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Evidence-Based Series #12-12-1

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

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 December 2017 deferred the review of Evidence-based Series (EBS) 12-12-1. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

This Evidence-Based Series (EBS) consists of 3 sections:

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

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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.

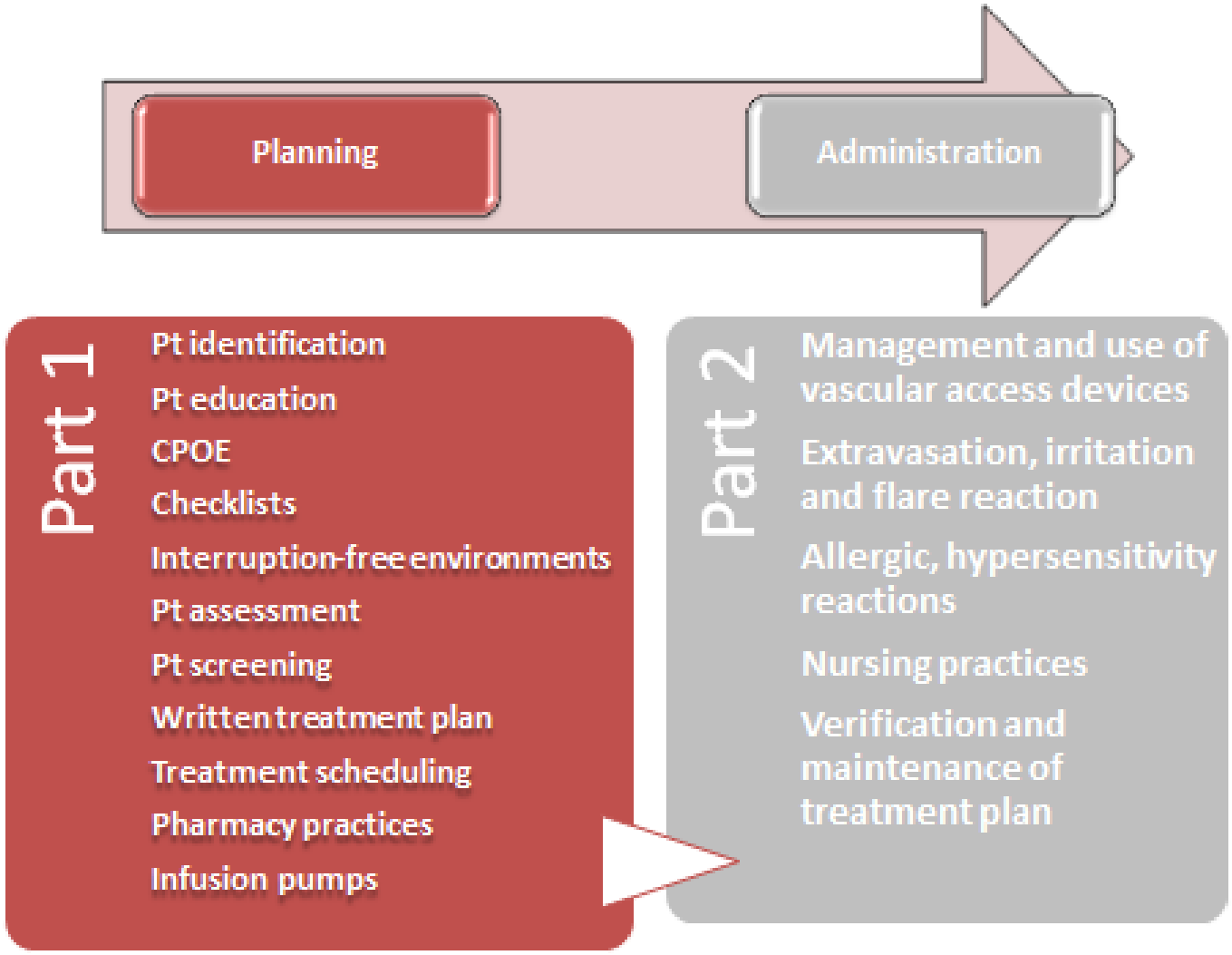
The Working Group values patient-centered care and believes that empowered patients can help in the delivery of safer care. The Working Group also values giving freedom to individual institutions to implement recommendations in a manner that is best suited for their specific contexts. Therefore, the 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 COMPENDIUM 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 wrong-patient error may occur at the ordering, transcribing, dispensing, and administrating steps of the medication administration process (3). Appendix 1 contains examples of procedures for AVOIDING WORKAROUNDS 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 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 (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 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 CHECKLIST 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 PATIENT ASSESSMENT 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.

Table 1. Screening 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

Dimension to be assessed	Tool	Web link to resources
		Cancer-related Pain Management Guideline (available at http://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=44127)
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 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: 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):**
  http://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=50191
  - **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):**
  http://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=14282
  - **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 VERIFYING A CHEMOTHERAPY ORDER, and of a method for organizing chemotherapy PACKAGING AND DELIVERY.

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.

Table 2. Safety characteristics of infusion pumps.

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

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.
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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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