions	3.47 (69.4%)	3.99 (79.8%)	+10.4%
I understand the process to follow if a limit is reached within the drug library and how to communicate this if I would like the settings to be modified.	N/A	3.19 (63.8%)	N/A

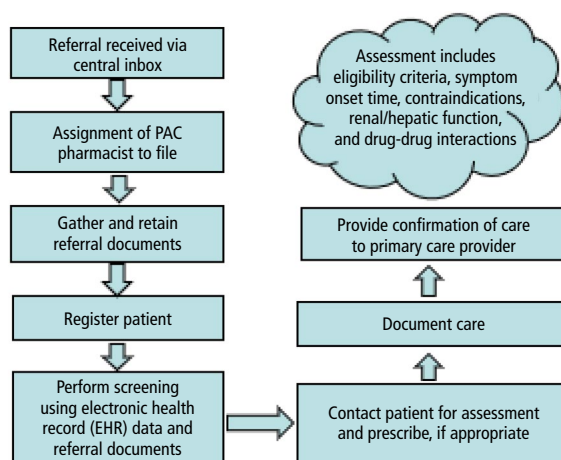
\*Respondents were asked to rate their experience using a scale from 1 to 5 where 1 = completely disagree and 5 = completely agree

**TABLE 2. Clinician Comments Grouped by Topic\*\***

Drug Library-related	Change Management/ Training-related	Pump Design-related
<ul style="list-style-type: none"> <li>- Revision of limits (including hard and soft limits)</li> <li>- Adjusting air in line detection threshold</li> <li>- Drug nomenclature modifications for easier/ more intuitive search</li> <li>- Adding missing drugs or drug concentrations</li> </ul>	<ul style="list-style-type: none"> <li>- Programming steps</li> <li>- Adjustment of alarm volumes</li> <li>- Management of alerts and alarms</li> <li>- Pump cleaning after use</li> </ul>	<ul style="list-style-type: none"> <li>- Interest in touch screen functionality</li> <li>- More extensive memory of recently used drugs on the pump</li> <li>- Interest in "standby" functionality</li> </ul>

\*\*Most commonly reported topics

Appendix to : Adams B, Sansom B, Doiron N, Doucette D, Gagnon J, Landry D, et al. The New Brunswick Pharmacy Assessment Clinic: a novel, hospital pharmacist-led collaborative practice hub [abstract]. *Can J Hosp Pharm.* 2023;76(2):163.



**FIGURE 1. PAC Process Map.**