

Evidence-Based Series #12-12-1 IN REVIEW

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO), and CCO's Systemic Treatment and Nursing Programs

Safe Administration of Systemic Cancer Therapy Part 1: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification

M. Leung, R. Bland, F. Baldassarre, E. Green, L. Kaizer, S. Hertz, J. Craven, M. Trudeau, A. Boudreau, M. Cheung, S. Singh, V. Kukreti, R. White, and the Safe Administration of Systemic Cancer Treatment Expert Panel

Report Date: July 9, 2012

An assessment conducted in March 2021 placed Evidence-based Series (EBS) 12-12-1 IN REVIEW. This means that it is undergoing a review for currency and relevance. It is still appropriate for this document to be available while this updating process unfolds. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

EBS 12-12-1 is comprised of 3 sections. You can access the summary and full report here:

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/1196

Section 1: Guideline Recommendations

Section 2: Evidentiary Base (For content not in EBS 12-12M General Methods) Section 3: EBS Development Methods and External Review Process

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Draft Evidence-Based Series 12-12-1: Section 1

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO), and CCO's Systemic Treatment and Nursing Programs

Safe Administration of Systemic Cancer Therapy Part 1: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification Guideline Recommendations

M. Leung, R. Bland, F. Baldassarre, E. Green, L. Kaizer, S. Hertz, J. Craven, M. Trudeau, A. Boudreau, M. Cheung, S. Singh, V. Kukreti, R. White, and the Safe Administration of Systemic Cancer Treatment Expert Panel

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PURPOSE

The purpose of this document is to provide guidance on processes, technologies, and devices for the prevention of errors during systemic cancer treatment administration in adult patients in areas that cut across the entire process and in the planning and preparation stages.

TARGET POPULATIONS

Adult patients who are going to receive chemotherapy treatment or who are already receiving chemotherapy treatment for cancer in hospital settings.

INTENDED USERS

- Organizations that provide chemotherapy treatment to cancer patients.
- Clinicians and health care providers (e.g., nurses, pharmacists, physicians, clerks) involved with the administration of chemotherapy agents, and hospital administrators.

DEVELOPMENT OF THIS REPORT

This document is the first part of a two-part series of guidelines on the safe administration of chemotherapy sponsored by the CCO Systemic Treatment Program and Nursing Program. For a summary description of the other part, the interested readers can refer to Evidence-based Series (EBS) 12-12M: Safe Administration of Chemotherapy:

Introduction and General Methods. The two parts of this series are also pictorially represented in Figure 1 below as a reference. This guidance document is based upon the results of an environmental scan for relevant guidelines from other guideline developers and other jurisdictions, and on a systematic review for published guidelines and for primary literature, as described below. The existing evidence was integrated through the clinical expertise of the Working Group to create actionable recommendations for Ontario.

The Working Group values patient-centered care and believes that empowered patients can help in the delivery of safer care. The Working Group also values giving freedom to individual institutions to implement recommendations in a manner that is best suited for their specific contexts. Therefore, the recommendations provided are general directions without specific details. However, in recognition of the complexity of the administration of chemotherapy, and of the need for some guidance on detailed procedures, a <u>COMPENDIUM</u> of example procedures and requirements is provided in Section 2, Appendix 1 that can be used and evaluated independently. The recommendations are hyperlinked with the examples in the compendium.

This Part 1 document presents recommendations for areas of interest that are common to various steps of the chemotherapy administration process (e.g., patient identification, patient and family education, distraction-free environments) and areas of interest pertaining to the planning and preparation phase, (e.g., ordering of drugs, transcribing of orders, dispensing of drugs).

This document is in three sections: Section 1 provides a summary of the recommendations and the justification for the recommendations with a link to the evidence base. Section 2 describes the methods used to provide evidence for each of the specific areas of interest described in Part 1, while the related EBS 12-12M general methods document provides a description of the methods used to produce the entire four-part guideline. Section 3 describes the internal and external review process used to arrive at the recommendations.

The EBS guidelines developed by the Program in Evidence-Based Care (PEBC), CCO, use the methods of the Practice Guidelines Development Cycle (1). The PEBC is supported by the Ontario Ministry of Health and Long-Term Care through CCO. All work produced by the PEBC is editorially independent from its funding source. Figure 1. Organization of the safe chemotherapy administration report according to the process of chemotherapy administration.



Abbreviation: Pt = patient

AREAS OF INTEREST AND SUMMARY RECOMMENDATIONS

Within the main objective, the Working Group highlighted several areas of interest. Some of these areas encompass the entire process of chemotherapy administration, and some are specific to the planning and preparation stages. Each area of interest is presented below, followed by a summary of the recommendations. The justification for the recommendations and the link to supporting evidence can be found in Section 2 of this document.

A) Areas of interest encompassing the entire process of chemotherapy administration

The areas that encompass the entire process of chemotherapy administration include the production of distraction- and interruption-free environments; patient identification; patient and family teaching and provision of information; patient and family role in the plan of care; and the use of computerized prescriber order entry (CPOE) and checklists.

Environmental Considerations

A direct relationship between distractions and interruptions, during all of the steps of medication administration, and various kinds of errors has been documented (2).

Physical and staffing resources allowing the completion of tasks in an environment free from distractions and interruptions are fundamental to the safe administration of chemotherapy.

Customized interventions to obtain a distraction- and interruption-free environment will need to be tested on a case-by-case basis.

Patient identification

The correct identification of the patient prevents "wrong patient" errors. A wrongpatient error may occur at the ordering, transcribing, dispensing, and administrating steps of the medication administration process (3). Appendix 1 contains examples of procedures for <u>AVOIDING WORKAROUNDS</u> when using barcoding technology.

The Working Group recommends that organizations should set up a process for patient identification such that patients are identified at entry in the system, and then at each step of the treatment process, by the different members of the healthcare team involved.

This process should include the use of at least two identifiers, the first being the patient's full name and the second being the patient's date of birth, medical record number, or other patient-identifying information, and specifics about the methods for the proper identification of patients with language barriers or special needs.

Patients should receive an identification wristband at entry to the organization, and this should be used during their stay in the organization while receiving treatment.

If possible, a technology such as automated identification and data capture (e.g., barcoding, radiofrequency) should be used for patient identification. Institutions that use these technologies should have policies, procedures, and staff education in place so that workarounds that threaten patient safety using automated identification systems are avoided.

Information and Education for Patients and Their Families/Caregivers and Their Role in the Plan of Care

Every encounter between patients and their families and their healthcare providers is an opportunity to communicate information and provide education. Informing and educating patients and their families about any treatment and what to expect may prevent "wrong drug", "wrong reason", "wrong frequency", "wrong route", and "wrong time" errors. Besides helping to improve their own safety, patients can work with organizations to improve general patient safety at the organization and unit level and can also advocate for the public reporting and accountability of organizations (4). Appendix 1 contains examples of specific components of <u>EDUCATION</u>.

The Working Group recommends that **patients who are to receive or who are already** receiving chemotherapy should be provided with oral and written information that enables them to comprehend the aims, effects, and outcomes of the proposed or ongoing treatment. Information should cover the following, at a minimum:

- diagnosis
- goals of therapy
- treatment process
- regimen, and its short and long term effects
- management of side effects

The signing of the informed consent form is the starting point at which chemotherapy administration formally begins (5). The Working Group believes, however, that informed consent is a continuous process of communication between healthcare providers and patients that is not limited to the completion and signature of a consent form and that consent can be withdrawn by the patient at any point in the chemotherapy trajectory. This process is central to the relationship between caregivers, patients, and their relatives, because it allows patients to make autonomous decisions about their treatment.

The Working Group recommends that patients (or their substitute decision makers) should play a major role in preventing medication errors by being actively involved in all phases of the treatment process in a patient-centered model of care. Healthcare providers need to be open, receptive, and responsive to patient questions.

Computerized Prescriber Order Entry (CPOE)

CPOE can have a role in the chemotherapy administration process phases of ordering, transcribing, dispensing, and administering chemotherapy.

The Working Group recommends CPOE as the standard to reduce adverse events for protocols and orders. Where CPOE is not available, standardized, regimen-level preprinted forms should be used to improve consistency and readability and to avoid prescription error. Handwritten orders are not acceptable.

Protocol templates stored electronically should be in a read-only format to avoid unapproved alteration of the original. A process should be in place for the creation and upkeep of the templates. Access to the original protocol document should be restricted to authorized persons.

Checklists

Checklists are designed to prevent errors of omission and can be used during the entire process of chemotherapy administration. Appendix 1 contains an example of a <u>CHECKLIST</u> for chemotherapy administration.

The Working Group recommends checklists as a tool for the administration process when multiple, complex, mechanistic tasks are required.

B) Areas Specific to the Planning and Preparation Phases of Chemotherapy Treatment

The areas of interest that are specific to the individual steps of the chemotherapy administration process are patient assessment, patient screening, the written plan, scheduling models, pharmacy practice, and infusion devices.

Patient Assessment

A thorough assessment can prevent such errors as the "wrong drug", "wrong time", "wrong dose", and "wrong frequency". Appendix 1 contains an example of the requirements for <u>PATIENT ASSESSMENT</u> before chemotherapy is administered.

The Working Group recommends that organizations should have written protocols and procedures for patient pretreatment assessment by clinicians.

A patient assessment prior to chemotherapy administration is the responsibility of the clinical team. The assessment for chemotherapy administration should include, but may not be limited to, the following:

- Baseline observations, specific to the protocol
- Patient history and treatment plan
- Current medications, including alternative therapies
- Presence of allergies or other hypersensitivity reactions
- Patient performance status and physical findings that may impact on the treatment process
- Patient weight, height, and body surface area
- Laboratory results
- Response to previous treatment and previous toxicities that may impact on treatment
- Compliance with home premedication treatment
- Assessment for and maintenance of access devices required for administration
- Presence of psychosocial concerns

Tools for Patient Screening and Assessment

The Working Group recognizes that the use of validated tools is preferred for patient screening and assessment. The table below is a resource of available tools.

Dimension to be assessed	Tool	Web link to resources
Performance status	ECOG	http://www.ecog.org/general/perf_stat.html
Pain	ESAS	https://www.cancercare.on.ca/common/pages/UserFile. aspx?fileId=13846 or refer to tools contained in the CCO

Table 1. Screening tools.

Dimension to be assessed	Tool	Web link to resources
		Cancer-related Pain Management Guideline (available at <u>https://www.cancercareontario.ca/en/guidelines-</u> advice/types-of-cancer/2271)
Fatigue	ESAS	https://www.cancercare.on.ca/common/pages/UserFile. aspx?fileId=13846
Nausea	ESAS	https://www.cancercare.on.ca/common/pages/UserFile. aspx?fileId=13846
Sensory/ motor neuropathy	NCI common terminology for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf See Appendix 1. For oxaliplatin related sensory motor neuropathy the use of the tool in use for oxaliplatin (6).
Diarrhea	NCI common terminology for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf
Oral mucositis	NCI common terminology for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf
Rash	NCI common terminology for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf

Abbreviations: ECOG= Eastern Cooperative Oncology Group; ESAS = Edmonton Symptom Assessment System; NCI = National Cancer Institute

Parts of a Written Plan

A written plan is an important document that is referred to by all the team members during the treatment process. The plan is a communication tool that can be the centre of interdisciplinary collaboration, thus preventing medication errors. Appendix 1 provides an example of the elements that should be included in a <u>WRITTEN PLAN</u>.

The Working Group recommends that a systemic treatment plan should be documented and available and should include other decisions made for the patient such as surgery and radiation therapy, as well as requirements related to nursing and allied healthcare staff. The plan should ideally be in a computer-generated format and should be part of or filed with the patient record at all times.

Any change in the plan of treatment (i.e., a new protocol is initiated or a medication dose is changed), should be clearly documented on the treatment plan, noting the time the change was initially ordered.

A copy of the treatment plan should be distributed to all facilities involved in the patient's care as well as the patient's primary care healthcare provider.

Treatment Scheduling Models: Same Day versus Non-Same-Day

Currently, there are two chemotherapy-delivery scheduling models in use in Ontario: Same-day and Non-same-day. The Same-day model minimizes the number of patient visits for

care but can be associated with long patient waits on the day of treatment and significant workload pressures for the staff, especially when the treatment protocols are long or when order clarifications are required.

Non-same-day chemotherapy scheduling may be an appropriate option for many patients undergoing chemotherapy.

Organizations should weigh the pros and cons of each scheduling model as it pertains to their environment, geographic challenges, and patient population.

Individual patient circumstances should always be considered.

Pharmacy Practices: Chemotherapy Preparation and Delivery

Pharmacy practices include chemotherapy preparation and delivery. Errors at this point of the process may involve the issuing of the wrong drug or the wrong dose and the provision of labelling that can be misleading or misread or that indicates the wrong patient, route, or frequency. The inadvertent exposure of other patients and personnel to the chemotherapy during its transport to the specific patient is also a risk.

The Working Group recommends that good practices in chemotherapy preparation and delivery include the following:

- Verification of the chemotherapy order and preparation.
 - Verifying a chemotherapy order should include a systematic check of all the components of the chemotherapy order and its preparation and dispensing. Verification and independent double checking processes should be regulated by oncology-specific policies and procedures and training and certification programs to maintain accuracy and quality.
 - Independent double checking at various points of the chemotherapy preparation process should be as frequent as possible. Independent double checking may still be required when CPOE is in place because of the possibility of major variations or deviations in protocol, protocols that are new or not yet built into the CPOE program, or complex calculations involved in chemotherapy preparation.
 - Independent double checking during the chemotherapy preparation process is ideally made by a second pharmacist or, depending on physical and staffing resources, by a pharmacy technician (Tech-Check-Tech procedure where one technician checks the order-filling accuracy of another), or by another healthcare professional with appropriate knowledge, skills and training to perform this function."
- Appropriate chemotherapy labelling (see PEBC EBS 12-11: Patient Safety Issues: Key Components of Chemotherapy Labelling) (7):
- <u>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/1191</u>
 - Labelling of outsourced drugs is still required. An analysis of labelling from outsourced products should be performed to ensure that it does not conflict with in-house products.
- Appropriate packaging and transportation of chemotherapy drugs and the education of personnel who handle chemotherapy drugs (see PEBC Special Report: Safe Handling of Parenteral Cytotoxics (8):
- https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2161

Chemotherapy should be packaged for dispensing and delivered in a manner that meets acceptable safety standards and reduces chances for confusion or patient errors.

Appendix 1 outlines examples of parameters to be checked when <u>VERIFYING A</u> <u>CHEMOTHERAPY ORDER</u>, and of a method for organizing chemotherapy <u>PACKAGING AND</u> <u>DELIVER</u>Y.

Infusion Pumps

Currently, the following four types of pumps are in use in Ontario: volumetric pumps, elastomeric pumps, smart pumps, and smart pumps integrated with barcoding technology. The adoption of different kinds of pumps depends on an individual institution's contextual factors.

If an organization intends to change their infusion delivery devices, and given that each kind of pump in the current state of the art technology presents some advantages and disadvantages, the Working Group recommends considering the following comparison table.

Safety characteristics	Smart pump	Smart pump + barcoding	Volumetric (CADD)	Elastomeric
Prevents a "wrong patient" error	No	Yes	No	No
Prevents a "wrong drug" error	No	Νο	No	No
Prevents a "wrong dose" error	Yes (only if hard limits used)	Yes (only if hard limits used)	No (subject to programming errors)	No (variations in flow rate depending on temperature and position)
Prevents a "wrong route" error	Yes	Yes	No	No
Prevents a "wrong time" error	Yes	Yes	No	No
Prevents a "wrong documentation" error	Yes	Yes	No	No
Easy implementation	No	No	Yes	Yes
Ambulatory use	No	No	Yes	Yes

Table 2. Safety characteristics of infusion pumps.

Organizations that decide to migrate to smart pump systems need to employ the potential capabilities of the technology and to understand the limitations. It must be kept in mind that smart pump technology involves a complete drug delivery system redesign and that a completely integrated approach between smart pumps with barcoding and all other medication management technologies has to occur.

Implementation issues, however, are beyond the scope of this document. For a more thorough discussion on implementation issues, the interested reader can refer to the Healthcare Human Factors recommendations available at:

http://www.ehealthinnovation.org/files/SmartMedicationDeliverySystems_FullReport.pdf (9).

CONCLUSIONS AND FUTURE RESEARCH

Most of the guidelines identified during the environmental scan for Part 1 were not evidence based but that evidence base was rarely randomized controlled trials. The Working Group did a thorough review of the literature and integrated the information retrieved for each topic through clinical expertise to make it relevant to Ontario. However, most of the recommendations are based on expert opinion, because applicable evidence was not available at this time. One issue for safety topics such as this one concerns the effectiveness of strategies to improve safety. Another issue concerns how the strategies that have been proven effective are to be implemented in different settings. These two factors are not independent from one another in that the effectiveness of an intervention can be modified by the way it is implemented and integrated within the work flow. Efforts are needed to improve the evidence base for interventions that have the potential to be effective if implemented properly. A lot of efforts are also needed on the part of individual institutions in the implementation phase of this process.

RELATED CCO GUIDELINES

• Green E, Johnston M, Macartney G, Milliken D, Poirier S, Reynolds P, et al. Safe handling of parenteral cytotoxics guideline recommendations. Toronto, Ontario: Cancer Care Ontario; 2007 [cited 2012 Mar 21]. Program in Evidence-Based Care 16-3 EBS: December 2013 Available from:

https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=293471.

• Trudeau M, Green E, Cosby R, Charbonneau F, Easty T, Ko Y, et al. Patient safety issues: key components of chemotherapy labelling: guideline recommendations. Toronto, Ontario: Cancer Care Ontario; 2009 [cited 2012 Mar 21]. Program in Evidence-Based Care, Evidence-Based Series No.: 12-11. Available from:

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/1191.

- Members of the Central Venous Access Device Guideline Panel. Managing central venous access devices in cancer patients. Toronto, Ontario: Cancer Care Ontario, 2006 [cited 2012 Mar 21]. Program in Evidence-Based Care Evidence-Based Series No.: 16-1.
- Cancer-related Pain Management Working Panel. Cancer-related pain management: a report of evidence-based recommendations to guide practice. Toronto, Ontario: Cancer Care Ontario; 2008 [cited 2012 Mar 21]. Program in Evidence-Based Care Evidence-based Series No.: 16-2. Available from:

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2271.

• Friedman A, Cosby R, Boyko S, Hatton-Bauer J, Turnbull G. Effective teaching strategies and methods of delivery for patient education. Toronto, Ontario: Cancer Care Ontario; 2009 [cited 2012 Mar 21. Program in Evidence-Based Care Evidence-based Series No.: 20-2]. Available from:

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/851

 Vandenberg T, Trudeau M, Coakley N, Nayler J, DeGrasse C, Green E, et al. Regional models of care for systemic treatment. Toronto, Ontario: Cancer Care Ontario; 2007 [cited 2012 Mar 21]. Program in Evidence-Based Care Evidence-based Series No: 12-10, Available from: <u>https://www.cancercareontario.ca/en/guidelines-advice/types-ofcancer/1186</u> • Healthcare Human Factors Group. Smart medication delivery systems: infusion pumps. Toronto, Ontario: Centre for Global eHealth Innovation; 2009 [cited 2012 Mar 21]. Available from:

http://www.ehealthinnovation.org/files/SmartMedicationDeliverySystems_FullReport.pdf.

Updating

This document will be reviewed in three years time to determine if it is still relevant to current practice and to ensure that the recommendations are based on the best available evidence. The outcome of the review will be posted on the CCO website. If new evidence that will result in changes to these recommendations becomes available before three years have elapsed, an update will be initiated as soon as possible.

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- 1. Browman GP, Levine MN, Mohide EA, Hayward RS, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol. 1995 Feb;13(2):502-12 Comment in: Ann Oncol. 2002 Sep;13(9):1507-9; author reply: 9.
- 2. Westbrook JI, Woods A, Rob MI, Dunsmuir WT, Day RO. Association of interruptions with an increased risk and severity of medication administration errors. Arch Intern Med. 2010 Apr 26;170(8):683-90.
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- 4. Gibson R. The role of the patient in improving patient safety: perspective. AHRQ M&M [Internet]. 2007 [cited 2010 Nov 10]: Available from: http://www.webmm.ahrq.gov/perspective.aspx?perspectiveID=38.
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http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_96h02_e.htm.

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- 7. Trudeau M, Green E, Cosby R, Charbonneau F, Easty T, Ko Y, et al. Patient safety issues: key components of chemotherapy labelling: guideline recommendations. Toronto, Ontario: Cancer Care Ontario; 2009 [cited 2010 Feb 12]. Program in Evidence-based Care Evidence-based Series No.: 12-11. Available from: https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/1191.
- 8. Green E, Johnson M, Macartney G, Milliken D, Poirier S, Reynolds P, et al. Safe handling of parenteral cytotoxics. Toronto, Ontario: Cancer Care Ontario; 2007 [cited 2010 Nov 10]. Program in Evidence-based Care Evidence-based Series Special Report. Available from:

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9. Healthcare Human Factors Group. Smart medication delivery systems: infusion pumps. Toronto, Ontario: Centre for Global eHealth Innovation; 2009 [cited 2010 Nov 10]. Available from:

http://www.ehealthinnovation.org/files/SmartMedicationDeliverySystems_FullReport. pdf.



Evidence-Based Series 12-12-1: Section 2

Safe Administration of Systemic Cancer Therapy Part 1: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification: Evidentiary Base

M. Leung, R. Bland, F. Baldassarre, E. Green, L. Kaizer, S. Hertz, J. Craven, M. Trudeau, A. Boudreau, M. Cheung, S. Singh, V. Kukreti, R. White, and the Safe Administration of Systemic Cancer Treatment Expert Panel

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO), the Systemic Treatment Program, CCO, and the Nursing Program, CCO Developed by the Safe Administration of Systemic Cancer Treatment Expert Panel

Draft Report Date: July 9, 2012

PURPOSE

The purpose of this document is to provide guidance on processes, technologies, and devices for the prevention of errors during systemic cancer treatment administration in adult patients in areas that cut across the entire process and in the planning and preparation stages.

TARGET POPULATION

• Adult patients who are going to receive chemotherapy treatment or who are already receiving chemotherapy treatment for cancer in hospital settings.

INTENDED USERS

- Organizations that provide chemotherapy treatment to cancer patients.
- Clinicians (e.g., nurses, pharmacists, physicians, clerks) involved with the administration of chemotherapy agents and hospital administrators.

INTRODUCTION

Assuring patient safety during chemotherapy administration is an important objective for healthcare institutions. Medication errors are of particular importance largely because of their preventable nature. A total of 519 medication errors involving cancer chemotherapy agents were voluntarily reported to the Institute for Safe Medication Practices (ISMP) Canada between 2002 and 2009. Of these incidents, 40 (7.7%) had an outcome of harm, and 4 (0.8%) had an outcome of death (1). The qualitative analyses of the incidences indicated that chemotherapy medication errors occurred in all of the major areas within the administration process: treatment scheduling, prescribing, order entry or transcription, clinical assessment and communication of treatment changes, dispensing, administration, and monitoring (1). A root cause analysis of a medication incident involving fluorouracil identified system failures and a combination of actions and conditions that ultimately resulted in the death of a 43-year old woman in 2006. The report concluded that a similar incident could happen in other institutions as the system failures that were identified also exist in other cancer centres (2).

The chemotherapy delivery process is heavily dependent on the vigilance of the multidisciplinary team (oncologists, clinic nurses, treatment nurses, and pharmacists) to recognize and prevent medication errors before they affect the patient. In assessing the overall safety of the outpatient chemotherapy process, a study determined that the medication error rate in outpatient chemotherapy orders were approximately 3%, of which 2% had the potential to cause harm. Thankfully, the majority of these errors were intercepted by the pharmacists and nurses, and none caused adverse outcomes to the patient during the study period (3).

Reducing the frequency of chemotherapy medication errors requires standardized approaches, tools, policies, and procedures. Institutional policies and procedures are often based on consensus and may differ between facilities. Although there are published guidelines focused on the safe administration of chemotherapy, none of the guidelines provide a comprehensive summary and/or systematic review of the available evidence (4-7). Cancer Care Ontario (CCO) formed the Safe Administration of Chemotherapy Expert Panel to discuss best practices and review the current literature. The panel is composed of representatives from nursing, medicine, and pharmacy. Through evidence and consensus, this document, promoted by the CCO Systemic and Nursing Programs, is to develop recommendations on patient-relevant issues that can be applied in the settings where people with cancer will receive systemic therapy. Initiatives designed to assist with pretreatment planning, prescribing, scheduling, pharmacy preparation, and chemotherapy administration will be discussed in this document.

METHODS, SUMMARY RESULTS, AND DISCUSSION

The following section describes how the recommendations shown in Section 1 were built from the available evidence. The areas of interest are discussed in detail below (see also Appendix 1). The Working Group considered areas of interest that spanned the whole chemotherapy administration process and those specific to individual steps of the process. For each area of interest, the Group used specific questions to guide the search for evidence and to address topics of relevance to the recommendations. Appendices 2A-D contain the methods and results, with study flow charts and evidence tables, for each systematic review specific to a topic area that was conducted.

A) Areas of Interest Encompassing the Entire Process of Chemotherapy Administration

The areas of interest that encompass the entire process of chemotherapy administration include the provision of interruption- and distraction-free environments, patient identification, patient and family information and education, and role in the plan of care; and the use of computerized provider order entry (CPOE) and checklists.

Table 1 below shows the specific questions that were addressed in each area of interest along with the evidence that was used as a basis for the recommendations presented in Section 1. The following paragraphs present the process that led to the formulation of the recommendations for each area of interest.

Table 1. Areas of interest that encompass the entire chemotherapy administration process: specific questions, evidence base, and target audience for the recommendations.

Questions	Evidence base
Environmental considerations	
What are the best strategies to reduce distractions and	Clinical expertise
interruptions during chemotherapy administration?	
Patient identification	
When, how often, and by whom should patients be identified?	Clinical expertise
Which and how many pieces of information should be required for patient identification (ID)?	Clinical expertise
What are the most effective technologies for patient identification? (wristbands, barcoding, radiofrequency	Clinical expertise
identification systems, automated ID, data capture)	Systematic review
Patient information and education and role in plan of care	
What are the pieces of information that need to be conveyed to the patients and their families, and what is the timing for information delivery, regarding the chemotherapy drugs that are going to be administered, or regarding any changes in treatment plan?	Australian guideline (5)
What role do patients play in determining the plan of care? Is there a role for informed consent in safety outcomes?	Clinical expertise
CPOE	
What is the most effective technology to reduce adverse drug events at the time of ordering, prescribing, and transcribing for chemotherapy drugs?	Australian guideline (5)
Checklists	
Are checklists effective in preventing medication-related adverse events during the administration of chemotherapy agents?	Systematic review

Environmental Considerations

Both the Working Group and the literature (8,9) report the contribution to errors caused by distractions and interruptions during drug administration. Various environments, by their physical set up, and by the structure of the team involved, may be more or less conducive to uninterrupted, distraction-free drug administration. Because the environmental scan and systematic review of evidence-based guidelines did not identify evidence for this contention, however, the Working Group decided to undertake a systematic review specific to it. Appendix 2A provides a detailed description of the methods and results for this systematic review, with the study flow chart and evidence tables.

The systematic review resulted in three full-text publications (9-11) and one abstract (12). Overall, these data were heterogeneous and of poor quality. Therefore, the recommendations issued were based on informal consensus among the Working Group members.

Patient Identification

The guidelines search identified ten documents relevant to patient identification, but because they were not based on a systematic search of the evidence, they were excluded (see Appendix 3 for a list of excluded guidelines).

The Working Group was aware of existing evidence on the effectiveness of automated identification technologies for preventing patient misidentification errors. A systematic review was undertaken specific to this question. Appendix 2B contains the methods specific to this systematic review and the study flow chart and evidence tables with detailed descriptions of the studies.

Eleven studies were included in the systematic review on patient identification technologies (13-23). Of these, nine studies evaluated a barcoding technology (13,14,16-19,21-23), one evaluated a radiofrequency technology (15), and one evaluated a reminder system for providers to check the patient wristband for correct patient identity (20). Because of feasibility issues none of the studies compared one technology to another.

The body of evidence found was composed mostly of studies with a before-after design and was considered generally weak. However, this evidence consistently showed large effects in favour of the use of automated data capture technologies. If it is implemented appropriately, this technology can reduce misidentification errors, and the Working Group therefore decided to recommend its use. The inappropriate use of the technology can introduce errors (i.e., healthcare providers use workarounds to bypass some features of the technology (24)).

Readers interested in the design of wrist bands, and how the barcode can be integrated in the wristband can refer to the National Health Service (NHS) guidelines in the United Kingdom (UK) (25). Appendix 1 contains an example of a procedure for <u>AVOIDING</u> <u>WORKAROUNDS</u> when using barcoding technology.

Information and Education to Patients and Their Families/Caregivers and Their Role in the Plan of Care

An Australian guideline (5) pertaining to giving information and education to patients was selected for adaptation because it was evidence-based and compatible with the reality in Ontario. The quality of the guideline has been evaluated with the Appraisal of Guidelines for Research and Evaluation (AGREE) Tool II (26) by the methodologist and by one of the clinicians in the Working Group. It was rated as high in the AGREE domains of scope and purpose (92%), stakeholder involvement (75%), clarity of presentation (67%), and rigour of development (51%). The rating for applicability was 35%, and the rating for editorial independence was 0. The content of this guideline was adapted with minor changes, led by the expertise of the Working Group members, to create guidance for informing patients and their families.

Seven more guidelines pertaining to giving information and education to patients and ten more guidelines about informed consent and about the patient role in the plan of care were identified by the environmental scan and systematic review. These guidelines were either consensus based, or presented tools such as leaflets that could be used as examples, but did not state what information should be conveyed to patients. They were excluded (please see Appendix 3 for a list of excluded studies). A search of the literature was attempted, but none of the research evidence found was specific to chemotherapy administration, and evidence from other settings was considered inadequate by the Working Group. Therefore, it was decided to create a recommendation for the role that patients should play in the plan of care, based on the clinical expertise of members of the working group.

Appendix 1 contains an example of the key components for <u>PATIENT AND FAMILY</u> <u>EDUCATION</u> that can be used to structure a procedure manual.

Computerized Prescriber Order Entry (CPOE)

The systematic search for guidelines about technologies used to prevent errors at the time of ordering, prescribing, and transcribing chemotherapy drugs identified eight documents. Again, the Australian guideline (5) was selected for adaptation because it is evidence-based and applicable to Ontario. The quality of the document has been reported above. The Working Group integrated the evidence from the Australian guideline with their clinical expertise to make the recommendation relevant to the context in Ontario. The other seven guideline documents were based on consensus, or were not based on a systematic search of the evidence; therefore they were excluded and are listed in Appendix 3.

Checklists

The search for guidelines on the use of checklists identified two documents. One reported examples of checklists for chemotherapy administration (27) but without an evaluation of their effectiveness, and the other (28) was not based on a systematic search of the evidence. These guidelines were excluded and are listed in Appendix 3. The Working Group, however, used the checklist presented in the first of these documents, and the World Health Organization (WHO) surgical safety checklist (29) as a model to produce the example <u>CHECKLIST</u> for chemotherapy administration reported in Appendix 1. The Working Group then decided to conduct a systematic review to determine whether evidence on this document existed (see Appendix 2C for detailed methods and results).

The systematic review (see specific methods and result in Appendix 2C) identified one study relevant to this question (30). The study was a well-conducted observational study conducted in a laboratory setting that reproduced a chemotherapy suite. Although a laboratory study presents serious limitations for the generalizability of the results, the results of this study were consistent with previous consensus-based recommendations. The Working Group therefore decided to use this evidence as a base for the recommendations presented in Section 1.

B) Areas Specific to the Planning and Preparation Phases of Chemotherapy Treatment

The areas of interest that are specific to individual steps of the process of chemotherapy administration are patient assessment, patient screening, the written plan, scheduling models, pharmacy practices, and the use of infusion pumps.

Table 2 below shows the specific questions that the Working Group used to address topics of relevance within the areas of interest and the evidence base used for the recommendations presented in Section 1. In the following paragraphs, the process that led to the formulation of the recommendations is presented for each area of interest.

Table 2. Areas of interest for individual steps of the chemotherapy administration process: specific questions, evidence base, and target audience for the recommendations.

Patient assessmentWhat are the essential components of patient assessment (for new and returning patients)?Australian guideline (5)Screening toolsClinical expertiseWhat are the most effective screening tools for symptom assessment?Clinical expertiseWritten planVeritten plan?What are the necessary parts of a written treatment plan?Australian guideline (5)Scheduling modelsVeritten plan?What is the most effective scheduling model for reducing errors in the administration of chemotherapy to cancer patients?Clinical expertiseWhat are the most effective pharmacy practices for reducing errors in the administration of chemotherapy to cancer patients?Australian guideline (5)What are the most effective pharmacy practices for reducing errors in the administration of chemotherapy to cancer patients?Australian guideline (5)What are the most effective strategies to reduce errors in the packaging and transporting chemotherapy drugs?Australian guideline (5)Unical expertise packaging and transporting chemotherapy drugs?Australian standardsWhat is the most effective type of infusion pump for preventing errors during the administration of chemotherapy (31)Healthcare Human Factors	Questions	Evidence base
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	Infusion pumps	
preventing errors during the administration of chemotherapy (31)	What is the most effective type of infusion pump for	Healthcare Human Factors
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agents?	agents?	

Patient Assessment

The Australian guideline (5) was selected for adaptation for this topic, because it was evidence-based and compatible with the reality in Ontario. The quality assessment of the guideline has been reported above (see the Information and Education to Patients subsection).

Screening Tools for Symptom Assessment

The Working Group based the list of relevant symptoms on their clinical expertise. A search was done to find evidence on the effectiveness of tools for the assessment of each symptom, but it was difficult to find research articles that were specific to the chemotherapy setting. Using indirect evidence was considered inappropriate, and the Working Group decided to base this recommendation on their expert opinion and on what is current practice in many hospitals in Ontario.

A consensus-based guideline (6) and a portal presenting some tools for assessment that the Working Group considered not relevant to the context of Ontario for this topic (27) were identified by our search and are listed in Appendix 3.

Parts of a Written Plan

The Australian guideline (5) was selected for adaptation for this topic because it was evidence-based and applicable to Ontario. The quality assessment of this guideline is reported above. Appendix 1 provides an example of the elements to be included in a <u>written plan</u>.

The environmental scan identified seven other guidance documents relevant to this question that were based on consensus of experts or on narrative reviews. These documents were excluded, however, and are listed in Appendix 3.

Scheduling Models

No guidance documents were identified by the environmental scan and systematic search for this topic. The Working Group felt that evidence might be available on the effectiveness of Non-Same-day versus Same-day scheduling models; therefore a systematic review was conducted (see specific methods and result in Appendix 2D). In one published study, the Non-Same-day model resulted in improved efficiencies for pharmacy and nursing and a decrease in the waiting time for patients to receive their chemotherapy (32). It was not possible to determine whether there was risk of bias in this study; therefore, the Working Group based this recommendation on their clinical expertise. There is a clear need for further study of the impact of the scheduling model on patient- and provider-related outcomes.

Pharmacy Practices

The Australian guideline (5) was again selected for adaptation because it was evidence-based and relevant to Ontario. The quality of the guideline has been reported above (see the Information and Education to Patients subsection). The environmental scan and systematic search for guidelines identified four other guidance documents on this topic, all based on consensus of experts. These were excluded and are listed in Appendix 3.

The recommendation on packaging and transporting chemotherapy drugs is based on previous CCO guidelines "Patient Safety Issues: Key Components of Chemotherapy Labelling" (33) available at: <u>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/1191</u> and "Safe handling of parenteral cytotoxics" guideline (34) available at: <u>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2161</u>.

Considerations specific to the administration of chemotherapy have been added, based on the expert opinion of the Working Group members.

Four consensus-based guidance documents identified by the environmental scan and systematic search were excluded and are listed in Appendix 3.

In Appendix 1, examples are provided for elements that need to be <u>VERIFIED AND</u> <u>CHECKED</u> in a chemotherapy order, and of a method for organizing chemotherapy <u>PACKAGING</u> <u>AND DELIVERY</u>.

Infusion Pumps

An evidence-based guideline by the Healthcare Human Factors (HHF) (31) was identified by our environmental scan and systematic search for guidelines. However, this guideline was directed more to guide implementation than to evaluate the effectiveness of different devices in preventing errors, and implementation issues are beyond the scope of this

document. Readers interested in a more thorough discussion on implementation issues can refer to the HHF recommendations available at:

http://www.health.gov.on.ca/English/providers/program/mas/tech/reviews/pdf/rev_smd_2 0090401.pdf

To facilitate the decision process of those organizations that consider changing their devices, the Working Group constructed a table (shown in Section 1) with the safety characteristics of each type of device. This table was based on the evidence found (31) and on the expert opinion of the Working Group.

CONCLUSIONS

The majority of the recommendations issued in this document were based on the expert opinion of the Working Group. Of those, three were also consistent with other consensus-based guidelines (role of patient in the plan of care, identifiers needed for patient identification, and packaging and transporting of chemotherapy drugs). Six recommendations were adapted from already existing evidence-based guidelines (components of patient assessment, information for patients, parts of a written plan, pharmacy practices, CPOE, and infusion pumps). The Working Group conducted systematic reviews for the following four areas of interest: distraction-free environments, technologies for patient identification, scheduling models, and checklists. Unfortunately, these systematic reviews often did not identify evidence that could be used as a foundation for recommendations. In fact, due to the nature of the phenomena studied, the literature on safety is not rich on high-quality studies; often existing guidelines are solely based on expert opinion without a systematic search of the literature, and the individual studies are rarely focussed on chemotherapy administration. This document contains a thorough systematic search of the evidence for all the areas of interest and highlights existing knowledge gaps.

The Working Group hopes that this document will provide a reference and a starting point for clinicians, institutions, and organizations that provide chemotherapy services to cancer patients. In order to prevent errors during chemotherapy ordering, prescribing, transcribing, and administration, it is important that institutions develop their own policies and procedures that further adapt the concepts presented here to individual contexts. Along with the recommendations that are shown in Section 1, examples are provided in the appendices (e.g., checklists for chemotherapy administration; key components of patient education). This document could also be used as a basis for the implementation of new research projects in areas where evidence is lacking such as the best strategies to prevent distractions and interruptions of healthcare personnel while prescribing, transcribing, dispensing, and administering chemotherapy drugs; the best technologies for patient identification; the scheduling models; and the use of checklists for chemotherapy administration.

CONFLICT OF INTEREST

The conflict of interest details are shown at the end of Section 3.

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Appendix 1. Compendium of examples of procedures relevant to chemotherapy administration.

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Oxaliplatin neurotoxicity assessment tool	

Example of procedure for the use of barcoding technology (adapted from Koppel et al). (1).

The following will help health care provider prevent "wrong patient", "wrong drug" and "wrong dose" or "wrong frequency" errors. These steps are suggested because alarms from the technology should not be the only confirmation of correctness.

- 1. Nurse: Check medication label and compare with Electronic Medication Administration Record (eMAR) before scanning barcode.
- 2. Physician: Routinely review eMAR to verify current medications. (Some un-needed medications may be kept if not checked).
- 3. Nurse: Review parameters for medication administration before administering the drug. (Often all administration information is not in one screen in the barcoding technology).
- 4. Nurse: Do not bypass "medication double check policy" by a second nurse.
- 5. Nurse: Check new medication orders before administration. (The barcoding system is updated after pharmacist entry, but it is not final until verified by the nurse at the administration point).
- 6. Nurse: Scan patient ID before administering drug. (A patient wristband that is missing/inaccessible may prompt the nurse to scan only medications).
- 7. Nurse: Scan medication barcode before administering drug. (A damaged drug barcode may prompt to not scanning the medication at the time of administration).
- 8. Nurse: Document medication administration AFTER administration is complete. (Barcoding system prompts to document after scanning of the medication, but it may take hours before the administration is complete).
- 9. Nurse: Do NOT place patient ID on other objects (e.g. arm band placed on table besides the patient, or copies of patient barcode ID placed in nursing station).
- 10. Nurse: Prepare, scan and transports medications for only 1 patient at a time.
- 11. Nurse: Do NOT scan drug barcodes that have been removed from the drug package.
- 12. Nurse: If there are multiple packages for the full dose of the drug, scan each package, and do not scan the same package multiple times. (This may prevent wrong dose error).
- 13. Nurse: Do not use the scanner if you cannot see the screen where the alarms appear. (For example taking the scanner far away from the cart).
- 14. Nurse: If giving partial dose, do not document full dose. (Documenting partial dose may be more time consuming).
- 15. Nurse: Do not disable audio alarms in barcoding device.

Chemotherapy and biotherapy patient education: key components.

Purpose

Using principles of adult education, and recognizing that information overload is a frequent problem for people living with a cancer diagnosis, it is essential that health care providers consider the following components to plan and deliver education programs and resources for patients and their family members. Consideration should be given to using multiple media and methods; reinforcement of information along every step of the journey; measuring patient satisfaction with the delivery and content; revision and updating of resources on a regular basis based on evaluation; and engagement of the inter professional team.(4-5)

Key components

What is chemotherapy and biotherapy: provides some background on how these treatments work and are administered (include parenteral and oral)

- Side effects and what to do when these occur
- Nausea and vomiting
- Fatigue or shortness of breath: low red cell count
- Bruising or bleeding: low platelet counts
- Loss of appetite
- Soreness/discomfort in the mouth/throat
- Soreness/discomfort in the stomach
- Hair loss
- Infection: low white cell count (include in safety)
- Sexuality (include in lifestyle)
- Fertility (include in lifestyle)
- Change in bowel habits: diarrhea or constipation
- Changes in bladder function
- Changes to skin, nails
- Sensitivity to sun
- Cognitive changes (Chemo 'fog')

Lifestyle changes and strategies to manage

- Eating, nutrition and hydration
- Exercise
- Alcohol
- Smoking
- Sexuality and intimacy; relationship changes
- Complementary therapies
- Working
- Emotional changes
- Talking with my children, friends, family
- Supportive care resources in the community

Safety factors

- Why nurses wear gowns and gloves
- Accidental spills
- Toilet: doubling flushing for 48 hours post chemo

- Infection
- Other medications and alternative / complementary therapies
- Family members (exposure to chemotherapy though handling drug, waste, and personal contact)

Preparing for first visit

- Location
- What to bring
- What will the experience be like
- Coverage for drugs; insurance
- Appointments
- Where to find information

The team

- Oncologists
- Oncology nurses
- Pharmacists and technicians
- Supportive care (e.g., social work, psychologist, dietitian, spiritual care).
- Others (radiation therapist if patient is on concurrent chemoradiation).

What happens when treatment is completed

It is useful to provide patients with a list of relevant web links and other resources that can provide supplementary information. The education plan includes family, caregivers, or others based on the patient's ability to take responsibility for managing therapy.

References (pages 26-27)

- 1. Koppel R, Wetterneck T, Telles JL, Karsh BT. Workarounds to barcode medication administration systems: their occurrences, causes, and threats to patient safety. J Am Med Inform Assoc. 2008 Jul-Aug;15(4):408-23.
- 2. Welcome to the Carlo Fidani Peel Regional Cancer Centre: Chemotherapy education program. Mississauga, Ontario: The Credit Valley Hospital; 2010.
- 3. Learning about chemotherapy treatment for patients and families. In: Juravinski Cancer Centre HHS, editor. Hamilton, Ontario: Hamilton Health Sciences; 2008.
- 4. Chemotherapy: A guide for Odette Cancer Centre Patients. In: Centre SOC. Toronto, Ontario: Sunnybrook Hospital; 2010.
- 5. Chemotherapy and you. Toronto, Ontario: Sunnybrook Hospital; 2011.

Example of a checklist.

Checklist for	chemotherapy	administration	(adapted	from	the	EVIQ	"time	out"
procedure) (1)								

Patient name		Diagnosis			
DOB		Treatment			
	Treatment				
Record number	Specialist				
	Initials	Notes			
Anticipated critical events:					
Risk for hypersensitivity					
Allergies/previous drug reaction					
Antibiotic Resistant Organisms (ARO)					
Patient education:					
Has patient attended a class?					
Has patient attended a one-on-one session?					
Consent signed					
CBC/CHEM checked					
Toxicities or changes in patient's ECOG					
Documentation completed					
Pre-medication given if indicated					
Peripheral device patent with brisk blood return					
Central device patent with brisk blood return					
Independent double check for programmable pumps or other situation.					
5 Rs					
RIGHT Patient identity confirmed					
RIGHT treatment					
RIGHT dose including BSA					
RIGHT route					
RIGHT date					
Independent double check of drug prior to administration					
Signature status					
Print name Initial	.S				

References (page 28)

 New South Wales Government. EviQ, Cancer Treatments Online. Time out procedure checklist 2010. [cited 2010 Sept 16]. Available from: https://www.eviq.org.au/Protocol/tabid/66/categoryid/217/id/6/Timeout+Procedure.aspx.

Example of requirements for patient assessment before administration of chemotherapy treatment.

An assessment of the patient should be carried out and documented by the nurse prior to administration. The assessment should include:

- Baseline observations specific to the protocol. e.g., Patients taking nephrotoxic medications must be assessed for renal function.
- The patient's history, and treatment plan.
 - o confirmation of diagnosis,
 - o review of treatment plan and protocol.
- Presence of allergies or other hypersensitivity reactions.
- The patient's physical and performance status that may impact on the treatment process, e.g. ECOG score e.g., Objective and subjective assessment of physical and performance status using a validated tool.
- The patient's weight, and height and body surface area. e.g., Changes in weight and height should be assessed and evaluated for their subsequent impact on body surface area (BSA) and chemotherapy dose.
- Laboratory results. e.g., Relevant laboratory results (such as full blood counts, renal and liver function tests) should be documented and ensured appropriate by the oncologist, the pharmacist, and the nurse before proceeding with treatment.
- Response to previous treatment and previous toxicities that may impact on treatment.

e.g., nausea and vomiting, mucositis, neuropathy.

• Psychosocial concerns.

e.g.,

- the patient's and family's coping mechanisms,
- o anxiety level,
- o any cultural issues that may have an impact on the administration process;
- the patient's comprehension regarding medication regimens, including information regarding disease and self-care.
- Pre-medication required to be taken at home has been taken by the patient as instructed.

e.g., Corticosteroids required prior to docetaxel.

- Access devices required for administration are in place and patent.
- e.g., peripherally inserted central line, venous catheter.

Example of elements to be included in a written plan.

- Patient name and TWO other unique identifiers (e.g. hospital number, date of birth).
- Diagnosis.
- The patient's height and weight.
- Name of the chemotherapy protocol to be given and the drugs involved in the protocol.
- The date the treatment is intended to commence.
- Intended duration of treatment and the number of cycles for treatment.
- Tests to be performed after specified number of cycles.
- Therapeutic goal of treatment (e.g. curative, palliative).
- Details of other therapeutic modalities i.e. surgery, radiation in relation to the chemotherapy treatment process.
- Treatment changes such as a new treatment protocol should be documented in a new treatment plan. Changes in the dose should be documented in the medical plan but not involve a change in the treatment plan.
- The name and contact details of the physician completing the treatment plan.

Pharmacy practices: elements to be verified and checked in a chemotherapy order.

Parameters that should be checked by a pharmacist may include:

Patient Height, Weight and Body Surface Area (BSA)

• The patients' height, weight and BSA should be recorded on the chemotherapy order and an independent check carried out.

Chemotherapy Protocol and Allergies

e.g., All drugs have been prescribed according to protocol and that the patient has no documented allergies/hypersensitivity reactions to any of the medications prescribed

Dosing

e.g., All doses are correct for the patient in accordance to BSA and protocol and maximum and cumulative doses are not exceeded for the drug or the course.

Scheduling

e.g., Verify that the length of course and time interval between each cycle is appropriate for the protocol and tumour type and that such a time period has passed between last cycle and current cycle.

Patient Labwork

Includes:

- The absolute neutrophil count, platelets are appropriate for administration of the chemotherapy.
- The renal and liver function is appropriate for the dose of the drug to be administered.

Drug-Drug, Drug-Disease Interactions

e.g., Chemotherapy ordered does not interfere or interact with the patient's underlying co-morbidities, chemotherapy concurrent medications, nonprescription medications and alternative therapies.

Adverse drug reactions

e.g., Previous chemotherapy toxicities experienced will not predispose the patient to increased toxicity with the current regimen

Past chemotherapy and supportive medication history

e.g., response to supportive medications with past chemotherapy can guide the need or use of supportive medications for current chemotherapy

Pharmacy practices: method for organizing chemotherapy packaging and delivery.

- Chemotherapy should be delivered in ready-to-administer dosage forms to minimize the need for further manipulation by the nurse prior to administration
- For regimens that involve multiple chemotherapy drugs: all of the drugs involved, except intrathecal chemotherapy should be delivered for a patient at one time
- For multiple-day regimens: a container delivered to the chemo suite should only have that specific day dose issued at one time
- For regimens that require chemotherapy to be scheduled more than once a day: the doses for each scheduled time should be labelled, packaged and, preferably, delivered separately

For regimens involving intrathecal drugs: intrathecal drugs should be packaged and/or delivered separately to distinguish it from the other chemotherapy drugs in the regimen

Oxaliplatin neurotoxicity assessment tool.

Toxicity (grade)	
Grade1	Paresthesias/dysesthesias ^a that do not interfere with function
Grade 2	Paresthesias/dysesthesias ^a interfering with function, but not activities of daily living (ADL)
Grade 3	Paresthesias/dysesthesias ^a with pain or with functional impairment that also interferes with ADL
Grade 4	Persistent paresthesias/dysesthesias that are disabling or life- threatening
Acute (during or after the 2 hour infusion) laryngopharyngeal dysesthesias ^a	

Neurologic toxicity scale for oxaliplatin

^a May have been cold-induced.

Adapted from: Sanofi-Aventis Canada Inc. "^{Pr}Eloxatin®: Oxaliplatin for injection" Product monograph. Submission Control No.: 140864. Accessed Sept 17, 2010, page 29 (1) at <u>http://www.sanofi-aventis.ca/products/en/eloxatin.pdf</u>.

References (page 33)

Eloxatin: oxaliplatin for injection. Product monograph. Laval, Quebec: Sanofi-Aventis 1. Canada Inc.; 2010 [cited Submission Control No. 140846]; [cited 2010 Sept 17]. Available from: http://www.sanofi-aventis.ca/products/en/eloxatin.pdf.

2. Appendix 2A. Systematic review: distractions and interruptions.

Question: What are the best strategies to reduce distractions and interruptions during chemotherapy administration?

Search strategy:

We searched the following electronic databases: MEDLINE, EMBASE, Cochrane, and CINAHL, our own files, and the references of included articles for citations of studies on strategies aimed to reduce distractions and interruptions during the process of identifying patients, prescribing, transcribing, dispensing and administering drugs. The search strategy for the Medline database with specific key terms is shown below; this search strategy was adapted for the other databases.

Systematic review: Distractions and interruptions search strategy.

Database: Ovid MEDLINE(R) <1996 to November Week 3 2010>, Ovid MEDLINE(R) Daily Update <November 17, 2010>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <November 29, 2010> Search Strategy:

- 1 (distraction: not (distraction adj3 pain)).tw.
- 2 (interrupt: not interrupted time-series).tw.
- 3 *Attention/
- 4 Medical Errors/
- 5 Safety Management/
- 6 Medication Systems/
- 7 Workload/
- 8 Efficiency, Organizational/
- 9 1 or 2 or 3
- 10 4 or 5 or 6 or 7 or 8
- 11 9 and 10
- 12 limit 11 to (english language and yr="2000 -Current")

Selection criteria

We included systematic reviews or comparative studies that assessed strategies for reducing distractions and interruptions of healthcare personnel during the process of chemotherapy ordering, prescribing, transcribing, dispensing, identifying patients, and administration of the drugs. Systematic reviews or comparative studies were included if published in English from 2000 to 2010 December week 4.

Studies were excluded if they were not about strategies aimed at reducing healthcare personnel distractions and interruptions and if they were publication types such as editorials, comments, letters, and news.

The methodologist screened the titles and the abstracts. Full-text articles were retrieved in the library if the citations met the inclusion criteria or if the title and the abstract did not contain enough information to decide. A clinician member of the Working Group and the methodologist independently reviewed the full text of the included citations against the selection criteria.

Synthesizing the evidence

The methodologist created evidence tables (Table 2B.i-ii) and a narrative synthesis of the evidence was performed. A statistical pooling of the results was not possible because the studies were too heterogeneous.
Results

The search strategy culled 839 citations. The full text of 68 articles was retrieved in the library and reviewed and 4 studies were included, 3 full text publications (1-3) and 1 abstract (4). No new references were found in the reference list of the included studies. Figure 2B.i below shows the study flow chart. None of the included studies was related to chemotherapy administration in ambulatory setting, and the setting of included studies was hospital wards. This indirectness made the evidence found weak for answering our question, therefore no further quality assessment was performed. The interventions aimed at reducing interruptions and distractions included a medication cupboard in the patient's room, "do not disturb" signs in the area of medication dispensing carts, "do not disturb tabards" worn by nurses on medication rounds, and a "do not disturb zone" demarcated on the floor in the area of medication preparation. Three of the studies were before-after observational studies (1, 3, 4), and one involved a times study and focus groups (2). The study by Bennet et al did not report any statistics (2). The study by Anthony et al., in abstract form, did not report any results (1), therefore it will not be discussed any further. The outcomes included time saved, number of interruptions/distractions, medication errors, and patient safety. A sign to reduce distractions was effective in reducing the total distraction score as measured with the Medication Administration Observation Sheet in the study by Pape et al. (3) (p=0.000), and a tabard was effective in reducing the number of distraction in the study by Scott et al. (4) (p<0.001). For more detailed characteristics and results see tables below.

Conclusions

The evidence found was indirect; none of the studies was related to chemotherapy administration. Although weak, this evidence consistently showed that customized interventions may work in reducing distractions and interruption during medication administration.

Figure 2A.i. Distractions and interruptions systematic review: study flow chart.



Author (year) source of funding	Study Design, duration	Population and Setting	Intervention	Outcomes Outcome assessment method
Bennett, 2006(2) Funding: NR	Non-experimental, descriptive, times study and focus groups (results not reported here). Duration: 4 12-hour shifts.	Nurses in two 24-bed general medicine units	Compare a unit dose medication system to a system using a locked medication cupboard in each pt room.	 Medication errors Missing doses Interruptions Time saved
Pape, 2005(3)	Before after observational Duration: 4 weeks	Staff nurses N = 78 in 5 nursing units.	 A process improvement strategy called Rapid Cycle Testing on a medication administration protocol. A tool was used to measure distractions. This involved: nurses education checklist cards with medication steps. "Do not disturb" signs posted about the automated medication dispensing machines. 	 Nurses' compliance with protocol steps (one of the steps is avoided distractions, interruptions, and conversation Distractions before and after the use of a sign to reduce distractions.
Scott, 2010(4)	Before after observational Duration: 5 weeks.	Staff nurses in 3 wards (acute medical - 21 beds-, cardiology 38 beds- and urology -25 beds- in a 900 beds acute teaching hospital in Grampian, UK.	"Do not disturb" tabard indicating a drug round in progress.	 Number of interruptions Patient safety.
Anthony(1) [abs]	Pre-post survey, pilot study Duration: 2 weeks	ICU	"No-interruption zone"	

Table 2A.i. Distractions and interr	uptions: general characteristics table.
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Abbreviations: Abs= abstract; ICU= intensive care unit; NR= not reported; pt= patient;

Author (year)	Intervention	Results	Analysis	Authors' conclusions, reviewer's comment
Bennett, 2006(2)	IG: a locked medication cupboard in each pt room system CG: unit dose medication system	 Time saved: RN/shift: 23 min difference (63 vs. 40 min) Interruptions: 9 (64%) difference (14 vs. 5) Time pharmacy technician spent on bin exchange 15 min difference (7 vs. 22 min) 	Average time was calculated.	The decentralized medication distribution system saved annually 1,950 hours of nursing work, (0.72 of a FTE per 24 -bed unit) (p.37) Comment: although interruptions are one of the outcomes the goal of the interventions was not to reduce interruptions and distractions. The study is not about chemotherapy. Time study with no statistics
Pape, 2005(3)	IG: Sign to reduce distractions CG: No sign	 The greater reduction in distractions was in the distractions caused by other nurses (mean 5.6, SD 2.989 before vs. 2.9 SD 1.792 after). The total distraction score ranged from 26 to 56 (M=42; SD ±10.4) before the signs and 16 to 45 (M=31, SD ±8 after) p= 0.000. 	M and SD were calculated before and after and compared with a Student <i>t</i> test.	The "Do not disturb" were effective in reducing the number of distractions. Comment: this study is not about chemotherapy. Compares with baseline with statistics. Possible Hawthorne effect.
Scott, 2010(4)	IG: "Do not disturb" clothing CG: no clothing	 Average number of interruption per drug round was 6 before and 5 after the intervention (p<0.001) There was a slight reduction in incidents reported over the 5 wks period compared with previous year (results not reported) 	369 drug rounds before and 233 after were analyzed.	This was an audit. Further studies need to be conducted to provide better understanding of the effectiveness of the tabards. Comment: this study is not about chemotherapy. Compares with baseline with statistics.
Anthony(1)		• NR	NR	Comment: this study is not about chemotherapy.

Table 2A.ii. Distractions and interruption: results table.

FTE= full time equivalent; M= mean; Min= minutes; NR= not reported; SD= standard deviation; vs.= versus

Appendix 2A.i & 2A.ii. Distractions and interruptions: references.

- 1. Anthony K, Kotora K, Wiencek C. Translating ideas from the NTI into practice: the "No-Interruption Zone". Crit Care Nurse. 2008;28(2):e48-9.
- 2. Bennett J, Harper-Femson LA, Tone J, Rajmohamed Y. Improving medication administration systems: an evaluation study. Can Nurse. 2006 Oct;102(8):35-9.
- 3. Pape TM, Guerra DM, Muzquiz M, Bryant JB, Ingram M, Schranner B, et al. Innovative approaches to reducing nurses' distractions during medication administration. J Contin Educ Nurs. 2005 May-Jun;36(3):108-16; quiz 41-2.
- 4. Scott J, Williams D, Ingram J, Mackenzie F. The effectiveness of drug round tabards in reducing incidence of medication errors. Nurs Times. 2010 Aug-Sep;106 (34):13-5.

Appendix 2B. Systematic review: patient identification technologies.

Question: What are the most effective technologies for patient identification? (wristbands, barcoding, radiofrequency identification systems, automated ID, data capture)

Search strategy

The following electronic databases were searched: MEDLINE, Cochrane (Database of Abstracts of Reviews of Effects; Central Register of Controlled Trials, and Database of Systematic Reviews), EMBASE, CINAHL; the reference lists of included studies, and the Working Group's own files for citations of studies on patient identification technologies to prevent medical errors. The search strategy with specific key terms designed for MEDLINE is reported below; this search strategy was adapted for the other databases.

Search strategy for patient identification technologies to prevent misidentification:

Database: Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process Search Strategy: Search date from 1996 to August 30, 2010

- 1 Patient Identification Systems/
- 2 Automatic Data Processing/
- 3 Medical Order Entry Systems/
- 4 *Radio Waves/
- 5 Health Services Administration/
- 6 Point-of-Care Systems/
- 7 wristband:.tw.
- 8 (bar-cod: or barcod:).tw.
- 9 e-MAR.tw.
- 10 (radio frequency adj2 identification).tw.
- 11 data capture.tw.
- 12 (automated adj3 (ID or identification)).tw.
- 13 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
- 14 Medical Errors/ae, mt, nu, pc [Adverse Effects, Methods, Nursing, Prevention & Control]

15 Pharmaceutical Preparations/ad, ae, sd [Administration & Dosage, Adverse Effects, Supply & Distribution]

- 16 Safety Management/mt, og, ut [Methods, Organization & Administration, Utilization]
- 17 14 or 15 or 16
- 18 13 and 17

19 limit 18 to (english language and (addresses or bibliography or biography or case reports or comment or dictionary or directory or editorial or festschrift or historical article or in vitro or interactive tutorial or interview or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index or portraits or published erratum or retracted publication or "retraction of publication" or webcasts))

20 18 not 19

Selection criteria

Systematic reviews or comparative studies that assessed technologies used for wrong patient error prevention in medication administration, irrespective of the context were included. Studies were included if published in English from 2005 to 2010 August week 4.

Studies were excluded if they were not about technologies used for patient identification and if they were publication types such as editorials, comments, letters, news (see literature search strategies below for more details).

The methodologist screened the titles and the abstracts. Full text articles were retrieved in the library if they met the inclusion criteria or if the title and the abstract did not contain enough information to decide, and were reviewed, see the study flow chart below.

Synthesizing the evidence

The evidence was not pooled statistically because of the heterogeneity of the included studies, and a narrative synthesis was performed. The methodologist extracted the data and summarized them in evidence tables (see Tables 2A.i-ii below).

Results

The search strategies identified 1939 citations (Figure 2A.i). The full text of 135 articles was retrieved in the library. Among those, eleven studies were included (1-11): nine evaluated a bar-coding technology, one evaluated a radiofrequency technology and one evaluated a reminder system for providers to check patient identify on the wristband. None of the included studies used patient identification technology in a chemotherapy ambulatory setting. One study evaluating a reminder system used a randomized, cluster, design (8). One study was a systematic review (1). Eight studies used a before-after design (2-7,9,10), and one study used a historical control (11). The outcomes measured were error rates or adverse drug events (6 studies), mislabelling events (2 studies), incidence of administration errors (1 study), relative risk of detecting a misidentification (1 study). Outcomes were assessed by observation or audit (7 studies), by counting lab alerts or reviewing computer records (1 study), by comparing with voluntary reporting (1 study), or the assessment method was not reported (2 studies).

Nine studies reported that the technology (either barcoding or radiofrequency identification) was significantly effective in reducing errors and in reducing adverse drug events (1, 3-7, 9-11). One study reported that not enough mature evidence was available to decide on the efficacy of barcode medication administration (2), and one study reported that a warning tag reminding practitioners to check the patient's wristband was not effective in making sure all bedside checks were performed (8). For more details refer to evidence tables below.

Conclusions

The evidence found was indirect because none of the studies was related to chemotherapy administration to adult cancer patients. Although weak, this evidence consistently showed that automated data capture technologies may be largely effective in reducing and preventing errors of identification. Figure 2B.i. Patient identification technologies: study flow chart.



Patient identification technologies: evidence tables of included studies.

Author, year source of funding	Study Design, duration	Population and Setting	Intervention	Outcomes Outcome assessment method
Hodgkinson, 2006 (1)	Systematic review	Aimed at older adults, but included all populations.	Barcoding	Error rates. Assessment: Not reported
Morriss, 2009 (7) American Society of Health-System Pharmacits Research and Education Foundation and the University of Iowa Pharmaceutical Enterprise.	Before-after Prospective cohort, Duration : 50 weeks.	IG: 483 neonates and 46,308 doses of medication administered. CG: 475 neonates and 46,090 doses administered. Setting: 36-bed Neonatal Intensive Care unit. Not chemo setting.	Barcoding	Error rates. Potential Adverse drug events rates (ADE). Assessment: Daily audit.
Poon, 2010 (10) AHRQ grant	Before-and- after, quasi- experimental. Duration: 9 months	 1.7 million medication orders written by physicians and 5.9 million doses of medications administered by nurses in one year. Setting: 35 adult medical, surgical and intensive care units in a 735- bed tertiary academic medical centre. Not chemo setting. 	Bar-code e-MAR Medication orders appear on the pt's electronic record once the pharmacist has approved them. The system alerts the nurse if a med is overdue or if medication does not correspond to a valid order.	Error rates in transcribing and administering medications were considered: Errors in timing (administrations that were early or late by > 1 hour) and errors not related to timing were the main outcomes. Assessment: Observation.
Paoletti, 2007 (9) Funding source not declared.	Before-after. Duration: Not reported	934 doses of medications ordered. Setting: CG: 20-bed cardiac telemetry unit. IG ₁ : 20-bed cardiac telemetry unit. IG ₂ : 36-bed medical-surgical unit. Not chemo setting.	Electronic medication records (EMAR) and bar-coded medication administration.	Errors observed. Assessment: Observation of errors as compared with self reporting.
Morrison, 2010 (6) Source of funding not reported.	Before-after. Duration: 21 months.	215,000 blood samples drawn from the inpatient phlebotomy team. Setting: a 777-bed academic medical centre Not chemo setting.	Bar-code bedside labeling system.	Percentage of phlebotomy samples reported as mislabelled or unlabeled by the lab. Patient satisfaction. Assessment: Observation. Survey for pt satisfaction.
Helmons, 2009 (5) No funding declared.	Before-after Duration: 4 months	Nurses administering medications. Setting: 2 medical-surgical	Bar-code- assisted medication administration	Error rate. Assessment: Observation using the Accuracy indicator of

Table 2B.i. Patient identification technologies: general characteristics table.

Author, year source of funding	Study Design, duration	Population and Setting	Intervention	Outcomes Outcome assessment method
		units, one medical intensive care unit, and one surgical ICU of a 386-bed academic teaching hospital. Not chemo setting.		the California Nursing Outcomes Coalition.
Hayden, 2008 (4) No funding declared	Before-after Duration: 3 years	Tissue and body fluid specimens collected at the hospital. Setting: pediatric cancer centre. Not chemo setting.	Computer- assisted bar- coding system	Mislabelling events (wrong label used or wrong patient) reported as absolute number and as percentage. Assessment: Retrospectively before (phone calls or lab alerts) Prospectively during and after (events recorded by computer)
Doyle, MD 2005 (2) No funding declared.	Before-after Duration: 12 months.	23,251 patient-days at time 1 and 25,878 patient-days at time 2. Setting: 8 medical-surgical unit in a tertiary hospital. Not chemo setting.	Bar-code administration	 Incidence of administration errors. Adherence of nurses to bar-code administration procedure. Assessment: 1)from hospital Medication Administration Errors database. 2) questionnaire to nurses.
Porcella, 2005 (11) AHRQ grant	Historical cohort. 2004 (study year) compared with 2003 and with 2002.	Blood products administered during the pilot period (8 mos) and during implementation (3 mos) Setting: 1 adult inpatient, 1 pediatric inpatient, 1 intensive care, and 1 adult transplant units of a 772 bed tertiary care teaching facility. Not chemo setting.	Bar-code technology for pt identification for the administration of blood products.	Relative risk of detecting a misidentification. Assessment: Errors detected by bar- coding system were compared with voluntary reporting of errors in the manual system.
Murphy, 2007 (8) Funding source not reported.	Cluster- randomized, matched-paired. Duration: 20 months.	IG: 122 audits CG: 116 audits Setting: 15 matched (by # of red blood cells [RBC] units received per week) pairs of clinical areas in 12 hospitals. Not chemo setting.	IG: Warning tag positioned on the blood bag in such a way that the transfusionist was required to remove the tag to spike the unit. CG: No extra label.	Proportion of patients transfused with RBC units for whom the key elements of the bedside check were all correctly completed. (i.e. check pt ID with wristband, Pt name and surname with wristband, check that unit number on blood bag and on the blood bank). Assessment:

Study Design, duration	Population and Setting	Intervention	Outcomes Outcome assessment method Observation (audit by
			trained observers).
Before-after Duration: 6 months.	8231 specimens sent to the pathology for evaluation before implementation and 8539 after implementation. Setting: gastroenterology and colorectal surgery outpatient endoscopy unit. Not chemo setting.	Radio-frequency identification, paperless requisition, and confirmation of correct site and correct patient by two healthcare providers.	Error rate in specimen labelling. Assessment: not reported.
	duration Before-after Duration: 6	duration 8231 specimens sent to the pathology for evaluation before implementation and 8539 after implementation. Setting: gastroenterology and colorectal surgery outpatient endoscopy unit.	duration8231 specimens sent to the pathology for evaluation before implementation and 8539 after implementation.Radio-frequency identification, paperless requisition, and confirmation of correct site and correct patient endoscopy unit. Not chemo setting.

Abbreviations: IG= Intervention group; CG= Control group

Author (year)	Intervention	Results	Analysis	Authors' conclusions, reviewer's comment
Hodgkinson, 2006 (1)	Barcoding.	Error rate decreased from 17% before to 0.05% after (P value not reported).	Qualitative synthesis.	The use of the barcoding system is encouraging, but it was "easily and frequently circumvented" p 11. Comment: Not chemo setting.
Poon, 2010 (10)	Bar-code e-MAR	 A 41.4% relative reduction in errors (P<0.001) was observed with the use of barcoding; a decrease from 11.5% to 6.8 error rate. The rate of potential ADE fell from 3.1% to 1.6% (50.8 relative reduction (P<0.001). 	Rao-Scott x ² test accounting for clustering by nurse. Clustered logistic regression models.	Bar-code substantially reduced the errors rate in order transcription and in medication administration. Comment: it does not speak specifically of wrong-patient error.
Morrison, 2010 (6)	Bar-code bedside labeling system.	The average labelling error decreased significantly post- implementation versus pre- implementation (rate ratio 0.59; 95% Confidence Interval 0.43 - 0.81; P = 0.0013.	Logistic regression.	The intervention technology is effective in reducing labelling errors. Comment: it does not speak specifically of wrong-patient error.
Helmons, 2009 (5)	Bar-code-assisted medication administration.	The Error rate (excluding wrong time errors) decreased by almost 58% after implementation.	Chi square and Fisher's exact test. Unpaired t test.	The intervention is effective in preventing medication errors.
Morriss, 2009 (7)	Barcoding.	 Decrease in serious errors from mean 0.11 to mean 0.033 (P<0.001). Reduction of preventable adverse drug event of 47%: RR of preventable ADE after implementation 0.53 (95% CI 0.29 to 0.91, P = 0.04) Increase in detected wrong-time errors of 117%; (P<0.001) 	x ² or Fisher's exact tests; Analysis of variance and a Kruskal- Wallis test; General estimating equation.	The intervention significantly decreased the relative risk of targeted preventable adverse drug events (ADE). Comment: it does not speak specifically of wrong-patient error.
Hayden, 2008 (4)	Computer-assisted bar-coding system.	A decline from 0.03% to 0.005% (P<0.001) was observed in the median percentage of mislabelled specimens.	Non parametric regression. Kruskal- Wallis test.	The intervention is effective and should be recommended.
Paoletti, 2007 (9)	Bar-code e-MAR	Error rate (excluding time and technique errors): CG: 1.6% P = 0.76 IG1:1.6% P = 0.959 IG2: 2.9% P = 0.045	Not reported.	The intervention has substantially reduced error rate. Comment: it does not speak specifically of wrong-patient error, however they describe the use of bar-coded wristbands during the

Table 2B.ii. Patient identification	n technologies: results table.
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Author (year)	Intervention	Results	Analysis	Authors' conclusions, reviewer's comment
				implementation phase to prevent this type of error.
Doyle, 2005 (2)	Bar-code medication administration	A difference between time 1 and time 2 was observed for wrong-route error (P = 0.031). No statistically significant results for wrong-patient and wrong-dose error.	Independent samples t test.	Not enough mature evidence is available to decide on the efficacy of the intervention. Comment: Useful considerations are made about taxonomy of errors and outcome assessment strategies in this field of study.
Porcella, 2005 (11)	Bar-code technology for pt identification for the administration of blood products.	Pilot period: 2004 vs. 2003: RR: 9.98 (95% CI 1.28, 78.0). 2004 vs. 2002: RR: 3.33 (95% CI0.92, 12.1). Post house-wide go-live period: At sample processing: 2004 vs. 2003: RR 9.98 (95% CI: 2.9, 34.5) In any step of the process: 2004 vs. 2003: RR 30.6 (95% CI: 9.5, 98.4)	Relative risk and CI were calculated.	The technology allows for early detection of the misidentification errors.
Francis, 2009 (3)	Radio-frequency identification, paperless requisition, and confirmation of correct site and correct patient by two healthcare providers.	Mislabelled or unlabeled specimens: Time 1: 765; Time 2: 47 (P <0.001)	Fisher's exact test.	The intervention decreased specimen- labeling errors. RFID was responsible for prevention of most serious errors.
Murphy, 2007 (8)	IG: Warning tag positioned on the blood bag in such a way that the transfusionist was required to remove the tag to spike the unit. CG: No extra label.	There was no effect of the label intervention: OR: 1.09 (95% Cl 0.54, 2.17). Z = 0.24, P = 0.81. The study has < 80% power.	Odds ratio (OR) was used to measure the effect. Logistic regression.	The intervention was ineffective perhaps because it was an irritant?

Appendix 2B.i & 2B.ii. Patient identification technologies: references.

- 1. Hodgkinson B, Koch S, Nay R, Nichols K. Strategies to reduce medication errors with reference to older adults. Int J Evid Based Healthc. 2006 Mar;4(1):2-41.
- 2. Doyle MD. Impact of the bar code medication administration (BCMA) system on medication administration errors [dissertation]: University of Arizona; 2005.
- 3. Francis DL, Prabhakar S, Sanderson SO. A quality initiative to decrease pathology specimenlabeling errors using radiofrequency identification in a high-volume endoscopy center. Am J Gastroenterol. 2009 Apr;104(4):972-5.
- 4. Hayden RT, Patterson DJ, Jay DW, Cross C, Dotson P, Possel RE, et al. Computer-assisted barcoding system significantly reduces clinical laboratory specimen identification errors in a pediatric oncology hospital. J Pediatr. 2008 Feb;152 (2):219-24.
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- 8. Murphy MF, Casbard AC, Ballard S, Shulman IA, Heddle N, Aubuchon JP, et al. Prevention of bedside errors in transfusion medicine (PROBE-TM) study: a cluster-randomized, matched-paired clinical areas trial of a simple intervention to reduce errors in the pretransfusion bedside check. Transfusion. 2007 May;47(5):771-80.
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- 11. Porcella A, Walker K, editors. Patient safety with blood products administration using wireless and bar-code technology. Proceedings of the American Medical Informatics Association (AMIA) Annual Symposium; 2005; Nov 30-Dec 3, Austin, TX; 2005.

Appendix 2C. Systematic review checklists.

Question: Are checklists effective in preventing medication-related adverse events during the administration of chemotherapy agents?

Search strategy:

We searched the following electronic databases: MEDLINE, EMBASE, Cochrane and CINAHL our and own files for citations of studies on the effectiveness of checklists in preventing medication errors (Figure 2C.i.). The search strategy for the Medline database with specific key terms is reported in Appendix 9; this search strategy was adapted for the other databases.

Database: Ovid MEDLINE(R) <1996 to November Week 2 2010>, Ovid MEDLINE(R) Daily Update <November 17, 2010>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <November 23, 2010> Search Strategy:

.....

1 Checklist/

- 2 checklist:.tw.
- 3 Medical Errors/pc [Prevention & Control]
- 4 Medication Errors/pc [Prevention & Control]
- 5 adverse drug events.tw.
- 6 Safety Management/
- 7 safety.tw.
- 8 Quality Assurance, Health Care/
- 9 1 or 2
- 10 3 or 4 or 5 or 6 or 7 or 8
- 11 9 and 10
- 12 Antineoplastic Agents/
- 13 chemotherapy.tw.
- 14 Neoplasms/dt [Drug Therapy]
- 15 12 or 13 or 14
- 16 11 and 15

Selection criteria

We included systematic reviews or comparative studies that assessed the use of chemotherapy administration checklists for safety purposes.

Studies were included if published in English from 1996 to 2010, November week 4.

Studies were excluded if they were not about the use of checklists for chemotherapy and if they were publication types such as editorials, comments, letters, and news.

The methodologist screened the titles and the abstracts. Full text articles were retrieved in the library if they met the inclusion criteria or if the title and the abstract did not contain enough information to decide.

Synthesizing the evidence

The evidence was not pooled statistically because one study was included. The methodologist extracted the data and summarized them in evidence tables (Tables 2.C.i-ii; also see Appendix 2.D)

Results

The search of electronic databases for primary studies culled 46 citations. One study was included (1). The included study has an observational design and it is a laboratory study.

It compares two different kinds of checklists for the reduction of errors. See evidence tables below for more details.

Conclusion

The included study shows that checklists are useful in preventing errors for mechanistic tasks, less so for tasks that involve critical thinking.

Figure 2C.i. Checklists: study flow chart.



Author (year) source of funding	Study Design, duration	Population and Setting	Intervention	Outcomes Outcome assessment method
White, 2010 (1)	Comparative, observational and contextual enquiry	Laboratory study	IG: new checklist with independence characteristic for chemotherapy administration CG: old checklist already in use	Error detection rates Efficiency

Table 2C.i. Checklists: general characteristics.

2C.ii. Checklists: results table.

Author (year)	Intervention	Results	Analysis	Authors' conclusions, reviewer's comment
White, 2010 (1)	IG: new checklist with independence characteristic for chemotherapy administration CG: old checklist already in use	The new checklist helped to detect more errors of any type than the old checklist (p<0.01). Errors in pump programming: IG: 80% vs. CG: 90% p>0.05 Errors in pt identification: IG: 80% vs. CG: 15% (p<0.01) Mismatches between order and label: IG: 60% vs. CG: 45% Clinical decision errors: None of the errors was detected with either checklist (p>0.05) Efficiency: NS	Error detection rates were analyzed with a 2 (checklist type; old vs. new)x 4 (error type; pump programming vs. mismatch vs. patient ID vs. clinical decision) repeated- measures analysis of variance (ANOVA) with an a level of 0.05.	The checklists may be better at detecting errors which required mechanistic tasks than those requiring critical thinking.

IG= intervention group; CG: control group; NS= not significant; pt= patient

Appendix 2C.i & 2C.ii. Systematic review checklists: references.

1. White RE, Trbovich PL, Easty AC, Savage P, Trip K, Hyland S. Checking it twice: an evaluation of checklists for detecting medication errors at the bedside using a chemotherapy model. Qual Saf Health Care. 2010 Aug 19;19(6):562-7.

Appendix 2D. Systematic review: scheduling models.

Question: What is the most effective scheduling model for reducing errors in the administration of chemotherapy to cancer patients?

Search strategy

We searched the electronic databases: MEDLINE, Cochrane (Database of Abstracts of Reviews of Effects; Central Register of Controlled Trials, and Database of Systematic Reviews), EMBASE, and CINAHL and HealthStar, and our own files for citations of studies on same-day versus non-same day scheduling for outpatient chemotherapy. The search strategy with specific key terms designed for MEDLINE and HealthStar is reported below; this search strategy was adapted for the other databases.

Search strategy for scheduling models: P1F3.

Database: Ovid HealthStar <1966 to September 2010>, Ovid MEDLINE(R) <1996 to October Week 1 2010>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <October 18, 2010> Search Strategy:

- 1 Antineoplastic Agents/ad, tu [Administration & Dosage, Therapeutic Use]
- 2 chemotherapy.mp.
- 3 outpatient.mp. or Outpatients/
- 4 ambulatory.mp. or Ambulatory Care/
- 5 (systemic adj therapy).mp.
- 6 1 or 3 or 4 or 5
- 7 alternate day.mp.
- 8 (appointments and schedules).mp. [mp=ti, ot, ab, nm, hw, ui]
- 9 "Appointments and Schedules"/
- 10 Efficiency, Organizational/
- 11 Practice Management/og [Organization & Administration]
- 12 workflow.mp. or Workflow/
- 13 Workload/
- 14 patient flow.mp.
- 15 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
- 16 6 and 15
- 17 limit 16 to (english language and yr="2000 -Current")

18 limit 17 to (addresses or bibliography or biography or case reports or comment or dictionary or directory or editorial or festschrift or in vitro or interactive tutorial or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index or portraits or webcasts) [Limit not valid in HealthSTAR; records were retained]

19 17 not 18

20 remove duplicates from 19

Selection criteria

We included systematic reviews or comparative studies that assessed same day versus non-same-day chemotherapy scheduling. Studies were included if published in English from 2000 to 2010 October Week 1.

Studies were excluded if they were not comparative, if the intervention was an alternative scheduling method and if they were publication types such as editorials, comments, letters, news (see search strategy for more details).

The methodologist screened the titles and the abstracts. Full text articles were retrieved in the library if they met the inclusion criteria or if the title and the abstract did not contain enough information to decide and were reviewed.

Synthesizing the evidence

Only one study was included after full text review (Figure 2.D.i). The methodologist extracted the data and summarized them in evidence tables (Tables 2.D.i-ii).

Results

The search strategies culled 1299 citations. Of those 16 were included after title and abstract screening. One article was included (1) after full text relevance review. The included study was a program evaluation; an observational study with no detailed description of the methods, therefore it is difficult to evaluate its internal validity and the generalizability of the results. This article showed that the pharmacy was better able to deliver drugs on time for patient appointments with this model (see evidence tables below for more details).

Conclusions

No firm conclusions can be drawn from the available evidence.

Figure 2D.i. Scheduling modules: study flow chart.



Table 2D.i. Scheduling models: evidence tables. General characteristics table.

Author (year) source of funding	Study Design, duration	Population and Setting	Intervention	Outcomes Outcome assessment method
Dobish, 2003 (1) No funding declared.	Comparative observational	Chemotherapy suite	IG: Next-day chemotherapy scheduling CG: same-day chemotherapy scheduling	Ability of the pharmacy to prepare chemo in time for appointments.

Table 2D.ii. Scheduling models: results table

Author (year)	Intervention	Results	Analysis	Authors' conclusions, reviewer's comment
Dobish, 2003 (1)	IG: Next-day chemotherapy scheduling CG: same-day chemotherapy scheduling	IG: Pharmacy was able to meet the appointment times in 95% of the cases. CG: Pharmacy was able to meet the appointment times in 44% of the cases.	Not reported	The time table change was successful in improving pharmacy ability to prepare the chemotherapy in time for patients' appointments.

Appendix 2D.i & 2D.ii. Systematic review: scheduling models: references.

1. Dobish R. Next-day chemotherapy scheduling: A multidisciplinary approach to solving workload issues in a tertiary oncology center. J Oncol Pharm Pract. 2003;9 (1):37-42.

Appendix 3. Excluded guidelines: not based on a systematic search of the evidence.

Patient identification

- 1. Jacobson JO, Polovich M, McNiff KK, LeFebvre KB, Cummings C, Galioto M, et al. American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. Oncol Nurs Forum. 2009 Nov;36(6):651-8.
- The Joint Commission. National Patient Safety Goals: The Joint Commission; 2007. [cited 2012 Sep 16]. Available from: <u>http://www.patientsafety.gov/TIPS/Docs/TIPS_JanFeb07.pdf</u>.
- 3. Schulmeister L. Patient Misidentification in Oncology Care. Clin J Oncol Nurs. 2008;12(3):1-4.
- 4. National Patient Safety Agency. Wristbands for hospital inpatients improves safety. London, UK: National Patient Safety Agency NHS; 2005. [cited 2010 Sep 16]. Available from: <u>http://www.google.ca/search?q=Wristbands+for+hospital+inpatients+improves+safety&ie=utf-8&o</u>
- National Patient Safety Agency. Guidance on the standard for patient identifiers for identity bands. London, UK; National Patient Safety Agency - NHS; 2009. [cited 2010 Sep 16]. Available from: http://www.google.ca/search?g=Guidance+on+the+standard+for+patient+identifiers+for+identity+

http://www.google.ca/search?q=Guidance+on+the+standard+for+patient+identifiers+for+identity+ bands&ie=utf-8&oe=utf-8&aq=t&rls=org.mozilla:en-US:official&client=firefox-a.

- 6. Norris B. Standardising wristbands improves patient safety: guidance on implementing the Safer Practice Notice (SPN 24, July 2007) and the related information standard on core patient identifiers approved by the Information Standards Board for Health and Social Care in March 2009. London, UK; National Patient Safety Agency; 2009. [cited 2010 Sep 16]. Available from: http://www.google.ca/search?q=Standardising+wristbands+improves+patient+safety&ie=utf-8&tag=t&rls=org.mozilla:en-US:official&client=firefox-a.
- 7. National Patient Safety Agency. Your guide to implementing standard wristbands. London, UK: National Patient Safety Agency; 2009. [cited 2010 Sep 16] Available from: <u>http://www.google.ca/search?q=Your+guide+to+implementing+standard+wristbands&ie=utf-8&o=utf-8&aq=t&rls=org.mozilla:en-US:official&client=firefox-a.</u>
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- 9. Schulmeister L. Preventing Chemotherapy Errors. The Oncologist: The Community Oncologist. 2006;11:463-8.
- 10. Catalano K. JCAHO'S National Patient Safety Goals 2006. J Perianesth Nurs. 2006 Feb;21(1):6-11.

Patient information and education

Pieces of information to be given to the patient

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- 2. Richard Wells Research Centre. Prevention of healthcare-associated infections in primary and community care. London: Thames Valley University; 2003.
- 3. Aspden P, Wolcott J, Bootman JL, Cronenwett LR, Committee on identifying and preventing medication errors. Preventing medication errors: quality chasm series. Quality chasm. Washington, DC: National Academies Press; 2007.
- 4. Infusion nursing standards of practice. J Infus Nurs. 2007;30(3).
- 5. Polovich M, Whitford JM, Olsen M. Chemotherapy and biotherapy guidelines and recommendations for practice. Pittsburg, PA. : Oncology Nursing Society; 2009.
- 6. EviQ: Cancer Treatments Online. New South Wales Government; South Wales (Australia) 2011; [cited 2011 Sep 16]. Available from: <u>https://www.eviq.org.au/</u>.
- 7. Gullatte MM. Clinical guide to antineoplastic therapy: A chemotherapy handbook. Second ed. Pittsburgh, PA: Oncology Nursing Society; 2007.

Informed consent

1. Jacobson JO, Polovich M, McNiff KK, LeFebvre KB, Cummings C, Galioto M, et al. American Society

of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. Oncol Nurs Forum. 2009 Nov;36(6):651-8.

- 2. Storm C, Casillas J, Grunwald H, Howard D, McNiff K. Informed Consent for Chemotherapy: ASCO Member Resources. J Oncol Pract. 2008;4:289-95.
- 3. Treleaven J, Cullis JO, Maynard R, Bishop E, Ainsworth-Smith I, Roques A, et al. Obtaining consent for chemotherapy. Br J Haematol. 2006 Mar;132(5):552-9.
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- National Chemotherapy Advisory Group. Chemotherapy Services in England: Ensuring quality and safety. London, UK: National Chemotherapy Advisory Group; 2009. [cited 2010 Sep 16]. Available from:

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Role of the patient in the plan of care

- 1. Aspden P, Wolcott J, Bootman JL, Cronenwett LR, Committee on identifying and preventing medication errors. Preventing medication errors: quality chasm series. Quality chasm. Washington, DC: National Academies Press; 2007.
- National Chemotherapy Advisory Group. Impact Assessment of National Chemotherapy Advisory Group recommendations: Department of Health; 2008. [cited 2010 Sept 16]. Available from: <u>http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_114</u> 974.
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CPOE

- 1. Jacobson JO, Polovich M, McNiff KK, LeFebvre KB, Cummings C, Galioto M, et al. American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. Oncol Nurs Forum. 2009 Nov;36(6):651-8.
- 2. Aspden P, Wolcott J, Bootman JL, Cronenwett LR, Committee on identifying and preventing medication errors. Preventing medication errors: Quality chasm series. Quality chasm. Washington, DC: National Academies Press; 2007.
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- 6. Wells B. Pharmaceutical bar coding to improve patient safety: options for technical standards in the Canadian environment. Toronto: Institute for Safe Medication Practices Canada; Tornoto, (ON)

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7. Oncology Nursing Society. Prevention and reporting of medication errors. Oncology Nursing Society. Oncol Nurs Forum. 2001 Jan-Feb;28(1):15-6.

Checklists

- 1. New South Wales Government. EviQ, Cancer Treatments Online. Time out procedure checklist: New South Wales (Australia) 2010. [cited 2010 Sep 16]. Available from: https://www.eviq.org.au/Protocol/tabid/66/categoryid/217/id/6/Timeout+Procedure.aspx.
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Tools for symptoms assessment

- 1. Polovich M, Whitford JM, Olsen M. Chemotherapy and biotherapy guidelines and recommendations for practice. Pittsburg, PA. : Oncology Nursing Society; 2009.
- New South Wales Government. EviQ, Cancer Treatments Online. Time out procedure checklist New South Wales (Australia) 2010. [cited 2010 Sep 16]. Available from: <u>https://www.eviq.org.au/Protocol/tabid/66/categoryid/217/id/6/Timeout+Procedure.aspx</u>.

Parts of a written plan

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Pharmacy practices

- 1. Graham K. Pharmaceutical bar coding to improve patient safety: options for technical standards in the Canadian environment: Canadian Patient Safety Institute; 2008. [cited 2010 Sep 16]. Available from: <u>http://www.ismp-canada.org/download/BarCoding_Roundtable_Proceedings.pdf</u>.
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Evidence-Based Series 12-12-1: Section 3

Safe Administration of Systemic Cancer Therapy Part 1: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification EBS Development Methods and External Review Process

M. Leung, R. Bland, F. Baldassarre, E. Green, L. Kaizer, S. Hertz, J. Craven, M. Trudeau, A. Boudreau, M. Cheung, S. Singh, V. Kukreti, R. White, and the Safe Administration of Systemic Cancer Treatment Expert Panel

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO), the Systemic Treatment Program, CCO, and the Nursing Program, CCO Developed by the Safe Administration of Systemic Cancer Treatment Expert Panel

Draft Report Date: July 9, 2012

THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (CCO) (1). The PEBC mandate is to improve the lives of Ontarians affected by cancer, through the development, dissemination, implementation, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer care.

The PEBC supports a network of disease-specific panels, termed Disease Site Groups (DSGs), as well as other groups or panels called together for a specific topic, all mandated to develop the PEBC products. These panels are comprised of clinicians, other health care providers and decision makers, methodologists, and community representatives from across the province.

The PEBC is well known for producing evidence-based guidelines, known as Evidencebased Series (EBS) reports, using the methods of the Practice Guidelines Development Cycle (1, 2). The EBS report consists of an evidentiary base (typically a systematic review), an interpretation of and consensus agreement on that evidence by our Groups or Panels, the resulting recommendations, and an external review by Ontario clinicians and other stakeholders in the province for whom the topic is relevant. The PEBC has a formal standardized process to ensure the currency of each document, through the periodic review and evaluation of the scientific literature and, where appropriate, the integration of that literature with the original guideline information.

The Evidence-Based Series

Each EBS is comprised of three sections:

- Section 1: Guideline Recommendations. Contains the clinical recommendations derived from a systematic review of the clinical and scientific literature and its interpretation by the Group or Panel involved and a formalized external review in Ontario by review participants.
- Section 2: Evidentiary Base. Presents the comprehensive evidentiary/systematic review of the clinical and scientific research on the topic and the conclusions reached by the Group or Panel.
- Section 3: EBS Development Methods and External Review Process. Summarizes the EBS development process and the results of the formal external review of the draft version of Section 1: Guideline Recommendations and Section 2: Evidentiary Base.

DEVELOPMENT OF THIS EVIDENCE-BASED SERIES

Development and Internal Review

This EBS was developed by the PEBC, CCO, and the CCO Systemic Treatment and Nursing Programs. The series is a convenient and up-to-date source of the best available evidence on the safe administration of chemotherapy developed through review of the evidentiary base, evidence synthesis, and input from external review participants in Ontario.

Report Approval Panel Review and Approval

Prior to the submission of this EBS draft report for External Review, the report was reviewed and approved by the PEBC Report Approval Panel, a panel that includes oncologists and whose members have clinical and methodological expertise. Key issues raised by the Report Approval Panel included the following:

Comment	Response
 Improve the readability and clarity of the document, for example by: changing the general questions to statements of the objectives/goals or purpose of the guideline reduce the number of questions asked by clustering in bigger units; Make the tone of the recommendations less patronizing. 	 The "General question" was changed to "Purpose"; the question for Part 1 document was changed to General objective. The areas of interest were clustered into areas of interest that encompass the entire process of chemotherapy administration and areas of interest specific to individual steps of the process. The questions leading the searches have been shown in a table in Section 2. The recommendations have been re-phrased highlighting their target users. Some recommendations have been deleted, and some re-phrased.
Clarify the meaning of the title to indicate whether the document addresses also non-cytotoxics and non-intravenous agents.	• The title has been changed from: "Safe administration of chemotherapy" to "Safe administration of systemic cancer therapy"
Clarify the area of expertise of the	Appendix 1 in the General Methods document has been

Table 1. Feedback from the Review Approval Panel and the Working Group response.

working group/ expert panel members. Clarify whether community	modified to indicate the professional characteristics of each component of the Working Group and of the Expert Panel. One of the members of the Expert Panel is a patient
chemotherapy providers and patients were involved.	representative. This Part 1 document is dedicated to chemotherapy delivered in a hospital setting, not in a community setting.
"I am not sure systematic review was appropriate for some of the questions (e.g., distractions and interruptions, same day versus non same day). The return on investment was very limited. How the review was executed was fine, I am just not sure always necessary."	Scoping reviews will be conducted in subsequent parts of this document.
"The recommendation on scheduling models is based on the assumption that less staff pressure leads to greater safety, and this is not an evidence-based statement." "Does this conflict with other CCO guidelines and activities that promote a streamlined approach for patients?"	The recommendation on scheduling models has been rephrased.
"The recommendation about interruption and distraction-free environments is ambiguous because it is based on work volume data that are not provided."	The wording of this recommendation has been changed.
 Ambiguous recommendations: Recommendation about patient assessment. Recommendation about patient active participation in care. Recommendation about patient identification: use of wrist bands. Recommendations framed as an informed consent and reads as shared decision making; there may be some significant legal issues in how it is framed. 	 The wording of the recommendation has been changed to say: "The assessment for chemotherapy administration should include but may not be limited to". The wording has been changed to: "Patients (or their substitute decision makers)". The recommendation talks about patients staying in the organization. The recommendation framed as informed consent: "The Working Group believes that informed consent is a continuous process of communication between healthcare providers and patients, and not limited to the completion and signature of a consent form. This process is central to the relationship between caregivers and patients and their relatives, because it permits the patients to make autonomous decisions about their treatment." was re-framed as a value statement as an introduction to a recommendation on patient role in the plan of care. The recommendation "Informed consent should be documented at the start

	of treatment and with each new change in treatment protocol." Was left out because this matter is regulated by legislation.
Section 2. The description of the process needs to be streamlined further.	The recommendations were clustered in 2 larger groups, and the evidence in support was summarized in 2 tables. Explanation of what was done is briefly given in the paragraphs following the tables.

External Review by Ontario Clinicians and Other Experts

The PEBC external review process is two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a small number of specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners.

Following the review and discussion of <u>Section 1: Recommendations</u> and <u>Section 2:</u> <u>Evidentiary Base</u> of this EBS and the review and approval of the report by the PEBC Report Approval Panel, the safe administration of systemic treatment Expert Panel circulated Sections 1 and 2 to external review participants for review and feedback. Box 1 summarizes the draft recommendations and supporting evidence developed by the Safe chemotherapy Expert Panel.

BOX 1:

DRAFT RECOMMENDATIONS (approved for external review on April 2, 2012) **PURPOSE**

The purpose of this document is to provide guidance on processes, technologies, and devices for the prevention of errors during systemic cancer treatment administration in adult patients in areas that cut across the entire process and in the planning and preparation stages.

TARGET POPULATIONS

Adult patients who are going to receive chemotherapy treatment or who are already receiving chemotherapy treatment for cancer in hospital settings.

AREAS OF INTEREST AND SUMMARY RECOMMENDATIONS

Within the main objective, the Working Group highlighted several areas of interest. Some of these areas encompass the entire process of chemotherapy administration, and some are specific to the planning and preparation stages. Each area of interest is presented below, followed by a summary of the recommendations. The justification for the recommendations and the link to supporting evidence can be found in Section 2 of this document.

A) Areas of interest encompassing the entire process of chemotherapy administration

The areas that encompass the entire process of chemotherapy administration include the production of distraction- and interruption-free environments; patient identification; patient and family teaching and provision of information; patient and family role in the plan of care; and the use of computerized prescriber order entry (CPOE) and checklists.

Environmental Considerations

A direct relationship between distractions and interruptions, during all of the steps of medication administration, and various kinds of errors has been documented {Westbrook, 2010 #3340}.

Physical and staffing resources allowing the completion of tasks in an environment free from distractions and interruptions are fundamental to the safe administration of chemotherapy.

Customized interventions to obtain a distraction- and interruption-free environment will need

to be tested on a case-by-case basis.

Patient identification

The correct identification of the patient prevents "wrong patient" errors. A wrong-patient error may occur at the ordering, transcribing, dispensing, and administrating steps of the medication administration process {Shojania, 2003 #3179}. Appendix 1 contains examples of procedures for <u>AVOIDING WORKAROUNDS</u> when using barcoding technology.

The Working Group recommends that organizations should set up a process for patient identification such that patients are identified at entry in the system, and then at each step of the treatment process, by the different members of the healthcare team involved.

This process should include the use of at least two identifiers, the first being the patient's full name and the second being the patient's date of birth, medical record number, or other patient-identifying information, and specifics about the methods for the proper identification of patients with language barriers or special needs.

Patients should receive an identification wristband at entry to the organization, and this should be used during their stay in the organization while receiving treatment.

If possible, a technology such as automated identification and data capture (e.g., barcoding, radiofrequency) should be used for patient identification. Institutions that use these technologies should have policies, procedures, and staff education in place so that workarounds that threaten patient safety using automated identification systems are avoided.

Information and Education for Patients and Their Families/Caregivers and Their Role in the Plan of Care

Every encounter between patients and their families and their healthcare providers is an opportunity to communicate information and provide education. Informing and educating patients and their families about any treatment and what to expect may prevent "wrong drug", "wrong reason", "wrong frequency", "wrong route", and "wrong time" errors. Besides helping to improve their own safety, patients can work with organizations to improve general patient safety at the organization and unit level and can also advocate for the public reporting and accountability of organizations {Gibson, 2007 #3180}. Appendix 1 contains examples of specific components of EDUCATION.

The Working Group recommends that patients who are to receive or who are already receiving chemotherapy should be provided with oral and written information that enables them to comprehend the aims, effects, and outcomes of the proposed or ongoing treatment. Information should cover the following, at a minimum:

- diagnosis
- goals of therapy
- treatment process
- regimen, and its short and long term effects
- management of side effects

The signing of the informed consent form is the starting point at which chemotherapy administration formally begins {, 1996 #3181}. The Working Group believes, however, that informed consent is a continuous process of communication between healthcare providers and patients that is not limited to the completion and signature of a consent form and that consent can be withdrawn by the patient at any point in the chemotherapy trajectory. This process is central to the relationship between caregivers, patients, and their relatives, because it allows patients to make autonomous decisions about their treatment.

The Working Group recommends that patients (or their substitute decision makers) should play a major role in preventing medication errors by being actively involved in all phases of the treatment process in a patient-centered model of care. Healthcare providers need to be open, receptive, and responsive to patient questions.

Computerized Prescriber Order Entry (CPOE)

CPOE can have a role in the chemotherapy administration process phases of ordering, transcribing, dispensing, and administering chemotherapy.

The Working Group recommends CPOE as the standard to reduce adverse events for protocols and orders. Where CPOE is not available, standardized, regimen-level pre-printed forms should be used to improve consistency and readability and to avoid prescription error. Handwritten orders are not acceptable.

Protocol templates stored electronically should be in a read-only format to avoid unapproved alteration of the original. A process should be in place for the creation and upkeep of the templates. Access to the original protocol document should be restricted to authorized persons.

Checklists

Checklists are designed to prevent errors of omission and can be used during the entire process of chemotherapy administration. Appendix 1 contains an example of a <u>CHECKLIST</u> for chemotherapy administration.

The Working Group recommends checklists as a tool for the administration process when multiple, complex, mechanistic tasks are required.

B) Areas Specific to the Planning and Preparation Phases of Chemotherapy Treatment

The areas of interest that are specific to the individual steps of the chemotherapy administration process are patient assessment, patient screening, the written plan, scheduling models, pharmacy practice, and infusion devices.

Patient Assessment

A thorough assessment can prevent such errors as the "wrong drug", "wrong time", "wrong dose", and "wrong frequency". Appendix 1 contains an example of the requirements for <u>PATIENT</u> <u>ASSESSMENT</u> before chemotherapy is administered.

The Working Group recommends that organizations should have written protocols and procedures for patient pretreatment assessment by clinicians.

A patient assessment should be carried out by the nurse prior to chemotherapy administration. The assessment for chemotherapy administration should include, but may not be limited to, the following:

- Baseline observations, specific to the protocol
- Patient history and treatment plan
- Presence of allergies or other hypersensitivity reactions
- Patient performance status and physical findings that may impact on the treatment process
- Patient weight, height, and body surface area
- Laboratory results
- Response to previous treatment and previous toxicities that may impact on treatment
- Compliance with home premedication treatment
- Assessment for and maintenance of access devices required for administration
- Presence of psychosocial concerns

Tools for Patient Screening and Assessment

The Working Group recognizes that the use of validated tools is preferred for patient screening and assessment. The table below is a resource of available tools.

Dimension to be assessed	Tool	Web link to resources
Performanc e status	ECOG	http://www.ecog.org/general/perf_stat.html
Pain	ESAS	https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=13 846 or refer to tools contained in the CCO Cancer-related Pain Management Guideline (available at http://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=44 127)
Fatigue	ESAS	https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=13 846
Nausea	ESAS	https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=13 846
Sensory/ motor neuropathy	NCI common terminolog y for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf See Appendix 1. For oxaliplatin related sensory motor neuropathy the use of the tool in use for oxaliplatin (6).
Diarrhea	NCI common terminolog y for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf
Oral mucositis	NCI common terminolog y for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf
Rash	NCI common terminolog y for adverse events version 3	http://www.eortc.be/services/doc/ctc/ctcaev3.pdf

Parts of a Written Plan

A written plan is an important document that is referred to by all the team members during the treatment process. The plan is a communication tool that can be the centre of interdisciplinary

collaboration, thus preventing medication errors. Appendix 1 provides an example of the elements that should be included in a WRITTEN PLAN.

The Working Group recommends that a systemic treatment plan should be documented and available and should include other decisions made for the patient such as surgery and radiation therapy, as well as requirements related to nursing and allied healthcare staff. The plan should ideally be in a computer-generated format and should be part of or filed with the patient record at all times.

Any change in the plan of treatment (i.e., a new protocol is initiated or a medication dose is changed), should be clearly documented on the treatment plan, noting the time the change was initially ordered.

A copy of the treatment plan should be distributed to all facilities involved in the patient's care as well as the patient's primary care healthcare provider.

Treatment Scheduling Models: Same Day versus Non-Same-Day

Currently, there are two chemotherapy-delivery scheduling models in use in Ontario: Sameday and Non-same-day. The Same-day model minimizes the number of patient visits for care but can be associated with long patient waits on the day of treatment and significant workload pressures for the staff, especially when the treatment protocols are long or when order clarifications are required.

Non-same-day chemotherapy scheduling may be an appropriate option for many patients undergoing chemotherapy.

Organizations should weigh the pros and cons of each scheduling model as it pertains to their environment, geographic challenges, and patient population.

Individual patient circumstances should always be considered.

Pharmacy Practices: Chemotherapy Preparation and Delivery

Pharmacy practices include chemotherapy preparation and delivery. Errors at this point of the process may involve the issuing of the wrong drug or the wrong dose and the provision of labelling that can be misleading or misread or that indicates the wrong patient, route, or frequency. The inadvertent exposure of other patients and personnel to the chemotherapy during its transport to the specific patient is also a risk.

The Working Group recommends that good practices in chemotherapy preparation and delivery include the following:

- Verification of the chemotherapy order and preparation.
 - Verifying a chemotherapy order should include a systematic check of all the components of the chemotherapy order and its preparation and dispensing. Verification and independent double checking processes should be regulated by oncology-specific policies and procedures and training and certification programs to maintain accuracy and quality.
 - Independent double checking at various points of the chemotherapy preparation process should be as frequent as possible. Independent double checking may still be required when CPOE is in place because of the possibility of major variations or deviations in protocol, protocols that are new or not yet built into the CPOE program, or complex calculations involved in chemotherapy preparation.

 Independent double checking should ideally be made by a second pharmacist or, depending on physical and staffing resources, by a pharmacy technician (Tech-Check-Tech procedure where one technician checks the order-filling accuracy of another), or by another healthcare professional with appropriate knowledge, skills and training to perform this function.

- Appropriate chemotherapy labelling (see PEBC EBS 12-11: Patient Safety Issues: Key Components of Chemotherapy Labelling):
 - <u>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/1191</u>Labelling of outsourced drugs is still required. An analysis of labelling from outsourced products should be performed to ensure that it does not conflict with in-house products.
- Appropriate packaging and transportation of chemotherapy drugs and the education of personnel who handle chemotherapy drugs (see PEBC Special Report: Safe Handling of Parenteral Cytotoxics:
- <u>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2161</u> Chemotherapy should be packaged for dispensing and delivered in a manner that meets acceptable safety standards and reduces chances for confusion or patient errors.

Appendix 1 outlines examples of parameters to be checked when <u>VERIFYING A</u> <u>CHEMOTHERAPY ORDER</u>, and of a method for organizing chemotherapy <u>PACKAGING AND DELIVER</u>Y.

Infusion Pumps

Currently, the following four types of pumps are in use in Ontario: volumetric pumps, elastomeric pumps, smart pumps, and smart pumps integrated with barcoding technology. The adoption of different kinds of pumps depends on an individual institution's contextual factors.

If an organization intends to change their infusion delivery devices, and given that each kind of pump in the current state of the art technology presents some advantages and disadvantages, the Working Group recommends considering the following comparison table.

Safety characteristics	Smart pump	Smart pump + barcoding	Volumetric (CADD)	Elastomeric
Prevents a "wrong patient" error	No	Yes	No	No
Prevents a "wrong drug" error	No	No	No	No
Prevents a "wrong dose" error	Yes (only if hard limits used)	Yes (only if hard limits used)	No (subject to programming errors)	No (variations in flow rate depending on temperature and position)
Prevents a "wrong route" error	Yes	Yes	No	No
Prevents a "wrong time" error	Yes	Yes	No	No
Prevents a "wrong documentation" error	Yes	Yes	No	No
Easy implementation	No	No	Yes	Yes
Ambulatory use	No	No	Yes	Yes

Table 2. Safety characteristics of infusion pumps.

Organizations that decide to migrate to smart pump systems need to employ the potential capabilities of the technology and to understand the limitations. It must be kept in mind that smart

pump technology involves a complete drug delivery system redesign and that a completely integrated approach between smart pumps with barcoding and all other medication management technologies has to occur.

Implementation issues, however, are beyond the scope of this document. For a more thorough discussion on implementation issues, the interested reader can refer to the Healthcare Human Factors recommendations available at:

http://www.ehealthinnovation.org/files/SmartMedicationDeliverySystems_FullReport.pdf.

Methods

Targeted Peer Review: During the guideline development process, 10 targeted peer reviewers from Ontario and British Columbia considered clinical and/or methodological experts on the topic were identified by Safe Chemotherapy Administration Working Group. Several weeks prior to completion of the draft report, the nominees were contacted by email and asked to serve as reviewers. Four reviewers agreed and the draft report and a questionnaire were sent via email for their review. The questionnaire consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a guideline. Written comments were invited. The questionnaire and draft document were sent out on April 2, 2012. Follow-up reminders were sent at two weeks (email) and at four weeks (telephone call). The safe administration of systemic cancer treatment Expert Panel reviewed the results of the survey.

Professional Consultation: Feedback was obtained through a brief online survey of healthcare professionals who are the intended users of the guideline. All oncology nurses, pharmacists and medical oncologists from Ontario, Quebec, Alberta and British Columbia in the PEBC database were contacted by email to inform them of the survey. Participants were asked to rate the overall quality of the guideline (Section 1) and whether they would use and/or recommend it. Written comments were invited. Participants were contacted by email and directed to the survey website where they were provided with access to the survey, the guideline recommendations (Section 1) and the evidentiary base (Section 2). The notification email was sent on April 12, 2012. The consultation period ended on May 23, 2012. The safe administration of systemic cancer treatment Expert Panel reviewed the results of the survey.

Results

Targeted Peer Review: Three responses were received from four reviewers. Key results of the feedback survey are summarized in Table 2.

		Reviewer Ratings (N=3*)					
Question	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)		
1. Rate the guideline development methods.				3			
2. Rate the guideline presentation.			1	1	1		
3. Rate the guideline recommendations.				3			
4. Rate the completeness of reporting.				3			
5. Does this document provide sufficient information to inform your decisions? If not, what areas are missing?			1	1	1		
6. What are the barriers and enables to the implementation of this guideline report?	Skipp	Skipped (see comments below)			low)		

Table 2. Responses to nine items on the targeted peer reviewer questionnaire.

		Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
7. I	Rate the overall quality of the guideline report				3	
8.	I would make use of this guideline in my professional decisions.			1	2	
9.	I would recommend this guideline for use in practice.			1	1	1

*One of the four reviewers who accepted to review this guideline did not complete the questionnaire.

Summary of Written Comments The main points contained in the written comments were:

Ine	he main points contained in the written comments were:						
	Comment	Response/Modification					
1.	Reviewer a. Although I noted previous reviewers comments had been addressed, I still find that the guideline doesn't flow well and is difficult to read. Reviewer b. Yes, no significant concerns. Excellent attention to feedback from review approval panel to working group response.	This is a complex topic that is difficult to present in a more simplified way.					
2.	Many patients are on alternative therapies that are not necessarily considered drugs. This needs to be addressed. Suggest that alternative therapy and dietary status must be recorded and patients counseled on use with chemotherapy as with drug-drug interactions (e.g., use of megavitamins, grapefruit juice, other examples?). This leads to an omission in one of the guidelines regarding the responsibilities of patients/substitute decision makers. Suggest adding as follows "Healthcare providers need to be open, receptive, and responsive to patient questions. Patients and substitute decision makers need to provide healthcare providers with complete information regarding current medication, alternative therapy use."	The recommendation has been modified to reflect that patient assessment is the responsibility of the entire clinical team and that current medications, including alternative therapies, should be included in this assessment. In Appendix 1, the drug-to-drug and drug- disease interactions has also been changed to: e.g., Chemotherapy ordered does not interfere or interact with the patient's underlying co-morbidities, chemotherapy concurrent medications, non prescription medications and alternative therapies.					
3.	Scheduling not mentioned as a patient error process. I'm not sure that chemo prep checks should be as "frequent as possible." Too many does not add value. Need distinction between types of checks for pharmacist and technician.	The specific recommendation, Section 1, page 9, has been changed to: "Independent double checking during the chemotherapy preparation process is ideally made by a second pharmacist or, depending on physical and staffing resources, by a pharmacy technician (Tech-Check-Tech procedure where one technician checks the order-filling accuracy of another), or by another					

		healthcare professional with appropriate knowledge, skills and training to perform this function."
4.	Did not mention medication reconciliation process.	This issue has been dealt with the response to comment #2 above. Institutions should conform to the requirements of Accreditation Canada for medication reconciliation in their policies and procedures, and this is out of scope for this document.
5.	More specific pump info/recommendations. Perhaps web tutorial re: different pumps/ risks/	This guideline is at a provincial level: tutorials with information about different kind of pumps are out of scope. They would be better placed in individual institutions' policies and procedure manuals.
6.	Major enabler is interest of all in minimizing toxicity of treatment and interest of all to provide care closer to home based on a consensus regarding how we administer chemotherapy safely.	No change required.
	An important enabler is providing flexibility as to how each region implements.	
7.	Only deals with specific components of ordering. Dispensing patient ID. Sometimes difficult to enact changes in isolation of whole process. Good highlight of those key components.	Future documents will deal with following processes.
8.	Enablers: CCO / PEBC document to reference consolidated evidence; proactive.	No changes required.
9.	 Implementation of new guidelines should be done in a consistent manner for regional programs so as to avoid confusion and mistakes associated with multiple standards of care in the region. Because much of the guideline is based on expert opinion, rather than evidence, it will be critical to prospectively monitor the impact once implemented 	No changes required.

Professional Consultation: Thirty-eight responses were received. Key results of the feedback survey are summarized in Table 3.

			Number 36 (%)					
	General Questions: Overall Guideline Assessment	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)		
1.	Rate the overall quality of the guideline report.	0	0	2 (5)	23 (64)	11 (31)		
		Strongly Disagree (1)	(2)	(3)	(4)	Strongly Agree (5)		
2.	I would make use of this guideline in my professional decisions.	1 (3)	0	4 (11)	16 (44)	15 (42)		
3.	I would recommend this guideline for use in practice.	0	0	5 (14)	15 (42)	16 (44)		

Table 3. Responses to four items on the professional consultation survey.

4. What are the barriers or enablers to the implementation of this guideline report?

- 1. Developing space for quiet medication checking area with access to computer (OPIS). Not working with same equipment across province.
- 2. Some data in the guideline is derived from non-oncology settings. General principles should still apply to oncology settings but these data may not capture some issues specific to oncology.
- 3. I agree with all the recommendations...a couple of other issues 1) the part about Handwritten orders are not acceptable....that would mean that if you get a rare or unusual case, we would not accept handwritten orders. Not sure how that would work practically. 2) The part about non-same day treatment should be stronger I think that having a pharmacy and pharmacy technician try to rush through so that patients don't wait too long causes unnecessary risk. We often get interruptions for same day chemo when nurses ask "where is Mr. Smith's chemo" and that is also a source of error. While not convenient, non-same day chemo is, in my opinion, far safer for the patient as the chemo can be prepared and double checked without rushing and I think the guideline should point out that non-same day is a safer schedule. 3) They don't say anything about having all sorts of chemo every day instead of "breast day" or whatever. This is another source of risk for wrong drug manufacturing for pharmacy as we need to prepare all types of different chemo regimens and many of them are similar. 4) There is no mention about IV robots in the preparation of chemotherapy. 5) I think the use of Independent double check is used loosely. When you are preparing chemo, it is practically as the technician is under a hood, so you can verify, but cannot do an independent double check. 6) In preparation of chemo, there should be mention of direct observation of chemo preparation, as opposed to a syringe draw back method 7). Under recommendation B: Patient Assessment - reference should be made to the specialized oncology nurse when stating "assessment for chemotherapy administration" and referred to CANO standards and oncology nursing documentation standards 8) Tools for Patient Screening and Assessment there is no mention of psychosocial assessment within the chart for dimensions to be assessed and screening tools use eg. Canadian Problem Checklist, ESAS with source from CAPO; also as a source for Fatigue assessment include CPAC/CAPO fatigue guidelines in the chart.
- 4. Not all sites have a formal signed consent. I find infusion pump content a little confusing and interrupts flow of document. (Table 2).

- 5. The main barrier is that this can require an institution to have more staffing, can slow down processes. Enabler is the need to adhere to safety standards/best practices for malpractice protection. These recommendations are very reasonable.
- 6. Barriers: cost (OPIS implementation, pumps etc). Time (EDAS for every patient). Enabler: links with example (written plan) and other resources.
- 7. No barriers. Need to develop written forms for patients. Forms to be checked by doctor, pharmacist and chemo nurse.
- 8. To ensure safe administration of chemotherapy I would imagine that many centres would require both physical and staffing resources to be optimized to prevent the "workaround" scenario.
- 9. Well organized and gives a framework to work on safety issues. The lack of strength of the recommendation may be a barrier eg for non same day chemo. That could be an important element in implementing all of the other solutions eg checklists, distraction free environment, ensuring proper patient education.
- 10. Guideline should enable/justify the cost and time necessary for implementation. Well done.
- 11. It is a little vague. For example, a written treatment plan is recommended to be available. What is this? This sounds like the physician's notes to me. If it isn't, is additional work justified? Also, the same day vs. non-same day chemotherapy says--to be frank--absolutely nothing. Why include it? Given the absence of data, it is important to minimize fluff.
- 12. The physical and staffing resources allowing the completion of tasks in an environment free from distractions and interruptions would be a big barrier at our facility as we are already a bare staffing. We are going to a paperless system and I am unsure at this time if a treatment plan including surgery, radiation and systemic treatments can be easily documented.
- 13. This is a very simple guideline to implement. Common sense really to protect the person receiving chemo. I like the structure. The only reason I scored low on quality is because there is little evidence on which it is based.
- 14. Small satellite units are limited in what they can do by the larger centre, ie., treatment plan. This need to be available. Can often access info on OPIS but if oncologist has not dictated notes not on OPIS then satellite nurses and pharmacy have no idea what the plan is.
- 15. Computerised order entry is a great thing but requires financial support of institution.
- 16. Lack or recent data.
- 17. The barriers to implementation of this guideline is to have the resources (personnel, workspace, computers). Some of the guidelines have been implemented here and others we have found very difficult to implement because of the resource issues. I believe we need to do more networking to help places implement guidelines like these because we are all at different places in implementation and valuable lessons can be learned and shared as we all move forward.
- 18. a) Complexity b) Funding (e.g.non interference, double checking is expensive) c) Ultimate efficacy (e.g. the process of confidentiality now largely works against the patient it was supposed to protect).
- 19. Support from hospital administration, especially in rural areas. Assess and education for nursing staff regarding patient screening tools.
- 20. I think this is a great high-level guideline to help oncology practitioners establish baseline practice standards. The implementation might be limited by availability of resources in oncology institutions to provide training for staff in this regard. I am fortunate enough to

work in a large enough institution to have resources available to establish such practice standards. In my day to day practice I see many issues that we could potentially work on to help improve oncology patient care. Perhaps this can be included in future guidelines.

- 21. Barriers 'most of the recommendations are based on expert opinion' Enablers This guideline has pointed out that processes used in the administration of systemic therapy are not evidence based. This guideline has provided organizations with a 'framework' to review their processes. This guideline also has opened the door to research on safe administration.
- 22. a. Providing a suitable environment challenging most communal clinic areas are noisy and distracting b. every pt must have a wrist band even for outpatients? good idea but can it be implemented? c. section on clinical assessment confusing. implies that RN must do even if MD already done. Is that the intent? d. same day section also implies that is RN responsibility to review labs before CT. This is a difficult area in many centres as not always clear who is actually, and legally responsible and whether the responsibility has been formally assigned to someone else (rather than an assumption) e. NSD CT chemo suite staff like it but pts generally are resentful of it in my experience.
- 23. At my facility (PMH), not all orders are CPOE; many still hand written.
- 24. Currently computer studies (systemic and radiation) are not linked or attached to electronic patient record hence it is very difficult to develop a single copy of a treatment plan.
- 25. a. Centres where hand-written orders are still acceptable in the absence of CPOE or preprinted forms (i.e. at McGill where work). b. A lack of sensitization of all staff (health care and administrative) to the urgent need for this approach to be respected and followed to avoid error.
- 26. a. Implementation of equipment i.e., computer upgrades, infusion pump (with bar-coding) etc, very cost prohibitive. b. Staff upgrading or continuing education also must be included in being able to safely administer cancer therapy. c. Guidelines for chemotherapy administration in community hospital settings... do we have a standard" or EBS guidelines? d. Thank you for a great draft.
- 27. The guidelines cover a number of areas with respect to chemotherapy administration and it is unlikely that all centres would have resources to address them all. It would probably require province wide work to develop appropriate patient information sheets, etc.
- 28. It is very long and a bit unruly. There is lots of 'methodology' and 'analysis of evidence' mixed in with the actual recommendations. There is also a lot of stuff that is simply common sense with little obvious need for evidence (eg. minimize distractions). There is also very little here of practical value to physicians other than recommending that they use electronic order entry. There are no doubt errors that occur at the physician end of things that could perhaps be avoided. eg. 1) Patients should be evaluated by a physician before each cycle of chemotherapy 2) Chemotherapy should not be ordered until a few days before it is to be given so that all side effects of previous chemotherapy cycle and tumour status (by history, p/e or tests) can be evaluated so that appropriate dose modification or changes to chemo regimen can be made.

Summary of Written Comments

The main points contained in the written comments were:

- 1. Funding required for education visuals available for chemo IV line set-ups. Update NCI toxicity to Version 4 or most current version. Still need to upgrade infusion pumps/increase education for home infusor equipment.
- 2. A definition of CPOE would be helpful. There are many institutions that still require a step to transcribe from the ordering computer system to the pharmacy module for

dispensing. Have we addressed minimizing this error? Do the checks in the system account for that?

- 3. The medical literature may be sparse on these topics, but I wonder about a broader, more creative survey. For example, there may be aerospace systems literature or such which might be applicable in principle.
- 4. Help is needed to develop "environment that is free from distractions and interuptions" Must be realistic. Small unit, talkative patients, phones ringing, pumps beeping -- it is the reality.
- 5. I felt there should be some basic guidelines about communication between the base hospital and satellite hospital sites. E.g., new patients starting at a satellite site at times, the advance notice is too short.
- 6. What about the 'human factor' (Alec Guiness)? Automation or not: no system is foolproof against the human mind. Selection, qualification, training, pay of staff?
- 7. Excellent job keep up the good work and make sure guidelines are distributed and get to nursing staff who should be using them -- once again in small rural hospitals!
- 8. Thank you to the Working Group for pulling this guideline together! Just a few editorial comments, my apologies if these are not appropriate to this section. Recommendations pg 4 Part 1 - Planning - the acronym CPOE, I feel, should be included in abbreviations along with Pt Part 4 - Chemo at home (the term chemotherapy is mainly used throughout the document.) Parenteral ad ministration of chemo - spacing change AVOIDING WORKAROUNDS - When I went to the hyperlink of this, there was no reference to 'avoiding workarounds'. Recommendations - page 5 This process should included the use of at least two...., and specifics about the methods for the proper identification of patients with language.... This is a very long sentence. The last points in the sentence relating to language and special needs get lost but are very important considerations. I might suggest a separate sentence for this. Recommendations - page 8 See Appendix 1. For oxaliplatin related sensory motor neuropathy the use of the tool in use for oxaliplatin (6). This sentence, I feel, needs rewording as it does not make sense to me. Recommendations - page 11 Most of the guidelines identified during the environmental scan for Part 1 were not evidence based but that evidence base was rarely randomized controlled trials. This sentence is unclear to me. Evidentiary base - page 20 Past chemotherapy and supportive medication history e.g., response to supportive medications with past chemotherapy can guide the need or use of supportive medications for current chemotherapy For all the other e.g., the first word after the comma is capitalized except this one. Evidentiary base - page 21 For multiple-day regimens: a container delivered to the chemo {chemotherapy} suite should only have that specific day dose issued at one time. This sentence could be written more clearly. Evidentiary base - page 2 Table 2A.ii. Distractions and interruption: results table. Column 2 Intervention on - wording needs to be respaced? Evidentiary base - page 16 Informed consent - the list of excluded guidelines appears on the next page. Just wondering if they could be grouped/spaced with the title 'informed consent'.
- 9. On page 10, not sure how a smart pump can prevent wrong route, wrong time or wrong documentation, but could be incorrect. I understand you required a bar code link to prevent the types of errors.

CONFLICT OF INTEREST

In accordance with the PEBC Conflict of Interest (COI) Policy, the guideline authors, members of the Nursing and Systemic Treatment Program, and internal and external reviewers were asked to disclose potential conflicts of interest.

Among the members of the working group, Dr. Simron Sing declared having received research support and o=honoraria from Novartis; Dr. Vishal Kukreti declared having received a grant for research on bar-coding for the safe administration of chemotherapy from the National Cancer Institute of Canada. All the other members of the working group declared no conflict of interest.

Among members of the Expert Panel, Venetia Bourrier declared to have received educational grants exceeding CAD5,000 from pharmaceutical industry for the pharmacy department, to have received research support (co-investigator) for a study on improving the safety of ambulatory IV chemotherapy in Canada by CPSI and Cancer Services , and to be cancer care Manitoba director of the provincial oncology drug program.

None of the members of the Report Approval Panel, and of the PEBC declared a conflict of interest.

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Section 3: EBS Development Methods & External Review Process