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Burnout: A Real Problem in Need of Multifaceted Solutions

Peter J Zed

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Burnout is a syndrome resulting from chronic workplace stress, which can be characterized by emotional exhaustion, depersonalization, and reduced sense of personal accomplishment.[1] Burnout can occur in any workplace and has been well described in the profession of pharmacy.[2-4] In this issue of *CJHP*, Dempsey and others[5] present the results of a national survey to determine whether interventions are currently implemented in Canadian pharmacy residency programs to manage resident burnout and to describe the perceived effectiveness of any existing interventions. A total of 107 pharmacy residents representing all provinces in Canada completed the Maslach Burnout Inventory (MBI) section of the survey, of whom 62% were determined to be at high risk of burnout according to at least one MBI subscale. Most respondents (93%) felt that burnout was an issue affecting pharmacy residents, and 75% expressed interest in interventions to help alleviate burnout. Interventions offered to pharmacy residents included mentorship programs, schedule changes, and promotion of self-organization. These findings were consistent with a similar study in the United States, which demonstrated that 81% of pharmacy residents were at high risk of burnout according to at least one MBI subscale.[6]

This survey of pharmacy residents adds to the growing and consistent findings that burnout does affect our profession, and, as is the case for other health care providers, we can anticipate it will ultimately result in impaired clinical decision-making, increases in medical errors, and poor patient safety outcomes.[7,8] The demands and challenges of the health care environment are often difficult to alter. As a consequence, systematic approaches to managing and preventing burnout are essential and must be offered to health care providers throughout their careers. Indeed, the need for suitable interventions should be viewed as an opportunity to which our profession should pay attention at every step, from initial training to retirement.

First, both awareness of and strategies to prevent and manage burnout should be introduced to students in our faculties and schools of pharmacy throughout the country. Doing so can help our students to be prepared for this common challenge long before they complete their entry-to-practice degree. Yet in a recent survey of all 10 Canadian pharmacy schools by Weichel and others,[8] only one reported having a burnout-prevention curriculum. Second, further awareness as well as relevant education should be incorporated into pharmacy residency and other postgraduate training programs. These programs place high demands on pharmacists and closely mimic the challenges they will face upon completion of their training. Role models and mentors, who are common and valued in residency programs, should make purposeful attempts to support pharmacists as they learn to recognize burnout and should also offer strategies to prevent the problem. Finally, employers can pay more attention to the issue of burnout to optimize the well-being of all pharmacists and other pharmacy team members.

Blue and others[2] found that two independent factors associated with burnout were dissatisfaction with work–life balance and a feeling that one's contributions were unappreciated. As such, employers' strategies must go beyond awareness and should incorporate interventions such as self-care workshops, as well as managing workloads and adjusting schedules where possible. Contingency arrangements for unexpected periods of demand in the workplace should also be considered. In addition, employers should ensure that all members of the pharmacy team are aware of the resources and supports available to anyone who is experiencing burnout or other challenges to their professional and workplace well-being.

Burnout is real, and addressing it takes the collective effort of everyone involved in the journey toward practising as effective pharmacists in our health care system. Ensuring the well-being of all members of our profession is essential if we are to function as effective and valued members of the health care team and offer the best of our abilities to the patients under our care.

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ON THE FRONT COVER

St Lawrence River, Brockville, Ontario

This photograph of the St Lawrence River was taken by Helena Trabulsi on a beautiful day in late August in Brockville, Ontario. She and her husband were travelling from Quebec back to their home in Oakville, Ontario, when they stopped to enjoy the peaceful riverfront park area in Brockville.

Helena is enjoying retirement after many years as a hospital director of pharmacy. She works occasionally as a consultant providing advice on equipment planning for new or renovated hospital pharmacy departments. Her other activities include gardening, arranging speakers for the local horticultural society, and researching her family history.

The *CJHP* would be pleased to consider photographs featuring Canadian scenery taken by CSHP members for use on the front cover of the Journal. If you would like to submit a photograph, please send an electronic copy (minimum resolution 300 dpi) to publications@cshp.ca.

L'épuisement professionnel : un vrai problème qui demande des solutions multiformes

par Peter J. Zed

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L'épuisement professionnel est un syndrome résultant d'un stress chronique au travail qui peut se caractériser par un épuisement émotionnel, une dépersonnalisation et un sentiment réduit d'accomplissement personnel[1]. L'épuisement professionnel peut survenir sur n'importe quel lieu de travail et a été bien décrit dans la profession de la pharmacie[2-4]. Dans ce numéro du *JCPH*, Dempsey *et al.*[5] présentent les résultats d'un sondage national visant à déterminer si des interventions sont actuellement mises en œuvre dans les programmes canadiens de résidence en pharmacie pour gérer l'épuisement professionnel des résidents; le sondage visait en outre à décrire l'efficacité perçue de toute intervention existante. Au total, 107 résidents en pharmacie représentant toutes les provinces du Canada ont rempli la section de l'inventaire d'épuisement mis au point par Maslach (MBI) du sondage. Selon au moins une sous-échelle du MBI, 62 % de ces personnes ont été jugées à risque élevé d'épuisement professionnel. La plupart des répondants (93 %) estimaient que l'épuisement professionnel était un problème qui touchait les résidents en pharmacie et 75 % ont exprimé leur intérêt pour les interventions visant à atténuer l'épuisement professionnel. Les interventions offertes aux résidents en pharmacie comprenaient des programmes de mentorat, des changements d'horaire et la promotion de l'auto-organisation. Ces résultats étaient cohérents avec ceux d'une étude similaire aux États-Unis, qui a démontré que 81 % des résidents en pharmacie présentaient un risque élevé d'épuisement professionnel selon au moins une sous-échelle du MBI[6].

Ce sondage auprès des résidents en pharmacie s'ajoute aux conclusions croissantes et constantes selon lesquelles l'épuisement professionnel touche notre profession et, comme c'est le cas pour d'autres prestataires de soins de santé, nous pouvons anticiper qu'il entraînera en fin de compte un affaiblissement de la prise de décision clinique, une augmentation des erreurs médicales et des résultats médiocres en matière de sécurité des patients[7,8]. Les exigences et les défis de l'environnement des soins de santé sont souvent difficiles à modifier. Par conséquent, des approches systématiques de gestion et de prévention de l'épuisement professionnel sont essentielles et doivent être proposées aux prestataires de soins tout au long de leur carrière. En effet, la nécessité d'interventions adaptées doit être vue comme une occasion à laquelle notre profession doit être attentive à chaque étape, de la formation initiale à la retraite.

Premièrement, la sensibilisation et les stratégies de prévention et de gestion de l'épuisement professionnel devraient être présentées aux étudiants de nos facultés et écoles de pharmacie partout au pays. Cela peut aider nos étudiants à se préparer à ce défi commun bien avant qu'ils ne terminent leur diplôme d'entrée à la pratique. Pourtant, dans un récent sondage mené auprès des 10 écoles de pharmacie canadiennes par Weichels *et al.*[8], une seule a déclaré avoir un programme de prévention de l'épuisement professionnel. Deuxièmement, une plus grande sensibilisation ainsi qu'une formation pertinente devraient être intégrées aux programmes de résidence en pharmacie et aux autres programmes de formation postdoctorale. Ces programmes imposent des exigences élevées aux pharmaciens et reproduisent fidèlement les défis auxquels ils seront confrontés à la fin de leur formation. Les modèles de rôle et les mentors, qui sont courants et appréciés dans les programmes de résidence, devraient tenter de soutenir les pharmaciens alors qu'ils apprennent à reconnaître l'épuisement professionnel; ils devraient également proposer des stratégies pour prévenir le problème. Enfin, les employeurs peuvent accorder plus d'attention à la question de l'épuisement professionnel afin d'optimiser le bien-être de tous les pharmaciens et des autres membres de l'équipe de la pharmacie.

Blue *et al.*[2] ont découvert que deux facteurs indépendants associés à l'épuisement professionnel étaient l'insatisfaction à l'égard de l'équilibre travail-vie personnelle et le sentiment que les contributions n'étaient pas appréciées. Par conséquent, les stratégies des employeurs doivent aller au-delà de la sensibilisation et devraient intégrer des interventions telles que des ateliers de soins personnels, ainsi que la gestion des charges de travail et l'ajustement des horaires lorsque cela est possible. Des dispositions d'urgence pour les périodes de demande imprévues sur le lieu de travail doivent également être envisagées. De plus, les employeurs doivent s'assurer que

tous les membres de l'équipe de la pharmacie sont au courant des ressources et des soutiens disponibles pour toute personne qui souffre d'épuisement professionnel ou d'autres défis quant à son bien-être professionnel et au travail.

L'épuisement professionnel est réel et y remédier nécessite l'effort collectif de toutes les personnes impliquées dans le cheminement vers la pratique en tant que pharmaciens efficaces dans notre système de soins de santé. Assurer le bien-être de tous les membres de notre profession est essentiel si nous voulons fonctionner comme des membres efficaces et appréciés de l'équipe de soins de santé et offrir le meilleur de nos capacités aux patients dont nous prenons soin.

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Assessment and Prevention of Burnout in Canadian Pharmacy Residency Programs

Caitlin Dempsey, Kirsten Fox, Kaitlyn Pagel, and Stephanie Zimmer

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ABSTRACT

Background: There is a paucity of literature describing the incidence of burnout among Canadian pharmacy residents, despite evidence that pharmacy professionals are at high risk of burnout.

Objectives: To characterize Canadian pharmacy residents experiencing high levels of burnout, as defined by the Maslach Burnout Inventory (MBI), to describe existing interventions that Canadian pharmacy residents perceive to be effective in managing burnout, and to describe opportunities for Canadian pharmacy residency programs in managing resident burnout.

Methods: An online survey, consisting of 22 validated questions from the MBI and 19 nonvalidated questions developed by the investigators, was distributed by email to 558 Canadian pharmacy residents from the 2020/21, 2019/20, and 2018/19 residency years.

Results: A total of 115 partial or complete survey responses were included in the analysis, and 107 respondents completed the MBI section of the survey. Of these, 62% (66/107) were at high risk of burnout according to at least 1 MBI subscale, with a slight majority of the entire sample being at high risk of burnout on the emotional exhaustion subscale (55/107 [51%]). The most common interventions offered to pharmacy residents to reduce or prevent burnout were mentorship programs, schedule changes, and promotion of self-organization. Current interventions reported to be the most useful were self-care workshops, discussion groups, and workload adjustment. Potential future interventions perceived to be most useful for reducing and preventing burnout were schedule changes and workload adjustment.

Conclusions: More than half of Canadian pharmacy residents who responded to the survey were at high risk of burnout. Canadian pharmacy residency programs should consider implementing additional interventions to help reduce and prevent resident burnout.

Keywords: burnout, pharmacy residents, Maslach Burnout Inventory, Canadian pharmacists

RÉSUMÉ

Contexte : Il y a peu de documentation qui décrit l'incidence de l'épuisement professionnel chez les résidents en pharmacie canadiens, malgré les preuves de risques élevés auxquels les professionnels en pharmacie sont exposés.

Objectifs : Décrire les résidents canadiens en pharmacie qui connaissent des niveaux élevés d'épuisement professionnel, tels que définis par l'inventaire d'épuisement mis au point par Maslach et Jackson [en anglais *Maslach Burnout Inventory (MBI)*]; décrire les interventions existantes que ces personnes perçoivent comme efficaces pour le gérer; et décrire les possibilités de gestion de l'épuisement professionnel dans les programmes canadiens de résidence en pharmacie.

Méthodes : Une enquête en ligne comprenant 22 questions validées du MBI et 19 questions non validées, préparées par les enquêteurs, a été envoyée par courriel à 558 résidents canadiens en pharmacie des années de résidence 2020-2021, 2019-2020 et 2018-2019.

Résultats : Au total, 115 réponses partielles ou complètes ont été incluses dans l'analyse, et 107 répondants ont rempli la section MBI de l'enquête. Parmi ces derniers, 62 % (66/107) présentaient un risque élevé d'épuisement professionnel selon au moins 1 sous-échelle du MBI, une légère majorité de l'ensemble de l'échantillon présentant un risque élevé d'épuisement professionnel sur la sous-échelle d'épuisement émotionnel (55/107 [51 %]). Les interventions les plus courantes offertes aux résidents en pharmacie pour réduire ou prévenir l'épuisement professionnel étaient les programmes de mentorat, les changements d'horaire et la promotion de l'auto-organisation. Les interventions actuelles signalées comme étant les plus utiles étaient les ateliers d'autosoins, les groupes de discussion et l'adaptation de la charge de travail. Les interventions futures potentielles perçues comme les plus utiles pour réduire et prévenir l'épuisement professionnel étaient les changements d'horaire et l'adaptation de la charge de travail.

Conclusions : Plus de la moitié des résidents canadiens en pharmacie qui ont répondu à l'enquête présentaient un risque élevé d'épuisement professionnel. Les programmes canadiens de résidence en pharmacie devraient envisager de mettre en œuvre des interventions supplémentaires pour aider à le réduire et à le prévenir.

Mots-clés : épuisement professionnel, résidents en pharmacie, Maslach Burnout Inventory, pharmaciens canadiens

INTRODUCTION

Health care professionals can experience burnout at any stage of their careers.[1] The World Health Organization defines burnout as a syndrome resulting from chronic workplace stress. It is classified in the *International Classification of Diseases*, 11th revision, as an occupational phenomenon and not as a medical condition.[2] Burnout can be characterized by a constellation of physical and behavioural symptoms, including increased career frustration, excessive inflexibility in practice, and the appearance of features of depression.[1] Burnout progresses through 3 stages: emotional exhaustion, depersonalization, and reduced sense of personal accomplishment.[1,3,4] This process begins with emotional exhaustion, a state in which the individual feels indifferent about their job and lacks devotion to their work. The person then advances to depersonalization, developing a negative attitude toward their job and workplace. Finally, the person will progress to a reduced sense of personal accomplishment, which may include feelings of incompetence even when achieving success.[1,3,4] As a result, practitioners may begin to despise a once-loved job, which can have negative effects on them and on others, including patients.[1]

Although burnout may affect health care professionals at any point of their career, it has been suggested that younger practitioners may be at increased risk of burnout because they have less practice experience.[3,5,6] Pharmacy has previously been identified as a stressful profession, with front-line pharmacists being at high risk of burnout.[3,6] Furthermore, pharmacy residents are at an increased risk of experiencing burnout because of their long working hours, busy schedules, and high stress levels.[1,6,7] It has been shown that pharmacy residents working more than 60 hours per week have higher levels of stress and anxiety, as measured by the validated 10-item perceived stress scale, which puts them at increased risk of burnout.[6,8] Additionally, there is some evidence that female pharmacy residents and residents with children may have higher levels of stress than their respective counterparts.[9] Other significant stressors that may increase the risk of burnout include a person's financial situation, work overload, fear of making an error, and inability to achieve work–life balance.[9]

The Maslach Burnout Inventory (MBI) is a validated tool for measuring the severity of burnout.[4,5] In a study aimed at quantifying burnout in hospital pharmacists, Durham and others[3] found that pharmacists most frequently reported feelings of emotional exhaustion (36.5%), followed by reduced personal accomplishment (32.2%) and depersonalization (20.1%), according to the MBI. In a similar study utilizing the MBI, Kang and others[10] found that health-system pharmacists most commonly experienced emotional exhaustion (49.6%), followed by depersonalization (35%), and reduced personal accomplishment (33.3%).

It is well documented that burnout among health care practitioners is associated with poor clinical decision-making, medical errors, and poor patient safety outcomes.[1,11,12] A survey completed in Ireland revealed that 64% of medical residents experiencing burnout reported making a medical error, compared with 22% of those who had not experienced burnout.[1] Likewise, a survey of US surgeons showed that every 1-point increase in depersonalization on the MBI was associated with an 11% increase in the likelihood of reporting a medical error, and each 1-point increase in emotional exhaustion was associated with a 5% increase.[13]

A variety of interventions have been proposed and assessed in terms of their effectiveness in preventing and managing health care professional burnout. Typically, such interventions are grouped into 2 categories: individual-led interventions and organization-directed interventions. Individual-led interventions include mindfulness training (which involves in-depth personal and situational reflection), meditation exercises, communication skills training, discussion groups related to stress and job satisfaction, and self-care workshops discussing risk factors and coping behaviours for burnout.[14,15] In contrast, most organization-directed interventions focus on changes in scheduling to reduce workload, as well as projects to improve communication and workflow.[15] A meta-analysis comparing the effectiveness of individual-led and organization-directed interventions found that the latter were associated with higher treatment effects and greater reductions in burnout.[15] Other interventions that have been suggested to promote resilience and prevent burnout include engaging in leisure activities outside of work, mentorship programs for younger clinicians, and increasing self-organization.[16]

Identifying useful interventions will help pharmacy residency programs to reduce the incidence of burnout among residents. The purpose of this study was to determine whether interventions are currently implemented by Canadian pharmacy residency programs to manage resident burnout and to describe the perceived effectiveness of any existing interventions. The specific objectives were to quantify and characterize Canadian pharmacy residents experiencing high levels of burnout as defined by the MBI, to describe existing interventions that Canadian pharmacy residents perceive to be effective in managing burnout, and to describe current opportunities for Canadian pharmacy residency programs in managing resident burnout.

METHODS

This study was approved by the Saskatchewan Health Authority Research Ethics Board.

Study Design

An anonymous online survey, consisting of 22 validated questions from the MBI and 19 nonvalidated questions

about interventions to manage burnout during residency developed by the study investigators, was distributed to study participants (survey questions available by request to the corresponding author). The survey consisted of a mix of multiple choice and free-text questions. None of the survey questions were mandatory, and incomplete responses were accepted for data analysis.

The MBI uses 3 subscales to describe the frequency with which respondents experience feelings of emotional exhaustion, depersonalization, and reduced personal accomplishment. There are 9 items in the emotional exhaustion subscale, 5 items in the depersonalization subscale, and 8 items in the personal accomplishment subscale. Each item is written in the form of a statement describing a personal feeling, for which frequency is measured on a scale of 0 (never experiencing such a feeling) to 6 (experiencing that feeling every day).[4]

Inclusion and Exclusion Criteria

Pharmacy residents who participated in a Canadian Pharmacy Residency Board year 1 (PGY1) or year 2 (PGY2) program or a 16-month Master's degree at the Université de Montréal or Université Laval during the 2020/21, 2019/20, or 2018/19 residency year were eligible to participate in the study.

Participant Recruitment

A survey invitation was sent by email in early 2021 to Canadian pharmacy residency program coordinators with a request to distribute to all pharmacy residents who were or had been enrolled in their respective programs for the 2020/21, 2019/20, and 2018/19 residency years. The target population consisted of 558 individuals, the number of Canadian PGY1, PGY2, and Quebec Master's residency program positions filled for the aforementioned academic years. The survey was available online from January 18 to February 12, 2021. A reminder email was sent to the program coordinators on February 1, 2021.

Data Collection

Study data were collected and managed using REDCap electronic data-capture tools hosted at the Saskatchewan Health Authority. REDCap is a secure, web-based software platform designed to support data capture for research studies. It provides an intuitive interface for validated data capture, audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages, and procedures for data integration and interoperability with external sources.[17,18]

Statistical Analysis

Each subscale of the MBI is evaluated separately, to produce 3 separate scores. High risk of burnout is defined as a high score on either the emotional exhaustion subscale (defined as z = mean + [SD * 0.5]) or the depersonalization subscale (defined as z = mean + [SD * 1.25]) or a low score on the personal accomplishment subscale (defined as not being a high score at z = mean + [SD * 0.10]), where SD is the standard deviation.[4] Partial survey responses were included in the data analysis and in calculation of burnout risk.

For the nonvalidated questions, statistical analyses were performed using SPSS software (IBM SPSS Statistics 22.0). Descriptive statistics were computed and expressed as frequencies and percentages. Continuous variables were summarized as means or medians with SDs. Categorical data were analyzed using frequency distributions and percentages. Free-text data were coded, grouped into common categories, and summarized by the primary investigator (C.D.).

RESULTS

Overview of Respondents

Of the pharmacy residents eligible for study inclusion (n = 558), a total of 129 (23%) responded to the survey. Of these, 14 were excluded from the data analysis because although they initiated a survey response, they did not answer any of the survey questions; therefore, a total of 115 partial or complete responses were included in the analysis. Given that none of the survey questions were mandatory, the total number of respondents for each question varied and is denoted for each finding. The survey respondents represented all 9 provinces with a pharmacy residency program. The median age while completing residency was 26 (SD 2.58) years, and 75% (86/115) of the respondents identified as female. The majority of participants (89/115 [77%]) were enrolled in a PGY1 program, and 46% (53/115) of the responses came from those participating in the 2020/21 residency year. The median number of vacation days offered to pharmacy residents was 10 (SD 4.90), and the median number of hours spent on residency-related activities per week was 60 (SD 13.43). Just over half of the residents participating in this study (52% [59/114]) reported having successfully completed their residency program, whereas 46% (52/114) were in the process of completing their program at the time of survey distribution (Table 1).

Maslach Burnout Inventory

A total of 107 respondents were included in the MBI analysis. The remaining 8 respondents were excluded because they did not complete all components of the MBI, which is required for the determination of burnout risk with this tool. Overall, 62% (66/107) of these respondents were at high risk of burnout on at least 1 subscale. A slight majority of respondents scored high on the emotional exhaustion subscale (55/107 [51%]), and 14% (15/107) were at high risk of burnout on all 3 subscales (Table 2). Demographic differences between respondents at high risk of burnout and those not at high risk were not statistically significant (data not shown).

Interventions to Reduce Pharmacy Resident Burnout

Overall, 75% (80/106) of respondents expressed interest in interventions to help alleviate burnout. According to survey responses, the most common intervention offered to pharmacy residents was a mentorship program (54/107 [50%]), followed by scheduling changes (31/107 [29%]) and promotion of self-organization (25/107 [23%]). Figure 1 depicts the interventions offered to pharmacy residents during their programs, as reported by survey respondents.

Of the interventions offered at the time of residency enrolment, a mentorship program was reported to be useful by 73% (37/51) of the residents to whom it was offered. Schedule changes were reported to be useful by 70% (21/30) of respondents, and promotion of self-organization was reported to be useful by 56% (14/25) of respondents. Self-care workshops (5/5) and discussion groups (7/7) were reported to be useful by 100% of the residents to whom they were offered, and workload adjustment was reported to be useful by 87% (13/15). Interventions most frequently reported as somewhat or not useful included a weekly cap on hours spent on residency-related activities (2/4 [50%]) and mindfulness-based training (3/9 [33%]) (Figure 2).

With regard to the perceived effectiveness of potential or future interventions to reduce burnout, respondents most frequently indicated that implementing schedule changes (78/97 [80%]) would be useful. This was followed by workload adjustment, reported to be potentially useful by 77% (75/97), and a mentorship program, perceived to be useful by 74% of respondents (72/97) (Figure 3).

TABLE 1. Characteristics of Survey Participants

Characteristic	No. (%) of Respondents
Province	*n* = 115
Alberta	17 (15)
British Columbia	19 (17)
Manitoba	< 5%[a]
New Brunswick	8 (7)
Newfoundland and Labrador	< 5%[a]
Nova Scotia	< 5%[a]
Ontario	22 (19)
Quebec	25 (22)
Saskatchewan	14 (12)
Gender	*n* = 115
Female	86 (75)
Male	26 (23)
Prefer not to say	3 (3)
Type of program	*n* = 115
PGY1	89 (77)
PGY2	4 (3)
16-month Master's	22 (19)
Year in residency program	*n* = 115
2020/21	53 (46)
2019/20	44 (38)
2018/19	18 (16)
Marital status during residency	*n* = 114
Single	35 (31)
Married or common law	21 (18)
In a relationship (not married or common law)	55 (48)
Prefer not to say	3 (3)
Child in direct care during residency	*n* = 114
No	113 (99)
Successful completion of residency program	*n* = 114
Yes	59 (52)
No	3 (3)
In progress	52 (46)
Age (years)	*n* = 113
Median ± SD	26 ± 2.58
Vacation during residency[b] (days)	*n* = 113
Median ± SD	10 ± 4.90 (minimum 0, maximum 38)
Time spent on residency activities[b] (h/week)	*n* = 114
Median ± SD	60 ± 13.43 (minimum 10, maximum 100)

PGY = postgraduate year, SD = standard deviation.
[a]Reported as "< 5%" to maintain anonymity.
[b]Potential misinterpretation of survey questions; see Discussion for further explanation.

DISCUSSION

We asked survey respondents if they thought burnout was an issue affecting pharmacy residents, and 93% (99/106) agreed. Furthermore, our survey showed that more than half of pharmacy residents (62%) were at high risk of burnout as

TABLE 2. Overall Assessment of Burnout among Pharmacy Residents Responding to the Survey

Variable	No. (%) of Respondents (*n* = 107)
Distribution of MBI scores by subscale	
High emotional exhaustion[a]	55 (51)
High depersonalization[b]	27 (25)
Low personal accomplishment[c]	32 (30)
Risk of burnout, as scored by MBI subscales	
High risk of burnout on at least 1 subscale	66 (62)
No high risk of burnout on any subscale	41 (38)
High risk of burnout on only 1 subscale	34 (32)
High risk of burnout on 2 subscales	17 (16)
High risk of burnout on all 3 subscales	15 (14)

MBI = Maslach Burnout Inventory.
[a]High risk of burnout defined as a score ≥ 27.
[b]High risk of burnout defined as a score ≥ 10.
[c]High risk of burnout defined as a score ≤ 33.

determined by the MBI. In a similar study conducted in the United States, Gonzalez and Brunetti[19] found that an even greater proportion of pharmacy residents (35/43 [81.4%]) were at high risk of burnout on at least 1 MBI subscale.

In our study, a high risk of burnout was most commonly attributable to a high score on the emotional exhaustion subscale. Similarly, Gonzalez and Brunetti[19] found that the majority (62.8%) of pharmacy residents at high risk of burnout scored high on the emotional exhaustion subscale. Our survey findings mirrored burnout assessments conducted by Durham and others[3] and Kang and others,[10] who found that 53.2% and 55.5%, respectively, of US health-system

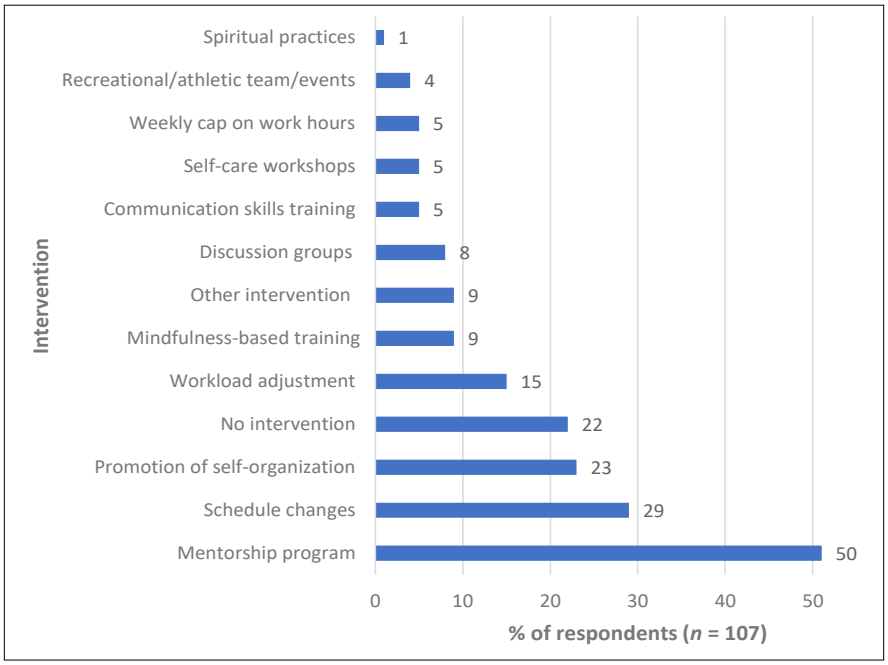

FIGURE 1. Interventions to reduce burnout currently offered to pharmacy residents, as reported by survey respondents. Percentages sum to more than 100%, as survey respondents were allowed to select more than 1 answer.

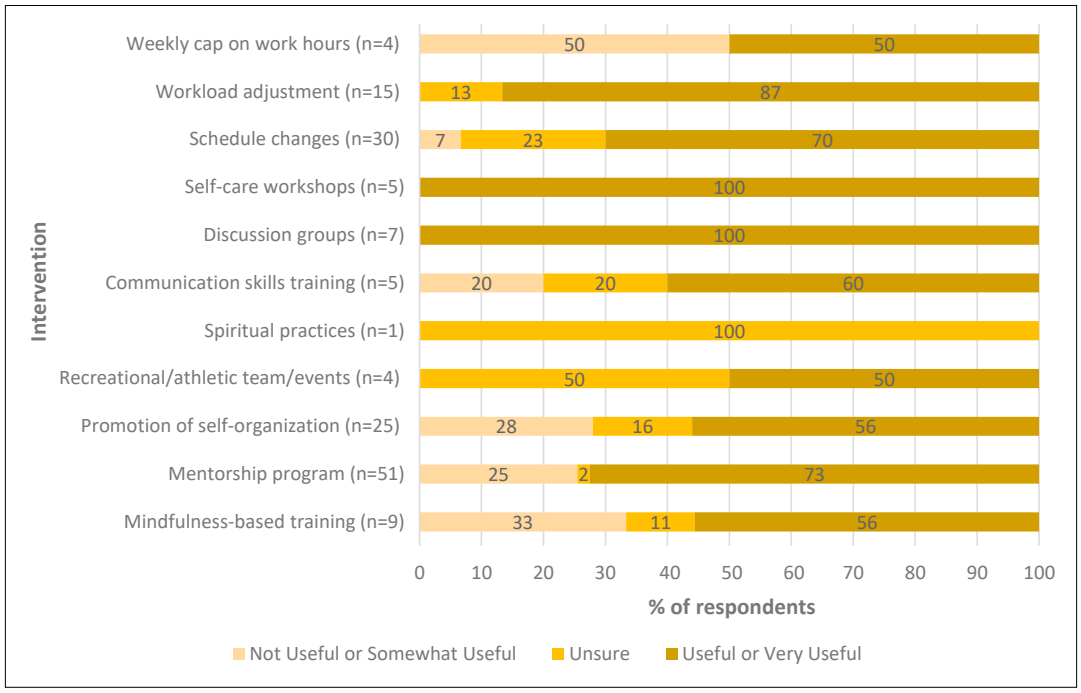

FIGURE 2. Effectiveness of interventions currently offered to pharmacy residents, as reported by survey respondents.

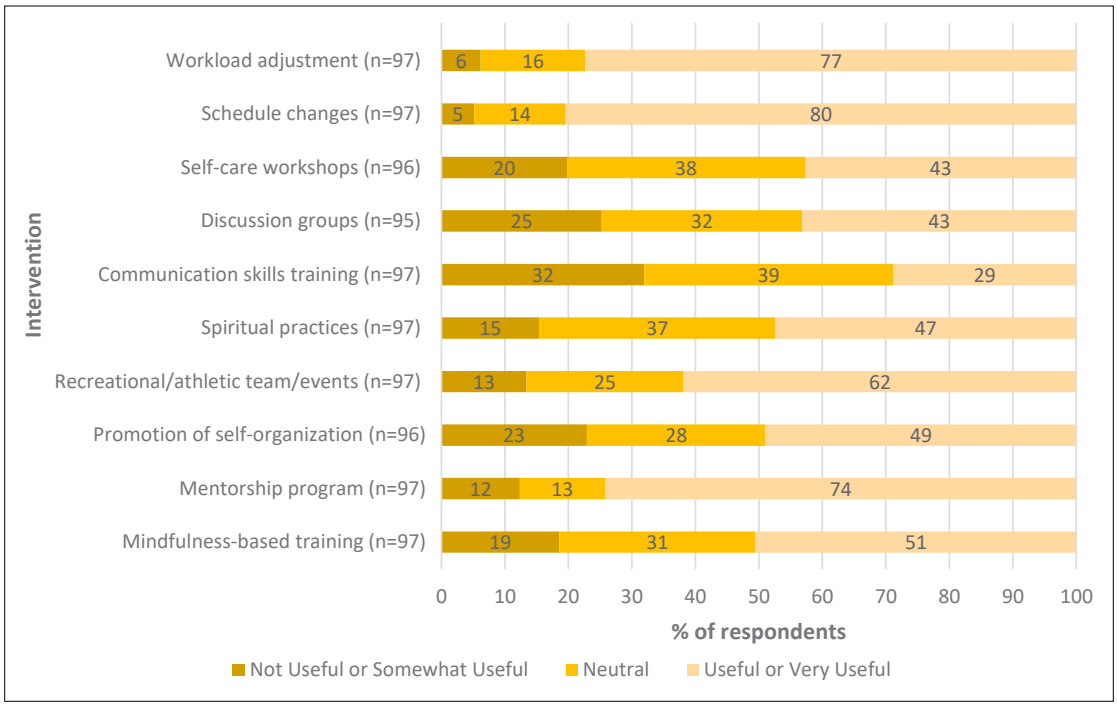

FIGURE 3. Predicted effectiveness of potential future interventions to reduce burnout, as reported by survey respondents.

pharmacists were at high risk of burnout according to the MBI. Similarly, the pharmacists in those studies most frequently scored high on the emotional exhaustion subscale (36.5% and 49.6%, respectively).[3,10] Consistently high emotional exhaustion scores among pharmacists and pharmacy residents may indicate that emotional exhaustion is the driving cause of burnout among pharmacy professionals. Experiencing emotional exhaustion is often the first stage of burnout to affect an individual, which may explain why pharmacy professionals were at higher risk according to this subscale, relative to the other 2 subscales.[1,2-4]

Kang and others[10] found 3 factors that were significantly associated with increased burnout among pharmacists: female gender, working more hours per week (50–59 versus 40–49), and working primarily in a distribution role.[10] Although these factors were not statistically significant in our study, the majority of our survey respondents were female (75%) and the median amount of time spent on residency-related activities was 60 hours per week, which may have been associated with the high risk of burnout that we observed. Our survey findings add to the growing body of evidence that burnout is an issue affecting pharmacists and pharmacy residents and that strategies to reduce or prevent burnout are therefore needed in Canadian pharmacy residency programs.

Of the interventions already offered to pharmacy residents, self-care workshops and discussion groups were reported to be useful by every respondent who had participated in either of these types of intervention. Examples of self-care workshops included tips from a psychologist on reducing stress, self-care improvement, and burnout prevention. Descriptions of discussion groups included scheduled meetings with the residency coordinator or other residents to discuss progress or hardships in the program. Despite these methods being reported as potentially effective in reducing burnout, their utilization appears to be low, and opportunities exist for many residency programs to implement them. Martins and others[20] found that among pediatric medical residents participating in self-care workshops (focused on discussing the negative effects of burnout, recognizing risk factors for burnout, and identifying strategies to cope with burnout) for 2 months, there was no reduction in the prevalence of burnout according to the MBI; however, depersonalization scores did improve significantly. Given that 25% of pharmacy residents in our study scored high on the depersonalization subscale, implementing self-care workshops in Canadian pharmacy residency programs may have utility.

About half of respondents in our study reported that mentorship programs were available, and nearly three-quarters of this group deemed them useful. Jordan and others[21] assessed the impact of a mentorship program on fourth-year medical students and found that mentorship led to a statistically significant improvement in the personal accomplishment score of the MBI.

Although workload adjustment was rarely offered to pharmacy residents (reported by only 15% of respondents), nearly all of these (87%) reported that the intervention was useful. Likewise, workload adjustment was perceived by 77% as a potentially useful future intervention in residency

programs. Similarly, schedule changes were deemed by most respondents (80%) to be a potentially useful future intervention. The perceived utility of schedule changes and workload adjustment is consistent with the meta-analysis conducted by Panagioti and others,[15] who found that organization-directed interventions (including schedule changes and workload reduction) were more effective than individual-led interventions at reducing burnout in physicians. Addressing pharmacy resident burnout at the organizational level was also supported by Potter and Cadiz[22] in a commentary on this topic. The interventions perceived to be effective by study respondents were commonly organization-directed. One proposed explanation for the benefit of organization-directed interventions in reducing burnout, relative to individual-led interventions, may be that the latter are perceived as an "add-on burden" to an already busy schedule.[23] As such, there may be more benefit (in terms of reducing burnout) in removing nonessential tasks and burdens from residents' workload than in introducing an additional activity into their schedule.

Our study had limitations inherent to surveys. For example, it appears that some participants misinterpreted the questions about hours per week spent on residency-related activities and number of vacation days allotted to residents. Each of these questions received multiple outlying responses (e.g., reporting only 10 working hours per week or 38 days of vacation); such outliers indicate possible misunderstanding of the question. Our survey was also subject to recall and response bias, because individuals from the earlier years were asked to retrospectively report how they felt during residency. There was also a risk of misinterpretation of results by the researchers, given the abundance of free-text responses provided. The incidence of burnout may have been underestimated for the 2020/21 residents, depending on the start date of their program in relation to survey distribution. In addition, the COVID-19 pandemic may have affected the incidence of burnout among the 2020/21 and 2019/20 residents. Lastly, our survey was not offered in French, which may have affected the number of responses received from French-speaking pharmacy residents.

Currently, there are no mandatory requirements for Canadian pharmacy residency programs to offer programs or supports to help reduce burnout, despite the majority of pharmacy residents being at high risk. Our findings indicate that it may be beneficial for programs to offer mentorship programs, self-care workshops, and discussion groups to their residents. It may also be beneficial to implement workload adjustment and scheduling changes for residents who are struggling with burnout, since these were the interventions most frequently perceived as useful by pharmacy residents. More research is needed to measure the effectiveness of interventions at reducing burnout among pharmacy residents.

CONCLUSION

More than half of the pharmacy residents who responded to our survey were found to be at high risk of burnout as defined by the MBI. Emotional exhaustion was the most frequent MBI subscale on which residents had a high risk of burnout. Residency programs should continue to offer interventions perceived to be useful, such as mentorship programs, discussion groups, and self-care workshops. They should also consider looking for opportunities to incorporate workload adjustment and schedule changes to help reduce resident burnout.

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Get Smart, Canada: Exploring Smart Pump Implementation, Management, and Compliance with Standards through a Nationwide Survey

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ABSTRACT

Background: Smart pump technology is relatively new, and uncertainty exists regarding best practices for development and management of the drug libraries in these devices. In Canadian hospitals, IV smart pumps and their drug libraries are created and maintained according to recommendations from Accreditation Canada and guidelines from the US Institute for Safe Medication Practices (ISMP). Current compliance with these standards in Canada is unknown. However, neither organization provides specific operational steps detailing how to effectively create and manage a drug library, which leaves significant room for interpretation. Furthermore, the human resources dedicated to creation and management of these libraries in accordance with guidelines and standards are unknown.

Objectives: To describe current compliance with standards and guidelines for smart pump drug libraries; the processes used for drug library set-up, management, training, and support; and the resources currently used for these activities in Canadian hospitals.

Methods: A 43-question online survey was made available in spring 2021 to multidisciplinary team members involved in implementation of IV smart pumps and/or management of drug libraries in Canadian hospitals.

Results: A total of 55 complete or partial responses were received. Most responses indicated that standards set by Accreditation Canada and ISMP were not being met, with only 30% (14/47) updating their libraries at least quarterly and 47% (20/43) performing quality reviews at least every 6 months. Although the majority of respondents reported regular monitoring of compliance, 30% (11/37) did not perform such monitoring. Results further indicated variation across Canadian hospitals in set-up, management, training, and support related to drug libraries, as well as variation in the human resources available for these activities.

Conclusions: Canadian health authorities and organizations are not meeting current ISMP and Accreditation Canada standards for smart pumps. Variation exists in terms of strategies for creating and managing drug libraries, as well as in the training and resources needed to support these initiatives. Canadian health authorities and organizations should prioritize meeting these standards and should closely review the resources required to do so.

Keywords: smart pumps, drug library, dose error reduction system, health technology

RÉSUMÉ

Contexte : La technologie des pompes « intelligentes » est relativement nouvelle et des zones d'ombre subsistent quant aux meilleures pratiques de développement et de gestion des bibliothèques de médicaments intégrées à ces appareils. Dans les hôpitaux canadiens, les pompes IV intelligentes et leurs bibliothèques sont créées et maintenues conformément aux recommandations d'Agrément Canada et aux lignes directrices de l'Institute for Safe Medication Practices (ISMP; États-Unis). Le respect actuel de ces normes au Canada est inconnu. Cependant, aucune des organisations ne fournit de mesures opérationnelles particulières détaillant comment créer et gérer efficacement une bibliothèque de médicaments, ce qui laisse une grande marge d'interprétation. De plus, on ne connaît pas les ressources humaines consacrées à la création et à la gestion de ces bibliothèques conformément aux lignes directrices et aux normes.

Objectifs : Décrire, dans un premier temps, dans quelle mesure les lignes directrices et les normes régissant les bibliothèques de pompes « intelligentes » sont respectées; ensuite, les processus utilisés pour mettre en place la bibliothèque de médicaments, la gérer, former et soutenir le personnel; et, finalement, les ressources actuellement utilisées pour ces activités dans les hôpitaux canadiens.

Méthodes : Au printemps 2021, un sondage en ligne comportant 43 questions a été mis à la disposition des membres d'équipes multidisciplinaires impliquées dans la mise en œuvre des pompes intelligentes IV et/ou la gestion des bibliothèques de médicaments dans les hôpitaux canadiens.

Résultats : Au total, 55 réponses complètes ou partielles ont été reçues. La plupart des réponses ont signalé que les normes établies par Agrément Canada et l'ISMP n'étaient pas respectées. En effet, seulement 30 % (14/47) actualisaient leur bibliothèque au moins tous les trimestres et 47 % (20/43) effectuaient des examens qualitatifs au moins tous les 6 mois. Bien que la majorité des répondants aient fait état d'un contrôle régulier de la conformité, 30 % (11/37) n'effectuaient pas un tel contrôle. Les résultats ont en outre indiqué des variations entre les hôpitaux canadiens en matière de configuration, de gestion, de formation et de soutien liés aux bibliothèques de médicaments, ainsi que des variations dans les ressources humaines disponibles pour ces activités.

Conclusions : Les autorités et organismes de santé canadiens ne respectent pas les normes actuelles de l'ISMP et d'Agrément Canada pour les pompes intelligentes. On observe des variations en termes de stratégies de création et de gestion de bibliothèques de médicaments, ainsi que de formation et de ressources nécessaires pour soutenir ces initiatives. Les autorités et les organismes de santé canadiens devraient accorder la priorité au respect de ces normes et devraient examiner de près les ressources nécessaires pour y parvenir.

Mots-clés: pompes « intelligentes », bibliothèque de médicaments, système de réduction des erreurs de dose, technologie de la santé

INTRODUCTION

Intravenous (IV) pumps with a dose error reduction system (DERS), also known as smart pumps, represent an advancement in health technology and patient safety.[1] Smart pumps have improved drug delivery accuracy and control, and they also prevent medication infusion errors.[1] As a result, smart pump technology has become a standard of practice, with 89% of Canadian hospitals using this technology.[2] For a glossary of terms used in this article, please refer to Appendix 1 (available at https://www.cjhp-online.ca/index.php/cjhp/issue/view/215).

The US Institute for Safe Medication Practices (ISMP) has published guidelines for "Optimizing Safe Implementation and Use of Smart Infusion Pumps."[1] These guidelines recommend standardization of smart pump drug libraries contained in the DERS across facilities within a health network, interoperability with electronic health record (EHR) and computerized prescriber order entry (CPOE) systems, compliance auditing, interdisciplinary teams for library management, and implementation of a systematic process for review. They also endorse the use of care areas/profiles, hard and soft limits, and standardized management of container overfill and clinical alerts.[1] Specifically ISMP recommends quarterly quality reviews and drug library updates.

Similarly, Accreditation Canada recommends that established dosing limits be reviewed every 6 months (with changes being made as required) and that updates to drug libraries be performed not less than quarterly (unless no updates are required for a given quarter).[3] Currently, compliance of Canadian health care organizations with ISMP guidelines and Accreditation Canada standards is unknown.

Information regarding methods of subcategorizing drug libraries, organization of user interfaces, maximum number of entries for individual drugs (where entries may differ by concentration, as well as by limits on concentration, dosing, and/or rate), the health care professionals responsible for setting limits, strategies to account for overfill, clinical alerts of importance, and use of "keep vein open" rates, is unclear.[1]

There has been little research describing best practices for the creation and maintenance of drug libraries in the Canadian context. Studies on error rate reduction after implementation of IV smart pumps have been reported from the United States, Spain, and Canada.[4-6] However, this work has not described or evaluated methods for creating drug libraries, other than recommending approval of content by a multidisciplinary group of health care professionals.[5,6]

In 2017, ISMP conducted a survey to gather perceptions of US smart pump users; respondents identified many challenges with the implementation and use of these devices. That study provided little information about drug library set-up but did include information on library organization. The results indicated that multiple organizational strategies could be implemented in the same library, including organization based on care area (reported by 89% of respondents), weight (47%), therapeutic drug class (35%), and/or patient age (6%).[7] Information on drug library set-up in the Canadian context is unknown.

Collection and review of continuous quality improvement (CQI) data and regular updates of drug library content are necessary processes for drug library management. Although most Canadian sites report annual updates,[2] no data are available describing compliance with the 2019 Accreditation Canada standards, which specify quarterly drug library updates and biannual drug library quality reviews.[3]

Furthermore, the current processes used for performing updates and quality reviews, including the frequency and method of obtaining feedback and CQI data, are undefined. Lack of a clear process may delay library updates, leading to a risk of harm when IV infusions are administered with outdated drug limit settings.[8] Among 778 multidisciplinary respondents from 5 US health systems, approximately half felt that the process for updates and quality reviews was effective, and only 10% could correctly relay required steps.[9] Knowledge of the current methods used for drug library audits and updates, including how feedback is obtained and how end-users are informed of changes, could help health care organizations develop safer and more effective processes.

Staff education and training on infusion pump use, including use of DERS, can reduce the frequency of infusion errors and severe adverse drug events.[10] Accreditation Canada recommends standardized training and competency assessments biennially[11] but does not describe the type of training to be offered. Studies have indicated that education from a manufacturer may be less effective than hands-on training.[12] In addition, the efficacy of virtual training has been mixed.[13,14] The choice of trainer may be an important factor; for example, one study found that a group led by a nurse-champion was successful in improving pump compliance.[15] Simulation-based training, 24/7 vendor support after implementation, and ongoing clinical support for nursing staff have also been used,[5] but research has been lacking on the efficacy of these approaches. The current frequency of retraining in Canada is unknown.

Although ISMP recommends "dedicated time" for maintenance of pump software,[1] to the authors' knowledge no studies exist evaluating human resource requirements to create and manage drug libraries. At present, the number of full-time equivalents (FTEs) allocated to each profession within a smart pump team is unknown.

Given that IV smart pump technology has reached its 20th anniversary of mainstream use, this study was undertaken to determine rates of compliance with ISMP and Accreditation Canada standards, the processes for implementation and maintenance of smart pumps (including those for drug library set-up, management, training, and support), and the human resources allocated to these efforts.

METHODS

Survey

A 43-question online survey was distributed to smart pump team members to determine compliance with ISMP guidelines and Accreditation Canada standards and to identify knowledge gaps. The survey was divided into 6 sections: demographic characteristics (3 questions), organization of the drug library–user interface (6 questions), drug library entries (7 questions on naming, number of entries, drug library limits, and overfill), process for implementation and review (8 questions on quality reviews, compliance audits, and pump updates), clinical implications and training (15 questions on clinical alerts, alert fatigue, transfer policies, "keep vein open" rates, and training), and resources (4 questions about FTEs allocated). Six health care professionals familiar with smart infusion pumps reviewed and provided feedback on the survey before circulation.

Participants and Procedure

Given that ISMP recommends the use of multidisciplinary teams in the development and maintenance of smart pump drug libraries, participants from pharmacy, nursing, medicine, and clinical engineering, with experience in building and/or management of smart IV pumps, were eligible to complete the survey.

The survey link was circulated by email to pump team members known to the authors and through a post on several of the Canadian Society of Hospital Pharmacist's Pharmacy Specialty Networks (Parenteral Services, Drug Information, Medication Safety, and Hospital Pharmacy), as well as by email to known drug library team members involved in implementation and maintenance of smart pumps based on contacts provided by the Institute for Safe Medication Practices Canada and pump manufacturers. Participants were encouraged to forward the survey to additional pump team members in an effort to ensure participation of different disciplines. The survey was available from February 23 to April 6, 2021. The LimeSurvey tool (https://www.limesurvey.org/en/) was used to create and distribute the survey and to store the responses.

Data Analysis

All responses were analyzed descriptively, and quantitative data are reported as valid percentages (with exclusion of missing responses). The 2 authors, who are pharmacists working with DERS libraries, reviewed the free-text responses for common themes and summarized them descriptively.

RESULTS

Overall, 55 participants responded. All questions had varying levels of missing data. For clarity, only valid percentages are reported.

The percentage of respondents by province is shown in Figure 1. Most respondents were from Ontario (22/55, 40%). Most were pharmacists (42/54, 78%), followed by clinical engineers (8/54, 15%) and nursing professionals (4/54, 7%). Half of respondents (26/52) reported that a single drug library was used across their organization, while only 19% (9/48) reported a single drug library for their entire province (specifically, Alberta, Manitoba, Northwest Territories, Nova Scotia, Prince Edward Island, and Saskatchewan). Respondents managed an average of 1.6 pump brands. Most managed large-volume pumps (46/50, 92%), and less than half (20/50, 40%) managed multiple pump types (large-volume, syringe, patient-controlled analgesia, epidural). Table 1 presents information on pump standardization, brands, and types.

Compliance with Standards

Compliance with Accreditation Canada's 2019 standards and with ISMP guidelines was generally low (Table 2). Only 47% of respondents reviewed and analyzed smart pump data at least every 6 months, and only 30% updated their drug libraries at least quarterly. Regular monitoring of drug library compliance was reported by 62%. One respondent (2%) reported integration of smart pumps with an EHR, which would allow information to flow from the EHR to the smart pump and thus facilitate auto-programming of orders entered in the EHR and auto-documentation of administration information from the pump into the EHR. Similarly, one respondent (2%) reported integration of smart pumps with a CPOE system, which would allow auto-programming of orders entered by authorized prescribers on the smart pump.

Drug Library Set-up

As shown in Table 3, most drug libraries were categorized by care area (92%) and age (70%). The pump–user interface was most often organized alphabetically, with 29% of respondents reporting that frequently used medications were placed at the top of the list. The maximum number of entries for a specific drug within a particular care area (e.g., by concentration or limits) varied greatly; only 30% (out of 10 respondents) limited the number to 1 or 2 entries. Pharmacists were almost always responsible for setting limits in the pump (92%), although 62% of respondents reported that nursing professionals were also responsible. There was great variation in how overfill was managed within a pump library, and 18% of respondents stated that they did not account for overfill. Most respondents (81%) used the "keep vein open" rate on their pumps. Reasons for not using "keep vein open" rates included inappropriateness of this setting for the clinical setting or pump type and the requirement for a patient-specific order. Most respondents (76%) used some form of clinical alert; the top 3 most effective alerts related to administration/filter requirements

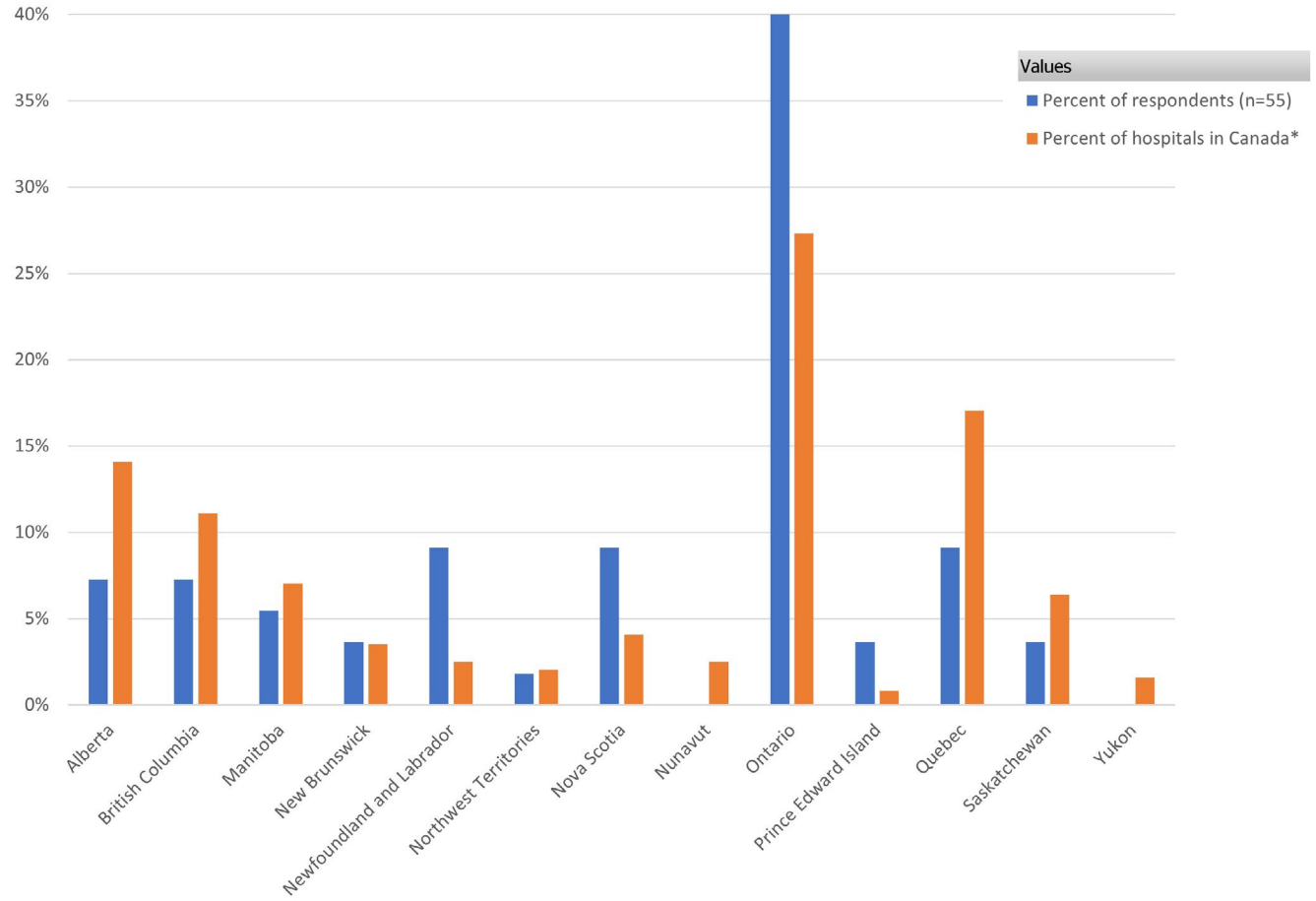

FIGURE 1. Percentage of respondents in each province or territory compared with percentage of all Canadian hospitals in each province or territory in 2021 (n = 1080). *Percentage of hospitals in Canada based on Government of Canada data, using hospitals listed as "employers".[16]

(50%), high-alert medications (43%), and weight, dose, or infusion time (36%).

Drug Library Management

Methods for drug library management, including common strategies to obtain user feedback, are shown in Table 4. Use of proactive feedback methods, such as CQI data, formulary changes, and direct communication with end-users were relatively uncommon. Email (80%), memos/newsletters (55%), and huddles/meetings (41%) were the most commonly used methods to inform end-users of updates to the drug library. Most respondents reported using data downloaded from the pump for compliance audits (72%).

To reduce alert fatigue (overuse of alarms, leading users to ignore them), 58% of respondents reported actively re-evaluating clinical alerts and minimizing the clinical alert list, 42% reported updating limits using CQI data, and 11% reported optimizing pump settings.

Training and Support

Most respondents (84%) reported training of personnel at the time of drug library implementation (Table 5). In terms

TABLE 1. Pump Standardization, Brands, and Types

Characteristic	No. (%) of Respondents[a]
Single drug library used across health authority/ organization	n = 52
Yes	26 (50)
No	26 (50)
Single drug library for province/territory	n = 48
Yes	9 (19)
No	39 (81)
Smart pump brands in a single organization	n = 53
Multiple brands	21 (40)
Mean no. of brands	1.6
Median no. of brands	1
Smart pumps managed	n = 50
Multiple pump types	20 (40)
Large-volume pump	46 (92)
Syringe pump	18 (36)
Patient-controlled analgesia or epidural pump	17 (34)

[a]Except where indicated otherwise. Percentages are based on the number of responses (missing responses excluded).

of training methods, most respondents reported that nursing staff had hands-on training (83%) and live information sessions (68%), whereas webinars were less commonly used (45%). Methods to train clinical pharmacy staff were most likely to include live information sessions (57%), followed equally by webinars (30%) and hands-on training (30%).

Open-ended responses described on-site support, provided by the vendor or manufacturer, for the pump "go-live" date. Other common support personnel included "superusers", clinical educators, and, less commonly, clinical engineers, information services professionals, and pump team members. Additional support was provided by pharmacy and extra floor staff (profession unspecified). One respondent reported the unique approach of having superusers wear distinctive t-shirts during the implementation period. On-site support for clinical staff, covering pump use and troubleshooting, was the most frequently described support type for the "go-live" date.

Two-thirds (67%) of respondents reported that training was provided for drug library maintenance. According to open-text responses, vendor-provided training was the most common type of maintenance training, and the training itself was same as that provided for implementation. Less commonly reported training included programs created by pump team members and provided by other staff.

The most common frequency for competency assessment and retraining of end-users was every 2 years (21% of respondents) or annually (17%). Notably, 15% of respondents reported no competency assessment or retraining.

Human Resources

As shown in Table 6, most respondents reported that pharmacists (98%) and nursing professionals (94%) were involved in implementation of the drug library, whereas for drug library maintenance, nursing involvement was reported less often than pharmacist involvement (56% versus 98%).

TABLE 2. Compliance with ISMP Recommendations and Accreditation Canada Standards

Survey Question	No. (%) of Respondents	ISMP Recommendation	Accreditation Canada Standard	% Meeting Recommendation or Requirement
Do your IV smart pumps communicate with the electronic health record (EHR)?	*n* = 52	5.1 Implement bi-directional (i.e., auto-programming and auto-documentation) smart infusion pump **interoperability with the EHR**.	Not a requirement	2%
Yes	1 (2)		NA	
No	51 (98)		NA	
Are your IV smart pumps linked to drug order entry?	*n* = 51	5.1 Implement bi-directional (i.e., **auto-programming** and auto-documentation) smart infusion pump interoperability with the EHR.	Not a requirement	2%
Yes	1 (2)		NA	
No	50 (98)		NA	
Frequency of drug library quality reviews	*n* = 43	3.1 Provide dedicated time and resources for regular review and analysis of smart infusion pump data, at least on a quarterly basis.	12.5 Established dosing limits are reviewed every six months and changes are made as required.	% reviewing dosing limits at least every 6 months: 47% (20/43)
Never	13 (30)			
Annually or less	6 (14)			
Biannually	8 (19)			
Quarterly or more often	12 (28)			
As needed	4 (9)			
Frequency of drug library amendments or updates	*n* = 47	2.1 …update the library at least quarterly.	12.3 Updates to the medication libraries are performed… not less than quarterly unless no updates for that quarter.	% updating library at least quarterly: 30% (14/47)
Never	1 (2)			
Annually or less	15 (32)			
Biannually	11 (23)			
Quarterly or more often	14 (30)			
As needed	6 (13)			
Frequency of drug library compliance audits	*n* = 37	3.3 Regularly monitor … to assess drug library compliance and identify barriers to use: facility compliance rate with DERS, compliance rate with DERS by care area/profile.	Not a requirement.	% regularly monitoring compliance (excluding never or as needed): 62% (23/37)
Never	11 (30)		NA	
Annually or less	10 (27)		NA	
Biannually	2 (5)		NA	
Quarterly or more often	11 (30)		NA	
As needed	3 (8)			

DERS = dose error reduction system, NA = not applicable.

TABLE 3 (Part 1 of 2). Organization and Design of IV Smart Pump Drug Libraries

Survey Question	No. (%) of Respondents[a]
Categorization of drug library[b]	*n* = 53
By care area	49 (92)
By patient weight	10 (19)
By age (e.g., adult or pediatric)	37 (70)
By therapeutic drug class	8 (15)
Organization of user interface[b]	*n* = 49
Alphabetical	48 (98)
By therapeutic drug class	3 (6)
By frequency of use (most frequently used at top of list)	14 (29)
Maximum number of entries used for a given drug	*n* = 39
Yes	12 (31)
No	27 (69)
If yes, maximum no. of entries used	*n* = 10
1	1 (10)
2	2 (20)
3 or 4	3 (30)
Limited by pump capabilities	4 (40)
Health care professional responsible for setting limits for each drug entry[b]	*n* = 50
Nursing professional	31 (62)
Pharmacist	46 (92)
Physician	24 (48)
Collaborative approach	35 (70)
Strategies to account for overfill when setting limits[b]	*n* = 38
Use estimated overfill of 10% of the total drug volume	11 (29)
Use estimated overfill of 15% of the total drug volume	1 (3)
Use average overfill volume from the manufacturer	10 (26)
Use maximum overfill volume from the manufacturer	5 (13)
Use 50% overfill volume from the manufacturer	1 (3)
Do not account for overfill	7 (18)
Not applicable (no overfill or use of syringe pumps)	4 (11)
Use of clinical alerts	*n* = 37
Yes	28 (76)
No	9 (24)
If yes, clinical alerts found to be most effective[b]	*n* = 14
Administration/filter requirements	7 (50)
High-alert medication	6 (43)
Weight, dose, infusion time alerts	5 (36)
Monitoring requirements	3 (21)
Central line only	2 (14)
Clarify drug name	2 (14)
Hazardous labelling	1 (7)
Mixing instructions	1 (7)
Premedication requirements	1 (7)

TABLE 3 (Part 2 of 2). Organization and Design of IV Smart Pump Drug Libraries

Survey Question	No. (%) of Respondents[a]
Clinical alerts removed to reduce alert fatigue[b]	*n* = 9
None	5 (56)
Infusion time	2 (22)
Mixing instructions	2 (22)
Adverse effects	1 (11)
Filter requirements	1 (11)
Use of "keep vein open" rates	*n* = 37
Yes	30 (81)
No	7 (19)

[a]Parenthetical values refer to valid percentages, excluding missing responses.
[b]Multiple responses were allowed.

Trends were similar, with greater levels of participation during implementation than for maintenance, for clinical engineers (65% versus 33%), information services professionals (48% versus 12%), and physicians (42% versus 12%).

Dedicated FTEs for smart pump team members also appeared to be higher for implementation than for maintenance. Of note, 46% of respondents reported less than 1 pharmacist FTE dedicated to creation of a new drug library, and 68% reported less than 1 pharmacist FTE for library maintenance (including 28% who reported no dedicated pharmacist hours for maintenance). For nursing professionals, the rates were similar: 39% of respondents reported less than 1 FTE for implementation and 70% reported less than 1 FTE for maintenance.

Of the 9 respondents who reported a provincially standardized drug library, 5 reported some number of pharmacist FTEs for maintenance of the library: 0.5 FTE reported by 1 respondent, 1 FTE reported by 2 respondents, 2 FTEs reported by 1 respondent, and 2.5 FTEs reported by 1 respondent. One respondent reported 1 FTE pharmacist position that had been approved but not yet implemented; this FTE is included in the data reported in Table 6.

DISCUSSION

This study describes the current landscape in Canadian hospitals with regard to compliance with smart pump standards and guidelines, the characteristics of smart pumps in use (including drug libraries), and the health care professionals managing them. Most respondents (40%) were from Ontario, the province with the greatest proportion of hospitals in Canada (27%)[16] (Figure 1). Although the second and third highest proportions of Canadian hospitals are in Quebec (17%) and Alberta (14%),[16] only 9% and 7% of respondents, respectively, were from those provinces. For Alberta, this result may have been due to the existence of a standardized provincial drug library, which may have

reduced the number of pump teams required. For Quebec, the limited number of responses may have been related to availability of the survey only in English.

Compliance with Standards

This study showed low rates of compliance with standards and guidelines. Less than half of respondents reported biannual quality reviews of their drug library, as required by Accreditation Canada, and only 30% updated their library at least quarterly, as recommended by both ISMP and Accreditation Canada. We did not explore the reasons why standards were not being met; however, given the limited number of FTEs that most respondents reported for drug library maintenance, human resources may play a role. Furthermore, the ISMP guidelines were published in February 2020, shortly before the World Health Organization declared COVID-19 a pandemic. With the demands created by the pandemic, organizations may not have had resources available to implement the recommended changes. Further research is needed to understand potential contributing factors.

Most respondents in this study reported that drug libraries had not been standardized across their province/territory. Half of the respondents reported standardization within their health authority or organization, a practice recommended by ISMP.[1] Large-scale standardization presents many challenges, including attaining agreement

TABLE 4. Methods for Managing IV Smart Pump Drug Libraries

Survey Question	No. (%) of Respondents[a]
Method used to obtain drug library feedback from end-users[b]	*n* = 43
Email	17 (40)
Committee/meetings	15 (35)
Request form	13 (30)
Informal verbal request	10 (23)
Website/portal	6 (14)
Continuous quality improvement data	7 (16)
Formulary changes	5 (12)
Direct communication to end-users for feedback	3 (7)
No process developed	2 (5)
Method used to inform end-users of updates to the drug library[b]	*n* = 51
Email	41 (80)
Memo/newsletter	28 (55)
Huddles/meetings	21 (41)
Website/portal	2 (4)
End-users not notified	1 (2)
Data reviewed during drug library compliance audits[b]	*n* = 50
Data downloaded from the pumps	36 (72)
Floor audits	9 (18)
Data retrieved from electronic health record	2 (4)
User-submitted reports	3 (6)
Direct communication with end-users	1 (2)
No compliance audits performed	6 (12)
Designation of person(s) responsible for conducting drug library compliance audits[b]	*n* = 48
Staff member (nonmanagerial)	26 (54)
Manager	16 (33)
Interdisciplinary committee	1 (2)
Strategies used to reduce alert fatigue[b]	*n* = 19
Actively reassess and minimize clinical alert list	11 (58)
Continuous quality review of library entries/limits	8 (42)
Optimize pump settings (e.g., occlusion pressure)	2 (11)
Add clinical alerts to certain medications only (e.g., high-risk medications)	2 (11)
Minimize wording of clinical alerts	1 (5)
Combine clinical alerts	1 (5)
None	3 (16)

[a]Parenthetical values refer to valid percentages, excluding missing responses.
[b]Multiple responses were allowed.

TABLE 5. Support and Training of IV Smart Pump End-Users

Survey Question	No. (%) of Respondents[a]
Training provided to drug library implementation team members during implementation	*n* = 37
Yes	31 (84)
No	6 (16)
Type of training provided to nursing staff during implementation[b]	*n* = 47
Hands-on training	39 (83)
Live information sessions	32 (68)
Webinar	21 (45)
Online training modules	3 (6)
Type of training provided to clinical pharmacy staff during implementation[b]	*n* = 47
Live information sessions	27 (57)
Webinar	14 (30)
Hands-on training	14 (30)
None	4 (9)
Training completed by pump team members for pump maintenance	*n* = 33
Yes	22 (67)
No	11 (33)
Frequency of end-user competency assessment and retraining	*n* = 47
Never	7 (15)
Annually	8 (17)
Every 2 years	10 (21)
After any extended leave	5 (11)
As needed	4 (9)
Unsure/unknown	13 (28)

[a]Parenthetical values refer to valid percentages, excluding missing responses.
[b]Multiple responses were allowed.

TABLE 6. Resources Allocated for IV Smart Pump Drug Libraries

Resource	Stage; No. (%) of Respondents[a] Implementation	Maintenance
Team members involved in drug library[b]	*n* = 52	*n* = 52
Pharmacist	51 (98)	51 (98)
Nursing professional	49 (94)	29 (56)
Clinical engineer	34 (65)	17 (33)
Information services professional	25 (48)	6 (12)
Physician	22 (42)	6 (12)
Full-time equivalents		
Pharmacist	*n* = 26	*n* = 25
0	5 (19)	7 (28)
> 0 to < 1	7 (27)	10 (40)
1.0 to 1.9	11 (42)	5 (20)
≥ 2	3 (12)	3 (12)
Nursing professional	*n* = 18	*n* = 10
0	4 (22)	4 (40)
> 0 to < 1	3 (17)	3 (30)
1.0 to 1.9	8 (44)	2 (20)
≥ 2	3 (17)	1 (10)
Clinical engineer	*n* = 7	*n* = 3
0	2 (29)	1 (33)
> 0 to < 1	3 (43)	1 (33)
1.0–1.9	2 (29)	1 (33)
≥ 2	0	0
Information services professional	*n* = 9	*n* = 1
0	2 (22)	0
> 0 to < 1	4 (44)	0
1.0–1.9	2 (22)	1 (100)
≥ 2	1 (11)	0
Physician/medical student	*n* = 4	*n* = 5
0	2 (50)	3 (60)
> 0 to < 1	2 (50)	1 (20)
1	0	1 (20)

[a]Parenthetical values refer to valid percentages, excluding missing responses.
[b]Multiple responses were allowed.

among practitioners about medication concentration, dosing units, medication dose range, administration rate, and/or time of administration. Because of these complexities, it was not surprising that few pump team members were working with a provincially standardized drug library.

Standardization of drug libraries is considered a crucial step in realizing interoperability,[1] which may help to improve compliance, thus leading to increased patient safety.[17] Consistent with data from Ontario,[18] the current study revealed that Canadian hospitals have not integrated smart infusion pumps with EHR or CPOE systems, as recommended by ISMP. Interoperability has been found to improve dose administration, monitoring, accuracy of clinical data, documentation, and efficiency of systems, leading to overall improvement in patient safety.[19-21] However, given that implementation and maintenance of smart pump interoperability is complex, difficult, and costly,[22] achieving such interoperability may be challenging for some organizations. For these reasons, it should be a goal for health care organizations to connect smart infusion pumps to an EHR system.

Drug Library Set-up

Categorization of libraries by care area, organizing the user interface alphabetically, and direct involvement of a pharmacist in setting dosing limits were reportedly employed by most facilities, but other topics exhibited less consensus. Although 70% of respondents reported categorization by age, the responses were not analyzed separately for hospitals serving adults, pediatric patients, and/or neonates. Presumably organizations that do not serve pediatric/neonatal populations would be less likely to arrange their drug library by age.

The use of smart pump drug library programming to support an organization's strategy for overfill management presents a significant opportunity to improve patient care. Failing to account for overfill when administering intermittent infusions can result in significant underdosing of medication, which can affect patient outcomes.[23,24] Reported strategies to manage overfill varied among respondents; surprisingly, 18% of respondents had no strategy for this situation. Therefore, the use of drug library programming to improve overfill management may be an underutilized tool that organizations could consider to improve patient safety.

Patient safety can also be improved by using clinical alerts.[17] Such alerts intentionally interrupt the administration of drugs and must be acknowledged by the user,[1] which increases programming time. To avoid alert fatigue, they should only provide information that is essential to the safe administration of the drug. Surprisingly, the use of alerts for "high-alert medication" was reported with a high frequency of almost 43%. The literature indicates that alerts for "high-alert medications" may be a source of alert fatigue, especially in a critical care setting where most drugs are high alert[25]; as such, this specific alert should not be included. However, the current study did not separate clinical alerts by care area, so the frequency of alerts in the intensive care setting is unknown. Only 50% of respondents reported alerts for administration/filter requirements; this type of alert is believed to be effective in reducing medication administration errors.[25] Canadian hospitals should consider implementing strategies to optimize use of clinical alerts during smart pump programming.

Drug Library Management

Respondents reported predominantly reactive strategies for obtaining feedback from users, which suggests that reporting typically does not occur until a problem arises. Proactive strategies, such as use of CQI data, formulary changes, and direct communication, may increase patient safety and provide additional data that would be valuable for improving drug libraries over time; these strategies should be considered by Canadian health care organizations.

Support and Training

Organizations should recognize the value of providing staffing resources for training and recertification related to smart pump technology. Most respondents in the current study reported hands-on training for nurses during implementation, a method that has been demonstrated as effective in increasing compliance.[26] To the authors' knowledge, however, there is no literature on the best method of training other pump team members. This situation could benefit from future research.

Despite the Joint Commission's recommendations to perform initial and yearly recertification[21] and Accreditation Canada's requirement to perform reassessment every 2 years,[3] many participants reported no retraining or retraining only after an extended leave or as needed. Given the risk of medication administration errors, ensuring that staff maintain competence in smart pump use is essential. Canadian hospitals should work toward the Accreditation Canada standard.

Human Resources

According to this survey study, few full-time staff are dedicated to the implementation and management of drug libraries, despite accreditation requirements and the effects on patient safety. Almost 40% of participants were managing multiple pump brands within a single organization; the need for a separate drug library for each brand of pump adds to the pump team's workload. Depending on the size and complexity of a drug library and the frequency of updates, clinician time to review and update the drug library could be substantial. Although most IV pump teams include pharmacy and nursing personnel, this study showed that not all other disciplines are involved. Even where other disciplines are involved, only limited resources are dedicated to this work, despite guideline recommendations for the use of interdisciplinary teams to develop, test, and update drug libaries.[1] Many pump team members who responded to our survey mentioned, in open-text responses, that they were managing drug libraries alongside other regular responsibilities, which could potentially affect the quality of their work. However, most respondents who reported provincially standardized drug libraries also reported 1 or more pharmacist FTEs; this finding indicates that organizations recognize the need for pharmacist positions to support larger, more complex libraries. More data are needed on the human resources required to manage a drug library, according to size or complexity, to help guide health care organizations in properly supporting these initiatives.

Limitations

Given that the numbers of pump teams and pump team members across Canada are unknown, the response rate in this study could not be determined. Because the perspectives of various health care professionals were desired, the survey was open to any health care professional managing smart pumps, and multiple members of the same team may have participated. This might have led to overrepresentation of larger pump teams or inconsistent reporting of actual practices from single sites.

Pharmacists are generally involved in building drug libraries because of their understanding of drug dosing, pharmacokinetics, drug stability, and proper administration; as such, they were purposely targeted as participants. The organizations used to recruit survey respondents were pharmacy-based, and referral by pharmacists was the main source of recruitment for nonpharmacist participants. This approach likely led to underrepresentation of nonpharmacist team members.

In terms of FTEs, only 3 respondents indicated that more than 2 pharmacist FTEs were dedicated to drug library maintenance. Although 2 of these respondents stated that their province had a provincial drug library (which would likely require more resources to manage), it is possible that the question was misinterpreted; as such, reports of more than 2 pharmacist FTEs may be an overrepresentation.

Finally, although respondents from all Canadian provinces participated, the survey was available only in English, which may have presented a barrier to non–English-speaking pump team members.

CONCLUSION

Variation exists in methods for the implementation and maintenance of IV smart pumps across Canadian hospitals. Although slight variations in process are expected in each unique setting, consensus on best practices for drug library management would benefit the teams responsible for optimizing use of smart pump technology. Determining the impact on medication administration errors of processes related to drug library set-up, management, training, and support, as well as required resources, could benefit from further study. While many pump teams are moving toward meeting available guidelines and standards, it is apparent that Canadian hospitals do not currently meet these standards, and additional human resources may be required to maximize the patient safety benefits offered by smart infusion pumps.

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Feasibility of a Hospital Peer Review Continuous Quality Improvement Program for Pharmacists' Documentation: A Mixed-Methods Study

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ABSTRACT

Background: Peer review to assess the quality of documentation is essential, as it provides a framework for constructive feedback, using evaluators with similar qualifications to increase acceptability.

Objective: To determine the feasibility of implementing a peer review continuous quality improvement program for pharmacists' documentation at the Montreal Children's Hospital.

Methods: A prospective, single-centre mixed-methods feasibility study was conducted (from January to June 2021) to evaluate the practicality and acceptability of a peer review program (PRP) for assessing the quality of pharmacists' documentation. A peer review committee of 5 pharmacists evaluated their peers' clinical notes using a standardized assessment tool. Practicality was determined through the time required for administrative and evaluative tasks and the resources needed for each evaluation cycle. Acceptability was determined through pooled quantitative data related to pharmacists' perceived relevance of the PRP, confidence in their peers, and satisfaction with the evaluation process. Qualitative data collected through surveys, a focus group, and semistructured individual interviews helped to further explain the results.

Results: A total of 37.4 hours was required to complete both administrative and evaluative tasks in one peer review cycle, which respected the budgeted cut-off for practicality. Acceptability was also achieved, given that more than 80% of survey respondents found the PRP relevant to their practice, were confident in their peers, and were satisfied with the PRP. Qualitative results showed that participants found the PRP to be instructive and that qualitative feedback was preferred over a grade issued as a percentage.

Conclusion: This study showed that it is feasible to implement a PRP to assess the quality of pharmacists' documentation. To ensure success, it is key that documentation objectives and department resources be predefined.

Keywords: peer review, pharmacist, documentation, quality improvement

RÉSUMÉ

Contexte : L'évaluation par les pairs afin d'évaluer la qualité de la documentation est essentielle, car elle fournit un cadre pour une rétroaction constructive émise par des évaluateurs ayant des qualifications similaires afin d'augmenter l'acceptabilité.

Objectif : Déterminer la faisabilité d'implanter un programme d'évaluation par les pairs en continu de la qualité de la documentation des pharmaciens à l'Hôpital de Montréal pour Enfants.

Méthodes : Une étude de faisabilité prospective, monocentrique et de méthodes mixtes a été menée (de janvier à juin 2021) pour évaluer la praticité et l'acceptabilité d'un programme d'évaluation par les pairs (PEP) ayant pour but d'évaluer la qualité de la documentation des pharmaciens. Un comité d'évaluation par les pairs composé de 5 pharmaciens a évalué les notes cliniques de leurs pairs à l'aide d'un outil d'évaluation standardisé. La praticité a été déterminée par le temps requis pour les tâches administratives et d'évaluation et les ressources nécessaires pour chaque cycle d'évaluation. L'acceptabilité a été déterminée grâce à des données quantitatives regroupées liées à la pertinence perçue du PEP par les pharmaciens, à la confiance envers leurs pairs et à la satisfaction à l'égard du processus d'évaluation. Les données qualitatives recueillies par le biais de sondages, d'un groupe de discussion et d'entretiens individuels semi-structurés ont permis d'expliquer davantage les résultats.

Résultats : Un total de 37,4 heures a été nécessaire pour accomplir les tâches administratives et d'évaluation dans un cycle d'évaluation par les pairs, ce qui respectait le seuil budgété pour des raisons pratiques. L'acceptabilité a également été atteinte puisque plus de 80 % des répondants au sondage trouvaient le PEP pertinent pour leur pratique, avaient confiance en leurs pairs et étaient satisfaits du programme. Les résultats qualitatifs ont montré que les participants trouvaient le PEP instructif et que la rétroaction sous forme de commentaires était préférée à une note émise en pourcentage.

Conclusion : Cette étude a démontré qu'il est possible de mettre en place un PEP pour évaluer la qualité de la documentation des pharmaciens. Pour garantir sa réussite, il est essentiel de prédéfinir les objectifs de documentation et les ressources départementales à disposition.

Mots-clés : évaluations par les pairs, pharmacien, documentation, amélioration de la qualité

INTRODUCTION

Pharmacists' clinical documentation in patients' health records is a practice standard recommended by the Canadian Society of Hospital Pharmacists (CSHP).[1] High-quality documentation ensures good communication among health care providers and better continuity of care.[2] Conversely, failure to document may lead to undesirable consequences for both the patient and the health care team.[1] A recent study in a large Montréal university hospital showed that pharmacists' documentation was "sufficient or extensive" in only 66% of patient medical records, and the rate of conformity with pre-established criteria was 57%.[3] The CSHP recommends the "implementation of an educational program ... and processes to assess each pharmacist's documentation skills as a means to promote and support high-quality pharmacy practice".[1] For quality control, peer review engages individuals with similar qualifications to provide constructive feedback, continuous learning, and reflection on current practices.[4,5]

As pharmacists' roles become more differentiated and specialized, managers and supervisors may not have sufficient expertise to judge the quality of care provided. The main barrier appears to be lack of anonymity during assessment, because those being assessed fear repercussions in the workplace.[6] Therefore, evaluation by the manager or supervisor may have poor acceptability. Few papers could be found specifically describing peer review programs (PRPs) related to pharmacists' documentation, and these studies often lacked details on the feasibility of implementation.[6-8] Milchak and others[8] developed a peer review audit tool to assess pharmacists' documentation in primary care clinics. Although the audit tool was not assessed for interrater reliability, results showed that the peer review process generated significant and sustainable improvement in pharmacists' clinical documentation in electronic medical records.[8] In the study by Haines and others,[6] pharmacists expressed, in response to surveys and during focus groups, that peer review was important for quality control but was also time-consuming. However, these authors did not mention the time or resources required to undertake a cycle of peer review.

The primary objective of the current study was to determine the feasibility of implementing a peer review continuous quality improvement program for pharmacists' documentation according to predefined criteria for practicality and acceptability. The secondary objectives were to identify aspects of the assessment tool requiring improvement and to explore pharmacists' opinions about facilitators of and obstacles to the PRP.

METHODS

Study Design and Population

This prospective, single-centre feasibility study used a convergent mixed-methods approach. The study was conducted from January to June 2021 at the Montreal Children's Hospital (MCH), a pediatric hospital that is part of the McGill University Health Center (MUHC). During the study period, 21 pharmacists provided pediatric pharmaceutical care at the MCH, and 10 pharmacy residents completed their residency at the MUHC. Documentation standards at our institution are based on the standards of the Ordre des pharmaciens du Québec.[2] No specific formal standards have been developed or adopted within the pediatric department. In our centre, all pharmacists are assigned dispensary hours, and the majority also practise in a clinical area (neonatal intensive care unit, pediatric intensive care unit, hematology–oncology, and/or general pediatrics). An invitation to participate on the peer review committee (PRC) was sent by email to all pharmacists, and 5 individuals were selected to represent, to the extent possible, each of the above clinical areas. The investigators were not allowed to be members of the PRC, to participate in any surveys, or to attend any focus groups or interviews. However, the investigators' clinical notes could be included, if selected, for evaluation by the PRC.

Given that this was a quality improvement study, the Research and Ethics Board of the MUHC waived the requirement to obtain ethics approval. Participants signed consent forms before taking part in the focus group and interviews and provided implicit consent when they completed the surveys.

Peer Review Cycles

During the study, 2 cycles of peer review were performed. Detailed steps and associated timing are presented in Table 1. During each cycle, every instance of documentation by all pharmacists was eligible for review by the PRC.

For both cycles, the investigators extracted an electronic listing of all pharmacists' notes from the institution's electronic medical record system, OACIS (Telus Health). For each pharmacist, the notes were numbered chronologically, Research Randomizer (https://www.randomizer.org/) was used to generate 5 random numbers, and the corresponding 5 notes were selected for evaluation, such that a total of 105 clinical notes were selected per cycle. If a pharmacist had fewer than 5 eligible notes for a given cycle, then additional notes from the other pharmacists were randomly selected on a pro rata basis, to ensure a total of 105 notes per cycle. The notes were then anonymized and randomly distributed among the 5 PRC members. If, after random assignment of notes, the investigators detected that any member of the PRC would be reviewing one of their own notes, any such note was switched with a note previously assigned to another PRC member. The same pharmacists served as PRC members for both cycles.

During each of the 2 cycles, each PRC member was allowed a paid 8-hour day to complete their assessment of 21 clinical notes using the Standardized Tool for the Evaluation of Pharmacists' Documentation (STEP-D). This tool was previously developed using a modified Delphi method

based on a survey of pharmacists from 2 Canadian pediatric centres, the MCH and the Children's Hospital of Eastern Ontario. It consists of 43 items, divided into 5 sections (Appendix 1, available from https://www.cjhp-online.ca/index.php/cjhp/issue/view/215). The investigators created, on the basis of anticipated use, a user guide (Appendix 2, available from https://www.cjhp-online.ca/index.php/cjhp/issue/view/215), which was provided to each PRC member to assist in standardization of their evaluations. At the end of each cycle, all 21 pediatric pharmacists received a feedback report by email, which included the number of notes evaluated, the average grade obtained, copies of the selected notes, and the completed STEP-D form associated with each note. The pharmacists were blinded to the PRC members who assessed their notes.

Data Collection

The time required to complete each administrative task (i.e., extraction, preparation, randomization, and distribution of notes; preparation and distribution of feedback) was measured by the investigators. The time required to complete evaluation of each note with the STEP-D was self-reported by PRC members. Because it was possible to adjust the evaluation process on the basis of results of the surveys and focus groups conducted after cycle 1, data for these time measures were collected only in cycle 2. Also, using the measures of time from cycle 2 was more representative of reality, given that the PRC members became familiar with the flow of each step during cycle 1.

To assess pharmacists' acceptance of the PRP, an anonymous survey was sent, at the end of each cycle, to all pharmacists whose documentation was assessed. Similarly, an anonymous survey was sent to all members of the PRC to obtain their assessment of PRP relevance and their confidence in their ability to complete the steps appropriately.

After completion of cycle 1, a focus group, led by the pharmacy residents (S.G., T.M., C.P., R.S.-A.) and involving PRC members, was held to address the fluidity of the

TABLE 1. Steps of the Study and Associated Timing

Step of Feasibility Study	Period	Included in Operational Version*
Before study		
Adaptation of STEP-D tool and development of STEP-D user guide	June to November 2020	NA
Period of inclusion for electronically written and stored notes for study cycle 1	August 10 to October 10, 2020	NA
Period of inclusion for electronically written and stored notes for study cycle 2	October 11 to December 11, 2020	NA
Initial presentation of research project to pharmacists in the institution	January 12, 2021	NA
Study cycle 1		
Recruitment (by email) of pharmacists for PRC	January 21–29, 2021	Yes
Extraction of notes from electronic medical record system (OACIS, Telus Health) and randomization	January 2021	Yes
Distribution of notes by email to PRC members	January 29, 2021	Yes
Period for assessment of notes by PRC members	January 29 to February 21, 2021	Yes
Calculation of grades and preparation of feedback	February 22 to 28, 2021	Yes
Anonymous survey of PRC members (multiple-choice and open-ended questions)	February 21 to 24, 2021	No
Focus group with PRC members	February 25, 2021	No
Distribution of feedback by email to all pharmacists	March 1, 2021	Yes
Anonymous survey of all pharmacists (multiple-choice and open-ended questions)	March 1 to 15, 2021	No
Study cycle 2		
Extraction of notes from electronic medical record system (OACIS, Telus Health) and randomization	March 2021	Yes
Distribution of notes by email to PRC members	March 16, 2021	Yes
Period for assessment of notes by PRC members	March 16 to April 27, 2021	Yes
Calculation of grades and preparation of feedback	April 28 to May 7, 2021	Yes
Recruitment (by email) of pharmacists who were evaluated for interviews	March 26, 2021	No
Distribution of feedback reports to pharmacists	May 10, 2021	Yes
Anonymous survey of all pharmacists who were evaluated (multiple-choice and open-ended questions)	May 10 to 21, 2021	No
Individual semistructured interviews with PRC members and pharmacists who were evaluated	May and June 2021	No

STEP-D = standardized tool for evaluation of hospital pharmacist documentation, NA = not applicable, PRC = peer review committee.

*"Operational version" is the version of the peer review program (using STEP-D tool) to be implemented in the Pharmacy Department of Montreal Children's Hospital, incorporating changes based on outcomes of the feasibility study.

PRP and any logistic problems. After completion of cycle 2, semistructured individual interviews were conducted by the same pharmacy residents with 5 of the pharmacists whose documentation was evaluated and the 5 PRC members.

Outcome

To determine the feasibility of the PRP, we assessed its practicality and acceptability. The PRP was considered practical if the time required to complete administrative tasks was 16 hours or less per PRP cycle, the average time required to assess a note with the STEP-D was 24 minutes or less for at least 4 of the 5 PRC members, and the total human resources needed to complete 1 PRP cycle was 56 hours or less. The PRP was considered acceptable if, when responses to survey questions related to each of the primary and secondary objectives were pooled (i.e., considered as a group), at least 80% of survey respondents answered 4 (partially agree) or 5 (totally agree) on the 5-point Likert scale for all questions, weighted by the number of questions per objective. This threshold was deemed reasonable by the investigators, given that the PRP could be improved after completion of the study. Table 2 presents the pre-established evaluation criteria and their associated thresholds for feasibility.

The various thresholds were set to fit within typical 8-hour days and were approved by the management team of the MUHC pharmacy department. The investigators and pharmacy administrators met during the drafting of the protocol to assess the time available to devote to peer review for the following year based on actual resources and anticipated constraints. With respect to prioritizing core departmental activities, including medication dispensing and patient care, it was deemed possible to free up each of the 5 reviewers for 1 day per cycle (for the evaluations) and the investigators for 2 days per cycle (for administrative tasks related to the process), with an expectation of 4 cycles per year. To complete the necessary workload of 21 notes per PRC member, 24 minutes per note was considered a reasonable cut-off to fit within the schedule and was tested by the investigators before initiation of the current study. To address the secondary objectives, facilitators and obstacles related to the PRP were explored qualitatively through open-ended questions in the surveys, interviews, and focus group. The interviews and the focus group were held on the Microsoft Teams platform. Questions used to guide the interviews and focus group are available in Appendix 3 and Appendix 4, respectively (available from https://www.cjhp-online.ca/index.php/cjhp/issue/view/215).

TABLE 2. Pre-established Evaluation Items and Associated Thresholds for Feasibility

Evaluation Item	Minimum Acceptable Result
Practicality	
Administrative task	Requires ≤ 16 h per PRP cycle
Average time to assess 1 note	Requires ≤ 24 min for at least 4 out of 5 PRC members
Total human resources	Requires ≤ 56 h per PRP cycle
Acceptability	
Answers to survey question, pooled by objective	≥ 80% of respondents "partially agree" or "totally agree"[a]

PRC = peer review committee, PRP = peer review program.
[a]The surveys used a 5-point Likert scale: 1 = totally disagree, 2 = partially disagree, 3 = neither agree nor disagree, 4 = partially agree, 5 = totally agree.

Qualitative Analysis

Inductive coding was used. A coding frame was developed, and if modifications were made to the coding frame, the qualitative data were updated.

RESULTS

The total time to perform administrative tasks for cycle 2 of the PRP was 14.9 hours (details shown in Table 3). For the same PRP cycle, the total time required by all 5 members of the PRC to complete their review of all 105 notes was 22.6 hours, for an average of 12.9 (standard deviation 8.7) minutes for each note assessment using the STEP-D. The proportion of PRC members who reported that the allotted 8-hour day was sufficient to evaluate the 21 notes assigned was 80% for cycle 1 and 100% for cycle 2. The administrative and evaluative tasks required a total of 37.4 hours for the second PRP cycle, which was within the predetermined threshold of 56 hours.

The rate of survey participation among pharmacists whose documentation was evaluated was 71% (n = 15) for cycle 1 and 43% (n = 9) for cycle 2. All 5 PRC members (100%) participated in the PRC survey for both cycles.

When survey results pertaining to the same primary or secondary objective were pooled, the threshold of at least 80% of respondents answering favourably (i.e., "partially agree" or "totally agree") was reached in cycle 2 for each surveyed group. Scores for pertinence and confidence in the PRP were below 80% in the cycle 1 surveys, especially the survey of PRC members, driven by lower rates of satisfaction with the STEP-D and limited self-confidence in evaluating their peers during cycle 1. Table 4 contains detailed results from the acceptability survey.

The PRP was appreciated by PRC members mostly for its instructive potential, as it allowed them to review notes written by colleagues working in different clinical units. These new perspectives offered ways for them to improve their own documentation and to reflect on their own practice and the importance of documenting activities and interactions.

All pharmacists viewed the idea of a continuous PRP as an opportunity to keep the quality of their documentation on track and to standardize documentation within the MCH. When discussing peer review, some pharmacists limited their concept of "peers" to health care professionals

TABLE 3. Total Time to Perform Administrative Tasks for Cycle 2 of Documentation Peer Review Program

Task	Definition	Time (h)
Note extraction	Total time required to extract notes	3.5
Note preparation	Total time required to anonymize and convert documentation before distribution	3.1
Note randomization	Total time required to randomize and assign notes	0.8
Note distribution	Total time required to distribute anonymized notes to PRC members	0.4
Preparation of feedback	Total time required to calculate the overall grade and prepare the feedback report for all pharmacists whose documentation was evaluated	5.5
Distribution of feedback report	Total time required to distribute feedback reports to all pharmacists whose documentation was evaluated	1.6
Total	Total time required to perform all administrative tasks	14.9

PRC = peer review committee.

within the same clinical unit, while others viewed any MCH pharmacists as peers. Those who showed a preference for evaluators to be drawn from their own clinical unit felt that only pharmacists with a similar practice could adapt the evaluation to the clinical unit's reality. Conversely, other pharmacists found that having an evaluator from a different unit encouraged improvement of documentation by bringing a different perspective and disrupting the status quo. However, given that the main objective of the PRP was to assess the quality of documentation, not the quality of the clinical act itself, all pharmacists found it acceptable to have their notes evaluated by a pediatric pharmacist from any clinical unit. Although the pharmacists who were interviewed informed us that anonymization was pertinent to avoid bias or judgment by peers, complete anonymization was not fully achievable. Indeed, the MCH pharmacy team is small, and pharmacists were able to guess who had written a particular note or who had performed an evaluation. Interestingly, 2 pharmacists shared that they would prefer to lift anonymity to allow exchange with their evaluators on how to improve their documentation.

According to survey results, PRC members' satisfaction with the PRP increased after cycle 2, especially their satisfaction with the STEP-D, which evolved from 60% in cycle 1 to 100% in cycle 2. Notably, no changes were made to either the PRP or the STEP-D between cycles 1 and 2, because no major issues were raised during the focus group. The main cause of dissatisfaction with the STEP-D was concern for high interrater variability, reported by both the PRC members (evaluators) and the pharmacists whose documentation was evaluated. The PRC members commented that some elements of the STEP-D were interpreted differently by their colleagues. In addition, some PRC members found the STEP-D items too rigid. For example, a note that they considered appropriate for certain contexts might have resulted in a low grade because of the restrictive nature of the grading scale. This rigidity diminished their acceptance of the tool. PRC members also noticed a lot of repetition in the STEP-D items, and many felt that the evaluation grid could be made more concise. Ultimately, all study participants agreed on the necessity of using a standardized assessment tool to ensure consistency among evaluators. They expressed that the STEP-D facilitated documentation assessment through its structure and its focus of evaluating the quality of the note, rather than the clinical aspect described in the documentation. Moreover, pharmacists greatly appreciated the comments sections in the STEP-D, explaining that these were more valuable than the grade itself, especially when recommendations on how to improve documentation were provided. The user guide was especially useful during cycle 1, when all PRC members reported using it, although the proportion using the guide dropped to 40% during the second cycle, when PRC members had become more familiar with the process.

The grades generated by the STEP-D offer objectivity and precision, but many participants argued that they were perceived as degrading and were useless in terms of suggesting ways to improve; these limitations could reduce the acceptability of the PRP. Some feared that the negative perception of grades would discourage pharmacists from writing notes, because of a fear of workplace repercussions. Overall, it was suggested that the PRP should be used only to provide qualitative feedback, with summarized and personalized recommendations for improvement.

DISCUSSION

The findings of this study suggest that it is feasible to implement a peer review process for evaluating pharmacists' documentation according to the practicality and feasibility criteria established within our method. The average time required to complete a STEP-D was shorter than originally allocated and was similar across evaluators. However, the time required was highly variable depending on a note's length and complexity. Pharmacists shared that the PRP helped them to reflect on their documentation practice

TABLE 4. Results of Acceptability Surveys in Terms of Perceived Relevance, Confidence in Peers, and Satisfaction with PRP

Objective and Survey Item[a]	Phase of Study; No (%) in Agreement[b] Cycle 1	Cycle 2
Survey of evaluated pharmacists	***n*** **= 15**	***n*** **= 9**
Perceived relevance		
The PRP is pertinent to assess the quality of pharmacists' documentation at the MCH	12 (80)	8 (89)
The PRP is pertinent to improve the quality of pharmacists' documentation at the MCH	12 (80)	9 (100)
The tool used to assess the quality of pharmacists' documentation is pertinent	11 (73)	7 (78)
Pooled result	78%	89%
Confidence in peers		
My colleagues are sufficiently skilled to assess the quality of my documentation	13 (87)	8 (89)
Pooled result	87%	89%
Survey of PRC members	***n*** **= 5**	***n*** **= 5**
Perceived relevance		
In general, the use of a standardized tool to assess my colleagues' documentation quality is pertinent	4 (80)	4 (80)
My experience as an evaluator helped me acquire new knowledge	4 (80)	5 (100)
My experience as an evaluator helped me acquire new skills	4 (80)	5 (100)
Pooled result	80%	93%
Confidence in peers		
I am sufficiently skilled to assess the quality of my colleagues' documentation	3 (60)	5 (100)
Pooled results	60%	100%
Satisfaction		
I am satisfied with the standardized tool used to evaluate my colleagues' quality of documentation	3 (60)	5 (100)
The tool's user guide was useful during the evaluation process	4 (80)	4 (80)
I am satisfied with my experience as an evaluating pharmacist and member of the PRC	5 (100)	5 (100)
Pooled results	80%	93%

MCH = Montreal Children's Hospital, PRC = peer review committee, PRP = peer review program

[a]The survey used a 5-point Likert scale: 1 = totally disagree, 2 = partially disagree, 3 = neither agree nor disagree, 4 = partially agree, 5 = totally agree.

[b]"Agreement" is the sum of "partially agree" and "totally agree". Survey participation rates were as follows: for pharmacists who were evaluated, cycle 1 = 71% (*n* = 15), cycle 2 = 43% (*n* = 9); for PRC members, cycle 1 = 100% (*n* = 5), cycle 2 = 100% (*n* = 5).

and to develop their skills in this area, and PRC members considered their exposure to a variety of notes highly constructive. Milchak and others[8] also reported that their peer review process was highly appreciated and considered it a unique learning experience because pharmacists were involved in performing the evaluations.

Despite meeting our threshold of 80% for acceptability, some factors affecting pharmacists' approval of the PRP should be addressed. Although the STEP-D had the lowest proportion of acceptability in survey results, its use was crucial to allow evaluators to focus on the quality of documentation rather than the quality of the clinical act. PRC members' satisfaction with the STEP-D improved by 40 percentage points after cycle 2, which suggests that exposure to the tool promoted its appreciation. Some participants suggested adding more options in the evaluation scale to make the tool less rigid and grouping certain items together to avoid redundancy. Our primary objective concerned the feasibility of the PRP as a whole, and thus we did not consider its success to be defined by the assessment tool alone.

To our knowledge, no validated tool to assess pharmacists' documentation has been previously described in the literature, and it is therefore difficult to compare the STEP-D with other methods. In our opinion, the method used to develop the STEP-D was a reasonable attempt to create a tool specifically adapted to our project, since the evaluation criteria were based on what has been published in the literature, and the modified Delphi approach allowed Canadian pediatric hospital pharmacists to select the criteria most pertinent to their practice for inclusion in the tool. Moreover, to improve the acceptability of this method, we suggest that grades be omitted from the feedback report sent to pharmacists whose notes are evaluated. In the version of the PRP to be implemented in our department (the operational version), grades will be presented as a performance indicator for the entire pharmacist team, to allow us to track yearly progress, and we will emphasize that the PRP is not meant to be either competitive or punitive. Likewise, double anonymization should be preserved for subsequent cycles, as most pharmacists felt that such an approach would reduce their fear of

judgment. The importance of anonymity to avoid tension among peers was also noted by Haines and others.[6] Although the use of grades was criticized, pharmacists highly valued constructive feedback through comments, which were included at the evaluators' discretion. Future PRC members will be encouraged to add comments more consistently.

The main limitation of this study was the potential for selection bias during evaluation of the PRP's acceptability. Indeed, most PRC members showed interest in participating in the project, which suggests that they may have been inclined to have a more favourable opinion of the PRP. To limit confirmation bias, the investigators were excluded from surveys, focus groups, and interviews. Moreover, the low cycle 2 response rate for our survey of pharmacists whose documentation was evaluated might not accurately reflect the opinion of the entire study population. It is possible that some pharmacists felt it was not pertinent, and was perhaps redundant, to answer the same questions for both cycles, which likely introduced participation bias. It would also have been interesting to stratify satisfaction according to the number of notes evaluated, to verify whether pharmacists for whom no or only a few notes were evaluated necessarily had a negative view of the PRP. However, because of the small size of our pharmacist team, such stratification would have jeopardized the anonymity of survey responses. We also note the absence of prior validation of the survey questionnaires and the STEP-D as limitations. Our predetermined and detailed feasibility criteria certainly represented a strength of this study, as they allowed us to limit confirmation bias.[9] Although the quantitative data offered us clear and objective measures to answer our study question, qualitative data and the use of a mixed methodology offered us a deeper insight into pharmacists' opinions.

CONCLUSION

The results from this study are of particular interest not only for the MUHC pharmacy department, but also for other health care centres. Our results may inspire others to reflect on the quality of their documentation and to implement a similar PRP. Other centres can easily adapt our PRP model to their department, with or without using an evaluation tool. Now that it has been shown that implementation of such a program is feasible, future research should focus on validating the tool and evaluating the impact of the PRP on the quality of documentation over time.

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Vancomycin Therapeutic Drug Monitoring: A Cross-Sectional Survey of Canadian Hospitals

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ABSTRACT

Background: Little is known about the current landscape of vancomycin therapeutic drug monitoring (TDM) in Canadian hospitals, which operate within publicly funded health care systems.

Objectives: To determine current TDM practices for vancomycin and associated challenges and to gather perceptions about TDM based on area under the concentration–time curve (AUC) in Canadian hospitals.

Methods: An electronic survey was distributed to hospital pharmacists in spring 2021 through multiple national and provincial antimicrobial stewardship, public health, and pharmacy organizations. The survey gathered data about hospital characteristics, TDM methods, inclusion criteria for patient selection, pharmacokinetic and pharmacodynamic targets, vancomycin susceptibility testing and reporting, and perceived barriers and challenges.

Results: In total, 120 pharmacists from 10 of the 13 provincial and territorial jurisdictions in Canada, representing 12.5% of Canadian acute care hospitals (n = 962), completed at least 90% of survey questions. The predominant TDM method was trough-based (107/119, 89.9%); another 10.1% of respondents (12/119) reported performing AUC-based TDM (with or without trough-based TDM), and 17.9% (19/106) of those not already using AUC-based TDM were considering implementing it within 1 to 2 years. Among hospitals performing trough-based TDM, 60.5% (66/109) targeted trough levels between 15 and 20 mg/L for serious infections with methicillin-resistant *Staphylococcus aureus*. One-quarter of the respondents using this method (27/109, 24.8%) agreed that trough-based TDM was of uncertain benefit, and about one-third (33/109, 30.3%) were neutral on this question. Multiple challenges were identified for trough-based TDM, including sub- or supra-therapeutic concentrations and collection of specimens at inappropriate times. Overall, 40.5% (47/116) of respondents agreed that AUC-based TDM was likely safer than trough-based TDM, whereas 23.3% (27/116) agreed that AUC-based TDM was likely more effective.

Conclusions: This survey represents a first step in developing evidence-based, standardized best practices for vancomycin TDM that are uniquely suited to the Canadian health care system.

Keywords: vancomycin, therapeutic drug monitoring, area under the curve, trough, survey

RÉSUMÉ

Contexte : On connaît peu de choses sur le paysage actuel du suivi thérapeutique pharmacologique (STP) de la vancomycine dans les hôpitaux canadiens, dont les activités s'inscrivent dans le cadre des systèmes de soins de santé financés par les deniers publics.

Objectifs : Déterminer les pratiques actuelles de STP de la vancomycine et les défis associés et recueillir les perceptions concernant le STP sur la base de l'aire sous la courbe de la concentration en fonction du temps (ASC) dans les hôpitaux canadiens.

Méthodes : Un sondage a été distribué électroniquement aux pharmaciens d'hôpitaux au printemps 2021 par plusieurs organismes nationaux et provinciaux de gestion de l'utilisation des antimicrobiens, de santé publique et de pharmacie. Le sondage a permis de rassembler des données concernant les caractéristiques des hôpitaux, les méthodes de STP, les critères d'inclusion pour la sélection des patients, les objectifs pharmacocinétiques et pharmacodynamiques, les tests de sensibilité à la vancomycine et les rapports des résultats, ainsi que les obstacles et les défis perçus.

Résultats : Au total, 120 pharmaciens de 10 des 13 provinces et territoires du Canada, représentant 12,5 % des hôpitaux canadiens de soins actifs (n = 962), ont répondu à au moins 90 % des questions du sondage. La méthode de STP prédominante utilisée était celle de la concentration minimale (107/119, 89,9 %); un autre 10,1 % des répondants (12/119) ont déclaré effectuer un STP basé sur l'ASC (avec ou sans STP basé sur la concentration minimale), et 17,9 % (19/106) de ceux qui n'effectuaient pas déjà le STP basé sur l'ASC envisageaient de le mettre en œuvre d'ici 1 à 2 ans. Parmi les hôpitaux pratiquant le STP basé sur la concentration minimale, 60,5 % (66/109) ciblaient des concentrations minimales entre 15 et 20 mg/L pour les infections graves à *Staphylococcus aureus* résistant à la méthicilline. Un quart des répondants qui utilisaient cette méthode (27/109, 24,8 %) convenaient que les avantages du STP basé sur la concentration minimale étaient incertains, et environ un tiers (33/109, 30,3 %) étaient neutres. De multiples défis ont été identifiés pour le STP basé sur la concentration minimale, notamment des concentrations sous- ou supra-thérapeutiques et la collecte d'échantillons à des moments inappropriés. Dans l'ensemble, 40,5 % (47/116) des répondants convenaient que le STP basé sur l'ASC était probablement plus sûr que le STP basé sur la concentration minimale, tandis que 23,3 % (27/116) convenaient que le STP basé sur l'ASC était probablement plus efficace.

Conclusions : Ce sondage représente une première étape dans l'élaboration de pratiques exemplaires normalisées et fondées sur des données probantes pour le STP de la vancomycine qui sont particulièrement adaptées au système de santé canadien.

Mots-clés : vancomycine, suivi thérapeutique pharmacologique, aire sous la courbe, concentration minimale, sondage

INTRODUCTION

For decades, vancomycin has been the standard treatment for serious infections caused by gram-positive bacteria.[1] Its narrow therapeutic index, coupled with pharmacokinetic variability, has made it a primary focus of inpatient therapeutic drug monitoring (TDM) services.[2] Yet despite more than 60 years of clinical use and a vast body of research investigating vancomycin pharmacokinetics and pharmacodynamics, the optimal dosing and TDM strategy remains unclear. This situation is concerning, given that dose optimization is a key antimicrobial stewardship strategy to maximize efficacy, minimize adverse effects, and slow the emergence of antimicrobial resistance.[3]

To address this uncertainty and to standardize practice, in 2009 the Infectious Diseases Society of America (IDSA), the American Society of Health-System Pharmacists (ASHP), and the Society of Infectious Diseases Pharmacists (SIDP) published guidelines for vancomycin dosing and TDM.[2] A key recommendation was to use more aggressive dosing for serious methicillin-resistant *Staphylococcus aureus* (MRSA) infections, targeting a value of at least 400 for the ratio of area under the concentration–time curve (AUC) over 24 hours to minimum inhibitory concentration (MIC) and using a trough range of 15 to 20 mg/L as a practical surrogate.[2] At that time, it was concerns about the emergence of *S. aureus* strains with reduced vancomycin susceptibility and reports of treatment failure in patients infected with *S. aureus* isolates having higher vancomycin MIC that prompted the guideline authors to advocate for more aggressive dosing, despite the absence of supporting clinical evidence.[4,5] However, since publication of the guidelines in 2009, data have become available indicating that higher trough levels are associated with a greater risk of nephrotoxicity without any improvement in effectiveness.[6,7]

Given the well-documented harms associated with high vancomycin trough concentrations,[6,7] the updated IDSA/ASHP/SIDP vancomycin guidelines, published in 2020, do not include this recommendation and instead recommend transitioning to AUC-guided TDM.[8] This form of TDM can be accomplished with Bayesian modelling software (preferred), 2-point pharmacokinetic–pharmacodynamic equations, or population-based pharmacokinetic–pharmacodynamic estimates.[8] Several observational studies have reported reduced nephrotoxicity after implementation of AUC-based TDM.[9,10] However, other studies, in which vancomycin dosing, exposure, and duration were more balanced between groups, did not report differences in nephrotoxicity.[11,12] Additionally, clinical data supporting AUC/MIC ≥ 400 as predictive of efficacy have been of poor quality and inconsistent, which has prompted others to suggest that widespread adoption of AUC-based TDM may be premature.[13-16] The resources required to support AUC-based dosing and opportunity costs are additional considerations. Furthermore, proprietary or subscription-based Bayesian software may be cost-prohibitive in many health care settings. Alternative methods, such as 2-point pharmacokinetic–pharmacodynamic equations, require multiple, precisely timed patient blood samples coupled with a considerable investment of pharmacy, laboratory, and nursing resources.

Little is known about the current landscape of vancomycin TDM in Canadian hospitals, which operate under publicly funded health care systems. To address this gap, we conducted a national survey of Canadian acute care hospitals. Our primary objectives were to determine current vancomycin TDM practices and associated challenges and to gather perceptions about AUC-based TDM.

METHODS

We developed an electronic survey based on an environmental scan of vancomycin TDM practices in Canadian hospitals, input from stakeholders, and previous surveys conducted in the United States.[17-19] The online survey, provided in English only, was developed using REDCap (Research Electronic Data Capture, Vanderbilt University, hosted at the University of Toronto)[20] and can be viewed at https://redcap.utoronto.ca/surveys/?s=T7FWJJPMXT. We piloted the survey with pharmacists at Mount Sinia Hospital, Toronto, Ontario, and modified it on the basis of their feedback. We distributed an introductory letter and link to the survey through the Canadian Society of Hospital Pharmacists' newsletter, the Antimicrobial Stewardship Hospital Pharmacists in Ontario Network, the Public Health Ontario email listserv, and personal email messages to antimicrobial stewardship pharmacists across Canada who were known to the authors. We provided instructions that the survey should be completed by 1 pharmacist per hospital, preferably the antimicrobial stewardship pharmacist. The survey was open for 8 weeks (March 8 to May 3, 2021). Results and interpretation are reported according to the CHEcklist for Reporting Results of Internet E-Surveys (CHERRIES).[21]

The Mount Sinai Hospital Research Ethics Committee approved the survey. There were no monetary incentives to participate. Respondents were informed that consent was implied by survey submission.

We used descriptive statistics to summarize the data. We used IBM SPSS Statistics for Windows, version 27.0, for all calculations.

RESULTS

In total, 120 pharmacists from 10 of the 13 provincial and territorial jurisdictions, representing 12.5% of acute care hospitals in Canada (n = 962), completed at least 90% of the survey questions,. The highest provincial representation was from Ontario and New Brunswick (20.5% and 22.7%, respectively) (Table 1). Responding hospitals were

predominantly university-affiliated (97/120, 80.8%) and located in urban centres (91/120, 75.8%), and most had a formal antimicrobial stewardship program (101/120, 84.2%) (Table 2). At least 1 full-time equivalent antimicrobial stewardship or infectious diseases pharmacist was employed at approximately half (62/120, 51.7%) of responding hospitals. The predominant pharmacy model was decentralized (62/120, 51.7%).

At more than half of the hospitals represented (69/120, 57.5%), pharmacists only or pharmacists and physicians were primarily responsible for vancomycin TDM; the majority (96/119, 80.7%) of respondents reported having a medical directive to order serum vancomycin concentrations and/or adjust doses autonomously. Institution-specific vancomycin TDM guidelines had been developed by many hospitals (99/120, 82.5%), and specific training or credentialling for pharmacists was required to perform vancomycin TDM at more than half (73/119, 61.3%). TDM was routinely performed for patients with risk factors for nephrotoxicity (117/119, 98.3%), confirmed or suspected invasive gram-positive infections (114/119, 95.8%), anticipated duration of vancomycin therapy at least 5 (± 2) days (112/119, 94.1%), and critical illness (104/114, 91.2%). However, most respondents (105/119, 88.2%) reported that TDM was "always" or "sometimes" performed for short courses of therapy (less than 5 days) for patients with stable renal function. The predominant method of vancomycin administration was intermittant infusion (104/119, 87.4%); a few respondents (14/119, 11.8%) reported using continuous infusions for selected patient populations.

With regard to testing and reporting of susceptibility of *S. aureus* to vancomycin, approximately half of hospital laboratories (61/120, 50.8%) reported interpretive susceptibility criteria only (i.e., no specific MIC was reported). Nearly half (51/120, 42.5%) of respondents were unsure of the method that their laboratory used to determine the MIC of vancomycin against *S. aureus*. Among respondents who did know this information, Vitek-2 (Bio-Mérieux Canada) was the most commonly used automated platform (51/69, 73.9%); vancomycin MICs for *S. aureus* specimens taken from sterile sites were confirmed using gradient test strips by about half (37/69, 53.6%) of laboratories.

TABLE 1. Representation of Canadian Hospitals by Province or Territory

Province or Territory[a]	No. of Hospitals[b]	No. (%) of Respondents
Ontario	268	55 (20.5)
Quebec	170	12 (7.1)
British Columbia	126	15 (11.9)
Alberta	132	10 (7.6)
Manitoba	61	7 (11.5)
New Brunswick	44	10 (22.7)
All other jurisdictions[c]	161	11 (6.8)
Total	962	120 (12.5)

[a]Listed in descending order of number of hospitals.
[b]Number of hospitals in 2019, as reported in the Government of Canada's Canadian industry statistics.[22]
[c]Provinces and territories with fewer than 6 respondents were grouped to protect anonymity.

TABLE 2. Hospital and Pharmacy Characteristics

Characteristic	No. (%) of Respondents (*n* = 120)
Geographic location	
Urban	91 (75.8)
Rural	29 (24.2)
Type of hospital	
Academic	47 (39.2)
Community, teaching	52 (43.3)
Community, nonteaching	21 (17.5)
Hospital's university affiliation	
Medical and pharmacy schools	56 (46.7)
Pharmacy school only	5 (4.2)
Medical school only	36 (30.0)
None	23 (19.2)
Predominant patient population served	
Inpatient mixed	114 (95.0)
Inpatient oncology	0
Inpatient continuing complex care	4 (3.3)
Inpatient other	2 (1.7)
Formal antimicrobial stewardship program	101 (84.2)
Antimicrobial stewardship pharmacist (no. of FTEs)	
0	35 (29.2)
0.5–0.75	23 (19.2)
1	40 (33.3)
2	16 (13.3)
≥ 3	6 (5.0)
Pharmacy model	
Centralized	58 (48.3)
Decentralized	62 (51.7)
Pharmacy residency program	60 (50.0)
Respondent's position	
Antimicrobial stewardship or infectious diseases pharmacist	86 (71.7)
Internal medicine pharmacist	13 (10.8)
Critical care pharmacist	8 (6.7)
Pharmacy manager	3 (2.5)
Other[a]	10 (8.3)

FTE = full-time equivalent.
[a]"Other" consisted of 4 staff pharmacists, 1 clinical resource pharmacist, 1 clinical coordinator, 1 professional practice lead, 1 family medicine pharmacist, 1 antimicrobial stewardship/critical care/medicine pharmacist, and 1 multifunctional pharmacist.

The predominant TDM method was trough-based (107/119, 89.9%), with smaller proportions of respondents reporting use of AUC-based TDM (9/119, 7.5%) or a mix of AUC- and trough-based TDM (3/119, 2.5%). Among those not currently using AUC-based TDM, nearly one-fifth (19/106, 17.9%) were considering implementing AUC-based TDM within 1 to 2 years; a further two-fifths (43/106, 40.6%) were unsure about making the transition. In hospitals performing trough-based TDM, target vancomycin troughs for serious *S. aureus* infections (e.g., bacteremia, infective endocarditis, pneumonia, bone and joint infections) were commonly between 15 and 20 mg/L (66/109, 60.5%) or between 10 and 20 mg/L (19/109, 17.4%). By contrast, the majority of respondents (78/110, 70.9%) reported targeting 10 to 15 mg/L for noninvasive infections (e.g., skin and soft tissue infections). Respondents identified multiple challenges associated with trough-based TDM. Most respondents agreed or strongly agreed that collection of specimens at inappropriate times (83/110, 75.5%) and supra- or sub-therapeutic concentrations (80/109, 73.4%, and 60/109, 55.0%, respectively) were major challenges, but less than one-quarter (26/110, 23.6%) identified cost as a barrier. Overall, one-quarter (27/109, 24.8%) of respondents agreed or strongly agreed that trough-based TDM was of uncertain benefit; about one-third (33/109, 30.3%) had a neutral opinion on this question.

Of the 12 hospitals currently using AUC-based TDM, 10 were located in Quebec, 1 in Ontario, and 1 in Manitoba. Eight were located in urban centres, and 11 had a university affiliation. Publicly available Bayesian modelling software was used by 6 of the hospitals, the 2-sample trapezoidal method by 5, and population pharmacokinetic equations by 1. All of these hospitals targeted an AUC/MIC therapeutic range of 400 to 600, although 2 further qualified their ideal target as 400 to 515. For the purposes of TDM, the vancomycin MIC for *S. aureus* was assumed to be 1 mg/L at 7 hospitals.

Among hospitals considering or unsure about making the transition to AUC-based TDM, just over half (32/61, 52.5%) did not currently have a preference for the method to estimate AUC; others favoured pubicly available Bayesian software (16/61, 26.2%) or the 2-sample trapazoidal method (11/61, 18.0%), and a small proportion (2/61, 3.3%) were considering using proprietary or subscription-based Bayesian software. Among hospitals that were *not* currently using AUC-based TDM, the most commonly anticipated challenges in adopting this approach were lack of physician familiarity (95/104, 91.3%), need for training (94/104, 90.4%), requirement for multiple concentrations (84/103, 81.6%), need for laboratory and nursing resources (79/104, 76.0%), collection of specimens at inappropriate times (77/104, 74.0%), allocation of pharmacists' time (77/104, 74.0%), cost (66/102, 64.7%), and potential errors (66/104, 63.5%). Interestingly, among hospitals that *were* currently using AUC-based TDM, allocation of pharmacists' time, need for laboratory and nursing resources, lack of physician familiarity, and cost were perceived as challenges by less than 30% of respondents. Collection of specimens at inappropriate times and the requirement for multiple specimens (8/12, 66.7%, and 7/12, 58.3%, respectively) were the major challenges reported by those already using AUC-based TDM.

Overall, only two-fifths (47/116, 40.5%) of respondents agreed or strongly agreed that AUC-based TDM was likely safer than trough-based TDM; a smaller proportion (27/116, 23.3%) agreed or strongly agreed that AUC-based TDM was likely more effective. By contrast, among respondents whose hospitals had already implemented AUC-based TDM, most (11/12, 91.7%) agreed or strongly agreed that it was safer and half (6/12, 50.0%) agreed or strongly agreed that it was more effective than trough-based TDM.

DISCUSSION

To the best of our knowledge, this survey represents the first broad assessment of vancomycin TDM in Canadian hospitals. Our sample included respondents from a wide range of rural and urban centres representing approximately 1 of every 8 acute care hospitals across 10 provincial and territorial jurisdictions in Canada. The survey revealed several important aspects of current TDM practices for vancomycin. Notably, although Canada does not have national guidelines to define best practices for vancomycin TDM, we found remarkably low variability across centres in certain TDM practices. Approximately 90% of hospitals participating in the survey performed trough-based TDM, intermittent infusions were the predominant administration method, and nearly two-thirds of hospitals targeted troughs between 15 and 20 mg/L for serious MRSA infections. This latter finding is troubling, given the overwhelming evidence that high vancomycin troughs are associated with increased rates of nephrotoxity without improvements in effectiveness.[6,7] The updated vancomycin guidelines, released more than 12 months before we distributed our survey, were specifically revised to omit the recommendation to target high troughs, citing safety concerns.[8] However, as has been observed in multiple areas of medicine, once something is ingrained in clinical practice, de-adoption is a slow and difficult process.[23] Moving forward, we must commit to abandoning interventions that have been shown to be of no benefit to patients and are actually harmful.

Implementing accurate and clinically valuable TDM services is complex and involves coordination across multiple disciplines. It should not be surprising that pharmacists responding to this survey identified many challenges with trough-based TDM that have been repeatedly documented in the literature: trough results above or below the therapeutic range, collection of specimens at inappropriate times, the need for pharmacist training, and allocation of

time for this work.[24] These challenges were not counterbalanced by positive assessments of the value of TDM. Nearly one-quarter of pharmacists responding to the survey agreed that trough-based TDM was of uncertain benefit, and approximately one-third were neutral. Despite what appears to be prevalent uncertainty, nearly 90% of respondents reported routinely performing vancomycin TDM for patients receiving short courses of therapy without risk factors for nephrotoxicity, a population unlikely to derive any benefit from this practice. Standards of practice, adapted from clinical guidelines, or institutional protocols can sometimes promote "defensive medicine" motivated by fear of liability. Our findings reveal a need to support pharmacists if they deviate from expected practice when patient-specific considerations suggest that a different therapeutic approach may be preferred. The prevalences of MRSA and other multidrug-resistant (MDR) gram-positive bacteria are relatively low in Canada (16.9% for MRSA and 7.7% for MDR *Streptococcus pneumoniae*, as of 2016)[25,26]; most patients may be better served by early vancomycin discontinuation, rather than TDM of an unneeded drug.

An obvious follow-up question is "How can we improve upon current vancomycin TDM practices?" Very few hospitals in our survey had transitioned to AUC-based TDM, and only 17.9% were planning to make the transition in the near future. These results appear to be driven by both uncertainty about the benefits and anticipation of multiple challenges relating to resource use, opportunity costs, and buy-in from relevant stakeholders. A survey of inpatient hospitals in the United States, conducted shortly before the updated guidelines were released, reflected similar uncertainty.[17] Among 78 hospitals surveyed, less than one-quarter reported performing AUC-based vancomycin TDM.[17] Nearly 90% of hospitals performing trough-based TDM did not plan to transition to AUC-based TDM within the next year or were uncertain about doing so. In a more recent US survey (n = 202), approximately 70% of respondents had not implemented AUC-based TDM, but over half were planning to do so within the next year.[19] Interestingly, in our survey, respondents from institutions that *had* already implemented AUC-based TDM did not perceive many of the challenges anticipated at other hospitals as being relevant, and their certainty about the safety benefit was nearly unanimous.

This survey had several limitations. Respondents represented predominantly university-affiliated medical centres with established antimicrobial stewardship and pharmacy residency programs. Several provinces were overrepresented, and others were underrepresented. Most respondents were antimicrobial stewardship or infectious diseases pharmacists; their responses may not be generalizable to pharmacists not specializing in antimicrobial stewardship or infectious diseases, and responses might vary from one pharmacist to another at the same site. Although the survey instructions requested that only 1 pharmacist from each hospital complete the survey, it is possible that more than 1 pharmacist from the same health region, governed by the same practice standards, were included. We focused on vancomycin TDM in adult inpatients, but additional research is needed to understand TDM practices for other populations, including pediatric patients, neonates, outpatients, and residents of nursing homes or rehabilitation facilities. Because we used multiple methods to distribute the survey, which covered overlapping populations, we were unable to calculate a denominator to determine the response rate or assess response bias. We used national hospital numbers as an imperfect proxy for gauging the reach of our survey. Finally, the response period for our survey partly coincided with the devastating third wave of the COVID-19 pandemic in Canada. Response rates from harder-hit hospitals were likely depressed, and the study team's attention was diverted from promoting the survey. Moreover, plans to implement vancomycin AUC-based TDM may have been delayed because of the pandemic.

CONCLUSION

Understanding the current landscape of vancomycin TDM across Canada, as well as the challenges experienced by pharmacists performing TDM, is a first step in developing evidenced-based, standardized best practices that are uniquely suited to Canadian health care. Concerns have been raised about the quality and consistency of the evidence supporting AUC-based vancomycin TDM.[14-16] Prematurely adopting AUC-based TDM before it has been proven to work (through appropriately designed clinical trials) and shown to be feasible in Canadian hospitals risks diverting resources from other higher-yield interventions. In the meantime, de-adopting high trough targets should be a patient safety priority. Vancomycin is one of the most commonly used antimicrobials for hospitalized patients; generating robust evidence to guide its optimal use is our next step and should be a priority for funding agencies.

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Older Adults' Use of and Interest in Technology and Applications for Health Management: A Survey Study

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ABSTRACT

Background: Older adults face challenges with managing their medications, obtaining health education, and accessing health services. Mobile health (mHealth), defined as any medical or public health practice facilitated through mobile devices, could help to overcome these difficulties.

Objectives: To determine what technologies and apps are in current use by older adults, to explore the types of technologies and apps that may be of interest to people in this age group, to explore concerns about technologies, and to examine any age-related differences.

Methods: Adults 60 years of age or older were invited to complete a 35-item electronic survey, in either French or English, which was distributed through social media and by email from organizations working with older adults. The survey was conducted in mid-2020.

Results: A total of 266 respondents completed some or all of the survey. Most participants had a mobile phone (229/243, 94.2%), and approximately one-third (78/222, 35.1%) had used a health-related app in the previous 12 months; this level of usage was consistent across age groups. Most respondents were interested in using an app to improve their health (171/225, 76.0%), with variation by age: highest among those 60–64 years of age (82/95, 86.3%), lower among those 80 years or older (40/52, 76.9%), and lowest among those 65–69 years of age (6/14, 42.9%). Most older adults were interested in using an app to ask questions of pharmacists (161/219, 73.5%) and to review their medications (154/218, 70.6%). Participants' mHealth concerns focused on costs, disclosure of personal information, effectiveness, usability, and endorsement by health care providers. The study limitations included challenges related to electronic recruitment and survey distribution, as well as a high representation of participants with postsecondary education.

Conclusions: These findings suggest that a substantial proportion of older adults are already using and are interested in using mHealth for health information, to ask questions, and/or to review their medications with a health care team member.

Keywords: older adults, mobile health (mHealth), apps, electronic health (eHealth), medication, seniors

RÉSUMÉ

Contexte : Les personnes âgées sont confrontées à des difficultés pour gérer leurs médicaments, s'informer sur la santé et accéder aux services de santé. Les applications de « santé mobile », définies comme toute pratique médicale ou de santé publique facilitée par des appareils mobiles, pourraient aider à surmonter ces difficultés.

Objectifs : Déterminer quelles technologies et applications sont actuellement utilisées par les aînés; examiner celles qui pourraient être intéressantes dans cette tranche d'âge; étudier les préoccupations concernant les technologies et examiner les différences liées à l'âge.

Méthodes : Des adultes d'au moins 60 ans ont été invités à répondre à un sondage électronique comprenant 35 questions en français ou en anglais. Ce sondage, mené à la mi-2020, a été diffusé par des organismes travaillant avec des aînés via les médias sociaux et par courriel.

Résultats : Au total, 266 participants y ont répondu en partie ou en totalité. La plupart des répondants avaient un téléphone portable (229/243, 94,2 %) et environ un tiers (78/222, 35,1 %) avaient utilisé une application liée à la santé au cours des 12 derniers mois; ce taux d'utilisation était constant tous groupes d'âge confondus. La plupart des répondants souhaitaient utiliser une application pour améliorer leur santé (171/225, 76,0 %), avec des variations du taux d'utilisation selon l'âge : le plus élevé chez les 60 à 64 ans (82/95, 86,3 %), un peu moins chez les 80 ans ou plus (40/52, 76,9 %), et le plus bas chez les 65 à 69 ans (6/14, 42,9 %). La plupart des personnes âgées souhaitent utiliser une application pour poser des questions aux pharmaciens (161/219, 73,5 %) et pour s'informer sur leurs médicaments (154/218, 70,6 %). Les préoccupations des participants en matière de « santé mobile » portaient sur les coûts, la divulgation d'informations personnelles, l'efficacité, la convivialité et l'approbation par les prestataires de soins de santé. On notera, parmi les limites de l'étude, les défis liés au recrutement électronique et à la distribution électronique des sondages, ainsi qu'une forte représentation de participants ayant fait des études postsecondaires.

Conclusions : Ces résultats portent à croire qu'une proportion importante d'adultes âgés utilisent déjà la technologie de « santé mobile » et souhaitent l'utiliser pour obtenir des informations sur la santé, poser des questions et/ou s'informer sur leurs médicaments auprès d'un membre de l'équipe de soins de santé.

Mots-clés : personnes âgées, santé mobile (mHealth), applications, santé électronique (eHealth), médicaments, aînés

INTRODUCTION

New Brunswick has the highest proportion of persons 65 years of age or older in Canada.[1] In 2021, nearly one-quarter (22.4%) of the provincial population was 65 or older,[2] a proportion that is expected to increase to 32.4% by 2043.[1] Of New Brunswick residents in this age group, 39% have at least 3 chronic diseases, and this proportion is also projected to increase over time.[1] As of 2010, adults with chronic disease were consuming 64% of health care resources,[3] and this high level of consumption coincides with increased health care costs over the past decade.[1]

New Brunswick has high levels of need because of health care unavailability and long wait times, particularly in rural areas.[4] Approximately 47% of those 65 or older live in rural communities, in contrast to 20% across Canada,[1] and health disparities exist between rural and urban communities. Fewer health care providers in rural areas means fewer support options for older adults.[1] Lack of transportation options is also an issue in both urban and rural New Brunswick.[1]

Alternative methods of providing care are needed, in light of the identified need to improve timely access to care for older patients[3] and the shortage of primary health care providers in New Brunswick.[5] The New Brunswick Health Council identified 4 initiatives to improve care for older adults in the province, one of which was self-management, which could include online tools to enable patients to access their health information or a health system that provides up-to-date information for self-management.[3] However, empowering patients in their own care is offset by findings of low health literacy in the older adult population. Two-thirds (60%) of Canadian adults[6] and 88% of those older than 65 have low health literacy.[7] The Canadian government's goal of establishing high-speed internet access for all Canadians by 2030 offers an opportunity to establish mobile health (mHealth) practices to improve health literacy and to better educate, engage, and empower Canadians in their own care.[8]

The COVID-19 pandemic has driven health care providers to incorporate virtual care into their practices. Virtual care can facilitate access to health care providers[9] and can help overcome the challenges faced by older adults in rural areas or in areas with transportation issues. The World Health Organization considers mHealth to be any medical or public health practice facilitated through mobile devices (e.g., mobile phones, patient monitoring devices).[10] Virtual care, including mHealth interventions to help provide education and facilitate self-management, may represent a novel mechanism to increase health care access for older adults.

In the United States, 42% of adults older than 65 years own a smartphone, and individuals between 65 and 69 years of age self-report higher smartphone usage than those older than 80 (59% versus 17%).[11] Greater smartphone ownership also is associated with higher income and education.[11] In addition, research suggests that use of mobile technologies may improve chronic disease outcomes in older populations.[12-14] Less information is available about the use of mobile applications (apps).

Limited data exist regarding older adults' use of mHealth in Canada. In one study, the feasibility and acceptability of mHealth interventions was investigated in older adults with a recent fracture.[15] Most owned a mobile device and were somewhat interested in mHealth technology. In contrast, a survey of primary care clinics in low- and middle-income areas found that less than half of participants older than 70 years were interested in mHealth.[16] Privacy concerns and lack of face-to-face communication with clinicians were noted as reasons.[16] Neither study explored what older adults would like from a mobile app or mHealth technology.

The aforementioned Canadian studies were conducted in large urban centres,[15,16] which limits their generalizability to rural areas. Additionally, little is known about the use of health technology, mHealth, smartphones, and apps, or the barriers to their use, among older adults in New Brunswick. In that province, pharmacists play a key role in medication education, yet there are no studies assessing patients' interest in mHealth pharmacist services. Thus, the objectives of the current study were as follows:

- To determine what mobile technologies and apps are currently used by older adults in New Brunswick.
- To explore the types of technologies or apps that may be of interest for health and medication management.
- To explore concerns related to these technologies.
- To examine age-related differences among older adults relating to app use on devices, interest in using health-related apps, and interest in using an app to ask pharmacists questions and review medications.

METHODS

Participants

Although people are considered senior citizens at age 65, the survey was open to anyone over the age of 60, given that these patients will be approaching the age of 65 by the time resources suggested by this research will have been developed and launched.

Survey Instrument

The survey used in the current study was based on an existing 25-item survey that inquired about mobile phone and app usage.[17] Given that New Brunswick is a bilingual province, the survey was made available in English and French. Wording was modified to align with the ethnic group identities used by Statistics Canada,[18] and app-specific questions were added (e.g., "What particular health-related app feature do you think would be useful?"). The survey is available from the corresponding author upon request.

The final survey consisted of 35 questions. Section 1 sought demographic and clinical information: location

(urban/rural), sex on birth certificate, gender identity, ethnic identity, language, relationship status, household income, education, medical conditions, and number of daily medications. Section 2 asked about mobile phone and app usage, as well as interest in using apps for health management, to learn about medications, to improve medication adherence, and to interact with a pharmacist or peer/family member. Section 3 asked about concerns with technology and apps.

Procedure

Institutional approval was obtained from the Horizon Health Network Research Ethics Board. The survey was hosted by LimeSurvey (http://www.limesurvey.org). A link to the anonymous survey was distributed in June and July 2020 through social media and by email from organizations that work directly with older adults in New Brunswick. Data were stored in the locked office of the primary investigator (A.S.). Only the coauthors and a statistician had access to the data file.

Data Analysis

All survey responses had missing data; therefore, only valid frequencies and percentages are reported. All data were summarized with descriptive statistics. χ^2 analyses were used for age-based comparisons, according to Statistics Canada age groups: 60–64, 65–69, 70–74, 75–79, and 80 years or older. Using the software program G*Power,[19] we estimated a sample size of 133 for χ^2 analyses based on the following parameters: medium effect size (w = 0.30), $\alpha = 0.05$, power = 0.80, degrees of freedom = 4 (based on 5 age groups).

RESULTS

Demographic Characteristics

After screening for nonresponses and duplicate entries, the final sample size was 266 respondents who answered some or all of the survey questions. As shown in Table 1, 40.6% of the sample was 60–64 years of age and 39.8% were 75 years or older. Most of the sample was female, white, English-speaking, and married. Just under half (47.8%) lived in rural areas or small centres. The most frequent clinical conditions (past and present) were cardiovascular and circulatory (166/243, 68.3%), musculoskeletal or related to connective tissue (111/243, 45.7%), and endocrine, nutritional, or metabolic (73/243, 30.0%). Almost all (222/242, 91.7%) self-reported taking at least 1 daily medication; progressively smaller proportions reported taking 2 or more medications (195/242, 80.6%), 5 or more medications (99/242, 40.9%) and more than 10 medications (21/242, 8.7%).

Current Use of Technology

Mobile Devices

The most frequently owned devices were mobile phones (229/243, 94.2%), tablets (191/243, 78.6%), and laptop computers (187/243, 77.0%). Only 3 participants (3/243, 1.2%) did not own any devices. When those to whom the question applied were asked whether they had accessed

TABLE 1. Demographic Characteristics (*n* = 266)

Characteristic	No. (%) of Patients[a]
Age (years)	*n* = 266
60–64	108 (40.6)
65–69	18 (6.8)
70–74	34 (12.8)
75–79	47 (17.7)
≥ 80	59 (22.2)
Sex on birth certificate	*n* = 264
Female	194 (73.5)
Male	70 (26.5)
Gender identity	*n* = 242
Female	183 (75.6)
Male	58 (24.0)
Gender nonconforming	1 (0.4)
Racial or cultural group	*n* = 257
White	253 (98.4)
Other	4 (1.6)
Primary language	*n* = 260
English	235 (90.4)
French	24 (9.2)
Both	1 (0.4)
Marital status	*n* = 256
Married	172 (67.2)
Single	34 (13.3)
Widowed	24 (9.4)
Living with partner	13 (5.1)
Divorced/separated	12 (4.7)
Living apart together	1 (0.4)
Area of current residence (population size)	*n* = 255
Rural (< 1000)	58 (22.7)
Small centre (1000–29 999)	64 (25.1)
Medium centre (30 000–99 999)	89 (34.9)
Large centre (> 100 000)	44 (17.3)
Annual household income ($)	*n* = 207
< 20 000	11 (5.3)
20 000–40 000	55 (26.6)
40 001–60 000	45 (21.7)
60 001–80 000	31 (15.0)
80 001–100 000	29 (14.0)
≥ 100 000	36 (17.4)
Highest level of education	*n* = 247
Grade 5–12	15 (6.1)
High school graduate	43 (17.4)
Some college or university	48 (19.4)
College or university degree	98 (39.7)
Master's, professional degree, PhD	43 (17.4)

[a]Except for age, all variables had missing data. Only valid percentages (excluding missing data) are reported.

the internet from their mobile phone during the previous 12 months, 80.8% (181/224) responded in the affirmative.

Health-Related Apps

The frequency of using apps on mobile phones and tablets was similar (165/229, 72.1%, and 154/229, 67.2%, respectively). More than a third of respondents (78/222, 35.1%) had used health-related apps in the previous 12 months, with no differences in usage across age groups: $\chi^2(4,222) = 4.06$ ($p = 0.39$). Most participants (171/225, 76.0%) reported interest in using a mobile app to improve health, and for this variable, there was a difference among age groups: $\chi^2(4,225) = 17.18$ ($p = 0.002$). Interest was lowest among those 65–69 years of age (6/14, 42.9%); progressively higher among those 70–74 years old (17/27, 63.0%), 75–79 years old (26/37, 70.3%), and 80 years or older (40/52, 76.9%); and highest among those 60–64 years of age (82/95, 86.3%).

Among participants with an interest in using health apps, 43.3% (74/171) said they would use them every week and 33.3% (57/171) said they would use them every day. As shown in Table 2, health-related app features that were reportedly most useful were disease information (128/178, 71.9%), medication education (110/178, 61.8%), and nutrition information (100/178, 56.2%).

Medication Management on Devices

Most respondents (156/211, 73.9%) indicated that they would be comfortable allowing a caregiver or family member to access their medication adherence or other health information through an app. Most (161/219, 73.5%) indicated an interest in using mobile apps to contact pharmacists with questions, with this interest differing by age: $\chi^2(4,219) = 11.14$ ($p = 0.025$). Interest was lowest among those 65–69 years of age (5/13, 38.5%); progressively higher among those 70–74 years old (17/26, 65.4%), 75–79 years old (28/39, 71.8%), and 60–64 years old (72/92, 78.3%); and highest among those 80 years of age or older (39/49, 79.6%). Most respondents (154/218, 70.6%) indicated an interest in using a mobile app to contact pharmacists for a review of medications, with interest differing by age group: $\chi^2(4,222) = 10.01$ ($p = 0.040$). The pattern by age group was similar to that for interest in using an app to contact a pharmacist: those 65–69 years of age were least interested (5/13, 38.5%), with progressively stronger interest among those 70–74 years old (15/24, 62.5%), 75–79 years old (26/39, 66.7%), and 60–64 years old (69/93, 74.2%); those 80 years of age or older were most interested (39/49, 79.6%).

TABLE 2. Most Useful Health-Related App Features ($n = 178$)

Useful Feature	No. (%) of Participants[a]
General information about diseases	128 (71.9)
Learn more about your medication	110 (61.8)
Nutrition information	100 (56.2)
Mental wellness techniques	75 (42.1)
Other	10 (5.6)
Fitness (e.g., yoga, exercise, physical activity)	3 (1.7)
Access to medical records/files	2 (1.1)
Virtual visits	1 (0.6)
New Brunswick Drug Plans Formulary	1 (0.6)
COVID-19 testing	1 (0.6)
Only apps by medical schools/government (e.g., not pharmaceutical companies)	1 (0.6)
Unspecified	1 (0.6)
Prefer to use web-based search engine (e.g., Google) rather than individual apps	2 (1.1)

[a]The percentages shown are not mutually exclusive because each participant could endorse more than 1 category.

Concerns about Using Mobile Devices and Applications

Half of the participants (111/224, 49.6%) had concerns about disclosure of personal information, and more than half (124/224, 55.4%) indicated concerns related to phone or monthly plan costs. Other concerns, including lack of a recommendation from a health care provider (23/224, 10.3%), are listed in Table 3.

DISCUSSION

In this study, we aimed to describe older adults' current use, interest in using, and concerns with using mobile technologies and apps. Our results indicate that most older adults who participated in the survey were using mobile devices, and most owned at least 1 mobile device. Similar rates have been reported in other Canadian studies.[15,20] Although older age is generally associated with lower app use,[20-23] this study found high app use overall relative to other studies of older adult populations[20] and the general adult population.[17,21,23-25] Reasons may include the online recruitment method, the COVID-19 pandemic (which forced older adults to embrace new technology), and the inclusion of middle-aged adults (i.e., entering their 60s) who have already embraced technology.[11]

Interest in Using Health Apps

More than 75% of participants expressed interest in using a mobile app to improve health, although the level of interest differed by age. Other studies have found similar rates of interest in the general adult population (≥ 18 years).[17,24,25] Among adult orthopedic patients (≥ 18 years) in an urban centre, 71% felt that an app would improve their health care experience.[24] Younger age is associated with obtaining medical information via smartphone: in the same study, those up to age 40 were more likely to obtain information using a smartphone relative to those over 40 years of age.[24] The current study indicates that an association may also exist between age and interest in using a mobile app to improve health among individuals 60 years of age or older.

The proportion of participants taking more than 5 medications was greater than the rate observed by a pan-Canadian study of adults 65 years and older[26] (40.9% versus 27%). In the earlier study, taking 5 or more medications was associated with a higher rate of adverse effects requiring medical attention and increased emergency department use.[26] As a result, these individuals may benefit from an app to improve medication management. Further research should explore this notion.

Desired App Features

Most of the app features desired by participants focused on health-related information or improving medication management. The provision of information as an app feature has been described in the literature. For example, in a multisite US study, participants 55 years of age or older who were taking 5 or more medications reported that the most desired app feature was medication information, specifically the ability to choose a medication from their medication list and access "need-to-know" information.[27] These findings, combined with the current study, highlight a potential niche and current unmet need to support patients taking 5 or medications with mHealth-based applications.

Although their study was not specific to older adults, Ramirez and others[17] found that nutrition information and general information about diseases were among the most useful health app features reported by primary care patients. Similarly, among ambulatory surgery patients, access to literature, pictures, and videos explaining surgical procedures and information about potential surgical complications were highly ranked app features.[28] Among patients with type 2 diabetes, recommendations for future app design also centred on educational features.[13]

Information-related app features may be desired because of the belief that more information is linked to better outcomes. Khurana and others[29] found that patients (particularly those over 45 years of age) believed they were more likely to take proactive measures if they had more knowledge about their disease. This is consistent with New Brunswick's aging strategy, which recommends promoting self-management through the provision of information.[1] Therefore, app designers should include features related to medication, health management, and health information in future apps.

It is also worth noting that 73.9% of respondents were willing to share health app information with family members or caregivers. In Canada, 88% of seniors have low health literacy.[30] Thus, caregivers, family members, and friends represent an underused resource in supporting the older adult population.[31] Mobile health-based interventions may offer the opportunity to better educate and engage a support network for this patient population to improve health outcomes.

TABLE 3. Concerns about Using Mobile Apps and Mobile Phones (n = 224)

Concern	No. (%) of Participants[a]
Related to mobile apps	
Personal information disclosure	111 (50.0)
Fees to use apps	78 (34.8)
Apps use a lot of data	48 (21.4)
Unsure of effectiveness	44 (19.6)
Not easy to use	35 (15.6)
Not recommended by a health care provider	23 (10.3)
Take too much time to use	19 (8.5)
Other	20 (8.9)
Uninterested in app use	6 (2.7)
Lack of app-related knowledge	5 (2.2)
Privacy concerns	3 (1.3)
Security concerns	2 (0.9)
No data on device	2 (0.9)
Lack of accuracy	1 (0.4)
Already using apps	1 (0.4)
None of the above	45 (20.1)
Related to mobile phones	
Cost concerns (e.g., phone, monthly plans)	124 (55.4)
Not easy to use	22 (9.8)
Reducing face-to-face interaction	56 (25.0)
Other	14 (6.3)
Security	3 (1.3)
Privacy	4 (1.8)
Accessibility (hearing, vision)	2 (0.9)
No data/voice only	2 (0.9)
Poor/unreliable service	1 (0.4)
Telemarketers/being "too available"	1 (0.4)
None of the above	63 (28.1)

[a]The percentages shown are not mutually exclusive because each participant could endorse more than 1 category.

Interactions with Health Care Providers

Most participants were interested in using an app to connect with a pharmacist to ask questions (73.5%) or review medications (70.6%). Although interest in mHealth interactions with pharmacists has not been previously reported in the literature, more than 80% of respondents in a previous study (aged 35–79 years) were interested in electronic interactions with their physicians to manage and treat type 2 diabetes.[29] Among ambulatory surgery patients, top-rated app features were the ability to contact a health care provider and ability to consult a health care provider before and after surgery.[28] In a study involving Spanish oncology patients, more than 40% expressed interest in communicating with their health care provider through an app or email, and approximately one-third would have liked remote monitoring by health care professionals as an app feature.[21] These findings, combined with the results of the current study, indicate that using mHealth and apps to facilitate patient–pharmacist interactions may be one approach to improving medication management in older adults.

Concerns with Mobile Phones and Apps

The most common concern related to the use of mobile phones and, to a lesser degree, apps was the cost, specifically extra fees and the cost of data. This finding is consistent with user concerns about remote health interventions and device and app costs to both individuals and the health care system that have been reported by others.[16,21,22,32,33] Hopefully, these cost concerns will be partially addressed with incoming nationwide high-speed internet access,[8] which may allow Canadians to access mHealth options without costly data charges.

The most frequent app-based concern was worry about disclosure of personal health information, as has been consistently noted in the literature.[16,34-36] For example, semi-structured interviews conducted in England indicated that privacy and confidentially constituted 1 of 6 distinct barriers reported among adults over 50 years of age.[35] Given that privacy and security of personal health information are key concerns among older adults, these would need to be addressed in the development of future mHealth technologies.

Concerns about app efficacy (i.e., whether they accomplish their intended task) and usability (e.g., ease of use) were noted by study participants. People would be unlikely to use an app that has not been proven effective or is difficult to use. The concern about efficacy has also been voiced by veterans,[34] and a systematic review found that efficacy was a major barrier to remote health interventions.[32] Usability is a well-documented barrier to app use.[33,36] Mendiola and others[33] found that usability was 1 of 4 features associated with positive user ratings of mHealth apps, and all 4 features were related to making disease management less time-consuming and more efficient. Therefore, apps for older adults need to be efficacious, usable, and more efficient relative to currently used methods.

One novel finding in this study was that older adults were concerned when an app had not been recommended by a health care provider, likely because of the high level of trust that people place in clinicians.[37,38] Satisfaction with apps and willingness to use an app may increase if the apps are recommended by a health professional.[13] Lack of provider engagement has been found to be a barrier to user engagement in mHealth solutions.[32] Thus, health care providers should be involved in the development and review of apps for older adults to ensure they feel comfortable recommending them to patients.

Limitations

One limitation of this study was the self-selection of individuals who were already active online to complete the survey, which may have introduced some bias. Because of the COVID-19 pandemic, the survey could only be distributed and completed electronically, and the rate of app usage may have been higher in the surveyed population than in the general population. Furthermore, most participants had postsecondary education, which is associated with increased use of technology and apps.[21,22] Most of the sample was female, white, English-speaking, and married, and these characteristics warrant caution when interpreting and generalizing the results of this research. Future research is needed among older adults who are generally not active online, do not use technology/apps, and have lower levels of formal education, to determine their levels of use, interest, and concerns regarding mHealth and apps.

CONCLUSION

The findings in this study highlight that a substantial proportion of older adults are already using mobile technology and apps and are interested in using apps for health and to interact with health care providers. Concerns relating to cost, disclosure of personal information, effectiveness, usability, and provider endorsement should be considered when developing mHealth interventions for this patient population. Concepts of health literacy must also be considered, to ensure that these resources are easily understood and applicable to improve the health of this population.

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Characterizing the Use of Nabiximols (Δ9-Tetrahydrocannabinol–Cannabidiol) Buccal Spray in Pediatric Patients

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ABSTRACT

Background: Nabiximols is a commercially available cannabinoid buccal spray containing 2.7 mg Δ9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD) per spray. It is approved by Health Canada for adults with cancer pain or spasticity/neuropathic pain related to multiple sclerosis. Despite a lack of published studies regarding the use of nabiximols in children, it is being used in clinical practice for indications of pain, nausea/vomiting, and spasticity.

Objective: To describe the use of nabiximols in children.

Methods: This retrospective single-cohort study involved hospitalized pediatric patients who received at least 1 dose of nabiximols between January 2005 and August 2018. Descriptive statistical analyses were performed.

Results: A total of 34 patients were included. The median age was 14 (range 0.6–18) years, and 11 patients (32%) were admitted under the oncology service. The median dose of nabiximols was 1.9 (range 0.3–10.8) sprays per day, and the median duration was 3.8 (range 1–213) days. Nabiximols was most commonly used to treat pain and nausea/vomiting and was most frequently prescribed by pain specialists. Perceived effectiveness was documented in 17 (50%) of the cases, with variable results being reported. The most commonly reported adverse effects were drowsiness and tachycardia (3/34, 9%, for each).

Conclusion: In this study, nabiximols was prescribed for children in all age groups, for a variety of conditions, but most commonly for pain and nausea/vomiting. Further study, in the form of a large, prospective randomized controlled trial with clearly defined efficacy and safety end points for nausea/vomiting and/or pain, is needed to determine whether nabiximols is effective and safe in children.

Keywords: nabiximols, Sativex, pediatric

RÉSUMÉ

Contexte : Le nabiximols est un vaporisateur buccal cannabinoïde disponible dans le commerce qui contient 2,7 mg de Δ9-tetrahydrocannabinol [THC] et 2,5 mg de cannabidiol [CBD] par vaporisation. Il est approuvé par Santé Canada pour les adultes souffrant de douleur cancéreuse ou de spasticité/douleur neuropathique liée à la sclérose en plaques. Malgré le manque d'études publiées concernant l'utilisation du nabiximols chez les enfants, il est utilisé en pratique clinique pour des indications de douleur, de nausées/vomissements et de spasticité.

Objectif : Décrire l'utilisation du nabiximols chez les enfants.

Méthodes : Cette étude rétrospective à cohorte unique comprenait des patients pédiatriques hospitalisés ayant reçu au moins 1 dose de nabiximols entre janvier 2005 et août 2018. Des analyses statistiques descriptives ont été réalisées.

Résultats : Au total, 34 patients ont été inclus. L'âge médian était de 14 ans [intervalle de 0,6 à 18 ans] et 11 enfants (32 %) étaient des patients en oncologie. La dose médiane de nabiximols était de 1,9 [intervalle de 0,3 à 10,8] vaporisation par jour et la durée médiane était de 3,8 [intervalle de 1 à 213] jours. Le nabiximols était le plus couramment utilisé pour traiter la douleur et les nausées/vomissements et était le plus souvent prescrit par des spécialistes de la douleur. L'efficacité perçue a été documentée dans 17 (50 %) des cas, avec des résultats variables rapportés. Les effets indésirables le plus fréquemment rapportés étaient la somnolence et la tachycardie (3/34, 9 % chacun).

Conclusion : Dans cette étude, le nabiximols a été prescrit à des enfants de toutes les tranches d'âge, pour diverses pathologies, mais le plus souvent pour des douleurs et des nausées/vomissements. Une étude plus approfondie, sous la forme d'un vaste essai contrôlé randomisé prospectif avec des paramètres d'efficacité et d'innocuité clairement définis pour les nausées/vomissements et/ou la douleur, est nécessaire pour déterminer si le nabiximols est efficace et sûr chez les enfants.

Mots-clés : nabiximols, Sativex, pédiatrique

INTRODUCTION

Over the past several years, anecdotal reports at our institution have indicated an increase in the use of cannabinoids for medicinal purposes in children, particularly those with neurological disorders or cancer and those receiving palliative care.

Medicinal cannabinoids exist in many forms, including products for inhalation, oral ingestion, and topical administration. The 2 cannabinoids with known pharmacologic effects are Δ9-tetrahydrocannabinol (THC) and cannabidiol (CBD).[1] THC is believed to have euphoric, analgesic, and antiemetic properties, whereas CBD is believed to

possess anticonvulsant and anxiolytic properties.[2,3] The concentration of THC and the ratio of THC to CBD (in combination products) determine the therapeutic effects of a cannabinoid product.

One challenge in clinical use is the lack of standardization in terms of THC and CBD content, because of variable manufacturing practices, which typically lack both quality control and standardized testing for product content.[4] Both the lack of evidence and the lack of standardized products may make clinicians uncomfortable with prescribing medicinal cannabinoids for their patients. However, products from pharmaceutical companies that use Good Manufacturing Practices are available.[5]

Currently, 2 standardized, commercially available cannabinoid products are approved by Health Canada: nabilone (Cesamet) and nabiximols (Sativex). Nabilone is a synthetic cannabinoid that is chemically similar to THC and is administered orally.[6] It is approved for adults with chemotherapy-induced nausea and vomiting. Adverse effects include drowsiness, vertigo, dry mouth, and euphoria.[6] Nabiximols is a plant-derived cannabinoid buccal spray containing 2.7 mg THC and 2.5 mg CBD per spray. Nabiximols is approved for adults with spasticity, neuropathic pain related to multiple sclerosis, and cancer pain.[7,8] Adverse effects include tachycardia, vertigo, fatigue, blurred vision, dry mouth, and nausea.[8] Compared with THC-predominant products, the approximately equal ratio of THC and CBD in nabiximols may theoretically reduce the risk of psychotropic effects, because of the antagonistic effect of CBD on THC.[9] Nabilone contains no CBD, and therefore is expected to have different clinical effects and potential applications from those of nabiximols.

Case reports and small studies have described the use of cannabinoids in children for refractory seizure disorders, dystonia, pain, and chemotherapy-associated nausea and vomiting.[10,11] A 2017 systematic review of medicinal cannabinoids in children concluded that further research is needed.[12] Despite evidence of benefit for chemotherapy-induced nausea and vomiting and seizure disorders, the review's conclusions were limited by small sample sizes, a lack of randomized controlled trials, and heterogeneous products.[12] Furthermore, there is concern about potential adverse effects in children, including the risk of mental illness, psychosis, and impaired neurodevelopment.[13-15] In a recent randomized controlled trial of pediatric patients, nabiximols was used for spasticity related to cerebral palsy or traumatic brain injury.[16] No significant reduction in spasticity was observed in the group that received nabiximols, but the medication was well tolerated.[16]

Nabiximols is a regulated product, and many clinicians are therefore comfortable prescribing and administering it in a health care setting, because they can trust that the product contains the labelled ingredients. Despite the limited literature regarding the efficacy and safety of nabiximols in children, it is being prescribed in clinical practice at our institution for a variety of indications, which reportedly include seizures, dystonia and dystonic crises, pain, nausea and vomiting, and possibly others.

The primary objective of this study was to describe the use of nabiximols in children admitted to hospital. The secondary objectives were to describe the effectiveness of nabiximols as perceived by the health care team and by patients/caregivers and to describe the adverse effects of nabiximols.

METHODS

This retrospective single-cohort study involved patients admitted to BC Children's Hospital, a tertiary care teaching pediatric hospital, who received nabiximols on an inpatient basis, as supplied by the hospital pharmacy. Patients were identified using the Pharmacy Department's database. One of the study team members (L.H.) used a standardized data collection tool to retrieve data from patients' health records; the data were then entered into REDCap (Research Electronic Data Capture), a secure, web-based application designed for managing online databases. Of the data collected, 10% were chosen randomly for audit by a second study investigator (S.L.) to ensure the integrity of data collection. The study was approved by the institutional research ethics board.

Pediatric inpatients (up to 19 years of age) who received at least 1 dose of nabiximols during their hospital stay between January 1, 2005, and August 31, 2018, were included. Patients who received nabiximols before admission without receiving a dose in hospital were excluded.

For any given patient, if 10 or more days elapsed between nabiximols doses during the same hospital admission, the courses of nabiximols therapy were analyzed as separate incidents. Given the irregular frequency of administration, the average dose per day of nabiximols was calculated by dividing the total number of sprays received by the number of days between the first and last doses. Therefore, the final dose is presented in terms of number of sprays per day.

Effectiveness was assessed on the basis of documentation in the health record that a health care provider or patient/caregiver reported nabiximols to be effective or ineffective. Any documentation indicating a response to nabiximols was recorded, including notes by the patient's physician or any other health care providers. The indication for use was inferred by reviewing inpatient documentation and the prescriber's practice area (e.g., pain service team).

Adverse effects were reported if they occurred within 48 hours after a nabiximols dose, based on documentation in the health record. The Naranjo Adverse Drug Reaction Probability Scale was used to determine the likelihood that the adverse effect was associated with nabiximols.[17] The Naranjo score was calculated independently by 2 of the investigators (L.H., S.L.). Discrepancies were resolved by the third

investigator (R.C.), who was blinded to the assessments of the first 2 investigators. Adverse effects with Naranjo scores of 3 or greater (possible adverse effect) were reported.

Statistical Analysis

Descriptive statistics were used. A sample size of convenience was used.

RESULTS

Fifty-five patients were screened for inclusion in the study, of whom 34 were included. Of the 21 excluded patients, 14 had a prescription for nabiximols but did not receive a dose in hospital, 4 had health records that were unavailable for data extraction, and 3 were older than 19 years of age when they received nabiximols.

The characteristics of patients and their use of nabiximols are described in Table 1. The majority of patients (n = 23) were adolescents, 12 to 19 years of age; in addition, 1 patient was an infant (7 months of age), and 10 patients were 9 to 12 years of age. The indications for nabiximols use are described in Figure 1. Five patients received nabiximols for both pain and nausea/vomiting, and one of these patients also received nabiximols for a third indication, anxiety. Nabiximols was used on an as-needed basis by 10 (29%) of the patients. Nabiximols was prescribed by pain specialty services for 18 patients (53%), by palliative care for 7 patients (20%), by oncology for 5 patients (15%), by general pediatrics for 1 patient (3%), by psychiatry for 2 patients (6%), and by hematology for 1 patient (3%). Eleven patients (32%) had been admitted under the oncology service.

For 2 patients, the dose received was unclear because a dosage range had been prescribed (e.g., 1–2 sprays), and the amount received was not documented in the health record. In these cases, we assumed that the number of sprays received was the highest possible number based on the physician's order. This assumption did not affect the value for median number of sprays received per day.

TABLE 1. Characteristics of Patients and Their Use of Nabiximols

Characteristic	Result *n* = 34
Patients	
Age (median and range)	14 (0.6–18) years
Weight (median and range)	50 (7.4–81.9) kg
Sex, male (no. and %)	16 (47)
Nabiximols use	
Dose (median and range)	1.9 (0.3–10.8) sprays/day
Duration of therapy (median and range)	3.8 (1–213) days
No. of admissions per patient during which nabiximols was received (mean and range)	1 (1–4)
Changes in prescribed dosage (no. and %)	18 (53)
Nabiximols discontinued in hospital (no. and %)	11 (32)[a]
Nabiximols prescribed on discharge (no. and %)	13 (38)[b]

[a]Three of these patients had subsequent admissions during which nabiximols was not discontinued.
[b]For 2 of these patients, nabiximols was prescribed on discharge multiple times.

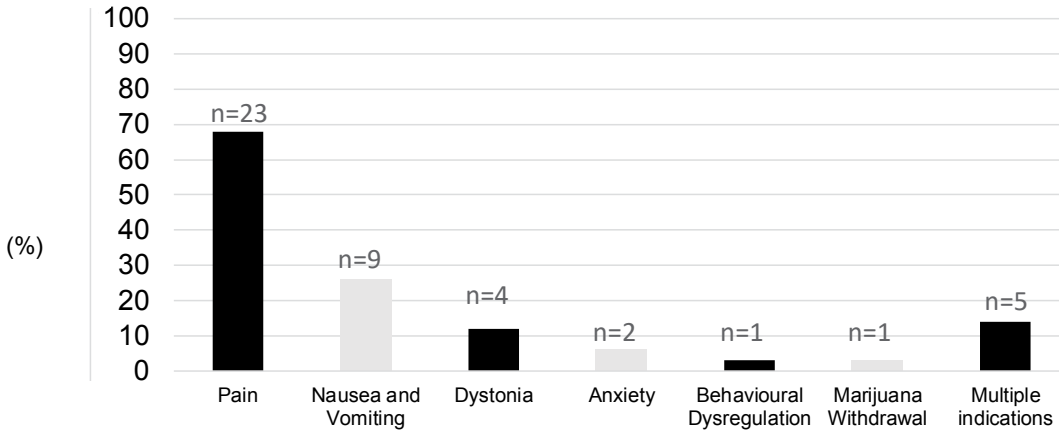

FIGURE 1. Indications for use of nabiximols.

The perception of effectiveness (or lack thereof) by the health care team and by the patient/caregiver was documented for approximately 50% of patients (Figure 2). Two patients had conflicting documentation in the health record indicating that nabiximols was both effective and ineffective. Five patients (15%) agreed with their health care provider that nabiximols was effective, 3 patients (9%) agreed with their health care provider that nabiximols was ineffective, and 3 patients (9%) disagreed with their health care provider as to whether nabiximols was effective.

The most commonly reported adverse effects were drowsiness and tachycardia (9% each) (Table 2). A burning sensation in the mouth upon application of nabiximols spray was reported for 2 patients, who had pre-existing mucositis. Two patients experienced more than 1 adverse event: one of these patients experienced drowsiness, euphoria, mouth burning, and tachycardia, whereas the other patient experienced agitation and bradycardia. Among the 11 patients for whom nabiximols was discontinued in hospital, none of the discontinuations were due to adverse events.

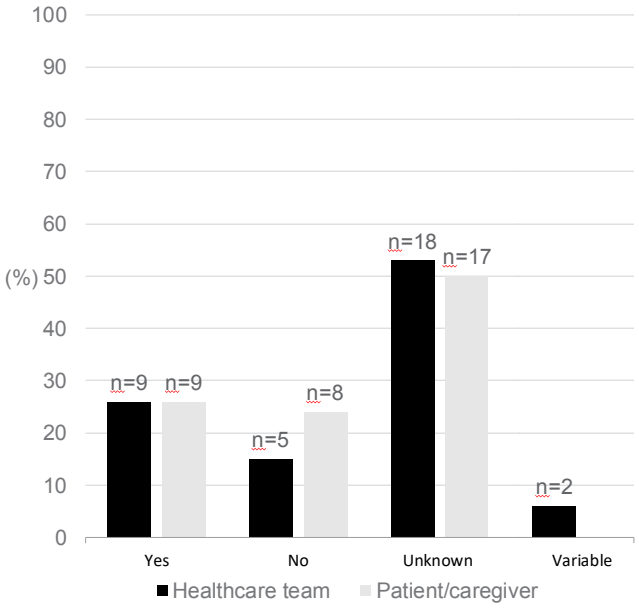

FIGURE 2. Perceived effectiveness of nabiximols.

TABLE 2. Adverse Effects

Adverse Effect	No. (%) of Participants (*n* = 34)
Drowsiness	3 (9)
Tachycardia	3 (9)
Mouth burning	2 (6)
Euphoria or "feeling high"	1 (3)
Agitation	1 (3)
Vision changes	1 (3)
Bradycardia	1 (3)
Hypertension	1 (3)
Vomiting	1 (3)
Patients with > 1 adverse effect	2 (6)

DISCUSSION

Despite the limited evidence supporting use of cannabinoid products for pain and nausea/vomiting in children and despite the fact that nabiximols is not approved by Health Canada for use in children, this product is being prescribed in this age group and fills a gap in terms of a cannabinoid product that is produced by a manufacturer compliant with Health Canada Good Manufacturing Practices.[5]

The low use of nabiximols for dystonia and seizures observed in this study may relate to the use of alternative medicinal cannabinoid products. Cannabidiol (Epidiolex) is an oral CBD solution that is commercially available in the United States, which has demonstrated benefit in reducing seizure frequency for patients at least 2 years of age who have Dravet syndrome or Lennox–Gastaut syndrome.[18] This product is not currently available in Canada, and anecdotal reports indicate that other forms of cannabidiol are commonly used at our institution; however, it was not possible to quantify such use in our study. Concerns remain about prescribing and administering products that may not meet quality assurance standards for content and manufacturing practices. In accordance with institutional policies during the period of the study, such products could not be administered by nurses or entered onto a patient's medication administration record. In addition, because Epidiolex does not contain THC, its clinical effects and use in practice may differ from products such as nabiximols or nabilone.

The doses of nabiximols observed in this study were generally lower than doses used in adult studies. The median dose in our study was approximately 2 (range 0.3 to 10.8) sprays per day (representing 5.4 mg THC and 5 mg CBD), whereas the dose in adult studies has ranged from 7 to 9 sprays per day.[19-22] The product monograph recommends between 4 and 8 sprays per day for adults as the usual dose range.[8] In a recent pediatric study of nabiximols administered for spasticity, the mean number of sprays per day ranged from 5 to 7.[16] There have been few studies of medicinal cannabinoid use in children, and these have used heterogeneous products with differing concentrations and dosages; as such, it is challenging to make comparisons with these studies and determine appropriate doses for children.[13]

It was difficult to assess the perceived effectiveness of nabiximols because of a lack of documentation in the health records and subjective monitoring of the indications for which nabiximols was prescribed. Further measures of

effectiveness, such as frequency of vomiting for patients with nausea/vomiting or pain scores for patients with pain, were considered but were found to have many confounding variables. For example, a patient's pain score before and after receipt of nabiximols was often confounded by concurrent changes in other analgesics and/or changes in disease states that would affect pain. Therefore, it was not possible to draw meaningful conclusions from these outcome measures. Given the retrospective nature of this study, there were no standardized monitoring procedures or documentation in place for assessment.

Similarly, assessment of the safety of nabiximols was challenging, because most patients could have experienced effects such as drowsiness, tachycardia, and vomiting from concurrent medications or medical conditions. However, the rates of documented adverse effects were generally low and similar to rates reported in adults.[19-22]

Our study was limited by reliance on health record documentation to determine effectiveness and safety and by the small sample size. Collecting information about medications used concurrently by the patients might have been useful for better assessment of the effectiveness and safety of nabiximols. To mitigate these limitations, the Naranjo Adverse Drug Reaction Probability Scale was used to help determine the likelihood that adverse effects were associated with nabiximols.

CONCLUSION

To the authors' knowledge, this study is the first to characterize the use of nabiximols in children. Further study, in the form of large, prospective randomized controlled trials for treatment of nausea/vomiting and/or pain with well-defined doses of THC and CBD and clearly defined efficacy end points, is needed to determine whether nabiximols is effective and safe for children with these indications.

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Impact of Pharmacist-Provided Education Using New Information Sheets on Activation in Patients Treated with Oral Antineoplastic Drugs (IMPACT-OAD Project)

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ABSTRACT

Background: Oral antineoplastic drugs (OADs) play an increasing role in the treatment of cancer. Patients must have a high degree of understanding and autonomy to manage the numerous adverse effects at home. In Quebec, recommendations have been made for oncology pharmacists to systematically counsel all patients who are starting an OAD.

Objective: To measure the impact of education provided by oncology pharmacists on patient activation.

Methods: In this prospective, single-centre, observational cohort study, patients starting an OAD received education from oncology pharmacists, who used the 2020 updated version of information sheets from the Groupe d'étude en oncologie du Québec (GEOQ, www.geoq.info). The Patient Activation Measure (PAM-13) questionnaire was used to measure patients' activation before and after the intervention.

Results: Of the 43 patients recruited in the intention-to-treat analysis, 41 were included in the modified intention-to-treat analysis. The mean difference between PAM-13 scores before and after the intervention was 2.30 (standard deviation [SD] 11.85) ($p = 0.22$) in the intention-to-treat analysis and 3.63 (SD 10.33) ($p = 0.032$) in the modified intention-to-treat analysis; these differences were less than the 5 points required for a result to be considered clinically meaningful. None of the effect-modifying variables for which data were collected had a significant impact on the degree of activation; however, a weak negative correlation was observed between the level of health literacy and the change in PAM-13 score.

Conclusions: The study did not show a clinically meaningful change in patient activation following pharmacist-provided education, according to the updated GEOQ information sheets. Further studies are needed to evaluate these data in a larger population and to determine whether the impact of education persists beyond the first treatment cycle.

Keywords: oral antineoplastic drugs, oncology pharmacist education, patient activation measure

RÉSUMÉ

Contexte : Les médicaments antinéoplasiques par voie orale (MAVO) occupent une place grandissante dans le traitement du cancer. Les patients doivent avoir un degré élevé de compréhension et d'autonomie pour gérer les nombreux effets indésirables à domicile. Au Québec, des recommandations ont été émises pour que les pharmaciens en oncologie conseillent systématiquement tous les patients qui débutent des MAVO.

Objectif : Mesurer l'impact des enseignements effectués par les pharmaciens en oncologie sur l'activation du patient.

Méthodes : Dans cette étude de cohorte prospective, monocentrique et observationnelle, les patients qui commençaient à prendre des MAVO ont reçu un enseignement effectué par un pharmacien en oncologie. Ceux-ci utilisaient les feuillets d'information pour les patients du Groupe d'étude en oncologie du Québec (GEOQ, www.geoq.info) mis à jour en 2020. Le questionnaire de Mesure d'activation du patient (MAP-13) a été utilisé pour mesurer l'activation des participants avant et après l'intervention.

Résultats : Sur les 43 participants recrutés dans l'analyse en intention de traiter, 41 ont été inclus dans l'analyse en intention de traiter modifiée (mITT). La différence moyenne entre les scores MAP-13 avant et après était de 2,30 (écart type [SD] 11,85) ($p = 0,22$) dans l'analyse en intention de traiter et de 3,63 (SD 10,33) ($p = 0,032$) dans l'analyse mITT; ces différences étaient inférieures aux 5 points requis pour qu'un résultat soit considéré comme cliniquement significatif. Aucune des variables modificatrices d'effet pour lesquelles des données ont été recueillies n'a eu d'effet significatif sur le degré d'activation; cependant, une faible corrélation négative a été observée entre le niveau de littératie en santé et la variation du score MAP-13.

Conclusions : L'étude n'a pas démontré de changement cliniquement significatif dans l'activation des patients à la suite de l'enseignement effectué par le pharmacien en oncologie sur la base des feuillets d'information actualisés du GEOQ. D'autres études sont nécessaires pour évaluer ces données chez une plus grande population et pour déterminer si l'impact de l'enseignement perdure au-delà du premier cycle de traitement.

Mots-clés : médicaments antinéoplasiques par voie orale, enseignement par le pharmacien en oncologie, mesure d'activation du patient

INTRODUCTION

Oral antineoplastic drugs (OADs) play an increasing role in therapy for many cancers.[1] Indeed, in 2015, approximately 25% of antineoplastics were in oral form.[2] In Quebec, given the growing use of OADs and the considerable risks associated with their utilization, pharmacist organizations recommend that oncology pharmacists provide patient education about these drugs using information sheets developed by, among others, the Groupe d'étude en oncologie du Québec (GEOQ).[3] This practice differs considerably from one facility to another, in part because of the significant resources involved.[3] The information sheets developed by the GEOQ are short and are intended for patients taking an OAD. Each information sheet includes, among other details, precautions regarding the particular drug and the management of main adverse effects. The sheets were modified in winter 2020 to standardize their content and to focus on the relevant information, with the addition of a treatment diary, pictograms, and colour-coded recommendations to help the patient be more independent in managing their treatment.

Patient activation is defined as having the knowledge, skills, and confidence required to successfully manage one's health or a chronic disease.[4] Patients with higher levels of activation tend to have better adherence, to adopt self-management behaviours, to manage their adverse effects, and to have better health outcomes.[1,5-9] There is a lack of data in the literature supporting the effect of pharmacist-provided education on patient activation, although a few studies have shown positive effects.[10-12] Health literacy is another factor that can potentially affect activation, but mixed results have been reported in the literature.[13-16]

The purpose of this study was to measure the effect of education led by an oncology pharmacist, using the GEOQ's new information sheets (available in both French and English), on patients receiving an OAD, by assessing patient activation with validated questionnaires. This study was conducted by pharmacy residents and their preceptors in the context of a Master in Advanced Pharmacotherapy curriculum at the Université de Montréal.

METHODS

Study Population

This prospective, single-centre, observational cohort study involved patients starting an OAD. Patients were eligible for enrolment if they were 18 years of age or older, were starting a new OAD, and were patients of the Centre intégré de cancérologie de Laval (CICL) oncology clinic during the data collection period (May to November 2020). The exclusion criteria were a prescription for an OAD that had no dedicated GEOQ information sheet; hormone therapy alone for breast or prostate cancer (because the regimens are less complex and have a more tolerable side-effect profile); concomitant treatment with a parenteral antineoplastic or curative radiotherapy (because such patients already have more intensive follow-up by the radio-oncology team); a prescription for lenalidomide, pomalidomide, or venetoclax (because patients taking these drugs already receive education provided by an external specialty pharmacist); participation in another research project; inability to self-manage the antineoplastic therapy (based on their answer, when asked during screening, to the question of whether they manage their own medications); and inability to speak French or English (because GEOQ information sheets are available only in those languages).

Questionnaires

To measure patient activation, the 13-item Patient Activation Measure (PAM-13) questionnaire of Insignia Health was used (https://www.insigniahealth.com/pam/).[4,17] This questionnaire has been validated for face-to-face or telephone administration in several languages, including French and English.[18,19] Participants' answers were entered into an Excel spreadsheet provided by Insignia Health, which then generated a PAM-13 score between 0 and 100, with higher scores being associated with better activation.[4,17]

To measure the effect of health literacy, the validated Set of Brief Screening Questions (SBSQ) presented by Chew and others[20] was chosen, because of its simplicity. The potential responses to the 3 SBSQ questions (referred to as "confident with form", "help read", and "problems learning") correspond to choices on a Likert scale from 0 to 4, depending on the response.[20] A score of less than 3 indicates an inadequate level of health literacy, whereas a score of 3 or higher indicates adequate health literacy.[20,21]

Study Protocol

Potentially eligible patients were referred by hematologist–oncologists and by oncology pivot nurses. The recruitment interviews were conducted by telephone because of the COVID-19 pandemic. After giving informed verbal consent, each patient completed the baseline PAM-13 and SBSQ questionnaires. Subsequently, education was provided by an oncology pharmacist by telephone using the pertinent GEOQ sheet, previously sent to the patient by email or regular mail. The PAM-13 questionnaire was completed a second time 7 days after initiation of the OAD or, if the OAD had already been started, 7 days after the provision of education. At the end of the first treatment cycle, the patient returned the completed treatment diary, and the final data collection was carried out. Patients could withdraw their consent at any time, and pharmacist-led education was offered even if they declined to participate in the study or were not eligible.

Outcomes

The primary outcome was the degree of activation among patients starting an OAD following oncology

pharmacist–led education using the new GEOQ sheets. The secondary outcomes were the relationship between health literacy level and degree of patient activation, patients' use of health professionals (as indicated by number of calls to a CICL team member and number of visits to the emergency department), associated interventions performed during the first treatment cycle, use of the treatment diary section of the GEOQ sheet, and treatment adherence.

Statistical Analysis

Assuming a standard deviation (SD) of 15, based on the literature, a minimum sample size of 73 participants was required to detect a clinically meaningful difference of 5 points in the PAM score, with 80% power and 2-sided α of 0.05.[6,22,23]

The data were normally distributed, and parametric tests were therefore used for all analyses. In the intention-to-treat (ITT) analysis, a paired-observations *t* test was used to compare the mean pre- and post-intervention scores on the PAM-13 questionnaire. Univariate and multivariate linear regressions were performed to adjust for effect-modifying variables and to examine the relationship between the level of health literacy (based on SBSQ scores) and the change in PAM-13 scores. The Pearson correlation coefficient (*r*) was chosen to simplify the presentation of regression results, the relationship between the effect-modifying variables, and changes in the PAM-13 scores. Absolute correlations less than 0.20 were considered negligible.[10] An independent-observations *t* test, not included in the original protocol, was used to compare the mean PAM-13 scores between 2 subgroups (those with adequate and inadequate levels of health literacy).

A sensitivity analysis for the primary outcome, not included in the original protocol, was performed to exclude participants in special situations. In this modified ITT (mITT) analysis, 2 participants were excluded because of a significant protocol violation.

For the descriptive analysis, continuous variables are represented by the mean and SD and categorical variables by numbers and percentages. A *p* value less than 0.05 was considered statistically significant.

Ethics Approval

The original protocol and an amendment were submitted to and approved by the ethics board of the Centre intégré de santé et de services sociaux de Laval. Recruitment for the study was suspended for 10 weeks because of the COVID-19 pandemic. Before the study was allowed to resume, the protocol was amended to specify that all communication with participants would be by telephone.

RESULTS

Of the 81 patients who were referred, a total of 43 were recruited. Among those not recruited, 24 were excluded because they met various exclusion criteria; the other 14 declined to participate (Figure 1). In addition, 1 patient who was initially recruited did not complete the study because the OAD was discontinued. Data for the primary outcome were therefore available for 42 participants (98%). Of these, 2 participants were excluded from the mITT analysis because the interval between their PAM-13 questionnaires was much longer than initially planned.

Demographic and clinical data for the 43 patients initially recruited are shown in Table 1. These patients were predominantly female (60%), their mean age was 65.7 (SD 11.3) years, they were predominantly receiving palliative therapy (86%), and most were not antineoplastic-naive (84%). None of the patients had received their diagnosis of cancer within the 2 weeks preceding the first PAM-13, which could have influenced the results (Insignia Health: Best practices when administering PAM; internal document consulted on October 19, 2019). The results for the primary outcome, patient activation, are shown in Table 2. The mean score on the first PAM-13 was 67.11 (SD 14.30), whereas the mean score on the second PAM-13 was 69.09 (SD 11.90).

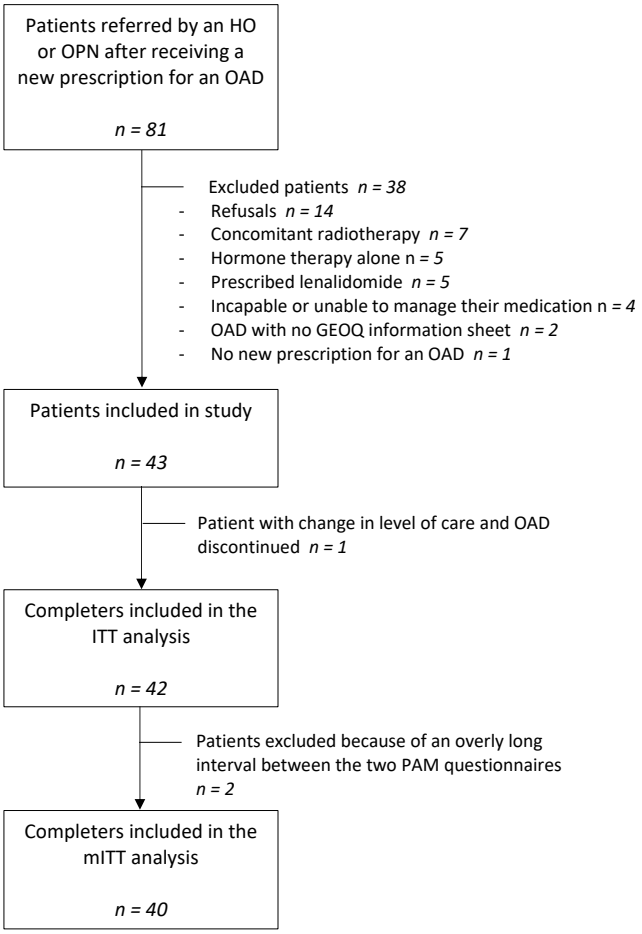

FIGURE 1. Patient selection. GEOQ = Groupe d'étude en oncologie du Québec, HO = hematologist–oncologist, ITT = intention to treat, mITT = modified ITT, OAD = oral antineoplastic drug, OPN = oncology pivot nurse, PAM = Patient Activation Measure.

TABLE 1. Baseline Characteristics

Characteristic	No. (%) of Patients[a] (*n* = 43)
Age (years) (mean ± SD)	65.7 ± 11.3
Sex	
Men	17 (40)
Women	26 (60)
Goal of care	
Adjuvant	6 (14)
Palliative	37 (86)
Tumour site or type	
Breast	16 (37)
Colorectal	8 (19)
Kidney	5 (12)
Lung	4 (9)
Chronic myeloid lymphoma	3 (7)
Other[b]	7 (16)
Oral antineoplastic drug started	
Capecitabine	10 (23)
Trifluridine–tipiracil	5 (12)
Palbociclib–fulvestrant	3 (7)
Palbociclib–letrozole	3 (7)
Alectinib	2 (5)
Cabozantinib	2 (5)
Everolimus–exemestane	2 (5)
Imatinib	2 (5)
Osimertinib	2 (5)
Pazopanib	2 (5)
Ribociclib–letrozole	2 (5)
Other[c]	8 (19)
Antineoplastic-naive	7 (16)
ECOG performance status	
0	8 (19)
1	11 (26)
2	4 (9)
Unknown	20 (47)
Charlson comorbidity index (mean ± SD)	7.7 ± 2.7
No. of concomitant drugs (mean ± SD)	6.0 ± 3.6
Education	
No diploma	8 (19)
High school diploma	12 (28)
Vocational diploma	4 (9)
Diploma from private college or general and vocational college	6 (14)
Certificate, diploma, or other university degree	13 (30)
Caregiver present	10 (23)

ECOG = Eastern Cooperative Oncology Group, SD = standard deviation.
[a]Except where indicated otherwise.
[b]Other tumours and sites were non-Hodgkin lymphoma, gastrointestinal stromal tumour, myxofibrosarcoma, myeloproliferative neoplasm–myelofibrosis, esophagus, thyroid, and site of origin unknown.
[c]Other oral antineoplastic drugs were axitinib, dasatinib, ibrutinib, nilotinib, regorafenib, ruxolitinib, sorafenib, and sunitinib.

The mean interval between the 2 questionnaires was 14.8 (SD 10.0) days, ranging from 7 to 58 days (median 12 days). The reasons for intervals longer than 7 days were not systematically noted, but included patient preference, patient leaving on vacation, delay for insurance acceptance or for the pharmacy to receive the medication, and hospitalization.

In the ITT analysis, the mean difference between the 2 PAM-13 questionnaires was 2.30 (SD 11.85) ($p = 0.22$). There was no statistically significant difference between participants with adequate and inadequate levels of health literacy (1.25 [SD 12.86] versus 5.26 [SD 8.15], $p = 0.34$). In the mITT analysis, the mean difference was 3.63 (SD 10.33) ($p = 0.032$). Various effect-modifying variables such as age, sex, goal of care, antineoplastic naivety, health literacy level as determined by the SBSQ, education level, presence of a caregiver during counselling, and the Charlson comorbidity index did not have a significant effect on the degree of activation.

Results for the secondary outcomes are shown in Table 3. The mean responses to the SBSQ questions were 3.4 (SD 0.9) for each of the first 2 questions and 3.5 (SD 0.8) for the third question; these results indicate an adequate level of health literacy. The Pearson correlation coefficients (r values) between health literacy level as determined by the 3 SBSQ questions and the degree of activation were −0.183 ($p = 0.25$) for the first question, −0.079 ($p = 0.62$) for the second question, and −0.164 ($p = 0.30$) for the third question. The correlation between health literacy level and degree of activation was therefore weak, given that the Pearson correlation coefficients were below the 0.20 threshold established in the literature.

Results describing patients' use of health professionals were available for all 43 participants, but only 38 returned their treatment diaries for evaluation of the secondary outcomes pertaining to this tool. The total number of treatment-related calls to the treatment team during the first cycle was 33, or 0.77 calls per patient, and a total of 25 interventions, or a mean of 0.58 interventions per patient, were performed as a result of these calls. The mean number of visits to the emergency department was 0.09 per patient, based on 4 of the 43 patients making such a visit during their first treatment cycle. The rate of utilization of the treatment diary was 82% for the diaries returned. Adherence was determined from the number of days "ticked" in the diary; about two-thirds of participants (25/38) had good adherence (75%–100%), and about one-third (12/38) had poor adherence (0%–25%).

DISCUSSION

This study was designed to measure activation among patients starting a new OAD before and after provision of education by an oncology pharmacist using GEOQ information sheets. The ITT analysis showed no significant difference in the degree of activation following the intervention, although the required sample size was not reached. In contrast, a statistically significant difference between

TABLE 2. Results for Primary Outcome

Result	Patient Activation Measure (PAM); Score			
	First PAM	Second PAM	Difference	*p* Value[a]
Intention to treat				
No.	43	42	42	
Mean ± SD	67.11 ± 14.30	69.09 ± 11.90	2.30 ± 11.85	0.22
Modified intention to treat				
No.	41	40	40	
Mean ± SD	66.25 ± 14.08	69.51 ± 11.92	3.63 ± 10.33	0.032

SD = standard deviation.
[a]A *t* test for paired observations was performed.

TABLE 3. Results for Secondary Outcomes

Secondary Outcome	Result
Health literacy (no. and %, *n* = 43)	
Adequate (SBSQ ≥ 3)	32 (74)
Inadequate (SBSQ < 3)	11 (26)
Total no. of calls to team (*n* = 43)	33 (0.77 per patient)
Total no. of interventions performed (*n* = 43)	25 (0.58 per patient)
Total no. of visits to ED (*n* = 43)	4 (0.09 per patient)
Treatment adherence rate (no. and %, *n* = 38)	
0%–25%	12 (32)
26%–50%	1 (3)
51%–75%	0 (0)
76%–100%	25 (66)
Use of treatment diary (no. and %, *n* = 38)	31 (82)

ED = emergency department, SBSQ = Set of Brief Screening Questions.

scores on the 2 PAM-13 questionnaires was found in the post hoc mITT analysis. However, the difference was not clinically meaningful, given that a 5-point difference was required with the calculated sample size. The mean and median intervals between the PAM surveys (14.8 and 12 days, respectively) were within expectations, as a 7-day interval is the shortest interval permitted, and patients often started their OAD a few days after the pharmacist-led education. In the mITT analysis, 1 participant was excluded because of an 8-week interval between their PAM-13 questionnaires (because of a hospital admission); another went on vacation for 5 weeks before starting their treatment. These long intervals increased the risk of events that could have affected the calculated difference in activation, such as patients not remembering enough of the advice received; therefore, these patients were excluded from the analysis.

In a similar study, Bates and others[10] used the PAM-10, a 10-item questionnaire, before and after oncology pharmacist–led education to investigate activation in patients receiving new chemotherapy. However, patients with a solid malignancy were not included, and the before and after PAM-10 questionnaires were administered 2 business days apart.[10] A statistically significant difference in the PAM-10 score was observed, specifically, an increase from 68.5 (SD 14.7) to 75.0 (SD 14.3) (p = 0.001), and a weak negative correlation with health literacy level also appeared to affect the degree of activation.[10] The shorter interval between the 2 questionnaires in the study by Bates and others[10] potentially had an effect on the results, but the goal of a minimum interval of 7 days in the current study was intended to enable patients to experience taking their medication and applying the knowledge acquired during the education.

According to the authors of the PAM-13, a 1-point difference in the PAM-13 score could be clinically meaningful if the desired sample size is reached (Insignia Health: Patient activation measure (PAM) basics: understanding health activation; administering the PAM survey: internal document consulted on October 19, 2019), which was not the case here. In addition to the 2 participants excluded from the mITT analysis, others who experienced suboptimal conditions for completing the PAM-13 questionnaire may

have negatively influenced the results (e.g., 1 participant was in severe pain during questionnaire administration).

The level of health literacy as determined by the SBSQ showed a weak negative correlation with the change in the PAM-13 score, which suggests that the lower the health literacy level, the greater the post-intervention difference. Most participants' activation tended to increase nonsignificantly following the pharmacist-led education with the GEOQ information sheets, and this effect appeared to be greater among those with lower health literacy level.

Certain hypotheses can be derived from the descriptive data gathered for the secondary outcomes. Some emergency department visits did not require a call to the treatment team beforehand because the patient was able to manage their adverse event well, possibly thanks to the information sheet and education. However, 8 (24%) of the 33 patient calls would not have been necessary had the patients referred to their information sheet (e.g., for management of mild nausea)—the patients could have handled these calls themselves. Some patients seemed to need confirmation from the treatment team of the measures they took, despite having the necessary information available.

This study had several strengths. In evaluating a knowledge transfer method, the study addressed a fundamental issue, namely, the information provided to patients for the purpose of optimizing management of their disease and their treatments. This is especially important in oncology, considering the complexity that management can entail. Also, compared with patients who are receiving parenteral antineoplastics, whose treatment is provided at a health care facility, patients taking OADs receive less close follow-up at home. Therefore, optimal-quality initial education is important, and it is essential to evaluate the methods used to ensure their continuous improvement. Using a prospective cohort study design, we evaluated the actual impact of information provided to patients on their management skills to ensure good external validity. In terms of the results, there were few treatment discontinuations and losses to follow-up. Furthermore, additional analyses were performed to identify any confounding variables, but no effects were found, apart from a weak negative correlation with the level of health literacy.

The study also had some limitations. First, the absence of a control group prevented a comparison with patients not exposed to the intervention. It was assumed that pharmacist-provided education using the new information sheets was superior to no education or to using the previous version of the information sheets. We could therefore not control certain variables that can modify the effect of pharmacist-led education on activation, which might have led to confounding bias. Second, the small number of participants can be explained by the COVID-19 pandemic, which led to the suspension of recruitment for several weeks, although recruitment was later extended for 2 months to compensate. The decrease in cancer screening and diagnosis during the COVID-19 pandemic probably reduced the number of patients eligible for this research project.[24] The recruitment difficulties can also be explained by the relatively strict exclusion criteria for patients who had more frequently scheduled medical follow-up or who might have been better equipped by their follow-up with other oncology professionals during their treatment. In the absence of a control group, these criteria were essential to limit confounding and better isolate the effect of the intervention. Furthermore, the fact that all of the interventions were conducted by telephone resulted in additional difficulty communicating with certain participants because of the absence of nonverbal components. However, being able to read the information sheet before the education sessions aided comprehension for a number of participants, as it gave them the opportunity to prepare for the interview and write down their questions. It would have been interesting to assess whether participants reviewed the materials in advance and how doing so might have affected their activation. Participants may also have obtained additional instruction from other health professionals, which could have increased their activation.

In other respects, the intervention was measured in the short term. It is therefore not possible to evaluate the effect of the intervention over longer periods. In addition, the responses probably reflected social desirability bias because the data were self-reported or came from a treatment diary completed by the participant. For example, 12 participants added a checkmark for no more than 25% of their OAD doses. It is possible that these participants took their medication but forgot to put a checkmark in the diary. Lastly, a few participants seemed to realize the complexity of their treatment only after treatment had started. Consequently, their confidence in managing the treatment in its entirety may have been influenced upward on the first PAM questionnaire but downward on the second, which would have led to a reduction in the measured difference.

CONCLUSION

This study did not show a clinically meaningful change in patient activation following pharmacist-provided education with the updated GEOQ information sheets, possibly because of failure to reach the target sample size and the presence of confounding factors. However, the results showed a statistically nonsignificant trend in favour of pharmacist-led education using the information sheets for activation in participants with lower health literacy levels. The various effect-modifying variables measured had no effect on participants' activation. Further studies are needed to evaluate these data in a larger population and to determine whether the effect of education persists after the first treatment cycle.

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Training for Collaborative Care: How Hospital Team Members View Pharmacy Students

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ABSTRACT

Background: Interprofessional education activities are prevalent across health professional curricula in Canada. Students develop collaborative roles through structured on-campus programming; however, the ways in which established teams engage learners in hospital settings are unknown.

Objective: To explore how mixed-discipline professionals describe expectations and experiences related to collaborating with pharmacy students who join their team for training.

Methods: Mixed-discipline team members of an acute medicine clinical teaching unit were interviewed according to a semistructured interview guide. Participants described encounters with pharmacy trainees and shared expectations of the students' collaborator roles in patient care. Audiorecordings of the interviews were transcribed and coded independently by 2 researchers, who synthesized the data and used the template analysis method to derive themes.

Results: Fourteen team members from various disciplines were recruited. Participants' descriptions of collaborative roles were organized into 2 main themes: pharmacy students as informants and pharmacy students as a bridge. A third integrative theme, engagement, encompassed how team members described pharmacy trainees enacting these roles. Team members sought pharmacy students' medication-oriented expertise (e.g., dosing, compatibilities), and physicians often relied on the students' familiarity with study data to guide treatment choices. Nonphysicians capitalized on pharmacy student proximity to physicians to understand such decision-making and inform their own patient care. Accounts of pharmacy students' consultations with team members for patient assessments or to access other multidisciplinary knowledge were infrequent.

Conclusions: Most team members' expectations of pharmacy students in terms of the collaborator role lacked routine engagement or shared decision-making. These views represent challenges to the development of skills in collaborative care in workplace-based learning, which might be addressed through intentional interprofessional exercises assigned by preceptors. Further study is required to understand the potential of practice-based interprofessional education initiatives.

Keywords: collaborative care, interprofessional teams, pharmacy student training

RÉSUMÉ

Contexte : Les activités de formation interprofessionnelle sont répandues dans les programmes d'études des professionnels de la santé au Canada. Les étudiants développent des rôles collaboratifs grâce à des programmes structurés sur les campus; cependant, on ne sait pas comment les équipes de fournisseurs de soins de santé font participer les apprenants en milieu hospitalier.

Objectif : Étudier comment des professionnels de disciplines variées décrivent les attentes et les expériences liées à la collaboration avec les étudiants en pharmacie qui se joignent à leur équipe pour se former.

Méthodes : Les membres de l'équipe mixte d'une unité de formation clinique en médecine aiguë ont été interviewés selon un guide d'entretien semi-directif. Les participants ont décrit leurs rencontres avec des stagiaires en pharmacie et ont communiqué leurs attentes concernant les rôles collaboratifs des étudiants dans le domaine des soins aux patients. Les enregistrements audio des entretiens ont été retranscrits et codés indépendamment par 2 chercheurs qui ont synthétisé les données et utilisé la méthode d'analyse de modèles pour en dériver les thèmes.

Résultats : Quatorze membres de l'équipe provenant de diverses disciplines ont été recrutés. Les descriptions des rôles collaboratifs offertes par les participants ont été organisées en 2 thèmes principaux : les étudiants en pharmacie « informateurs » et les étudiants « passerelles ». Un troisième thème d'intégration, « l'engagement », englobait la façon dont les membres de l'équipe décrivaient les stagiaires en pharmacie jouant ces rôles. Les membres de l'équipe recherchaient l'expertise des étudiants en pharmacie en matière de médicaments (par exemple, dosage, compatibilités), et les médecins s'appuyaient souvent sur leur familiarité avec les données d'études pour guider les choix de traitement. Les non-médecins tiraient parti, eux, des échanges entre les étudiants en pharmacie et les médecins pour comprendre ce processus décisionnel et informer leurs propres soins aux patients. Les comptes rendus des consultations des étudiants en pharmacie avec les membres de l'équipe pour l'évaluation des patients ou pour accéder à d'autres connaissances multidisciplinaires étaient peu fréquents.

Conclusions : Les attentes de la plupart des membres de l'équipe à l'égard des étudiants en pharmacie en termes de rôle de collaborateur manquaient d'engagement de routine ou de prise de décision partagée. Ces points de vue représentent des défis pour le développement des compétences en soins collaboratifs dans l'apprentissage en milieu de travail, qui pourraient être abordés par des exercices interprofessionnels intentionnels confiés par les précepteurs. Une étude plus approfondie est nécessaire pour comprendre le potentiel des initiatives de formation interprofessionnelle fondées sur la pratique.

Mots-clés : soins collaboratifs, équipes interprofessionnelles, formation des étudiants en pharmacie

INTRODUCTION

Teams represent the basis for contemporary health care. Cooperative communication and interdependent work involving members with complementary expertise have benefits for patient safety and clinical outcomes.[1] Unsurprisingly, collaboration-oriented skills and abilities appear as educational outcomes at graduation for many health professions, as well as in interprofessional competency frameworks.[2,3] For example, core competencies or capabilities outlined for pharmacists and other medical and social care providers in North America, Australia, and Great Britain include interprofessional communication, role clarification, teamwork, conflict resolution, and ethical practice.[3,4] In Canada, expectations of graduating pharmacists to create and maintain collaborative professional relationships for health services delivery are outlined by both national accrediting bodies (for education programs) and regulatory organizations.[5,6] As such, campus-based interprofessional education (IPE) programming for trainees, whereby "students from two or more professions learn about, from and with each other",[7] is being adopted in pharmacy curricula throughout the country to help prepare trainees to function in multidisciplinary teams.[8] Yet it remains unclear, in practical terms, how collaborative care is taught or reinforced, once pharmacy students reach actual patient care settings for off-campus training.[9,10]

Workplace-based learning is fundamental to pharmacy students' development of practice competencies, especially those that are not readily simulated in other parts of the curriculum.[11] Workplace-based learning necessitates trainee enactment of interprofessional competencies within established teams under real practice conditions. For example, pharmacy trainees join teams in hospital settings to devise and provide advice on medication treatment plans and to monitor and evaluate drug safety and effectiveness for patients who are also receiving care from other health professionals.[5] Providing this type of pharmacist care requires team interaction with clear communication and the negotiation of care priorities with others. Unfortunately, the experiential curriculum may be falling short in terms of capitalizing on opportunities for health professional trainees to develop and enact the comprehensive skill set required for shared care in the workplace-based learning environment. As examples, medical, nursing, and physiotherapy trainees are among those learners who have reported inability to informally engage with hospital team members or to exercise conflict resolution.[12-14]

Workplace participatory practices theory provides a framework through which we might learn how students engage interprofessional team members in the conduct of clinical work.[15] One aspect of this perspective views the workplace as offering certain opportunities for learning, and access to such participation involves negotiated interactions with established members. For pharmacy students in hospital training settings, the participatory practices required for collaborative care involve establishing "positive relationships, negotiating overlapping responsibilities, and joining in respectful, shared decision-making".[2]

In this study, we explored how mixed-discipline professionals describe their experiences and expectations of the collaborative roles of pharmacy students who joined their team. Our goal was to gain a greater understanding of how interprofessional competencies are viewed and how their development among pharmacy students in hospital settings might be augmented.

METHODS

Methodology

We adopted a social constructivist perspective to underpin the design and analysis of semistructured interviews with participants representing different perspectives, in this case, team members from various health disciplines (referred to here as "mixed-discipline professionals"). Through this lens of investigation, participants constructed and shared their own interpreted reality of experiences with pharmacist trainees, which may be stimulated through contrast with expectations of students from their own discipline.

Participants and Setting

Study data were collected at a major Canadian teaching hospital affiliated with the University of British Columbia, where students from nearly 100 health professions and medical subspecialties train in team contexts. Mixed-discipline team members on the 2 adult acute medicine clinical training units (total of 54 beds) were invited to participate between December 2018 and August 2019. In addition to the 4 pharmacists affiliated with these units, patient care is provided by 3 each of dietitians and physiotherapists and 2 each of occupational therapists and social workers. A speech language pathologist and a wound care nurse are accessible by consult. A roster of more than 50 nurses cover shifts, and 9 internists serve as the regular attending physicians. These clinical staff are exposed to many and varied health professional trainees in their day-to-day practice and often supervise workplace-based learning of students within their respective disciplines.

Training on this service is a core clerkship experience for students within several disciplines and medical subspecialties and may last a few weeks to several months, depending on the professional program. Pharmacy students from the University of British Columbia who join the acute medicine unit are in their fourth (and final) program year and are completing an 8-week inpatient clerkship. By this point, trainees will already have completed at least 20 weeks of experiential education over the prior 3 years. In any given month, team pharmacists may be supervising 1 to 3 pharmacist trainees in this clinical learning environment.

Data Collection

Consenting participants were drawn from a convenience sample of health professionals who had worked as part of the acute medicine team for 1 year or more, with purposeful sampling from the distinct disciplines to ensure a broad range of experiences. Information about the study and an invitation to participate were distributed by email by both the director of the acute medicine unit and discipline-specific department heads; in addition, posters advertising the study were positioned throughout the unit.

The semistructured interview guide was informed by the social constructivist perspective[16] and included questions exploring the *collaborator* role expectations that health professionals express for pharmacy students joining the team (Box 1). Two pilot interviews were performed to test the wording and length of the interview guide. The volunteers for these pilots were a nurse and a dietitian from another unit in the hospital; their interviews were not included in the data analysis reported here.

One researcher (K.W.) conducted all of the study interviews, which were audiorecorded and lasted on average 36 (range 28–41) minutes. These recordings were transcribed verbatim by a third-party service, and the transcriptions were verified and finalized by a research assistant and the same researcher (K.W.).

Data Analysis

The interview transcripts were subjected to template analysis, which involves the development of a coding "template" or summary of themes that the researchers derive from the data set.[17] Following repeated reading of and familiarization with the transcripts, open coding of the data was carried out by the interviewer (K.W.) and the research assistant, who worked independently to develop preliminary coding structures. The first author (K.W.) then developed an initial template derived from the open data-coding process, which was sensitized by a priori themes derived from *collaborator* roles previously described in pharmacy and interprofessional competency frameworks.[2,3] However, our coding template was developed according to how team members constructed these roles through actual experiences with pharmacy students in the practice curriculum.

The authors (K.W., T.P.) worked separately to analyze the first 3 interview transcripts and met to agree upon a common coding template. The subsequent interviews were coded by the first author. We practically exhausted the study population of eligible participants from certain health professions on the team (i.e., dietitians, occupational therapists). We sought enrolment of representatives from other health professions (1 nurse and 1 physician) to achieve informational redundancy (i.e., no new information to yield additional and distinct codes). We shared (through blinded group email) our finalized themes with participants, worked with them to select suitable supporting comments, and offered an opportunity for their further input before moving on to final data synthesis and interpretation. The authors maintained dialogue with each other throughout the analysis process to ensure consistent application of the coding template and to deliberate on interpretations of the data.

The first author (K.W.) is a pharmacist who previously provided inpatient team-based care and supervised pharmacist trainees and whose research now focuses on curriculum evaluation in practice settings. The second author (T.P.) is a pharmacist providing patient care at the study institution, who also coordinates undergraduate pharmacy student placements across the patient care units at this site.

Ethics approval was obtained from both the University of British Columbia Behavioural Ethics Review Board and the research institute that has operational jurisdiction over the tertiary care centre in question.

BOX 1. Semistructured Interview Guide

1.	How long have you been working in this particular team-care setting?
2.	Have or do you currently train students in your own profession?
3.	Do you work or remember working with pharmacy students training on this unit?
4.	What types of activities do you observe pharmacy students conducting on your unit?
5.	In what ways do you encounter and interact with pharmacy students?
6.	What are your expectations of pharmacy student communication during these encounters/interactions?
7.	What are your expectations of pharmacy student collaboration during these encounters/interactions?
8.	What are features of a "team-ready" pharmacist trainee?
9.	What are your expectations of a "team-ready" trainee from your own profession?
10.	Do you have anything you wish to add?

RESULTS

We interviewed 14 team members (3 dietitians, 3 nurses, 2 occupational therapists, 4 general internist physicians, 1 physiotherapist, 1 social worker), who reflected on their encounters with and the work of pharmacy students. The only male participants were 3 of the 4 white physicians. All others were white females, except for 2 Asian-Canadian females (a dietitian and an occupational therapist). All of the team members were experienced in supervising students from their own discipline who joined the unit to train, but had not necessarily formally participated as facilitators in IPE. Participants' descriptions of collaborative roles were

organized into 2 main themes: the pharmacy student as *informant* and the pharmacy student as a *bridge*. A third integrative theme, *engagement,* encompassed how team members described pharmacy students enacting these roles.

Informant

All study participants indicated that pharmacy students training on the unit were a source of medication information. This expertise was sought by participants across the various disciplines. For instance, nurses and dietitians often looked to pharmacy students for clarification about drug properties, such as compatibilities with concurrently administered medications or with nutritional feeds. Drug dosing and drug effects (e.g., interactions, adverse drug reactions) were particularly relevant to the care provided by nurses and physicians (medical students, residents, attending physicians). Collectively, participants were interested in patient-specific treatment updates relevant to discharge planning during multidisciplinary rounds.

Physician participants expressed broader expectations for the collaborative roles of pharmacy students. On this unit, the pharmacy students were expected to join the attending physician, residents, and medical students during bedside rounds and to actively contribute to decision-making. Pharmacy students were regularly viewed as extensions of the medical team who augmented the quality of care decisions. Physicians not only wanted information related to appropriate and evidence-based medication selection and dosing, but also relied upon pharmacy students' holistic view of the patient's drug therapy.

> One of the things I find really useful though is when the pharmacy student is using their expertise to independently identify the important issues and, um, instead of [only] being sort of a resource who I can ask or we can come to with specific questions, they come to me, like, "Have you thought about, you know, evidence-based therapy for heart failure in this person?" (Physician 2)

> I will kind of think of the pharmacy student as more of a closer part of the team, if that makes sense. Like physically attached to us in a way. Like where we are, they should be. (Physician 1)

Bridge

Other health professionals witnessed and capitalized upon the proximity to prescribers described by Physician 1 (see above). From this perspective, the collaborative pharmacy student tendered insight into physician plans and could often offer insight into the rationale underlying a plan. Team members were accustomed to such information-sharing by the pharmacists with whom they worked and projected this expectation onto the trainees under their colleagues' supervision.

> One thing that is really good is if it's a major medication change, they will go and say, "Hey, we changed this because.…" That really helps foster that sharing of knowledge, because the nurse won't necessarily know the rationale of why that happened. (Nurse 2)

Participants expressed greater confidence in the safety and appropriateness of drug therapy when pharmacy personnel were contributing to care. Team members also used the pharmacy student to dispatch or reinforce messages to prescribers. For example, nurses asked the pharmacy students to reiterate documented patient issues or concerns when decisions were being made during physician rounds.

Engagement

Although well acquainted with the professional role of pharmacy students, multidisciplinary team members participating in this study described various levels of engagement with these students on the unit. As previously described, they welcomed these learners in structured interprofessional settings (rounds), but their presence did not appear routine, and nonphysicians did not necessarily expect active participation.

> I have never been introduced to a pharmacy student. They just kind of show up, and you can tell they are a student because they talk less [laughs]. They just kind of sit there quietly. (Occupational Therapist 1)

Participants were pleased when pharmacy students actively sought their knowledge and patient assessment when recommending or monitoring drug therapy, but these were largely reported as anomalous encounters. Although information was freely exchanged for parallel practice, truly interdependent care involving pharmacy students seemed infrequent.

DISCUSSION

On an acute medicine clinical teaching unit where learners from many health professions train, it was reassuring to find that team members did not overlook pharmacy students' contributions to care. Their attendance at bedside and multidisciplinary rounds was recognized, and their drug information knowledge was being accessed. However, we found that descriptions and performance expectations of collaborative roles, especially among nonphysician participants, reflected limited actual engagement or interprofessional practice with pharmacy students.

The interactions with pharmacy students described by participants would not strictly qualify as defined episodes of shared care. Such interprofessional collaborations would entail reciprocal information transmission to jointly arrive

at decisions,[3,11] and these features were not evident from participant interviews. Conversely, the on-campus IPE curriculum is replete with exercises in which pharmacy students and diverse nonphysician trainees (e.g., dietitians, occupational and physical therapists, social workers) actively cooperate to prevent and resolve issues in simulated patient cases.[18] A gap between the formal IPE curriculum modelling interprofessional care and how collaborative skills for pharmacy students continue to develop in the actual clinical learning environment is apparent. In the following paragraphs, we consider the reasons underlying these findings and propose remedies that could be implemented in the hospital learning environment.

In practice, consistent opportunities for genuine sharing of care between team members and mixed-discipline learners can be thwarted by prioritization of competing demands and the limited time available to fulfill intradisciplinary roles.[19] Relationships facilitating cohesive teamwork among health professionals are built over time, and the relatively few weeks that pharmacy students are members of the team may not be sufficient.[20] Lack of interdependence in patient decision-making may also stem from learner relegation (benevolent or otherwise) to the periphery of practice by this community of acute medical care providers.[15] Indeed, although health professionals may readily affirm that their team constituents support common goals of providing safe and effective patient care, they may not view themselves as part of a wider teaching community of practice for pharmacy students or other learners outside their own professional discipline who train on the unit.[21]

Recognizing the untapped potential for interprofessional contributions to learners' training with teams, Stalmeijer and Varpio proposed a framework of Landscapes of Healthcare Practice (LoHCP), promoting "deliberate, intentional and guided boundary crossing".[22] The LoHCP framework aims to situate and reinforce health professional students' membership in a community of patient care (such as an inpatient team), with the students going on to develop interdisciplinary knowledge and a shared understanding of the community's goals, skill sets, conduct, and resources. In the same vein, our data showed how pharmacists on the care team might readily reinforce the developing collaborative care skill set of pharmacy students under their supervision in this particular clinical learning context. Specific examples to drive purposeful mixed-discipline engagement in the hospital care environment begin with the preceptor ritualizing the introduction of new pharmacy students to other team members when they join the patient care unit for training. Preceptors can require that pharmacy students provide an updated nursing assessment when presenting patient cases and explicitly demonstrate that they have identified and consulted relevant team members when proposing a drug therapy and associated monitoring plan. Preceptors may also help facilitate exercises whereby pharmacy students conduct joint patient history-taking or discharge counselling with other health professionals.[23] These interprofessional care assignments may be embedded as mandatory clerkship activities in the experiential curriculum as structured attempts to purposefully extend the design of multidisciplinary cooperation for on-campus IPE activities.

More challenging initiatives facilitating collaborative care and LoHCP may lie beyond those under the control of any individual supervisor or program, such as systems-level adoption of formal interprofessional models of clinical supervision or interprofessional-based clerkships. However, we recognize how the hospital pharmacy preceptor can adopt straightforward and effective strategies to promote integration of their pharmacy students into daily team-based care.[24,25] To optimize such efforts, further workplace-based study is needed to understand the joint care relationships between established team members and pharmacy students. Such inquiry would inevitably encompass the influences of the hospital pharmacist's own positionality on the team and the effects of these influences on the pharmacy students under their preceptorship.

Limitations

The perspectives of the mixed-discipline team members at this large teaching hospital may differ from those of health professionals who serve on teams caring for other inpatient or outpatient populations. Participants' stated collaborative expectations and interactions with pharmacy students may not reflect what might be recorded through direct observation of actual encounters on the unit. We studied collaborative care expectations and experiences with pharmacy students in practice to help inform potential local or discipline-specific changes to IPE; however, team members' interactions with learners from other professions and associated descriptions of collaborative roles may demonstrate greater consistency with authentic shared care.

CONCLUSION

In this study, the mixed-discipline team members' expectations of pharmacy students were bound to the provision of medication information and only infrequently progressed to shared decision-making. Physicians were more likely than others to collaborate with pharmacy students. Challenges to the development of collaborative care skills in the clinical learning environment were evident, but intentional interprofessional exercises assigned by clinical supervisors may support more frequent and more meaningful interactions with team members and promote the interdependent care that is modelled in campus-based IPE activities. Further workplace-based study remains necessary to understand the joint care relationships between established team members and pharmacy students and thus to optimize supervisor- and system-level initiatives.

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BRIEF RESEARCH REPORT

Neonatal Abstinence Syndrome: A Review of Treatment in the Neonatal Intensive Care Unit

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ABSTRACT

Background: Neonatal abstinence syndrome (NAS) is a collection of symptoms that neonates may experience following antenatal exposure to substances that induce withdrawal. Optimal management remains unknown, and there is variation in management and outcomes.

Objectives: To describe the management, length of hospitalization, and adverse events in near-term and full-term neonates with NAS for whom treatment (pharmacotherapy and/or supportive care) was initiated in the neonatal intensive care unit (NICU).

Methods: A chart review was conducted of neonates admitted to the NICU of Surrey Memorial Hospital, Surrey, British Columbia, who received treatment for NAS between September 1, 2016, and September 1, 2021.

Results: A total of 48 neonates met the inclusion criteria. Opioids represented the most frequent type of antenatal exposure. Polysubstance exposures occurred in 45 (94%) of the neonates. Morphine was given to 29 (60%) of the neonates, and phenobarbital to 6 (13%); 5 of these neonates received both medications. The average duration of morphine treatment was 14 days, and the average length of hospitalization (all patients) was 16 days. All of the neonates experienced adverse events; in particular, 9 (30%) of the 30 who received pharmacotherapy were too sedated to feed, compared with 0% of the 18 with no pharmacotherapy.

Conclusions: The common finding of polysubstance antenatal exposure, involving predominantly opioids, was associated with scheduled morphine pharmacotherapy for the majority of patients, prolonged hospitalization, and frequent adverse events. Pharmacotherapy for NAS was associated with levels of sedation that interfered with feeding in neonates.

Keywords: neonatal abstinence syndrome, withdrawal, morphine, phenobarbital, neonatal intensive care

RÉSUMÉ

Contexte : Le syndrome d'abstinence néonatale (SAN) est un ensemble de symptômes que les nouveau-nés peuvent ressentir après une exposition prénatale à des substances qui induisent le sevrage. La prise en charge optimale reste inconnue et il existe des variations quant à la prise en charge et les résultats.

Objectifs : Décrire la prise en charge, la durée de l'hospitalisation et les événements indésirables chez les nouveau-nés prématurés et nés à terme atteints d'un SAN pour lesquels un traitement (pharmacothérapie et/ou soins de soutien) a été initié dans l'unité de soins intensifs néonatals (USIN).

Méthodes : Un examen des dossiers a été effectué sur les nouveau-nés admis à l'USIN de Surrey Memorial Hospital, en Surrey (Colombie-Britannique) qui ont reçu un traitement pour le SAN entre le 1er septembre 2016 et le 1er septembre 2021.

Résultats : Au total, 48 nouveau-nés répondaient aux critères d'inclusion. Les opioïdes représentaient le type d'exposition prénatale le plus fréquent. Des polyexpositions étaient présentes chez 45 (94 %) des nouveau-nés. De la morphine a été administrée à 29 (60 %) nouveau-nés et du phénobarbital à 6 (13 %) nouveau-nés, 5 ayant reçu les deux médicaments. La durée moyenne du traitement morphinique était de 14 jours et la durée moyenne d'hospitalisation (tous patients confondus) était de 16 jours. Tous les nouveau-nés ont présenté des événements indésirables; en particulier, 9 (30 %) des 30 qui avaient reçu une pharmacothérapie n'étaient pas capables de se nourrir à cause de la sédation, contre 0 % des 18 n'ayant pas reçu de pharmacothérapie.

Conclusions : La découverte commune d'une exposition prénatale à plusieurs substances, impliquant principalement des opioïdes, était associée à une pharmacothérapie programmée à base de morphine pour la majorité des patients, à une hospitalisation prolongée et à des événements indésirables fréquents. La pharmacothérapie était associée à des niveaux de sédation empêchant l'alimentation.

Mots-clés : syndrome d'abstinence néonatale, sevrage, morphine, phénobarbital, réanimation néonatale

INTRODUCTION

The incidence of perinatal opioid use disorder has increased 3-fold in the past decade, paralleling the magnitude of the opioid crisis in the general population.[1] Consequently, the incidence of neonatal abstinence syndrome (NAS) has nearly doubled, from 2.6 per 1000 live births in 2010 to 4.7 per 1000 live births in 2018.[2] NAS is a constellation of symptoms that a neonate may experience following antenatal exposure to substances that induce withdrawal. Symptoms vary in severity and include neurologic, gastrointestinal, and musculoskeletal effects. Substances implicated in NAS include opioids, stimulants, and other psychotropics.[3] The goal of NAS management is to use supportive care and

pharmacologic interventions to promote physiologic stability, including adequate nutrition, sleep, weight gain, and ocialization.[4]

A scoring tool is generally used to quantify symptom burden and guide pharmacotherapy in patients with NAS.[5] The Finnegan Neonatal Abstinence Scoring System (FNASS)[6] has been adopted and subsequently modified by many groups around the world since its introduction in 1975.[3,5,7] Subsequent variants, including the tool used in the NICU of Surrey Memorial Hospital (SMH), have modified the original criteria and overall score in attempts to quantify NAS symptoms and to reflect changes in practice. However, the criteria remain subjective, and the recommended score of 8 or more to initiate pharmacotherapy remains unchanged, despite changes to the total possible score.[1,7,8] These scoring systems may therefore overestimate symptom severity, which can lead to inappropriate introduction, escalation, and duration of pharmacotherapy. A simplified tool introduced in 2017 by Grossman and others[9] emphasizes caregiver involvement and supportive care through assessment of symptoms of withdrawal according to 3 items: the infant's ability to eat, sleep, and be consoled. Use of this tool reduced the length of hospitalization, the number of NICU admissions, and the provision of pharmacotherapy relative to the use of FNASS in the pre-intervention period.[9]

To date, no standard assessment or optimal treatment strategy for NAS has been described in the literature. In the NICU, pharmacologic therapies often prevail, including morphine for opioid exposures and phenobarbital or clonidine for non-opioid or polysubstance exposures.[10] Because NAS is a self-limiting withdrawal process, many perinatal units across North America, including the NICU at SMH, have begun to shift the focus of management from pharmacotherapy to supportive care. Therefore, the purpose of this study was to describe management, length of hospitalization, and adverse events in near-term and full-term neonates with NAS in the NICU.

METHODS

Ethics approval for this review was obtained from the Fraser Health Research Ethics Board.

Neonates who received treatment for NAS in the 36-bed NICU of SMH between September 1, 2016, and September 1, 2021, were identified from a list of inpatient neonatal prescriptions for morphine, phenobarbital, and zidovudine. In this NICU, clonidine was not used as a treatment for NAS during the study period. Historically, the majority of neonates with NAS presenting to the SMH NICU have been born to mothers with ongoing use of illicit substances and high-risk behaviours. Therefore, zidovudine treatment in the NICU was used to identify neonates from high-risk pregnancies where the neonate might have received supportive care alone for management of NAS.

The inclusion criteria for the study required that neonates have a diagnosis of NAS documented by the medical team, with receipt of treatment for NAS (including pharmacotherapy and/or supportive care) in the SMH NICU during the study period. Neonates who needed only supportive care for management of NAS were included to determine the proportion of patients requiring pharmacologic treatment, as well as to determine adverse effects associated with pharmacologic treatment. Neonates for whom pharmacotherapy for NAS was initiated outside the SMH NICU did not meet the inclusion criteria, as treatment strategies vary among sites. Neonates of gestational age less than 35 weeks were excluded, because preterm neonates have different behaviours, as well as different needs for pharmacotherapy, and the scoring systems have not been validated in this population. Neonates were also excluded if they had significant comorbidity compromising interpretation of NAS scoring or if the child died before 7 days of age.

Confirmation of NAS was based on documented symptoms consistent with NAS, along with maternal history of medication and substance use near the time of delivery or, if such maternal history was suspected but not available, a positive result on neonatal drug screening. Management of NAS was at the discretion of the clinical team providing care, based on neonatal withdrawal symptoms, including but not limited to their FNASS scores. The team provided supportive care or supportive care plus regular and/or as-needed medications. Assessment of each neonate by the clinical team occurred at least twice daily, nursing observations occurred at least hourly, and FNASS scores were documented every 2 to 4 hours.

The following demographic data were collected: gestational age, birth weight, Apgar score, assigned sex, prenatal care, hypoglycemia, respiratory support at birth, other neonatal medications, substance exposures in utero, year of admission, length of hospitalization, and duration of NICU admission. The following data concerning treatment regimen were also collected: daily dosing information for morphine and phenobarbital and breast milk exposure in the first 3 days of life. The modified FNASS used in the SMH NICU assesses 21 criteria, with the maximum possible score being 46. It is identical with the 2012 modified FNASS of the American Academy of Pediatrics,[3] with the addition of a score for "excoriation" as its own category at SMH. Data collected for assessment of efficacy included highest total daily FNASS score and neurologic and gastrointestinal scores from the same time point. Safety was assessed in terms of the following events, as documented by the nurse or physician caring for the patient: respiratory rate less than 30/min, systolic blood pressure less than 60 mm Hg, heart rate less than 100/min, requirement for respiratory support, being too sedated to feed, and other adverse reactions. Neonates were described as being too sedated to feed when nursing notes documented that feeding was attempted by

nursing staff or caregivers and oversedation resulted in ineffective or unsafe feeding.

Descriptive statistics were used to analyze the data. All treatment regimens were converted to milligrams per kilogram (mg/kg) according to birth weight. Safety data were analyzed for the duration of pharmacotherapy (or 14 days for untreated neonates). The Fisher exact test was used to determine the statistical significance of different rates of adverse events between treated and untreated groups.

RESULTS

A total of 103 patients were identified for review. Nineteen of these patients did not meet the inclusion criteria (because there was no NAS diagnosis or because the neonate received treatment at another site), which left 84 patients treated for NAS in the NICU at SMH over the 5-year period, or 3.5 per 1000 live births. This group did not include neonates with NAS managed outside the SMH NICU. Thirty-six additional patients were then excluded for the following reasons: gestational age less than 35 weeks (n = 31), significant comorbidity (n = 3), and death before 7 days of age (n = 2). Thus, a total of 48 patients were included for data collection and analysis.

The average gestational age was 37 weeks, and the average birth weight was 2886 g (Table 1). The most common antenatal substance exposure was opioids (n = 41, 85%) (Table 1), and 45 (94%) of the neonates had polysubstance exposures. Twenty-nine neonates (60%) received morphine therapy (5 of whom also received phenobarbital), 1 (2%) received phenobarbital monotherapy, and 18 (38%) received no pharmacotherapy for NAS.

For the 29 neonates who received morphine, this drug was initiated on day 1 to 3 of life; the dosage was from 0.03 to 0.05 mg/kg every 3 hours for 25 (86%) of these neonates and from 0.01 to 0.04 mg/kg as needed for 4 neonates (14%). The average cumulative morphine dose (total morphine exposure within the treatment period) was 2.6 (range 0.3–6.1) mg/kg. The average number of scheduled morphine doses per patient was 93 (range 0–222), and the average number of as-needed doses was 3 (range 0–17). The average duration of morphine pharmacotherapy was 14 (range 6–28) days, including an average of 8 days for scheduled morphine taper to discontinuation. Neonates transferred out of the NICU before morphine discontinuation had a longer duration of therapy (20 days) than those not transferred out (12 days). Average cumulative and peak morphine doses decreased in the years 2017 and 2020 (Figure 1).

Six (13%) of the neonates received phenobarbital as needed, initiated on day 2 to 7 of life, with cumulative doses ranging from 10 to 62 mg/kg. The average duration of therapy was 5 (range 2–11) days. Of these 6 neonates, 4 had known polysubstance exposure in addition to concurrent morphine therapy, whereas the other 2 had either polysubstance exposure or concurrent morphine therapy.

For the 29 neonates who received morphine, the average FNASS score at morphine initiation for each year from 2016 to 2021 was 16, 13, 16, 14, 18, and 16, respectively (Figure 1). The average score at initiation of morphine tapering

TABLE 1. Characteristics of Patients and Substance Exposure

Characteristic	Mean (Range) or No. (%) of Patients (n = 48)
Patient	
Gestational age (weeks)	37 (35–42)
Birth weight (g)	2886 (1620–3825)
Apgar score at 5 minutes	9 (6–10)
Sex, female	33 (69)
Parent received prenatal care	8 (17)
Experienced hypoglycemic event	10 (21)
Received any feeds with parent's own milk	10 (21)
Required respiratory support at birth	20 (42)
Received HIV prophylaxis	38 (79)
Received antibiotics	25 (52)
Substance exposure in utero	
Opioids	41 (85)
Fentanyl	25 (52)
Heroin	26 (54)
Methadone	24 (50)
Other (oxycodone, hydromorphone, or buprenorphine)	3 (6)
Amphetamines	35 (73)
Nicotine	24 (50)
Cocaine	15 (31)
Cannabis	10 (21)
Benzodiazepines	6 (13)
SSRI or SNRI	5 (10)
Alcohol	4 (8)
Gabapentin	1 (2)
Barbiturates	0 (0)
Tricyclic antidepressants	0 (0)

SNRI = serotonin–norepinephrine reuptake inhibitor, SSRI = selective serotonin reuptake inhibitor.

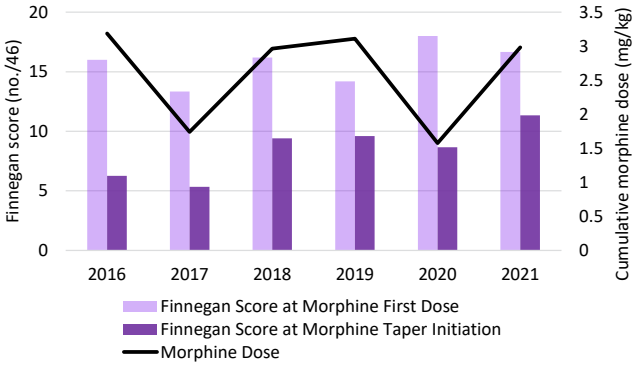

FIGURE 1. Mean score with the Finnegan Neonatal Abstinence Scoring System (FNASS) and morphine use (as cumulative dose per patient), by year (n = 29 neonates who received morphine). The modified FNASS used in the Surrey Memorial Hospital neonatal intensive care unit assesses 21 criteria, and the maximum possible score is 46.

increased over the study period, from 6 in 2016 to 11 in 2021 (Figure 1). Of the 18 neonates who received no pharmacotherapy, 14 were assessed using FNASS, with an average score of 7 (range 0–17) on day 2 of life.

The average length of hospitalization for each year from 2016 to 2021 was 22, 13, 17, 14, 11, and 19 days, respectively. The overall average for the entire study period was 16 days.

All 48 neonates experienced a minimum of 1 adverse event. The rate of bradypnea was 93% (28/30) among those who received pharmacotherapy and 100% (18/18) among those with no pharmacotherapy (p = 0.52); no neonates in either group required respiratory support. The rate of hypotension was 10% (3/30) and 22% (4/18), respectively (p = 0.40), and the rate of bradycardia was 10% (3/30) and 6% (1/18), respectively (p > 0.99). Nine (30%) of the neonates who received pharmacotherapy were too sedated to feed, compared with none (0%) of those not receiving pharmacotherapy (p = 0.018). The average number of adverse events per patient was 1 among those who received no morphine (0 mg/kg), 6 among those with cumulative morphine dose between 0.1 and 2 mg/kg, and 15 among those with cumulative morphine dose between 3.6 and 6.1 mg/kg. The average number of adverse events per patient was 3 among those with cumulative phenobarbital dose between 10 and 17 mg/kg and 7 among those with cumulative phenobarbital dose between 31 and 62 mg/kg.

DISCUSSION

In this study, management of NAS with pharmacotherapy (especially regularly scheduled morphine, 0.03 to 0.05 mg/kg orally every 3 hours), led to unanticipated sedation, whereby 30% of neonates who received pharmacotherapy, compared with 0% who received no pharmacotherapy, were too compromised to feed. Oversedation may be related to a prolonged half-life in neonates and accumulation of morphine when administered routinely every 3 hours.

The occurrence of other adverse events, including bradypnea and absence of respiratory support, was similar between the groups that did and did not receive pharmacotherapy. Perhaps the definitions of bradypnea, bradycardia, and hypotension used in this study were not sensitive enough to identify a difference between groups, given hemodynamic variability in the early neonatal period. Sedation also precedes respiratory depression, so it is possible that the neonates in this study did not reach an opioid level associated with respiratory depression requiring respiratory support. Additionally, Hocker and others[11] have hypothesized that neonates may develop tolerance to respiratory depression after in utero exposure to maternal opioids.

Overall, in this study, as the cumulative dose of pharmacotherapeutic agents increased, so did the incidence of adverse events associated with both morphine and phenobarbital. Similarly, DeAtley and others[12] reported that a higher initial dosing regimen of morphine (0.06 mg/kg) was linked to oversedation events, necessitating dose adjustment.

Phenobarbital is being used more conservatively at SMH than has been reported in the literature. As-needed doses were used for 13% of neonates in this study, whereas Merhar and others[4] reported adjunctive phenobarbital therapy for 32% of neonates, despite polysubstance exposures being less prevalent in their study than at SMH, ranging from 55% to 72%, compared with 94% in this study. The cumulative doses of 10 to 62 mg/kg that we observed were also significantly lower than what was reported in several other studies, which used regularly scheduled doses ranging from 2.5 to 12.5 mg/kg/day, with phenobarbital therapy often continuing after discharge for an average duration of up to 3.8 months.[4,13-15]

The length of hospitalization in our study was 16 days, much longer than the 6 days reported by Grossman and others.[9] Differences in study populations may have contributed to the prolonged hospitalization that we observed. First, substance exposures in the previous study involved primarily methadone,[9] with fewer polysubstance exposures than in the SMH population (33% versus 94%). Second, on average, the neonates described by Grossman and others[9] had older gestational age than those at SMH (38.9 weeks versus 37 weeks). Gestational age can affect the interpretation of NAS symptoms, as preterm neonates exhibit different behaviours from full-term neonates, which may influence management. Third, the population described by Grossman and others[9] included non-NICU patients, who may receive more frequent supportive care while rooming-in with parents after birth, possibly reducing the need for pharmacologic intervention.

Scheduled morphine therapy requires dose tapering before discharge; therefore, exposure and hospitalization are prolonged. In our study, the average time required to taper morphine was more than 50% of the total duration of morphine treatment. If regularly scheduled morphine is used, a faster taper, such as 10% up to 3 times daily (as suggested by Grossman and others[9]), should be considered, instead of the prolonged historical weaning process of 10% every 24 to 48 hours.

Education plays a role in supporting practice changes, and ongoing education is required as staff rosters change continually. In 2017, 2019, and 2020, presentations were delivered to SMH NICU staff to introduce and reinforce an emphasis on supportive care and limiting morphine use, which appeared to temporarily affect management. Additionally, supportive care may have been limited in 2020 and 2021 because of the burden of the COVID-19 pandemic and restricted NICU access. This situation may have contributed to a larger cumulative morphine dose and longer hospitalization in 2021.

Some limitations of this study include the small sample size and our retrospective interpretation of outcomes.

Neonates born to mothers with no recent high-risk activity and a diagnosis of NAS, who required only supportive care in the NICU, would have been missed by our selection process. On average, 8 near-term and full-term patients per year were admitted to the NICU for NAS management. Observed trends in FNASS, pharmacotherapy dosing, and length of hospitalization may have been influenced by the small sample size. The high rate of polysubstance exposures, the average gestational age, and the rates of breastfeeding are unique to SMH, and differences in these characteristics should be considered when these results are applied to other populations. Finally, the retrospective analysis made it difficult to interpret the clinical status of neonates, given our reliance on documented nursing and physician assessments.

CONCLUSION

Morphine and phenobarbital were used for pharmacologic management in 60% and 13% of neonates, respectively. The number of adverse events increased as cumulative pharmacotherapy doses increased. Current management using regularly scheduled morphine led to prolonged pharmacotherapy and a high rate of accumulation, with 30% of neonates being too sedated to feed. Opportunities exist to emphasize supportive care and use pharmacotherapy as needed, instead of on a scheduled basis, to reduce adverse events and length of hospitalization.

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Considering Sex and Gender in Therapeutics throughout the Product Life Cycle: A Narrative Review and Case Study of Gilteritinib

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ABSTRACT

Background: Biological sex–related factors influence pharmacokinetic, pharmacodynamic, and disease processes that may affect the predictability of drug dosing and adverse effects, which may in turn have clinical consequences for patients' lives. Nonetheless, sex-related factors are not always taken into account in clinical trial design or clinical decision-making, for multiple reasons, including a paucity of studies that clearly and objectively study and measure sex-disaggregated and sex-related outcomes, as well as gaps in regulatory and policy structures for integrating these considerations.

Objectives: To complete a narrative review and use a case study to understand available evidence, inform future research, and provide policy considerations that incorporate information on sex- and gender-related factors into clinician-facing resources.

Methods: A comprehensive review of available literature was conducted using a sex- and gender-based analysis plus (SGBA Plus) approach to identify sex- and/or gender-disaggregated information for gilteritinib, a chemotherapeutic agent. Systematic searches were performed in MEDLINE (Ovid), Embase (Ovid), CENTRAL (Wiley), International Pharmaceutical Abstracts (Ovid), Scopus, and ClinicalTrials.gov, from inception to March 18, 2021. The information was then summarized and compared with the Canadian product monograph for this drug.

Results: Of 311 records screened, 3 provided SGBA Plus information as a component of outcomes, rather than just as categories or demographic characteristics. Of these, 2 were case studies, and 1 was a clinical trial. No studies from the ClinicalTrials.gov database that were in progress at the time of this review provided details about sex-disaggregated outcomes. The Canadian product monograph did not include sex-disaggregated outcome data.

Conclusions: The available evidence from clinical trials, other published literature, and guidance documents does not provide details about sex-disaggregated outcomes for gilteritinib. This paucity of available evidence may create a challenge for clinicians who are making decisions about the efficacy and safety of prescribed therapies in sex-specific populations that have not been well studied.

Keywords: sex-related factors, oncology, knowledge translation, sex- and gender-based analysis Plus (SGBA Plus, SGBA+), drug management

RÉSUMÉ

Contexte : Les facteurs liés au sexe biologique influencent les processus pharmacocinétiques, pharmacodynamiques et pathologiques, qui peuvent avoir une incidence sur la prévisibilité du dosage des médicaments et des effets indésirables. Ceci peut à son tour avoir des conséquences cliniques sur la vie des patients. Néanmoins, les facteurs liés au sexe ne sont pas toujours pris en compte dans la conception des essais cliniques ou la prise de décision clinique, et cela pour de nombreuses raisons – notamment le manque d'études qui examinent et mesurent clairement et objectivement les résultats ventilés par sexe et liés au sexe ainsi que les lacunes dans les réglementations et structures politiques pour intégrer ces considérations.

Objectifs : Mener un examen narratif et utiliser une étude de cas pour comprendre les preuves disponibles, éclairer les recherches futures et fournir des considérations politiques qui intègrent des informations sur les facteurs liés au sexe et au genre dans les ressources destinées aux cliniciens.

Méthodes : Une revue complète de la littérature disponible a été réalisée à l'aide d'une analyse comparative fondée sur le sexe et le genre Plus (ACSG Plus) pour identifier les informations ventilées par sexe et/ou par genre pour le giltéritinib, un agent chimiothérapeutique. Des recherches systématiques ont été effectuées dans MEDLINE (Ovid), Embase (Ovid), CENTRAL (Wiley), International Pharmaceutical Abstracts (Ovid), Scopus et ClinicalTrials.gov, depuis la création de chaque base de données jusqu'au 18 mars 2021. Ces informations ont ensuite été résumées et comparées avec la monographie canadienne de produit pharmaceutique pour ce médicament.

Résultats : Sur les 311 documents examinés, 3 ont fourni des informations ACSG Plus en tant que composante des résultats, plutôt que simplement en tant que catégories ou caractéristiques démographiques. Parmi ceux-ci, 2 étaient des études de cas et 1 était un essai clinique. Aucune étude de la base de données ClinicalTrials.gov en cours au moment de cette revue n'a fourni de détails sur les résultats ventilés par sexe. La monographie de produit canadienne ne comprenait pas de données sur les résultats ventilées par sexe.

Conclusions : Les preuves disponibles issues d'essais cliniques, d'autres publications et de documents d'orientation ne fournissent pas de détails sur les résultats ventilés par sexe pour le giltéritinib. Ce manque d'éléments probants disponibles peut constituer un défi pour les cliniciens qui prennent des décisions sur l'efficacité et l'innocuité des thérapies prescrites chez des populations sexospécifiques qui n'ont pas été bien étudiées.

Mots-clés : facteurs liés au sexe, oncologie, application des connaissances, analyse comparative fondée sur le sexe et le genre Plus (ACSG Plus, ACSG+), gestion des médicaments

INTRODUCTION

There is evidence that biological sex-related factors influence pharmacokinetics, pharmacodynamics, disease processes, and response to therapeutic agents.[1] More specifically, pharmacokinetic and pharmacodynamic evidence shows sex-related biological variations in gastrointestinal motility, gastric pH, and enzymatic activity, which can affect the absorption and bioavailability of oral medications.[1] Examples of therapeutic variability by sex include reduced absorption of metoprolol and verapamil due to prolonged gastrointestinal transit time for females relative to males and reduced renal clearance of some antimicrobials, such as fluoroquinolones and cephalosporins, in females relative to males.[1]

Furthermore, a relationship between sex and drug metabolism exists for most of the major cytochrome P450 (CYP450) enzymes. Cytochrome P450 isozymes, such as CYP1A2, CYP2C9, CYP2C19, and CYP2D6, appear to be more active in males, whereas CYP3A4 is more active in females.[2] This difference is important to consider, given that CYP3A4 is the major CYP450 isozyme in the gastrointestinal tract and liver[2] and that it is responsible for the metabolism of more than half of all medicines, including oncology medications such as gilteritinib.[3] These processes are highly relevant to investigating molecular features that may act as drivers in various types of cancer.[4]

A component of understanding the effect of sex and gender on therapeutics is assessing the effect of a medication's efficacy and safety on clinical outcomes and the effect of biological sex on disease distribution. In the case of leukemia, for which gilteritinib is predominantly studied, the biological sex of an individual confers a risk for development of disease with an excess risk of acute myeloid leukemia (AML) in males who are very young or elderly and a U-shaped distribution of sex-related differences in the epidemiologic presentation.[5] Studies have shown that sex-specific mutations, such as the *fms*-like tyrosine kinase 3 internal tandem duplication (*FLT3*-ITD), and other important marker mutations may be overexpressed in females.[6,7] *FLT3* is the target for agents such as gilteritinib. A recent study examined 4 patient cohorts, focusing on sex and *FLT3* mutation status in the sex differences related to clinical parameters.[6] Multiple allelic mutations and variations may be associated with drug sensitivity and survival, with sex-associated molecular differences being prevalent in the AML population with *FLT3*-ITD mutations.[7] Based on this evidence, it is likely that sex-specific considerations could potentially affect prognostication, prediction, and therapeutic strategies in AML.[7]

Despite this knowledge, sex-related factors are not often taken into account in clinical trial design or clinical decision-making, in part because of the paucity of studies that clearly and objectively measure a range of sex-related outcomes. Furthermore, the lack of available evidence regarding the effect of sex- and/or gender-related factors on therapeutics limits clinicians' ability to determine whether differences in pharmacokinetic properties lead to significant effects on clinical factors such as drug efficacy and safety. A lack of evidence pertaining to sex- or gender-related factors in a tertiary reference, such as a product monograph, can prevent a clinician from accurately applying evidence to all patients. The clinician may often have to depend on the experts who synthesize the evidence into a usable tertiary reference to assist in constructing sex- and/or gender-related interpretations. Key questions that clinicians might ask of tertiary references that could affect their interpretation of the reference include the following:

- Was sex-related outcome information collected in the conduct of preclinical and clinical trials or in other literature that informs the tertiary reference being used for clinical decision-making?
- Has such information on sex-related outcomes been reviewed in the knowledge synthesis process, and if so, has it been determined nonsignificant to the clinical decision-making process?

In the current review, we applied these questions to the pharmacist's role in caring for patients with cancer. The pharmacist is often involved with reviewing medication regimens, educating patients and caregivers about therapies, titrating dosages, monitoring, mitigating drug interactions and drug–disease interactions, and providing information and education to members of the health care team about medications used in cancer care.[8] To make the best clinical decisions, pharmacists reviewing oncology medication regimens require information about various target populations, such as males and females with reproductive potential; pregnant, lactating, pediatric, or geriatric populations; racialized/ethnic groups; gender-diverse individuals; or other underresearched populations. However, if sex-related information was not considered, other than descriptive statistics based on demographic characteristics in trials,[9] then the full understanding and effect of sex-related factors on different aspects of therapeutics, such as adverse effects or therapeutic efficacy, may be limited. It is important to note a paucity in the primary literature itself that may lead to a different interpretation of the strength of the evidence informing the knowledge synthesis in a product monograph.

To gather further evidence about the inclusion of sex and gender in therapeutic interpretation, we conducted a comprehensive review of available literature using a sex- and gender-based analysis plus (SGBA Plus) approach to identify evidence related to sex and gender in the life cycle of a prescription drug, which includes premarketing, clinical trial, review and approvals, and postmarketing pharmacovigilance phases. In our review, sex- and/or gender-disaggregated information incorporates sex as a biological variable and gender as a sociocultural variable.[10]

The SGBA Plus approach involves assessing data, policies, and/or programs for differential effects on diverse groups of females, males, men, women, and gender-diverse people. Gilteritinib was selected to understand how SGBA Plus has been integrated into the assessment of a recently approved drug in Canada. This review summarizes published literature and clinical trials related to gilteritinib that discuss sex-, gender-, or equity-related factors; it also provides details on various sex-related outcomes defined a priori. We compared this with public information from Health Canada, including the available contents of the drug product monograph in the Drug Product Database. Drawing upon our findings, we make recommendations for future research and policy considerations that incorporate SGBA Plus into clinician-facing resources, such as product monographs.

METHODS

Search Strategy

A search of the literature was completed to identify potentially relevant studies. An experienced health sciences librarian (M.-L.L.) designed the search, using a combination of subject terms and keywords, which was then translated for each database. Systematic searches were performed in MEDLINE (Ovid), Embase (Ovid), CENTRAL (Wiley), International Pharmaceutical Abstracts (Ovid), Scopus, and ClinicalTrials.gov, from inception to March 18, 2021. The MEDLINE search can be found in Appendix 1 (available from https://www.cjhp-online.ca/index.php/cjhp/issue/view/215), and all strategies are available upon request to the corresponding author. Identified studies were deduplicated in EndNote (version X9). Studies were indexed in COVIDENCE for review by a single individual (M.M.). A secondary search of the ClinicalTrials.gov database was performed on July 15, 2021, to ensure that all clinical trials still in progress and those that had begun since March 2021 were considered for inclusion. Screening of this literature was performed by the same reviewer.

Inclusion Criteria

Literature on clinical trials review, submission review, monitoring, intervention, and pharmacovigilance studies was included. All study designs (case–control, case report, case series, cohort studies, cross-sectional studies, correlational studies, interrupted time series, mixed methods, qualitative, randomized trials, and systematic reviews or meta-analyses, where the primary focus is on an aspect of the life-cycle management of drugs) were considered, as were in-progress studies indexed in the ClinicalTrials.gov database that included sex-disaggregated outcomes defined a priori. Pharmacokinetic and pharmacodynamic trials with SGBA Plus commentary, as well as phase 1, 2, or 3 and postmarketing trials that included SGBA Plus commentary, were also included.

Exclusion Criteria

The following materials were excluded: literature focused primarily on cost, budget, or cost analysis; abstracts that did not specifically mention gilteritinib; book chapters; in vitro trials; conference abstracts, presentations, and posters; editorials, commentaries, perspective articles, and opinion pieces; literature focused primarily on the theory behind mechanisms of action; studies that did not include sex, gender, or SGBA Plus commentary; clinical trial protocols that did not describe a focus on sex-disaggregated outcomes (outcomes related to males, females, women, men, sex, gender, pregnancy, lactation analysis of sex-related factors, or information related to gender); and studies unavailable in the English language.

RESULTS

After removal of duplicates, there were 311 unique studies, for which titles and abstracts were screened against the exclusion criteria. Of these, 187 were excluded for various reasons (see Figure 1). The remaining 124 studies underwent full-text review, which resulted in exclusion of an additional 121 articles (see Figure 1).

Therefore, of all articles screened, only 3 included information related to sex as a component of outcomes, rather than just as categories or demographic characteristics, and none included information regarding gender. Figure 1 incorporates the PRISMA diagram for the case study search process. None of the studies from the ClinicalTrials.gov database that were enrolling participants at the time of the initial search provided details about sex-disaggregated outcomes, and the secondary search of this database, performed on July 15, 2021, yielded only 3 additional trials, none of which met the inclusion criteria.

SGBA Plus Literature Review of Gilteritinib

Of the 3 included studies, one was a case report of acute macular neuroretinopathy associated with gilteritinib in a 28-year-old female, with improvement in the scotoma and optical coherence tomography 3 months after gilteritinib was switched to azacitidine and midostaurin.[11] Another case report described Sweet syndrome in a 55-year-old female who presented with neutrophilic dermatosis after 4 weeks of gilteritinib therapy for AML.[12] The patient was started on prednisone but experienced flare with tapering. The gilteritinib was eventually stopped because of nonresponse and the drug's potential contribution to the Sweet syndrome flare. The patient died shortly afterward, secondary to disease progression and complications of sepsis.[12] The third included study aimed to investigate the clinical benefit of gilteritinib in the treatment of relapsed or refractory *FLT3*-mutated AML in a randomized trial comparing gilteritinib with conventional salvage chemotherapy regimens, also known as the ADMIRAL trial.[13] In the ADMIRAL trial,

females accounted for 53% of participants in the gilteritinib arm and 56.5% in the salvage chemotherapy arm. An analysis of overall survival looked at sex-disaggregated outcomes related to the hazard ratio for death between gilteritinib and salvage chemotherapy, based on the number of events relative to the total number of patients enrolled in each arm. The findings showed that males in the gilteritinib arm experienced fewer events than males in the chemotherapy arm, but this result was not statistically significant. Similarly, females in the gilteritinib arm experienced fewer events than females in the chemotherapy arm, with this being a statistically significant outcome. Reported adverse events and response to therapy were not sex-disaggregated. We reviewed the supplementary material for any further outcome data that were sex-related but found none.

SGBA Plus of the Product Monograph

The overall project (from which the current article is derived) is described in a report entitled *Risk Reviewed: Integrating Sex and Gender into the Lifecycle Management of Prescription Drugs*.[14] The project reviewed the processes for approval, regulation, and monitoring of prescription drugs in Canada, with a view to understanding how sex- and gender-related factors are considered in their life-cycle

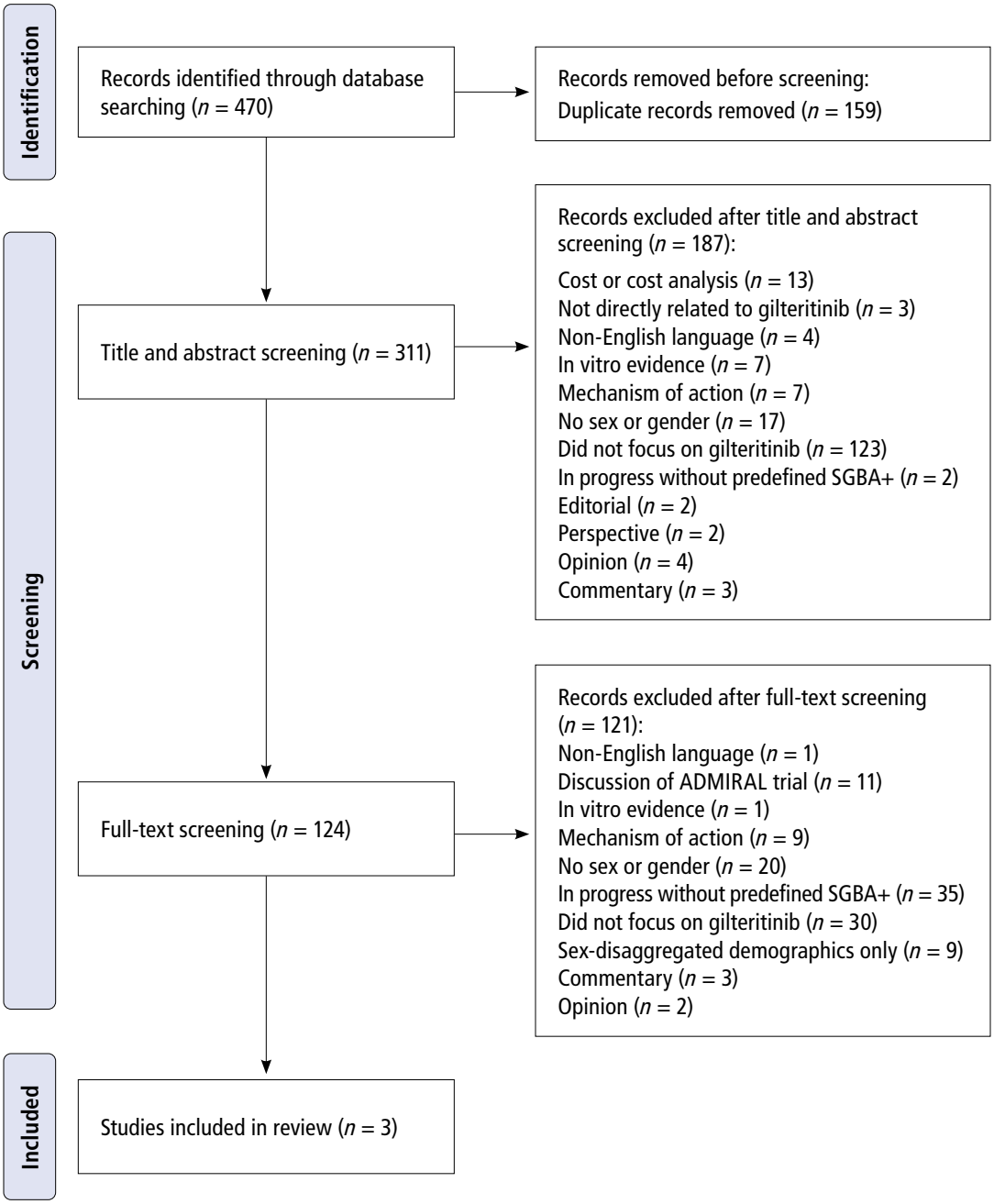

FIGURE 1. PRISMA diagram for case study. SGBA+ = sex- and gender-based analysis Plus approach.

management. A component of this project focused on a case study of gilteritinib, for which a review of the product monograph was conducted.

The product monograph is a resource that is commonly accessed by clinicians. A survey of Quebec community and hospital pharmacists in 1987 indicated that the *Compendium of Pharmaceuticals and Specialties* (*CPS*), which contains Canadian product monographs, was one of the resources most frequently found in community and hospital pharmacies.[15] A 2014 study intended to identify how clinicians obtain information about dry mouth in pharmaceutical products included the *CPS* in the referenced databases, and the authors of the study noted that at least 40% of medication monographs were included in this resource.[16] Finally, the Canadian Drug Product Database, which includes medications authorized for sale by Health Canada, is a comprehensive and freely accessible database of product monographs, which clinicians can use as a tertiary reference for drug information related to medications, such as gilteritinib. We assessed this popular resource for the present case study of gilteritinib, and areas where information was present, absent, or unclear are discussed below.

General Sex-Based Considerations

The product monograph for gilteritinib[17] includes data from the ADMIRAL study. Sex was mentioned as a demographic descriptor, with the monograph noting that 47.0 % of participants were male and 53.0% female in the gilteritinib arm versus 43.5% male and 56.5% female in the chemotherapy arm. However, sex-disaggregated outcomes and further SGBA Plus analyses were not provided. The sex-disaggregated outcomes from the ADMIRAL trial, noted above, were not discussed in the monograph.[17]

Evidence for Pregnancy and Lactation

The sections of the product monograph that discuss pregnancy and lactation note that there is no available evidence regarding human pregnancy or human milk, the drug-associated risk of adverse developmental outcome(s), or pharmacokinetics/pharmacodynamics. However, the monograph includes some data from animal studies, in which administration of gilteritinib to pregnant rats caused embryo and fetal deaths and suppressed fetal growth at exposures below the exposure that occurs in patients receiving the recommended dose based on the nonclinical toxicology section[17]; in addition, gilteritinib and/or its metabolite(s) were distributed to the tissues of infant rats through the dams' milk. On the basis of these animal data, the monograph concludes that because of the potential for fetal and offspring exposure to gilteritinib and serious adverse reactions, this agent is to be avoided in pregnancy and lactation. Although the product monograph provides important safety parameters recommending against use of the drug in pregnancy and lactation, supporting references for the chosen timeline for avoidance of pregnancy or breastfeeding after cessation of gilteritinib are not provided.

Patient Information

The section of the monograph dealing with patient medication information mentioned that use of effective birth control is needed while taking gilteritinib and for 6 months after stopping this medication; however, there was no mention of why 6 months is the chosen timeline. This section did suggest that male patients should use condoms during sex while under treatment and for 4 months after stopping gilteritinib. Again, although the information in the product monograph provided parameters for safety, there was no explanation for the timelines chosen.

DISCUSSION

A range of pharmacokinetic and pharmacodynamic sex-related factors support an argument for ensuring that manufacturers consider and include information regarding the efficacy, safety, and tolerability of medications and that regulators apply a comprehensive SGBA Plus approach during approval processes for prescription drugs. For example, according to the product monograph for gilteritinib, this agent can be administered with or without food; however, concomitant food intake delays absorption. Considering sex differences in absorption of medications, the difference in delayed absorption with food may be more significant in females; however, sex-disaggregated data are unavailable to support or refute this hypothesis. Furthermore, according to the pharmacokinetic profile of gilteritinib, this drug is primarily metabolized through the CYP3A4 isozyme.[17] Hence, sex-related considerations regarding drug interactions and metabolism should be taken into account in sex-disaggregated outcomes and in product information.

Despite Canadian guidance documents, such as *Considerations for Inclusion of Women in Clinical Trials and Analysis of Sex Differences*,[18] the availability of evidence from clinical trials to allow an analysis on sex-related factors is limited. Most clinical trial designs are limited to recording and reporting participant sex simply as a demographic characteristic. Indeed, some of the studies excluded from our review reported the sex of participants without further analyses regarding outcomes. If sex is not considered as a category of analysis, sex-disaggregated outcomes cannot be provided in the published literature. Similarly, none of the studies indexed in the ClinicalTrials.gov database had a prior plan for analyses that include sex disaggregation of the outcomes or any other sex-related factors, such as those involved in the pharmacokinetic/pharmacodynamic processes related to the cytochrome P450 pathway. Our review of the literature yielded only 3 studies providing sex-disaggregated outcomes: 2 case reports of adverse drug events in female patients and a large, randomized trial (the

ADMIRAL study). Although case reports do not provide amalgamated evidence on trends for efficacy and safety, each one adds to the available evidence for whether sex-related factors matter in postmarket use of a drug and can potentially inspire questions for assessment through post-marketing pharmacovigilance.

Although a policy of the National Institutes of Health (US) requires the inclusion of women and minorities as participants in clinical research[19] and provides information on how to report results and conduct subgroup analyses based on sex, only 1 clinical trial identified in our search met the inclusion criteria for this review. The other included studies were case reports of adverse reactions. Furthermore, stratification of most outcomes by sex was not presented in either the ADMIRAL study or its supplementary material, creating a void of information regarding the potential effect on clinical decision-making. Whether or not the outcomes were statistically significant, the information might have been clinically significant. This paucity makes it even more important for regulators to ask for such data in submission review processes.

For clinician-facing resources, such as product monographs,[17] information related to sex-disaggregated outcomes is typically not available, nor are references to the primary literature listed in the monographs, which prevents further review by pharmacists, physicians, other health care professionals, and research scientists. Although the recommendations set forth in the monograph for gilteritinib may be reasonable in terms of the risk associated with an oncology medication in females and males with reproductive potential, the primary references are not provided. In practice, recommendations about the use of medications in special populations, such as patients who are pregnant or breastfeeding, are usually based on expert opinion informed by available pharmacokinetic data and evidence extrapolated from animal models. Including such references in the product monograph could help clinicians in better understanding and providing clinical support regarding the evidence about fertility, pregnancy, and lactation to patients with reproductive potential who are being considered for therapy with gilteritinib.

Limitations

The literature was systematically reviewed by a single pharmacist reviewer. In addition, the literature about gilteritinib could be indexed under a different name (such as a preclinical drug reference name), and such information might not have been found in our search. The lack of referencing in the product monograph limited our ability to cross-reference information in the monograph with any further relevant studies. Lastly, grey literature (unpublished reports, conference abstracts, theses or dissertations, preprint servers, and other internet or print reports and resources)[20] was used for context, but was not examined in detail in this review because of our focus on acquiring evidence for sex- and gender-related outcome measures in the published literature that would be considered by regulatory bodies for purposes of evaluation and eligibility for marketing.

Recommendations

On the basis of our review of the literature and information available in the product monograph for gilteritinib,[17] we make the following recommendations to Health Canada for its consideration of SGBA Plus in the drug approval process for this drug and others:

- Require that product monographs include references for recommendations and supporting studies.
- Note the paucity of evidence related to sex-disaggregated data in the primary literature used to support the review and approval processes for the medication.
- State possible effects based on general pharmacokinetic and pharmacodynamic considerations, where available.
- Clarify whether sex-disaggregated outcomes are present or absent for a medication.
- Require that manufacturers submit information related to SGBA Plus to the regulator.
- Provide a section on the Health Canada website where SGBA Plus commentary for approved medications can be accessed, to improve review processes by scientists, clinicians, and interested consumers.

CONCLUSION

Although a growing body of knowledge illustrates the importance of understanding and incorporating sex-related pharmacokinetic and pharmacodynamic factors into clinical decision-making related to drug therapies, evidence from clinical trials, research literature, and guidance documents does not typically integrate this knowledge or provide details about sex-disaggregated outcomes. This situation results in a paucity of available data regarding sex-related outcomes in the primary literature. The emblematic case study summarized here illustrates this paucity for a specific medication and the subsequent lack of SGBA Plus analyses that can potentiate suboptimal prescribing or differences in drug efficacy and safety, where sex- or gender-based differences exist for certain medications. An SGBA Plus review of other medications would provide further evidence of the generalizability of our conclusions. Drug regulators could make changes to assist in the clinical interpretation of drug monographs, to facilitate more sex-sensitive and sex-specific care and treatment.

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Hospital Pharmacy Contribution to COVID-19 Vaccination Rollout in Rural Communities

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INTRODUCTION

Vaccination is a key strategy to protect against coronavirus disease 2019 (COVID-19). In December 2020, Ontario started its COVID-19 vaccination rollout, beginning with the Pfizer-BioNTech COVID-19 vaccine. A phased approach was implemented to prioritize individuals at the greatest risk of severe disease.[1] This approach was also used for booster doses. Hospital clinics and mass immunization clinics were some of the earlier settings for vaccine administration. As the vaccination rollout evolved, more COVID-19 vaccines and administration channels became available.

The storage and handling requirements for the Pfizer-BioNTech COVID-19 vaccine posed many operational challenges. The lack of ultra-low-temperature freezers, the difficulty of transporting vaccines across large geographic areas, and the scarcity of health human resources were particularly difficult for rural communities to tackle in the initial stage of the rollout.[2] Leveraging staff pharmacists' and pharmacy technicians' expertise in medication management and their skills in administering injections, the Pharmacy Department of the Norfolk General Hospital (NGH), in Simcoe, Ontario, pivoted quickly to address these challenges and support local vaccination efforts across the counties of Haldimand and Norfolk.

DESCRIPTION OF THE PROGRAM

The NGH is a community hospital that provides a range of clinical services to the more than 64 000 residents of Norfolk County. This hospital shares several members of the management team, including the director of pharmacy, with West Haldimand General Hospital (WHGH), a rural hospital serving the nearly 46 000 people of Haldimand County, which includes a larger proportion of Indigenous peoples, such as the Six Nations of the Grand River and the Mississaugas of the New Credit First Nations, compared with Norfolk County. With consideration of space, equipment, and health human resources, NGH and its Pharmacy Department were identified as being better equipped to be the primary hospital partner, collaborating with Haldimand Norfolk Health Unit (HNHU) on the vaccination campaign to serve approximately 110 000 residents over an area of about 2900 km^2.

The NGH became a designated vaccine delivery site, following the Pharmacy Department's purchase of an ultra-low-temperature freezer at the beginning of 2021. From then until June 2022, the Pharmacy Department dedicated 1.2 full-time equivalent pharmacy technicians (out of a total of 6 on staff) to COVID-19 vaccine–related tasks; the then-director of pharmacy (K.W.L.) and the hospital's clinical pharmacists also took on additional duties during that time.

Receipt, Storage, and Transport of COVID-19 Vaccines

The NGH received its first shipment of Pfizer-BioNTech COVID-19 vaccine in the second week of January 2021. With input from the NGH Purchasing Department, Maintenance Department, and security personnel, pharmacy staff prepared a standard operating procedure in alignment with the product monograph and Ontario's *General COVID-19: Vaccine Storage and Handling Guidance*.[2] This procedure ensured timely notification of shipment arrival, secure movement to the storage location, and proper placement into storage equipment without causing temperature excursions.

Furthermore, the Pharmacy Department played an integral role in the transport of Pfizer-BioNTech COVID-19 vaccines across the catchment area of HNHU. Pharmacy staff championed the training of external partners, such as paramedics and staff at congregate living settings, on cold chain and vaccine transport. In addition to transferring vials from one storage condition to another and securely packing them to avoid potential agitation during transport by the external partners, pharmacy staff were heavily involved in logistics, coordinating with HNHU for just-in-time delivery of vaccines in a frozen state on the morning of each clinic day.

Hospital On-Site Vaccination Clinic

After supporting the immunization of older adults in congregate living settings, such as long-term care and retirement homes, with their first doses, NGH opened

its vaccination clinic in the third week of February 2021. Before this launch, internal and external stakeholder meetings were held to review clinic flow, infection prevention measures, and other operational requirements, including repurposing of hospital offices and conference rooms. The director of pharmacy was responsible for management of the vaccine inventory and later oversaw the entire operation of the clinic.

The clinic was typically staffed with 3 registration clerks, 5 immunizers, and 1 pharmacy technician. The pharmacy technician, paired with 1 immunizer to perform an independent double check, prepared COVID-19 vaccines in unit-dose syringes twice daily, before clinic opening and in the early afternoon, according to the vaccine shelf-life, the number of appointments, the potential for cancellations, and possible no-shows. Different colours of syringe labels were used to differentiate the various vaccines and dosages.

Through a temporary amendment of Ontario Regulation 107/96, pharmacy professionals, among others, were able to administer COVID-19 vaccines in selected settings.[3] This led to an expansion of the pool of immunizers from nurses to include pharmacists and pharmacy technicians.

Vaccination of Inpatients

On inpatient units, clinical pharmacists helped identify patients eligible for COVID-19 vaccines; they also answered vaccine-related questions from other health care providers. Upon receiving an order, a pharmacist confirmed the dose, especially in the case of the Moderna COVID-19 vaccine, for which the dose varies according to a multitude of factors, such as age, immunocompetency, and previous COVID-19 vaccination history. Then, the pharmacist relayed the information to the mobile vaccination team to organize vaccine administration.

Off-Site Vaccination Clinics

The NGH Pharmacy Department also assisted other vaccination clinics in various ways. Hospital leaders, including the director of pharmacy, were part of a logistics working group led by HNHU, which participated in the dry run for the mass immunization clinic in Dunnville, Ontario. In addition, pharmacy staff worked at several mass immunization clinics across Haldimand–Norfolk and helped with vaccine preparation at specialized clinics for Indigenous persons organized at and with partners on the reserve. Finally, pharmacy staff, working with HNHU staff, supported a pop-up clinic held at WHGH for immunization of hospital workers.

EVALUATION OF THE PROGRAM

As of June 24, 2022, the number of doses of various COVID-19 vaccines administered across Haldimand–Norfolk was approximately 214 000. The NGH Pharmacy Department participated in the transfer of vaccine supplies for the majority of those doses, given that it was involved in transferring all of the Pfizer-BioNTech vaccines. Vaccines were transferred from NGH to its own vaccination clinic, HNHU-led mass immunization clinics, local physician and primary care offices, and local pharmacies, where the quantities desired were less than the distributor's minimum of 10 vials per order. No instances of temperature excursion were reported at any stage of the transport process.

The NGH vaccination clinic operated 5 days per week from its inception until its closure on June 24, 2022, with a temporary reduction in hours (to 3 days per week) in September and October 2021, when community vaccine demand was at its lowest. Occasional weekend pop-up clinics were held to ensure local access to vaccines in early 2021. On average, the daily throughput was nearly the maximum feasible, at 300 doses, decreasing only when community demand declined. Throughput was limited primarily by the space of the post-vaccination monitoring area, to allow for 15-minute monitoring and safe physical distancing.

In 2021, a total of 51 548 doses were administered, with 202 doses (0.39%) wasted. Most wastage occurred during the "Last Mile Strategy" in fall 2021, which aimed to increase vaccine uptake among individuals not yet fully vaccinated and in communities with a low overall vaccination rate. In Haldimand–Norfolk, local vaccination coverage increased steadily in the early months of the vaccination campaign, and uptake for subsequent doses was generally slower (Figure 1). The NGH vaccination clinic supported the administration of all eligible doses to eligible populations during its time open (Table 1). The established process involving clinical pharmacists allowed for the timely provision of primary series and booster doses of COVID-19 vaccines to inpatients and hospital staff members. Although no formal evaluation was conducted, the tone of feedback received from partners, hospital staff, and the community was overwhelmingly positive.

IMPLICATIONS AND SIGNIFICANCE FOR PRACTICE

The rollout of COVID-19 vaccines across Ontario has required collaborative engagement of health care providers from all levels of care and from all public health units. Hospital pharmacies are uniquely positioned to take on a critical role in this pandemic response, given hospital pharmacists' and pharmacy technicians' knowledge and skills in cold chain management, sterile compounding, medication safety, and inventory management. The NGH Pharmacy Department filled the gaps in local rural communities by offering the above-mentioned expertise to launch and sustain the vaccination campaign with HNHU.

As local health human resources became more strained, pharmacists and pharmacy technicians at NGH

further supported vaccination clinics through administration of COVID-19 vaccines. Normally, the scope of practice of pharmacy professionals can be affected by their practice setting; the vaccines that pharmacy professionals can administer are also strictly specified. To address these potential barriers, a temporary amendment to Ontario Regulation 107/96 was issued, allowing pharmacy professionals to administer COVID-19 vaccines that would otherwise be out of scope.[3] The inclusion of pharmacy professionals in the immunizer pool increased system capacity for the local vaccination rollout. Based on this experience, discussions were underway at NGH and WHGH, at the time this manuscript was submitted (in late spring 2022), to explore the inclusion of pharmacists in the medical

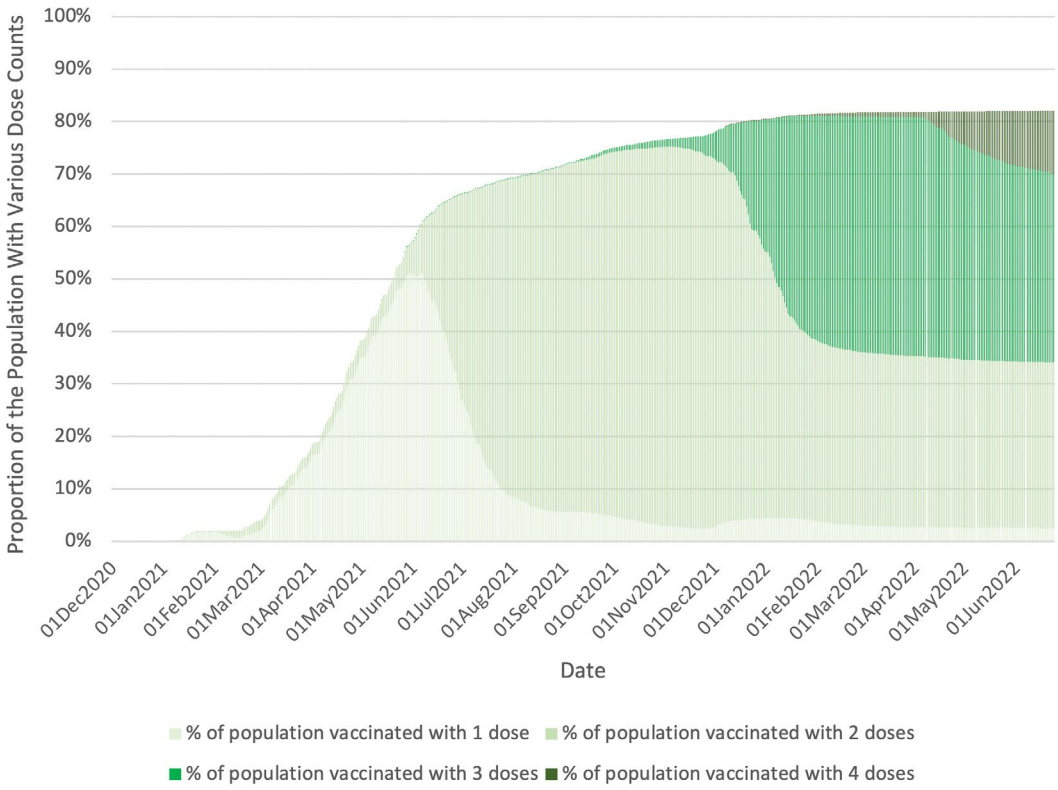

FIGURE 1. Vaccination coverage rates in the catchment area of Haldimand Norfolk Health Unit from initiation of Ontario vaccination program in December 2020 to June 24, 2022.

TABLE 1. Vaccine Product Types Available at Norfolk General Hospital (NGH) Vaccination Clinic and Respective Eligibility Considerations, Labelling Practices, and Number of Doses Administered (as of June 24, 2022)

Vaccine Type	Eligible Population[4]	Label Colour	No. of Doses Administered
Pfizer-BioNTech COVID-19 vaccine			
For those 12 years of age or older	Any individual ≥ 12 years of age, any dose number[a]	White	52 066
For those 5–11 years of age	Individuals 5–11 years of age, 2-dose primary series only	Pink	1 245
Moderna COVID-19 vaccine			4 125[b]
100 µg	Individuals ≥ 18 years of age (Pfizer preference for individuals < 30 years); primary series doses or doses for immunocompromised or those aged ≥ 70 years for any dose number	Green	
50 µg	Individuals ≥ 18 years of age (Pfizer preference for individuals < 30 years); booster doses only for those with sufficient immune status and < 70 years	Yellow	
Total no. of doses administered at NGH			57 436

[a]Initial rollout was phased.
[b]The number of doses of Moderna COVID-19 vaccine could not be split according to dose (100 versus 50 µg) because of database capacity and varying eligibility criteria.

directive for administration of influenza vaccines to hospital staff as a way to ensure sustainability of the annual hospital influenza vaccine campaign, given local health human resources challenges.

CONCLUSION

Overall, pharmacists and pharmacy technicians can greatly contribute to public health through disease prevention and control, specifically by means of vaccine administration.[5] Such a contribution was observed during the COVID-19 pandemic, when pharmacy professionals used their skill set to contribute to the success of the vaccination rollout. To build system capacity and drive positive public health outcomes, actions in the forms of developing medical directives or making policy changes at the level of individual hospitals or, preferably, government should be considered to allow pharmacy professionals across all settings to practise to their full scope, as well as to allow expansion of the specific vaccines that pharmacy professionals can administer.

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Positive Effects of an Escape Room Game on Members of a Pharmacy Department

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INTRODUCTION

Serious gaming is used for purposes other than entertainment, such as teaching and continuing education, and can help to improve knowledge acquisition and to enhance cognitive or technical skills.[1,2] In recent years, escape games have been increasingly exploited for educational purposes, especially in professional settings and university pharmacy programs.[3-8] In a university pharmacy program, escape rooms can be used for training second- and third-year students to address various clinical situations (e.g., diseases/conditions such as diabetes, cancer, or heart failure; activities such as nonsterile compounding).[6-11] However, to the authors' knowledge, only 2 studies have evaluated the effects of escape games on hospital pharmacists and pharmacy technicians.[12,13]

In a fun context, escape games allow for the development of essential team skills such as communication, listening, and leadership. To take advantage of this trend, an escape game was created as a special event for the department of pharmacy of the Centre hospitalier de l'Université de Montréal. The goal of this study was to determine whether the activity had any effect on participants' knowledge about their colleagues, their happiness at work, their feeling of belonging to the department, and the translation of skills (communication, listening, logic, leadership, deduction, teamwork) from the game to "real life".

DESCRIPTION OF THE ESCAPE GAME

An escape room game was specially created and set up for members of the pharmacy department of a 772-bed academic hospital. A pharmacy student (A.M.) spent a total of 11 hours writing the scenario, creating the puzzles and riddles, setting up the game materials, and preparing some tests to validate the activity. The escape room used classic mechanisms related to this type of game: chests and 3-digit padlocks, a complex success code, an ultraviolet lamp, and objects to be inserted into specially designed supports.

The game was divided into 5 parts: arrival of participants and determination of the game objective (to open the nurse's coded computer session in final part of the game); solving the first puzzle to open chest 1; placing petri dishes to open a second room; deciphering symbols (runes and numbers) in a fictitious patient's file to open chest 2; and collecting the 15 pieces of the final puzzle and solving it to get out of the second room (for more detail, see Table 1). The game included elements related to infectious diseases and cardiology to provide a context like that of a hospital. However, the observation and logic challenges were not intended for participants to acquire knowledge about these clinical topics.

In teams of 4, the participants had to solve a series of riddles related to a fictitious medical case within a 25-minute period after a short briefing. Each team was allowed to receive up to 3 clues. The pharmacy student supervised the event for a total of 8.25 hours; supervision consisted of preparing for and monitoring each game and resetting the game rooms after completion of each game. The escape room events took place in the morning or afternoon over a period of 3 days in February 2020. After the activity, participants were asked to complete a written 6-question survey (Table 2).

EVALUATION OF THE ACTIVITY

A total of 51 people participated in the escape room game, representing 20% of the 258 members of the department (pharmacists, technicians, and administrative staff, as well as residents and students). Responses to the questionnaire are shown in Table 2.

The activity was appreciated by all participants, with a mean global appreciation rating of 9.34 on a scale of 1 to 10. All participants stated that they would retry an activity like this at work. The 25-minute escape room experience resulted in a moderate increase in happiness at work and a feeling of belonging to the pharmacy department (reported by 86% and 73% of participants, respectively). Two-thirds (67%) of the participants felt they knew their coworkers better after the escape room game. More than 40% of the players believed they would transfer skills used during the game to their work. Communication, listening,

and logic were the 3 skills most likely to be transferred into professional life (reported by 33%, 24%, and 27% of participants, respectively).

IMPLICATIONS AND SIGNIFICANCE FOR PRACTICE

Over the past decade, escape room games have become more popular for educational purposes in health care, and they have been adapted for undergraduate students in several health care disciplines, such as pharmacy, nursing, and medicine.[1,14] Outside this context, escape room games are rarely used in health care or professional settings such as hospitals.[15] To the authors' knowledge, this study is the third to describe an escape room exercise involving a population of pharmacists, technicians, and administrative staff in a professional pharmacy environment. Given the heterogeneous population, the objective of this activity was slightly different from escape rooms in educational settings and did not include the transmission of knowledge. The collegial and entertainment nature of the escape room allows employees to build motivation and engagement while developing teamwork and communication.[14] These activities have been proposed by some private employers for team building among their workers.

In this context, the escape room was offered during work hours to members of our department and students. The activity led to a moderate increase in happiness at work and a feeling of belonging to the pharmacy department for about three-quarters of participants. These 2 factors are important for employee retention, even more so in a pandemic context. Happiness at work affects not only the engagement and satisfaction of individual staff members, but also the patient experience, quality of care, patient safety, and organizational performance.[16]

CONCLUSION

In the pharmacy department of an academic centre, an escape room game had a positive impact on participants' knowledge of their coworkers, their happiness at work, their feeling of belonging to the department, and the translation of skills. To our knowledge, this is the first study to show increases in level of happiness at work and the feeling of belonging after participation in an escape room game.

TABLE 1. Parts and Activities of the Escape Game

Part of Game	Activities
1. Briefing, followed by participants' entrance into first room	Start of the game: Pieces of information (notes, a fictitious patient file) are present in the first room to help participants deduce the objective of the game, which was to open the nurse's coded computer session to escape the second room (part 5 of the game, below). The fictitious patient's medical record includes 3 runes (see part 4 of the game, below).
2. Solve the first puzzle to open chest 1	Riddle 1: Street art image representing a heart and a hand, accompanied by numbers, appears on a second computer. Search for hidden clues: Find 3 petri dishes positioned in the first room, with images of 3 bacteria of interest in infectious diseases. Three hidden coloured cubes, each with a fragment related to the street art image, indicate where participants are to place the petri dishes. Solve puzzle 1: Players must deduce the combination of 3 numbers related to the street art image. Open chest 1 with 3-digit padlock: Chest 1 contains 7 Valentine's Day puzzle cards, a small pocket UV lamp (false clue), and one of the missing pages from the patient's medical file (the infectious diseases page, with clues about the petri dishes [i.e., the puzzle of part 3 of the game, below]).
3. Position the petri dishes correctly to open the second room	Riddle 2: Placement of the 3 petri dishes on the 3 coloured cubes according to information on the infectious diseases page of the patient's file. Access to the second room: A visible and audible signal is emitted to participants to notify them that the second room has been opened.
4. Decode symbols (runes and numbers) in the fictitious patient file to open chest 2	Riddle 3: Find the conversion table hidden in the second room, which allows participants to convert the 3 runes into 3 numbers. Open chest 2 with 3-digit padlock: Chest 2 contains 4 Valentine's Day puzzle cards and another missing page from the patient's medical file (the cardiology page).
5. Collect the 15 pieces of the puzzle and solve it to escape from the second room	Collect and complete the puzzle: A total of 15 pieces are hidden in the first room (4), chest 1 (7), and chest 2 (4). Riddle 4: Inscription on 13 of the 15 pieces of the puzzle refers to Tako-tsubo (a fictitious patient illness) and the resolution of the final riddle with the elements of the periodic table (Ta, Co, Ts, B, and O). Riddle 5: Conversion of the 5 elements of the periodic table into a 9-digit code is required to open the nurse's coded computer session and finish the activity.

UV = ultraviolet.

TABLE 2. Results of Questionnaire Distributed to Participants

Question	Staff Pharmacists (*n* = 17)	Technicians and Administrative Staff (*n* = 21)	Pharmacy Residents and Students (*n* = 13)	Total (*n* = 51)
Q1: Global appreciation of the activity, on a scale of 1 (not appreciated at all) to 10 (appreciated a lot)	9.29 ± 0.92	9.25 ± 0.85	9.46 ± 0.78	9.34 ± 0.85
Q2A: Did this activity increase your happiness at work? (0 = no, 1 = yes)	15 (88)	16 (76)	13 (100)	44 (86)
Q2B: If yes, how would you rate this increase, on a scale of 1 (a little) to 5 (great)?	3.1 ± 1.2	3.6 ± 1.1	4.2 ± 0.7	3.7 ± 1.0
Q3A: Did this activity increase your feeling of belonging to the pharmacy department? (0 = no, 1 = yes)	13 (76)	13 (62)	11 (85)	37 (73)
Q3B: If yes, how would you rate this increase, on a scale 1 (a little) to 5 (great)?	2.6 ± 1.3	3.4 ± 1.0	3.2 ± 1.4	3.1 ± 1.2
Q4: Did this activity increase your knowledge of coworkers? (0 = no, 1 = yes)	9 (53)	16 (76)	9 (69)	34 (67)
Q5: After the activity, did you transfer skills used during the game to your work?[a]				
Communication	2 (12)	9 (43)	6 (46)	17 (33)
Listening	0 (0)	8 (38)	4 (31)	12 (24)
Logic	2 (12)	7 (33)	5 (38)	14 (27)
Leadership	1 (6)	4 (19)	2 (15)	7 (14)
Deduction	1 (6)	5 (24)	3 (23)	9 (18)
Teamwork	0 (0)	2 (10)	0 (0)	2 (4)
Understanding of other co-workers	1 (6)	0 (0)	0 (0)	1 (2)
Absence of skill transfers	14 (82)	11 (52)	5 (38)	30 (59)
Q6: Will you retry an activity like this one at work?	17 (100)	21 (100)	13 (100)	51 (100)

[a]Respondents could choose more than 1 option.

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Gestion de l'interaction entre le tacrolimus et le nirmatrelvir/ritonavir dans le traitement de la COVID-19 en transplantation d'organe solide

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INTRODUCTION

La population ayant reçu une transplantation d'organe solide (TOS) est davantage à risque de complications, d'hospitalisations et de mortalité liées à la maladie à coronavirus 2019 (COVID-19)[1]. Les premières séries de cas décrivent un taux de mortalité de 16 % parmi les patients ayant développé des symptômes[1]. Malgré l'arrivée de la vaccination, le risque de complication demeure élevé, en partie à cause d'une réponse immunitaire aux vaccins sous-optimale et d'une diminution de la clairance virale pour cette population[2-5]. Les traitements précoces qui empêchent la réplication du virus et peuvent prévenir les complications reliées à la COVID-19 deviennent ainsi particulièrement intéressants. L'immunosuppression sévère causée par la médication antirejet nécessaire à la suite d'une TOS est d'ailleurs un critère d'admissibilité aux différents traitements disponibles à l'heure actuelle au Québec[6-8]. De ce lot, seul le nirmatrelvir/ritonavir s'administre par voie orale. Toutefois, le ritonavir est, entre autres, un inhibiteur puissant des isoenzymes du cytochrome P450, dont le 3A4 (CYP3A4), ainsi que de la glycoprotéine-P. Ces inhibitions causent des interactions avec les traitements immunosuppresseurs, tels que le tacrolimus, le sirolimus ou la cyclosporine[9]. Une augmentation non négligeable de leur biodisponibilité et de leur clairance est observée[9]. Puisque ces médicaments sont considérés à dose critique, des différences de concentration sanguines peuvent entraîner des réactions indésirables graves ou des échecs thérapeutiques[10]. Nous rapportons ici un cas d'utilisation de nirmatrelvir/ritonavir pour le traitement de la COVID-19 d'un patient prenant du tacrolimus pour la prévention du rejet en TOS.

DESCRIPTION DU CAS

Un patient de 45 ans ayant reçu une transplantation cardiaque il y a 8 ans a contacté la clinique de transplantation cardiaque en mentionnant avoir, depuis 48 heures, des symptômes compatibles avec la COVID-19*. Un test antigénique rapide a été effectué dont le résultat était positif. Le patient avait reçu une primo-vaccination, soit deux doses complètes, ainsi que deux doses de rappel de vaccin à ARN messager contre la COVID-19, la dernière depuis plus de 14 jours. Son traitement immunosuppressif se composait de mycophénolate sodique 360 mg deux fois par jour et de tacrolimus 5 mg le matin et 4,5 mg le soir pour un dosage pré-dose cible d'environ 6 à 7 µg/L. La plus récente créatinine sérique était de 133 µmol/L (valeurs usuelles de la personne : 130 à 150 µmol/L) et le dosage sanguin de tacrolimus de 7,4 µg/L. Aucun épisode de rejet du greffon n'avait été répertorié depuis la greffe pour ce patient. Devant l'impossibilité d'administrer des traitements intraveineux rapidement à la suite de l'appel, le nirmatrelvir/ritonavir a été prescrit à dose ajustée selon un débit de filtration glomérulaire d'environ 40 mL/min/1,73 m^2, soit 150 mg/100 mg de nirmatrelvir/ritonavir deux fois par jour pendant 5 jours. Le traitement fut commencé environ 72 heures après le début des symptômes. Le tacrolimus a été suspendu durant les 5 jours de traitement avec le nirmatrelvir/ritonavir. La dose de mycophénolate sodique n'a pas été modifiée. Un prélèvement sanguin avant la dose de tacrolimus a été fait le jour 4 du traitement de nirmatrelvir/ritonavir, puis les jours 10, 12 et 18. Le tableau 1 présente les résultats de ces dosages en relation avec les doses quotidiennes de tacrolimus. Le dosage du jour 4 est demeuré dans les cibles thérapeutiques usuelles du patient, tout comme la créatinine. Le tacrolimus a été repris au jour 5 en soirée, soit 12 heures après l'arrêt du nirmatrelvir/ritonavir, à 60 % de la dose usuelle pour 48 heures, puis augmentée à 85 % de la dose usuelle jusqu'à l'obtention du dosage subséquent. Au jour 10, le résultat du dosage sanguin de tacrolimus fut de 18,6 µg/L et la créatinine de 284 µmol/L. En raison d'un dosage suprathérapeutique, le tacrolimus a été suspendu pour 2 doses, puis repris à 60 % de la dose usuelle jusqu'au prochain dosage prévu. Au jour 12, le résultat de dosage de tacrolimus fut revenu dans

*Le consentement écrit du patient a été obtenu.

TABLEAU 1. Évolution des doses, des dosages sanguins de tacrolimus et de la créatinine

	Dose quotidienne tacrolimus (mg matin/mg soir)[a]	Dosage sanguin tacrolimus (µg/L)	Créatinine (µmol/L)
J -127	5/4,5	7,4	133
Début nirmatrelvir/ritonavir en soirée	0		
J +4	0	8,7	156
J +5 – Fin nirmatrelvir/ritonavir au matin	0/3		
J +6	3/3		
J +7	3/3		
J +8	4/4		
J +9	4/4		
J +10	4/0	18,6	284
J +11	0/2		
J +12	3/3	7	153
J +13	3/4		
J +14	5/4		
J +18	5/4,5	5,3	117

J = premier jour du traitement.
[a] La dose quotidienne de tacrolimus indiquée au tableau est poursuivie à chaque jour jusqu'à modification. Les résultats des dosages sanguins sont obtenus en journée avec modification de la dose du soir si nécessaire.

les valeurs cibles et la créatinine vers les valeurs usuelles du patient. Le tacrolimus a été augmenté à 95 % de la dose quotidienne habituelle. À la suite du dosage du jour 18 de tacrolimus et de la créatinine, la dose fut augmentée à nouveau à la dose usuelle du patient. Durant toute la durée de suivi, aucun signe et symptôme de rejet du greffon n'a été noté. Les symptômes de la COVID-19 se sont résolus à la suite de la prise du nirmatrelvir/ritonavir sans nécessiter d'intervention supplémentaire. Outre des nausées et de la dysgueusie, le traitement fut complété et toléré.

DISCUSSION

Le ritonavir inhibe de façon irréversible le CYP3A4[11,12]. Suivant la fin du traitement, la fonction de ces enzymes prend quelques jours avant de revenir à la normale[11,12]. L'exposition totale des inhibiteurs de la calcineurine, mesurée par l'aire sous la courbe, lors de l'utilisation de ritonavir augmente de 5,8 fois pour la cyclosporine et de 57 fois pour le tacrolimus[13]. Des données provenant de patients traités contre l'hépatite C ayant subi une transplantation hépatique et devant recevoir un traitement à base de ritonavir suggèrent que la dose de cyclosporine doit être réduite à 20 % de la dose quotidienne et celle de tacrolimus réduite à 0,5 mg en prise hebdomadaire[13,14]. Des modèles pharmacocinétiques estiment que le CYP3A4 ne retrouve qu'entre 70 et 90 % de sa fonction de base entre les jours 3 et 5 suivant l'arrêt du ritonavir 100 mg pris deux fois par jour, selon l'âge du patient[12]. Bien que l'utilisation concomitante du nirmatrelvir/ritonavir et du tacrolimus ne soit pas formellement contre-indiquée par la monographie du produit, le risque de surexposition avec cette combinaison est bien réel[15]. Certains auteurs ont proposé un algorithme afin de guider l'utilisation concomitante de nirmatrelvir/ritonavir et d'un inhibiteur de la calcineurine[16]. La conduite du cas présenté a été basée sur leur recommandation de suspendre le tacrolimus pendant le traitement de nirmatrelvir/ritonavir. Le cas décrit ici suggère que l'utilisation concomitante de ces produits est possible en surveillant étroitement les dosages de tacrolimus. Le dosage sanguin dans l'intervalle thérapeutique au jour 4 démontre qu'il est adéquat de suspendre le tacrolimus pendant le traitement de nirmatrelvir/ritonavir. Cependant, la reprise du tacrolimus est plus complexe. Bien qu'il existe des recommandations et des outils d'aide à la décision pour la gestion d'interaction médicamenteuse avec le nirmatrelvir/ritonavir, celles-ci restent imprécises et le moment opportun pour revenir à la dose usuelle est inconnu[17,18]. Une reprise trop précoce peut, tel que décrit, entraîner un dosage sanguin supra-thérapeutique et des effets indésirables associés, tels qu'une néphrotoxicité. Une reprise trop tardive pourrait entraîner un dosage sous-thérapeutique et ainsi précipiter un rejet aigu du greffon. Les risques individuels de rejet et de toxicité du patient doivent être intégrés à la prise de décision du moment de reprise du tacrolimus et de la dose choisie, en sachant que l'effet du ritonavir sur le métabolisme du tacrolimus persiste encore quelques jours après son

arrêt. Cette variabilité interindividuelle est illustrée dans l'article de Salerno *et al*.[19] Dans leur revue de 21 patients greffés ayant reçu le nirmatrelvir/ritonavir en combinaison avec le tacrolimus, le retour à la dose usuelle de tacrolimus s'est fait entre 2 et 5 jours suivant l'arrêt du nirmatrelvir/ritonavir. Des 19 patients ayant des dosages de suivi, 4 dosages supérieurs à 15 µg/L ont été observés[19]. L'ensemble des dosages supra-thérapeutiques ont été observés à la suite de la reprise du tacrolimus. Tous les dosages sanguins effectués pendant le traitement de nirmatrelvir/ritonavir ou au lendemain du traitement se sont avérés dans la cible thérapeutique[19]. Ces observations ont aussi été effectuées dans le cas rapporté. Le suivi rapproché des dosages sanguins est primordial à la suite de la reprise du tacrolimus, et ce, peu importe le moment de reprise choisi ou la dose prescrite. L'obtention de prélèvements sanguins fréquents peut s'avérer problématique pour certains patients en région éloignée. De plus, un retard dans l'obtention des résultats de dosage sanguin de tacrolimus peut complexifier la reprise sécuritaire de l'immunosuppression. Il est important pour le clinicien de mesurer les risques d'une reprise hâtive du tacrolimus contre ceux d'un délai trop important à la suite de l'arrêt du nirmatrelvir/ritonavir, tout en tenant compte des contraintes logistiques inhérentes aux dosages sanguins fréquents nécessaires.

Le cas décrit démontre la faisabilité de la prise en charge en ambulatoire de l'interaction entre le nirmatrelvir/ritonavir et le tacrolimus pour un patient avec une TOS. Il est impératif que la décision d'utiliser ce traitement se prenne conjointement avec la clinique de transplantation du patient afin d'assurer un suivi étroit des dosages sanguins de tacrolimus. Il faut prendre en considération l'effet inhibiteur résiduel du ritonavir lors de la reprise du tacrolimus et individualiser celle-ci.

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1

COVID-19

2

Compounding

3

Infectious Diseases

4

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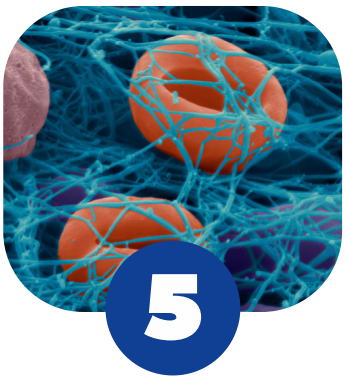

5

Anticoagulation

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QID

2022 Recipients of Foundation Education Grants and ASHP PLA Scholarship

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CONGRATULATIONS TO THE 2022 RECIPIENTS OF THE CSHP FOUNDATION EDUCATION GRANTS

Shirin Abadi

Pharmacy Clinical & Education Coordinator, BC Cancer – Vancouver
Clinical Professor, Faculties of Pharmacy and Medicine, UBC
BC Cancer Pharmacy's Oncology Drug Interactions Module

Education Grant: $5,000
Facility: Provincial Health Services Authority, BC Cancer

Melanie MacInnis

Residency Program Coordinator
Clinical Coordinator & Professional Practice Leader
Clinical Pharmacy Specialist, Pediatric Emergency Medicine
IWK Health
Women's & Children's Pharmacotherapy Primer for Pharmacy Professionals

Education Grant: $4,955
Facility: IWK Health Centre, Halifax, NS

CONGRATULATIONS TO THE 2022 RECIPIENT OF THE CSHP FOUNDATION PHARMACY LEADERSHIP ACADEMY (PLA) SCHOLARSHIP

Ginny Cummings

Pharmacy Clinical Practice Leader

CSHP Foundation Scholarship: $5,000
Program: American Society of Health-System Pharmacists (ASHP) Foundation Pharmacy Leadership Academy

Setting Our Sights on a Sustainable Future

Megan Riordon

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It's hard to believe four years have passed since members of the Board gathered in Dartmouth, Nova Scotia, alongside the beautiful Halifax Harbour, for the Annual General Meeting, where we had to grapple with the news that our CSHP ship was struggling to stay afloat. During those 2019 Board meetings, we discussed the financial impacts of a trend of deepening operating deficits coupled with diminishing industry sponsorship and a slow decline in membership since our peak in 2013. Following extensive consultation, collaboration, and negotiation, our strategic planning session that year was ambitious but essential, to not only fill those holes and bring CSHP up from underwater, but also to ensure a sustainable future for the Society, so as to deliver the value that members expect and deserve. The organization's 2020–2023 Strategic Plan detailed our foundational responsibilities, core business, and strategic priorities, with the goal of securing the future for a sustainable and engaging CSHP.

As our plan draws to a close at the end of this year, we have so much to be proud of, in terms of what we have accomplished, and during a global pandemic too! Although we had to trim our sails to take account of COVID, we have met or exceeded our goals for membership growth and engagement, and we are moving toward a balanced budget.

In terms of membership, we have added more than 500 new people since 2020 and now have just under 3800 members. In addition, for the very first time, we have reached the $1 million mark of membership support, an achievement reached not by raising fees, but by attracting new members and holding on to them once they joined. We've even done a makeover of our hospital and institutional membership categories, bringing down costs and upping the benefits. We have directed these membership revenues directly back into developing even more of the quality tools, services, and opportunities for which CSHP has always been known.

Our members have responded by becoming engaged in major ways. More than 900 attended the Together conference virtually last year, and just a few months ago, we hosted our first national hybrid conference in Banff, Alberta, with a combined in-person and online attendance of over 800! With more than two-thirds of members registered on one or more of our Pharmacy Specialty Networks (PSNs), CSHP is also expanding its online presence on social media, with a collective following across all platforms of over 10 000 and well over 6000 likes on our posts.

Financial sustainability has been the overarching goal of our current Strategic Plan. We needed to reinvest in the Society itself to ensure its continuance for the next generation of hospital pharmacists and pharmacy technicians. We have increased non–dues-related revenues and found ways to cut costs—including the sale of our national office building. As a result, we have reinforced the hull of our CSHP ship and are building back toward a balanced and sustainable budget for 2024 while continuously pushing ourselves to create more member value.

With sustainability on our minds, CSHP is now also taking steps toward the creation of a more environmentally sustainable future for hospital pharmacy as we do our part to combat climate change. Our new Sustainability in Pharmacy Task Force, along with our Task Force on the Vision for the Hospital Pharmacy Profession, will be instrumental in guiding us during the next segment of our voyage.

I'm proud to be part of such a resilient and progressive society. Together, we've achieved remarkable growth in membership and engagement to reach and sustain a balanced budget. As such, I look forward to our upcoming strategic planning session where we will set our sights on what else CSHP can achieve through advocacy, education, information sharing, promotion of best practices, facilitation of research, and recognition of excellence.

Megan Riordon, BSc(Pharm), RPh, ACPR, DPLA, is the Treasurer of the Canadian Society of Hospital Pharmacists.

Cap sur un avenir durable

par Megan Riordon

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Difficile à croire que quatre années se sont déjà écoulées depuis la réunion du conseil d'administration à Dartmouth, en Nouvelle-Écosse, à côté du magnifique port d'Halifax, pour l'assemblée générale annuelle, où nous avons dû encaisser la nouvelle que notre SCPH avait des difficultés à se maintenir à flot. Au cours de ces réunions du conseil d'administration de 2019, nous avons discuté des impacts financiers d'une tendance à l'aggravation des déficits d'exploitation associée à une diminution des commandites de l'industrie et à une lente baisse du nombre de membres depuis notre pic en 2013. Après de nombreuses consultations, collaborations et négociations, notre séance de planification stratégique cette année-là était ambitieuse, mais essentielle, non seulement pour éviter ces récifs et remonter la SCPH à la surface, mais aussi pour assurer un avenir durable à la Société, afin d'offrir la valeur que les membres attendent et méritent. Le plan stratégique 2020-2023 de l'organisation détaille nos responsabilités fondamentales, nos activités principales et nos priorités stratégiques, dans le but d'assurer l'avenir d'une SCPH durable et engageante.

Tandis que notre plan s'achèvera à la fin de cette année, nous avons tellement de raisons d'être fiers de nos accomplissements … le tout, il faut le souligner, pendant une pandémie mondiale! Bien que nous ayons dû baisser nos voiles pour tenir compte de la COVID-19, nous avons atteint ou dépassé nos objectifs de croissance et d'engagement des membres et nous mettons le cap sur l'équilibre budgétaire.

En ce qui concerne les adhésions, nous avons ajouté plus de 500 nouvelles personnes depuis 2020 et comptons maintenant un peu moins de 3800 membres. De plus, pour la toute première fois, nous avons atteint la barre du million de dollars de soutien aux membres : un jalon atteint non pas en augmentant les cotisations, mais en attirant de nouveaux membres et en les retenant une fois inscrits. Nous avons même procédé à une refonte de nos catégories de membres hospitaliers et institutionnels, tout en réduisant les coûts et en augmentant les avantages. Nous avons réorienté ces revenus d'adhésion directement vers le développement d'encore plus d'outils, de services et d'occasions de qualité pour lesquels la SCPH a toujours été reconnue.

Nos membres ont réagi en s'engageant de plus belle. Plus de 900 personnes ont participé virtuellement au congrès Together l'année dernière, et il y a quelques mois à peine, nous avons organisé notre premier congrès hybride national à Banff, en Alberta, avec une participation combinée en personne et en ligne de plus de 800 personnes! Avec plus des deux tiers des membres inscrits sur un ou plusieurs de nos Réseaux de spécialités pharmaceutiques (RSP), la SCPH élargit également sa présence en ligne sur les médias sociaux, avec un suivi collectif, toutes plateformes confondues, de plus de 10 000 et bien plus de 6000 « J'aime » sur nos messages.

La viabilité financière a été l'objectif primordial de notre plan stratégique actuel. Nous devions réinvestir dans la Société elle-même afin d'assurer sa pérennité pour la prochaine génération de pharmaciens hospitaliers et de techniciens en pharmacie. Nous avons augmenté les revenus non liés aux cotisations et trouvé des moyens de réduire les coûts, y compris la vente de l'immeuble abritant notre bureau national. Par conséquent, nous avons renforcé la coque de la SCPH et reconstituons un budget équilibré et durable pour 2024, tout en nous efforçant continuellement de créer plus de valeur pour nos membres.

Avec la durabilité à l'esprit, la SCPH prend maintenant des mesures pour créer un avenir plus durable sur le plan environnemental pour la pharmacie hospitalière, alors que nous faisons notre part pour lutter contre le changement climatique. Notre nouveau Groupe de travail sur la durabilité en pharmacie et notre Groupe de travail sur la vision de la profession de la pharmacie hospitalière joueront un rôle déterminant pour nous guider au cours de la prochaine étape de notre odyssée.

Je suis fière de faire partie d'une société aussi résiliente et progressiste. Ensemble, nous avons réalisé une croissance remarquable du nombre de membres et de l'engagement pour atteindre et maintenir un budget équilibré. J'attends donc avec impatience notre prochaine séance de planification stratégique où nous nous pencherons sur ce que la SCPH peut accomplir d'autre en défendant la profession, en sensibilisant les gens, en partageant les informations, en faisant la promotion des meilleures pratiques, en facilitant la recherche et en reconnaissant l'excellence.

Megan Riordon, B. Sc. (Pharm.), R. Ph., A.C.P.R., D.P.L.A., est la trésorière de la Société canadienne des pharmaciens d'hôpitaux.