Cancer Care Ontario
Action Cancer Ontario

Computerized Prescriber Order Entry (CPOE) for Systemic Treatment: Best Practice Guideline

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Guideline Authors

Vishal Kukreti MD
eTools and Technology, Clinical Lead
Cancer Care Ontario

Sara Lankshear
Manager, Knowledge Transfer and Exchange
Cancer Care Ontario

Annie Cheung
Formulary Pharmacist, Clinical Programs
Cancer Care Ontario

Roxanne Cosby
Research Coordinator
Program in Evidence Based Care
McMaster University

Marc Theriault
Methodologist, Informatics
Cancer Care Ontario

Cecelia Marie Hamasoor
Client Advocate
Cancer Care Ontario

Sinthujah Sivasambu
Project Coordinator
Cancer Care Ontario

For further information about this guideline, please contact:
Dr. Vishal Kukreti, Cancer Care Ontario
620 University Avenue, Toronto, ON, M5G 2L7
Phone: 416-971-9800 Fax: 416-971-9688 E-mail: vishal.kukreti@cancercare.on.ca

Expert panel members

CCO wishes to acknowledge the following for their contribution in the development of the Computerized Prescriber Order Entry (CPOE) for Systemic Treatment: Best Practice Guideline, review of the document and providing valuable feedback.

Supporting Tools Expert Panel
(Information and Technology Standards)

Carl Lemp
Privacy and Security Architect
eHealth Ontario

Garry Cruickshank
Pharmacist
eHealth Ontario

Maricel Teodoro
Medication Management Program
eHealth Ontario

Monique Pitre
Manager, Pharmacy Clinical Informatics
University Health Network

Philomena Sousa
Process Specialist, Odette Cancer Centre
Sunnybrook Health Science Centre

Rachel White
Human Factors Specialist
University Health Network

Rhonda Stewart
Information Systems Coordinator
Thunder bay Regional Health Sciences Centre

Sean Hopkins
Pharmacist
The Ottawa Hospital

Clinical Practice Expert Panel

Darrilyn Lessels
Clinical Education Leader – Oncology
Durham Regional Cancer Centre

Diane S. Incekol
Advanced Practice Nurse Educator – Systemic Therapy
Princess Margaret Hospital

Dr. Gregory J Knight
Grand River Regional Cancer Centre

Dr. Jonathan Noble
Systemic Lead
Northeast Cancer Centre

Jennifer Daley-Morris
Pharmacy Coordinator, Oncology
Southlake Regional Cancer Center

Rachel White
Human Factors Specialist
University Health Network

Sherrie Hertz
Manager, Clinical Programs
Cancer Care Ontario

Cancer Care Ontario Supporting Tools Subject Matter Experts Group

Lyndee Yeung
Clinical Program Manager
Cancer Care Ontario

Lalin Perera
Sr. Technical Architect
Cancer Care Ontario

Jenny Gangadeen
OPIS Product Manager
Cancer Care Ontario

Ann Marie Legaspi
Senior Analyst, Informatics
Cancer Care Ontario

Rob Spalding
Development Team Lead
Cancer Care Ontario

Vikki Catahan
Senior Programmer Analyst
Cancer Care Ontario

External reviewers

CCO wishes to acknowledge the following for their contribution in reviewing the Computerized Prescriber Order Entry (CPOE) for Systemic Treatment: Best Practice Guideline and providing valuable feedback.

Avril Kwiatkowski
Staging & Pathology Specialist
Canadian Partnership Against Cancer

Barbara A. Rudolph
Senior Science Director
The Leapfrog Group, Washington, DC.

Denis J. Protti
Professor Emeritus
University of Victoria

Jennifer Zelmer
Senior Vice President, Clinical Adoption and Innovation
Canada Health Infoway

Dr. Tony Easty
Senior Scientist, Centre for Global eHealth Innovation
University Health Network

Flay Charbonneau
Manager, Pharmacy, Odette Cancer Centre
Sunnybrook Health Sciences Centre

Janice Stewart
Patient Safety Expert
University Health Network

Laura Wilcock
Pharmacist
Lakeridge Health

Sharon Meeke
Pharmacist, Juravinksi Cancer Centre
Hamilton Health Science Centre

Nancy Ross
Registered Nurse – Chemotherapy, Juravinski Cancer Centre
Hamilton Health Sciences

Dr. J. Matt Austin
Armstrong Institute for Patient Safety and Quality
Johns Hopkins University

Karen Levac
Oncology Outpatient Pharmacy
London Health Sciences Centre

Dr. Lynn M. Nagle
Assistant Professor, Faculty of Nursing
University of Toronto

Mark Berry
Interim Vice President Cancer and Pharmacy Services
Interim Regional Vice President, Cancer Care Ontario
Grand River Hospital

Niphaphone Nancy Omdara
Pharmacist
Princess Margaret Cancer Centre

Dr. Philip Kuruvilla
Brampton Civic Hospital

Roger Cheng
Project Leader
Institute for Safe Medication Practices Canada (ISMP Canada

Kathy Fraser
Manager, Information Technology
Lakeridge Health

Jeanette Van Norden
Clinical Leader, Chemotherapy, Juravinski Cancer Centre
Hamilton Health Sciences Centre

Dr. Callista Phillips
Medical Oncologist
Joseph Brant Memorial Hospital

EXECUTIVE SUMMARY

The Computerized Prescriber Order Entry for Systemic Treatment (ST CPOE): Best Practice Guideline provides guidance on the key features, functionalities and components of a ST CPOE system which are required to ensure safe, high quality systemic chemotherapy treatment.

This guideline incorporates the synthesis of the available evidence and information gathered from literature reviews, environment scans, established industry guidelines and key informant interviews with cancer centres known for their expertise with ST CPOE systems.

The recommendations included in the guideline were identified by including factors such as the extent to which the information was present in the peer reviewed and/or grey literature, the strength of the available evidence, clinical and/or technological relevance, and the opinion of the Expert Panel members. In addition to the review by the Expert Panels, the complete guideline was reviewed externally by known subject matter experts as well as targeted end users of the guideline.

The purpose of this guideline is to provide evidence-based recommendations that can be used to guide the design, selection, implementation and/or evaluation of an ST CPOE system. This guideline can be used by clinicians (e.g. physicians, pharmacists and nurses) to determine optimal safe clinical practice and efficient process flow.

This guideline can also be used by those in clinical informatics, health technology and decision support areas as they determine the necessary system features and functionalities to support the safe delivery of chemotherapy.

The recommendations here are based on the best available evidence, and should be applied with the unique needs of the organization, patient population clinicians, practice patterns and workflow processes in mind. The degree of customization of ST CPOE features and functionalities required to meet the unique needs at the point of care should be considered in light of the evidence reflected in the guideline.

Recommendations to support Clinical Practice and Information & Technology Practice

<u>Clinical Practice Recommendations</u>

CPOE with Clinical Decision Support (CDS) is a promising technology that can contribute to the reduction of medication errors and potential adverse drug events associated with those medication errors. Based on the review of the literature included in this guideline, the following conclusions are identified:

1. CPOE systems should be used in the outpatient chemotherapy delivery setting to decrease chemotherapy related medication errors. Although the focus of this evidence summary was outpatient CPOE, it is likely that many of the principles in this document would also apply to inpatient CPOE.

2. Health information technologies such as CPOE systems can directly impact clinician workflow practices, therefore a comprehensive, multi-faceted change management approach is required in order to effectively implement and sustain the practice and process

changes associated with the introduction of CPOE. Strategies include the use of local opinion leaders with input into decision-making (e.g. clinical, technical, and leadership champions), educational supports and timely quality monitoring through audit/feedback loops.

3. A multidisciplinary team approach in the design, selection, workflow evaluation, implementation and/or evaluation, and ongoing monitoring of the CPOE system should be used.

4. Ensure that CPOE processes complement current practice and work-flow processes to enhance adoption by clinicians.

5. Carefully design CPOE systems, clinical decision supports, and associated interface design elements to reduce the potential for error.

6. The development and implementation of a risk-assessment process to identify actual/potential unanticipated consequences and new errors generated, as well as the development of strategies to modify the system accordingly, are warranted.

Information and Technology Recommendations

To enable optimal utilization of the recommendations in considering the design and implementation of an ST CPOE, the recommendations have been categorized according to the following criteria: Essential (E) or Desired (D). *Essential* recommendations must be included in the design/implementation of the CPOE system in order to achieve desired quality, patient safety and user satisfaction. *Desired* recommendations are those that not absolutely necessary for success, but inclusion would increase the likelihood of success and/or achieving significant gains in quality and patient safety.

Additionally, the recommendations have also been categorized according project phases where they would be most useful (e.g. system selection/design and implementation). This will enable users to apply the recommendations in a more systematic and purposeful manner whether in the Pre-implementation phase (e.g. early design/selection phase, generation of elements for inclusion in vendor RFP), implementation phase (e.g. building or enabling components to meet user needs) or post-implementation (e.g. considering upgrades and enhancements).

PRE-IMPLEMENTATION PHASE

System feature, functionality or component(s)	Recommendation	Priority Level
USABILITY	Incorporate a human-centred approach in the design, implementation and evaluation of CPOE systems	E
	Involve key stakeholders and end users in system design (e.g. physicians, pharmacists, nurses, information technology professionals, decision support, clinical informatics)	E
	Develop an evaluation strategy in the design, implementation and post-implementation phases	E

System feature, functionality or component(s)	Recommendation	Priority Level
	Determine indicators for ongoing quality monitoring re: usability	E
	Ensure important information "stands out" from surrounding information (e.g. bolded, highlighted, larger font); with all relevant information within one screenshot	E
	The terminology should be consistent with organizational and professional descriptions The process flow should closely reflect current clinical / best practices	E
	All required information is presented in a logical sequence, without requiring the user to "recall" information (e.g. previous screens) or process (e.g. where is…?)	E
	Minimize the number of steps or mouse clicks required to complete the task (e.g. use of auto-tabbing, default values, organization of information)	E
	Include feedback features to the user about the steps they are about to take and/or that actions have had the desired effect (e.g. warning message before deleting or changing information)	D
	Appropriate density: Avoid displaying too much information on a single screen, organize data at the summary level before drilling down to more details; control density through font size, character count and screen resolution Meaningful use of colour: Colour should be used to convey meaning to the user in a consistent way throughout (e.g. red = warning/alert; yellow = highlight important information; green = proceed, normal) Readability: The ability to find and scan information quickly; use of font (e.g. no less than 12 point, sans serif font); high contrast between background and text (e.g. black on white)	D
	Keep screen changes and visual interruptions to a minimum during the completion of the task Ensure pop-up boxes does not obscure vital information Changes made are immediately available for viewing by the user without having to refresh screens	E
FUNCTIONALITY	System Access and Permissions The system must be able to control access to personal health information to comply with information safety and security legislation – including the use of electronic signatures and secure passwords). A secondary level of assigning access permissions by role or individual is required that is consistent with organizational policy and/or professional scope of practice	E E D

System feature, functionality or component(s)	Recommendation	Priority Level
	Consideration should be given to congruent functionality factors to leverage provincial access mechanisms (e.g. One ID)	
	Regimen Templates The system must support the development and use of regimen templates including ability to link to specific diagnosis group or clinical trial Functionality must include the ability to monitor patient entrance/exit screening processes; set minimum and maximum dose levels, dose ceilings and rounding values	E E
	Order Template The system must contain data fields to capture information as outlined in professional and jurisdictional standards (e.g. ASCO/ONS complete order standards and CCO Databook systemic treatment file)	E
	Medication Management The system must contain functionality to support the medication ordering, verification, dispensing and administration process. This includes drug eligibility, performance status capture, and independent double check, co-signature and administration checklists	E
	System Integration The system must have the ability to integrate with the EHR, barcoding for medication administration and decision support modules. The drug database must support Canadian requirements for drug identification	D
	Information Display and Alerts The system must display version and subversion numbers for any system embedded information (TMN pathology diagnosis, staging) The information display should be clear and organized to prevent the clinician from making juxtaposition errors (tall man lettering) Ability to set alert sensitivities and clinician review of order alerts	D E E
	Reporting Capability Reporting tools must enable end users to query relevant tables and data elements Systems should have some prebuilt reports available. There should be flexibility in writing simple queries to constructing complex reports and the system should allow multiple tools or report writers (e.g. Excel, Crystal Reports, ETL tools) to extract data The system must have reports for auditing and monitoring	D E E D

System feature, functionality or component(s)	Recommendation	Priority Level
	functionality such as interfaces or alert generation or printing log files Report templates to be designed for interoperability (e.g. HL7)	
SYSTEM INTEGRATION	Client Registry Standards Allows the patient to be uniquely identified across the continuum of care. The patient identifier must be unique (only one in the system), exclusive (only used for this patient) and eternal (never reused)	E
	Provider Registry Standards Allows the unique identification for the healthcare service provider. Demographic information includes name, role, gender, regulatory college license number and the locations the provider delivers their service	E
	Laboratory Standards Allows access, management and storage of patient laboratory orders and results through a jurisdictional laboratory information system	E
	Drug Standards Provides clinicians with an improved ability to manage complete medication profiles through a jurisdictional drug information system	E
	Interoperable EHR Standards Allow sharing of relevant clinical information through a jurisdictional shared health information repository to support timely clinical decision-making and continuity of care	D
	Order details from the CPOE system should flow automatically into the pharmacy system. Medications ordered on the CPOE system would match to products listed in the pharmacy system (Chaffee et al, 2004, New England Healthcare, 2006)	E
	Synchronization When an update of information is made in one system then the corresponding table in the second system is automatically updated (e.g. when the admission–discharge–transfer (ADT) system updates its "patient beds" table, an HL7 message is transmitted to the CPOE system to initiate an immediate update)	D
	Medication data building and maintenance The CPOE system must provide a clear method for building, maintaining, and implementing the parent/child relationship for medication data	E
	Reduction of redundant work User-centred interfaces with automated systems need to be	E

System feature, functionality or component(s)	Recommendation	Priority Level
	carefully planned to reduce the need for redundant work	
	CPOE systems should enable electronic prescribing	E
E = Essential; must be included in CPOE application D = Desirable; not as critical for initial implementation, but will be required in the future		

IMPLEMENTATION PHASE

System feature, functionality or component(s)	Recommendation	Priority Level
USEFUL ALERTS AND PREVENTION OF ALERT FATIGUE	Software must have appropriate computer display and screen sizing so the alerts are displayed properly	E
	Alerts need to fit into the appropriate workflow process at the right time – too early or late will require extra time for the clinician to rectify and add to the burden of work	E
	Complete, accurate and current information makes the launching of alerts highly specific and sensitive	E
	Test drug to drug interactions for high sensitivity and determine if medication interactions will alert with clinical significance	E
	Categorize alerts into groups and assign action to the alert based on severity and risk: **Trivial:** No clinical significance; no real time alert required; included on batch reports sent to the ordering clinician and auditing system at predetermined time intervals (e.g. daily, weekly) **Minor**: Alerts can be over-ridden by the prescriber **Moderately serious**: Alerts can be over-ridden by prescriber but reason must be given **Serious:** No ability to override the alert, unable to proceed in order process, and change in the order should be made	E
	Collaboration must occur with key stakeholders such as informatics experts, clinical application specialists and clinicians, who are the end user of these alerts in the safe design, testing and use of the alerts	E
BUILDING OF PROTOCOLS AND REGIMENS	Pre-loaded starter set of modifiable regimen templates assist in the building of a final version by the user	E
	Capability to customize rules for decision support tools and specific warnings (e.g. lab parameters displayed to trigger decision support)	E
	Dose calculation built into ordering system (e.g. pre-built dosing formulas, dose checking, optimal dosing logic and dose	E

System feature, functionality or component(s)	Recommendation	Priority Level
	rounding)	
	Capturing proper sequencing of treatment (e.g. multi-modality therapy, linked order, sequencing of regimens within a treatment plan or medications within an order)	E
	Documentation section should follow guidelines from relevant health professional organizations and/or regulatory bodies (e.g. ASCO/ONS practice guidelines)	E
	Allow screens for the entry of changes in chemotherapy treatment including reasons for modification which can be accessed by relevant system users	E
	Order locking mechanism post order verification	E
	Ability to incorporate logic for determining cycle scheduling and treatment duration (days between cycles and total number of cycles)	E
	Flexibility to allow for therapeutic options during regimen builds (e.g. different routes of administration, selection of anti-emetic agents within a drug class)	D
	Ability to incorporate text instructions or recommendations within order sets (e.g. items that do not fit typical categories or templates such as dietary or fluid restrictions)	D
	Enable direct linkage to the Medication Administration Record (MAR)	E
PRIVACY	The purposes of data collection and interoperabilities with other systems must be identified with clear rationales provided	E
	Development of framework and criteria that describes the desired set of controls and best privacy practices that the organization is required to have in place	E
	Development of a risk assessment and a privacy impact/breach assessment process for internal monitoring and evaluation	E
E = Essential; must be included in CPOE application D = Desirable; not as critical for initial implementation, but will be required in the future		

POST IMPLEMENTATION PHASE

System feature, functionality or component(s)	Recommendation	Priority Level
AUDIT LOGS AND MONITORING OF WORKAROUNDS	Audit trails to include the following information: date and time recorded for each entry, any change in recorded information, and the original content of the recorded information that was changed or updated	E
	Capable of being printed separately from the recorded information	E
	Ensure logging is turned on in the software application	E
	Record the percent of alerts that fire and number of alerts ignored or overridden	E
	Regular review and analysis of log data should be done to identify system performance, trends and identify issues early so they can be addressed	E
	Aggregate log information to provide meaningful information	E
	Apply appropriate permissions for access to audit log information and reports	E
	Monitor the technology in the clinical setting for impacts and barriers to performance including human factors and ergonomics prior to and after implementation	E

OVERVIEW OF THE DOCUMENT

The Computerized Prescriber Order Entry for Systemic Treatment (ST CPOE): Best Practice Guideline provides guidance on the key features, functionalities and components of a ST CPOE system which are required to ensure safe, high quality systemic chemotherapy treatment. The complete guideline is comprised of four distinct, yet interconnected chapters and reflects a synthesis of the available literature within the clinical and health information technology fields. The individual chapters can be used as stand-alone resources or in conjunction with the information contained throughout the guideline. The chapters are:

1. Clinical Best Practices: Program in Evidence-Based Care (PEBC) Evidence Summary: Synthesis of the literature describing the clinical best practices supporting clinical decision-making pertaining to appropriate and safe systemic treatment.
2. Information and Technology Standards: Information standards for collecting, harmonizing and integrating data from cancer sites to support clinical and business requirements for sharing information with the Ministry of Health and Long-Term Care (MOHLTC) and other key partners and stakeholders. Technology standards provide guidance regarding the desired interface between ST CPOE systems and other information systems (e.g. patient information, pharmacy, reporting).
3. Indicators and Measurement plan: Description of the measurement plan, including the identification of indicators for monitoring the impact and outcomes of ST CPOE systems. In addition to clinical indicators, a series of recommendations regarding optimal system features, functionalities and components can be used to determine the degree of system/software concordance with the recommendations included in this guideline.
4. Conclusions: Synthesis of the key findings and recommendations from the three previous chapters, along with considerations for practice, policy, research and future innovations.

INTRODUCTION

The Systemic Treatment Program at Cancer Care Ontario (CCO) aims to improve equitable access to high quality cancer care across Ontario by setting standards and guidelines for all systemic cancer patients. The program works with oncologists and other oncology professionals to ensure optimal patient safety is achieved by incorporating best practices, clinical guidelines and new research into practice and system designs.

New cancer drugs and new combinations of drugs, coupled with the growing number of cancer patients referred for treatment, are boosting demand for chemotherapy in Ontario. To optimize the safe delivery of chemotherapy, computerized prescriber order entry (CPOE) has been increasingly adopted within the healthcare industry. CPOE refers to a variety of computer-based systems designed specifically for automating the medication ordering process (1). The literature varies in the phrase used to describe the "user" of the computerized order system, with examples including: physician, provider, practitioner and prescriber. For the purposes of this document *computerized prescriber order entry* will be used.

The implementation of ST CPOE systems within Ontario has grown by 23% since 2004 with 75.5% of all chemotherapy visits in 2010 being supported with some type of ST CPOE system (2). See Figure 1: Percentage of systemic treatment supported by CPOE in Ontario.

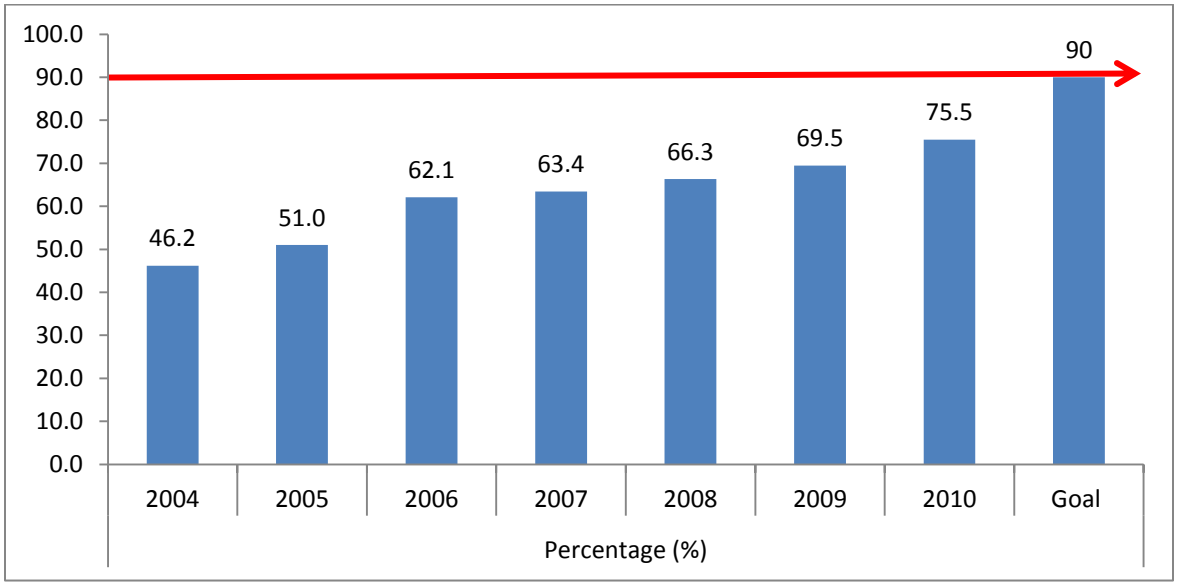


Figure 1: Percentage of systemic treatment supported by CPOE in Ontario

Chemotherapy drug ordering is one of the most complex processes in patient care, and can be improved through the use of ST CPOE systems. To support this growing need, CCO's clinically-driven Systemic Treatment Information Program (STIP) provides information management, information technology and eHealth solutions to improve the quality, safety and efficiency of systemic treatment across Ontario. The STIP vision for improved patient safety is to achieve the goal of 90% of all parenteral systemic treatment (outpatient) visits supported by ST CPOE across Ontario.

To support the safe delivery of chemotherapy, CCO developed the Oncology Patient Information System (OPIS), the most fully-automated, broadly-used, cancer-specific drug ordering system in Canada. The CPOE Program at CCO works to develop, maintain and implement the OPIS system at hospitals delivering chemotherapy across Ontario. The program has an excellent physician adoption rate and is in the process of expanding implementation to an additional 15 hospitals across Ontario. No other jurisdiction in Canada has successfully used electronic health record technologies to achieve this level of CPOE adoption.

Medication ordering software that provides point of care clinical decision support to prescribers and other healthcare providers can circumvent potentially dangerous medication errors (3). In 2007-2008, CCO conducted an extensive evaluation of ST CPOE vendors in the market to assess if there were viable alternative ST CPOE systems for oncology systemic treatment. During the evaluation of vendor systems, CCO identified a gap regarding the availability of guidelines for evaluating high quality ST CPOE solutions that follow clinical best practices, provide clinical decision support and patient safety functionality, and meet technology and information

standards. Furthermore, Ontario has specific requirements including CCO Data Book, New Drug Funding Program and CCO Drug Formulary standards that are designed to serve the quality and information needs for the Regional Cancer Programs and CCO.

Purpose

The purpose of the ST CPOE Best Practice Guidelines project is to develop a best practice guideline document that addresses multiple areas of oncology systemic treatment practice, including clinical best practice, patient safety issues, evaluation/use of ST CPOE solutions, and data collection and management for the purposes of quality assurance, planning, performance management and funding. These guidelines will provide direction in the following areas:

1. CPOE functionality, including decision support, for clinical best practice;
2. Information and technology standards and;
3. Measurement plan for determining guideline concordance and clinical outcomes.

The development of an evidence-informed best practice guideline document requires a systematic and structured process that is methodologically rigorous, incorporates the best evidence available and demonstrates successful implementation of the resulting guideline document. This document incorporates the available evidence and information gathered from literature reviews, environment scans, established industry guidelines and key informant interviews with cancer centres known for their expertise with ST CPOE systems.

Goal

The goal of this document is to develop evidence-based guidelines specific to ST CPOE systems within the outpatient/ambulatory setting. The guidelines will address clinical, information and technological best practices that would be used to guide the design and implementation of ST CPOE at the organizational and provincial levels, regardless of the specific software/systems used.

Intended Audience/Users of the Guideline

The purpose of this complete guideline is to provide evidence-based recommendations that can be used to guide the design, selection, implementation and/or evaluation of an ST CPOE system. This guideline can be used by clinicians (e.g. physicians, pharmacists and nurses) to determine optimal safe clinical practice and efficient process flow. It can also be used by those in clinical informatics, health technology and decision support areas as they determine the necessary system features and functionalities to support the safe delivery of chemotherapy.

Scope

While it is recognized that the potential for medication errors can occur at various points in the medication process (e.g. ordering, dispensing, labelling and administration), the scope of the ST CPOE Best Practice Guidelines is on the *order entry phase* of chemotherapy administration. This enables input from the various members of the interprofessional team (e.g. physicians, pharmacists and nurses) who are directly and indirectly involved in the provision of chemotherapy treatment, and provides recommendations designed to facilitate the detection of potential prescribing errors that may occur at each of the stages of the chemotherapy

administration process. Although the prescribing phase will be the main focus of this guideline, the outcomes can be used to reinforce the importance of designing, building and testing an "end-to-end" solution. In addition, as more than 90% of all chemotherapy is provided in the outpatient/ambulatory setting, the primary focus for ST CPOE implementation will be in the context of the *outpatient practice setting*. See Figure 2: Steps within chemotherapy medication process.

Figure 2: Steps within chemotherapy medication process

In recognition of the various stages involved in the medication process, the CCO Systemic Treatment Program evidence-based series has developed the *Patient Safety Issues: Key Components of Chemotherapy Labelling* (4) guidelines and is in the process of developing guidelines specific to chemotherapy medication administration. The individual and collective impacts of these guidelines will provide a wealth of information and clinical decision support to all clinicians involved in the various steps of the chemotherapy medication process with the information here having applications to both the inpatient and outpatient settings.

Computerized Prescriber Order Entry (CPOE): A brief overview of the evidence

CPOE systems have been consistently identified in the literature as an important mechanism with the potential to reduce prescribing errors and patient injury. An initial search revealed three systematic reviews regarding the effects of CPOE systems on areas such as medication errors, adverse drug events, cost, and guideline adherence and user satisfaction. Ammenwerth et al, (1) conducted a systematic review analyzing the effect of CPOE system implementations and concluded that 23 of the 25 studies demonstrated a reduction in the risk of medication errors and adverse drug events ranging from 13% – 99%.

Eslami, Abu-Hanna & deKeizer (5) conducted an evaluation of outpatient CPOE systems and reported that only 4 of the 30 studies included in the review focused on safety, with one study showing a decrease in the number of medication errors, and most studies demonstrating a positive impact on adherence to guidelines. This is consistent with the findings of a second review conducted by Eslami, deKeizer & Abu-Hanna (6) which showed medication errors were reduced with the implementation of CPOE. This review, of 67 studies, also demonstrated an increase in adherence to guidelines, increase in ordering time for physicians and a decrease in medication turnaround time.

Despite the growing number of published evaluation studies regarding the impacts of CPOE on a variety of outcomes, the limitations of the studies have also been cited in the literature. Wier, Staggers & Phansalkar (7) conducted a systematic review of the quality of the research on CPOE (46 studies) and determined that 30% of the studies had occurred in only four institutions. Other concerns included poorly described study design, instrumentation bias and the lack of blinded or

randomized processes. In addition to concerns regarding internal validity, the wide variation in how CPOE is defined challenges the ability to define and measure the construct in a consistent and meaningful manner. Ammenwerth et al (1) also identified the need for improvement in the quality of evaluation studies related to health information technology / informatics. As a result, the Statement on Reporting of Evaluation Studies in Health Informatics (STARE-HI) was developed as a guide for use in the planning of studies and description of results (8). STARE-HI covers areas such as how to describe the study context, methods, results, discussions and conclusions to increase validity and generalizability of research findings.

Principles of Safe Administration of Chemotherapy

Chemotherapy is an effective course of treatment in the fight against many cancers. The very nature of chemotherapy's toxic impact on cancer cells, also creates potential for harm and possibly death if the patient is not monitored well by members of the healthcare team involved in the various steps of the chemotherapy medication process. In a study of adverse drug events conducted by Leape (9), 39% of errors occurred in the physician order phase with drug dosing accounting for 28% of all errors. Specific to chemotherapy, Gandhi (10) revealed that the most common source of error was within the order phase and these were 48% more likely to be serious in nature as compared to non-chemotherapy medication errors.

Although the focus of this guideline is on best practices regarding CPOE for chemotherapy, it is vital to consider the roles of all professionals (e.g. physicians, pharmacists and nurses) who are involved in all stages from order entry to dispensing and administration. Each has a key role in the identification of actual or potential sources of error in the provision of chemotherapy that may result in harm to the patient.

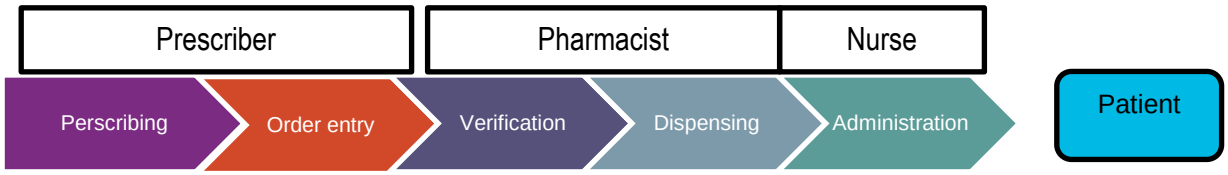
Due to the complexity of chemotherapy regimens and the potential for risk to patients, the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) developed interprofessional Chemotherapy Administration Safety Standards (11). Specific to the ordering of chemotherapy, the standards state that "the practice maintains and uses standardized, regimen-level, preprinted or electronic forms for chemotherapy prescription writing". The standard also describes the various elements to be included in a complete order such as: diagnosis, regimen name, route dosage, cumulative lifetime dosage and supportive care treatments (e.g. premedication, hydration). The Canadian Association of Nurses in Oncology (CANO) identified the quality practice environment for the safe administration of chemotherapy to include organizational policies that would outline standards for prescribing orders, and standardized order regimes with supporting references and processes for order verification (12).

The Standards of Practice for Oncology Pharmacy in Canada (Version 2) produced by the Canadian Association of Pharmacists in Oncology (13), provide direction regarding pharmacy practice in oncology. Included in the standards are recommendations for preventing medication errors such as "standard use of oncology-specific computerized physician order entry or pre-printed physician orders for specific anti-cancer drug regimens (pg. 10). Also outlined is the role of the pharmacist in medication order review, with the standard as "the oncology pharmacist should verify the medication order against the treatment protocol, the patient's medication profile and the patient's health record prior to dispensing" (pg 16). In addition to standards specific to the medication review, the CAPhO standards also specifically identify the importance of teamwork to optimize patient safety and treatment outcomes. The Institute of Medicine (14)

noted that up to 80 percent of healthcare errors can be linked to poor team communication and collaboration. The importance of human interaction and team communication is a vital "system" that should not be overlooked when considering the various stages of chemotherapy medication administration.

Systemic treatment and the role of the interprofessional team

The three main roles involved in the safe provision of chemotherapy are physicians, pharmacists and nurses. As each profession has a distinct role in the chemotherapy process, there are also distinct supportive functionalities within ST CPOE to enable best practices (e.g. clinical decision-making) and patient outcomes (e.g. safety). See Figure 3: Role of the Interprofessional Team.



Although the scope of this guideline is specific to the *order entry* phase, the functionalities system design features within an ST CPOE system enable additional checks by the professional and the system. Table 1 provides some examples of profession specific features that would optimize patient safety.

Table 1: Profession specific features for inclusion in ST CPOE system

System Features	Prescriber	Pharmacist	Nurse
User authentication with tiered access based on user designation and degree of risk of the medication (only certain users have access to order chemotherapy)	X		
Mechanisms within the system to allow for verification / validation of order		X	X
Ability to document/communicate vital information that would impact the orders	X	X	X
Chemotherapy Practice Standards	X	X	X
Integration of patient information (e.g. height, weight, lab values)	X	X	X

By incorporating a variety of system checks across all phases of the medication administration process, there is less likelihood of an adverse patient event.

The role of health information technology in patient safety

Information technology has the potential to improve the quality and safety of patient care (15). As a result, organizations such as the Canada Health Infoway, IOM, the Leapfrog Group, and Certification Commission for Health Information Technology (CCHIT) have advocated increased use of technology to improve patient safety (16).

The ordering step of the chemotherapy medication process is crucial and often involves the integration and synthesis of information from a variety of data sources. The introduction of CPOE system can address some of the challenges but should not be viewed as the sole solution to increased patient safety, as CPOE also has the potential to create unanticipated consequences and may actually increase errors (Lawler). The outpatient setting, where the majority of chemotherapy is provided, provides additional challenges due to the lack of CPOE integration with inpatient systems, clinical decision support tools and documentation sources (e.g. Medication Administration Records, laboratory results, client assessment).

In order for information technology (e.g. CPOE) to be effective, it needs to interconnect with other vital information systems such as laboratory and radiology (Eslami et al., 2007). In order to be of benefit to patients and prescribers, CPOE functionality needs to go beyond order entry to include integration and interface with clinical decision support tools, alerts, and treatment protocols/regimes (Finch & Mayne, 2004). See Figure 4: Examples of patient related information inputs specific to ST CPOE.

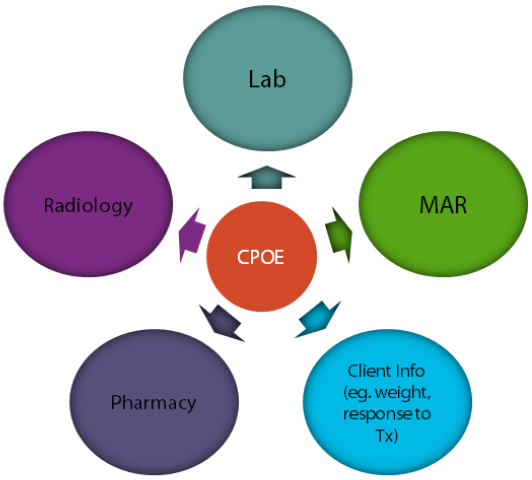


Figure 4: Examples of patient related information inputs specific to ST CPOE

Information technology can also provide a wealth of data to support evidence-based quality monitoring and improvement, by providing timely information regarding prescribing and prescriber practices that can be used to guide organizational and clinical processes.

To monitor the adoption of electronic medical record components, HIMSS Analytics has created an EMR Adoption Model (EMRAM) that identifies seven stages of EMR capabilities ranging

from limited ancillary department systems through a paperless EMR environment. The stages of the model range from 0 to 7, from stage 0 being minimal integration to stage 7 having complete integration and all necessary components (17). Currently, only 2.5% of Canadian hospitals have achieved Level 4 with 36.2% at Level 3. See Table 2: EMR Adoption Model results.

Table 2: EMR Adoption Model (Data from HIMSS Analytics® 2012; Q1)

Stage	**Cumulative Capabilities**	**United States**	**Canada**
7	Complete EMR, CDD transactions, data warehousing, data continuity with ER, inpatient and outpatient	1.2%	0.0%
6	Physician documentation (structured templates), CDSS (variance and compliance), full RIS-PACS	6.2%	0.5%
5	Closed loop medication administration	9.4%	0.3%
4	CPOE, Clinical decision support (clinical protocols)	13.2%	2.5%
3	Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside of Radiology	43.9%	36.2%
2	CDR, Controlled medical vocabulary, CDS, document imaging, HIE capable	12.1%	21.9%
1	All ancillaries installed : Lab, Radiology, Pharmacy, Radiation Therapy	5.5%	15.2%
0	No ancillaries installed	8.4%	23.5%
		N= 5318	N= 639

Research questions used to guide the review of the literature

The development of an evidence-informed best practice guideline document requires a systematic and structured process that is methodologically rigorous, incorporates the best evidence available and promotes a successful implementation of the resulting guideline document. This project incorporates available evidence, current established guidelines and data sets.

Overall research question: What are the features, functionalities and components of a ST CPOE system which are required to ensure safe, high-quality systemic treatment?

Drawing from this overall research question, specific questions were developed to guide the review of the available literature specific to the clinical practices as well as the health information and technology standards that should be incorporated in the design of CPOE systems

to optimize and ensure safe, high quality systemic treatment. See Table 3: Research Questions used to guide the literature review.

Table 3: Research Questions used to guide the literature review

Practices in Evidence-Based Care (Clinical)	Information and Technology Standards
1. Does ST CPOE decrease medication errors in chemotherapy prescribing and if so, what types of errors does it decrease? 2. Does ST CPOE generate new errors or unanticipated consequences? 3. What is the impact of ST CPOE on practice (e.g. workflow, workload, team communication)? 4. What are the strategies that enhance implementation of ST CPOE? 5. What are the types of clinical decision supports and degree of effectiveness?	1. What are the information standards required for an ST CPOE system (e.g. nomenclature; MOHLTC/CCO information requirements) 2. What are the system integration requirements for a ST CPOE system? 3. What features enhance usability of a ST CPOE system? 4. What are the features to enable audit logs/tracking of alerts and workarounds? 5. What are the system features that enable building/modification of protocols/treatment regimens and documentation? 6. What are the privacy considerations for ST CPOE?

The Guideline Development Process

As the scope of this guideline encompassed both clinical and technology domains, a variety of approaches were utilized to enhance the quality, relevance and application of the guideline in practice. The approaches used throughout the guideline development process included review of the literature, utilization of Expert Panels and an external review by a select group of subject matter experts, key stakeholders and identified end users of the guideline (e.g. clinicians and information technology professionals).

Two distinct Expert Panels (i.e. Clinical Expert Panel and Supporting Tools Expert Panel) were convened with the purpose of providing input based on their area of expertise on the research questions used to guide the literature review, the guideline drafts to ensure key areas of importance were reflected and the identification of external reviewers. Members of the Expert Panels were chosen to ensure broad representation of the subject areas, and represented the various specialty areas including clinical oncology, pharmacy, nursing, human factors design, usability professionals, clinical decision support experts, information technology specialists, and included those experienced with a variety of ST CPOE systems. See the Expert Panel acknowledgement for a complete list.

Determining the final list of recommendations

The recommendations included in the guideline were weighed by the extent to which the information was present in the peer reviewed and/or grey literature, the strength of the available evidence, the clinical and/or technological relevance, and the opinion of the Expert Panel members. In addition to the review by the Expert Panels, the complete guideline was reviewed

externally by known subject matter experts as well as targeted end users .See the Stakeholder acknowledgment for a complete list.

How to Use the Guideline

The purpose of this guideline is to provide evidence-based recommendations that can be used to guide the design, selection, implementation and/or evaluation of an ST CPOE system. This guideline can be used by clinicians (e.g. physicians, pharmacists and nurses) to determine optimal safe clinical practice and efficient process flow.

This guideline can also be used by those in clinical informatics, health technology and decision support areas as they determine the necessary system features and functionalities to support the safe delivery of chemotherapy.

The recommendations here are based on the best available evidence, and should be applied with the unique needs of the organization, patient population clinicians, practice patterns and workflow processes in mind. The degree of customization of CPOE features and functionalities required to meet the unique needs at the point of care should be considered in light of the evidence reflected in the guideline.

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Computerized Prescriber Order Entry (CPOE)

for Systemic Treatment:

Best Practice Guideline

Clinical Best Practices
Program in Evidence-Based Care (PEBC)
Evidence Summary

Evidence-Based Series Evidence Summary 12-14

Computerized Prescriber Order Entry (CPOE) in the Outpatient Oncology Setting: Evidence Summary

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Report Date: May 8, 2012

Draft Evidence-based Series (EBS) Evidence Summary 12-14 is comprised of an Evidentiary Base

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Dr. Vishal Kukreti, Cancer Care Ontario
620 University Avenue, Toronto, ON, M5G 2L7
Phone: 416-971-9800 Fax: 416-971-9688 E-mail: vishal.kukreti@cancercare.on.ca

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EBS Evidence Summary 12-14: Section 1

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QUESTIONS

GLOBAL QUESTION

What are the features, functions and components of a Systemic Therapy Computerized Prescriber Order Entry (ST CPOE) system that are required to ensure safe, high quality systemic treatment?

SPECIFIC QUESTIONS

(1) Does ST CPOE decrease medication errors in chemotherapy prescribing compared to usual practice, and if so, what types?

(2) Does ST CPOE generate new errors, and if so, what types?

(3) What is the impact of ST CPOE on practice (e.g. workflow, workload, team communication)?

(4) What are the strategies that enhance or limit implementation of ST CPOE?

(5) What types of clinical decision supports are available and are they effective or ineffective?

INTRODUCTION

Medication errors are deviations from the intended use of a medication. Delivery of the wrong medication or the wrong dosage, a missed dose, and a dose at the wrong time or by the incorrect route are examples. These types of errors can occur anywhere from medication ordering to medication administration and can compromise patient safety (1,2). Medication errors accounted for an estimated 7,000 deaths in the United States in 1993 alone (3). A Canadian study (4) estimated that 7.5% of patients admitted to acute care hospitals in Canada in 2000 experienced at least one adverse event. Drug-related adverse events were the second most common type of these events, accounting for approximately 24% of all adverse events. Medication errors in oncology can be particularly serious because of the narrow therapeutic ranges of antineoplastic drugs and their high toxicities (5,6). Even a moderate difference from the intended dose can have serious consequences. Overdosing can result in considerably more toxicity than usual, and underdosing can result in an unfavourable therapeutic outcome (6). A recent study of outpatient care in the oncology setting found that 7% of adult visits and 19% of paediatric visits were associated with a medication error, either in the clinic or at home (7). Another study in the chemotherapy setting reported an overall 3% medication error rate. Of these, 82% of the adult errors and 60% of the paediatric errors were potential adverse drug events (ADEs), and one third of these potential ADEs were considered potentially serious (8).

Computerized prescriber order entry (CPOE) has been consistently shown to reduce medication errors and ADEs in various settings (9-12), but their use in the oncology setting has not been as well established empirically. Most errors occur during the ordering stage of the medication pathway (13,14), and only a small percentage of hospitals in the United States use CPOE for complex chemotherapy regimens (15). It was decided, therefore, that a systematic review of the CPOE literature in the oncology setting was warranted. This systematic review and evidence summary was designed to cover many aspects of ST CPOE, including medication error reduction, medication error generation, other possible benefits, impact on practice, implementation strategies and clinical decision supports.

METHODS

The EBS guidelines developed by the CCO PEBC use the methods of the Practice Guidelines Development Cycle (16). For this project, the core methodology used to develop the evidentiary base was the systematic review. Evidence was selected and reviewed by one member of the ST CPOE working group (Appendix 1), which is a subset of the ST CPOE Guideline Development Group (Appendix 2).

This systematic review is a convenient and up-to-date source of the best available evidence on ST CPOE in the oncology setting (Question 1) and on ST CPOE in the adult outpatient (oncology or non-oncology) setting (Questions 2-5). The body of evidence in this review is primarily comprised of two-arm trials, before/after comparisons, surveys, cohort studies, and qualitative studies. The systematic review is intended to promote evidence-based practice in Ontario, Canada. The PEBC is supported by the Ontario Ministry of Health and Long-Term Care. All work produced by the PEBC is editorially independent from the Ministry.

Literature Search Strategy

The MEDLINE (1996 through Nov [week 3] 2011), EMBASE (1996 through week 46 2011), CINAHL (1982 through November 24, 2011) and COMPENDEX (1969 through November 24, 2011) databases were searched for relevant evidence. The full MEDLINE, EMBASE, CINAHL, and COMPENDEX literature search strategies can be found in Appendix 3.

Study Selection Criteria

Inclusion Criteria

Question 1

Articles were included if they were:

- published English-language reports of CPOE in the oncology setting,
- phase II or III randomized controlled trials (RCTs), other comparative studies, single-arm studies, practice guidelines, and systematic reviews, with or without meta-analyses,
- the most recent paper that evaluated a given data set.

Question 2

Articles were included if they were:

- published English-language reports of CPOE in the oncology setting,
- published English-language reports of CPOE (non-oncology) in the adult outpatient setting,
- phase II or III randomized controlled trials (RCTs), other comparative studies, single-arm studies, practice guidelines and systematic reviews, with or without meta-analyses,
- the most recent paper that evaluated a particular given data set.

Questions 3-5

Articles were included if they were:

- published English-language reports of CPOE in the oncology setting,
- published English-language reports of CPOE (non-oncology) in the adult outpatient setting,
- phase II or III randomized controlled trials (RCTs), other comparative studies, single-arm studies, practice guidelines and systematic reviews, with or without meta-analyses, process evaluations (summative and/or formative), surveys, qualitative (including studies using focus group or individual interviews, grounded theory,
- the most recent paper that evaluated a given data set.

Exclusion Criteria (all questions)

Abstracts, letters, editorials, notes, commentaries and non-systematic reviews were not eligible. Any papers that only included theoretical or conceptual outcomes were excluded as well.

Synthesizing the Evidence

Owing to the varying designs of the identified studies and the lack of fully published RCTs, data were not pooled using meta-analytic techniques.

RESULTS

Literature Search Results

The MEDLINE search yielded 2108 hits, of which 379 were potentially relevant and were fully reviewed. Thirty-two were retained (Table 1, Appendix 4). The EMBASE search yielded 2486 unique hits, of which 70 were potentially relevant and were fully reviewed. Ten were retained (Table 1, Appendix 4). The CINAHL search yielded 935 hits, of which 19 were fully reviewed, and one was retained. The COMPENDEX search yielded 113 unique hits, of which seven were potentially relevant, but none were retained (Table 1, Appendix 4). Asking experts for suggestions yielded one paper, which was retained.

Table 1. Literature search results.

Database	Dates Searched	Hits	Fully Reviewed	Retained
MEDLINE	1996 – July [week3] 2011	2108	379	32
EMBASE	1996 – week 29 2011	2486	70	10
CINAHL	1982 – July 28, 2011	935	19	1
COMPENDEX	1969 – August 4, 2011	113	7	0
Asking experts	Not Applicable	0	1	1

In total, 32 unique quantitative and 16 unique qualitative documents from the literature search met the eligibility criteria for this systematic review and are listed in Table 2.

Table 2. Studies selected for inclusion by question (not mutually exclusive).

Question/Topic	QUANTITATIVE PAPERS		QUALITATIVE PAPERS	
	Number of Documents	Reference Numbers	Number of Documents	Reference Numbers
Medication error reduction	5	(17-21)	NA	-----
Medication error generation	5	(18,20-23)	NA	-----
Impact of ST CPOE on practice	12	(22,24-34)	5	(35-39)
Implementation strategies	3	(40-42)	5	(43-47)
Clinical decision supports	9	(48-56)	6	(36,37,57-60)

Study/Trial Design and Quality

The quantitative studies included in this guidance document varied in type. There were five pre-/post-implementation studies, five two-arm trials, 11 surveys, six cohort studies, two RCTs, and one systematic review. As most of the studies were not randomized data, the quality of the studies is evaluated below (Table 3), based on four criteria: whether funding, control details, and power calculations were reported and whether blinded assessment was used. The systematic review was evaluated using the Assessment of Multiple Systematic Reviews (AMSTAR) instrument (61).

Of the 30 unique quantitative studies included in this systematic, 18 (60%) reported the funding source for the study. Control details were well reported for those studies for which it was applicable. For most of the included studies, blinding was either impossible because of the nature of the two arms in the study, or not applicable because of the nature of the study design. Of the two randomized trials, one was blinded (49) and one was not blinded for intervention but blinded for outcome (48). Power calculations were only reported in four studies (17,22,23,27).

The qualitative studies identified for each question are listed and summarized in table format for each question. As they were not reported on in detail, they were not evaluated for quality.

Table 3. Quality attributes of the quantitative studies used to inform each of the specific topics regarding ST CPOE addressed in this report.

TOPIC	STUDY	DESIGN	N	FUNDING REPORTED	CONTROL DETAILS	BLINDED ASSESSMENT	POWER CALCULATED
Medication Error Reduction (Oncology)	Huertas Fernandez 2006 (17)	2-arm trial	Manual = 30 CPOE = 30	No	Yes	NP	Yes
	Kim 2006 (18)	Pre/Post Implementation	Pre = 1259 Post = 1505	Yes	NA	NP	No
	Voeffray 2006 (19)	Pre/Post Implementation	Pre = 940 Post = 1505	No	NA	NP	No
	Small 2008 (20)	2-arm trial	Manual = 602 CPOE = 1339	No	Yes	NP	No
	Collins & Elsaid 2011 (21)	Pre/Post Implementation	Pre=412 Post = 126	No	NA	NP	No
Medication Error Generation (Oncology)	Beer 2002 (22)	2-arm trial	Manual = 696 CPOE = 140	No	Yes	NP	Yes
	Kim 2006 (18)	as above					
	Small 2008 (20)	as above					
	Collins & Elsaid (21)	as above					
Medication Error Generation (Non-oncology)	Henderson 2010 (23)	Survey	Computer = 1069 Manual = 188	Yes	Yes	NR	Yes
Impact on Practice (Oncology)	Beer 2002 (22)	as above					
	Khajouei 2010 (24)	2-arm trial	Order Set = 10 No order set =10	No	Yes	NR	No
Impact on Practice (Non-oncology)	Eslami 2007 (25)	SR	AMSTAR SCORE =6				
	Hollingworth 2007 (26)	2-arm trial	Manual = 19 CPOE=50	Yes	Yes	NP	No
	Devine 2010 (27)	Pre/Post Implementation	Manual = 132 CPOE = 312	Yes	Yes	NP	Yes
	Wang 2009 (28)	Survey	Manual = 89 CPOE = 139	Yes	Yes	NA	No
	Duffy 2010 (29)	Pre/Post Implementation Survey	Pre = 1101 Post = 944 Providers = 17	No	Yes	NA	No
	DesRoches 2010 (30)	Survey	Stand Alone = 370 Integrated = 565	Yes	NA	NA	No
	Rupp 2008 (31)	Survey	N=1094	Yes	NA	NA	No
	Tan 2009 (32)	Survey	Physicians = 118 Pharmacy = 61	No	Yes	NA	No
	Hammar 2010 (33)	Survey	N=259	Yes	NA	NA	No
	Rahimi 2011 (34)	Survey	N=74	No	NA	NA	No
Implementation Strategies (Oncology)	None identified						
Implementation Strategies (Non-oncology)	Paré 2006 (40)	Survey	N=91	No	NA	NA	No
	Devine 2010 (41)	Survey	Prescribers = 59 Staff = 58	Yes	Yes	NA	No
	Kralewski 2008 (42)	Survey	N=27 practices	No	NA	NA	No
Clinical Decision Supports (Oncology)	None identified						
Clinical Decision Supports (Non-oncology)	Tamblyn 2008 (48)	Cluster RCT	Automated CDS = 14 On-demand CDS = 14	Yes	Yes	Intervention = No Outcome = Yes	No
	Johnson 2010 (49)	RCT	SYW on = 57 days SYW off = 62 days	Yes	Yes	Yes	No
	Taylor 2004 (50)	Prosp Cohort	N=30	Yes	NA	NA	No
	Ko 2007 (51)	Survey	Physicians = 258 Pharmacist = 84	Yes	NA	NA	No
	Weingart 2011 (52)	Retro Cohort	N=229,663 alerts	Yes	NA	NA	No
	Riedmann 2011 (53)	Prosp Cohort	N=69	Yes	NA	NA	No
	Weingart 2003 (54)	Retro Cohort	N=3481 alerts	Yes	NA	NA	No
	Grizzle 2007 (55)	Retro Cohort	N=291,890 alerts	Yes	NA	NA	No
	Shah 2006 (56)	Prosp Cohort	N=18,115 alerts	Yes	NA	NA	No

CDS=clinical decision support; N=number; NA=not applicable; NP=not possible (e.g., to blind a handwritten vs. computer-generated prescription); NR=not reported; pros=prospective; RCT=randomized controlled trial; SYW=show your work; retro=retrospective

Outcomes

(1) Does ST CPOE decrease medication errors in chemotherapy prescribing, and if so, what types?

Five studies demonstrating that CPOE decreases chemotherapy medication errors in the adult outpatient setting (17-21) were identified. Two were two-arm trials comparing errors from manual orders and CPOE at the same time (17,20), and three compared the error rate before and after CPOE implementation (18,19,21). All reported error reduction for at least some types of errors. For the sake of consistency, the percentage of a given type of error, when the information is provided, was calculated using the number of prescriptions in each arm as the denominator, rather than the number of errors. Percentages were recalculated, when needed, to ensure this consistency within and across each of the studies that provides this information.

Huertas-Fernandez et al. (17) compared manual (N=30) and computerized (N=30) prescriptions during one month in the medical oncology department of a university hospital. The chance of at least one error in a manual prescription was 100% compared to 13% in a computerized prescription ($p<0.001$). The median number of errors in manual versus computerized prescriptions was 5 versus 0 ($p<0.001$). The most common errors were errors of omission in manual compared to computerized prescriptions, including patient name ($p=0.0037$), age ($p<0.001$), height ($p=0.0393$), physician name ($p=0.0037$), physician signature ($p<0.001$), diagnosis ($p<0.001$), administration frequency ($p<0.001$), and duration of infusion ($p<0.001$) (Table 4).

Small et al. (20) also compared manual (N=602) and computerized (N=1339) prescriptions of complex chemotherapy prescriptions. The error rate in manual orders was 20.4%, and in computerized orders 11.8%. This represents an overall relative-risk (RR) reduction for errors of 42% (RR, 0.58; 95%CI, 0.47 to 0.72; $p<0.0001$). Moreover, the types of errors found differed significantly according to the prescription method ($p<0.001$). Specifically, computerized prescribing was associated with fewer dose or frequency errors, incomplete prescriptions, and unnecessary additional agents (Table 4). Small et al. (20) also categorized each prescribing error according to severity (minor, significant, serious and life threatening). As a proportion of the total errors, computerized prescribing was associated with fewer minor errors (36.6 versus [vs.] 16.5%; p=not reported [NR]). Overall, the severity of errors differed significantly according to prescribing method ($p=0.001$). However, the direction of that effect is not reported and is not obvious, given the data reported (Table 4).

Voeffray et al. (19) evaluated prescribing errors for 15 months prior to CPOE implementation and 21 months following CPOE. The error rate pre-CPOE was 15%, and the error rate post-CPOE was 5%. Interestingly, 92% of the post-CPOE errors were found in prescriptions that were still being handwritten, because the prescribing module was not yet available for all prescriptions. The post-CPOE error rate was 1% when only the computerized prescriptions were included in the calculation. These authors (19) also categorized errors as either major or minor. Pre-CPOE, 19% of errors were major, and 81% of errors were minor, whereas, post-CPOE, all errors were minor (Table 4). They calculate the monthly average error rate to be 13.1% pre-CPOE and 0.6% post-CPOE, representing a 22-fold reduction in error rate.

Table 4. Error rates for manual and CPOE prescribing systems in the oncology setting.

METHOD	STUDY	N Prescriptions	OVERALL ERRORS (%)	ERRORS BY TYPE – Manual vs. CPOE (%, p-value)
2-arm Trial	Huertas Fernandez 2006 (17)	Manual = 30 CPOE = 30	100 13 p<0.001	**Errors of Omission (in favour of CPOE)** Patient Name – p=0.0037 Age – p<0.001 Height – p=0.0393 Physician Name – p=0.0037 Physician Signature – p=0.0037 Diagnosis – p<0.001 Administration Frequency – p<0.001 Duration of Infusion – p<0.001
	Small 2008 (20)	Manual = 602 CPOE = 1339	20.4 11.8 RR=0.58, p<0.0001	**Types of Errors** Dose or frequency errors – 6.8 vs. 1.9, <0.001 Incomplete prescriptions – 4.3 vs. 0.4, p=NR Unnecessary additional agents – 1.8 vs. 0.07, p=NR Cycle number or stage errors – 2.5 vs. 5.6, p=0.003 Wrong data entered – 0.7 vs. 1.0, p=NR **Severity of Errors** Minor – 36.6 vs. 16.5, p=NR Significant – 32.5 vs. 35.4, p=NR Serious – 25.2 vs. 41.8, p=NR Life threatening – 5.7 vs. 6.3, p=NR OVERALL – p=0.001
	Beer 2002 (22)	Manual = 696 CPOE = 140	7.14 7.47, p=ns	NR
Pre/Post Implementation	Voeffray 2006 (19)	Pre-CPOE = 940 Post-CPOE = 1505	15 5	**Pre-CPOE** Minor Errors – 81 Major Errors – 19 **Post-CPOE** Minor Errors - 100 Major Errors - 0
	Kim 2006 (18)	Pre-CPOE= 1259 Post-CPOE = 1116	NR	**Types of Errors** Improper dosing on orders – 2.3 vs. 0.6, p=NR Incorrect dosing calculations – 5.8 vs. 0.54, p=NR Missing cumulative dose calculations – 18 vs. 5.7, p=NR Incomplete nursing checklists – 4.8 vs. 2.5, p=NR Matching order and treatment plans – 1.1 vs. 6.0, p=NR Improper dosing on treatment plans – 4.0 vs. 2.63, p=NR
	Collins & Elsaid 2011(21)	Pre-CPOE = 412 Post-CPOE = 126	CPOE results in reduction in prescribing errors OR=0.31; 95% CI: 0.11-0.89, p=0.023	**Errors in Clinical Decision-Making** Wrong dosing schedule/duration – 3.2 vs. 0.0, p=NR Dose that likely leads to high serum levels– 0.7 vs. 0.8, p=NR Dose that likely leads to low serum levels – 0.5 vs. 0.8, p=NR Dose that exceeds max range for the indication – 0.5 vs. 0.0, p=NR **Errors in Transcription** Omission or unclear drug name, route of administration – 0.2 vs. 0.0, p=NR **Errors related to Prescribing Policy** Prescribing policy not followed – 3.6 vs. 1.6. p=NR

CPOE=computerized prescriber order entry; max=maximum; NR=not reported; RR=relative risk; vs.=versus.
Shaded = types of errors that increased after CPOE implementation.

Kim et al. (18) evaluated CPOE in the paediatric setting using a pre-/post-CPOE implementation design. Compared to manual prescribing, CPOE resulted in fewer errors for: improper dosing on orders (2.3 vs. 0.6%; RR, 0.26; 95%CI, 0.11 to 0.61); incorrect dosing calculations (5.8 vs. 0.54%; RR, 0.09; 95%CI, 0.03 to 0.34); missing cumulative dose calculations (18 vs. 5.7%, RR, 0.32; 95%CI, 0.14 to 0.77); and incomplete nursing checklists (4.8 vs. 2.5%; RR, 0.51; 95%CI, 0.36 to 0.80). There was no difference with respect to improper dosing on treatment plans (4.0 vs. 2.6%; RR, 0.66; 95%CI, 0.42 to 1.04) (Table 4). Unfortunately, p-values are not provided for any of the reported types of errors.

Collins and Elsaid (21) report on the prescribing errors for oral chemotherapy in an inpatient setting for a 24-month period prior to CPOE implementation and six months after implementation. They report that the implementation of CPOE significantly reduced the risk of prescribing error by 69% (odds ratio [OR], 0.31; 95%CI, 0.11 to 0.86; p=0.023). Errors were divided into three categories: errors in clinical decision-making; errors in transcription; and errors related to prescribing policy, but significance levels for individual types of errors are not reported (see Table 4).

(2) Does ST CPOE generate new errors, and if so, what types?

Oncology Setting

Four studies that demonstrated that CPOE may increase chemotherapy medication errors in the adult outpatient setting were identified (18,20-22). Small et al. (20) report that the types of errors found differed significantly according to the prescription method (p<0.001). Computerized prescribing was associated with greater cycle number or stage errors and instances of wrong data entered (e.g., height, weight). These authors also categorized each prescribing error according to severity. Serious errors were defined as those errors that might cause either harm or significant undertreatment. Such errors were not considered to be fatal. Some examples include the wrong regimen for the right indication, overdoses (<50% above the required dose), subtherapeutic single doses for curative treatment, and inadequate prophylaxis for severe toxicities. Life-threatening errors were defined as those errors that have the potential to result in death. Some examples include overdoses (>50% above the required dose), repeating an order for three-weekly chemotherapy regimen within only seven days of administration, the wrong chemotherapy regimen for potentially curative treatment, and insufficient rescue medication for high-dose chemotherapy. CPOE was associated with more serious (25.2 vs. 41.8%; p=NR), significant (32.5 vs. 35.4%; p=NR, and life-threatening (5.7 vs. 6.3%; p=NR) errors than was manual prescribing, although it is unknown if these differences are statistically significant as p-values are not provided (Table 4).

Beer et al. (22) took a different approach in that they measured pharmacist intervention rate, which was defined as any problem with a medication order that required physician clarification before the pharmacist could process that order. There was no statistically significant difference in the intervention rates for manual versus computerized orders (7.14% vs. 7.47%; p=ns) (Table 4). Unlike Small et al. (20), Beer et al. (22) do not provide any information regarding the types of errors found or the types of interventions needed with respect to the chemotherapy orders. Neither of these papers (20,22) refer to any specific prescriber or system features that may have contributed to the increase in errors and/or interventions reported.

Kim et al. (18) evaluated CPOE in the paediatric setting using a pre-/post-CPOE implementation design. Compared to manual prescribing, CPOE resulted in more errors for matching order and treatment plans (1.1 vs. 6.0%; RR, 5.4; 95%CI, 3.1 to 9.5), although it is unknown if this is statistically significant.

Collins and Elsaid (21) report on the prescribing errors for oral chemotherapy in an ipatient setting for a 24-month period prior to CPOE implementation and six months after implementation. After CPOE implementation, there were more errors with respect to doses that would likely lead to high (0.7 vs. 0.8%) or low (0.5 vs. 0.8%) serum levels. The significance levels for these types of errors are not reported (Table 4).

Non-Oncology Setting

One paper (23) was identified that looked at the consequences of computerization on general practice in Australia. The authors report a few unanticipated consequences such as performing more Pap tests, ordering more HbA1c tests, and providing more referrals of diabetic patients to ophthalmologists. No consequences involved medication prescribing.

(3) What is the impact of ST CPOE on practice?

QUANTITATIVE STUDIES

Oncology Setting

Two studies were identified that measured the impact of CPOE on practice (22,24). Beer et al. (22) evaluated the effect of CPOE on pharmacy practice. In this two-arm trial comparing manual to computerized chemotherapy prescribing, pharmacist intervention rates were measured (see results of Question 2 above) as well as the time needed for the pharmacist to review each order. All medications listed on a given prescription for a given patient were considered to be one order regardless of the number of medications listed on that prescription. The amount of time to review each order was measured by stopwatch. If a pharmacist intervention was needed to complete the order review, the timing of the review process continued throughout the duration of the pharmacist intervention. The mean time to complete a prescription order review was significantly longer for a computerized prescription than for a manual prescription (11.1 vs. 5.96 minutes; $p<0.001$). Even when categorized by orders that required an intervention (18.32 vs. 13.49; $p<0.001$) and those that did not (10.56 vs. 5.35; $p<0.0001$), computerized prescriptions required significantly more pharmacist review time than did manual prescriptions.

Khajouei et al. (24) compared the effect of predefined order sets versus no order sets on the efficiency of chemotherapy prescribing within a CPOE system. Ten hematology/oncology physicians were provided a clinical scenario and asked to order medications, using a predefined order set and not using the order set, in a counter-balanced design. Optimally, the predefined order set required 61 keystrokes and mouse clicks, and the situation without an order set required 86. These authors counted the number of excess keystrokes and mouse clicks made by each physician when they were placing the medication order, and report that there was a significantly lower number of excess keystrokes and mouse clicks when the medication order was placed

using a predefined order set (p<0.01). These authors (24) also evaluated the usability problems associated with each type of medication ordering (with vs. without a predefined order set) and report that there were fewer usability problems overall with with-order sets compared with without-order sets. Furthermore, there were a significantly fewer mean number of major (3.78 vs. 5.11; p=NR) and catastrophic (0.67 vs. 3.11; p=NR) usability problems per physician when using order sets.

Non-Oncology Setting

One systematic review of various aspects of CPOE systems contained a section evaluating the effect of CPOE on practice, specifically time (25). They evaluated one oncology-specific RCT (22) that is reported separately in this report (see Question 4 – Oncology Setting). The results of the non-oncology studies found that the time for direct and indirect patient care increased after the implementation of a CPOE system, although an observational study demonstrated that physicians did not perceive that electronic prescribing was more time consuming than manual prescribing.

Four studies comparing (CPOE to no CPOE) that evaluated the effect of CPOE on practice (26-29) were identified. Hollingworth et al. (26) conducted a time-motion study of electronic (e)-prescribing and found that, on average, e-prescribers spent significantly less time writing tasks than did manual prescribers (weighted mean difference =-3.0 min/hr; 95%CI, -5.6 to 0.2; p<0.05), and e-prescribers spent significantly longer time on computer tasks than did manual prescribers (weighted mean difference=3.9 min/hr; 95%CI, 0.3 to 7.5; p<0.05). Overall, e-prescribing tasks took slightly longer than did manual prescriptions (adjusted mean difference = 12.0 seconds; 95%CI: -1.6 to 25.6, p=nonsignificant [ns]), although this difference was not statistically significant. Moreover, these authors report that e-prescribing did not significantly disrupt prescriber or staff workflow related to a variety of tasks, including but not limited to talking to colleagues, phoning colleagues, talking to patients/family, examining charts, and phoning patients. Devine et al. (27) also conducted a time-motion study and found that e-prescribing took longer than manual prescribing in the primary care setting (mean adjusted difference per prescription = 25 seconds; 99.5%CI, 12.0 to 38.0; p<0.01).

Wang et al. (28) carried out a survey of the perceptions of primary care physicians, both e-prescribers and non-e-prescribers. E-prescribers were significantly more likely than non-e-prescribers to feel that the information they had available about a patient's medication history (a) enabled them to identify clinically important potential drug-drug interactions (83 vs. 67%; p=0.004) and (b) prevented calls from pharmacies regarding potential safety issues (68 vs. 53%; p=0.02). Moreover, e-prescribers 'agreed' or 'strongly agreed' that e-prescribing: was easy to use (79%), made their work simpler (53%), made work easier for staff (49%), and increased productivity (40%).

Duffy et al. (29) conducted a pre-/post-e-prescribing study in the family medicine setting. One year after the implementation of e-prescribing, there was a 22% reduction (p≤0.05) in after-hours calls, especially with respect to upper respiratory infections, fever, nausea, vomiting and diarrhea, and an 81% decrease in calls related to medications (p≤0.05). These authors also conducted a survey of e-prescriber satisfaction and found that, whereas 71% respondents agree

that e-prescribing takes less time than does manual prescribing, and 75% agree that e-prescribing leads to fewer prescription errors than does manual prescribing, only 29% agree that e-prescribing reduces within-office-hours medication questions, callbacks and workload compared with manual prescribing, and only 44% agree that e-prescribing reduces after-hours medication questions, callbacks and workload compared with manual prescribing.

One study that undertook a survey which compared e-prescribing in integrated versus stand-alone systems (30) in the outpatient setting was identified. Physicians using an integrated system (i.e., integrated with an electronic health record [EHR]) were significantly more likely to report that they e-prescribe most or all of the time (78 vs. 58%; $p<0.001$). They also report that those prescribing within an integrated system found it easier to reconcile a patient's medication list (80 vs. 50%; $p<0.001$) and found that there were fewer calls from pharmacies regarding prescribing errors ($p=0.005$).

Four non-comparative surveys of community pharmacists and/or pharmacy personnel views on e-prescribing were identified (31-34). Rupp and Warholak (31) surveyed 1,094 pharmacists, technicians, and student interns in 276 chain community pharmacies in six American states (response rate = 65%). Respondents rated e-prescribing more favourably than manual prescribing for the following outcomes with respect to workflow and communication: efficiency of patient care, communication with patients, communication with prescribers, overall relations with patients and overall relations with prescribers.

Tan et al. (32) surveyed 118 doctors and 61 pharmacy staff (response rate not reported) in Singapore about their perceptions regarding e-prescribing. The majority of the physician respondents expressed satisfaction with several workflow issues, including the ability to create a new prescription, review prescription history, track health maintenance items, and amend prescriptions, as well as the speed of the system and the time required to enter prescription or patient information. A smaller majority of pharmacy personnel expressed their satisfaction with workflow issues pertinent to them, including the ability to download new prescriptions, read and understand the prescriptions, recall previously dispensed prescriptions, and process prescriptions, as well as the time required to process prescriptions and prescription amendments.

Hammar et al. (33) surveyed 500 community pharmacists in Sweden about their perceptions of e-prescribing and achieved a 52% response rate (N=259). Most respondents perceived that e-prescribing improved relationships with patients (81%) and prescribers (62%) and improved communication with patients (87%) and prescribers (65%).

Rahimi and Timpka (34) surveyed 74 Swedish pharmacists in one municipality regarding their perceptions of e-prescribing. The response rate was 70% (N=52). The majority of respondents reported that e-prescribing was useful for several workflow issues, including, but not limited to, reducing calls because of both incomplete and ambiguous prescriptions; faster prescription-processing time; overall time savings; ease of accessing e-prescribing systems and ease of entering data into e-prescribing systems. The most important barrier to the acceptance of e-prescribing technology was the loss of working time to computer-related problems.

QUALITATIVE STUDIES

Five qualitative studies pertaining to the impact of CPOE on practice were identified (35-39). They are briefly summarized in Table 5 below. These studies used various qualitative methods including interviews, focus groups and grounded theory to identify the impact of CPOE on practice. Collectively, many issues were identified that facilitate (e.g. ease of changing doses and renewing prescriptions) and impede (e.g. security concerns, duplication of work) practice particularly with respect to workflow. Understanding the impact of these issues may help in implementation of CPOE.

Table 5: Qualitative papers pertaining to the impact of CPOE on practice.

STUDY	TYPE OF STUDY	PARTICIPANTS	THEORETICAL FRAMEWORK STATED	OUTCOME(S)
Kozakiewicz 2005 (35) (oncology setting)	FMEA	Multidisciplinary team including: Clinical Pharmacist Oncology Nurse Manager Staff Oncology Nurse Oncology Clinical Nurse Specialist Information Service Representative	Yes	Developed a uniform and safe chemotherapy ordering system.
Ash 2007 (36)	Interviews Grounded Theory	Not specified	Yes	Workflow issues identified include: • Security concerns depending on the location of the computer stations • Duplication of work • Discomfort of IT personnel when having to fix a computer in an exam room with a patient in the room • Having to work through lunch, which also leads to loss of socialization time • Easier identification of workflow weaknesses • Tension among those who planned the implementation of the system
Weingart 2009 (37)	Focus Groups	Clinicians	No	Workflow issues identified included: • Ease of changing doses • Ease of renewing prescriptions • Assurance of legibility • Ease of sending prescriptions to pharmacies • Unreliability of successfully sending prescriptions to pharmacies • Inability to merge patient entries • Inability to get a patient's full medication list no matter who the prescriber • Inability to enter allergy information • Inability to write prescriptions for commonly ordered medications
Agarwal 2010 (38)	Focus Groups Direct Observation Semi-structured Interviews	Physicians Practice managers Nurses Other medical staff	No	Technological viewpoints can either facilitate or impose barriers on the effective use of e-prescribing. Understanding the impact of these viewpoints may help in any technological implementation
Lapane 2011 (39)	Focus Groups	Clinicians Office staff	No	The perceived efficiencies of e-prescribing such as knowing formularies, processing refills, and decreased errors were realized once e-prescribing was implemented.

(4) What are the strategies than enhance or limit implementation of ST CPOE?

QUANTITATIVE STUDIES

Oncology Setting

No studies on the implementation of ST CPOE in the oncology setting were identified that met the criteria established.

Non-Oncology Setting

Three studies were identified that looked at strategies that enhance or impede the implementation of CPOE (40-42). Paré et al. (40) evaluated the effect of a new construct known as 'psychological ownership' on physicians' acceptance of CPOE technology. They surveyed 125 physicians currently using a CPOE system and achieved a response rate of 73% (N=91). Their results indicate that in order to foster physicians' adoption of the new technology, a positive attitude toward that new system must be developed. Specifically, physicians who had acted as system 'champions' during CPOE implementation were found to have significantly stronger feelings of ownership of the new system than were non-champions (p=0.001). Compared with non-champions, champions also had significantly higher scores on perceived usefulness (p=0.021) and perceived ease of use (p=0.04) of the CPOE system and attitudes (p=0.036) towards this technology.

Devine et al. (41) conducted a survey of prescribers and staff in a large independent medical group to assess their attitudes towards e-prescribing as they transitioned from paper to CPOE, in order to inform strategies to increase successful adoption of the technology. The survey was sent to 188 respondents and achieved a 62% response rate. They found that prescribers (but not staff) who used a computer at home for professional reasons improved scores on several domains, including intent to use (p=0.01), perceived usefulness (p=0.001) and perceived ease of use (p=0.02). Moreover, self-assessed computer knowledge improved scores on perceived usefulness (p=0.01) and perceived ease of use (p<0.001).

One other study looked at specific variables (physician, structural, and cultural) that affect physician use of e-prescribing technology (42) in 27 primary care medical group practices that had e-prescribing available. The authors report that the only physician variable that influenced the use of computerized prescribing was speciality. Specifically, family physicians and paediatricians had higher use rates than did internists (p=0.001). Two practice structure features significantly influenced CPOE adoption rates; practice size and multispecialty practices. In particular, larger practices had higher adoption rates (p=0.02), as did practices with more than one specialty (p=0.03). Finally, several cultural characteristics of the practice affected CPOE adoption rates. Specifically, adoption rates were higher in practices that had high levels of organizational trust (p=0.04) and a business approach to decision-making within the practice (p=0.00) and that valued physician autonomy (p=0.01) and adaptation to change (p=0.00). Conversely, practices that highly valued cohesiveness had lower CPOE adoption rates (p=0.02), as did those that valued quality of care (p=0.05).

QUALITATIVE STUDIES

Five qualitative studies pertaining to strategies that enhance or limit the implementation of CPOE were identified (43-47) and are briefly summarized in Table 6. These studies used various qualitative methods including interviews, focus groups and process evaluation. Several of the more in-depth studies focus on key components of successful CPOE implementation and include but are not limited to involving stakeholders in decision-making to ensure ownership and empowerment, providing on-site training and support prior to implementation and providing ongoing customized support and maintenance after implementation.

Table 6: Qualitative papers pertaining strategies that enhance or limit implementation of CPOE.

STUDY	TYPE OF STUDY	PARTICIPANTS	THEORETICAL FRAMEWORK STATED	OUTCOME(S)
Ash 2003 (43)	Consensus Statement	Experts in CPOE	No	Considerations to guide CPOE implementation: • Motivation for implementation • CPOE vision, leadership and personnel • Cost • Integration: workflow, healthcare processes • Value to users/Decision support systems • Project management and staging of implementation • Technology • Training and Support 24/7 • Learning/Evaluation/Improvement
Ash 2005 (44)	Semi-structured Interviews Focus Groups Observation	Physicians Nurses Pharmacists IT staff Administrators Others	No	Twelve themes were generated from the data that included both inpatient and outpatient data. Authors conclude that the key to successful CPOE implementation is to maximize the upsides, minimize the downsides and have a plan on how to manage unintended consequences.
Greenberg 2006 (45) (oncology setting)	Descriptive Paper	Cancer institutions in Ontario	No	Key components to success: • Have a fully staffed project team • Get support of clinical and administrative leadership • Involve stakeholders in decision-making to ensure sense of ownership and empowerment • Provide in-depth, on-site training • Involve on-site pharmacists in the set-up of the system • Test the system extensively • Provide ongoing customized support and maintenance
Crosson 2008 (46)	Multi-method Qualitative Case Study	Practices scheduled for implementation of e-prescribing	No	Implementation must be carefully planned. E-prescribing users should be aware of the effects on their prescribing systems and workflow. High quality technical support should be provided. Plan changes to prescription workflow before implementation.
Hoffman 2011 (47)	Process Evaluation	Clinical Informatics Specialists Physicians	No	Key components to success: • Commitment to the priority of patient safety by the

STUDY	TYPE OF STUDY	PARTICIPANTS	THEORETICAL FRAMEWORK STATED	OUTCOME(S)
		Physician Assistants Nurse Practitioners Nurses Pharmacists		organization and department leaders as well as staff. • Appropriate resources for safe implementation of CPOE including support to respond promptly to issues that arise during implementation. • Dedication and collaboration among the healthcare and technical support providers involved. • Process redesign undertaken by a multidisciplinary team of healthcare and technical providers. • Use of risk assessment tools (ex., FMEA) • Logical step-wise implementation rather than an all-at-once approach. • Use of existing paper order sets to structure the electronic versions of each regimen. • Development of electronic order sets by multidisciplinary teams. • Sufficient functionality that allows for continuous review of a given order set; sequence order sets based on an anchoring order. • Sufficient flexibility so that not only can the process adjust to the software but also so that the software can adjust to the process. • Staff trainers should be included in the process redesign and development processes. • Continuous (24/7) support for staff after each go-live stage until all staff are comfortable with the new system.

(5) What are the types of clinical decision supports and how can they be effective or ineffective?

QUANTITATIVE STUDIES

Oncology Setting

No studies of effective and ineffective clinical decision supports within a CPOE system were identified that met the criteria established.

Non-Oncology Setting

Two RCTs of computerized decision supports (CDS) (48,49) were identified. Tamblyn et al. (48) conducted a cluster RCT in primary care. They randomized physicians to either automated or on-demand drug CDS. Physicians could set and change the severity level of the alerts they wished to view (Level 1 – definite and serious adverse effect; Level 2- likely adverse effect; and Level 3 – possible adverse effect). In the on-demand group, CDS was requested for 0.9% of the prescribing problems identified. The prescription was altered 75.6% of the time. In the automated arm, 10.3% of the alerts were seen, and prescriptions were altered 12.1% of the time. Most of the alerts were either ignored or not even seen in either group.

Johnson et al. (49) performed an RCT designed to bridge the gap that exists in the communication between the prescriber and the pharmacist. They implemented a "Show Your Work" (SYW) system that attaches alerts and any override comments to the e-prescription. They compare CPOE with and without SYW. There was no difference in the callback rate with or without the SYW system in place (p=ns).

Four non-comparative studies of CDS were also retained (50-53). Taylor and Tamblyn (50) evaluated the reasons for physician non-adherence to drug alerts in general practitioners. They found that 55% of drug alerts were ignored. Most of these pertained to toxicity, potential allergic reactions, therapeutic duplication, and known drug intolerances. The two most often cited reasons for ignoring alerts were that the interaction was already known and/or the alert was not clinically relevant. These two reasons were cited for 79% of all ignored alerts.

Ko et al. (51) conducted a survey designed to elicit physician and pharmacist opinions on computerized drug-drug interaction alerts in the Veteran's Affairs system in the United States. Response rates among physicians and pharmacists were 36% and 59%, respectively. Although the order differed, both groups agreed that the top three changes to drug-drug interaction alerts should be to (1) make it more difficult to override lethal interactions, (2) display alerts one time for each patient, and (3) provide management options for an alert.

Weingart et al. (52) evaluated whether or not physicians were more likely to accept drug-drug interaction alerts that had been judged to be clinically important by a group of experts. They convened a group of five experts to rate a series of drug-drug interaction alerts. Unfortunately, inter-rater reliability among the experts was quite low (Kappa ≤ 0.40 for all seven attributes they measured, with four of these being ≤ 0.20). They then compared the expert panel results to how

2,872 clinicians, who generated 229,663 electronic drug-drug interaction alerts over the course of one year, responded. The clinician alert acceptance rate increased 2.7% for alerts that the expert panel determined would result in an adverse event, 2.3% when the physician lacked prior knowledge of the information provided by the alert, and 3.3% when the physician could easily act on the alert.

Riedmann et al. (53) used a two-round Delphi approach to determine how to improve the delivery of drug alerts in a CPOE system. They invited 214 CPOE experts to participate, but only 34.1% participated in the first round and 32.2% in the second round. Of those who participated in both rounds, only 36.2% were healthcare providers who actually used CPOE. The top five context factors for prioritizing and filtering alerts were (1) severity of the adverse event, (2) clinical status of the patient, (3) probability of the adverse event occurring, (4) patient risk factors, and (5) strength of the evidence for the alert. They also determined that the best ways to deliver alerts and reduce adverse events were through an active alerting system and a proactive prescription simulation. They estimate that 25% of adverse drug events could be averted if these two methods of alerting are implemented.

Two retrospective studies of computerized drug alerts were identified (54,55). Weingart et al. (54) reviewed 3,481 drug interaction and drug allergy alerts generated over a three-month period. They report that physicians overrode 91.2% of the drug allergy alerts and 89.4% of the high-severity drug-drug interaction alerts. Interestingly, 36.5% of the alerts were deemed to be inappropriate by two physician reviewers.

Grizzle et al. (55) retrospectively reviewed 291,890 drug-drug interaction alert overrides at six Veteran's Affairs Medical Centres in the United States over a one-year period. Override reasons were sorted into 14 categories and then rated as to whether it was clinically useful or not to the pharmacist in determining the potential for an adverse event. Seventy-two percent of the alerts were considered critical, and 20% of the override reasons for these critical drug alerts were considered to be clinically useful to the pharmacist for order verification. Interestingly, 53% of the responses to the reason for override were "no reason provided".

Finally, Shah et al. (56) tried to improve clinician acceptance of drug alerts by designating only the critical/high severity (Level 1) alerts to be interruptive. Specifically, these alerts interrupted workflow in that physicians could not proceed with the prescription order without eliminating the contraindication. Level 2 and 3 alerts were non-interruptive. Level 2 alerts could be overridden as long as a reason for the override was provided. Level 3 alerts were displayed but did not require any action on the part of the physician. Sixty-seven percent of the interruptive drug alerts were accepted by physicians. These authors present a list of recommendations for improved alert acceptance as follows:

- Minimize workflow interruptions by presenting only the most relevant contraindications and mandating an interruption to workflow only for high-severity alerts.
- Minimize false-positive alerts by keeping alerts up to date based on the most current literature.
- Cancel versus modify actions. There should be recognition when evaluating clinical decision support that any modification that eliminates the contraindication represents acceptance of that alert.

- Facilitate clinician actions by including automatic ways in the system for clinicians to eliminate a drug contraindication.
- Collect override reasons. A clinician may have a good reason overriding an alert. This information should be collected and used in revisions to the alert system.
- Create a central repository of knowledge-base information for public sharing.

QUALITATIVE STUDIES

Six qualitative studies pertaining to effective and ineffective clinical decision supports were identified (36,37,57-60) and are summarized in Table 7. These studies used various qualitative methods including interviews and focus groups. Many of these studies identified similar issues with alerts, including receiving too many alerts that may be perceived as clinically trivial and disruptive and lead to alert fatigue, and ignoring of alerts. Alerts must be carefully chosen such that only those that are most likely to benefit patients are generated.

Table 7: Qualitative papers pertaining to effective and ineffective clinical decision supports.

STUDY	TYPE OF STUDY	PARTICIPANTS	THEORETICAL FRAMEWORK STATED	OUTCOME(S)
Ash 2007 (36)	Interviews Grounded Theory	Not specified	Yes	Alerts issues identified include: • Receiving too many alerts • Receiving alerts at inappropriate times
Lapane 2008 (57)	Focus Groups	Prescribers Staff	No	To improve overriding of alerts, prescribers recommend the following changes: • Increase the specificity of the alerts • Allow prescribers to set the severity threshold for alerts • Keep drug alert algorithms up to date by running them against current medication regimens
Vaziri 2009 (58)	Workshop	Primary care practitioners System developers Information suppliers Academics	No	• Clinicians are frustrated by unnecessary alerts. It draws their attention away from other important information • Alerts are disruptive • Alerts are often cancelled before even being read • Clinical risk assessment might be a method of choosing the alerts that are most likely to have the greatest patient benefit
Weingart 2009 (37)	Focus Groups	Clinicians	No	Alerts issues identified included: • Too many drug allergy and drug interaction alerts • Too many clinically trivial alerts • Too many alerts generated for interactions with out-of-date medications • Habitual ignoring of alerts • Alerts most helpful when clinician was unfamiliar with either the drug or the patient • Alerts prompted clinicians to advise patients about potential medication side effects, to check examination findings or to order laboratory tests • Unwillingness to forgo receiving alerts because they did not want to miss anything that was potentially important
Riedmann 2011 (59)	Semi-structured Telephone Interviews	Experts in CPOE	No	Context factors related to alerts that were identified were the severity of the effect and the strength of the evidence for the alert.
Robertson 2011 (60)	Semi-structured Interviews	General Practitioners General Practitioner Trainees	No	• Clinical decision support systems (CDSSs) need to take into account the time pressures of practice and the need to integrate information systems that complement the practitioner's clinical needs as well as their patterns of practice • High quality, inexpensive and continuously updated resources need to be available to everyone • Incentives and/or a national strategy may be required.\

ONGOING TRIALS

No studies identified to date have prospectively planned clinical trials. Therefore, it is difficult to search for ongoing studies that would meet the inclusion criteria for this review, because there is no relevant registry or database containing this information.

DISCUSSION

Patient safety has garnered much attention for many years, particularly since the 1999 Institute of Medicine (62) report estimating that, in the United States alone, 80,000 people are hospitalized and 7,000 die every year owing to medication errors in the inpatient setting, many of which are preventable. CPOE is one promising technology for the reduction of medication errors in both inpatient and outpatient settings. Medication errors in the oncology setting can be particularly serious given the toxicity of chemotherapeutic agents. The results of this systematic review have clearly demonstrated that there is a paucity of oncology-specific CPOE literature. Most studies take place in non-oncology inpatient settings, likely because this is where CPOE was initially introduced. The few studies that are available demonstrate that CPOE in the oncology setting does reduce medication errors (17-21) but the potential for increased errors also exists (18,20-22). Therefore, the CPOE system, CDS, and associated interface design elements must be carefully designed to reduce the potential for error. Moreover, vigilance in the form of constant monitoring and updating of systems must be maintained. Studies that demonstrate specific types of error generation are useful for identifying deficiencies that can be fixed either through technical changes (e.g. computer programming) or process changes.

CPOE can also have an impact on practice, particularly workflow and communication between healthcare professionals as well as between healthcare professionals and patients. Unfortunately, these studies do not show consistent results, probably reflecting the true nature of how things work in a real-world situation. In the oncology setting, Beer et al. (22) demonstrated that computerized prescriptions took pharmacists longer to review than did manual prescriptions even if there were no problems with the prescription, whereas Khajouei et al. (24) found that using predefined order sets resulted in fewer key strokes and usability problems than not using order sets. Several non-oncology studies also found that e-prescribing had a negative impact on workflow in terms of time and workload (25-27,30), whereas other studies reported a positive impact with respect to time and workload (28,31,32,34), productivity (28), and communications (31,33). One study reported both a positive and negative impact on different aspects of time and workload (29). The results of the qualitative studies (37-39) are similar to the empirical evidence. The totality of this evidence reveals that CPOE, as with any new technology, will have both positive and negative impacts on practice.

Only a handful of studies have evaluated CPOE implementation in the outpatient setting, either empirically or qualitatively. The empirical studies all look at very different aspects that may affect implementation, including the use of a CPOE ‘champion’ (40), respondent use of a home computer for work (41), and physician, structural and cultural variables (42). Overall, combined with the qualitative data, some common themes are: the need for a strong vision and motivation for introducing CPOE, the involvement of stakeholders in decision-making, the provision of in-depth, on-site and ongoing training before and after launch, and setting in place mechanisms to efficiently respond to problems identified by end-users (40,43,45-47).

Many studies looking at CDS systems were identified, both quantitative and qualitative. The overall message when looking at the totality of the data is that most alerts derived by clinical decision support systems are ignored, generally because there are too many of them, and they are not perceived to be clinically relevant (36,48,50,57). This leads to alert fatigue. Alerts, especially interruptive alerts, need to be carefully chosen to be the most likely to benefit patients, and the clinical decision support systems that generate the alerts need to be constantly updated and refined to achieve this goal (37,58,60).

There are some limitations to this systematic review. The overarching question that sought to identify the features, functionalities and components that are required to ensure safe and high quality systemic treatment could not be directly answered, because the research on CPOE does not structure itself in this way. For this reason, several specific questions were asked that were designed to speak to the issues the global question posed. The current CPOE literature focuses on the role of, and the impact on, physicians and pharmacy personnel. Unfortunately, none of the outpatient literature looks at the impact on the workflow of nurses, which is definitely a limitation in the CPOE research in general and one that should be considered as an area for future research.

CONCLUSIONS

CPOE with CDS is a promising technology for the reduction of medication errors and potential adverse drug events associated with those medication errors. Based on the review of the literature included in this guideline, we conclude:

1. CPOE systems should be used in outpatient chemotherapy delivery to decrease chemotherapy related medication errors. Although the focus of this evidence summary was outpatient CPOE, it is likely that many of the principles in this document would also apply to inpatient CPOE.
2. Health information technologies such as CPOE systems can directly impact clinician workflow practices, therefore a comprehensive, multi-faceted change management approach is required in order to effectively implement and sustain the practice and process changes associated with the introduction of CPOE. Strategies include the use of local opinion leaders with input into decision-making (e.g. clinical, technical and leadership champions), educational supports and timely quality monitoring through audit/feedback loops.
3. A multidisciplinary team approach in the design, selection, workflow evaluation, implementation and/or evaluation, and ongoing monitoring of the CPOE system should be used.
4. CPOE processes that complement current practice and work-flow processes to enhance adoption by clinicians should be ensured.

5. CPOE systems, clinical decision supports and associated interface design elements must be carefully designed to reduce the potential for error.

6. The development and implementation of a risk-assessment process to identify actual/potential unanticipated consequences and new errors generated, as well as the development of strategies to modify the system accordingly, are warranted.

CONFLICT OF INTEREST

In accordance with the PEBC Conflict of Interest (COI) Policy, the guideline authors, ST CPOE Expert Panel members, and internal and external reviewers were asked to disclose potential conflicts of interest. Three authors declared they had no conflicts. One other (VK) declared conflicts and reported receiving more than $5,000 in a single year in honoraria from Roche, Celgene, and Ortho Biotech pharmaceutical companies for talks, educational work and consultancy. However, the topics were unrelated to ST CPOE. In addition, this author has received an NCIC grant for barcoding use for delivering chemotherapy within the past five years.

For the Expert Panel, all members declared they had no conflicts of interest.

The COI declared above did not disqualify any individuals from performing their designated role in the development of this guideline, in accordance with the PEBC COI Policy. To obtain a copy of the policy, please contact the PEBC office by email at ccopgi.mcmaster.ca.

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Contact Information

For further information about this report, please contact:

Dr. Vishal Kukreti, Cancer Care Ontario, 620 University Avenue, Toronto, ON, M5G 2L7;

Phone: 416-971-9800 Fax: 416-971-9688 E-mail: vishal.kukreti@cancercare.on.ca

For information about the PEBC and the most current version of all reports,

please visit the CCO website at http://www.cancercare.on.ca/ or contact the PEBC office at:

Phone: 905-527-4322 ext. 42822 Fax: 905 526-6775 E-mail: ccopgi@mcmaster.ca

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Appendix 1. Members of the ST CPOE Working Group Panel.

Chair:

Vishal Kukreti	Hematologist	Princess Margaret Hospital, Toronto, ON

Panel Members:

Annie Cheung	Pharmacist	Cancer Care Ontario, Toronto, ON
Roxanne Cosby	Methodologist	PEBC, McMaster University, Hamilton, ON
Sara Lankshear	Nursing	Cancer Care Ontario, Toronto, ON

Appendix 2. Members of the ST CPOE guideline development group

Chair:

Vishal Kukreti	Medical Oncologist	Princess Margaret Hospital, Toronto, ON

Members:

Annie Cheung	Pharmacist	Cancer Care Ontario, Toronto, ON
Roxanne Cosby	Methodologist	PEBC, McMaster University, Hamilton, ON
Garry Cruickshank	Pharmacist	eHealth Ontario, Toronto, ON
Jennifer Daley-Morris	Pharmacist	Southlake Regional Hospital, Newmarket, ON
Sherrie Hertz	Clinical Programs	Cancer Care Ontario, Toronto, ON
Sean Hopkins	Pharmacist	The Ottawa Hospital, Ottawa, ON
Diana Incekol	Nursing	University Health Network, Toronto, ON
Gregory Knight	Medical Oncologist	Grand River Regional Cancer Centre, Kitchener, ON
Sara Lankshear	Nursing; Guideline Lead	Cancer Care Ontario, Toronto, ON
Darrilyn Lessels	Clinical Educator	Lakeridge Health Centre, Oshawa, ON
Jonathan Noble	Physician	Sudbury Regional Hospital, Sudbury, ON
Rachel White	Human Factors Specialist	University Health Network, Toronto, ON

Appendix 3. Literature search strategy.

MEDLINE

1. exp Medical Order Entry Systems/
2. exp Drug Therapy, Computer-Assisted/
3. computerized physician order entry.mp.
4. computerized prescriber order entry.mp.
5. computerized provider order entry.mp.
6. cpoe.mp.
7. or/1-6
8. limit 7 to english language

EMBASE

1. exp computerized provider order entry/
2. computerized physician order entry.mp.
3. computerized prescriber order entry.mp.
4. CPOE.mp.
5. MOE.mp
6. medication order entry.mp.
7. exp computer assisted drug therapy/
8. or/1-7
9. limit 8 to english language

CINAHL

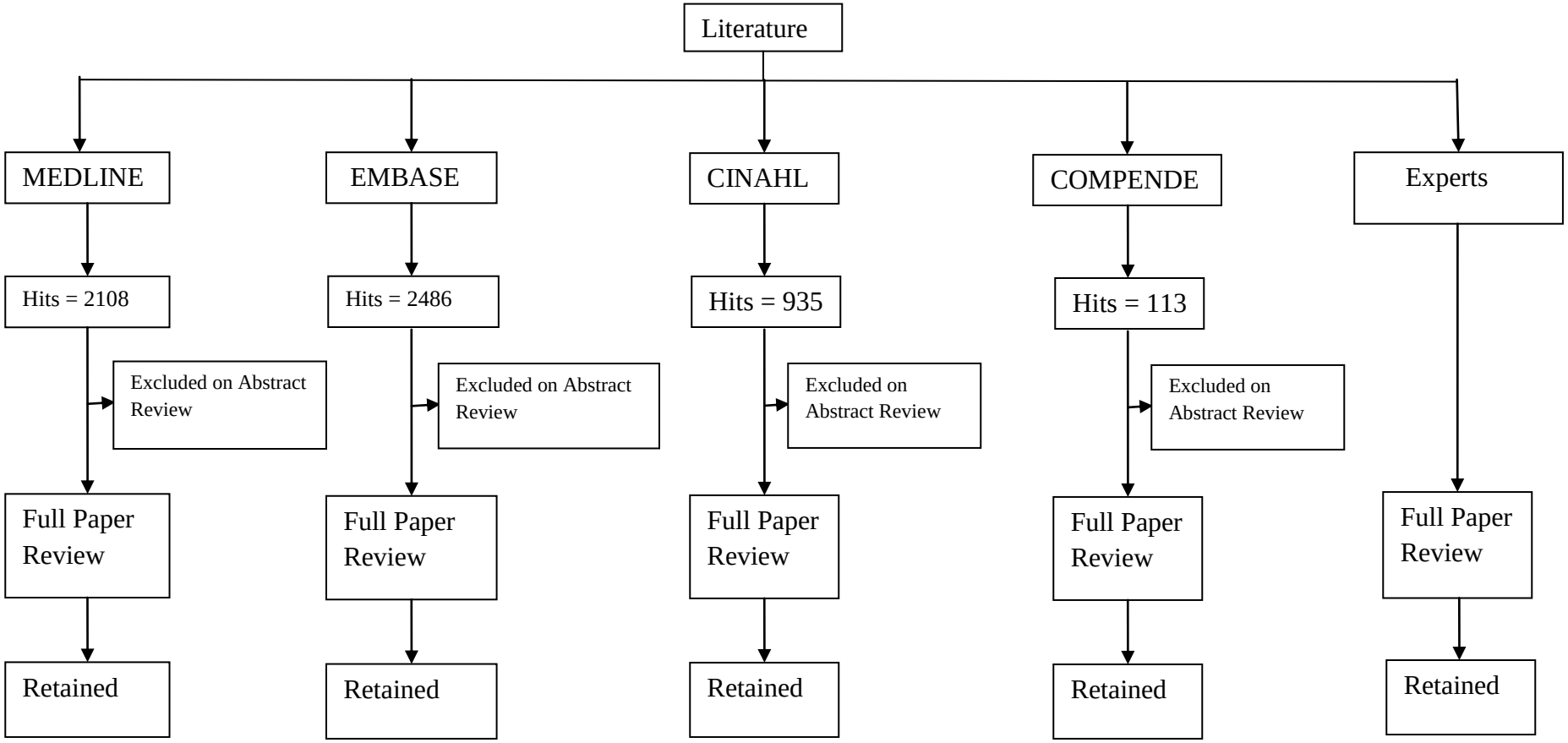
1. TX computerized physician order entry OR TX computerized prescriber entry OR TX computerized provider entry OR TX medication order entry OR TX cpoe or TX moe OR TX computer assisted drug therapy.

COMPENDEX

1. computerized physician order entry OR computerized prescriber order entry OR computerized provider order entry OR medication order entry OR cpoe.

Cancer Care Ontario
Action Cancer Ontario

Appendix 4. Flow diagram of literature search results.



Computerized Prescriber Order Entry (CPOE) for Systemic Treatment: Best Practice Guideline

Information and Technology Standards

INTRODUCTION

Organizations such as the IOM, Leapfrog Group, and the CCHIT advocate for increased use of technology to improve patient safety (1). Information technology has the potential to improve the quality and safety of patient care but also has the potential to create an increase in errors or other unanticipated consequences if not designed to support clinicians and the clinical work required (2).

Despite the documented benefits of CPOE in areas such as medication errors, adverse drug events, cost, guideline adherence, and user satisfaction (3), adoption of CPOE in healthcare organizations remains very low. The resistance is associated not only with the significant costs associated with the implementation of health technology, but also resistance from end users such as physicians and because of concerns about increase in workload and impacts on practice.

The incorporation of human factors principles into the design and implementation of CPOE systems will enhance the likelihood of user engagement and satisfaction, optimize system functionality and therefore deliver a positive contribution to the safe and effective delivery of systemic treatment. The aim of human factors engineering is to design easy to use and safe systems through the incorporation of knowledge regarding humans' cognitive and physical limitations and abilities and the application of a variety of investigative methods to the design and evaluation of technology and systems. Human factors principles of task analysis, interface design and computer supported collaborative work, enhances a multidisciplinary approach with the goal of enabling safe, comfortable human performance (4).

In order for CPOE systems to be effective, they need to be interconnected with other vital information systems such as laboratory and radiology (5). CPOE functionality needs to go beyond order entry to include integration with clinical decision support tools, alerts, and treatment protocols/regimes (1).

In addition to human factors considerations, due to the significant amount of personal health information (PHI) included in any electronic health record (EHR), CPOE functionality must also address relevant privacy legislation and security standards.

Guideline Aim

The aim of this section of the guideline is to synthesize the existing professional, industry and empirical literature describing the information and technology components of a CPOE system. This will help to develop a comprehensive understanding of the essential design and functionality features that need to be incorporated into the design, implementation and evaluation of a CPOE system.

Targeted Audience

The intended users of the information presented here are the various stakeholders and end users of a ST CPOE system. This may include, but is not limited to those directly involved in the various phases of systemic treatment for patients (e.g. physicians, nurses and pharmacists) and those who are directly involved in the design and implementation of the computerized prescriber order entry systems (e.g. clinical informatics, information technology, privacy and security).

QUESTIONS TO BE ADDRESSED

Global Question

What features, functionalities and components of a Systemic Treatment Computerized Prescriber Order Entry (ST CPOE) system are required to ensure safe, high quality systemic treatment?

Specific Questions

1. What features enhance the usability of a ST CPOE system?
2. What features enhance the functionality of a ST CPOE system (e.g. effective alerts)?
3. What are the features to enable audit logs / tracking of alerts and workarounds?
4. What are the system features that enable better building and modification of protocols/treatment regimens and documentation?
5. What are the system integration requirements for a ST CPOE system? (e.g. nomenclature, messaging, architecture, functional components)
6. What are the key privacy considerations for ST CPOE?

METHODS

Literature Search Strategy

The initial literature search was conducted in MEDLINE, EMBASE, CINAHL, and COMPENDEX utilizing the following search terms: CPOE; CPOE and systemic treatment or chemotherapy; CPOE and privacy; CPOE and security; CPOE and functionality; CPOE alerts AND/OR audits; CPOE and usability.

Additional searches were conducted by the section authors of relevant professional associations, publications of industry experts, professional standards and relevant legislation. The reference lists from retained articles were also searched for additional relevant articles.

Inclusion Criteria

Articles were included if they were published English-language reports of Phase II or III randomized controlled trials (RCTs), other comparative studies, single arm studies, practice guidelines, program evaluation studies and systematic reviews, with or without meta-analyses, that evaluated CPOE in the healthcare setting. If more than one study evaluated the same data set, only the most recent paper was selected for inclusion.

Exclusion Criteria

Abstracts, letters, editorials, notes and commentaries were not eligible.

RESULTS

WHAT ARE THE FEATURES THAT ENHANCE THE USABILITY OF A ST CPOE SYSTEM?

The usability of a CPOE system is the extent to which it can be used by clinicians to achieve the goal of safe ordering of medication effectively, efficiently and with a high degree of user satisfaction (6). Poor usability of medical information technology systems can have a negative impact on clinical performance and potentially lead to medication errors. In a study of medication errors associated with CPOE systems conducted by Koppel et al (7), the usability features identified with medication errors included poor screen displays, small font sizes, lack of vital information (e.g. patient name) on all screens and inconsistent layout of information.

An evaluation study of a single CPOE system conducted by Khajouei et al (8) identified seven categories including (1) unexpected system response (e.g. the response was not expected given the previous steps), (2) missing screen labels, (3) lack of data entry warnings, (4) poor visibility, (5) poor screen designs, (6) lack of functionality leading to increased workload and (7) alerts presented too late in the ordering process.

Chemotherapy orders in the CPOE system must be presented in an organized and clear manner, to improve communication of complex details and avoid human errors. Jeon and colleagues (9) provide guidance on the design and usability of chemotherapy preprinted orders. Some of the themes considered in order design include content organization, layout and formatting, typography, use of lines and spacing, presentation of order changes and use of checkboxes. Although cancer centres have varying policies and procedures in chemotherapy ordering and workflow, some principles on design process and content for preprinted orders may be applicable in the design of CPOE order screen or printed order copies.

Many of the challenges specific to usability can be diminished, if not eliminated by incorporating a human centred design (HCD) approach to the design and implementation of health information technologies such as CPOE systems (10). The benefits of a HCD approach include optimal product/system utilization, decreased training time and increased user satisfaction.

The international standard ISO 13407: Human-centred design process (11) defines a general process for including human-centred activities throughout a development life-cycle through four main iterative activities: specify the context (e.g. identify the users, the purpose/functions and the setting), specify the requirements (e.g. what is to be achieved), create the design solutions (e.g. general to specific), and apply appropriate evaluation methods (e.g. initial testing and ongoing monitoring). See Figure 1: Human Centered Design (Usability Professionals' Association)

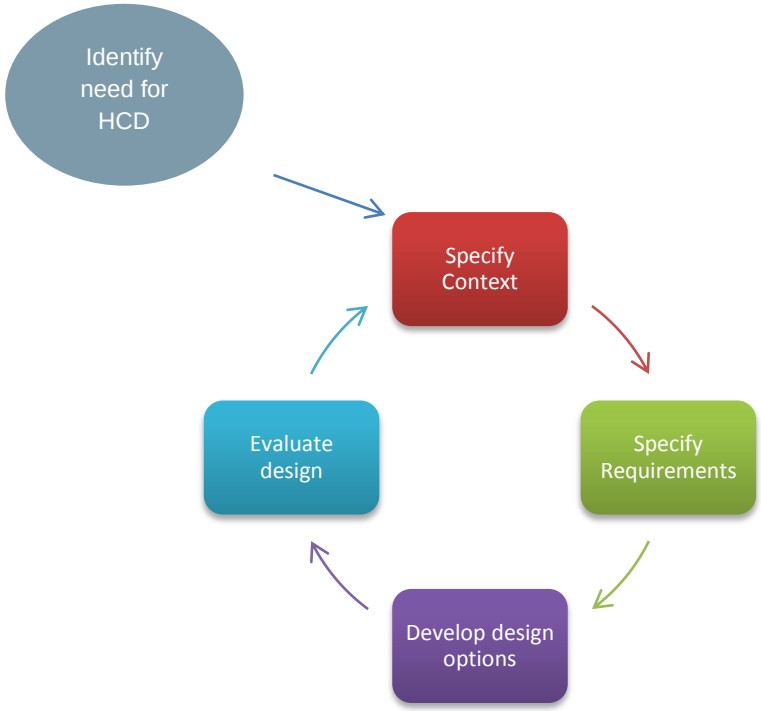


Figure 1: Human Centered Design; adapted from Usability Professionals' Association

Usability Evaluation Methods

Usability evaluation is used to determine if usability problems exist and/or to determine whether the desired objectives/outcome of the system have been achieved. Evaluation should be considered as part of the design phase, implementation phase and ongoing monitoring of system performance and outcomes. The most commonly cited methods for usability evaluation include cognitive walkthrough, heuristic evaluation, usability testing, logging actual use and user focus groups/ interviews. Cognitive walkthrough, heuristic evaluation and usability testing are commonly used in the design and testing phase, with logging actual use and user feedback obtained post-implementation.

Exercised in the usability testing phase, thinking out loud involves asking the user of the system to verbalize their thoughts, feelings, and opinions while interacting with the system as a whole, or with specific subcomponents. Test scenarios can also be used to test most common or most critical scenarios that may be encountered by the user. Cognitive walkthrough involves determining the users, the key functions and correct actions required. Heuristic method involves the use of several evaluators who independently evaluate a system to come up with potential usability problems.

Logging actual use requires the system to automatically collect information regarding system performance. Although enabled post-implementation, the performance indicators need to be identified in the design phase. Finally, user feedback obtained through interviews, focus groups or surveys is essential for to determining the degree of user satisfaction and areas for improvement.

In an effort to address challenges inherent in designing complex, technology based systems, the Usability Task Force of the Healthcare Information and Management Society (12) conducted an extensive review of the literature to determine the usability principles that would best support the design and/or purchase of technology to support the electronic medical record (EMR). The report *Defining and testing EMR usability: Principles and proposed methods of EMR usability evaluation and rating* (2009) provides a description of usability principles that can be applied to any CPOE system as part of the comparative selection process and includes usability principles specific to the following areas: simplicity, naturalness, minimizing cognitive load, efficient interactions, feedback, effective information presentation and preservation of context.

WHAT ARE THE FEATURES THAT ENHANCE THE FUNCTIONALITY OF A ST CPOE SYSTEM?

In information technology, functionality is the sum or any aspect of what a product, such as a software application or computing device, can do for a user. It is important to recognize that ST CPOE vendors will bundle different functionality in their applications. The Leapfrog Group (13) reported that ST CPOE systems are usually bundled with other software solutions that provide decision support during the medication ordering and verification process, as well as nursing administration and monitoring. Interfacing between the ST CPOE product and the hospital's collection of health information technologies (HIT) facilitates the population of appropriate information within the ST CPOE application or provides the application with access to the required patient information needed to safely prescribe, alert, verify, dispense, administer and monitor systemic treatment. Interfacing also facilitates the transfer of data and actions to and from the organization's HIT, so services that are requested would be completed and resulted.

Detailed information on specific functionality can be found by accessing the CCHIT Certified 2011 Oncology EHR Certification Criteria (14), ASCO/ONS Chemotherapy Safety Standards (15) documents and Institute of Safe Medication Practices (ISMP).

For CPOE applications within heterogeneous jurisdictional environments, and often involving different local implementation issues, site-specific software test plans can have an important role. The CCHIT has developed test scripts for certification of ambulatory Oncology EHRs that can be used to inform the development of site specific software test plans. Also, when a process is changed, software is upgraded or the environment experiences significant changes, workflow analysis should be done and policies and procedures reviewed to determine if the software continues to perform as designed so no new potential patient safety risks are introduced.

The use of alerts and prevention of alert fatigue

The implementation of electronic health records (EHRs), CPOE and clinical decision support tools has promoted the use of alerts. Alerts are pop-up boxes or notifications generated by the system that call attention to important information that meets criteria programmed into the system. The criteria can include, but are not limited to, patient demographics, lab, and pharmacy information. For example, when a clinician orders a medication for a patient, a pop-up box may alert the clinician that the dose is outside of the normal range for that patient's height and weight.

An intended use of alerting is to ease the burden of a clinician having to remember or merge details about a patient's medical history and condition with treatment plans to facilitate ordering systemic treatment safely. Beneficial in some cases, excessive alerting can result in "alert fatigue" where the clinician begins to ignore or override the alerts resulting in important information not being communicated effectively and patient safety impacted negatively (17-21).

A review of 17 studies regarding overriding of safety alerts in CPOE systems revealed that safety alerts were overridden in 49% - 96% of cases, with the most frequent reasons for overriding being alert not serious, irrelevant, or was shown repeatedly and ignored. The level of sensitivity and specificity is important in the alert functionality as the review included two studies that indicated that 36.5% - 39% of alerts were false positive (22). The sensitivity is the ability of the software to generate alerts when a potentially dangerous situation is identified and specificity is the ability of the software to generate the appropriate relevant alert during the ordering process. A safe alerting system is one that is balanced with high specificity and sensitivity and does not disrupt workflow of the clinician (21). In order to avoid alert fatigue, alerts should be clinically significant, with placement of alerts in line with established workflow process (21) and categorized based on severity and actions required (17).

WHAT ARE THE FEATURES THAT ENABLE AUDIT LOGS, TRACKING OF ALERTS AND WORKAROUNDS?

Logging and auditing are a critical component of a well-designed and secure software system. Without computer application and system logs, auditing would be difficult to accomplish. A log is a "record of an event or activity occurring within an organization's systems or networks" (23). Therefore, in a clinical system every change a physician makes to an order, a pharmacist makes in verifying an order and the nurse in administration of the order, can be audited and reported. Reports generated in clinical applications that tracks changes to orders are one example how a system can make use of application logs.

A majority of these logs exist in the system or applications background and are accessed by system administrators. Privacy, information safety and security are dependent upon closely monitoring application and system logs for real-time threat detection and mitigation and can be used for incident investigation, compliance to regulations and standards, system capacity planning and performance monitoring, troubleshooting system and network problems, evidence for legal and human resource cases, auditing employee activity and enforcing IT security policy (23). There is a wealth of knowledge contained in log files that can be utilized for quality assurance and risk mitigation purposes. A study conducted by Ash et al (24) recommends recording the percent of alerts that are triggered and number of alerts ignored or overridden as possible metrics for monitoring and evaluating ST CPOE systems. ISMP (16) advises organizations to ensure that alerts are generated and captured and to use this information to improve safe medication use processes and to support clinicians by providing feedback concerning their performance.

The management of logs is varied with some having parameters applied to purge them on a recurrent time frame (e.g. monthly) while other applications do not allow information purging. Organizations will have policies and procedures around retention of information from their

electronic systems and these are informed by health records best practices and medical information retention and disposal legislation. Knowledge of these policies and procedures and ensuring that the clinical hardware and software platforms can meet them are important in software design and vendor selection.

Lawler et al (2) defined workarounds as "deviations from prescribed care processes to more efficiently or effectively meet a task goal" (p. 344). Workarounds are used when there is a real or perceived barrier to accomplishing an activity or task and they are used to provide a temporary solution to an immediate issue. Examples of workaround for CPOE may include circumventing intentional blocks, overriding alerts, adjusting doses (despite default settings or caps) to obtain desired amount. Clinicians use of workarounds are viewed as an immediate fix and a way to expedite care, but over time and with multiple workarounds deviating from a standard of care, the risk of error is elevated and patient safety is compromised. Hence auditing of workarounds and appropriate modification of the CPOE system is required. The studying of workarounds can also provide an opportunity to identify potential improvements in the design of the system.

There are various frameworks applied at organizations for quality assurance and risk mitigation. These frameworks have process-improvement techniques to identify system inefficiencies, ineffective processes, workflow disruptions and preventable errors introduced by technology changes. Each of these techniques involves assessing performance and using findings to inform change. As such, workarounds can also be viewed as an indicator that the current practices/processes are not effective and an opportunity for quality improvement exists. If workarounds are not addressed, this continually creates opportunities for repeated workarounds and increased risk to both patient and provider.

WHAT ARE THE SYSTEM FEATURES THAT ENABLE BETTER BUILDING AND MODIFICATION OF PROTOCOLS AND TREATMENT REGIMENS AND DOCUMENTATION?

ASCO/ONS (15) defines a chemotherapy regimen as "one or more chemotherapeutic agents used alone or in combination in a well-defined protocol, generally administered cyclically". Standardization of chemotherapy regimens supports accuracy, enhances workflow by reducing uncertainty and decreases errors in the ordering, verification, and dispensing and administration process. Standardization is critical due to the complexity in the ordering and administration process of chemotherapeutic agents and the risk of severe adverse events, morbidity and mortality.

The CCHIT, criteria for Oncology includes the requirement that the EHR should support the use of oncology regimen templates (14). A regimen, or order set, typically includes the following components: start/end dates; patient demographics, height, weight, and body surface area, drug dosing, infusion and sequencing information, diagnosis; premedication, supportive care agents (e.g. intravenous hydration for cisplatin), and references (26).

Ordering of chemotherapy regimens requires information about the patient (age, sex, height, weight, diagnosis), the regimen and decision support (algorithms to calculate ideal dosages of medication, cycle reordering parameters, dose reduction parameters). These information requirements, the complexity in prescribing and the risk of severe adverse events impact the

design and functionality of a ST CPOE system used in the oncology setting and makes it unique from other systems used in the healthcare setting. See Appendix A for detailed descriptions and examples of the recommendations included.

The use of CPOE in Clinical Trials

The CPOE system should be flexible enough to allow for ordering of clinical-trial medications. This includes Phase I dose finding trials as well as Phase IV clinical trials. It should have the capability of capturing all the required clinical-trial information necessary to enroll a patient and ensure safe medication administration. This includes the following: protocol identifier, treatment arm (if applicable), regimens used for various treatment arms or dose levels (if applicable), clinical trial status, patient enrollment status, patient randomization number, kit number, ability to flag all medications that are part of the clinical trial (including marketed drugs) and any special directions or precautions necessary. Clinical trial data that can be captured in the CPOE system should comply with good clinical practices and Health Canada Food and Drug Regulations (27). Documentation should be accurate, complete, confidential, auditable, and accessible only to authorized, trained staff (28). The US FDA has also published a guidance document on "Computerized Systems Used in Clinical Investigations" (29), which provided recommendations on study protocols, standard operating procedures, source documentation and retention, internal and external security, personnel training, data entry/retrieval and other system features.

WHAT ARE THE SYSTEM INTEGRATION REQUIREMENTS FOR A ST CPOE SYSTEM? (E.G. NOMENCLATURE, MESSAGING, ARCHITECTURE, FUNCTIONAL COMPONENTS)

The electronic medical record (EMR) is an environment composed of multiple software platforms that can include administrative, pharmacy, laboratory, documentation and diagnostic software, CPOE, barcoding and clinical decision support (Lawler, 2011). The patient's electronic record is supported across inpatient and outpatient environments and is utilized by healthcare practitioners to document, monitor and manage care delivery. The data in the EMR is the legal record of what happened to the patient during encounters at the organization. These applications that can be custom programed or supplied by one or many vendors, might not be linked, causing healthcare clinicians to switch back and forth between several systems to glean all of the information necessary to treat their patients.

The safe ordering of systemic treatment for cancer patients involves some of the most complex ordering, testing, dosing and overall treatment plans of any type of illnesses. Yap et al (30) reported that outpatient oncology units that had a complete electronic medication system, including CPOE, had the lowest rates of medication error.

In addition to ISMP, Canada Health Infoway also provides direction and support for the development, maintenance and implementation of pan-Canadian health information standards to promote the transmission and sharing of information amongst healthcare providers and patients across Canada (31). In addition to these standards, Health Infoway, Ontario Medication

Management System Standards (e.g. CeRx) lists a number of pan-Canadian standards to support medication administration using health information technologies.

CPOE applications for oncology must support protocol-based ordering and require data elements or information collected or generated by other systems in the electronic health record (EHR) (Jacobson et al, 2009). Data elements such as patient demographics, allergies, height, weight, tumour identification and staging, diagnosis, pharmacy information and treatment plans are required for software to generate the appropriate treatment options and generate specific notifications and alerts (32-34).

For the CPOE application to access patient-specific data and information residing in different systems to support clinical decision-making, it must have, appropriate interfaces to manage messaging. The Institute of Safe Medication Practices (ISMP) defines an interface as a "link between two information systems such that the information from one system is immediately available to the user of the second system, and is integrated in a way that supports clinical decision-making" (http://www.ismp-canada.org/hmssa/hmssadef.htm). Interfaces are necessary for the sharing of clinical information in real time across the continuum of care and should support the consistent use of health information standards such as SNOMED CT and LOINC. Features that support such integration include the incorporation of mapping tables to keep systems synchronized for orders to transfer correctly and the merging of orders from different pathways/orders to remove redundant treatment ordering (35).

Interoperability refers to the ability of diverse systems to work together in a seamless manner. In order to facilitate the identification of the desired systems, organizations need to identify the types of functions/service requests required in order to support the requirements of the specific clinical activity (36).

Two types of interoperability are desired: interoperability with external entities and interoperability with internal/local entities. External entities may include cancer registries, provider registries, centralized systems (e.g. Ontario Laboratory Information System [OLIS]) and diagnostic imaging reports. Internal interoperability would enable integration with hospital systems such as laboratory, scheduling, diagnostic imaging, and patient information. Figure 2 depicts the various aspects of interoperability, as described by Ontario's eHealth Blueprint for the Electronic Health Record (2006).

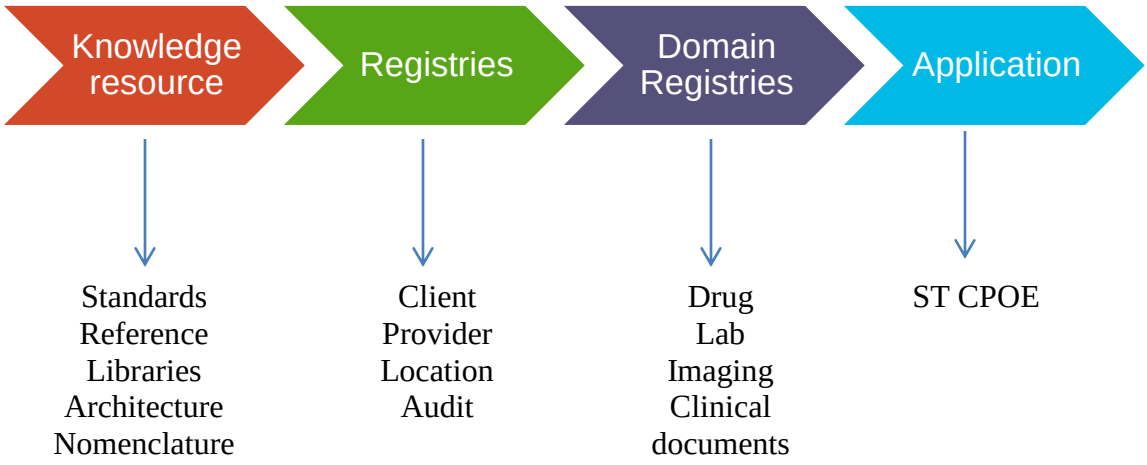


Figure 2: Interoperability, as described by Ontario's eHealth Blueprint for the Electronic Health Record (2006).

WHAT ARE THE KEY PRIVACY CONSIDERATIONS FOR A CPOE SYSTEM?

There are various privacy considerations that organizations should be aware of in relation to CPOE systems. Regardless of the CPOE system in place, organizations must ensure they are in compliance with relevant privacy legislation (e.g. Ontario's *Personal Health Information Protection Act, 2004*) and are maintaining privacy standards established though recognized associations (e.g. Canadian Standards Association). In addition to current legislated requirements, organizations need to be aware of any future changes that may impact how personal information can be collected, used and disclosed by various entities (e.g. healthcare providers and patients).

In order to balance the privacy rights of individuals, with the information requirements of organizations, the Canadian Standards Association developed the *Model Code for the Protection of Personal Information* (37) which outlines 10 generally accepted privacy principles: accountability, identifying purpose, consent, limiting collection, limiting use, disclosure & retention, accuracy, safeguards, openness, individual access and challenging compliance.

Privacy by Design (38) principles recognizes that privacy cannot be assured through regulatory frameworks, due to the growing use of networked data systems. The principles of Privacy by Design are: (1) proactive not reactive, (2) privacy as the default setting to ensure the maximum degree of privacy, (3) privacy embedded into the design of systems and practices, (4) full functionality based on win-win approach that recognizes it is possible to have balance (e.g. privacy and security), (5) full lifecycle protection of data from start to finish, (6) visibility and transparency in that the system is operating according to stated objectives, and (7) respect for user privacy by making the system user-centric.

Evaluation and monitoring mechanisms are a vital component of the privacy features of the ST CPOE system. Mechanisms need to be in place to conduct risk assessment as well as impact assessments of privacy and/or any privacy breeches.

RECOMMENDATIONS

Recommendation types

Recommendations included in the guideline are based on the review of the literature obtained that is specific to each of the questions provided above. To enable optimal utilization of the recommendations when considering the design and implementation of an ST CPOE, the recommendations have been categorized as being either Essential (E) or Desired (D). *Essential* recommendations are those deemed as being vital and, therefore must be included in the design / implementation of the CPOE system in order to achieve desired quality, patient safety and user satisfaction. *Desired* recommendations are those that are not absolutely necessary for success, but their inclusion would increase the likelihood of success and/ or achieving significant gains in quality and patient safety.

Additionally, the recommendations also have been categorized according project phases where they would be most useful (e.g. system selection / design and implementation). This will enable users to apply the recommendations in a more systematic and purposeful manner whether in the pre-implementation phase (e.g. early design/selection phase, generation of elements for inclusion in vendor RFP), implementation phase (e.g. building or enabling components to meet user needs) or post-implementation (e.g. considering upgrades and enhancements).

Pre-implementation Phase

System feature, functionality or component(s)	Recommendation	Priority Level
USABILITY	Incorporate a human-centred approach in the design, implementation and evaluation of CPOE systems	E
	Involve key stakeholders and end users in system design (e.g. physicians, pharmacists, nurses, information technology professionals, decision support, clinical informatics)	E
	Develop an evaluation strategy in design, implementation and post-implementation phases	E
	Determine indicators for ongoing quality monitoring re: usability	E
	Ensure important information "stands out" from surrounding information (e.g. bolded, highlighted, larger font); with all relevant information within one screenshot	E
	Ensure terminology is consistent with organizational and professional descriptions Ensure the process flow closely reflects current clinical/best practices	E

System feature, functionality or component(s)	Recommendation	Priority Level
	Ensure all required information is presented in a logical sequence, without requiring the user to "recall" information (e.g. previous screens) or process (e.g. where is…?)	E
	Minimize the number of steps or mouse clicks required to complete the task (e.g. use of auto-tabbing, default values, organization of information)	E
	Include feedback features to the user about the steps they are about to take and/or that actions have had the desired effect (e.g. warning message before deleting or changing information)	D
	Appropriate density: Avoid displaying too much information on a single screen, organize data at the summary level before drilling down to more details; control density through font size, character count and screen resolution. Meaningful use of colour: Use colour to convey meaning to the user in a consistent way throughout (e.g. red = warning/alert; yellow = highlight important information; green = proceed, normal) Readability: The ability to find and scan information quickly depends on the use of font (e.g. no less than font size of 12, sans serif font) andhigh contrast between background and text (e.g. black on white)	D
	Keep the screen changes and visual interruptions to a minimum during the completion of the task Ensure pop-up boxes do not obscure vital information Ensure changes made are immediately available for viewing by the user without having to refresh screens	E
FUNCTIONALITY	System Access and Permissions The system must be able to control access to personal health information to comply with information safety and security legislation including the use of electronic signatures and secure passwords. A secondary level of assigning access permissions by role or individual is required that is consistent with organizational policy and/or professional scope of practice Consideration should be given to congruent functionality factors to leverage provincial access mechanisms (e.g. One ID)	E E D
	Regimen Templates The system must support the development and use of regimen templates including the ability to link to a specific diagnosis group or clinical trial Functionality must include the ability to monitor patient entrance/exit screening processes; set minimum and maximum	E E

System feature, functionality or component(s)	Recommendation	Priority Level
	dose levels, dose ceilings and rounding values	
	Order Template The system must contain data fields to capture information as outlined in professional and jurisdictional standards (e.g. ASCO/ONS complete order standards and CCO Databook systemic treatment file)	E
	Medication Management The system must contain functionality to support the medication ordering, verification, dispensing and administration process. This includes drug eligibility, performance status capture, and independent double check, co-signature and administration checklists	E
	System Integration The system must have the ability to integrate with the EHR, Barcoding for medication administration and decision support modules. The drug database must support Canadian requirements for drug identification	D
	Information Display and Alerts The system must display version and subversion numbers for any system embedded information (TMN pathology diagnosis, staging) The information display should be clear and organized to prevent the clinician from making juxtaposition errors (tall man lettering) Ability to set alert sensitivities and clinician review of order alerts	D E E
	Reporting Capability Reporting tools must enable end users to query relevant tables and data elements Systems should have some prebuilt reports available. There should be flexibility in writing simple queries to construct complex reports and the system should allow multiple tools or report writers (e.g. Excel, Crystal Reports, ETL tools) to extract data The system must have reports for auditing and monitoring functionality, such as interfaces or alert generation or printing log files Report templates must be designed for interoperability (e.g. HL7)	D E E D
SYSTEM INTEGRATION	Client Registry Standards Allows the patient to be uniquely identified across the continuum of care. The patient identifier must be unique (only one in the system), exclusive (only used for this patient) and	E

System feature, functionality or component(s)	Recommendation	Priority Level
	eternal (never reused)	
	Provider Registry Standards Allows the unique identification for the healthcare service provider. Demographic information includes name, role, gender, regulatory college license number and the locations the provider delivers his/her service	E
	Laboratory Standards Allows access, management and storage of patient laboratory orders and results through a jurisdictional laboratory information system	E
	Drug Standards Provides clinicians with an improved ability to manage complete medication profiles through a jurisdictional drug information system	E
	Interoperable EHR Standards Allow sharing of relevant clinical information through a jurisdictional shared health information repository to support timely clinical decision-making and continuity of care	D
	Order details from the CPOE system should flow automatically into the pharmacy system. Medications ordered on the CPOE system would match to products listed in the pharmacy system (Chaffee et al, 2004, New England Healthcare, 2006)	E
	Synchronization When an update of information is made in one system then the corresponding table in the second system is automatically updated (e.g. when the admission–discharge–transfer (ADT) system updates its "patient beds" table, an HL7 message is transmitted to the CPOE system to initiate an immediate update)	D
	Medication data building and maintenance The CPOE system must provide a clear method for building, maintaining, and implementing the parent/child relationship for medication data	E
	Reduction of redundant work User-centred interfaces with automated systems need to be carefully planned to reduce the need for redundant work	E
	CPOE systems should enable electronic prescribing	E
E = Essential; must be included in CPOE application D = Desirable; not as critical for initial implementation, but will be required in the future		

Implementation Phase

System feature, functionality or component(s)	Recommendation	Priority Level
USEFUL ALERTS AND PREVENTION OF ALERT FATIGUE	Software must have appropriate computer display and screen sizing so the alerts are displayed properly	E
	Alerts need to fit into the appropriate workflow process at the right time – to early or late will require extra time for the clinician to rectify and add to the burden of work	E
	Complete, accurate and current information makes the launching of alerts highly specific and sensitive	E
	Test drug to drug interactions for high sensitivity and determine if medication interactions will alert with clinical significance	E
	Categorize alerts into groups and assign action to the alert based on severity and risk: **Trivial:** No clinical significance; no real time alert required; included on batch reports sent to the ordering clinician and auditing system at predetermined time intervals (e.g. daily, weekly). **Minor**: Alerts can be over-ridden by the prescriber **Moderately serious**: Alerts can be over-ridden by prescriber but reason must be given **Serious:** No ability to override the alert, unable to proceed in order process, and change in the order should be made.	E
	Collaboration must occur with key stakeholders such as informatics experts, clinical application specialists and clinicians, who are the end user of these alerts in the safe design, testing and use of the alerts	E
BUILDING OF PROTOCOLS AND REGIMENS	Pre-loaded starter set of modifiable regimen templates at assist in the building of a final version by the user	E
	Capability to customize rules for decision support tools and specific warnings (e.g. lab parameters displayed to trigger decision support)	E
	Dose calculation built into ordering system (e.g. pre-built dosing formulas, dose checking, optimal dosing logic and dose rounding)	E
	Capturing proper sequencing of treatment (e.g. multi-modality therapy, linked order, sequencing of regimens within a treatment plan or medications within an order)	E
	Documentation section should follow guidelines from relevant health professional organizations and/or regulatory bodies (e.g. ASCO/ONS practice guidelines)	E
	Allow screens for the entry of changes in chemotherapy treatment including reasons for modification which can be accessed by relevant system users	E

System feature, functionality or component(s)	Recommendation	Priority Level
	Order locking mechanism post order verification	E
	Ability to incorporate logic for determining cycle scheduling and treatment duration (days between cycles and total number of cycles)	E
	Flexibility to allow for therapeutic options during regimen builds (e.g. different routes of administration, selection of anti-emetic agents within a drug class)	D
	Ability to incorporate text instructions or recommendations within order sets (e.g. items that do not fit typical categories or templates such as dietary or fluid restrictions).	D
	Enable direct linkage to the MAR	E
PRIVACY	The purposes of data collection and interoperabilities with other systems must be identified with clear rationales provided	E
	Development of framework and criteria that describes the desired set of controls and best privacy practices that the organization is required to have in place	E
	Development of a risk assessment and a privacy impact/breach assessment process for internal monitoring and evaluation	E
E = Essential; must be included in CPOE application D = Desirable; not as critical for initial implementation, but will be required in the future		

Post Implementation Phase

AUDIT LOGS AND MONITORING OF WORKAROUNDS	Audit trails to include the following information: date and time recorded for each entry, any change in recorded information, and the original content of the recorded information that was changed or updated	E
	Capable of being printed separately from the recorded information	E
	Ensure logging is turned on in the software application	E
	Record the percent of alerts that fire and number of alerts ignored or overridden	E
	Regular review and analysis of log data should be done to identify system performance, trends and identify issues early so they can be addressed	E
	Aggregate log information to provide meaningful information	E
	Apply appropriate permissions for access to audit log information and reports	E
	Monitor the technology in the clinical setting for impacts and barriers to performance including human factors and ergonomics prior to and after implementation	E

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APPENDIX A: SYSTEM FEATURES THAT ENABLE THE BETTER BUILDING AND MODIFICATION OF PROTOCOLS AND TREATMENT REGIMENS AND DOCUMENTATION

Table 1: Features that reduce the potential for medication errors through integrated safety alerts and reminders

Features that reduce the potential for medication errors through integrated safety alerts and reminders	**Source**
Capability to customize rules for decision support tools, specific warnings. Safety guardrails for modifying orders o Starter set of rules for medications requiring consideration of renal or hepatic status in dosing o Warning based on patient diagnosis o Warnings based on patient age Appropriate alerts for treatment duplication, medication allergy, drug-drug intereactions	41-32
Current lab parameters added to computer generated order Allow proceed criteria to be documented on the regimen template o Regimen builder to preset treatment parameters, for verifying patient's actual lab work against these o Will provide warning if parameters do not meet criteria for proceed o Automatically calculated dose modifications	14-15; 43-44
Workflow management for patient-related outstanding tasks o View pending tasks such as: lab tests, expiring orders, etc.	41
Documentation of medication dispensing: o Lot number o Expiry date o Manufacturer	14
Improved Dosing logic o Allow complex sig (doses requiring multiple dosage strengths), alternate day dosing (100-125-100-125mg) o Can build taper dosing (steroids) o Can build dose titrations o Weekend interruptions of therapy o Total daily dose is calculated and displayed on the order o Ability to predefine template with absolute dose (vincristine, carboplatin) or AUC. Allow to cap certain medications in a specific regimen at a pre-set dosage o If dose is capped, system should alert user that value has been capped o Alert the user when a dose that exceeds the maximum recommended individual dose per regimen is entered	14, 41, 43, 45, 46
Dose calculation built into electronic ordering system o Automatically calculate dosing and modifications, based on dosing	14, 43

Features that reduce the potential for medication errors through integrated safety alerts and reminders	Source
algorithms using patient weight, height , ClCr, target AUC, sex, age o Express dose as weight based or BSA-based, weight-based, as target AUC or "flat dose", depending on the drug in ordering, dispensing and administering o Calculate and display BSA based on the most recent height and weight values recorded in the system o BSA and Clcr – option to select various equations available for calculating each type (Cockcroft Gault, Jelliffe, etc.) o Alerts the ordering physician to absolute and percentage changes in height, weight, or creatinine when the physician reordered an active regimen. Institute to set a tolerance threshold and expiry date for alerting height and weight or BSA changes.. The clinician can then choose whether to use the old or new values to calculate doses for the current treatment o Ability to calculate and display Clcr values in ml/min, and be able to ensure serum creatinine that is used for dose calculations does not fall outside of a pre-set acceptable range. The serum creatinine value used to calculate the dose should be recorded for reference	
Dose checking o Single dose medication dosage checking o Cumulative lifetime medication dosage checking o For single dose, set up minimum or maximum dose allowed, per dose, per day or per course for each available route of the drug o Designate explicit routes, units, diluents for medications and prohibit selection of other routes/units during the order process (e.g. IV only for vincristine)	14-15; 41-43, 47
Dose rounding rules incorporated into calculators o Automated to pre-defined rules o Rounds to a dose that can be reasonably measured based on vial size which is practical for the pharmacist to measure and deliver o Example: melphalan 153 mg rounded to 150 mg based on available vial size, to assure correct dosing of medication as well as serve as a potential cost-containment mechanism o Calculating does for oral chemotherapy drugs with multiple dosage strengths (e.g. round dose calculations appropriately capecitabine available in 500 and 150 mg strengths). Doses should be rounded to the nearest available combination.	14, 43, 45, 48
Site-defined order of options in choice lists for orders and order components and ability to highlight most appropriate or recommended choice o Propose alternative in a given order set (e.g. pre-set with certain breakthrough antiemetic medication options) o Ability to build IV/PO route alternatives for the same drug)	41

Features that reduce the potential for medication errors through integrated safety alerts and reminders	Source
Ability to incorporate text instructions or recommendations within order sets o For example, proceed parameters, drug funding information related to regimen, hospital formulary status, certain drugs need to be held on selected treatment days	41
Logic for displaying, timing and documenting linked orders based on: Sequential links, Time offset links, Mutually exclusive orders, Drugs mixed in same bag and Split dose **:** a) Two or more medications must be given in a specified sequence b) Allows regimen builder to set up relative times for chemo administration Example: mesna is to be given at four and eight hours after cyclophosphamide; system will automatically calculate mesna administration time on the order or the MAR if cyclophosphamide administration time is known (c) The standing and prn doses cannot be given at the same time. Incorporate logic for handling PRN dosing, have appropriate frequency logic (multiple doses over multiple days) (d) ifosfamide and mesna admixed in the same bag (e) doxorubicin dose volume required to be given in two separate syringes	15, 42 , 47, 49

Table 2: Features that enhance workflow with pertinent instructions that are easily understood and organized

Features that enhance workflow with pertinent instructions that are easily understood and organized	Source
System can configure eligibility screening criteria based on data in the system o Screening for treatment eligibility purposes o Criteria may include gender, cancer diagnosis, stage, performance status, etc.	14
Define user roles with access to order set management Provide ability to restrict access to individual order sets by user role or department o Can build two-party orders (physician writes orders in a pending status until completed by another authorized department, e.g. pending blood work, certain diagnostic procedures, requiring input from second user before order can proceed) o Allow signed chemotherapy orders to be verified by an authorized user prior to preparation. o Advanced orders can be kept in “hold” status until required to be	14, 41, 43

Features that enhance workflow with pertinent instructions that are easily understood and organized	**Source**
released.	
Facilitating ease and speed of building and changing orders Options are available for the users to locate and call up individual and groups of orders in different ways o Easy-to-find order sets (i.e. diagnosis based) o Shortcut to order sets frequently used by prescriber o Capture and display at least two protocol/clinical trial identifiers associated with a patient's single treatment regimen o Use of type-ahead, or other quick means to specify orderable item of interest	14, 41
Capture sequencing of multi-modality therapy o Capture the dates when patient will receive radiation following completion of chemotherapy) o Co-ordinate chemotherapy treatment dates with radiation days o Capture surgery performed (type/date) o Neoadjuvant versus adjuvant treatment	14
Documentation of adverse events and performance status o Capture and display adverse events as coded using NCI CTCAE o Capture and display patient performance status at each visit (e.g. ESAS, ECOG)	14
Building of documentation section should follow guidelines from health professional organizations o Example: Ability to capture independent checks and nurse co-signature	15
Medication sequencing within an order: o Medications within the order can be added, removed , copied or re-sequenced easily. o Subsequent doses can be placed relative to the date of the first dose (e.g. Day 7)	43
Capture and display disease-specific pathology information or non-anatomic prognostic indicators as discrete data or in a free text field o For example: anatomic site, histology/pathology, biomarkers, grade, lesion size, chromosomal rearrangements and other characteristics of cancers used to predict response, estimate prognosis and/or direct treatment	14
Allow free form order for miscellaneous items that do not fit typical categories or templates	41

Features that enhance workflow with pertinent instructions that are easily understood and organized	**Source**
○ For example: dietary restrictions, fluid restriction status, patient requiring isolation	
Documentation or update of staging, confirmation of diagnosis and treatment intent prior to ordering chemotherapy	14-15
System shall provide the ability to capture and display whether current treatment plan is part of a clinical trial	14
Order locking when order is in pharmacy or nursing review. Signing off on order review prior to processing • Verify orders electronically by nursing and pharmacy after physician signs • Prevent order changes once the order is in review by pharmacy or nursing • No option for order verification for active orders	42-43
Order statuses (from prescribing, dispensing to administration) appear on user screen with automatic real-time updates Order details from the CPOE system should flow automatically into the pharmacy system. Medications ordered on the CPOE system would match to products listed in the pharmacy system In addition to tracking order statuses, medication products can also be traced to an order from their preparation to administration Real-time electronic transmission to pharmacy application so that re-entry is not required to prevent delays and potential transcription errors Users must be able to view actual current medication orders at all times or be made aware of changes made by any other user. System can be enabled which would determine requirement for prescriber approval for any changes made by pharmacy or nursing.	40-41

Table 3: Features that reduce variation and unintentional oversight of orders

Features that reduce variation and unintentional oversight of orders	Source
Starter set of regimen templates, for jump-starting development of hospital-specific order sets o Pre-loaded regimens are intended to be modifiable templates to assist in the building of a final version by the user	14, 41
Provide adequate space for items in order data fields to allow entering and viewing information without truncating any data	41
Presentation of drug name, dose, route of administration, dosage form, dose units, diluent nomenclature and other abbreviations o Consistent with nomenclature used by the institution or ISMP standards o Allow tall man lettering (tall man letters are uppercase letters that are used within a drug name to highlight its primary dissimilarities with look-alike drug names) o Acceptance of generic drug names only o Ability to present brand names in upper case lettering	41, 43
Allow to set up some standard adjunctive regimens that can be linked to the chemotherapy o e.g. hydration, growth factors supportive medications or hypersensitivity management, rescue medications, urine alkalinization, etc. o Antiemetic modules or associations of individual antiemetics with chemotherapy medications specified at regimen build	14-15; 41-43
Cycle frequency and total number of cycles: o Preset the frequency of cycles o Day of cycle should be clearly defined for each drug o Cycles can be specified to repeat a number of times	14, 15, 51
Ordering subsequent cycles o Option to allow changes made in chemotherapy dosing to be carried into subsequent cycles, or cloning order from previous cycle, to reduce transcription errors o Notify user that the dose for this cycle is different from the prior cycle o Alert if chemotherapy drug is discontinued after the last cycle was ordered	14, 43

Features that reduce variation and unintentional oversight of orders	Source
○ Option to order subsequent cycle based on the regimen template	
Logic in dose modifications ○ A percentage value ○ An entered value (“flat” dose) ○ Via preset dose levels ○ When an alert is triggered, the user can take the actions suggested directly from the alert dialog box to modify or discontinue treatment; rationale for the modification are indicated on the order	14, 41, 43
Date logic in orders ○ Automatic date and time generation, dates fill in automatically for multiday/week therapy ○ Ability to update the calendar easily and push dates accordingly	15, 44
For selected orders, ability to include a field for user to select purpose ○ PRN meds, medications with different dosing for different indications	41

Table 4: Integrate and coordinate care by communicating best practices among healthcare providers

Features that integrate and coordinate care by communicating best practices among healthcare providers	Sources
Allow order screens for the entry of changes in chemotherapy treatment Reasons for modification are indicated on the order and can be accessed by relevant system users Should manage and track progress and changes in the regimen over time, ○ For example, hold, delay, omit, delete treatment, resuming chemotherapy, proceed notes, verbal orders, interventions by health professionals, with reasons for each ○ Allow documentation that certain treatment day(s) have been omitted or delayed or discontinued, so these do not appear as “not administered” in subsequent cycles ○ For a regimen that is completed or one that is discontinued before completion, capture and display (a) reason for discontinuing therapy or (b) best response achieved (e.g. stable disease, partial response) ○ When changing treatment or dosing to those different from the original protocol, system must request a reason for the changes	14, 15, 42, 43, 47

Features that integrate and coordinate care by communicating best practices among healthcare providers	Sources
Ability to select medication default to formulary options or have those listed first. o Making the selection of formulary medications increases compliance with formulary management o Ability to display recommended drug substitution (e.g. based on formulary or cost effective options)	41

Table 5: Features that modify practice through evidence-based care

Features that modify practice through evidence-based care	Source
Provide access to chemotherapy drug mixing instructions, solubility information, stability information, and storage expiration information o May reside within system or be provided through links to external sources	14
Link to protocol from the order o Link regimen template or order to references or treatment guidelines o Direct link from order to clinical trial protocols	15, 43

APPENDIX B: ABBREVIATIONS

ADE	Adverse Drug Events
ADT	Admission Discharge Transfer
AJCC	American Joint Committee on Cancer
ASCO	American Society of Clinical Oncology
ASTM	ASTM International (formerly known as American Society of Testing and Materials)
CCHIT	Certification Commission for Health Information Technology
CCI	Canadian Classification of Health Interventions
CCO	Cancer Care Ontario
CIHI	Canadian Institute for Health Information
CPOE	Computerized Prescriber Order Entry
DICOM	Digital Imaging and Communications in Medicine
DIN	Drug Information Number
EMR / EHR	Electronic Medical Record/Electronic Health Record
FDB	First Data Bank
FIPPA	Freedom of Information and Protection of Privacy Act, 1990
HCDPD	Health Canada Drug Product Database
HIPAA	Health Insurance Portability and Accountability Act, 1996
HIT	Health Information Technology
HL7	Health Level Seven International
ICD	International Statistical Classification of Disease
ICD-10-ca	Enhanced Canadian version of the 10th revision of the International Statistical Classification of Disease Related Health Problems
ISMP	Institute for Safe Medication Practices
ISO	International Organization for Standardization
LOINC	Logical Observation Identifiers Names and Codes
MAR	Medication Administration Record
MOHLTC	Ministry of Health and Long-Term Care
NACRS	National Ambulatory Care Reporting System
NIST	National Institute of Standards and Technology
OHRS	Ontario Health Reporting System
pCLOCD	pan-Canadian Laboratory Observation Code Database
PHI	Personal Health Information
PHIPA	Personal Health Information Protection Act, 2004
RCC	Regional Cancer Centres
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
ST CPOE	Systemic Treatment Computerized Prescriber Order Entry
UCUM	Unified Codes for Unit of Measure
WHO	World Health Organization

Cancer Care Ontario
Action Cancer Ontario

Computerized Prescriber Order Entry (CPOE)

For Systemic Treatment:

Best Practice Guideline

Measurement Plan: Clinical Practice Indicators

INTRODUCTION

Healthcare organizations and providers are increasingly being called upon to demonstrate the degree to which the various aspects of care delivery directly or indirectly contribute to quality patient outcomes. Evidence-based guidelines provide the road map that can be used to guide the implementation of processes, practices and systems to achieve desired outcomes.
Indicators provide a quantitative, evidence-based foundation for clinicians, organizations, researchers and health system planners to monitor and evaluate what happens to patients as a consequence of how well professional and organizational systems function to provide for the needs of patients (1).
The purpose of this component of the guideline, is to describe the process for the creation of an evaluation framework and identification of the quality indicators that will be used in the ongoing evaluation and monitoring of the ***clinical outcomes and impacts*** of the utilization of a systemic therapy computerized prescriber order entry system (ST CPOE) in outpatient chemotherapy setting.

Scope

The indicators identified were aligned with the overall process flow of CPOE. This process begins with activities initiated by the prescriber, followed by the pharmacist and ending with the nurse administration of the therapy. Although the scope of the guideline is to focus on the order entry phase of the chemotherapy medication administration process, indicators along the complete continuum will be investigated to determine the application of various checks and balances to optimize quality of care and patient safety. See Figure 1: Phases of Chemotherapy Medication process.
Indicators related to the effects of care on status of health were not considered in this plan. Those indicators include mortality, inpatient length of stay and ER visits, hospital costs and patient satisfaction.

Figure 1: Phases of Chemotherapy Medication process.

METHODS

The identification of indicators was conducted using a multi-phased approach: development of a conceptual framework, review of the literature, and obtaining consensus on the *vital few* indicators that would best contribute to the ongoing monitoring and evaluation of quality outcomes associated with the use of ST CPOE .

Phase 1: Development of Strategy Map

The measurement strategy map was developed to act as a guide in the identification of potential indicators specific to ST CPOE. The strategy map includes the overall big dot indicator or desired outcome of the utilization of ST CPOE – namely that there will be "no *unexpected adverse events related to the prescribing of chemotherapy".* To support this ultimate goal, at the macro-system level, the goal of the CCO STIP project is to achieve "90% of all outpatient chemotherapy visits supported by an ST CPOE system by 2015." The ST CPOE guideline then provides the evidence and recommendations for the design, selection, implementation and evaluation of ST CPOE system to ensure optimal quality outcomes. See Figure 2: Strategy Map: Alignment of indicators and quality dimensions.

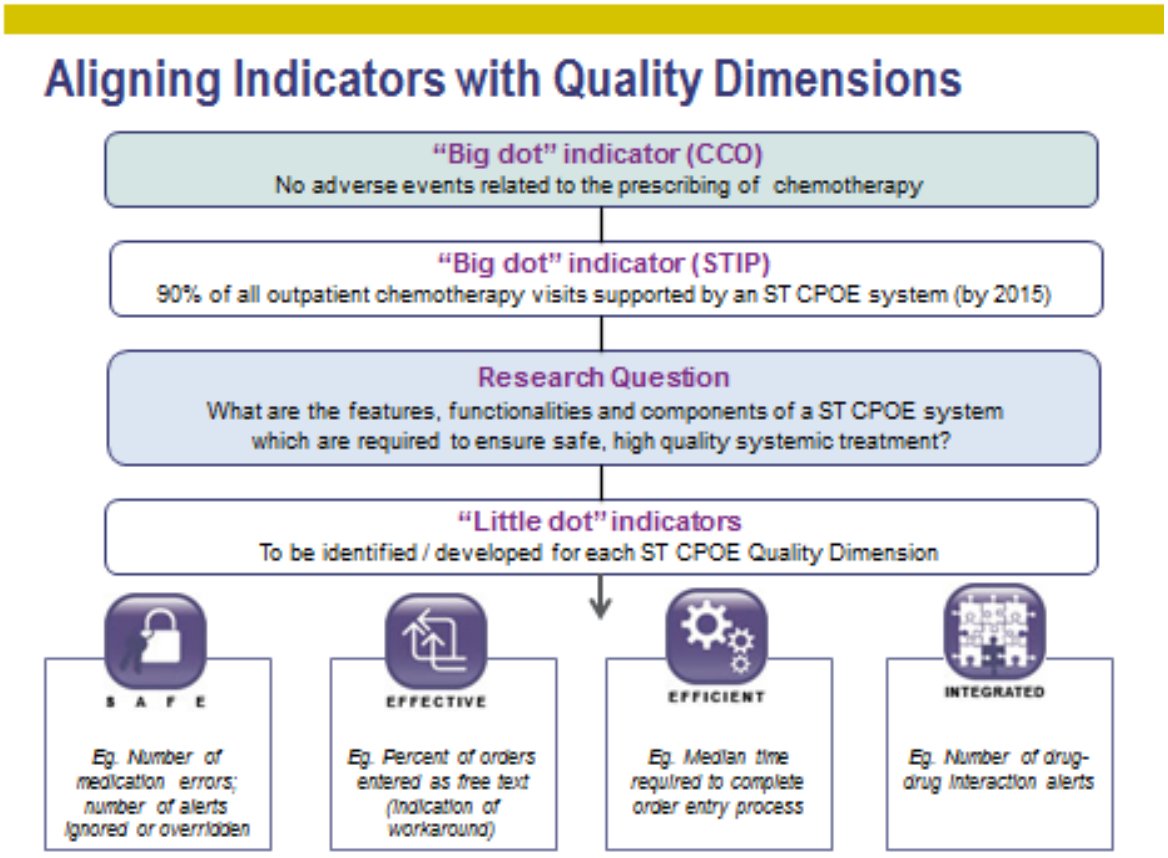

Figure 2: Strategy Map: Alignment of indicators and quality dimensions

To identify the quality dimensions most relevant to ST CPOE, CCO's Quality Dimensions were used as the foundation. See Appendix A: Cancer Care Ontario's Quality Dimensions, for complete description of the seven quality dimensions. Upon review of CCO quality dimensions and the relevant literature, the following four quality dimensions specific to this project are: safety, effectiveness, efficiency and integration. Table 1 below provides the definition of the of the ST CPOE Quality dimensions.

Table 1: ST CPOE Quality Dimensions	
Quality Dimension	ST CPOE-related definition
Safety	Avoiding, preventing and detecting adverse events related to the prescribing of chemotherapy
Effectiveness	Containing all the essential features, functions and components to enable safe delivery of chemotherapy
Efficiency	Enabling optimal and complete chemotherapy workflow through CPOE implementation and usability
Integrated	Linking the information and decision support systems relevant to the prescribing of chemotherapy

Phase 2: Review of the literature

The initial list of indicators was identified through a review of the literature used for the development of the ST CPOE guideline described in this document. Literature describing both clinical care and health information technology aspects of CPOE systems was included in the review. In additional to peer reviewed literature, environmental scans of grey literature, internal CCO reports (e.g. OPIS related reports, and logs) and key information interviews with from several cancer centres in North America implementing mature CPOE systems also provided some information on potential indicators.

Criteria for Indicator Selection

The literature provides a variety of criteria for the identification, selection or development of indicators. The National Quality Forum (2) evaluation criteria for measures require that proposed indicators must meet the following criteria:

1. Impact-opportunity-evidence: the extent to which the indicator is evidence-based, ability to impact healthcare quality and improving health outcomes
2. Reliability and Validity: the ability of the indicator to produce consistent (reliable) and credible (valid) results
3. Usability: the extent to which the intended end-users of the information (e.g. clinicians, researchers, health system administrators and clients) can understand the results and apply them for decision-making
4. Feasibility: the extent to which the required information is readily available or obtained without undue burden

Similarly, Mainz (1) describes seven key indicator characteristics as: (1) based on agreed definitions, (2) highly specific and sensitive, (3) valid and reliable, (4) discriminating, (5) high degree of meaningfulness and relevance, (6) permits useful comparisons and (7) is evidence based.

For the purpose of this project, the criteria for indicator selection included: Evidence based, valid, reliable, comparable, relevant and measureable/feasible.

Phase 3: Generation of potential list of indicators

The review of the literature resulted in an initial list of 118 indicators. Four members of the core team individually reviewed the complete list to determine any area of duplication and to categorize the indicators according to the one of the four quality dimensions included in the framework. Results from the independent review were then compared to determine the degree of concordance and consensus. For discordant results, the group met to review the specific indicators and reach appropriate consensus and mapping of the indicators. The initial review resulted in a total of 55 indicators each assigned within a distinct quality dimension.

For each of the 55 indicators, metadata were developed in order to fully describe and better determine the value of the indicator. Indicator metadata refers to indicator name, rationale and the information about how the indicator is constructed (3). This is distinct from the information used to measure the indicator (e.g. numerator and denominator). See Appendix B: Indicator Description Template.

The 55 indicators were again reviewed by the core team along with ST CPOE users and informatics specialists. This additional round of indicator review and validation resulted in a further reduction of indicators to 18 each aligned with one of the four quality dimensions.

Upon review the clustering of indicators within each quality dimension, sub-dimensions were identified within the safety and effectiveness dimensions. The safety quality dimension was further stratified into the following three sub-dimensions: Alerts (e.g. number of alerts triggered), Near misses/ intercepted errors (e.g. number of adjusted orders), and Non-intercepted errors (number of medication errors). The subthemes within the effectiveness dimension were described as regimen utilization (e.g. protocol consistent order rate) and CPOE utilization (e.g. physician utilization rate). See Appendix C: Description of outcome indicators.

Phase 4: External review and consensus building

To determine the vital few indicators to be used to monitor and evaluate ST CPOE systems, a Modified Delphi methodology was applied using a two phased approach. The Delphi technique uses a series of questionnaires or “rounds” of consultation to gather information and synthesize knowledge from targeted stakeholders from a variety of professional, regional and organizational perspectives (4).

Phase A involved content experts within CCO, who had not been directly involved in the development of the guideline and/or the indicators. Upon completion of the internal content expert review, the remaining indicators will then undergo review by external content experts representing various professional designations, regions and expertise with CPOE systems. See Table 1: Modified Delphi process and participants.

Table 1: Modified Delphi process and participants.

	Participants	Method	Desired outcome
Phase A	CCO; ST CPOE project sponsors; members of Project Leadership Team (PLT)	Face-face ; online	Obtain consensus on the list of indicators for external review
Phase B	Regional Systemic Treatment Program (RSTP) Leads, Systemic Treatment Program Leads, CPOE system superusers	Online format	Obtain consensus on the final list of indicators to be included in the measurement plan

Using a four point Likert scale (1 = Strongly disagree ; 4 = Strongly agree), participants for each modified Delphi exercise were asked the rate each of the indicators based on the degree to which the indicator supports safe patient care, optimal clinician practice, elimination of adverse events and enhances increased utilization of ST CPOE systems to support delivery of chemotherapy. Consensus was determined based on the percentage of respondents' level of agreement, which the threshold of 75 % agreement established a priori. See Figure 3: Process for selection of clinical indicators.

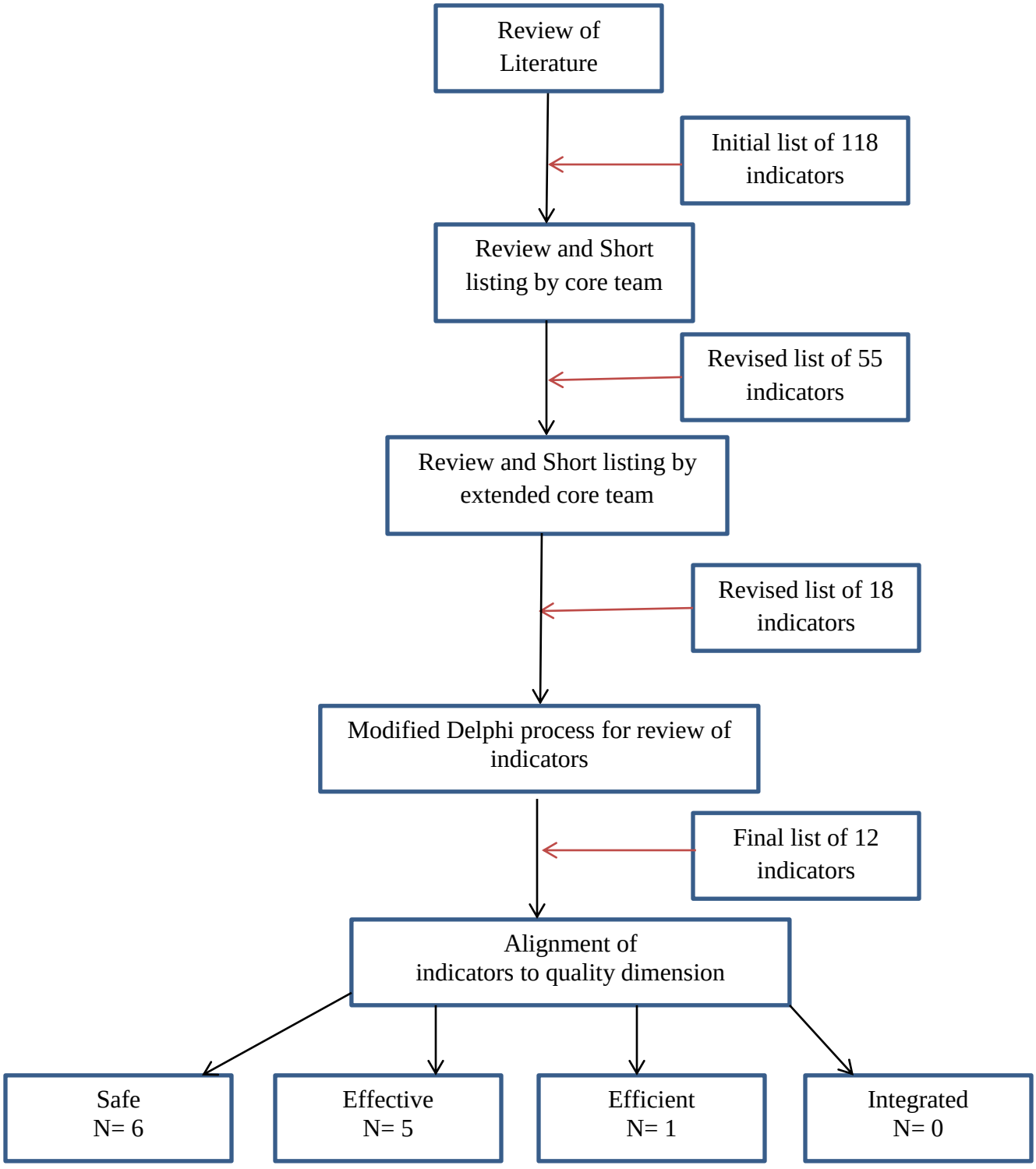

Figure 3: Process for selection of clinical practice indicators.

RESULTS

As a result of the Modified Delphi exercises, 12 clinical practice indicators (CPI) were deemed as relevant for overall evaluation and research purposes specific to ST CPOE systems. The final list of indicators was aligned with three of the four quality dimensions. See Appendix C: Description of Outcome Indicators. Within this group, four indicators were identified as being valuable for regular quality monitoring and reporting at the organizational, regional and provincial levels. These included: interception order rate (i.e. as a proxy for near miss), medication error rate, utilization rate of chemotherapy orders entered via ST CPOE and utilization rate of prescribers using ST CPOE.

Although there were no clinical practice indicators that aligned with the Integration quality dimension, the 68 recommendations specific to information and technology standards have been identified for key areas such as usability, functionality, system integration, alerts, audits, regimen protocol, and privacy features within ST CPOE systems. These recommendations, based on the best available evidence, can be used to support the design, implementation and evaluation of ST CPOE systems. See Information and Technology Standards chapter for details regarding the information and technology standards and recommendations.

CONCLUSIONS

Through engagement of experts and evidence review, clinical practice indicators for ST CPOE systems has been identified which will facilitate appropriate evaluation of the impacts of ST CPOE on clinical practice and quality of care outcomes.

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APPENDIX A: Cancer Care Ontario Quality Dimension

Each indicator is a specific measurement of progress against one of seven dimensions of quality. These quality dimensions were adopted by CCO to help us focus our efforts in improving the cancer system.

Avoiding, preventing and ameliorating adverse outcomes or injuries caused by healthcare management.

Providing services based on scientific knowledge to all who could benefit.

Making health services available in the most suitable setting in a reasonable time and distance.

Providing care that is respectful of and responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions.

Optimally using resources to achieve desired outcomes.

Providing care and ensuring health status does not vary in quality because of personal characteristics (gender, ethnicity, geographic location, SES).

Coordinating health services across the various functions, activities and operating units of a system.

APPENDIX B: Indicator Description Template

Component	Description
Indicator Number	Unique number assigned to each indicator
Indicator Definition	Description of indicator: Provides a concise statement of the specific aspects of healthcare, the PHC client/patient population, providers, setting(s) of care and time period that the measure addresses
Definition of Relevant terms	Objective, standardized and comprehensible definition of key words or phrases included in the indicator definition.
Quality Dimension	Assigned quality dimension (Safe, Efficient, Effective, Integrated)
Method of Calculation	Numerator for count indicators numerator and denominator for rate-based indicators, or other method of calculation, is presented
Numerator	Provides the description of the general specifications of any component (e.g. screened for depression) that is the basis for inclusions and exclusions in the numerator
Denominator	Provides the description of the general specifications of any component (e.g. screened for depression) that is the basis for inclusions and exclusions in the denominator
Data source, availability, limitations	Identifies the likely data source(s) necessary to calculate the measure (e.g. clinical administrative data, other administrative or survey) and whether it is available on a pan-Canadian basis. "Partial" refers to indicators that can be calculated for only some dimensions of the indicator (e.g. indicator can be calculated for physicians but not all PHC provider types). "No data source" refers to indicators that either would require a new data source, or would require that additions (i.e. new survey questions) be made to an existing data source to support pan-Canadian reporting
Data elements	Key data elements from the data source
Rationale and interpretation	Identifies the justification for the indicator and briefly explains the importance of the measure (i.e. why it is used), description of the best available evidence or literature to support the need for the indicator, and how the results can be interpreted. The evidence/policy base for indicators include: a. Clinical indicators—Grade A/B recommendations or Level 1 evidence. b. System indicators (non-clinical)—strong support by health policy initiatives; systematic literature reviews; NES objectives; participant consensus. Interpretation of score (directional statement) is classified according to whether the quantitative summary measure is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score
Caveats, Warnings	Potential for errors in collection, analysis and interpretation
Adapted from Good Indicator guide (2008)	

APPENDIX C: Description of Outcome Indicators (N=12)

Indicator Name	Indicator Definition	Quality Dimension	Quality subdimension
1. Triggered Alert Rate (per order, per visit, per patient)	The percentage of medication orders where alerts triggered during the order process	Safe	Alerts
2. Override Rate	The proportion of triggered alerts that where overridden or ignored during the order process	Safe	Alerts
3. Intercepted Order Rate (per order)	The percentage of medication orders where errors were intercepted	Safe	Near Miss / Intercepted
4. Adjusted Order Rate (per order)	The percentage of medication orders that where altered or adjusted	Safe	Near Miss / Intercepted
5. Chemotherapy Medication Error Rate (per order)	The percentage of medication orders resulting in nonintercepted serious medication errors	Safe	Non intercepted
6. Adverse Drug Event Rate	The proportion of nonintercepted chemotherapy medication orders resulting in serious adverse drug events	Safe	Non intercepted
7. Unsigned Order Rate (per order)	The percent of reduction in unsigned orders	Efficient	
8. Order Set Rate (per order)	The rate of order sets used per medication order	Effective	
9. Free Text Rate (per order)	The percentage of medication orders entered with free text or as "miscellaneous"	Effective	
10. Protocol-Consistent Order Rate (per order)	The percentage of medication orders where protocol-consistent dosage decisions was made	Effective	Regimen Utilization
11. Utilization Rate (per order)	The percentage of medication orders entered in the ST CPOE system	Effective	CPOE Utilization
12. Utilization Rate (per prescriber)	The percentage of prescribers using ST CPOE	Effective	CPOE Utilization

Computerized Prescriber Order Entry (CPOE)

For Systemic Treatment:

Best Practice Guideline

Conclusions

The chapters comprising this guideline reflect the synthesis of the literature reviewed to further our understanding of the features, functionalities, and components of a ST CPOE system must ensure safe, high quality systemic treatment. No previously published guideline has investigated both the clinical as well as the information and technology features of a CPOE system by bringing together two distinct spheres of literature to demonstrate the interdependence between clinical and health information technology sectors.
The synthesis of the findings included within this guideline provides new insights that can be clustered within the following areas:

1. There is significant amount of health research literature describing the benefits of CPOE systems in reducing chemotherapy medication errors.
2. The health information technology literature provides a wealth of guidance on the system design features that have been demonstrated to optimize the functioning of CPOE systems, enable clinical practice and contribute to patient outcomes.
3. The literature describing human factors demonstrated the value of incorporating human centred design principles in design, implementation and evaluation of CPOE systems to ensure the information technology system designed supports clinicians, clinical practice and processes.
4. The literature from both clinical and health information technology fields provide a foundation for measuring and/or evaluating ST CPOE systems in terms of process (e.g. efficiency and effectiveness), outcome (e.g. number of alerts triggered, impact on team communication) and impact (e.g. reduction in near misses and errors).

This guideline provides an innovative approach to technology evaluation focusing on clinical practice driving information technology and not the other way around. In order for information technology to support clinicians and clinical practices, human-centred design principles must be applied to ensure that system features enable clinical best practice and ultimately optimal patient outcomes. Figure 1 displays the relationship between human factors as a foundation for system design to support clinical practice and patient outcomes.

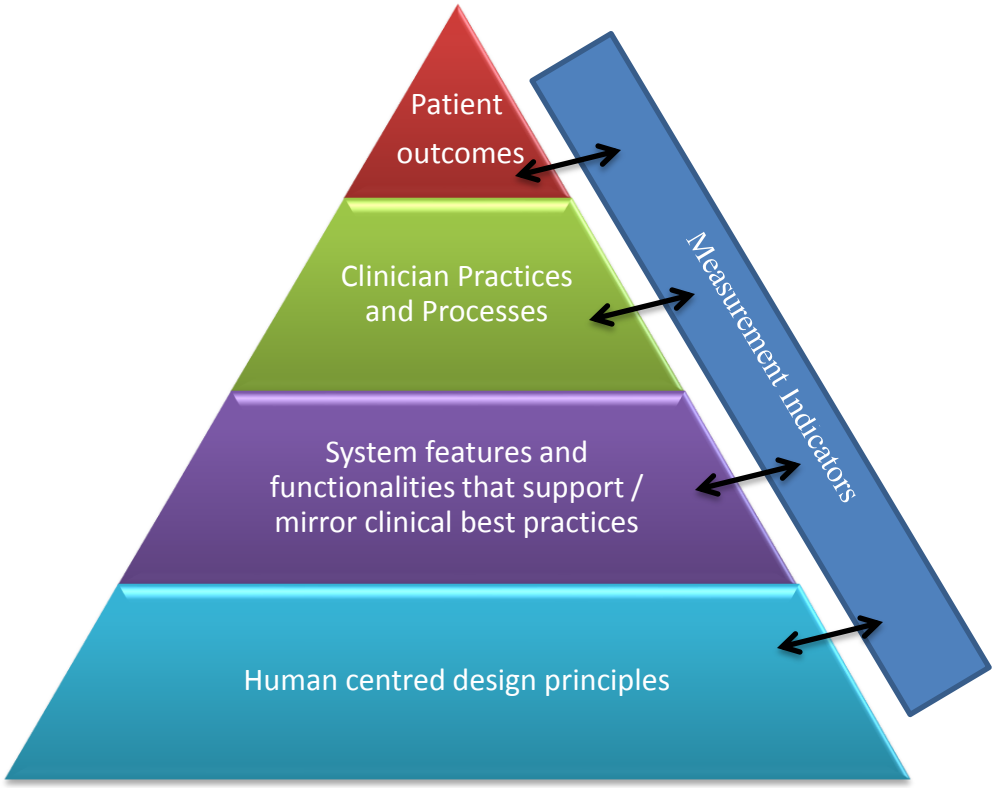


Figure 1: Relationship between human-centred design in supporting clinical practice and patient outcomes.

Cancer Centre Consultations

In addition to the review of the literature, consultations with cancer centres, known for their experience with ST CPOE systems were undertaken. A total of seven cancer centres were included in the consultations and represented centres from the United States and Canada. See Appendix A for centres included and semi-structured interview guide. Telephone interviews were held with individuals with direct involvement in the design, implementation and ongoing monitoring of the CPOE system (e.g. Director of Pharmacy; Director of Outpatient Oncology). Table 1 provides summary of key findings from the interviews.

Table 1 : Key findings from the Cancer Centre Interviews	
Theme	Description
System integration	Majority of the ST CPOE system were internally built and linked to pre-existing CPOE systems; systems are linked with other internal systems such as pharmacy, radiology, lab, path, etc. Fully integrated with decision supports such as pharmacy formulary, treatment protocols and regimens Although fully integrated with internal services, inpatient and outpatient systems remained separate causing challenges for data flow and planning

Table 1 : Key findings from the Cancer Centre Interviews	
Theme	Description
Data Use	Several reports available (e.g. drugs that are ordered but not administered; regimen usage reports, alerts around workarounds), yet there were few examples of utilization of outputs from reports for ongoing quality monitoring and improvements
Importance of multidisciplinary collaboration	The involvement of key stakeholders (e.g. clinicians, informatics, decision support) in working groups/committees to determine design, review enhancements was vital to successful uptake and optimal utilization Need to ensure that systems are built to support best practices and improve the workflow/practice processes (e.g. not just about status quo) Senior leadership sponsorship is key to sustainability
Benefits	Little/no empirical evidence being gathered/monitored for. Anecdotal evidence as to benefits were based on "we are noticing less of…"
Challenges	Potential negative impacts such as decreased team communication due to less need for face-face interaction

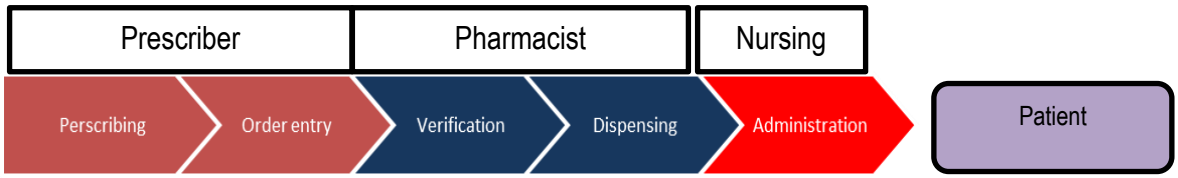
Key recommendations

Based on the review of the literature and the themes generated from the key informant interviews, the following recommendations are provided:

1. CPOE systems should be used in outpatient chemotherapy delivery to decrease chemotherapy related medication errors.
2. A human-centred design approach should be used in the design, implementation and evaluation of ST CPOE systems
3. Direct and active involvement of key stakeholders and end users of the system (e.g. physicians, pharmacists, nurses, information technology, decision support and clinical informatics professionals) is vital to ensure optimal system design, functionality and desired outcomes (e.g. design, implementation and ongoing monitoring and improvements)
4. ST CPOE processes must mirror, optimize and potentiate clinical best practices and optimal workflow
5. Optimal system integration is desired (e.g. diagnostic information, client data) in order to optimize clinical decision-making and enable multi-leveled verification and alerts
6. Reporting of data is required to support quality monitoring, evidence-based quality improvements and research

Implications for practice

The three main roles involved in the safe provision of chemotherapy are oncologists, pharmacists and nurses. As each profession has a distinct role in the chemotherapy administration process, there are distinct and overlapping functionalities within ST CPOE to enable best practices (e.g. clinical decision-making) and patient outcomes (e.g. safety).



Due to the inherent risk associated with the provision of chemotherapy, various professional associations have developed chemotherapy administration standards to optimize safety for both the professional involved (e.g. physician, pharmacist, nurse) and the patient. In recognition of the expanded roles of healthcare professionals, such as nurse practitioners, the more inclusive term of *prescriber* is used when referring to the ordering of chemotherapy.

The ASCOin partnership with the ONS have developed Chemotherapy Administration Safety Standards (1)that include standards regarding staffing (e.g. qualifications of prescribers, education requirements), documentation requirements (e.g. client assessment, diagnostics), order standards (e.g. process and content requirements), preparation (e.g. requirements for verification, drug labeling), administration (e.g. verification) and monitoring (e.g. client response to treatment).

Similarly, the CAPhO, has also provided standards of practice for oncology pharmacy (2). The standards provide clear guidance for pharmacists involved in chemotherapy medication process, their role as a member of the interprofessional team, and also recognises the role of the pharmacy technician in the medication process.

The standards for each of the professionals focus on the "what" that needs to occur in order to provide safe chemotherapy and recognize the interdependency of the interprofessional team in the medication administration process. As ST CPOE may have a negative impact on team communication and collaboration (3,4) it is necessary to ensure that all members of the interprofessional team are aware of their unique and collective roles in safe administration of chemotherapy.
See Table 2 for depiction of clinician roles in key steps of chemotherapy administration process.

Table 2: Clinician roles in steps of chemotherapy administration process.			
	Prescriber	**Pharmacist**	**Nurse**
Authentication of users from prescribing to administration processes and system access	X	X	X
Client identification	X	X	X
Client diagnostics (e.g. BSA)	X	X	X
Prescribe regimen (e.g. CHOP)	X		
Verification of order (e.g. dosage, contraindications)		X	X
Drug preparation and dispensing		X	
Administration			X
Documentation	X	X	X

In addition to the professional standards described above, ASCO/ONS has developed Sample Policies for Safe Chemotherapy Administration (5). The policy templates follow the standards and allow for customization at the organizational level, while reflecting the ASCO/ONS standards. The intention of the sample policy guide is to assist healthcare professionals and their employers to implement policies and procedures that will enhance role clarity for those involved in the chemotherapy medication process, with the desired end result of optimizing patient safety.

Implications for Research

The outcomes of the literature reviews revealed the presence of a significant body of research related to CPOE systems in general, yet a very limited number of publications or research studies that were specific to ST CPOE systems in either inpatient or outpatient oncology settings were discovered. Most of the studies reviewed were descriptive in nature (e.g. describing implementation; pre-/post-study designs) and did not include a description of the features, functionalities that may have contributed to the outcomes cited in the studies. As this guideline has demonstrated, the interface between the functionalities, clinician practice and outcomes is key to determining the collective impacts on patient safety. Based on the learnings from the guideline development process, the opportunities for future research include the following:

a. Due to the complexity of the ordering process and the significant potential for harm to the patient, there is a need for research specific to ST CPOE systems and their impacts on patient safety and clinical practice.

b. Despite the interprofessional interdependencies within the chemotherapy medication process, there is a paucity of literature describing the implication of CPOE for roles other than physician (e.g. the impacts specific to pharmacy and/or nursing).
c. The limited description of human factors engineering or human centred design principles in the design of CPOE systems warrants further study due to the importance of usability and functionality in the success of CPOE systems and user uptake.
d. Although the principles we have presented in this document encompass important aspects of a CPOE systems which are applicable to inpatient chemotherapy, paediatric chemotherapy and oral chemotherapy prescribing, we feel that these areas still have unique aspects that require formal evaluation.
e. CPOE system vendor design research is required to develop a standardized and optimal industry design of products for the safe prescribing of chemotherapy. This will not only include the design/architecture of the prescriber screen but requires evaluation of the verification screen by nurses and pharmacists, and the dispensing/preparation screen by pharmacists and pharmacy technicians.

Innovations and Future Direction

ePrescribing

Electronic prescribing is an electronic way of generating prescriptions through ePrescribing software and transmission networks that link with participating pharmacies. The number of drugs in cancer care has increased and a larger portion of these drugs are oral chemotherapy agents. While these drugs are taken at home, oral chemotherapy requires the same safety processes as IV chemotherapy including flow of vital information into the prescribing system, appropriate clinician decision support and pharmacy support for both verification and dispensing. ePrescrbing has been adopted effectively in many jurisdictions, hence the leveraging of CPOE systems with ePrescribing technology would be valuable. Prescriptions generated through the CPOE system directly linked to generate orders at participating pharmacies would ensure accurate transmission of information and potentially also include clinical decision support tools at the point of care. Safety concerns around such a model will require careful evaluation.

Bar-Coded Medication Administration (BCMA): Barcode technology has proven to significantly reduce the rate of dispensing errors and potential adverse drug events due to dispensing errors (6). A decrease in these types of errors should also be seen in dispensing processes involving pre-mixed intravenous medications (Poon et al, 2005). Possible future applications involve many areas of care whereby the nurse may scan a barcode from a master sheet for a particular service or action performed, simultaneously it is electronically inputting the action into an electronic health record (7). Barcoding technology has also shown its value in decreasing administration related errors as these systems inherently provide the five rights of nursing administration (i.e. right patient, right dose, right route, right time and right medication). As such, further innovation and advancement of barcoding technology for chemotherapy intravenous medications and services could have a substantial effect on CPOE as a tool to improve patient safety. This would require CPOE systems to link with administration modules or to have these features embedded within the system.

Radiofrequency Identification (RFID): RFID is a rapidly evolving technology, but more expensive than bar coding which uses older technology.A disadvantage of barcoding requires it to be scanned one at a time in the scanner's line of sight, whereas RFID allows multiple scanning at once and isn't limited to a user's line of sight. It is expected that RFID will in the near future, position itself in the healthcare market as an effective technology for patient, device and supply identification and tracking applications (8). High patient volume oncology centres, may one day greatly benefit from RFID technology incorporated into their ST CPOE systems which in turn could result in effective and efficient workflows.

Clinical Data Warehouses and Research: Having an effective, efficient and secure means of data storage, transfer and analysis is becoming a vital component in any healthcare research environment. Innovation and advancement in technology has created great strides in improving all of these aspects. Clinical data warehouses for research and web-based data capture systems are recent advancements that have been developed using state-of-the-art technology, to improve the storage, transfer and analysis of clinical data (8). Advancements in ST CPOE systems incorporating these types of platforms will ensure effective use of clinical data from the point of order entry.

Interoperability Standards: Innovation and advancement is required in healthcare in order to enforce a mechanism, via standards, of communicating technology (e.g. SNOMED, LOINC, etc.) and normalizing the discrete data captured by ST CPOE (HIMSS Analytics, 2005).

Tablets: Electronic tablets have made great strides since being first introduced to healthcare environments and have been applied in a number of US hospitals, in areas such as electronic prescribing, clinician access to electronic medical records, physician access to patient charts and data entry, patient assessment and education. Pen tablets provide a much larger screen area for viewing information, which is crucial in acute care settings. Studies have found, physicians like these devices for their simplicity, weight, and data input design, but can also create a disadvantage at it creates yet another device IT departments must support and maintain, resulting in relatively low adoption rates. In order for increased CPOE adoption on tablets, design for these devices must improve before adoption by physicians can occur (8).

Mobile Health: The feasibility of mobile devices supporting healthcare has also steadily improved over the past few years. Unlike CPOE, handheld devices and other mobile technologies have obtained higher adoption rates in healthcare. With the availability of handheld devices growing along with the demand for CPOE, vendors are looking towards implementing full CPOE functionality onto handheld devices. IT vendors, hospitals, and clinicians are trying to have full CPOE functionality on all platforms including computer workstations, rolling laptops, tablet PCs, and handheld devices. With increasing 3G and 4G rollouts and with fibreoptic data transmission to support, a whole new world of possibilities in using mobiles and the internet to address healthcare challenges has opened up (9).

Smart Infusion Pumps: Although Intravenous infusions pumps have come a long way in order to improve accuracy and continuity of IV infusions, they have also been identified as contributors to medication errors and the injuries that result from them, mainly as a result of manual input error. In order to reduce these types of errors healthcare manufacturers have

created pumps that have Dose Error Reduction Systems (DERS), which encompass hospital defined drug libraries with dosing limits and other clinical advisories built into the system. Many healthcare facilities have implemented smart pumps as a stand-alone system rather than integrating them with other clinical information systems such as CPOE's. This is mainly due to hospitals not having the proper infrastructure in place to support a fully established integrated approach that allows connectivity between various healthcare technologies. Future adoption of smart pump technology should incorporate wireless connectivity which will ensure an integrated wireless infrastructure as well as connectivity to CPOE to ensure a closed-loop medication administration system. Future innovations of smart pumps with CPOE, real-time vital sign alerts or laboratory results hold promise for improving overall safety benefits (10).

Server Based Voice Recognition and Auditory Dispensing Support: Innovation in voice recognition is also expected to have a significant impact on hospital CPOE systems (11). Transcription services in some facilities across the US and Canada have been eliminated, due to software that allows physicians to use voice recognition at any computer, including laptops and mobile devices (12). For example, a radiologist can open the next patient queued to the system and dictate a report using voice recognition. The report is immediately placed, the clinician is contacted, and results disseminated to staff, all of which are permanently documented (Macios, 2007). Auditory alert mechanisms have also proved to be beneficial in order to avoid picking the wrong drug from the cabinet. New innovative designs alert the user with an auditory alarm if the wrong bin opens for drug administration (13).

Robotics: Recent advancements and innovation have also been seen in the form of robotic technologies involved in the preparation of chemotherapy medications. Royal Victoria Hospital has implemented a state of the art robotic technology called Robotic Intravenous Automation System (RIVA; Intelligent Hospital Systems) to its new Cancer Centre (14). This system will be used for the preparation of chemotherapy medication and is currently being installed in one of their satellite pharmacies. The RIVA unit with its robotic arm will safeguard each of the very complex and patient-specific chemotherapy medications are prepared safely and accurately in a sterile, automated environment. The Mission Health System in Asheville, North Carolina has also implemented RIVA into Production (15).

CONCLUSION

This guideline provides an evidence-based summary of the use of a computerized prescriber order entry system for safe prescribing of outpatient chemotherapy. The guideline further highlights both the clinical and technical aspects related to the use of such systems and emphasize necessary features and functionalities within the CPOE system. It is anticipated that the use of this guideline in the selection, adoption or implementation of these systems will provide relevant insight for information technology teams on the clinical impact of CPOE and clinical teams on important technical aspects.

It is recognized that the ongoing adoption of such technology safety solutions within the field of medicine is central to further improve patient safety given the safety concerns associated with chemotherapy medications.

The universal adoption of ST CPOE systems is not without cost implications for hospitals not only in adopting such systems but also ensuring ongoing maintenance and evaluation; hence, the healthcare team is accountable for ensuring not only the safety improvements associated with these systems but also the maximal use and capability.

As the desired future state will have most centres using these systems within cancer care, the field of evaluation will need to change from pre-implementation/implementation phases to ongoing maintenance. This area has not been well evaluated in the literature and ongoing evaluation of quality indicators over time will provide the ability to develop a benchmark for the maximal use and effectiveness of these systems while recognizing the roles and work-flow of the clinical teams that use them.

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Appendix A: Cancer Centre Consultations

Participating Cancer Centres

1. Alberta Health Services
2. Cleveland Clinic
3. Dana Farber Cancer Institute
4. Harvard Brigham and Women's Hospital
5. Northwestern Memorial Hospital
6. Roswell Park Memorial Institute
7. University of California, Los Angeles - Jonnson Cancer Centre

Semi-structured interview guide

1. What ST CPOE system is in use at your Centre and how long has it been in place? Why did you choose this system? What were some of the critical factors in helping you select this system?
2. Does your existing ST CPOE system integrate with any other system(s)?
3. What type of alerts does the CPOE system include?
4. What type of Decision Support tools does the CPOE provide?
5. Please describe any reporting capabilities of your existing ST CPOE system.
6. What have been your implementation and adoption challenges with ST CPOE for acceptance and adoption by all of your clinicians/users?
7. What benefits have been achieved through the use of ST CPOE at your Centre?
8. Have negative impacts resulted from the use of ST CPOE at your Centre? If so, what are they (e.g. what are the risks of implementing ST CPOE?)
9. How is the ST CPOE product lifecycle managed? (E.g. Software upgrades, ongoing operational supports, etc.)
10. What key advice do you have to share with future sites implementing ST CPOE?