Evidence-Based Series 12-12 Methods

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

Safe Administration of Systemic Cancer Therapy: Introduction and General Methods


Report Date: July 9, 2012

An assessment conducted in January 2019 deferred the review of Evidence-based Series (EBS) 12-12-M. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

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Safe Administration of Systemic Cancer Therapy:
Introduction and General Methods


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INTRODUCTION

Assuring patient safety during systemic cancer treatment administration is an important objective for healthcare institutions. Medication errors are of particular importance because of their largely preventable nature. A medication error is described as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer (1,2). Chemotherapy agents have a narrow therapeutic index and can cause serious toxicity even when used appropriately. Medication errors involving agents for the systemic treatment of cancer would thus put the patient at a greater risk of harm compared to other drugs. Chemotherapy protocols are often complex combinations of agents and can be fraught with risk for error as they become altered in dose, route, schedule, or drugs used in accordance with the patient’s clinical diagnosis or condition. As oncologists attempt to balance the anti-cancer effect against the side effects of treatment, there is little margin for error. Overdosing can result in life-threatening toxicity while underdosing can have implications for disease control and patient outcome.

Medication errors resulting in patient harms are well documented in the literature. A total of 519 medication errors involving chemotherapy agents were voluntarily reported to the Institute for Safe Medication Practices (ISMP) Canada between 2002 and 2009: 40 (7.7%) had an outcome of harm, and four (0.8%) had an outcome of death (3). ISMP Canada noted the chemotherapy medication errors that were voluntarily reported spanned all of the major areas within the administration process: treatment scheduling, prescribing, order entry or transcription, clinical assessment and communication of treatment changes, dispensing, administration, and monitoring (3). The root cause analyses of a recent fatal chemotherapy
error identified system failures in the cancer centre that are known to exist in other centres (4). In the United States, approximately 15% of deaths related to medication error were associated with chemotherapy agents; chemotherapy drugs were the second most frequent cause of death compared to other classes of drugs and despite their relative low frequency of use (5).

The challenges to patient safety will continue to grow as the number of chemotherapeutic regimens expands, as treatment moves away from cancer clinics and into the community, and as oral drugs for cancer treatment become commonplace. There is increasing concern that non-adherence can contribute to medication errors as roles and responsibilities shift from the oncologist, nurse, or pharmacist to the patient or caregiver (6). In addition, the movement of chemotherapy delivery from an institutional setting to the home puts systemic cancer treatment delivery into an area where checks and balances, policies, and procedures are less established compared to hospitals and outpatient cancer clinics (7).

The reporting of errors plays a valuable role in improving patient safety. Reporting allows for an analysis of causes, facilitates improvement in systems and processes to reduce error, and allows lessons to be shared so that others can avoid the same mistakes (8). It is important to foster a reporting environment that is non-punitive and responsive, where staff can readily and easily report an error whenever it is encountered. However, the best means to establish such a reporting system is unclear.

Several organizations have developed guidance on the safe administration of chemotherapy (9,10). However, none of the guidelines adequately addresses the questions posed by the Working Group, or provide a comprehensive summary and systematic review of the available evidence. A challenge with patient safety research in general is that the events are rare but serious and sometimes fatal, and the interventions to prevent them are often complex, targeting organizations, large systems, and individual clinicians and teams (11). A further difficulty in this area is that the effectiveness of the interventions is largely dependent on the context within which they are implemented and on the strategies used for implementation (11).

Such concerns highlight the need for evidence-based recommendations to promote the safe administration of cancer treatment in Ontario. Cancer Care Ontario (CCO) formed the Safe Administration of Systemic Cancer Treatment Expert Panel to discuss best practices and review the available evidence. The panel includes clinicians from nursing, medical oncology, and pharmacy, members from hospital administration, and patient representatives (Appendix 1). One of the first tasks for the Working Group was to establish a general process map that approximated the trajectory of the patient who undergoes systemic cancer treatment (Appendix 2). The key activities and processes are subsequently summarized and illustrated in Figure 1. Using the map, guideline questions were created that addressed the effectiveness of processes, technologies, and devices ultimately designed to promote safety during the administration of systemic cancer treatment. The size of this project necessitated that the recommendations be published in four parts, in accordance with the following areas of the systemic cancer treatment administration process:

- **PART 1**: Planning and preparation stages: ordering, transcribing, dispensing of systemic cancer treatment, and patient identification
- **PART 2**: Administration proper: management and prevention of adverse events that occur during or in the aftermath of systemic cancer treatment administration

Recognizing that the care for patients undergoing systemic cancer treatment is very complex and can be highly context dependent and that the audience needed a detailed
description of some procedures, the Working Group also produced detailed examples that can be used in practice. These examples are presented in Appendix 1 of Part 1, and Part 2 of this document in the form of a compendium and can be used as the basis for the development of institutional policies and procedures.
Figure 1. Organization of the safe chemotherapy administration report according to the process of systemic cancer treatment administration.

Abbreviation: Pt = patient
Since errors can occur at all stages of the systemic cancer treatment administration process, the opinion of the Working Group is that implementation of changes should occur only after a thorough and systematic evaluation of this process. Institutions are responsible for the implementation of the safety interventions proposed in these documents and for the evaluation of their implementation strategies. The purpose of the two-part guideline is to develop recommendations that can be applied in all environments in which people with cancer will receive systemic therapy. The recommendations are intended to provide a framework for the development of institutional policies and procedures. In this series, the Working Group presents recommendations about safety interventions that can be both effective and effectively implemented in the larger context of Ontario.

This document provides the description of the general methods used to produce the two-part guideline on the safe administration of systemic cancer treatment with a focus on patient-relevant issues that the Systemic and Nursing Programs, CCO, promote. Results that are common across the two parts will also be reported here. The specific methods used to answer individual questions in each part are reported in the individual parts, as well as the results specific to each part, with a justification presented for each of the recommendations.

The PEBC is supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

TARGET POPULATIONS
- Adult patients who are going to receive systemic cancer treatment or who are already receiving systemic treatment for cancer in healthcare settings or at home.

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

PURPOSE

| The general purpose of this guidance document is to provide recommendations on processes, technologies and devices that can effectively prevent errors in the execution and planning of the administration of systemic treatment to cancer patients. |

Each part is organized according to a general objective and some specific areas of interest that reflect the processes, technologies, and devices relevant to the various steps of systemic cancer treatment administration. The aim is to provide recommendations directed to organizations and to individual clinicians, as appropriate. The overall objectives of each part are described below, with additional details regarding the topic areas that are covered.

**Part 1: Overall Objective**
The purpose of this document is to provide guidance on processes, technologies, and devices for the prevention of errors during systemic cancer treatment administration in adult patients in the areas that cut across the entire process and in the planning and preparation stages.

Some processes, technologies, and devices may impact upon the entire process of systemic cancer treatment administration, while others may have an impact only on specific steps.
The following activities may have an impact at any point during the entire process of systemic cancer treatment administration. The implementation of the recommendations in this area involves entire organizations, teams, or individual clinicians at different time points during the administration of systemic cancer treatment.

- Creating interruption-free and distraction free environments.
- Patient identification.
- Providing information and education for patients and families.
- Defining the patient and family role in care.
- Use of Computerized Prescriber Order Entry (CPOE).

The following technologies and devices may impact at several points in systemic cancer treatment administration care. The use of these technologies and devices involves changes at the organization level.

- Arm bands.
- Automated data capture.
- CPOE, decision support systems, regimen level forms, electronic records.
- Checklists.

The following processes are specific to the planning and preliminary phases of treatment. The implementation of recommendations in these areas involves changes at the organization, team, and clinician level.

- Patient assessment.
- Patient screening.
- Written treatment plan.
- Treatment scheduling: same day versus non-same day models.
- Pharmacy practices.

The following technologies and devices may impact at specific points in the systemic cancer treatment administration care process. The implementation of recommendations in these areas involves changes at the organization level.

- Infusion pumps.

Part 2: Overall Objective
The purpose of this document is to provide guidance on processes, technologies, and devices for the prevention and control of adverse effects that can happen during or in the aftermath of the administration of systemic treatment to adult cancer patients.

This document section is specific to the phase of systemic cancer treatment administration proper and its sequelae. The following areas of interest are specific to this section:

- Management and use of vascular access devices.
- Peripheral access devices.
- Management and use of other devices to deliver treatment such as intra-peritoneal devices and Ommaya reservoirs.
Management of extravasation, irritation, and flare reaction.
Identification and management of allergic or hypersensitivity reactions.
Nursing practices during and just after administration of chemotherapeutic agents in the hospital setting.
Verification and maintenance of the treatment plan.

The implementation of the recommendations in these areas involves changes at the team and clinician level.

OVERALL STRATEGY
The evidence-based series (EBS) guidelines developed by the PEBC, CCO, use the methods of the Practice Guidelines Development Cycle (12). For this project, the core methodology used to develop the evidentiary base was the environmental scan, adaptation and the systematic review.

A three-stage approach was used for the development of this guideline. In the first stage, a search was conducted for available existing guidelines with respect to the safe administration of systemic cancer drugs. For each area of interest, as described above, if a guideline that covered the topic was identified, that guideline was considered for endorsement or for adaptation to the context in Ontario. If no guidelines appropriate for endorsement or adaptation for any areas of interest were found, the Working Group proceeded to perform a systematic search for systematic reviews of the evidence on that area of interest or question. If one or more appropriate systematic reviews were identified, these were used as the evidence-base for that area of interest, and recommendations were developed from that foundation. If no relevant systematic review was identified, a systematic review was conducted for primary studies. That systematic review was used as the basis for the recommendations. If no relevant evidence was identified, the clinical experience of the Working Group formed the basis for the recommendations.

The first stage of this process (the search for existing guidelines) is described below. The details of any other systematic reviews that were necessary, and the development of the recommendations for each area of interest, is detailed in the separate parts of this guideline.

SEARCH FOR GUIDELINES
Methods
Search Strategy
The search for guidelines was performed across all of the four parts of this project at once and consisted of an environmental scan and a systematic review of the literature. The environmental scan involved a targeted search on 49 websites of organizations known for their interest in oncology or safety (see Appendix 3 for a complete list of the websites searched), a search of Working Group members’ own files, and an untargeted search by means of the search engine Google® and using such terms as “safety, medication administration, chemotherapy, and medication errors”. The systematic review consisted of a literature search using the databases MEDLINE and EMBASE. The databases were searched from 2000 through to February week 3, 2010. Terms identifying guidelines were combined with terms identifying safety and drug administration (see Appendix 4 for the original MEDLINE search strategy). The search strategy was designed for the MEDLINE database and then adapted for EMBASE.

Selection Criteria
We included guidelines that were relevant to Ontario, specified their objective, included a systematic review of the evidence, were published after the year 2000, were
about systemic cancer treatment administration safety or general drug administration safety and applicable to systemic cancer treatment administration, and were published in English. Guidelines that covered topics already covered by existing CCO guidelines (e.g., chemotherapy labelling), and guidelines for an exclusively pediatric population were excluded.

We organized the selection process in two steps. A first step, performed by the methodologist (FB), was aimed at excluding documents that were obviously not relevant (e.g., were not a guideline, did not have a reference list), and a second step, performed independently by the methodologist and by a clinician member (FB and ML, or RB or, SH, or JC, or MT or, AB, or MC) of the Working Group, was aimed at applying the full set of inclusion criteria. The full text of the documents identified by the environmental scan was examined, and the selection criteria were applied.

The citations identified by the systematic review search were screened at the title and abstract level by the methodologist as in step one described above. The full text of citations marked as “included” or “don’t know” were retrieved, and the selection criteria were applied by two members of the Safe Systemic Cancer Treatment Administration Working Group as in step two described above.

**Quality Appraisal**

One methodologist from the PEBC (FB) and one clinician (FB and ML, or RB or, SH, or JC, or MT or, AB, or MC) applied the Appraisal of Guidelines for Research and Evaluation (AGREE) II Instrument to the included guidelines (13). The AGREE II Instrument is a 23 item tool organized in six domains that test the scope and purpose of the guideline, the involvement of stakeholders, the rigour of development, the clarity of presentation, the applicability, and the editorial independence, and reports a general rating of the overall quality of the guideline; the tool is available at the AGREE Research Trust website (http://www.agreetrust.org).

**Synthesizing the Evidence.**

A matrix table was made of the topics covered by the included guidelines. The Working Group applied their clinical judgement to the highest quality guidelines and chose the ones that could be endorsed or adapted to the context of Ontario. For each question, a matrix of the relevant recommendations was created to make it easier for the Working Group members to examine and adapt them (for an example, see Appendix 5). The recommendations were slightly modified to adapt them to Ontario, according to the expertise of the Working Group.

**Results**

The environmental scan yielded 451 documents; the search of targeted websites, 240 documents from, the Working Group members’ own files, 137 documents; the untargeted search on the Google® search engine, 25 documents; and the MEDLINE and EMBASE search, 49 documents. After the first step of screening, 48 source documents were included. For Part 1: Safety During Systemic Cancer Treatment Ordering, Transcribing, Dispensing, and Patient Identification, one of the documents (10) met the inclusion criteria at the second step of selection (i.e., was relevant to Ontario and was based on a systematic review of the evidence) and was of high quality as measured with the AGREE II tool (see Appendix 6 for the AGREE II scores). The number of included guidelines for the subsequent parts of this series and their quality scores will be provided at a later date.
RELATED CCO GUIDELINES


ACKNOWLEDGEMENTS
The Nursing and Systemic Treatment Programs would like to thank the following participants in the guideline development process:
- Hans Messersmith & Sheila McNair, Assistant Directors, PEBC
- Carol De Vito, Documents Manager, PEBC
- James Bao and Dyda Dao, Student-Project Assistants, PEBC, for conducting the Data Audit and for refining the figures
- Xiaomei Yao and Erin Kennedy, PEBC Research Coordinators, internal Peer Reviewers

CONFLICT OF INTEREST DECLARATION
None of the members of the Working Group has declared a conflict of interest. Among the members of the Expert Panel, Venetia Bourrier declared having received educational grants from the pharmaceutical industry for the pharmacy department while she was in a managerial position and having received research support for safe chemotherapy-related projects.
EBS 12-12 METHODS

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

Funding
The PEBC is a provincial initiative of Cancer Care Ontario supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

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REFERENCES


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| Angela Boudreau       | Registered Nurse                                  | Sunnybrook Regional Cancer Centre                | 2075 Bayview Ave., Toronto, ON M4N 3M5                                    |
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<td>Regional Cancer Program</td>
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Appendix 2. Administration of systemic cancer treatment process map.

DISCLAIMER: This process map is for research use only and reflects the processes of a few institutions. This process map is not designed to reflect the processes for all oncology centres or clinics.
Appendix 3. Environmental scan: List of scanned organizations’ websites.

National Guidelines Clearinghouse

**International Guideline Developers:**

NICE (UK)  
SIGN (UK)  
ASCO (US)  
NCCN (US) - (consensus-based)  
National Health and Medical Research Council (Aus)  
New Zealand Guidelines Group

**Canadian provincial cancer agencies:**

BC Cancer Agency  
Alberta Cancer Board  
Saskatchewan Cancer Agency  
Cancer Care Manitoba  
Cancer Care Nova Scotia

**National cancer agencies (UK, US, AUS, NZ):**

NZ Cancer Control Trust  
NZ Cancer control Strategy  
The Cancer Council Australia  
Cancer society of New Zealand  
Regional Cancer Centre, Waikato Hospital, Hamilton, NZ  
National Cancer Control Initiative (AUS)  
The Collaboration for Cancer Outcomes Research and Evaluation (AUS)  
State Government of Victoria, Australia  
Peter MacCallum Cancer Centre (Australia)  
Medical Oncology Group of Australia  
Clinical Oncology society of Australia  
Cancer UK  
Cancer Services Collaborative, Avon Somerset and Wiltshire (UK)  
Cancer Services Collaborative NHS modernisation agency  
NHS (UK)  
NZ guidelines group

Accreditation Canada  
Joint Commission  
EviQ  
AHRQ M&M

**Organizations:** (project specific: e.g. radiation oncology associations, nursing associations):

Institute of Safe Medication Practices Canada (ISMP Canada)  
Institute of Safe Medication Practices US (ISMP)
Canadian Society of Hospital Pharmacists
Canadian Patient Safety Institute
Canadian Pharmacists Association
Canadian Association of Pharmacy in Oncology
International Society for Oncology Pharmacist Practitioners (ISOPP)
National Institute for Occupational Safety and health (NIOSH)
Agency for Healthcare Research and Quality (AHRQ)
FDA’s Manufacturer and User Device Experience (FDA MAUDE)
Emergency Care Research Institute (ECRI)
Humans Factors Literature
Health Canada
Medical Error Recognition and Revision Strategies
Quality Healthcare Network
Guidelines Advisory Committee
International Pharmaceutical Federation
Infectious Diseases Society of America

Institutional documents from hospitals in Canada:

Organizational or strategic plans
policies and procedures
terms of reference
standards of practice
affiliation agreements

Conferences:
community oncology conference
Appendix 4. Literature search strategies.

Search terms: Medline search
Search date February 26, 2010

1 chemotherapy.tw.
2 Oncologic Nursing/st [Standards]
3 Neoplasms/dt, nu [Drug Therapy, Nursing]
4 Antineoplastic Protocols/
5 Drug therapy/mt, st [Methods, Standards]
6 Antineoplastic Agents/ad, tu [administration & dosage, Therapeutic Use]
7 1 or 2 or 3 or 4 or 5 or 6
8 exp practice guidelines/
9 exp Guideline/
10 guideline?.tw,pt,sh.
11 (practice guideline or guideline?).mp,pt.
12 consensus.sh,tw,pt.
13 8 or 9 or 10 or 11 or 12
14 7 and 13
15 exp Medical Errors/
16 Medication Systems/
17 errors.tw.
18 Safety/
19 Quality Assurance, Health Care/
20 "Delivery of Health Care"/
21 15 or 16 or 17 or 18 or 19 or 20
22 7 and 13 and 21
Appendix 5. Example of matrix of individual recommendations.

Part 1, Focus 1, Question 1: What are the essential components of patient assessment (for new and returning patients)?

Components of patient assessment. Matrix of individual recommendations.

<table>
<thead>
<tr>
<th>Australian guidelines (Carrington et al. (i, ii))</th>
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<tr>
<td><strong>Pre-administration page 25</strong></td>
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<tr>
<td>The following should be available prior to commencing administration of therapy:</td>
</tr>
<tr>
<td>Current diagnosis,</td>
</tr>
<tr>
<td>medical and medication history of relevance including treatment history. Details of any drug allergies.</td>
</tr>
<tr>
<td>A patient treatment plan and an original or legible copy of the order. These should be completed with the detail specified in the prescribing section of this document.</td>
</tr>
<tr>
<td>Patient parameters (height, weight, BSA) and relevant laboratory values including blood counts, urea and electrolytes, liver function tests.</td>
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<tr>
<td>Nursing staff should confirm the performance of required tests and results and contact the medical officer where results fall outside acceptable parameters.</td>
</tr>
<tr>
<td>[...]</td>
</tr>
<tr>
<td>An assessment of the patient should be carried out by the nurse prior to administration including:</td>
</tr>
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<td><strong>The patient’s history and treatment plan</strong></td>
</tr>
<tr>
<td>The diagnosis, treatment plan and protocol should be confirmed.</td>
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<tr>
<td><strong>The patients weight and body surface area</strong></td>
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<tr>
<td>Changes in weight and weight should be assessed and the subsequent impact on BSA and dose.</td>
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<tr>
<td><strong>Pathology results.</strong></td>
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<td>Blood counts should be documented and confirmation given by the prescriber that they are appropriate for treatment to proceed.</td>
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<tr>
<td>Response to previous treatment and previous toxicities that may impact on treatment. e.g. nausea and vomiting, mucositis, neuropathy</td>
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<tr>
<td>Ensure that existing conditions or toxicities do not preclude treatment from proceeding.</td>
</tr>
<tr>
<td><strong>The patient’s coping mechanisms, anxiety level, and any cultural issues that may have an impact on the administration process</strong></td>
</tr>
<tr>
<td>Where concerns are identified, referral to another health care professional should be considered according to local procedure. Ensure that identified issues do not preclude treatment from proceeding.</td>
</tr>
<tr>
<td><strong>The patients physical and performance status that may impact on the treatment process</strong></td>
</tr>
<tr>
<td>Using a physical assessment and subjective performance status assessment e.g. Eastern Cooperative Oncology Group (ECOG).</td>
</tr>
<tr>
<td><strong>Pre-medications required to be taken at home has been taken by the patient as instructed</strong></td>
</tr>
<tr>
<td>e.g. Steroids required to be commenced 24 hours prior to docetaxel.</td>
</tr>
<tr>
<td><strong>Baseline observations specific to the protocol</strong></td>
</tr>
<tr>
<td>e.g. Patients taking nephrotoxic medications must be assessed for urine output and urinalysis.</td>
</tr>
<tr>
<td><strong>Access devices required for administration are in place and patent</strong></td>
</tr>
<tr>
<td>e.g. peripheral inserted central catheter (PICC, PORT or Hickman).</td>
</tr>
</tbody>
</table>

Areas that should be verified include:

| **The protocol** |
| Verify that all medications are prescribed according to documented protocol including all pre and post supportive medication and oral chemotherapy. |
| **Doses** |
| Verify that all doses are correct according to protocol and patient parameters e.g. weight, BSA, creatinine clearance and that maximum and cumulative doses are not exceeded for the dose or the course according to the protocol. Check any dose reductions are correct according to the protocol, patient parameters and doctor’s instructions. |
| **Scheduling** |
Verify the appropriate time period has passed between last cycle and current cycle.

**Administration route**
Verify that this is present and correct for each medication.

**Administration rate**
Verify that the rate is specified and is correct for each medication.

**Adverse drug reactions**
Verify that the patient has no reported or documented allergies or history of hypersensitivity to any of the medications to be administered.

**Verification of the medication (by 2 nurses) including:**
The patient name (first name and surname), date of birth and unique identifying number.
The name of the medication.
The dose of the medication.
The route of administration.
The date and time of administration.
The expiration date of the medication.
Patient drug allergies.

Questions regarding compliance, treatment tolerance, and adverse events must always be addressed at each appointment. The order should be verified and any discrepancies identified discussed with the prescribing medical doctor and/or the pharmacist prior to administering the medication(s). Documentation of any discrepancy and the resolution must be completed by the nurse in the patient’s medical record. Table 15 defines areas that should be verified. [...]

**Abstract 5 References:**


Appendix 6. AGREE scores of included guideline(s).

Part 1.

<table>
<thead>
<tr>
<th>AGREE domain</th>
<th>Carrington et al. (2)</th>
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<tbody>
<tr>
<td>1. Scope and purpose</td>
<td>92%</td>
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<tr>
<td>2. Stakeholder involvement</td>
<td>75%</td>
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<tr>
<td>3. Rigour of development</td>
<td>51%</td>
</tr>
<tr>
<td>4. Clarity of presentation</td>
<td>67%</td>
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<tr>
<td>5. Applicability</td>
<td>35%</td>
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<tr>
<td>6. Editorial independence</td>
<td>0</td>
</tr>
<tr>
<td>Overall assessment</td>
<td>Recommend for use with modifications</td>
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</tbody>
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