CRITICAL APPRAISAL OF THE HAZARDOUS MEDICATION PERSONAL PROTECTIVE EQUIPMENT GUIDE FOR HEALTH CARE WORKERS IN A SUPPORTIVE LIVING SETTING

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Abstract

Background and Purpose: Health care workers caring for adults in the Supportive Living setting (SLS) are at risk for exposure to hazardous medications. To control workers' exposure, Alberta Health Services developed the *Hazardous Medication Personal Protective Equipment Guide and List* (the Guide). The overall goal of this practicum was to conduct a critical appraisal of that Guide with recommendations for future implementation and evaluation. **Methods:** Three methods of data collection were used to inform the critical appraisal: a comprehensive review of the literature, consultations with key informants, and an environmental scan of hazardous medication management resources. **Results:** A critical appraisal of the Guide using the **A**ppraisal of **G**uidelines for **Re**search and **E**valuation (AGREE II) Instrument showed that it was a high quality clinical practice guideline. **Conclusion:** The Guide is recommended for use in the supportive living setting, with minor modifications in the *Applicability* and *Editorial Independence* domains.

Key Words: hazardous medication(s), critical appraisal of clinical practice guidelines, Supportive Living setting**.**

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Introduction

Health care workers (HCW) in the Supportive Living setting (SLS) are at risk for occupational exposure to hazardous medications, which can result in adverse health effects. As outlined in the Occupational Health and Safety (OHS) Code, an employer is responsible to assess a worksite for existing and potential hazards and take measures to eliminate or control said hazards (Government of Alberta, 2018). To control workers' exposure to hazardous medications, and enhance worker and patient safety, Alberta Health Services (AHS) developed the *Hazardous Medication Personal Protective Equipment (PPE) Guide and List*, henceforth referred to as the Guide (AHS, 2018a). The Guide was created by a panel of experts and frontline HCWs across the province of Alberta and, "is intended to provide guidance to all employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of AHS including contracted service providers as necessary" (AHS, 2018a, p. ii). The Guide consists of a list of medications that represent either, a known, potential, or reproductive hazard, and the safety measures needed to protect HCWs in performing any task involving an exposure to said hazards. This practicum project involved the critical appraisal of the Guide including stakeholder reactions to the implementation of the Guide at one test site.

Background

Prior to the inception of the Guide, HCWs in the SLS referred to the *Cytotoxic Drug Manual Administration and Handling Guidelines* (AHS, 2013) to identify the

required safety measures when working with cytotoxic medications. The new Guide deviates from the *Cytotoxic Drug Manual Administration and Handling Guidelines* (the Manual) in a number of ways, which will have significant implications for HCWs caring for older adults living in the community. While the Manual lists only cytotoxic drugs that necessitate control measures when being handled, the new Guide contains an extensive list of all hazardous medications, adopted directly from the National Institute for Occupational Safety and Health (NIOSH, 2016). The NIOSH list includes cytotoxic medications as well as those that are teratogenic, genotoxic, toxic to organs, and those that mimic other known hazardous medications (AHS, 2018a). As such, the list of medications representing an occupational hazard under the new guide is significantly longer and includes common medications such as carbamazepine, estrogen/progesterone containing medications, clonazepam, valproic acid, and warfarin. The Guide also contains specific recommendations for the use of PPE and the disposal of hazardous medications that will require changes to existing practices in the SLS.

Following a province wide educational roll out of the Guide in January of 2018, a number of questions and concerns came forward regarding how this Guide could be implemented successfully in the SLS which is a stream of the Continuing Care program that partners with contracted service providers to care for adults living in the community. Challenges to implementing the new Guide in this setting include the following: (1) increased costs associated with providing more PPE and spill kits, (2) communicating hazardous medication risk to all HCWs in the SLS, (3) ensuring pharmacies affix the correct hazardous medication warning labels to prescriptions, and (4) disposal of bio hazardous wastes in the SLS.

In an effort to validate the Guide as an appropriate clinical practice guideline (CPG) for the SLS setting, a critical appraisal of the Guide was conducted. This appraisal included consultations with key stakeholders to collect essential information about the implementation of the Guide in one test site. Findings from this critical appraisal and key informant reactions to implementing the Guide at one test site could provide essential information to formulate recommendations for the future implementation and evaluation of the Guide.

Goal and Objectives

The overall goal for this practicum was to critically appraise the *Hazardous Medication Personal Protective Equipment Guide and List* (AHS, 2018a) to determine whether it was a quality CPG that could be used by HCWs caring for adults in the SLS. The key practicum objectives are:

1. Demonstrate advanced nursing practice competencies through research, leadership, clinical, and collaborative activities.
2. Conduct a comprehensive literature review as it relates to the development and evaluation of CPGs for exposure to hazardous medications.
3. Appraise the quality of the Guide using the **A**ppraisal of **G**uidelines for **Re**search and **E**valuation (AGREE) Instrument.
4. Conduct consultations with key informants to determine reactions to the implementation of the Guide at one test site.
5. Identify the barriers and facilitators for successful implementation of the Guide.

6. Apply findings from the critical appraisal to make recommendations for future implementation and evaluation of the Guide.
7. Disseminate the findings of this practicum by participating in knowledge-transfer techniques such as presentations.

Methods

A number of methods were employed to achieve the aforementioned practicum objectives. First, a comprehensive review of the literature was completed to examine the current literature as it relates to the development and evaluation of CPGs (see Appendix A). From this review, the AGREE II was identified as a valid and reliable tool to critically appraise the quality of the Guide. Second, consultations were conducted with key informants to determine stakeholder reactions to the implementation of the Guide at one site (see Appendix B). Third, an environmental scan was conducted to create an awareness of available local, provincial, and national resources for handling hazardous medications in the SLS (see Appendix C). Finally, a critical appraisal of the Guide was completed using the AGREE II Instrument (see Appendix D).

Summary of Literature Review

A comprehensive review of the literature was conducted to examine the current state of evidence as it relates to the critical appraisal of CPGs using the AGREE II Instrument (see Appendix A). Questions that guided this literature review included: 1) What is the current literature as it relates to the development and evaluation of CPGs? 2) Has the AGREE II Instrument been used to evaluate the quality of CPGs for handling

hazardous medications? and 3) Is the AGREE II an appropriate instrument to critically appraise the Guide?

To complete this review, a search of the Cumulative Index of Nursing and Allied Health Literature and PubMed databases was conducted using the terms: clinical practice guidelines, hazardous medications, AGREE II, occupational health and safety *or* occupational medicine *or* workplace health and safety *or* occupational health nursing. A thorough review of the content of the AGREE Trust website was also completed. Results were limited to articles written in English with a publication date between 2010 and 2018 as version two of the AGREE Instrument was not released until 2010. Abstracts were reviewed for relevancy and any articles that met the exclusion criteria were discarded leaving seventeen articles for review. Exclusion criteria included: letters to the editor, those inaccessible through library holdings, and those that involved research using modified versions of the AGREE II Instrument.

Of the seventeen articles screened, eight were either research articles or literature reviews. Those articles underwent a critical appraisal using the Public Health Agency of Canada's (PHAC, 2014) Critical Appraisal Toolkit. In reading the aforementioned articles, the Guideline Implementability for Decision Excellence Model (GUIDE-M) was identified as a relevant adjunct to the AGREE II. As such, two articles about the GUIDE-M were also screened into the review and underwent a critical appraisal. The themes gleaned from this comprehensive review of the literature are described in depth in the Literature Review Report (see Appendix A) and key findings from the review are summarized below.

The first key finding from this review was that the Guide (2018a), did meet the requirements to be considered a CPG in that it is: 1) intended to aid clinicians in decision-making and 2) that it is the product of a systematic review of the evidence (Anaya, Franco, Merchan-Galvis, Gallardo, & Cosp, 2018). Another important finding from the literature review was identifying that the AGREE II was an appropriate tool to appraise the quality of CPGs such as the Guide (AGREE Trust, 2017). Two research articles demonstrated the validity and reliability of the AGREE II Tool, the use of which to appraise CPGs is widely cited in the literature. While no articles were found whereby the AGREE II was used to appraise a hazardous medication CPG, there were three articles found where the tool was used for other OHS related guidelines.

Another key finding from the literature review were the limitations of the AGREE II Instrument. The most widely cited limitation is the fact that the tool is intended to be used to evaluate the methodological quality of CPG development, not the clinical appropriateness or validity of the recommendations within it (Anaya et al., 2018; Bragge et al., 2014; Brouwers et al., 2010a; Joosen et al., 2015; MacQueen et al., 2017). Other limitations of the AGREE II are that it is not intended to appraise the quality of guidance documents that address health care organizational issues and it has not been formally evaluated as a tool to appraise health technology assessments (AGREE Trust, 2017). Additionally, the AGREE II does not provide a means to assess the end user's adherence to a CPG in practice nor evaluate the clinical impact of the guideline (Joosen et al., 2015). Finally, the instrument does not provide guidance regarding how the CPG should be implemented (Brouwers et al., 2010a; Joosen et al., 2015).

An additional key finding from the literature review was the identification of the GUIDE-M, a complimentary tool to the AGREE II. The GUIDE-M is a framework of intrinsic factors affecting the implementability of CPGs designed to support their implementation (AGREE Enterprise, 2018). The GUIDE-M was used as a theoretical point of reference to inform the critical appraisal and subsequent recommendations for future implementations of the Guide.

The final key finding from this review was the substantial evidence in the literature highlighting inconsistencies in the quality of CPGs, with many failing to meet even basic standards (Brouwers et al., 2010a; Brouwers et al., 2010b; Dewa, Trojanowski, Joosen & Bonato, 2016; Makarski & Brouwers, 2014). This represents a significant problem as a low level of quality limits the potential benefits of CPGs. The benefits of high quality CPGs include optimizing patient care, supporting the efficient use of resources, promoting a positive attitude among practitioners, and informing policy-, system-, and population-related decisions (Anaya et al., 2018; Brouwers, Makarski, Kastner, Hayden & Bhattacharyya, 2015). In summary the review of the literature revealed that the AGREE II instrument is a reliable and valid tool for critically appraising CPGs and although it has not been used to appraise CPGs for handling hazardous medications it is an appropriate instrument to guide the critical appraisal of the Guide.

Summary of Consultations

Consultations were conducted with key informants at one test site to identify the current implementation plan for the Guide, identify the key informants' perception of the Guide, examine barriers and facilitators that affect the implementation of the Guide and

identify strategies and recommendations to support the successful implementation of the Guide. Ten interviews were conducted with key informants using a face-to-face semi-structured interview. Informants included: an Administrative Manager, a Nursing Team Lead, three HCWs, a Case Manager, a Program Manager, a pharmacist from a contracted pharmacy, a representative from the Continuing Care **Haz**ardous **Me**dication **C**ommittee (HAZMEC), and a Continuing Care Senior Workplace Health and Safety Advisor. Data was collected until a critical point of data saturation was reached and then underwent content analysis. All findings from the consultations are documented in the Consultation Report (see Appendix B). Common themes revealed from the content analysis included: informants' perception of the guide (awareness and use), the factors that supported or hindered the implementation of the Guide, the current implementation plan, and strategies and recommendations to support the successful implementation of the Guide.

Informants' perception of the guide. The findings from the consultations revealed that all key informants were aware of the existence of the Guide, although the platform from which it was accessed varied. Some informants relied on paper copies of the Guide while others accessed it electronically from the organization's website. Some informants used the Guide in its entirety while others only referred to sections within it (e.g. the waste management posters or the list of hazardous medications). Key informants identified the main factors supporting the successful implementation of the Guide including: 1) easy to read, 2) the content is self-explanatory; 3) the visual material including the posters and pictures enhance the understanding of the content and provide quick access to important information; 4) the algorithm summarizing how to use the Guide, and 5) the inclusion of contact information for hazardous medication experts

within the organization. The main barriers to successful implementation included a lack of knowledge about the Guide and lack of resources to implement the recommendations (e.g. the cost of more spill kits, purchasing a waste disposal system, etc.).

Recommendations arising from consultations included the need for HCWs to have an orientation to the Guide, the need to identify the costs associated with implementing the recommendations, and the need to develop patient and family resources to address risk associated with handling hazardous medications.

Barriers and facilitators to implementation. Factors that hindered implementation of the recommendations from the Guide included: 1) the expanded, long, comprehensive list of medications and recommendations, 2) the length of the hazardous medication list is too inclusive by including commonly prescribed medications such as warfarin, 3) a lack of clarity whether common medications on the *potential* hazard list should in fact be handled as a hazardous medication if handled in low doses, e.g. warfarin, 4) the list contains medications that were not previously handled as hazardous, 5) it is a challenge to enforce the recommendations in the SLS, 6) program level processes have not been developed, and 7) having to contact an external resource for program specific processes could delay implementing the recommendations in the Guide.

Recommendations from informants to improve the content of the Guide included: 1) indicate the specific spill kits that are recommended, 2) clarify the precautions required for clients and families who are potentially exposed to hazardous medications, and 3) provide more direction regarding the difference between PPE to protect a worker from hazardous medication exposure and those required for infectious disease exposure.

Current implementation plan. Key informants identified four primary implementation strategies that were currently in use at the test site. One key strategy identified was the initial and ongoing education and support provided to the HCWs, clients and families of clients taking a known hazardous medication. Another strategy used to implement the Guide was the collaboration with community pharmacies to set up a process for identifying, preparing, and labeling hazardous medications. The third implementation strategy was the development of site-specific processes for managing hazardous medications. The final strategy was to ensure the equipment required for the management of hazardous medications was readily available to HCWs (e.g. PPE, waste disposal systems).

Implementation strategies and recommendations. Key informants made a number of specific recommendations to support the successful implementation of the Guide including providing an education session on the contents of the Guide, a demonstration of the donning and doffing of PPE and a demonstration of how to draw up, administer, and dispose of a hazardous medication. Key informants also recommended developing site-specific processes for hazardous medication management and assigning a clinical lead or resource person to implement the recommendations from the Guide. Continued collaboration with all pharmacy providers was also recommended to ensure processes are in place to identify and label hazardous medications.

Key informants also identified the need to evaluate ongoing compliance to the Guide by conducting regular audits to ensure: hazardous medications are correctly identified and labeled by pharmacy, hazardous medications are identified and communicated as being hazardous amongst the facility HCWs, the correct PPE is being

used, waste management requirements are being followed, and site specific hazardous medication management processes are followed. Key informant recommendations are discussed in detail in Appendix B.

Summary of Environmental Scan

An environmental scan was completed to identify local, provincial, and national CPGs for HCWs handling hazardous medications in the SLS. The data for this environmental scan was collected in three ways. First, a Google search using the terms "hazardous medications" and "Canada" was conducted. Second, the following websites/online platforms were reviewed to identify relevant resources: 1) Supportive Living Share Point, 2) Alberta Health Services Insite, 3) the Government of Alberta Occupational Health Services Online Resource Portal, 4) the Canadian Centre for Occupational Health and Safety (CCOHS) Website, and 5) the Canadian Clinical Practice Guideline Infobase. Finally, a question about the availability of hazardous medication resources (at the local, provincial, and national level) had been included in the consultations with the Continuing Care Workplace Health and Safety Advisor and Continuing Care HAZMEC Member.

Nine resources were found in conducting this scan, four of which met the criteria to be considered a CPG. These CPGs include: the AHS Edmonton Zone *Cytotoxic Drug Manual Administration and Handling Guidelines* (2013), *Safe Handling of Hazardous Drugs* from the British Columbia Cancer Agency (2017), *Safe Handling of Hazardous Drugs in Healthcare* authored by the Ontario Public Services Health and Safety Association (2017), and *NIOSH List of Antineoplastic and Other Hazardous Drugs in*

Healthcare Settings (2016). Also, three supporting documents for the Guide were identified: the *Hazardous Medication Personal Protective Equipment Frequently Asked Questions* (AHS, 2018b), the *Hazardous Medication Personal Protective Equipment Guide and List Tip Sheet* (AHS, 2018c), and the *Handling Human Wastes of Patients Receiving Known Hazard Medications Frequently Asked Questions* (AHS, 2018d). A complete report of the findings from this environmental scan can be found in the Environmental Scan Report (see Appendix C). The content of these resources were reviewed and taken into consideration during the critical appraisal of the Guide.

Summary of Critical Appraisal of the Guide

The overall goal for this practicum was to critically appraise the *Hazardous Medication Personal Protective Equipment Guide and List* (AHS, 2018a) to determine whether it was a quality CPG that could be used by HCWs caring for adults in the SLS.

Critical appraisal process. The critical appraisal process began with obtaining a copy of the Guide and carefully reading the entire document to become familiar with the contents. The content of the Guide was then compared to the resources found in the environmental scan to ensure the Guide contained the most recent evidence for practice in Canada. All of the supporting documents used in the development of the Guide were collected and reviewed as a part of the materials considered in the critical appraisal process. A member of the guideline development group was also consulted to obtain information about the development process of the Guide. All of this information was then used to complete the critical appraisal of the Guide using the AGREE II Instrument.

AGREE II critical appraisal. The AGREE II Online Guideline Appraisal Tool was used to conduct the appraisal and create a summary report (see Appendix D). Overall, the quality of the Guide was high and it is recommended HCWs use the Guide to help to control their exposure to hazardous medications, and enhance worker and patient safety. However, the low scores in two domains warrant consideration for future versions of the Guide.

Applicability and Editorial Independence domains. The Guide received high quality scores for all domains except for the *Applicability* domain, which received a medium quality score of 67%, and the *Editorial Independence* domain, which received a low quality score of 21%. A key reason for the lower score in the *Applicability* domain was a failure to address the resource implications of implementing the recommendations within the Guide, specifically the costs of the PPE, spill kits, waste management equipment, and waste management processing as well as who is responsible for those costs. Another reason for the lower *Applicability* score was that the Guide does not provide any monitoring or auditing criteria to evaluate implementation. The *Editorial Independence* domain received the lowest quality rating of 21%, well below the pre-set threshold. The low rating for this domain is due to the fact that there is no explicit statement acknowledging that the views or interests of the funding body have not influenced the content of the Guide, nor is there any conflict of interest statement on behalf of the guideline development group members.

Recommendations arising from the critical appraisal to improve the quality of the Guide include the following:

1. Add a section with the names, disciplines, relevant expertise, institution, geographic location, and the role of each member who was involved in the development of the Guide.
2. Describe the development process including the methodology used to conduct the external review, the strategy used to search for and select the evidence, and a description of the strengths and limitations of the evidence.
3. Develop a procedure for updating the contents of the Guide.
4. Identify the costs of PPE, spill kits, waste management equipment, and waste management processing as well as who is responsible for those costs.
5. Develop monitoring and/or auditing criteria to conduct an evaluation of the implementation of the Guide (e.g. hazardous medications are correctly identified and labeled by pharmacy, hazardous medications are identified and communicated as being hazardous amongst the facility HCWs, the correct PPE is being used, waste management requirements are being followed, and site specific hazardous medication management processes are followed).
6. Include a statement explicitly stating the role of the funding body in the development of the Guide.
7. Include a statement explicitly declaring the presence or absence of any conflicts of interest on behalf of the guideline development group members.

Summary of recommendations for the guide. In summary, the following recommendations have been developed based on the literature review, key informant consultations, an environmental scan and the critical appraisal of the Guide using the AGREE II and are in addition to the recommendations arising from the critical appraisal:

1. Develop site-specific processes to guide HCWs caring for clients receiving hazardous medications in the SLS.
2. Provide an orientation to- and ongoing education sessions on the Guide.
3. Develop an educational resource for clients and families based on the Guide (e.g. pamphlet).
4. Print and distribute the "point-of-care" visual aids that accompany the Guide (e.g. PPE poster).
5. Collaborate with pharmacy providers to ensure consistent processes are in place to identify and label all hazardous medications.
6. Ensure the required PPE and waste disposal equipment, as outlined in the Guide, is available to all HCWs at point of care.

Advanced Nursing Practice Competencies

In completing this critical appraisal of a CPG, I have demonstrated a number of advanced nursing practice competencies including: health system optimization, education, research, leadership, and consultation and collaboration (Canadian Nurses Association [CNA], 2019). The following is a discussion of examples of behaviours that demonstrate how I achieved those advanced practice competencies.

Health System Optimization

Health system optimization competencies involve making "contributions to the effective functioning of health systems through advocacy, promoting innovative client care and facilitating equitable, client-centered health care (CNA, 2019, p. 30)." The critical appraisal completed for this practicum yielded a number of recommendations that constitute a strategic plan to support the implementation of the Guide. By enhancing the implementability of the Guide, the objectives of the CPG, to control workers' exposure to hazardous medications and enhance worker and patient safety, can be realized. This will ultimately enhance care provision in the SL program, which will support the functioning of the healthcare system.

Education

Education competencies involve a commitment to the professional growth and development of HCWs as well as clients'/families' learning as it relates to health and wellness (CNA, 2019). Education competencies were demonstrated by identifying the learning needs of the HCWs who use the Guide. Through consultations with the test site HCWs, a number of learning needs with respect to the Guide were identified including: the use of the Guide, the correct donning and doffing of PPE, the site specific process for managing hazardous medications, and the correct way to draw up, administer, and dispose of an injectable hazardous medication. In order to support the professional growth of HCWs who use the Guide, a recommendation to provide education targeted at meeting the aforementioned learning needs was formulated. Furthermore, a need was identified to

provide education to clients taking hazardous medications, and their families, in order to protect them from unintended exposure to hazardous medications and ease their anxieties about the PPE being used during the provision of care.

Research

Research competencies involve the generation, synthesis, critique, and application of research evidence (CNA, 2019). Although the focus of this project was on evaluation not research, a number of these competencies were achieved in completing the critical appraisal of the Guide. First, findings from a comprehensive review of the literature were critiqued, interpreted, and synthesized into the final integrative review. This involved a critical appraisal of the literature, including the development of research summary tables. Furthermore, the results of the literature review were applied to inform the critical appraisal of the Guide. This included the decision to use the AGREE II Instrument for the critical appraisal, the development of questions for the semi-structured interviews, and the identification of relevant CPGs applicable through the environmental scan.

Second, data was collected by means of semi-structured interviews with key informants followed by content analysis to identify common themes. These findings were then applied, along with those identified in completing the critical appraisal of the Guide, to develop recommendations for the future implementation and evaluation of the Guide. Finally, this practicum project required me to act as a *knowledge broker* whereby I will share evidence informed recommendations with relevant stakeholders for the purpose of benefiting HCWs, client care, and the healthcare system as a whole. This evidence will be

further shared using multiple means including submitting an article for publication to the Canadian Journal of Public Health and presenting the findings to managers and HCWs in the SLS.

Leadership

Leadership competencies require the advanced practice nurse to be "agents of change, consistently seeking effective new ways to practice, improve care and promote advanced practice nursing (CNA, 2019, p. 33)." Leadership was demonstrated in completing this project first, by identifying the implementation of the Guide in the SLS as a complex problem cofounded by numerous barriers. Second, by completing a critical appraisal of the Guide to identify effective and innovative ways to address the challenges associated with implementing the Guide. Developing recommendations to support the implementation and ongoing evaluation of the Guide, demonstrates the leadership competency of being an *agent of change.*

Consultation and Collaboration

Consultation and collaboration advanced nursing practice competencies involve effective communication and collaboration with colleagues across sectors and at the organizational, provincial, national, and international levels (CNA, 2019). Collaboration with relevant stakeholders occurred throughout the project at the organizational and provincial level. This included collaborating with key informants to identify and define the need for the critical appraisal of the Guide. Consultation competencies were also

demonstrated in completing this project by conducting formal consultations with key informants, the findings from which were used to inform the critical appraisal.

Next Steps for Implementation and Evaluation of the Guide

With the critical appraisal complete and associated recommendations developed, the next step is to disseminate the findings of this practicum project in an effort to promote the successful implementation of the Guide in the future. A copy of this report will be provided to the contact person for this practicum and key informants as requested. The author will search for opportunities to present the findings of the critical appraisal at local or provincial education sessions. One possible venue for a presentation on the Guide would be through the Mentor Moment Session; an online education forum delivered through Skype. The next steps for the implementation of the Guide would be to develop a future plan for orientation and ongoing education sessions for HCWs throughout the organization.

Recommendations from the critical appraisal also indicate the need for an evaluation plan to determine whether the Guide is being implemented as proposed. That plan should include methods to measure whether or not hazardous medications are being correctly identified and labeled by pharmacy, hazardous medications are being communicated as being hazardous, the correct PPE is being used, waste management requirements are being followed, site specific hazardous medication management processes are followed, and incidences of exposures to hazardous medications are tracked. The development of an implementation and evaluation plan will be critical to the

success of the Guide to control HCWs' exposure to hazardous medications, and enhance worker and patient safety in the SLS.

Conclusion

In completing this practicum project the complex issue of how to support the implementation of the *Hazardous Medication Personal Protective Equipment Guide and List* in the SLS was identified and evaluated. This was achieved by completing a comprehensive review of the literature, consultations with key informants, an environmental scan, and a critical appraisal of the Guide. From this work, a number of recommendations were developed to improve the quality and implementability of the Guide. Implementing those recommendations will support the health and wellbeing of healthcare providers involved with hazardous medication management, which will in turn optimize outcomes at the level of the employee, the patient, and the healthcare system as a whole. In conclusion, the *Hazardous Medication Personal Protective Equipment Guide and List* is an excellent quality CPG that can be used as a clinical practice guideline to control HCWs' exposure to hazardous medications, and enhance worker and patient safety.

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Appendix A

Literature Review Report

Appraisal of Clinical Practice Guidelines for Hazardous Medications

Clinical practice guidelines (CPGs) are statements that guide health care workers (HCWs) when making decisions about appropriate care in specific situations, and are especially important in situations that affect patient safety. As outlined in the Occupational Health and Safety (OHS) Code; an employer is responsible to assess a worksite for existing and potential hazards and take measures to eliminate or control those hazards (Government of Alberta, 2018). In an effort to reduce or eliminate workers' exposure to hazardous medications, and enhance worker and patient safety, Alberta Health Services (AHS) developed the *Hazardous Medication Personal Protective Equipment Guide and List* (2018), henceforth referred to as the Guide.

There is a need to critically appraise this new Guide and to determine the quality of the document as a CPG for HCWs caring for adults in the Supportive Living setting (SLS). This literature review will examine the current literature as it relates to the development and evaluation of CPGs. Specifically, it will examine the use of the **A**ppraisal of **G**uidelines for **Re**search and **E**valuation Instrument (AGREE II) to assess the quality of- and guide the development and reporting of CPGs for handling hazardous medications. The questions guiding this review include: 1) What is the current literature as it relates to the development and evaluation of CPGs? and 2) Has the AGREE II Instrument been used to evaluate the quality of CPGs for handling hazardous medications?

Search Strategy

A search of the Cumulative Index of Nursing and Allied Health Literature and PubMed databases was completed using the terms: clinical practice guidelines, hazardous medications, AGREE II, occupational health and safety *or* occupational medicine *or*

workplace health and safety *or* occupational health nursing. A thorough review of the content of the AGREE Trust website was also completed. Results were limited to articles written in English with a publication date between 2010 and 2018 as version two of the AGREE Instrument was not released until 2010. Abstracts were reviewed for relevancy and any articles that met the exclusion criteria were discarded leaving seventeen articles for review. Exclusion criteria included: letters to the editor, those inaccessible through library holdings, and those that involved research using modified versions of the AGREE II Instrument.

Of the seventeen articles screened, eight were either research articles or literature reviews. Those articles underwent a critical appraisal using the Public Health Agency of Canada's (PHAC, 2014) Critical Appraisal Toolkit (see Appendix A). In reading the aforementioned articles, the **Gu**ideline **I**mplementability for **D**ecision **E**xcellence **M**odel (GUIDE-M) was identified as a relevant adjunct to the AGREE II. As such, two articles about the GUIDE-M were also screened into the review and underwent a critical appraisal (see Appendix B). The themes gleaned from this comprehensive review of the literature are summarized below and include: CPGs, the AGREE II Instrument (intent, research and development, use, applications, limitations), the GUIDE-M, and future research.

Clinical Practice Guidelines

There are a number of different terms used in the literature to describe CPGs. While the term CPG is the most commonly used term, alternatives include evidence based practice guideline, best practice guideline, or guiding practice resource to name a few (Anaya, Franco, Merchan-Galvis, Gallardo, & Cosp, 2018; Brouwers et al., 2010a; Dewa,

Trojanowski, Jose, & Bonato, 2016). For the purposes of this literature review, the term CPG will be used. Like the variation in terminology, there are also varying definitions of a CPG in the literature. However, despite this variation there are two key characteristics of CPGs consistently reflected in those definitions. The first is that CPGs are intended to aid clinicians in decision-making (Anaya et al., 2018; Brouwers et al., 2010c; Dewa et al., 2016; Joosen et al., 2015; MacQueen et al., 2017). Some authors maintain the CPGs are also intended to guide patients' decision making (Anaya et al., 2018; Brouwers et al., 2010a; Joosen et al., 2015; MacQueen et al., 2017).

The second characteristic is that CPGs are developed based on a systematic review of the evidence (Anaya et al., 2018; Brouwers et al., 2010c; Joosen et al., 2015; MacQueen et al., 2017; Mambulu-Chikankheni, Eyles, Eboreime, & Ditlopo, 2017). It is this requirement that differentiates CPGs from consensus statements, expert advice, and standards (Dewa et al., 2016). Perhaps the most widely cited definition of a CPG from the literature is that of Woolf, Grol, Hutchinson, Eccles, & Grimshaw (1999) who define CPGs as, "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances" (p. 528). In addition to the fact that this is the most commonly referenced definition, it is also the definition accepted by the AGREE Enterprise and therefore it is the definition used for the purposes of this literature review.

Despite variation in terminology and definitions, there is consensus on the value of CPGs. CPGs are viewed as essential tools to summarize and translate the best available scientific evidence into practice (Joosen et al., 2015). CPGs serve to inform clinical decision making and diminish inappropriate clinical discrepancies thus optimizing patient

care, supporting the efficient use of resources, and promoting a positive attitude among practitioners (Anaya et al., 2018; Bragge et al., 2014; Brouwers et al., 2010c; Dewa et al., 2016; Mambulu-Chikankheni et al., 2017). Furthermore, CPGs are useful to inform policy-, system-, and population- related decisions (Bragge et al., 2014; Brouwers et al., 2010a; Brouwers et al., 2010c; Dewa et al., 2016; Mambulu-Chikankheni et al., 2017). It is of vital importance to note that the potential benefits of CPGs are directly related to the quality of the guideline itself (Brouwers et al., 2010c). The quality of CPGs is defined as "the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid and are feasible for practice" (AGREE Trust, 2013, p. 16). Bragge et al. (2014) caution that CPGs of low quality can lead to ineffective, wasteful, and even harmful practices that negatively affect outcomes at the level of the patient and the healthcare system. This is concerning given the numerous references from the literature highlighting the varying quality of CPGs and the fact that many guidelines fail to meet even basic standards (Brouwers et al., 2010a; Brouwers et al., 2010c; Dewa et al., 2016; Makarski & Brouwers, 2014).

Appraisal of Clinical Practice Guidelines

The AGREE II is one established instrument that provides a systematic framework to critically appraise the quality of CPGs such as the Guide. The AGREE II Instrument, originally developed by an international team of guideline developers and researchers, has been translated into over 33 languages, is cited in over 600 publications, and has been endorsed by numerous health care organizations worldwide including the World Health Organization (Makarski & Brouwers, 2014). The AGREE II Instrument

was developed by the AGREE Collaboration to address the issue of the high variability in the quality of CPGs by providing a framework to critically analyze their quality. An assessment of the quality of a CPG requires an evaluation of the methods used for development, the components of the final recommendations, and the variables influencing the uptake of those recommendations. In addition to providing a framework for the assessment of the quality of CPGs, the AGREE II Instrument also provides a methodological strategy to guide CPG development and provides direction as to what and how information should be reported in CPGs (AGREE Trust, 2017).

AGREE II Instrument

The original AGREE Instrument was released in 2003 and was comprised of 23 items falling under six quality domains (AGREE Trust, 2017). To improve the reliability and validity of the AGREE Instrument and support its use by end users, the AGREE Collaboration conducted a two part research study. In the first part of the study, Brouwers et al. (2010a) employed a mixed method design where participants were asked to use the new AGREE items to evaluate a CPG based on a new seven point scale, complete three outcome measures related to guideline adoption, provide feedback on the instrument's usefulness, and identify areas in the instrument requiring improvement. Brouwers et al. (2010a) found that: 1) the psychometric properties of the new seven point Likert scale were promising, 2) quality ratings of the AGREE domains were good predictors of outcomes associated with guideline implementation, and 3) participants found the AGREE items and domains to be useful. In the second part of the study, Brouwers et al. (2010b) assessed the construct validity of 21 of the AGREE items and evaluated the new

manual. Brouwers et al. (2010b) were able to establish the construct validity of the 21 items and confirm that the instructions for the new manual were appropriate, easy to read, and instilled confidence to use the tool among participants. Several changes were made to the instrument based on the aforementioned study findings leading to the creation of the AGREE II in 2010. Refinements included; availability of the user's manual as a reference, changes to the items constituting the instrument, and a new 7 point response scale (Brouwers et al., 2010c).

Composition of AGREE II

Version two of the AGREE Instrument is comprised of 23 items that fall under 6 different quality domains in addition to two global rating items intended to capture the quality of the overall assessment of the CPG. The first quality domain, *Scope and Purpose*, addresses the overall intent of the CPG, the specific questions it addresses, and the target population. The second domain, *Stakeholder Involvement*, considers whether or not the relevant stakeholders were involved in the development of the CPG and if the perspective(s) of the intended users are reflected in it. The third domain, *Rigor of Development*, evaluates the process used to gather and synthesize the evidence, formulate recommendations, and update those recommendations. The fourth domain, *Clarity of Presentation*, pertains to format, structure, and language used in the CPG. The fifth domain, *Applicability*, considers implementation barriers/facilitators as well as the financial implications of instating the CPG. The sixth domain, *Editorial Independence*, addresses whether or not the recommendations made in the CPG were unduly biased. Finally, the *Overall Assessment* section includes a rating of the overall quality of the

guideline and a rating of whether the guideline is recommended for use (AGREE Trust, 2017).

Using the AGREE II to Critically Analysis Clinical Practice Guidelines

Owing to the aforementioned research conducted by Brouwers et al. (2010b), the AGREE II User's Manual was developed to support the use of the AGREE II Instrument. That manual outlines the type of CPGs that can be assessed using the instrument, appraisers who should use the instrument, the number of appraisers required, how to complete the scoring, and the interpretation of the scoring. In their study, Brouwers et al. (2010b) found that the new user's manual allowed even novice appraisers to apply the AGREE II Instrument with confidence to the critical analysis of many types of CPGs. The AGREE II Instrument was intentionally designed to be a generic tool with widespread usability. As such, the instrument can be used for many different types of CPGs developed at the local, regional, national, and even international level. It is suitable to appraise CPGs in any health or disease area targeting any steps of the health care continuum including health promotion, public health, screening, diagnosis, treatment, or intervention. Furthermore, the AGREE II Instrument can be used for paper or electronic CPGs. Finally, the instrument can be applied to original CPGs or to update existing CPGs (AGREE Trust, 2017).

Appraisers

The generic design of the AGREE II means the instrument can be used by a wide variety of different appraisers including: frontline healthcare providers appraising a guideline before incorporating it into their practice, guideline developers requiring

methodological guidance or an appraisal framework, policy makers needing to select a quality CPG, and even educators requiring a teaching aid to enhance others' ability to appraise or develop guidelines. To support the reliability of any quality assessment process using the AGREE II Instrument, it is recommended that at least two and preferably four appraisers rate the guideline (AGREE Trust, 2017). Based on this review of the literature, anywhere from two to six appraisers performed the appraisal. It is estimated that each appraisal of a CPG will take an average of 90 minutes per appraiser to complete (Brouwers et al., 2010c).

Likert Rating Scales

Each of the 23 items on the AGREE II Instrument is rated using a 7 point Likert scale (Brouwers et al., 2010c). A rating of 1 represents a poorly defined concept or a lack of information and a rating of 7 indicates exceptional quality in that all of the criteria outlined for that item have been met. A score between 2 and 6 means that the reporting of the item does not fully meet the outlined criteria. The more criteria that a CPG meets the higher the individual item scores and associated domain scores. Although it is discouraged, there are circumstances where certain items need to be excluded from the appraisal process because they are not applicable to a certain CPG. In these situations the appraiser cannot just indicate "not applicable" on the tool. Instead, the item should either be skipped with modifications made to the domain score calculations, or rated as a 1 with rationale provided in the notes. In addition to the aforementioned 23 items on the AGREE II, there are two *Overall Assessment* items at the end of the instrument. The user is required to make an objective judgement of the quality of the guideline (rated on a scale

from 1-lowest possible quality to 7-highest possible quality) as well as make a recommendation for the use of the guideline (yes, yes with modifications, or no) (AGREE Trust, 2017).

Scoring

Individual scores for the 23 items are used to calculate a quality score for each domain by summing all of the scores within a domain and dividing by the maximum possible score for the domain. The resulting quality scores for each domain are represented as a percentage and are considered to be independent. That is to say, the individual domain scores are not to be aggregated into a single score of overall quality. Individual domain scores are useful to identify high quality guidelines worth endorsing, identify the strengths and weaknesses of a CPG, and to compare methodological quality among different guidelines. Interpretation of these scores requires a comparison against the quality threshold set by the appraiser. The quality threshold is the domain score percentage that represents a minimum level of acceptable quality. There is no standard quality threshold percentage endorsed in the AGREE II: User's Manual due to a lack of empirical evidence establishing a relationship between specific domain scores to implementation outcomes. Instead, the manual maintains that quality thresholds must be defined based on stakeholder consensus taking into account the context in which the CPG is to be used (AGREE Trust, 2017).

From the literature review, minimum quality thresholds were set between 50%-70% (Anaya et al., 2018; Bragge et al., 2014; Dewa et al., 2016; Joosen et al., 2015; MacQueen et al., 2017; Shetty, Raaen, Khodyakov, Boutsicaris, & Nuckols, 2018).

Joosen et al. (2015) were the only appraisers to specifically assign quality thresholds for poor quality (30% or less), moderate quality (30-60%), and good quality (60% or above). Furthermore, the User's Manual makes a number of suggestions for how domain quality scores can be interpreted, depending on the users' objectives. One way is to prioritize one domain deemed to be of particular importance over the others. Another approach is to stage the appraisal whereby CPGs are screened in by first appraising the priority domain of interest before appraising the remaining five domains. Alternatively, the same- or different quality thresholds could be set for each domain. Finally, improvement thresholds can be used to evaluate improvements in CPG quality over time (AGREE Trust, 2017).

Reporting

With the AGREE II Framework serving as a foundation, the AGREE Reporting Checklist was created in 2016 (Brouwers, Kerkvliet, & Spithoff, 2016; Vernooij, Alonso-Coello, Brouwers, & Martinez Garcia, 2017). Each AGREE II item was incorporated into a reporting guide intended to be used by CPG developers to improve the completeness and transparency of *reporting* (AGREE Enterprise, 2018). Brouwers et al. (2016) maintain that the checklist can be used prospectively during the drafting stage of a CPG and retrospectively as a quality assurance step after the document has been completed.

To ensure the transferability and adaptability of the content constituting the AGREE Reporting Checklist, 15 guideline developers evaluated the checklist on its structure, ease of use, and its inclusion of all important reporting criteria, using a five point scale (Brouwers et al., 2016). Fourteen of the respondents indicated that the

required reporting criteria was reflected in the checklist, 13 indicated that they felt it would be useful for new and experienced CPG developers, and 13 reported that they themselves would use the checklist. Vernooij et al. (2017) then built upon the work of Brouwers et al. (2016) to develop a Checklist for the Reporting of Updated Guidelines (Check Up) intended to be used by CPG developers, users, and appraisers. Check Up supports the need to regularly review and update CPGs in order to assure trustworthiness by outlining the preferred reporting items for *updating* these documents (Vernooij et al., 2017). Again, the checklist is based on the AGREE II Framework and consists of 16 items that address: 1) presentation of the updated CPG, 2) editorial independence, and 3) the methodology of the update process (Vernooij et al., 2017). Both of the aforementioned checklists are designed to complement, not compete with, the AGREE II Instrument.

Applications of the AGREE II

As previously discussed, the AGREE II Instrument was designed to provide a framework for assessing the quality of CPGs as well as to guide the development and reporting of CPGs (AGREE Trust, 2017). Brouwers et al. (2010a) maintain that these functions of the AGREE II make it the ideal tool to be incorporated into CPG development protocols and reporting templates, to compare and contrast CPGs that are candidates for endorsement, to inform policy related decisions, to define reporting requirements for CPGs submitted for journal publication, and to serve as a framework for reaching consensus regarding methodological and reporting requirements for transnational cooperation. Many articles reflecting an application of the AGREE II were

found in this literature review, the vast majority of which involved the use of the tool for appraisal. None of the articles involved the use of the AGREE II Instrument to guide the reporting of CPGs.

Development of Guidelines

The only article found from a comprehensive review of the literature that involved the use of the AGREE II for the development of a CPG was that written by Besselaar et al. (2017). Besselaar et al. reported on the work of six Dutch orthopedic surgeons who collaborated with a parents association to develop a CPG for the diagnosis and treatment of primary idiopathic clubfeet in children. Although this was not a research article, the authors offer support for the use of AGREE II for CPG development. Most importantly, the authors report that the application of this framework ensured that optimal collaboration between all relevant stakeholders (medical professionals, patients, and parents) occurred. Also of importance to note is that the AGREE II Tool served to direct a systematic review of the literature from which the recommendations contained in the guideline were based. However, the authors do note a limitation of the AGREE II Instrument in that it is not intended to be used to appraise the quality of scientific evidence (Besselaar et al., 2017). For this the authors made use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method (Besselaar et al., 2017). Unfortunately, the authors do not address if and how the tool impacted the reporting of the CPG. This is unfortunate as transparency in describing how CPGs are developed is important for a quality appraisal and also to provide important contextual information that may explain variations in content from other guidelines (Dewa et al., 2016).

Appraisal of Clinical Practice Guidelines

The vast majority of articles retrieved in this literature review involved the application of the AGREE II Instrument to appraise CPGs. One article reported on the appraisal of a single CPG while the others involved an appraisal and comparison of as many as 21 CPGs. In each case, the authors identified inconsistencies in the quality of the guidelines, including inconsistencies from one guideline to another and inconsistencies in domain scores within individual guidelines. Numerous recommendations to improve the quality of CPGs can be found in the literature based on these findings.

Domain quality ratings. Despite the inconsistencies in quality within and among CPGs, a review of the literature did reveal consistency in those domains that typically scored highest and those that typically scored lowest. The domain that most consistently scored the highest quality rating was the *Scope and Purpose* domain. In their critical appraisal of four CPGs, Mambulu-Chikankheni et al. (2017) found that the *Scope and Purpose* domain had the highest domain quality score average at 89%. Likewise, in their systematic reviews, MacQueen et al. (2017), Joosen et al. (2015), Dewa et al. (2016), and Anaya et al. (2018) appraised CPGs and found this to be the top rated domain for quality. That is to say that across AGREE II appraisals of 56 different CPGs, *Scope and Purpose* was consistently the highest rated quality domain. Another domain that consistently received high quality scores was *Clarity of Presentation*. In fact, in Shetty et al. (2018) report on their use of the AGREE II to appraise the quality of a disability CPG, *Clarity of Presentation* received the highest domain score of 75%. Interestingly, this was also the second highest rated domain from MacQueen et al., Mambulu-Chikankheni et al., and Dewa et al.'s CPG appraisals.

The domain that was consistently rated the lowest in the literature was *Applicability*. In their systematic review of 11 CPGs, Bragge et al. (2014) found that *Applicability* was the lowest scoring domain with a median of 3.1%. The authors of three other systematic reviews, representing appraisals of 49 CPGs, also concluded that this was the lowest scoring quality domain (Anaya et al., 2018; Dewa et al., 2016; MacQueen et al., 2017). The second domain that was consistently rated low was *Editorial Independence*. In their critical appraisal, Mambulu-Chikankheni et al. (2017) found that the quality scores for this domain were the lowest ranging from 9-20%. Based on their systematic review involving an appraisal of 14 different CPGs, Joosen et al. (2015) also found *Editorial Independence* to be the lowest rated domain with an average quality score of 31%. Similarly, Bragge et al.'s appraisal of 11 CPGs revealed that this domain had the second lowest median of 20.8%. Given the pattern of consistently low quality domain scores presented above, it is not surprising that the recommendations made in the literature focus on strategies to improve the *Applicability* and *Editorial Independence* of CPGs by applying the AGREE II in the development phase.

Applicability. This domain emphasizes the need to consider the implementation barriers/facilitators as well as the financial implications of instating a CPG (AGREE Trust, 2017). Based on the findings of their appraisals, Shetty et al. (2018), MacQueen et al. (2017), Bragge et al. (2014), Joosen et al. (2015), Anaya et al. (2018), Mambulu-Chikankheni et al. (2017) and Dewa et al. (2016) all conclude that considering the implementability of a CPG in the development phase is of utmost importance. Shetty et al. argue that a failure to do so will inevitably hamper the adoption of a CPG and prevent the desired changes from being realized. In alignment with the AGREE II Framework,

MacQueen et al. and Bragge et al. maintain that advice and/or tools on how guideline recommendations can be put into practice must be explicitly addressed within the CPG itself. Shetty et al. and Bragge et al. provide a number of examples of such implementation strategies including education, training materials, reminders, computerized decision support, consultation, outreach visits, audits and feedback, peer review consultation, continuous quality improvement, and incentives.

Editorial Independence. This domain focuses on whether or not the recommendations made in a CPG are unduly biased (AGREE Trust, 2017). Based on the findings of their critical appraisals, Shetty et al. (2018), MacQueen et al. (2017), Bragge et al. (2014), and Mambulu-Chikankheni et al. (2017) all conclude that improvements are needed to improve the quality of reporting of conflicts of interest which in many cases is poorly done or not even documented at all. MacQueen et al. argue that such disclosures are essential to ensuring greater safeguards to minimize competing interests thus ensuring CPG independence from external forces. Mambulu-Chikankheni et al. go further to highlight that while every effort to minimize conflicts of interest should be exhausted, some are inevitable and in such cases CPG developers must provide a justification for same.

Miscellaneous. While the majority of recommendations made were related to the *Applicability* and *Editorial Independence* domains, there were areas for improvement identified that fall under other domains. Although the *Stakeholder Involvement* domain typically received moderate quality ratings on average, Shetty et al. (2018), MacQueen et al. (2017), and Bragge et al. (2014) called for the need to improve the stakeholder engagement item within this domain by demonstrating due considerations to the views

and preferences of the target population (e.g. patients, members of the public, etc.). Shetty et al. and Bragge et al. also made a recommendation to improve the *Rigor of Development* scores among CPGs by outlining a specific procedure and schedule for updating the document to ensure that the recommendations within it remain current.

Limitations of AGREE II

A number of limitations of the AGREE II Instrument were identified in completing this literature review. The most widely cited limitation is the fact that the tool is intended to be used to evaluate the methodological quality of CPG development, not the clinical appropriateness or validity of the recommendations within it (Anaya et al., 2018; Bragge et al., 2014; Brouwers et al., 2010c; Joosen et al., 2015; MacQueen et al., 2017). There are however other tools cited in the literature that serve as a framework for assessing the quality of evidence contained within a CPG, most common is the GRADE method (Besselaar et al., 2017; MacQueen et al., 2017). Both Besselaar et al. (2017) and MacQueen et al. (2017) employed the GRADE method along with the AGREE II Instrument as complimentary frameworks. Other limitations of the AGREE II are that it is not intended to appraise the quality of guidance documents that address health care organizational issues and it has not been formally evaluated as a tool to appraise health technology assessments (AGREE Trust, 2017). Additionally, the AGREE II does not provide a means to assess the end user's adherence to a CPG in practice nor evaluate the clinical impact of the guideline (Joosen et al., 2015). Finally, the instrument does not provide guidance regarding how the CPG should be implemented (Brouwers et al., 2010c; Joosen et al., 2015).

The GUIDE-M

In light of the aforementioned limitations of the AGREE II Instrument, the AGREE Research Collaboration set out to develop an additional tool that would serve to support the implementability of CPGs. The GUIDE-M is a framework of intrinsic factors affecting the implementability of CPGs that was developed in 2015 (AGREE Enterprise, 2018). According to Brouwers, Makarski, Kastner, Hayden & Bhattacharyya (2015), implementability refers to "characteristics of guidelines that promote their use, and these may be both intrinsic attributes- those related to the guideline itself- or extrinsic attributes- those related to the action of the healthcare system in which the guidelines are used" (p. 2). Brouwers et al. (2015) maintained that the development of a tool to support the implementability of CPGs was essential for two reasons. First, the full potential of CPGs cannot be realized when the documents are poorly implemented (Brouwers et al., 2015). When it comes to the intrinsic attributes of a CPG such as what and how the content is presented, relatively minor changes in CPG development should prove a low cost strategy that will yield substantial benefit (Brouwers et al., 2015). Second, at the time there was no other resource that incorporated a comprehensive approach involving all of the attributes relevant to guideline implementability, available for use (Kastner et al., 2015).

By means of a Realist Review, a survey of 248 members of the worldwide CPG community, and content analysis, a framework of intrinsic factors affecting the implementability of CPGs titled the GUIDE-M, was developed. This conceptual model reflects an evidence-informed international and multidisciplinary perspective to CPG

implementability. The framework consists of six layers of components intrinsic to CPGs that are related to implementability. The top layer of the GUIDE-M consists of three core implementability tactics with their associated domains, sub-domains, attributes, sub-attributes, and elements comprising the remaining five levels (AGREE Enterprise, 2018).

The three tactics include the following: *Developers of Content, Creating Content*, and *Communicating Content* (Brouwers et al., 2015). The *Developers of Content* tactic outlines the types and characteristics of the people required to make up a comprehensive group of CPG developers, the expected knowledge and credentials required of said developers, and the need to disclose any competing interests (Brouwers et al. 2015). The *Creation of Content* tactic outlines the need for widespread stakeholder involvement, the appropriate synthesis of evidence, consistent reporting of CPG elements, maintaining the currency of guidelines, the need to supplement scientific evidence with considered judgement, and making due considerations for the feasibility of implementing the recommendations (Kastner et al., 2015).

Finally, the *Communication of Content* tactic involves fine tuning the CPG message and format (Kastner et al., 2015). The message should be written in such a way that it is clear, simple, and persuasive and the format should consist of key headings (e.g. purpose, methods, recommendations) and be presented in multiple versions to address the needs of different users (Brouwers et al., 2015). The core assumption of the model is that an improvement in the quality of any of these intrinsic components will improve implementability by increasing the acceptability, ability to drive action, feasibility, and uptake of CPGs (AGREE Enterprise, 2018).

Based on members of the international CPG community's ratings of the structure and operational definitions of the GUIDE-M components, Brouwers et al. (2015) concluded that the model is a logical, relevant, and appropriate conceptualization of guideline implementability. Brouwers et al. (2015) maintain that the GUIDE-M can be used in a number of ways. It can be used to create documents with high implementability, to help consumers of guidelines, and to identify areas for further research (Brouwers et al., 2015). The goal of applying the GUIDE-M is to improve the implementability of CPGs thus improving the uptake of same and the quality of care delivered ultimately resulting in improved outcomes at the individual and health care system level (Brouwers et al., 2015). The AGREE Collaboration is currently in the process of refining a tool designed to evaluate the quality and implementability of CPGs based on the GUIDE-M titled the **AGREE R**ecommendation **Ex**cellence (AGREE-REX) (AGREE Enterprise, 2018). This tool is currently not available to the public.

Future Research

From this literature review, a number of areas with respect to the AGREE II Framework were identified as requiring further research. First, the AGREE II Instrument requires further empirical testing to reproduce the findings from Brouwers et al. (2010a, 2010b) studies investigating the construct validity and reliability of the instrument. This research should incorporate larger sample sizes, include an assessment of all 23 items comprising the tool, and should be conducted by researchers independent of the AGREE Research Collaboration to eliminate the potential influence of researcher bias. Additionally, there are currently no studies that have yielded empirical data to link specific quality threshold scores with specific implementation or clinical outcomes. This

makes it difficult for users of the AGREE II Instrument to select quality thresholds to differentiate between CPGs of high, moderate, and low quality.

Another area for future research is with respect to the GUIDE-M. Although the GUIDE-M was the product of a rigorous, systematic, and transparent methodology, there has been no empirical testing of the attributes proposed within the model in supporting CPG implementability. Finally, it is important to note that validity and reliability testing of the AGREE-REX as a tool to assess the quality and implementability of a CPG is currently underway (AGREE Enterprise, 2018).

ARGEE II and Hazardous Medications

Unfortunately, there were no examples of an application of the AGREE II Instrument for the development and/or evaluation of a CPG dealing with exposure to hazardous medications found in the literature. However, sufficient evidence has been obtained from the literature to support the use of this tool to conduct an appraisal of the AHS *Hazardous Medication Personal Protective Equipment Guide and List*. First, the Guide meets the AGREE II: User's Manual (2017) definition of a CPG. The writer also qualifies as an *intended user* as defined in the user's manual although at least one other appraiser is technically required to validate the findings (AGREE Trust, 2017). Finally, there were three different articles found in the literature where the authors made use of the AGREE II Instrument to appraise OHS related CPGs similar to the Guide.

Given the fact that the AGREE II Instrument does not provide guidance regarding how a CPG should be implemented (Brouwers et al., 2010c; Joosen et al., 2015), the writer will also make use of the GUIDE-M. While it would have been ideal that the GUIDE-M be used in the development stage of the Guide to support implementability

(Dewa et al., 2016), the conceptual model will still prove useful after the fact. The GUIDE-M will serve as a theoretical point of reference in completing the critical appraisal and will inform the development of recommendations to support the implementation of the Guide at other SL facilities.

Conclusion

From this comprehensive review of the literature the tremendous potential of CPGs to inform clinical decision making, therefore optimizing outcomes, became apparent (Anaya et al., 2018; Bragge et al., 2014; Brouwers et al., 2010c; Dewa et al., 2016; Mambulu-Chikankheni et al., 2017). Furthermore, the AGREE II was established as a valuable framework to appraise the quality of CPGs as well as guide the development and reporting of same (AGREE Enterprise, 2018). It was very apparent from the numerous articles reporting on the use of the AGREE II Instrument to appraise CPGs, that there is significant variability in the quality of guidelines, with many failing to meet even basic standards. This represents a significant problem as the poor quality of a CPG limits the potential benefits of the document (Brouwers et al., 2015).

Despite the fact that the AGREE II offers a methodological strategy for CPG development, there was only one article found in this review demonstrating this application of the instrument (Besselaar et al., 2017). This, along with the fact that the appraisals of existing CPGs showed highly variable quality scores, highlights the importance of using the AGREE II Framework in the development stage. Although it would have been ideal to apply the AGREE II Framework during development, the writer can still use the AGREE II Instrument to conduct an appraisal of the *Hazardous*

Medication Personal Protective Equipment Guide and List. Furthermore, the GUIDE-M will be used to inform the critical appraisal and subsequent recommendations for future implementations of the Guide. The goal is that the appraisal and recommendations will increase the quality and implementability of the Guide thus optimizing outcomes at the level of the employee, the patient, and the healthcare system as a whole (AGREE Enterprise, 2018).

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Critical Appraisal Summary Table - AGREE II Instrument

Author(s)	Study Objectives	Sample	Design and Methodology	Key Findings	Strengths/ Limitations	Rating
Brouwers, M., Kho, M., Browman, G., Burgers, J., Cluzeau, F., Feder, G., . . . Makarski, J. (2010a)	To determine the performance and reliability of a 7 point response scale To assess the usefulness of the AGREE items To determine if the AGREE ratings were associated with guideline use related outcomes To identify areas of improvement for the AGREE	Convenience sample 96: 40 clinicians, 16 policy makers, 40 researchers from Cancer Care Ontario and the Canadian Partnership Against Cancer	Cross-Sectional Study Participants used the AGREE items to evaluate a guideline using a 7 point scale, provided a rating for three guideline adoption outcome measures, and provided feedback on the usefulness of the tool and ways to improve it A series of ANOVA, multiple regression, Chronbach alpha, and intraclass correlations were used to analyze the quantitative data	5 of the 6 domains of the AGREE were found to be significant predictors of participants' outcome measures ($p<0.05$) Participants rated all domains and items of the AGREE as useful (mean score > 4) with no significant differences by user type ($p> 0.05$) Internal consistency ranged between 0.64 and 0.89	**Strengths** Use of a validated data collection tool (Global Rating Scale) **Limitations** Weak design Study sample size was half that of the a priori sample size calculation Convenience sample Potential for researcher bias as three of the researchers are members of the AGREE Research Trust	**Strength** Weak (PHAC, 2014) **Quality** High (PHAC, 2014) Data used for extrapolation

				Inter-reviewer reliability was satisfactory		
Brouwers, M., Kho, M., Browman, G., Burgers, J., Cluzeau, F., Feder, G., . . . Makarski, J. (2010b)	To assess the construct validity of the AGREE II items and the new user's manual	Convenience sample of 30 guideline developers, researchers, and clinicians from Cancer Care Ontario and the Canadian Partnership Against Cancer	Cross-sectional study Two study packages were created, each containing a low quality and high quality version (designed by the researchers) of 21 of the 23 different AGREE items Participants were randomly assigned to review and rate the content of one package using a survey Data from the survey was analyzed using MANOVA and univariable analysis	Construct validity of the AGREE II was confirmed: MANOVA revealed a significant main effect for guideline quality ($p=0.005$) Univariable analysis revealed significantly different scores for 18 of the 21 AGREE items The content of the high quality version was rated higher than the content of low quality version Instructions of the new user's	**Strengths** Over-sampling was used to obtain the target sample size One way ANOVA was used to confirm that there were no significant differences between the two versions of the study packages **Limitations** Weak design Study packages only addressed 21	**Strength** Weak (PHAC, 2014) **Quality** High (PHAC, 2014) Data used for extrapolation

			One way ANOVA was used to determine if differences existed between the two versions of the study packages	manual are appropriate, easy to apply, and created confidence among users Mean scores for the usability of the new user's manual were high including 5.43-6.43 for appropriateness, 5.33-6.33 for ease of application, and 5.21-6.27 for ability to discriminate Conclusion: there was a significant difference between the two versions of the AGREE items, with the high quality version rating higher	of the 23 items Convenience sample Potential for researcher bias as three of the researchers are members of the AGREE Research Trust	

MacQueen, G., Santaguida, P., Keshavarz, H., Jaworska, N., Levine, M., Beyene, J., & Raina, P. (2017)	To use the AGREE II to critically evaluate 21 CPGs for treating adults with depression	Two reviewers evaluated 21 CPGs for treating adults with depression	A systematic review of CPGs for treating adults with depression was conducted Seven databases and grey literature sources were searched Two reviewers screened articles, a third reviewer resolved any conflicts Two reviewers then evaluated the CPGs using the AGREE	The quality of the guidelines was highly variable, especially in certain domains (*Stakeholder Involvement*, *Rigor of Development*, and *Applicability*) AGREE II scores for the *Applicability* domain were the lowest (0-60%) AGREE II scores for the *Scope and Purpose* domain were highest (69-100%) followed by the *Clarity of Presentation* domain (61-94%)	**Strengths** Use of a third objective reviewer to resolve screening disputes Use of AGREE II tool for a consistent and systematic assessment of CPG quality Search was for CPGs related to adults with depression **Limitations** Search did not include non-English language articles Only two reviewers were used	**Strength** No rating (PHAC, 2014) **Quality** High (PHAC, 2014) Data used for extrapolation

Bragge, P., Pattuwage, L., Marshall, S., Pitt, V., Picenna, L., Stergiou-Kita, M., . . . Bayley, M. (2014)	To use the AGREE II to identify and evaluate the methodological quality of CPGs for cognitive rehabilitation following traumatic brain injury	Four reviewers appraised each of the CPGs using the AGREE II instrument	Systematic review of 11 CPGs for cognitive rehabilitation was conducted Five databases and 26 web based guideline portals were searched Two reviewers screened articles for inclusion Reviewer agreement was assessed using intraclass correlation coefficients (ICCs)	Overall, CPGs were unambiguous with clearly identifiable recommendation 3 domain scores were consistently low with medians of 3.1% (*Applicability*), 20.8% (*Editorial Independence*), and 26.4% (*Stakeholder Involvement*) 9 out of 11 CPGs received a 50% or greater overall quality rating	**Strengths** AGREE II tool provided a consistent and systematic assessment of CPG quality Search was for CPGs related to topic ICCs used to assess reviewer agreement **Limitations** Search did not include non-English language articles	**Strength** No rating (PHAC, 2014) **Quality** High (PHAC, 2014) Data used for extrapolation
Anaya, M., Franco, J., Merchan-Galvis, A., Gallardo, C., & Cosp, X. (2018)	To identify and systematically assess the quality of 12 CPGs on treatments for oral cancer	Four reviewers appraised 12 CPGs using the AGREE II instrument	A systematic review of evidence for CPGs for oral cancer treatment was conducted including a search of MEDLINE,	Mean quality scores for each AGREE II domain were: *Scope and Purpose* (88.4%), *Stakeholder*	**Strengths** Use of AGREE II tool for a consistent and systematic	**Strength** No rating (PHAC, 2014) **Quality** High (PHAC, 2014)

			EMBASE, TRIP, CPG Clearinghouse, and relevant CPG developer group websites Two reviewers screened articles for inclusion Inter-reviewer agreement was assessed using ICCs	*Involvement* (60.4%), *Rigor of Development* (60.9%), *Clarity of Presentation* (76.5%), *Applicability* (32.2%), and *Editorial Independence* (61.6%) 3 CPGs were rated as "recommended", 6 as "recommended with modifications", and 3 as "not recommended" Inter-rater agreement was high (ICC:0.865, 95%, confidence interval (CI):0.835-0.889)	assessment of CPG quality Use of ICCs to assess reviewer agreement Search was for CPGs related to oral cancer **Limitations** Search did not include non-English language articles	Data used for extrapolation
Joosen, M., Brouwers, E., van Beurden,	To identify OHS CPGs that focus on the	Four reviewers appraised	A systematic review of 14 CPGs on the	CPG quality varied considerably	**Strengths** Use of AGREE II	**Strength**

K., Terluin, B., Routsalainen, J., Woo, J., . . . Choi, K. (2013)	management of mental disorders/stress and use the AGREE II to describe them, compare content, and assess quality	each of the CPGs using the AGREE II instrument	management of mental disorders /stress was conducted including a search of PubMed, Guidelines International Network Library, and the National Guideline Clearinghouse Two reviewers screened articles for inclusion	4 out of 14 CPGs were rated as high quality CPGs scored highest on the *Scope and Purpose* domain (mean score of 73%) CPGs scored lowest on the *Editorial Independence* domain (mean score of 31%)	tool for a consistent and systematic assessment of CPG quality Search was not limited by language Search was for CPGs related to OHS **Limitations** Only one journal database was used to search for CPGs	No rating (PHAC, 2014) **Quality** High (PHAC, 2014) Data used for extrapolation
Dewa, C., Trojanowski, L., Joosen, M., & Bonato, S. (2016)	To identify CPGs for mental-disorder related disability practices for employers and assess their quality using the AGREE II	Two reviewers appraised each of the CPGs using the AGREE II instrument	A systematic review of 5 CPGs for mental-disorder related disability practices was conducted using publicly available grey literature (via a Google	Weakest area was in the *Applicability* domain; all 5 CPGs had scores <50% due to limited: recommendation for implementing	**Strengths** Use of AGREE II tool for a consistent and systematic assessment of CPG quality	**Strength** No rating (PHAC, 2014) **Quality** Medium (PHAC, 2014)

			Advance search) and best practice portals Two reviewers screened CPGs for inclusion and conducted the assessment	the CPG, information about resource implications, and monitoring/ auditing criteria Highest rated domains were *Scope and Purpose* (80-100%) and *Clarity of Presentation* (70-89%)	Search was for CPGs related to topic **Limitations** Search did not include non-English language articles Small number of CPGs included in review Poor explanation provided by authors as to why only grey literature was searched: "the target audience would not be expected to search the academic	Data used for extrapolation

					literature" (p. 177)	
Mambulu-Chikakheni, F., Eyles, J., Eboreime, E., & Ditlopo, P. (2017)	To identify CPGs related to malnutrition To assess the quality of the CPGs for malnutrition used in South Africa	5-6 reviewers assessed the quality of the 4 CPGs using the AGREE II instrument	Critical appraisal of 4 CPGs for malnutrition management was conducted using the AGREE II Google and government websites were searched for relevant CPGs used in South Africa Preliminary critical appraisal findings from the AGREE II were sent to each reviewer to enhance consistency in ratings	CPGs scored highest on the *Scope and Purpose* domain (mean score of 89%) and *Clarity of Presentation* domain (mean score of 86%) CPGs scored lowest on the *Editorial Independence* domain (9-20%)	**Strengths** Use of AGREE II tool for a consistent and systematic assessment of CPG quality Use of member checking **Limitations** Only government websites and Google were used to search for relevant CPGs used in South Africa A varying number of individuals with different backgrounds	**Strength** No rating (PHAC, 2014) **Quality** Medium (PHAC, 2014) Data used for extrapolation

					rated each CPG	

Critical Appraisal Summary Table- GUIDE-M

Author(s)	Study Objectives	Sample	Design and Methodology	Key Findings	Strengths/ Limitations	Rating
Brouwers, M., Makarski, J., Kastner, M., Hayden, L., & Bhattach-aryya, O. (2015)	Create a model of CPG implement-ability	Realist Review and content analysis was completed by the 5 core researchers 248 participants from CPG development communities worldwide	Realist Review was conducted by means of a systematic search, targeted search, and a reference list search to identify intrinsic CPG features of implementability An iterative consensus process was used by core members of the research team to create the beta version of the conceptual model (GUIDE-M) Survey participants rated the structure, nomenclature, and operational definitions of the GUIDE-M using a 7 point Likert scale (analyzed using	Beta version of the model consisted of 3 implement-ability tactics, 7 implement-ability domains, 9 subdomains, 44 attributes, and 40 sub-attributes Survey results rated the model as logical, relevant, and appropriate Unlike GUIDE-M, existing CPG tools failed to address the contextual-ization and deliberations domain	**Strengths** Comparison of GUIDE-M to other CPG models on the world stage Inclusion of international literature from seven different disciplines during the Realist Review resulted in a model amenable to multidisciplinary use internationally **Limitations** Potential for self-selection bias among survey participants Final GUIDE-M was evaluated by the core research	**Strength** No rating (PHAC, 2014) **Quality** High (PHAC, 2014) Data used for extrapolation

			descriptive statistics) Content analysis was used to compare the model to 7 existing international CPG tools		team, not independent researchers GUIDE-M does not indicate the relative importance of its components	
Kastner, M., Bhattach-aryya, O., Hayden, L., Makarski, J., Estey, E., Durocher, L., . . . Brouwers, M. (2015)	Identify factors associated with the implement-ability of CPGs Identify traits of CPGs that support their uptake	Two sets of reviewers independently screened articles for inclusion and extracted data 278 articles were included	Realist Review of 278 articles Three level process used for analysis: 1) development of a codebook, 2) validation of data, and 3) development of hierarchical explanatory narratives to explain guideline implementability	CPG implement-ability is associated with: 1) creation of content (relevant domains: stakeholder involvement, evidence synthesis, considered judgement, and implementation feasibility) and 2) effective communication of CPG content (relevant domains: message and format)	**Strengths** First systematic review to investigate CPG implementability from a comprehensive and multidisciplinary perspective **Limitations** Some disciplines may have been underrepresented as the majority of the articles were from the medicine literature	**Strength** No rating (PHAC, 2014) **Quality** High (PHAC, 2014) Data used for extrapolation

Appendix B

Consultation Report

Student's Name: Tracy Sorensen **Student ID #: 201389145**

Course Names and Numbers: NURS 6660

Supervisor: Dr. MacDonald

Title: Appraisal of a Hazardous Medication Personal Protective Equipment Guide and List for Health Care Workers Caring for Adults in the Community

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Date: November 22, 2018

1. Background

Health care workers (HCWs) are at risk for occupational exposure to hazardous medications, which can result in adverse health effects. As outlined in the Occupational Health and Safety (OHS) Code; an employer is responsible to assess a worksite for existing and potential hazards and take measures to eliminate or control said hazards (Government of Alberta, 2018). To control workers' exposure to hazardous medications, and enhance worker and patient safety, Alberta Health Services (AHS) developed the *Hazardous Medication Personal Protective Equipment Guide and List* (2018). Prior to the implementation of this Guide, HCWs referred to the *Cytotoxic Drug Manual Administration and Handling Guidelines* (AHS, 2013) to identify the required safety measures when working with cytotoxic medications. Both the Guide (AHS, 2018) and the Manual (AHS, 2013) provide clinical practice guidance for HCWs caring for adults in the community.

The *Hazardous Medication Personal Protective Equipment Guide and List* deviates from the existing *Cytotoxic Drug Manual Administration and Handling Guidelines* in a number of ways, which could have significant implications for HCWs caring for adults living in the community. The Manual lists the cytotoxic drugs that necessitate added control measures when being handled whereas the new Guide contains an extensive list of all hazardous medications adopted directly from the National Institute for Occupational Safety and Health (NIOSH). The NIOSH list includes cytotoxic medications as well as those that are teratogenic, genotoxic, toxic to organs, and those that mimic other known hazardous medications (AHS, 2018). As such, the list of medications representing an occupational hazard under the new Guide is significantly longer and includes common medications such as carbamazepine, estrogen/progesterone containing medications, clonazepam, valproic acid, and warfarin.

Following a province wide roll out of the *Hazardous Medication Personal Protective Equipment Guide and List* in January of 2018, a number of questions and concerns came forward regarding how this Guide could be implemented in the Supportive Living setting (SLS). Barriers to implementing the new Guide included the increase in costs for more personal protective equipment (PPE) and spill kits, a lack of resources and processes for the disposal of biohazardous wastes, and issues ensuring hazardous medication risks are communicated to all HCWs. These barriers could have a major impact on the implementation of the Guide in the SLS. To date, the only SL facility in AHS known to have fully implemented the Guide is the test site.

The overall purpose for this practicum project is to conduct a critical appraisal of the Guide using the **A**ppraisal of **G**uidelines for **Re**search and **E**valuation Instrument II

(AGREE II). This appraisal will serve to determine the value of the *Hazardous Medication Personal Protective Equipment Guide and List* as a clinical practice guideline for HCWs caring for adults living in the SLS. Furthermore, consultations with key informants at the test site will serve to reveal essential information about the implementation of the Guide in the SLS. In order to collect information from key informants about the Guide and apply that knowledge to the appraisal of the Guide, consultations were conducted. The specific objectives of the consultations were to:

1. Identify the current implementation plan for the Guide.
2. Identify the key informants' perception of the Guide.
3. Examine barriers and facilitators that affect the implementation of the Guide.
4. Identify strategies and recommendations to support the successful implementation of the Guide.

2. Sample and Data Collection

A total of ten interviews were conducted, one on one, with key informants. Six interviews took place in person in a private office and four interviews took place via telephone. Interviewees consisted of Managers, a Team Lead, HCWs, a pharmacist and representatives from the Continuing Care Hazardous Medication Committee and a Continuing Care Senior Workplace Health and Safety Advisor. Unfortunately, there were no nutrition and food services workers or linen and environmental services workers available for interviews. Interviews with the HCWs were arranged by the site Manager and all other interviews were booked by the author. Interviews were booked for a time

that was convenient for the informant. All interviews were conducted using a semi-structured Interview Guide. Each interview began with the author introducing herself, explaining her role, the objectives of the practicum project, and the specific objectives for the interview. The author also explained how the data would be analyzed and outlined the plan to use the information collected. Consent to participate was obtained from each participant before beginning the interview. Data collection continued until a critical point of data saturation was reached.

3. Data Management and Analysis

Notes were taken throughout the interview and immediately after each consultation the writer reflected upon the findings. Findings from the interviews, and the reflections upon same, then underwent content analysis whereby common themes in relation to each interview question were identified and analyzed.

4. Ethical Considerations

Based on the results of the Health Research Ethics Authority Screening Tool, Research Ethics Board review was not required for these consultations as the purpose of the project is quality/evaluation. However, permission to conduct the practicum project, which included the implementation of the consultation plan, was obtained from the writer's practicum supervisor from the Memorial University of Newfoundland, the SLS Program Manager, and the site Manager.

Although approval from a Research Ethics Board was not indicated for this consultation plan, a number of steps were still implemented to protect the rights of the key informants. First, free and informed consent to participate was obtained from each

key informant verbally. Each participant was given information in order to make an informed decision including: the purpose of the evaluation, that participation was voluntary, a description of participant responsibilities and time commitment required, the type of information that was to be collected, the potential risks and benefits of participation, how findings would be disseminated, measures that would be taken to safeguard information collected, the writer's contact information, and the participant's right to withdraw at any time (Government of Canada, 2014). Second, steps were taken to secure the data collected. Data recorded during and after the interviews was stored in a locked filing cabinet only accessible to the writer. This data will be kept for two years after completion of the practicum at which point the paper copies will be shredded. Also, the confidentiality and anonymity of participants' responses was maintained by removing any identifying information from the presented findings.

5. Results

Content analysis of the interview findings revealed common themes related to: informants' perception of the guide (awareness and use), the factors that supported or hindered the implementation of the Guide, the current implementation plan, and strategies and recommendations to support the successful implementation of the Guide.

Perception of the Guide

Awareness. All of the key informants interviewed were aware of the existence of the new *Hazardous Medication Personal Protective Equipment Guide and List.* Six of the ten informants were aware that the Guide could be accessed on the AHS Insite while three others relied on paper copies that had been printed and made available to them in

the nursing station. Four of the participants were also aware that the Guide had been posted to the external AHS website which is accessible to members of the public and so is accessible by those non-AHS employees who are stakeholders in the hazardous medication management process (e.g. community pharmacies).

Use of the Guide. All but one informant reported having used the *Hazardous Medication Personal Protective Equipment Guide and List*. Of the informants that have used the Guide, the way- and purpose- of using it varied. Five of the informants reported that they directly access the Guide, in its entirety, to use it. The other four informants who use it report that they do not access the complete Guide in their work. Three informants reported that they access only those portions of the guide relevant to their position and work. Relevant sections of the Guide, mainly the PPE and waste management posters, are printed and posted at the point of care. One key informant reported being able to access the hazardous medication list from his/her employer's computer system, which has been uploaded with the applicable content.

There was variation in the purpose for which the informants use the Guide. Five of the informants report using the Guide to identify the control measures required to reduce their risk of exposure to hazardous medications. Two of the informants report using the Guide as a reference in order to fulfill their responsibilities in preventing exposure to hazardous medication within the SLS. Two of the ten informants report using the guide to identify control measures and fulfill their responsibilities.

Facilitators for Implementation

Informants identified a number of factors associated with the *Hazardous Medication Personal Protective Equipment Guide and List* that supported its successful implementation at the test site. Five of the informants who have used the Guide report that it is easy to use and self-explanatory. Two informants elaborated that the Guide is broken down into tasks which makes it easy to use. One informant expressed that the comprehensiveness of the Guide is a real facilitator for implementation. Another pro of the Guide identified by three of the informants was that it contains posters that provide direction regarding PPE use and/or waste management requirements that can easily be printed and posted at the point of care for HCWs to refer to. Two informants identified the fact that the Guide contains pictures of tasks, PPE, and waste management equipment and supplies as being a pro. Similarly, two informants identified the algorithm summarizing how to use the Guide as facilitating implementation. Two informants stated that a pro of the Guide was that the WHS Advisors and Medication Management Steering Committee were consulted in its development to support applicability and usability. Finally, one informant identified that the contact information provided within the Guide to the hazardous medication experts was a plus as it ensures users will know where they can go if they have more questions about the contents.

Factors that Hinder Implementation

Informants identified a number of factors associated with the *Hazardous Medication Personal Protective Equipment Guide and List* that hindered the success of its

implementation. Four of the informants described the guide as “intense”, “robust”, or “overwhelming”, making it difficult to find the required information in a timely manner. One of these informants went further to criticize the already lengthy guide for containing numerous hyperlinks and references to additional documents that are also lengthy. While the overall Guide was criticized for being lengthy, three informants also criticized the inclusion of commonly prescribed medications such as warfarin, selective serotonin reuptake inhibitors, and risperidone. One informant stated “there is no scientific evidence that the drugs on the potential hazard list are in fact harmful when handled in low doses”. This informant felt that the previous list contained within the *Cytotoxic Drug Manual Administration and Handling Guidelines* was more appropriate because it only contained medications that were *known* hazards, described as “the big guns.”

One informant expressed concerns that the comprehensive list of hazardous medications, particularly those that are *potential* or *reproductive* hazards, lends the Guide to conveying an inaccurate portrayal of the risk associated with these medications. That is to say, the Guide exaggerates the true risk associated with the medications falling within the *potential* and *reproductive* categories. Another participant felt that the extensive list could lead to complacency where essentially a HCW might see the same hazardous medication label on warfarin as on methotrexate and so think that the risk of handling the methotrexate is as low as handling warfarin, or vice versa. Another significant criticism coming from one informant was that the Guide was written as a clinical practice guideline, not a policy, which could create problems enforcing the recommendations.

Despite the fact that the Guide was criticized for being lengthy, a number of criticisms regarding a lack of direction were also brought forward. Two informants identified the fact that the Guide does not outline the roles and responsibilities of AHS HCWs and contracted service provider HCWs, with respect to following the Guide. In partnership situations where both AHS and contracted service providers are involved in the provision of care, the Guide does not indicate who is responsible for providing and paying for the cost of PPE and waste management equipment and services. One informant pointed out that the Guide was written from an acute care perspective and assumes the end users of the document are all AHS HCWs, which of course is not the case in the SLS. For example, the Guide shows pictures of the acceptable hazardous medication labels readily available in acute care but not available to community pharmacies. Further to this, two informants pointed out that they were not sure if the recommendations in the Guide apply to contracted service providers who have their own processes for hazardous medication management.

Two informants criticized the Guide for failing to provide program level processes leaving programs without clear directions to meet the recommendations in the Guide (e.g. waste disposal). One informant pointed out that the Guide refers the user to contact their WHS Advisor for program specific processes for a specific task, which could result in a delay in receiving information. Key informants recommended the following content be added to the Guide: 1) specific spill kits recommended for use, 2) precautions required of clients/families potentially exposed to hazardous medications, and 3) direction regarding the selection of PPE where recommended PPE for the purposes of protecting a worker

from hazardous medication exposure contradict those required for infectious disease exposure.

Current Implementation Plan

Key informants reported that a number of different strategies were used in the current implementation of the Guide at the test site including education and site specific processes. One of the key strategies identified by seven of the participants was the education HCWs received about the Guide including an introduction to the Guide, a demonstration of the donning and doffing of PPE and a demonstration of how to draw up, administer, and dispose of a hazardous medication. Two informants also reported that HCWs responsible for the administration of cytotoxic medications, were also required to complete the Cytotoxic Medication Management e-module and test. Two other informants noted during their interviews that they had completed this e-module.

One key informant also noted that during their orientation "buddy shifts", their mentor provided information regarding the hazardous medication management process at the test site. She also noted that, HCWs who do not routinely administer hazardous medications do so under the guidance of an experienced nurse. Two informants reported that it was necessary to provide some education to the client/family who was receiving the hazardous medication that required PPE for administration. This was necessary to ease the client/family's anxiety about the PPE use by HCWs. Finally, one informant spoke of efforts to continually promote awareness regarding the hazardous medication management process during change of shift report, checking with HCWs to answer

questions about the recommendations in the Guide, and ensuring that HCWs are aware of how to reach out if they have questions.

Another strategy used to implement the Guide at the test site was to collaborate with community pharmacies supplying medications, to agree on a process for identifying, preparing, and packaging hazardous medications. Three informants report that at the test site they collaborated with the pharmacy to achieve this partnership. One of the three main pharmacies serving the site reported that they uploaded the NIOSH list into their computer system. The system then automatically printed the warning "HAZARDOUS MEDICATION" on the medication package, and the medication administration record. The pharmacy technicians also affixed the hazardous medication sticker to the drug package. The pharmacist then double checks to make sure the labeling is correct. It is noteworthy that the hazardous medication label does not specify whether or not the medication is a *known, potential*, or *reproductive* hazard.

The next strategy used to implement the Guide at the test site was to develop an internal process for managing hazardous medications. A large part of this process involves the communication of hazardous medication related risks. Six of the informants reported that the following is the process for managing hazardous medications at the test site: 1) when medications arrive from pharmacy the nurse reviews them to identify if any are labeled as hazardous, 2) if a hazardous medication is identified the nurse refers to the Guide to determine if it is a *known, potential*, or *reproductive* hazard, 3) the nurse informs the other HCWs of the hazardous medication during shift report and by means of updating the Kardex with the hazardous medication label, and 4) the nurse prints the PPE

and waste management posters applicable to the hazardous medication identified in the Guide and posts them in the client's individual medication cupboards in their rooms. The posters related to the required waste management processes are also posted in the client's bathroom. If the client's human waste poses a hazard the nurse would also communicate this to the site manager so other departments (e.g. environmental services) can be informed.

One informant reported that the Case Manager is informed of clients who have been prescribed hazardous medications either by attending rounds, through report from the nurse, or by reviewing the medication administration records. The Case Manager then documents that the client is taking hazardous medications on the *Safety Risk Assessment* and *Daily Living Support Plan Interventions* on the care plan. Furthermore, five informants reported that for the one client receiving a *known* hazardous medication, the precautionary period for handling human wastes is communicated to the team via change of shift report and written on the Kardex. All five key informants reported that any articles contaminated with human wastes during the precautionary period are disposed of in the biohazard bin. One informant added that a professional waste disposal company provides the biohazardous bins and picks them up when they are full.

Another implementation strategy that promoted the successful implementation of the recommendations from the Guide at the test site was obtaining the PPE and other equipment required for the management of hazardous medications, and making it readily available to the HCWs who need it at the point of care. Five of the informants reported that required PPE was stored in the client's medication cupboard, and in the bathroom if

PPE was indicated for human waste management. One informant clarified that the nurse who identifies the hazardous medication is responsible for ensuring the required PPE is put in the client's room and that each week the stock is replenished. Four of the informants reported that PPE has been readily available to them when needed. One informant reported that there have been cases where she has had to "track down" the PPE when it was needed.

Strategies to Address Barriers to Successful Implementation

The barriers to successful implementation of the Guide identified by the key informants at the test site were addressed by creating site-specific processes. Many of the challenges/barriers are related to the aforementioned cons of the Guide and include a lack of site specific processes, the long list of medications considered hazardous, level of exposure risk for HCWs and families, collaborating with pharmacy, and costs of PPE equipment.

Site specific processes. Three informants identified that the lack of SL specific processes within the Guide posed a challenge to its implementation. Two of the informants agreed that this challenge was overcome by creating their own site-specific processes for hazardous medication management that complied with the requirements outlined in the Guide. This process is described above and according to two informants has had the added benefit of supporting the efficient use of the robust content and addressing the challenge of navigating and interpreting the Guide.

List of medications. An additional barrier identified by two informants was the new, long list of medications included on the hazardous medication list contained within the Guide. One informant pointed out that the length of the list makes it difficult to identify hazardous medications quickly. This informant felt the hazardous medication list contained within the *Cytotoxic Drug Manual Administration and Handling Guidelines* was a better guide for the SLS. Strategies to overcome this barrier include pharmacy uploading the list to their computer system so that medications that are hazardous are automatically flagged and educating HCWs on the new list in the Guide.

Low risk medication. Another barrier to the implementation of the Guide at the test site, identified by three informants, was the fear of handling hazardous medications that were previously not considered to be hazardous. These informants reported that the education on the Guide and support provided to implement the recommendations from the Guide was sufficient to ease this worry and instill feelings of confidence among the HCWs in managing these medications. In addition to the initial response from HCWs to the Guide, three informants also reported that its implementation was intimidating and alienating for the clients taking the hazardous medications and their families and friends. Two of these informants reported that after they explained that the PPE was required to manage the *occupational risks* associated with hazardous medications, these concerns were addressed. One informant spoke of a client's family's concern that they themselves had been administering the same medication to the client for years without taking any precautions. The family was upset that they had not been cautioned to take measures to protect themselves. The informant explained that the client/family's concerns were

addressed in part by providing some education about the hazard, exposure, and relative risk but obviously they were unable to remedy previous exposures.

Collaboration with pharmacy. A number of additional challenges/barriers to the implementation of the Guide, unrelated to the perceived cons inherent to the document, were identified. First, collaborating with *all* pharmacy providers to ensure hazardous medications were identified and appropriately labeled was a challenge. Although most clients use the main pharmacy provider for the site, two informants reported that connecting with the other "smaller" community pharmacies and getting them "on board" required a lot of effort. However, both informants report that these efforts were successful as these smaller pharmacies are now identifying and labeling the medications appropriately.

Another challenge/barrier identified by an informant was that the requirement to affix the hazardous medication sticker to the medication package, in addition to the labeling printed on the package via the computer system, was "cumbersome" and not a failsafe as it requires the pharmacy staff member to manually add the sticker. This informant also questioned if adding a second flag to the packaging indicating that it contains a hazardous medication is "overkill" and possibly creates an overreliance by HCWs on the element of the hazardous medication labeling process that is susceptible to human error (i.e. the manual addition of the sticker versus the automatic labeling by the computer system). The informant recommended doing away with the use of the hazardous medication sticker and relying solely on the label printed from the computer, which indicates "HAZARDOUS MEDICATION." The informant also cautioned that a

process is required for any updates made to the hazardous medication list to be identified and uploaded into their computer system.

Costs of PPE. Another challenge/barrier to the implementation of the Guide was the costs associated with providing PPE, waste collection receptacles, and spill kits. Four informants identified extra costs associated with the overuse of PPE (e.g. using additional PPE to handle the biological wastes of a client who previously received a *known* hazardous medication, even though the precautionary period was over). Four key informants reported that the cost associated with the overuse of PPE was addressed by improving the communication processes in place to identify the clients on hazardous medications, the required precautionary periods, and the PPE and waste management equipment needed. This topic was also addressed in the education provided to all HCWs on the Guide.

One informant expressed a need to monitor the use of PPE on an ongoing basis to ensure it is used appropriately. In addition to the issue of cost, four informants identified the time it takes to don and doff PPE as a challenge/barrier. One informant explained that the time required to don and doff PPE was impacted by the availability of the required equipment at the point of care. Finally, one informant identified that a challenge associated with the implementation of the Guide, specifically the use of PPE as outlined within it, creates a significant amount of environmental wastes. However, key informants recognized that unnecessary waste can be minimized by ensuring HCWs use PPE appropriately.

Prefilled medications. Another challenge/barrier that was encountered was in obtaining prefilled methotrexate syringes for injection. Two informants report that initially they were required to manually draw up the medication from a vial prior to administration, thus increasing their risk of exposure. One informant said that she looked into having the pharmacy provide pre-filled syringes but that it was not possible as the client could not afford the difference in price, approximately $400 a year. Fortunately, another informant reported that they were able to secure the client additional funding from Blue Cross for the pre-filled syringes which are now being provided.

Organizational structure. The final challenge/barrier that informants encountered was a change to the organizational structure at the test site. Since the initial implementation of the Guide, another company has taken over the contract for nutrition and food services and linen and environmental services. This has created confusion as to which employer is responsible to supply the PPE for these workers. One strategy used to address this issue was to change the client's housekeeping day to a day that falls outside of the precautionary period (if the client is taking a *known* hazardous medication) and therefore the management of any bodily wastes does not require additional PPE beyond routine precautions.

Recommendations for Implementation

During the consultations, key informants made a number of recommendations for the successful implementation and evaluation of the Guide:

i) Develop site-specific processes for hazardous medication management.

ii) Assign an onsite clinical lead or resource person to assist HCWs to identify the control measures needed for each individual client taking hazardous medications.

iii) Post PPE and waste management posters at the point of care.

iv) Continue to consult with pharmacy to ensure the hazardous medication list has been uploaded into the computer dispensing system wherever possible and ensure a process is in place to update the list as necessary.

v) Educate all HCWs about the Guide at orientation and through ongoing education sessions tailored to the needs of the HCWs.

vi) Explore all HCWs, including contracted service providers, completing the Cytotoxic Medication Management e-module and test.

vii) Reassure and educate clients and families about controls required for the safe management of hazardous medications and bodily wastes: provide initial and ongoing education and support to clients and families, including written education resources.

viii) Collaborate with all pharmacy providers to ensure processes are in place to identify and label hazardous medications.

ix) Ensure HCWs are knowledgeable about when and what equipment to use and audit the use of that equipment on an ongoing basis.

x) Where possible, schedule housekeeping services on a day that falls outside of the precautionary period for hazardous medications.

xi) Ensure the required PPE is available to all HCWs at the point of care.

xii) Explore pharmacy providing pre-filled syringes for injectable hazardous medications as needed and seek financial support from insurance companies to cover additional costs associated with pre-filled syringes.

xiii) Clarify who is responsible for covering the costs associated with providing PPE and waste disposal equipment and services.

xiv) Evaluate ongoing compliance to the Guide by conducting regular audits to ensure: hazardous medications are correctly identified and labeled by pharmacy, hazardous medications are identified and communicated as being hazardous amongst the facility staff, the correct PPE is being used, waste management requirements are being followed, and site specific hazardous medication management processes are followed.

xv) Track exposure reports to identify incidences of exposures to hazardous medications (via My Safety Net for AHS HCWs).

xvi) Involve HCWs in developing and implementing an evaluation plan for the Guide at all sites (e.g. focus groups).

6. Conclusion

The results obtained from these consultations were used to complete the critical appraisal of the *Hazardous Medication Personal Protective Equipment Guide and List*. Data collected from informants regarding their awareness and use of the Guide, barriers to implementation, and strategies and recommendations to support implementation will prove vital in the formulation of final recommendations to support future implementation of the Guide.

7. References

Alberta Health Services. (2013). *Cytotoxic drug manual administration and handling guidelines*. Retrieved from http://extcontent.covenanthealth.ca/PatientResident/Cytotoxic_Drug_Manual_Nov_19_2013_complete.pdf

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Appraisal of a Hazardous Medication Personal Protective Equipment Guide and List for Health Care Workers Caring for Adults in the Community

Interview Guide

Information on the Project

The overall goal of this practicum is to appraise the *Hazardous Medication Personal Protective Equipment Guide and List* (AHS, 2018). I am interested in your opinions about the Guide including the barriers and/or facilitators to implementing the Guide and your recommendations for strategies to successfully implement the Guide. Your participation is voluntary and you can withdraw at any time before or during the interview. This interview should take 15 to 20 minutes and you will be asked a series of questions about the Guide. Notes will be taken during this interview and your comments will remain anonymous. No identifying information will be used. The findings from this interview will be used to inform the practicum project and will be included in a final report that will be available in the Health Sciences Library.

Do you agree to participate in this interview?

Interview Questions

1. Are you aware of the *Hazardous Medication Personal Protective Equipment Guide and List?*
2. Do you and/or your colleagues/HCWs use the Guide?
3. How was the Guide implemented at the test site?
4. Did the implementation of the Guide go as planned?
5. What evidence is there to show that the Guide was implemented at the test site?
6. What were some barriers to the implementation of the Guide?
7. How did you overcome these barriers in order to implement the Guide?
8. What were some enablers that facilitated the implementation of the Guide?
9. What do you think of the Guide? What do you like about it? What don't you like about it?
10. What do your colleagues/HCWs think of the Guide?

Health Research Ethics Authority Screening Tool

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review		✓
2.	Are there any local policies which require this project to undergo review by a Research Ethics Board?		✓
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. **IF NO** to both questions, continue to complete the checklist.	**N/A**	**N/A**
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?	✓	
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?		✓
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?		✓
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?	✓	
7.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?		✓
LINE A: SUBTOTAL Questions 3 through 7		**2**	
8.	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?	✓	
9.	Is the project intended to define a best practice within your organization or practice?		✓
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	✓	
11.	Does the statement of purpose of the project refer explicitly to the features of a particular program, Organization, or region, rather than using more general terminology such as rural vs. urban populations?	✓	
12.	Is the current project part of a continuous process of gathering or monitoring data within an organization?		✓
LINE B: SUBTOTAL		**3**	
	SUMMARY Purpose is evaluation		

Appendix C

Environmental Scan Report

Student's Name: Tracy Sorensen **Student ID #: 201389145**

Course Names and Numbers: NURS 6660

Supervisor: Dr. MacDonald

Title: Appraisal of a Hazardous Medication Personal Protective Equipment Guide and List for Health Care Workers Caring for Adults Living in the Community

Date: November 27, 2018

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1. Brief Overview of the Project

To control workers' exposure to hazardous medications, and enhance worker and patient safety, Alberta Health Services (AHS) developed the *Hazardous Medication Personal Protective Equipment Guide and List* (2018b). Prior to the implementation of this Guide, health care workers (HCWs) referred to the *Cytotoxic Drug Manual Administration and Handling Guidelines* (AHS, 2013) to identify the required safety measures when working with cytotoxic medications. Both the Guide (AHS, 2018b) and the Manual (AHS, 2013) provide clinical practice guidance for HCWs caring for adults in the community.

The overall goal for this practicum is to appraise the *Hazardous Medication Personal Protective Equipment Guide and List* (AHS, 2018b) using the **A**ppraisal of **G**uidelines for **Re**search and **E**valuation Instrument (AGREE II) (AGREE Trust, 2017).

The purpose of this environmental scan was to create an awareness of available local, provincial, and national resources for handling hazardous medications and using Personal Protective Equipment (PPE). The findings from this environmental scan will inform the appraisal of the *Hazardous Medication Personal Protective Equipment Guide and List*.

2. Specific Objective(s) for the Environmental Scan

To identify local, provincial, and national clinical practice guidelines for HCWs who are handling hazardous medications in the community.

3. Sources of Information

A google search for "hazardous medications" and "Canada" was conducted. Also, a question about the availability of hazardous medication resources (at the local, provincial, and national level) was included in the consultations with the Continuing Care Workplace Health and Safety Advisor and Continuing Care Hazardous Medication Committee Member. Finally, the following websites/online platforms were reviewed to identify clinical practice guidelines related to handling hazardous medications in the community:

A) Supportive Living SharePoint: the online platform that houses resources that are specific to Supportive Living-Edmonton Zone HCWs.

B) AHS Insite: the internal website for AHS which houses resources applicable to AHS HCWs across the province.

C) Government of Alberta Occupational Health and Safety (OHS) Online Resource Portal: contains OHS legislation and resources relevant to Albertans.

D) Canadian Centre for Occupational Health and Safety (CCOHS) Website: CCOHS is

Canada's national resource for the advancement of workplace health and safety.

E) The Canadian Clinical Practice Guideline Infobase: a database of evidence-based Canadian clinical practice guidelines maintained by the Canadian Medical Association.

4. Data Collection

The data for this environmental scan was collected from websites/online platforms and by examining the findings of the consultations.

5. Ethical Considerations

As evidenced by the completion of the Health Research Ethics Authority Screening Tool, Research Ethics Board review was not required for this environmental scan as the purpose of the project is quality/evaluation.

6. Results

Source	Resource Document
Supportive Living SharePoint	None
AHS Insite	Hazardous Medication Personal Protective Equipment Guide and List: https://insite.albertahealthservices.ca/main/assets/tms/pmmc/tms-pmmc-ppe-guidelines-all-HCWs.pdf Hazardous Medications Personal Protective Equipment Frequently Asked Questions (FAQ): https://insite.albertahealthservices.ca/main/assets/tms/pmmc/tms-pmmc-hazardous-medication-ppe-guide-faq.pdf Hazardous Medications Personal Protective Equipment Guide and List Tip Sheet: https://insite.albertahealthservices.ca/main/assets/tms/pmmc/tms-pmmc-hazardous-medication-ppe-guide-tip-sheet.pdf Handling Human Wastes of Patients Receiving Known Hazard

	Medications FAQ: https://insite.albertahealthservices.ca/main/assets/tms/pmmc/tms-pmmc-hazardous-medication-hazardous-human-waste-faq.pdf Cytotoxic Drug Manual Administration and Handling Guidelines: https://insite.albertahealthservices.ca/main/assets/tms/phm/tms-phm-ez-cytotoxic-manual.pdf
Alberta Government OHS Online Resource Portal	Cytotoxic Drug Exposure-OHS Information for Workers and Employers: https://ohs-pubstore.labour.alberta.ca/ch074 Protection of Workers from Synthetic Opioid Exposure: https://open.alberta.ca/dataset/e6a1bbaa-1aaa-4348-99ec-2464e999d723/resource/6bf0a66b-6e45-4a48-8ce2-6505a0df29b3/download/protection- of-workers-from-synthetic-opioid-exposure.pdf
British Columbia Cancer Agency	Safe Handling of Hazardous Drugs: http://www.bccancer.bc.ca/pharmacy-site/Documents/Safe%20Handling/2%20%20Module%201_Safe%20Handling%20of%20Hazardous%20Drugs.pdf
Ontario Public Services Health and Safety Association	Safe Handling of Hazardous Drugs in Healthcare: https://www.pshsa.ca/wp-content/uploads/2013/11/PSHSA-Whitepaper-Safe-Handling-of-Hazardous-Drugs-in-Healthcare.pdf
CCOHS	None
Canadian Clinical Practice Guideline InfoBase	None
National Institute of Occupational Safety and Health (NIOSH)	NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings: https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf *Referenced by the Continuing Care Workplace Health and Safety Advisor and Continuing Care Hazardous Medication Committee member during consultations

Resource Document Summary

i) **Hazardous Medications Personal Protective Equipment FAQ:** This document was created by the AHS Hazardous Medication Evaluation Committee (HazMEC); a multidisciplinary group that collaborates in the development and maintenance of the AHS *Hazardous Medication Personal Protective Equipment Guide and List* to ensure proper and safe handling of hazardous medications. The FAQ was written at the provincial level, applies to all AHS HCWs, and was developed to complement the Guide and support its implementation. The FAQ consists of 54 questions on a number of topics including applicability, definitions, disposal, labeling, PPE, medication preparation and administration, resources/contacts, spills management, storage, and transportation.

ii) **Hazardous Medication Personal Protective Equipment Guide and List Tip Sheet:** This tip sheet was also developed by the AHS HazMEC and is intended to complement the *Hazardous Medication Personal Protective Equipment Guide and List* and support its implementation. This is a concise one page document summarizing the purpose of the guide as well as actions required by managers/educators and front line HCWs.

iii) **Handling Human Wastes of Patients Receiving Known Hazard Medications FAQ:** This document was also created by the AHS HazMEC and is intended to compliment the Guide by serving as a resource for HCWs handling human wastes from patients receiving *known* hazardous medications.

This is a five page FAQ addressing when PPE is required, the length of the precautionary period, and waste disposal requirements.

iv) **Cytotoxic Drug Manual Administration and Handling Guidelines:** The Manual was developed by a working group in the Edmonton Zone which consisted of representatives from Nursing, Pharmacy, Workplace Health and Safety, and Materials Management. This Manual meets the criteria of a clinical practice guideline as it is based on a systematic review of the evidence and outlines guidelines for the safe handling and disposal of cytotoxic drugs in AHS healthcare facilities and in the homecare setting, in the Edmonton Zone (Anaya et al., 2018). The manual was updated in February 2018 to ensure it complements the *Hazardous Medication Personal Protective Equipment Guide and List.* It is noteworthy that unlike the Guide, the Manual does not endorse the NIOSH list of hazardous medications, it focuses on cytotoxic medications only.

v) **Cytotoxic Drug Exposure-OHS Information for Workers and Employers:** This three page resource is authored by Work Alberta, a division of the Government of Alberta. Like the *Hazardous Medication Personal Protective Equipment Guide and List*, this resource defines hazardous medications, references the NIOSH hazardous medication list, outlines potential exposures and effects, and identifies appropriate PPE. However, this resource is nowhere near as comprehensive as the Guide and is not based on a systematic review of the evidence. As such, it cannot be considered a clinical practice guideline (Anaya et al., 2018).

vi) **Protection of Workers from Synthetic Opioid Exposure:** This seven page resource, also authored by Work Alberta, focuses on synthetic opioid exposures, the PPE required, and steps for decontamination. Unlike the *Hazardous Medication Personal Protective Equipment Guide and List,* this resource emphasizes the fact that healthcare workers may be exposed to synthetic opioids unknowingly and outlines the appropriate PPE indications. Also unlike the Guide, this resource is not based on a systematic review of the evidence and as such cannot be considered a clinical practice guideline (Anaya et al., 2018).

vii) **Safe Handling of Hazardous Drugs:** This resource is authored by the British Columbia Cancer Agency which partners with regional health authorities to provide a comprehensive cancer control program for British Columbians. Like the Guide, this resource defines hazardous medications, endorses the use of the NIOSH hazardous medication list, and provides direction for the safe handling of these medications including waste disposal requirements. Given the fact that this document is based on a systematic review of the evidence and aids in decision making, it is a clinical practice guideline (Anaya et al., 2018).

viii) **Safe Handling of Hazardous Drugs in Healthcare:** This resource is authored by the Ontario Public Services Health and Safety Association, a division of the Ontario Ministry of Labor. Like the *Hazardous Medication Personal Protective Equipment Guide and List*, this document defines hazardous drugs, endorses the use of the NIOSH hazardous medication list, outlines potential routes of exposure and effects, and provides direction for

control measures. While this resource is not nearly as comprehensive as the Guide it does meet the criteria of a clinical practice guideline as it is based on a systematic review of the evidence and is intended to aid in decision making (Anaya et al., 2018).

ix) **NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings:** Given the fact that this document was referenced in numerous Canadian resources about hazardous medications and was mentioned in the consultations with the Continuing Care Workplace Health and Safety Advisor and Continuing Care HazMEC member, it was included in the environmental scan. This document is authored by the NIOSH, the federal OHS agency in the United States, and meets the criteria outlined by Anaya et al. (2018) to be considered a clinical practice guideline. The hazardous medication list contained within this guideline is endorsed in the *Hazardous Medication Personal Protective Equipment Guide and List* and in the documents authored by Work Alberta, the British Columbia Cancer Agency, and the Ontario Public Services Health and Safety Association cited above. Similar to the *Hazardous Medication Personal Protective Equipment Guide and List,* the intent of this guideline is to outline the control measures required to protect workers from exposure to hazardous medications. This clinical practice guideline is shorter than the Guide (42 pages versus 69) and is less prescriptive. That is to say, the NIOSH resource provides general direction for control measures based on task but is not role specific like the Guide.

7. Conclusion

The resources found in conducting this environmental scan will be used to complete the appraisal of the *Hazardous Medication Personal Protective Equipment Guide and List*. Specifically, the clinical practice guidelines (Cytotoxic Drug Manual Administration and Handling Guidelines, Safe Handling of Hazardous Drugs, Safe Handling of Hazardous Drugs in Healthcare, and the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings) identified at the local, provincial, and national level will serve as an important reference point from which to compare the *Hazardous Medication Personal Protective Equipment Guide and List*. This comparison will be important in completing the appraisal of the quality of the Guide using the AGREE II Framework, specifically as it relates to assessing the *Rigor of Development* domain which takes into consideration the selection of evidence (AGREE Trust, 2017). Furthermore, the supporting documents to the Guide identified in completing the environmental scan, will be referred to when assigning quality ratings for the critical appraisal.

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Health Research Ethics Authority Screening Tool

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review?		✓
2.	Are there any local policies which require this project to undergo review by a Research Ethics Board?		✓
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. **IF NO** to both questions, continue to complete the checklist.		
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?		✓
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?		✓
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?		✓
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?	✓	
7.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?		✓
LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses)		**1**	
8.	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?	✓	
9.	Is the project intended to define a best practice within your organization or practice?	✓	
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	✓	
11.	Does the statement of purpose of the project refer explicitly to the features of a particular program, organization, or region, rather than using more general terminology such as rural vs. urban populations?	✓	
12.	Is the current project part of a continuous process of gathering or monitoring data within an organization?		✓
LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses)		**4**	
	SUMMARY **Program evaluation research**		

Appendix D

Critical Appraisal Summary Report

A Summary Report on the Critical Appraisal of the Hazardous Medication Personal Protective Equipment Guide and List

Tracy Sorensen

Memorial University of Newfoundland

Health care workers (HCWs) caring for older adults in the Supportive Living setting (SLS) can be at risk for adverse health effects from exposure to hazardous medications. Hazardous medications are associated with carcinogenicity, teratogenicity, genotoxicity, and reproductive toxicity. To control HCWs' exposure to hazardous medications and enhance worker and patient safety, Alberta Health Services (AHS) developed the *Hazardous Medication Personal Protective Equipment Guide and List* (2018), henceforth referred to as the Guide. The Guide applies to all AHS HCWs and contracted service providers, including those working in the SLS. Prior to the implementation of the Guide, HCWs referred to the *Cytotoxic Drug Manual Administration and Handling Guidelines* (AHS, 2013). The following report summarizes the findings from a critical appraisal of the Guide using the **A**ppraisal of **G**uidelines for **Re**search and **E**valuation Instrument Version II (AGREE II) guideline appraisal tool.

The AGREE II Instrument offers a systematic framework for evaluating clinical practice guidelines (CPGs) and has been established as a valid and reliable appraisal tool (Makarski & Brouwers, 2014). The AGREE II is an appropriate appraisal tool for this project because the Guide meets the definition of a CPG and the author qualifies as an *intended user* of the tool (AGREE Trust, 2017). The AGREE II tool has also been used to guide the critical appraisal of similar Occupational Health and Safety related CPGs (Dewa, Trojanowski, Joosen & Bonato, 2016; Joosen et al., 2015; Shetty, Raaen, Khodyakov, Boutsicaris & Nuckols, 2018).

The AGREE II Appraisal Tool

The AGREE II appraisal tool consists of 23 items that fall under 6 different quality domains in addition to two global rating items intended to capture the overall quality of a CPG. The first quality domain, *Scope and Purpose*, addresses the overall intent of the CPG, the specific questions it addresses, and the target population. The second domain, *Stakeholder Involvement*, considers whether or not the relevant stakeholders were involved in the development of the CPG and if the perspective(s) of the intended users are reflected. The third domain, *Rigor of Development*, evaluates the process used to gather and synthesize the evidence, formulate recommendations, and update those recommendations. The fourth domain, *Clarity of Presentation*, pertains to the format, structure, and language used in the CPG. The fifth domain, *Applicability*, considers implementation barriers/facilitators as well as the financial implications of instating the CPG. The sixth domain, *Editorial Independence*, addresses whether or not the recommendations made in the CPG were unduly biased. Finally, the *Overall Assessment* section includes a rating of the overall quality of the guideline and a rating of whether the guideline is recommended for use (AGREE Trust, 2017).

The Critical Appraisal Process

The AGREE II: User's Manual (AGREE Trust, 2017) recommends that a minimum of two, preferably four appraisers, independently appraise a CPG to support the reliability of the assessment. However, for purposes of this practicum project, only the author completed the critical appraisal of the Guide. The critical appraisal process began

by obtaining a copy of the Guide and carefully reading the entire document to become familiar with the contents. All of the supporting documents used in the development of the Guide were collected and reviewed as a part of the materials considered in the critical appraisal. The author also consulted with a member of the Guide's development group to obtain information about the development of the Guide.

Data Analysis

The AGREE II Online Guideline Appraisal Tool was used to create the summary report on the critical appraisal of the Guide. All of the 23 items on the AGREE II Tool were scored on a scale of 1 to 7, with 7 representing the highest rating of quality. Frequencies and percentages were analyzed. Item ratings, domain total scores and quality score ratings are presented in Table 1.

There is no research to suggest that specific quality scores are linked to certain outcomes (AGREE Trust, 2017), but for purposes of this practicum, a score of 70% was considered high quality, between 50 and 69% medium quality, and less than 50% poor quality. This high quality threshold score (70%) is in keeping with the literature which states that domain quality threshold scores can be set at percentages ranging from 50% to 70% (Anaya, Franco, Merchan-Galvis, Gallardo & Cosp, 2018; Bragge et al., 2014; Dewa et al., 2016; Joosen et al., 2015; MacQueen, Santaguida, Keshavarz, Jaworska, Levine, Beyene & Raina, 2017; Shetty et al., 2018).

Table 1.

Domain Total Scores, Items Ratings, and Quality Score Ratings

Domain	Statement	Item Rating	Domain Total Scores	Quality Score Rating
Scope and Purpose	Overall Objective	7/7	21/21	100% HIGH
	Health Question	7/7		
	Population Described	7/7		
Stakeholder Involvement	Professional Groups	6/7	18/21	86% HIGH
	Target Population	6/7		
	Target Users	6/7		
Rigor of Development	Systematic Methods	6/7	44/56	79% HIGH
	Criteria for Evidence	7/7		
	Strengths and limitations	6/7		
	Methods to Formulate Recommendations	5/7		
	Benefits, Side Effects, and Risks	6/7		
	Links to Evidence	6/7		
	External Review	6/7		
	Updating *	2/7		
Clarity of Presentation	Specific Recommendations	7/7	21/21	100% HIGH
	Management of Health Issue	7/7		
	Recommendations	7/7		
Applicability	Facilitators and Barriers	6/7	19/28	67% MEDIUM
	Practice	6/7		
	Resource Implications	6/7		
	Monitoring and Auditing *	1/7		
Editorial Independence	Influence on Content	2/7	3/14	21% LOW
	Competing Interests	1/7		

Findings and Discussion

The interpretation of the results of this critical appraisal was completed in accordance with the AGREE User's Manual. The User's Manual offers a number of options for approaches to interpreting results. Common to all methods is the requirement that domain scores be interpreted independently and not aggregated into a single quality score as well as the requirement to compare scores against a pre-set quality threshold. As previously mentioned, the pre-set high quality threshold for this appraisal was ≥70%. The specific approach to interpretation used for this appraisal is one in which all domains are considered to be of equal priority, as opposed to prioritizing one domain over the other or assessing for an improvement in scores over time. In this approach, the quality threshold is the same across all six domains (AGREE Trust, 2017).

Scope and Purpose

With a quality score of 100%, the *Scope and Purpose* domain received one of the highest ratings of quality. This is consistent with other findings reported in the literature with *Scope and Purpose* being the highest scoring domain for CPGs (Anaya et al., 2018; Dewa et al., 2016; Joosen et al. , 2015; MacQueen et al., 2017; Mambulu-Chikankheni, Eyles, Eboreime & Ditlopo, 2017). Based on this score, it can be concluded that the Guide successfully outlines the overall intent, the specific questions it addresses, and the target population.

Stakeholder Involvement

The Guide was scored at 86% for the *Stakeholder Involvement* domain. This indicates that the Guide meets the expectations for involving relevant stakeholders in the development process with due consideration having been paid to the perspective(s) of the intended users (AGREE Trust, 2017). However, due to the fact that information relevant to the members of the development group was not reported in the Guide or supporting documents (e.g. names, discipline, relevant expertise, etc.), it is recommended that information on the development group be added to future versions of the Guide.

Rigor of Development

The *Rigor of Development* score for the Guide was high at 79%. This high quality of rigor in development is reflected in the best practice evidence that was collected and used to formulate the recommendations in the Guide. However, unfortunately, the process of how the evidence was synthesized and used in the formulation of the recommendations was not clearly outlined. Furthermore, this domain score was impacted by the fact that the Guide did not outline a process for updating and auditing. As such, it is recommended that a process for updating and auditing the content be included in future versions of the Guide.

Clarity of Presentation

The quality score calculated for the *Clarity of Presentation* domain was 100%, indicating that the different options for the prevention of the health issue for SL HCWs' occupational exposure to hazardous medications were clearly outlined in the document. It

also indicates that the options presented are tailored to the specific workers and clinical situations involved. This high score is reflective of a pattern of high scores for CPGs in the *Clarity of Presentation* domain, as shown in the literature (Dewa et al., 2016; MacQueen et al., 2017; Mambulu-Chikankheni et al., 2017; Shetty et al., 2018).

Applicability

The *Applicability* domain was scored at 68%, which reflects medium quality. This score indicates that implementation barriers and/or facilitators may not have been fully considered by the developers (AGREE Trust, 2017). Interestingly, patterns identified in the literature indicate that CPGs consistently score low on the *Applicability* domain (Anaya et al., 2018; Bragge et al., 2014; Dewa et al., 2016; MacQueen et al., 2017). The quality score for this domain is less than the pre-set threshold, partly due to the fact that there are no supporting documents to address the resource implications of implementing the recommendations. Specifically, the costs of the PPE, spill kits, waste management equipment, and waste management processing, as well as who is responsible for paying for these costs, are not discussed. Secondly, no monitoring or auditing criteria are provided to evaluate the implementation of the Guide. As such, these findings informed the development of recommendations to clearly identify the required resources for implementation of the Guide and to develop monitoring criteria to evaluate its implementation.

Editorial Independence

The domain score for *Editorial Independence* for the Guide was 21%, which was well below the pre-set threshold. The low rating for this item is based on the fact that there is no explicit statement acknowledging that the views or interests of the funding body have not influenced the content of the Guide and that group members have no conflict of interest in developing the Guide. Despite these omissions, it is clear that the content of the Guide is based on best practice evidence and not personal opinions.

This low score for the *Editorial Independence* domain is consistent with patterns from the literature in which other CPGs also received sub-threshold quality scores *(*Bragge et al., 2014; Joosen et al., 2015; Mambulu-Chikankheni et al., 2017). With such a low quality rating, one cannot be certain that the recommendations made in the Guide are not unduly biased (AGREE Trust, 2017). Therefore, it is recommended that the funding body and the group developing the Guide, explicitly state whether or not there are any conflict(s) of interest and that the content of the Guide was not influenced by personal views or opinions.

Overall Quality

The overall quality for the Guide was rated a 5 out of 7, which translates to a score of 71% thus indicating that the Guide is a high quality document. Furthermore, the Guide was recommended for use with the aforementioned modifications.

Limitations of the Critical Appraisal

There are three identified limitations of note with respect to this critical appraisal process. Firstly, only one appraisal was conducted while the User's Manual recommends that at least two and ideally four be conducted to support the reliability of the assessment (AGREE Trust, 2017). Secondly, the AGREE II is intended to be used to evaluate the methodological quality of CPG development, not the clinical appropriateness or validity of the recommendations within it (Anaya et al., 2018; Bragge et al., 2014; Joosen et al., 2015; MacQueen et al., 2017). As such, the results of this appraisal cannot confirm nor disaffirm the clinical appropriateness or the efficacy of the recommendations within the Guide. An evaluation of the efficacy of the recommendations to prevent occupational exposures to hazardous medications would require the application of a framework designed to assess the quality of evidence such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Method (Besselaar et al., 2017; MacQueen et al., 2017).

A third limitation of note is that the AGREE II Tool does not comprehensively appraise the implementability of CPGs (Makarski & Brouwers, 2014). While the *Applicability* domain contains a number of items related to implementability, such as barriers and facilitators to implementation as well as resource implications, developers of the AGREE II acknowledge the need for a more comprehensive assessment of implementability (Makarski & Brouwers, 2014). In fact, it is this limitation that inspired the development of the AGREE-**R**ecommendation **Ex**cellence (REX), a complementary tool to the AGREE II, intended to be used to conduct a comprehensive evaluation of a

guideline's clinical credibility and implementability (AGREE Enterprise, 2018). Unfortunately, this tool is still under development and not available for use at this time. It is acknowledged that the critical appraisal process completed for this report did not involve a comprehensive assessment of the implementability of the Guide.

Summary of Recommendations

1. Two to four appraisers use the AGREE II to appraise the Guide.
2. Add a section with the names, disciplines, relevant expertise, institution, geographic location, and the role of each member who was involved in the development of the Guide.
3. Describe the development process including the methodology used to conduct the external review, the strategy used to search for and select the evidence, and a description of the strengths and limitations of the evidence.
4. Develop a procedure for updating the contents of the Guide.
5. Identify the costs of PPE, spill kits, waste management equipment, and waste management processing as well as who is responsible for those costs.
6. Develop monitoring and/or auditing criteria to conduct an evaluation of the implementation of the Guide (e.g. hazardous medications are correctly identified and labeled by pharmacy, hazardous medications are identified and communicated as being hazardous amongst the facility HCWs, the correct PPE is being used, waste management requirements are being followed, and site specific hazardous medication management processes are followed).

7. Include a statement explicitly stating the role of the funding body in the development of the Guide.
8. Include a statement explicitly declaring the presence or absence of any conflicts of interest on behalf of the guideline development group members.

Conclusions

The critical appraisal of the *Hazardous Medication Personal Protective Equipment Guide and List* (AHS, 2018) using the ARGEE II Tool showed that the Guide is a high quality CPG that could provide expert guidance for HCWs in the SLS. However, there is room to improve the quality of the Guide, especially in the *Applicability* and *Editorial Independence* domains. Recommendations for improvement include outlining the resource implications of instating the Guide, developing monitoring and/or auditing criteria to evaluate its implementation, and including a statement indicating the views of the funding body and the interests of the guideline development group members. While the critical appraisal findings suggest that the methodological quality of the development of the Guide is high, further work is needed to comprehensively evaluate the clinical appropriateness and implementability of the guideline. In conclusion, based on the results of this critical analysis, the Guide is recommended for use to help control HCWs' exposure to hazardous medications, and enhance worker and patient safety in the SLS.

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AGREE II Online Guideline Appraisal Tool

A critical appraisal of: the Alberta Health Services Hazardous Medication Personal Protective Equipment Guide and List

Created with the AGREE II Online Guideline Appraisal Tool.

No endorsement of the content of this document by the AGREE Research Trust should be implied.

Appraiser: Tracy Sorensen

Date: 22 February 2019

Email: tlw730@mun.ca

URL of this appraisal: http://www.agreetrust.org/appraisal/62159

Guideline URL: https://www.albertahealthservices.ca/assets/info/hp/pharm/if-hp-pharm-hazardous-medicati ons-ppe-guide.pdf

Overall Assessment

Title: Hazardous Medication Personal Protective Equipment Guide and List

Overall quality of this guideline: 5/7

Guideline recommended for use? Yes with modifications.

Notes:

Recommended modifications: 1) include the name, disciplines, relevant expertise, institution, geographic location, and the role in development of each member of the guideline development group, 2) include a section outlining the guideline development process that was used including: the methodology used to conduct the external review, the strategy used to search for and select the evidence, and a description of the strengths and limitations of the evidence, 3) include a procedure for updating the Guide and supporting documents, 4) include a section that addresses the resource implications of implementing the recommendations including the costs of PPE, spill kits, waste management equipment, and waste management processing as well as who is responsible for paying for same, 5) include monitoring and/or auditing criteria for the Guide, and 6) include a statement addressing if and how the funding body influenced the final recommendations as well as a statement declaring the presence or absence of competing interests for the development group members.

Domain	Total
1. Scope and Purpose	21
2. Stakeholder Involvement	18
3. Rigor of Development	44
4. Clarity of Presentation	21
5. Applicability	19
6. Editorial Independence	3

1. Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

Rating: 7

The overall objective of the guideline is specifically described in the Preamble section: “to provide guidance for safe handling of hazardous medications in Alberta Health Services (AHS) and Covenant Health (CH) and to reduce occupational exposure to HCWs” (AHS, 2018b, p. ii).

2. The health question(s) covered by the guideline is (are) specifically described.

Rating: 7

A detailed description of the health questions covered by the guideline are specifically described. Key questions include: 1) What is a hazardous medication?, 2) What medications are hazardous?, 3) What is an occupational exposure?, 4) Who does this apply to?, and 5) How are occupational exposures to hazardous medications prevented or reduced? The key health questions covered by the Guide are listed individually in the table of contents which allows the user to easily access the required information. By answering each of the key questions, the authors indicate the target population, the potential exposures, the required interventions, and the intended outcomes of the Guide.

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Rating: 7

The population to whom the guideline is meant to apply is described in the Guide. The Preamble addresses who the Guide applies to; "all AHS and CH employees, members of the medical and midwifery HCWs, students, volunteers, and other persons acting on behalf of AHS or CH (including contracted service providers as necessary) (AHS, 2018b, p. ii). Unfortunately, there is no rationale provided within the Guide itself explaining exactly when it is necessary for contracted service providers to follow it. However, in the Hazardous Medication PPE Guide Frequently Asked Questions supporting document this is addressed under the question heading: "I am a contracted service provider, do I need to follow this Guide?" In this section of the Hazardous Medication PPE Guide Frequently Asked Questions document it is explained that contracted service providers are strongly encouraged to follow the Guide and use it as a resource for the development of their own policies and procedures. Additionally, under the Who Does This Apply To section, specific departments, including specific roles within those departments, to which the Guide applies are listed. Also, in the Reproductive Hazard Medication in AHS/CH section, the Guide defines the specific HCWs population to whom hazardous medications from the reproductive category pose a hazard: "men or women with a potential to conceive, women who are pregnant, or women who are breast feeding" (AHS, 2018b, p.6).

2. Stakeholder Involvement

4. The guideline development group includes individuals from all relevant professional groups.

Rating: 6

The guideline development group consisted of the AHS Hazardous Medication Evaluation Committee, the AHS Hazardous Medication Evaluation Panel, AHS Pharmacy Services Medication Quality and Safety Team, AHS Health Professions Strategy and Practice, AHS Pharmacy Services Technical Practice Leads, AHS Human Factors, AHS Workplace Health and Safety, and the CH Medication Management and Safety Team. However, neither the Guide, nor the supporting documents, indicate the name, discipline, relevant expertise, institution, geographical location, and role in development of each member of the guideline development group. However, the Hazardous Medication PPE Guide Frequently Asked Questions document does indicate that the development group consisted of a physician, pharmacists, and nurses.

5. The views and preferences of the target population (patients, public, etc.) have been sought.

Rating: 6

The Guide itself does not outline the development process that was used, or more specifically, the strategy used to capture workers' views and preferences. However, based on the fact that a number of AHS and CH committees, which consist of AHS and CH employees, were identified in the Guide as it's developers, it can be confirmed that at least some members of the target population participated in the development of the Guide. Furthermore, a consultation with a guideline development group member revealed that feedback was sought from members of the target population with revisions made to the documents based on same.

6. The target users of the guideline are clearly defined.

Rating: 6

The target users of the guideline are defined in the Preamble and in the Who Does This Apply To sections of the Guide. The Who Does This Apply To section is listed in the table of contents which allows users to readily access this information. However, as previously mentioned in the scoring for item #3, the Guide itself does not explain when it is "necessary" for contracted services providers to follow it. That being said, the Hazardous Medication PPE Guide Frequently Asked Questions supporting document provides clarity by advising that contracted service providers are strongly encouraged to follow the Guide and use it as a resource for the development of their own policies and procedures.

3. Rigour of Development

7. Systematic methods were used to search for evidence.

Rating: 6

While there is no description of the strategy used to search for evidence there is a note in the Resources and References section indicating that information contained within the Guide came from 15 difference sources, for which references are provided. Furthermore, consultation with a member of the guideline development group revealed that a comprehensive literature review on the subject matter was completed as a part of the development process.

8. The criteria for selecting the evidence are clearly described.

Rating: 7

There are numerous references to the National Institute of Occupational Safety and Health (NIOSH) list of hazardous medications and the NIOSH Preventing Occupational Exposures to Antineoplastics and Other Hazardous Drugs in Health Care Settings clinical practice guideline in the Guide. Although there is no report in the Guide or supporting documents as to the criteria that was used to select this evidence, the NIOSH organization is an international leader in the Occupational Health and Safety field and as such references to their resources are very appropriate.

9. The strengths and limitations of the body of evidence are clearly described.

Rating: 6

Although there is no description of the strengths and limitations of the body of evidence provided in the Guide or other supporting documents, the process by which the Guide was developed (as reported by a member of the guideline development group) as well as the references contained within it suggest that considerations of same were made.

10. The methods for formulating the recommendations are clearly described.

Rating: 5

While references to credible information sources are included, there is no description of the methods used to formulate the recommendations within the Guide itself. However, in the Hazardous Medication PPE Guide Frequently Asked Questions supporting document there is a brief rationale provided as to how hazard levels were assigned for hazardous medications under the question heading: “How did AHS assign hazard levels for hazardous medications?” The answer provided is that decisions were “based predominantly on NIOSH decisions (when known), application of NIOSH criteria when a NIOSH decision was not known, or evaluation of available data when necessary” (AHS, 2018c, p. 7).

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Rating: 6

There is evidence that the risks associated with occupational exposures to hazardous medications were considered in the development of the recommendations. The recommendations made within the Guide are accompanied with references to supporting data which highlight these risks.

12. There is an explicit link between the recommendations and the supporting evidence.

Rating: 6

There is a link between the recommendations made within the Guide and the supporting evidence as demonstrated by the references made to information sources. However, not every recommendation made within the Guide is accompanied by an explicit link to the evidence.

13. The guideline has been externally reviewed by experts prior to its publication.

Rating: 6

Although the methodology used to conduct an external review was not reported on within the Guide or supporting documents, a consultation with a guideline development group member revealed that the guideline was reviewed externally before it was approved and implemented. The Guide was distributed to leadership and frontline AHS HCWs as well as to contracted service providers for feedback. Revisions were made to the Guide and the supporting documents based on this feedback. Furthermore, the common questions posed by these external reviewers were collated into a Frequently Asked Questions resource document intended to support the use of the Guide.

14. A procedure for updating the guideline is provided.

Rating: 2

No procedure for updating the guideline is outlined in the Guide or supporting documents. The only mention of updates is made in the Hazardous Medication List-Key Points section of the Guide where it is stated that “The Hazardous Medication List will be reviewed and updated on a periodic basis as new medication or information becomes available” (AHS, 2018b, p. 52).

4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

Rating: 7

The recommendations contained within the Guide are specific and unambiguous. Based on the user's role and the type of Hazardous Medication (known, potential, or reproductive), the user looks up the task they will be performing to identify the specific PPE that is required (e.g. 2 pairs of gloves, a DMR Chemo gown, a N95 mask, etc.). Caveats are included in the recommendations to provide clarification where appropriate. For example, for medications posing a reproductive hazard, a description of the specific population at risk is provided.

16. The different options for management of the condition or health issue are clearly presented.

Rating: 7

This item was scored as a 7 because the Guide clearly presents recommendations for the prevention of the health issue (i.e. occupational exposure to hazardous medications). Furthermore, the recommendations made in the Guide are tailored to the specific worker and clinical situation involved.

17. Key recommendations are easily identifiable.

Rating: 7

Despite the fact that the Guide is dense with information, recommendations are easily identifiable. Recommendations are easy to identify because of the clear and logical organization of the Guide, the presentation of recommendations in chart format which includes pictures, and the existence of the Hazardous Medications Handling Risk Assessment Algorithm (AHS, 2018b, p. 61) which directs the user how to use the Guide.

5. Applicability

18. The guideline describes facilitators and barriers to its application.

Rating: 6

Some of the barriers to the application of the Guide are addressed within the Guide itself. For example, in the Preamble the Guide acknowledges that it may not cover all possible situations but advises that when the user is in doubt to assume precautions to protect themselves from occupational exposure to hazardous medications. Another barrier addressed in the Guide is that different sites use different waste disposal containers. However, examples are provided in the Guide of the most commonly used containers and it outlines which ones are preferred and which ones are acceptable for use if a preferred

container is not available. On the other hand, a number of barriers to implementation are not addressed within the Guide itself such as how to access the preferred waste containers. Fortunately, many of these barriers are addressed in the supporting documents which include the Hazardous Medication PPE Guide Frequently Asked Questions document (AHS, 2018c) and the Handling Human Waste of Patients Receiving Known Hazard Medications Frequently Asked Questions document (AHS, 2018a).

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Rating: 6

The Guide provides tools on how the recommendations can be put into practice. These tools include the Hazardous Medication PPE Guide Frequently Asked Questions document (AHS, 2018c), Handling Human Waste of Patients Receiving Known Hazard Medications Frequently Asked Questions document (AHS, 2018a), the Hazardous Medication PPE Guide Tip Sheet (AHS, 2018d), and the Safe Handling of Hazardous Medication Guiding Practice (AHS, 2018e). These tools are referenced within the Guide itself and are also available on the AHS Hazardous Medication landing page on Insite. However, no information is provided in any of the aforementioned documents as to the development and validation procedures used for these tools.

20. The potential resource implications of applying the recommendations have been considered.

Rating: 6

There is evidence that the potential resource implications of implementing the recommendations in the Guide were considered. Although not identified in the Guide itself, the Hazardous Medication PPE Guide Frequently Asked Questions document (AHS, 2018c) addresses the teaching resources that are available to support the employers\' education of their employees regarding hazardous medication management. However, the documents do not address what the costs of the PPE, spill kits, waste management equipment, and waste management processing are or who is responsible for paying for them.

21. The guideline presents monitoring and/or auditing criteria.

Rating: 1

There is no monitoring and/or auditing criteria identified in the Guide or supporting documents. No strategies for the evaluation of the guideline or associated quality or audit criteria are provided.

6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

Rating: 2

While the funding body for the Guide is identified, there is no explicit statement acknowledging that the views or interests of AHS and CH have not influenced the final recommendations.

23. Competing interests of guideline development group members have been recorded and addressed.

Rating: 1

Neither the Guide, nor its supporting documents, contain an explicit statement that all group members have declared whether or not they have any competing interests.