IMPROVING THE SAFETY OF AMBULATORY INTRAVENOUS CHEMOTHERAPY IN CANADA

FULL STUDY REPORT AND RECOMMENDATIONS
January 14, 2011
EXECUTIVE SUMMARY

Background
Incidents with IV ambulatory chemotherapy, including the death of a patient due to a fluorouracil over-infusion,¹ have highlighted the safety risks of this drug therapy. This project was funded by the Canadian Patient Safety Institute (CPSI), the Canadian Association of Provincial Cancer Agencies (CAPCA), the Institute for Safe Medication Practices (ISMP) Canada, and five provincial cancer care organizations to:

1. Identify the current practices for ordering, preparing, labeling, verifying & administering ambulatory IV chemotherapy in Canada,
2. Identify sources of risk in a wide variety of IV chemotherapy environments,
3. Recommend strategies to reduce risks.

Methods
Several methodologies were employed in the identification and prioritization of safety issues in ambulatory IV chemotherapy in Canada: a national survey of oncology care providers, field studies in six cancer treatment facilities, a proactive risk assessment based on Rasmussen’s Risk Management Framework in a Dynamic Society, and an adapted Healthcare Failure Modes and Effects Analysis.

Results
A total of 331 physicians, oncology pharmacists, oncology nurses and administrators involved in cancer care from across Canada completed the survey. There was widespread awareness of the fluorouracil incident and root cause analysis report¹: 95.5% of respondents were aware of the incident and 71% had reviewed the report. In total, 213 incidents were reported by the 331 respondents.

Differences between field study sites were observed in terms of: technology, models of teamwork, complexity of work processes, patient scheduling models, and role of the provincial cancer organization. Efficiency pressure was felt by staff at all sites, especially those working in pharmacy.

Data gathered using all the methodologies resulted in the identification of the following safety issues (Table 1):
TABLE 1. SAFETY ISSUES IDENTIFIED AND EXPLORED IN RESEARCH

<table>
<thead>
<tr>
<th>1. Elastomeric ambulatory infusion pumps (AIPs) and Access Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Unexplained elastomeric AIP malfunctions</td>
</tr>
<tr>
<td>1.2 Elastomeric AIP selection errors</td>
</tr>
<tr>
<td>1.3 Homecare and AIPs</td>
</tr>
<tr>
<td>1.4 Access devices used with elastomeric AIPs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Orders and Labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Change orders</td>
</tr>
<tr>
<td>2.2 Pre-printed orders: reuse of forms, handwriting, usability, flexibility</td>
</tr>
<tr>
<td>2.3 Large volume general purpose infusion pump programming errors and labeling</td>
</tr>
<tr>
<td>2.4 Free-form orders</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Pharmacy Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Organization of materials and work processes in biological safety cabinets</td>
</tr>
<tr>
<td>3.2 No double-check of reconstitution</td>
</tr>
<tr>
<td>3.3 Exposure to hazardous drugs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Additional Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Patient scheduling model</td>
</tr>
<tr>
<td>4.2 Simplification and standardization</td>
</tr>
</tbody>
</table>

**Recommendations**

As compared to health sciences research, in patient safety and practice research, it is rarely appropriate or feasible to use traditional quantitative evaluation methods such as randomized control trials in the development of recommendations. Issues and recommendations in this section are thus based on qualitative observations, end-user feedback, expert consensus, and, where they exist, best practices described in the literature.

In implementing recommendations from this report, care providers may need to be creative and make some challenging compromises to do with staffing, space and financial resources. Recommendations need to be taken in context of local opportunity. We recognize the commitment of cancer agencies and programs to work across disciplines and provinces, and would strongly encourage this kind of review to continue. This kind of involvement, including patients, pharmacy, nursing, administration, physicians, is critical to successful implementation and evaluation. We also encourage sharing of implementation stories between sites.

**AIPs and Access Devices**

- Elastomeric AIPs are a simple way of preventing massive flow rate errors that can occur with electronic programmable pumps, but several factors can lead to significant variance in flow rate. Improved staff and patient education is required to ensure that the pumps infuse as close to the nominal rate as possible.

- To prevent selection errors with elastomeric AIPs, which can result in significant over-infusions: the variety of models of elastomeric AIPs at each cancer treatment facility should
be minimized through the simplification and standardization of protocols; and models of elastomeric AIPs with different flow rates should be stored separately from each other in pharmacy areas to prevent selection errors.

**Orders and Labels**

Computerized Physician Order Entry (CPOE) is often considered the best and safest approach to ordering medication. Oncology specific systems with built in clinical decision support can reduce the risk of improper dosing and inaccurate body surface area and drug dose calculations. However, successful implementation requires significant resources and coordination, and is not an immediate possibility for many cancer care sites. For the many sites who are striving to implement pre-printed orders (PPO) as a strategy of moving away from handwritten orders, a focus of this study has been PPO design.

- For sites not using computerized prescriber order entry (CPOE) or for CPOE sites where some paper ordering still takes place, preprinted orders should be developed for all commonly used protocols. Free-form paper orders should be avoided.

- Preprinted orders should be developed according to guidelines outlined in the supplemental report Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.2

- To ensure current versions are always used, PPOs should be centrally managed and available electronically online or on the treatment centre’s intranet. Orders should be printed on a per-patient basis.

- To support nurses with the task of pump programming and verification, flow rate (in the same units as the pump, e.g., mL/hr) should be included on pharmacy-generated chemotherapy labels and/or preprinted orders for infusions administered via large volume infusion pumps as well as AIPs.

**Pharmacy Practices**

- To prevent mixing errors only one chemotherapy preparation should enter the biological safety cabinet (BSC) at a time.

- To ensure the correct label is applied to its associated bag, labels and/or mixing instructions should be paired at all times with their preparation supplies and final prepared product.

- A second individual (ideally a pharmacist) should check that the correct diluent type and volume have been drawn up in the syringe for reconstitution. These checks should be in addition to any existing checks of post-constituted volumes of chemotherapy.

- Research examining the quality of mixed chemotherapy bags through techniques such as high-performance liquid chromatography is necessary to establish the mixing error rate in Canadian chemotherapy pharmacies.

**Other Issues**

- Simplification and standardization at the highest possible level of the healthcare system in terms of protocols, ordering tools, dosing, and workflows, will result in the greatest safety and efficiency gains. Collaboration between provincial health organizations, cancer treatment facilities and individual cancer care providers is required.
• Given the many issues stemming from the same-day model, centres should evaluate the impact of implementing a multi-day model, and where and when it is appropriate, should strive for an implementation of this scheduling approach.
  
  o The ordering physician has access to blood test results at the time of chemotherapy ordering, and
  
  o Treatment takes place soon after chemotherapy orders are written, but
  
  o Treatment takes place at least one day after the orders are written so that pharmacy and nursing have time to prepare.

• Policies and procedures should be established to identify those patients for whom same-day treatment may be preferable (e.g., patients with mobility problems or those who must travel a great distance).

A complete list of recommendations can be found in Appendix G.
# TABLE OF CONTENTS

## IMPROVING THE SAFETY OF AMBULATORY INTRAVENOUS CHEMOTHERAPY IN CANADA

1

## EXECUTIVE SUMMARY

2

## TABLE OF CONTENTS

6

## LIST OF ABBREVIATIONS

9

## ACKNOWLEDGEMENTS

11

- Funding agencies ........................................... 11
- Study principal investigators ........................................... 11
- Study co-investigators .................................................. 11
- The study investigators gratefully acknowledge the contribution of the following people: .................................................. 12

## BACKGROUND AND INTRODUCTION

13

## PART A: IDENTIFICATION OF SAFETY ISSUES

14

- METHODS ......................................................... 14
  - Survey .......................................................... 14
  - Field Studies .................................................. 14
  - Identification and Prioritization of Safety Issues ................. 16

## RESULTS

18

- Survey .......................................................... 18
- Field Studies .................................................. 19
- Issue Identification and Classification .................................. 20

## PART B: ISSUE ANALYSIS AND SAFETY RECOMMENDATIONS

21

1 ELASTOMERIC AIPs AND ACCESS DEVICES ............................................. 21
   1.1 Unexplained elastomeric AIP malfunctions ...................................... 22
   1.3 Homecare and AIPs ................................................................. 27
<table>
<thead>
<tr>
<th>Chapter/Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Practices</td>
<td>77</td>
</tr>
<tr>
<td>4</td>
<td>79</td>
</tr>
<tr>
<td>Other Issues</td>
<td>79</td>
</tr>
<tr>
<td>APPENDIX H: EDUCATION TOPICS FOR THE SAFE USE OF ELASTOMERIC AIPS</td>
<td>81</td>
</tr>
<tr>
<td>APPENDIX I: EDUCATION MATERIALS FOR ELASTOMERIC AIPS FROM BAXTER CANADA</td>
<td>87</td>
</tr>
<tr>
<td>APPENDIX J: ISSUES HIERARCHIES FOR SITES USING THE SAME-DAY MODEL OF PATIENT SCHEDULING</td>
<td>121</td>
</tr>
</tbody>
</table>
# LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>AB</th>
<th>Alberta</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIP</td>
<td>Ambulatory infusion pump</td>
</tr>
<tr>
<td>BC</td>
<td>British Columbia</td>
</tr>
<tr>
<td>BSA</td>
<td>Body surface area</td>
</tr>
<tr>
<td>BSC</td>
<td>Biological safety cabinet</td>
</tr>
<tr>
<td>CANO</td>
<td>Canadian Association of Nurses in Oncology</td>
</tr>
<tr>
<td>CAPCA</td>
<td>Canadian Association of Provincial Cancer Agencies</td>
</tr>
<tr>
<td>CAPhO</td>
<td>Canadian Association of Pharmacy in Oncology</td>
</tr>
<tr>
<td>CPOE</td>
<td>Computerized prescriber/physician order entry</td>
</tr>
<tr>
<td>CPSI</td>
<td>Canadian Patient Safety Institute</td>
</tr>
<tr>
<td>CrCr</td>
<td>Creatinine clearance</td>
</tr>
<tr>
<td>GPO</td>
<td>General physician- oncology</td>
</tr>
<tr>
<td>HF</td>
<td>Human factors</td>
</tr>
<tr>
<td>HFMEA</td>
<td>Healthcare Failure Modes and Effects Analysis</td>
</tr>
<tr>
<td>ISMP</td>
<td>Institute for Safe Medication Practices</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>LASA</td>
<td>Look-alike, sound-alike</td>
</tr>
<tr>
<td>LPN</td>
<td>Licensed practical nurse</td>
</tr>
<tr>
<td>MB</td>
<td>Manitoba</td>
</tr>
<tr>
<td>NB</td>
<td>New Brunswick</td>
</tr>
<tr>
<td>NCR</td>
<td>Non-carbon required</td>
</tr>
<tr>
<td>OCAD</td>
<td>Ontario College of Art and Design</td>
</tr>
<tr>
<td>ON</td>
<td>Ontario</td>
</tr>
<tr>
<td>PICC</td>
<td>Peripherally inserted central catheter</td>
</tr>
<tr>
<td>PPO</td>
<td>Preprinted order</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Name</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>RCA</td>
<td>Root Cause Analysis</td>
</tr>
<tr>
<td>SDAHO</td>
<td>South Dakota Association of Healthcare Organizations</td>
</tr>
<tr>
<td>VA</td>
<td>Veterans’ Affairs</td>
</tr>
</tbody>
</table>
ACKNOWLEDGEMENTS

Funding agencies

CANADIAN PATIENT SAFETY INSTITUTE (CPSI)
CANADIAN ASSOCIATION OF PROVINCIAL CANCER AGENCIES (CAPCA)
BC CANCER AGENCY
ALBERTA CANCER BOARD (now ALBERTA HEALTH SERVICES)
CANCERCARE MANITOBA
CANCER CARE ONTARIO
NEW BRUNSWICK CANCER NETWORK

Study principal investigators

ANTHONY EASTY, BSc.(Hons), PhD, CE, P.Eng., University Health Network
ANTHONY FIELDS, MA, MD, FRCPC, FACP, Alberta Health Services

Study co-investigators

VENETIA BOURRIER, BSc, BSc Pharm, FCSHP, Cancer Care Manitoba
ANDREA CASSANO-PICHE, MAsc., P. Eng, University Health Network
DEBBIE CHAN, B.ASc., University of Toronto
DHALI DHALIWAL, M.D., M.B.Ch.B., Cancer Care Manitoba
ROXANNE DOBISH, BSc. Pharm., Alberta Health Services
ESTHER GREEN, RN, BScN, MSc(T), Cancer Care Ontario
SYLVIA HYLAND, BSc. Pharm., MHSc, Institute for Safe Medication Practices (ISMP Canada)
KAREN JANES, RN, BSN, MSN, BC Cancer Agency
JENNIFER JEON, MAsc., University Health Network
YOO-JOUNG KO, MD, MMSC, SM, FRCPC, Sunnybrook Odette Cancer Centre
S. ESHWAR KUMAR, M.B.B.S., FRCR., New Brunswick Cancer Network
HEATHER LOGAN, RN, BScN, MHSc, Canadian Association of Provincial Cancer Agencies
The study investigators gratefully acknowledge the contribution of the following people:

The Systemic Therapy Safety Committee of the Canadian Association of Provincial Cancer Agencies (CAPCA)

Staff at the six field study sites: Medicine Hat Cancer Centre, BC Cancer Agency Vancouver Island Centre, Toronto East General Hospital, CancerCare Manitoba, Thompson General Hospital, Saint John Regional Hospital

Field study site coordinators: Linda Cleveland, Carmen Olson, Johanna den Duyf, Mikki Layton, Grace Chung, Venetia Bourrier, Gillian Hardy, Jennifer Thackeray, and Linda Bridges

Participants in the survey

Participants in the expert review of preprinted orders

The Board of Directors of CAPCA

The CAPCA Communications Network

Keith Rushton, Richard Hunt, Patricio Davila, Jan Avendano, Rebecca Caswell, Joel Derksen, Bahar Ghaemi, Candy Yee Ting Lee, Jessica Leong, Symon Oliver, and Justin Rajbahadursingh at the Ontario College of Art and Design, Toronto, Ontario

Roy Lee, Janice Stewart, Vishal Kukreti and staff at the Princess Margaret Hospital, Toronto, Ontario

Rosemary Bland and staff at the Juravinski Cancer Centre, Hamilton, Ontario

Adelle McGill, Caterina Masino, Galina Kovacik and Anjum Chagpar at the Centre for Global eHealth Innovation, Toronto, Ontario
BACKGROUND AND INTRODUCTION

Incidents with IV ambulatory chemotherapy, including the death of a patient due to a fluorouracil over-infusion, have highlighted the safety risks of systemic therapy. A root cause analysis (RCA) of the fluorouracil event by the Institute for Safe Medication Practices (ISMP) Canada identified 16 causal factors and made several associated recommendations.1 These recommendations were of interest to all centres in Canada who provide ambulatory IV chemotherapy. However, there was a concern in the oncology community that additional safety hazards existed that had not been implicated in the incident. Further, this event highlighted that practices varied from site-to-site and province-to-province, but that little data existed to this effect. Thus, as a follow-up to the fluorouracil RCA, this research project was funded by the Canadian Patient Safety Institute (CPSI), the Canadian Association of Provincial Cancer Agencies (CAPCA), ISMP Canada, and five provincial cancer care organizations (BC Cancer Agency, Alberta Cancer Board, CancerCare Manitoba, Cancer Care Ontario and the New Brunswick Cancer Network). The goals of the project were to:

1. Identify the current practices for ordering, preparing, labeling, verifying & administering ambulatory IV chemotherapy in Canada

2. Identify additional sources of risk in a wide variety of ambulatory IV chemotherapy environments

3. Recommend strategies to reduce risks

The research team comprised human factors (HF) specialists, oncology nurses, oncology pharmacists and medical oncologists from across Canada, and was steered by the CAPCA Systemic Therapy Safety Committee. To achieve the above goals, a multi-method approach was employed, which included: a national survey; field study observations in six cancer treatment facilities across Canada; and in-depth analyses of issues with multi-disciplinary teams of clinicians, human factors experts and graphic designers.

The study took place from Fall, 2008 to Spring, 2010. This report summarizes the approach, findings and recommendations, and is divided into two main parts. Part A comprises the methods and results related to identifying and prioritizing the safety issues in ambulatory IV chemotherapy, and Part B presents the methods and results related to understanding and addressing these issues.

The particular topic of preprinted orders was examined in detail and is presented in a supplementary report entitled, Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders2. The creation of a separate report allowed for more freedom in terms of formatting and tone. Readers are encouraged to read both documents when assessing and improving practice for IV ambulatory chemotherapy.
PART A: IDENTIFICATION OF SAFETY ISSUES

This section of the report addresses the first two objectives of the study: to identify current practices and to discover safety issues with IV ambulatory chemotherapy safety across Canada.

Methods

Several methodologies were employed in the identification and prioritization of practices and safety issues: a survey, field studies, Rasmussen’s Framework for Risk Management in a Dynamic Society and Healthcare Failure Modes and Effects Analysis (HFMEA). These are described below.

Survey

The goals of the survey were: to understand current and planned practices around the ordering, labeling, verifying, administering, and documenting of ambulatory IV chemotherapy in Canada; to determine how cancer treatment facilities have responded to ISMP Canada’s RCA report on the fluorouracil incident; as well as to collect information on other adverse events that have occurred across the country.

The survey was administered through an online tool called Survey Monkey. The target respondents were health professionals at Canadian hospitals and/or cancer treatment facilities who had knowledge about ordering, preparing, labeling, administering and verifying practices related to IV chemotherapy in the ambulatory setting.

A hyperlink to the survey was distributed via provincial liaisons from the CAPCA Systemic Therapy Safety Committee, the Canadian Association for Nurses in Oncology (CANO) listserv, the Hospital Pharmacy Directors listserv, and through announcements made at the 2008 National Oncology Pharmacy Symposium of the Canadian Association of Pharmacy in Oncology (CAPhO). The survey was accessible online from October 15th, 2008 to December 12th, 2008 in both official languages (French and English).

Field Studies

The goal of the field studies was to thoroughly examine and understand the current practices for ordering, preparing, labeling, verifying, administering and documenting ambulatory IV chemotherapy in Canada, and to identify factors that may contribute to preventable adverse events.

Week-long field observations were conducted in six cancer treatment facilities across Canada during the period of October 2008 to February 2009. These centres were strategically chosen by the
steering committee to represent a range of small and large facilities, community and research hospitals, and rural and urban communities (Figure 1). The following facilities participated in the field studies:

- Medicine Hat Cancer Centre (AB)
- BC Cancer Agency Vancouver Island Centre (BC)
- Toronto East General Hospital (ON)
- CancerCare Manitoba -MacCharles site (MB)
- Thompson General Hospital (MB)
- Saint John Regional Hospital (NB)

Medical oncologists, oncology pharmacists, pharmacy technicians, oncology nurses and administrative clerks were observed and interviewed by two human factors (HF) specialists as they carried out their work. Potential hazards with their work processes were documented, and differences in practice, technology and organizational culture were noted. To manage the complexity of the information from each site, data were archived using several techniques: (see Appendices A, B, & C for examples):

- **Detailed process description**: Description of each of the processes observed in the clinic, pharmacy, and treatment areas in plain language.

- **Process maps**: Simplified visual representations of processes in clinic, pharmacy and treatment areas with boxes and arrows showing the flow of information.

---

1 Google Maps, http://maps.google.com
• **Data repository:** Spreadsheet detailing each step of the chemotherapy administration process in terms of who performs the task, where the task is completed, how the task is completed and any issues or concerns about the task.

Each of these documents was sent to the site coordinator for review and validation to ensure that the researchers had completely and accurately understood the processes.

**Identification and Prioritization of Safety Issues**

The above methods were most useful for identifying current processes. However, to identify potential safety hazards, adapted versions of two methods were used: Rasmussen’s 1997 Risk Management Framework and Healthcare Failure Mode and Effect Analysis (HFMEA).

**Rasmussen Framework for Risk Management in a Dynamic Society**

The ultimate aim of this study was to develop generalizable recommendations to improve the safety of ambulatory IV chemotherapy across Canada. Intrinsic to this goal is that recommendations must include every level of the healthcare system that influences the delivery of ambulatory chemotherapy. This includes levels where key decisions are made, not just work practice levels. Thus, it was important to understand how the interaction of decisions and actions across all levels of the system contribute to patient safety hazards.

Rasmussen’s 1997 Risk Management Framework aims to model the “socio-technical system involved in risk management [that] includes several levels ranging from legislators, over managers and work planners, to system operators.” The framework explains how and why large-scale accidents occur in complex systems and how they can be prevented, by first examining the factors that influence the behaviour of the system over time. The strength of the framework lies in its ability to provide a structured approach to identifying the actors in the system and the interaction mechanisms between actors and authority levels.

The framework includes a tool known as the structural hierarchy. To visually represent the actions and decisions across various levels of the system, structural hierarchies were developed for each field study site. A sample hierarchy can be found in Appendix D.

**Healthcare Failure Mode and Effect Analysis (HFMEA)**

Given the volume and variety of issues identified through analysis of the field study and survey data, a systematic method was required to prioritize which issues warranted further attention. The HFMEA methodology was therefore adapted to evaluate the relative impact of safety issues in three dimensions: severity, probability and detectability.

The ratings for potential severity and probability were adapted from the United States Department of Veterans Affairs’ (VA) HFMEA model to account for consequences specific to the field of oncology such as toxicity, unnecessary exposure to chemotherapy, less effective course of treatment, etc (Table 2, Table 3).
### TABLE 2. SEVERITY RATINGS

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Minor</td>
<td>Treatment could be less effective; unknown potential long-term harm (e.g., unnecessary exposure to chemotherapy)</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>Patient could be temporarily harmed (e.g., toxicity, intense side effects)</td>
</tr>
<tr>
<td>3</td>
<td>Severe</td>
<td>Patient could be permanently harmed</td>
</tr>
<tr>
<td>4</td>
<td>Critical</td>
<td>Patient could die</td>
</tr>
</tbody>
</table>

### TABLE 3. PROBABILITY RATINGS

<table>
<thead>
<tr>
<th>Probability Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Remote</td>
<td>Unlikely to occur (may happen sometime in 5 to 30 years)</td>
</tr>
<tr>
<td>2</td>
<td>Uncommon</td>
<td>Possible to occur (may happen sometime in 2 to 5 years)</td>
</tr>
<tr>
<td>3</td>
<td>Occasional</td>
<td>Probably will occur (may happen several times in 1 to 2 years)</td>
</tr>
<tr>
<td>4</td>
<td>Frequent</td>
<td>Likely to occur immediately or within a short period (may happen several times in one year)</td>
</tr>
</tbody>
</table>

Detectability ratings are not included in the VA’s HFMEA scoring system as detectability is analyzed using a decision tree. We added detectability ratings from the scoring scale based on the South Dakota Association of Healthcare Organizations (SDAHO; Table 4).10

### TABLE 4. DETECTABILITY RATINGS

<table>
<thead>
<tr>
<th>Detectability Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Moderate</td>
<td>There is a process for double-checks or detection, but the process relies on vigilance and/or is applied only to a sample.</td>
</tr>
<tr>
<td>2</td>
<td>Remote</td>
<td>Error can be detected with manual inspection but there is no process in place so the detection is left to chance.</td>
</tr>
<tr>
<td>3</td>
<td>Very remote</td>
<td>Failure can be detected only through inspection, which is not feasible or readily done.</td>
</tr>
<tr>
<td>4</td>
<td>No chance of detection</td>
<td>No mechanism for detecting the failure.</td>
</tr>
</tbody>
</table>
Severity, probability, and detectability scores were assigned for each issue. The issue’s total hazard score was then calculated by multiplying each of these values. Hazard scores were independently calculated by three HF specialists and then compared. When discrepancies in scoring occurred, issues were discussed until the group arrived at a consensus.

Results

Survey

A total of 331 physicians, oncology pharmacists, oncology nurses and administrators involved in cancer care in all provinces and territories except Nunavut and the Northwest Territories (where very little, if any cancer treatment is administered) completed the survey.

Response to the fluorouracil RCA

There was widespread awareness of the fluorouracil incident and RCA report: 95.5% of respondents were aware of the incident and 71% had reviewed the report. The most frequently reported changes in response to the incident related to staff training, chemotherapy labels, types of infusion devices, and policies and procedures. Respondents from six provinces reported that their centres or provincial cancer organizations had mandated use of elastomeric infusors, as opposed to electronic ambulatory infusion pumps (AIPs), whenever possible for chemotherapy.

Types of infusion pumps and ordering systems

Respondents reported widespread use of electronic AIPs and elastomeric infusors. There was a wide variation in the reported makes and models of electronic AIPs in use, the professional group responsible for programming the pumps, and the location where pumps are programmed. In some centres, multiple professionals were involved in pump programming. None of the reported electronic AIPs were “smart pumps” (pumps with drug libraries and dose limits). Over 96% of elastomeric infusors were reported to be manufactured by Baxter Corporation.

In terms of chemotherapy ordering, 74.5% of respondents indicated that at least some ordering was done using pre-printed paper orders. Only 47% indicated the use of computerized physician order entry (CPOE) for some orders, and paper orders with no templates were reported as being used by 34.8% of respondents.

Reported adverse events with ambulatory IV chemotherapy

An objective of the survey was to identify additional types of adverse events - both incidents and near misses - experienced in Canadian cancer treatment facilities. In total, 213 incidents were reported by the 331 survey respondents. These were analyzed into themes, and are presented in Appendix E in order of severity, from highest to lowest. Note that the same incident may have been reported by multiple respondents so total numbers may not reflect actual incident rates.
These incidents were taken into consideration during the issue prioritization, as well as in the analysis and recommendations phase.

**Field Studies**

The six centres differ greatly in size, patient volume, and staff complement, as they had been strategically chosen to represent a broad cross-section of facilities. Some cancer programs operate as units within hospitals, while others are stand-alone cancer treatment facilities. Patient volumes between the centres vary from 240 treatments to over 5,000 treatments per year, with the number of staff on shift at any given time ranging from 3 to 23.

The research team found that in addition to their size, the sites differed in a variety of ways:

- **Role of provincial cancer organizations**: Each of the six field study sites has an associated provincial cancer organization. However, the degree of regulation, oversight and funding of drug protocols varies greatly between provinces.

- **Patient scheduling model**: Two scheduling approaches were observed across the sites: the same-day model and the multi-day model. In the same-day model, blood work is ordered and reviewed by a clinician in the morning, and treatment is administered in the afternoon of the same day. In the multi-day model, blood work may be completed up to three days in advance. There were several variations and hybrids of these models (see Section 4.1 in Part B).

- **Ordering technology**: Only two sites used CPOE. However, even the two CPOE sites used paper orders (in the form of pre-printed orders) for the majority of their regimens.

- **Types of ambulatory infusion pumps (AIPs)**: In the survey, 88.5% of respondents had indicated that they use elastomeric AIPs for take-home IV chemotherapy. Four of the field study sites use elastomeric AIPs whereas the two other sites use electronic AIPs for take-home chemotherapy.

- **Complexity of work processes**: In some sites, work processes in clinics, pharmacies and treatment areas were more complex than others. For example, one site had seven individuals whose sole responsibility was transporting and finding patients’ paper charts because there was a policy for drug orders not to be copied or faxed. Whereas one site was standardized at the provincial level, another site had no standardization of protocols or processes, so ordering physicians each followed an idiosyncratic process.

- **Models of teamwork**: In clinics, pharmacies and treatment areas, teams are made up of different combinations of medical oncologists, general practitioners-oncology (GPOs), clinical nurse specialists, pharmacists, pharmacy technicians, nurses, licensed practical nurses (LPNs), volunteers, and clerks.

- **Efficiency pressure**: The main commonality between sites was the pressure on staff to work quickly, although this pressure was stronger in some sites. The impact of this efficiency pressure was most evident in pharmacies, where the mixing of drugs was often a bottleneck to patients receiving treatment, especially in the same-day model of scheduling.
**Issue Identification and Classification**

Thirty-seven unique issues were identified through analysis of the survey and field study data (Appendix F). Eleven issues achieved HFMEA hazard scores of 16 or higher and were therefore selected for further analysis. These fell into three themes (Table 5).

**TABLE 5. SAFETY HAZARDS IN AMBULATORY IV CHEMOTHERAPY IDENTIFIED THROUGH RASMUSSEN FRAMEWORK AND HFMEA**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Severity</th>
<th>Probability</th>
<th>Detectability</th>
<th>Hazard Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Elastomeric AIPs and Access Devices</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1 Unexplained elastomeric AIP malfunctions</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>64</td>
</tr>
<tr>
<td>1.2 Elastomeric AIP selection errors</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>24</td>
</tr>
<tr>
<td>1.3 Homecare and AIPs</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>1.4 Access devices used with elastomeric AIPs</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>2. Orders and Labels</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 Change orders</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>36</td>
</tr>
<tr>
<td>2.2 Pre-printed orders: reuse of forms, handwriting, usability, flexibility</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>24</td>
</tr>
<tr>
<td>2.3 Large volume general purpose infusion pump programming errors and labeling</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>18</td>
</tr>
<tr>
<td>2.4 Free-form orders</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>3. Pharmacy Practices</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 Organization of materials and work processes in biological safety cabinets</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>48</td>
</tr>
<tr>
<td>3.2 No double-check of reconstitution</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>32</td>
</tr>
<tr>
<td>3.3 Exposure to hazardous drugs</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
</tbody>
</table>
PART B: ISSUE ANALYSIS AND SAFETY RECOMMENDATIONS

The 11 issues identified in Part A with hazard scores of 16 or higher are examined in detail in this section. Each issue required a customized methodological approach, with some issues requiring more intense investigation than others. In the detailed analysis of the 11 issues, additional safety themes were uncovered, and these are presented after the top 11 issues.

A table summarizing all of the recommendations can be found in Appendix G.

STRENGTH OF EVIDENCE FOR RECOMMENDATIONS

As compared to health sciences research, in patient safety and practice research, it is rarely appropriate or feasible to use traditional quantitative evaluation methods such as randomized control trials in the development of recommendations. Issues and recommendations in this section are thus based on qualitative observations, end-user feedback, expert consensus, and, where they exist, best practices described in the literature.

In implementing recommendations from this report, care providers may need to be creative and make some challenging compromises to do with staffing, space and financial resources. Recommendations need to be taken in context of local opportunity. We recognize the commitment of cancer agencies and programs to work across disciplines and provinces, and would strongly encourage this kind of review to continue. This kind of involvement, including patients, pharmacy, nursing, administration, physicians, is critical to successful implementation and evaluation. We also encourage sharing of implementation stories between sites.

1 Elastomeric AIPs and Access Devices

Elastomeric ambulatory infusion pumps (also known as “elastomeric devices," “baby bottles” and “Infusors™") are disposable, nonelectric pumps used for one-time administration of intravenous chemotherapy (Figure 2). The drug is stored in a balloon-like reservoir made of elastomer material that is protected by an outer container. Since the device is nonelectric, there is no programming involved and rate is not displayed, but rather, determined by visual inspection. Following the release of the fluorouracil RCA report¹ there was a major migration away from electronic AIPs to elastomeric AIPs in Canada.
1.1 Unexplained elastomeric AIP malfunctions

**HAZARD SCORE: 64**

Field study participants often noted that elastomeric AIP infusions ran faster or slower than they expected. This observation was consistent with 26 adverse events described by survey respondents. Some of the described events appear quite severe, including an infusion of fluorouracil that ran too quickly causing the patient to suffer severe renal failure, and an event where the device infused only half of the drug in the prescribed infusion time. Descriptions and investigations into the events did not always provide insights into why they had performed outside of expected ranges.

**Incident Database Review**

The FDA MAUDE database\(^{12}\) is a collection of adverse event reports concerning medical devices. An analysis was conducted of reports related to elastomeric AIPs from January 1\(^{st}\), 2008, to May 1\(^{st}\), 2009. Seventy-four unique events with elastomeric AIPs were identified, 70 of them over-infusions. Only 45 of these reports explicitly stated the expected and actual infusion times. Among these, on average, infusions ran 33% faster than expected. Out of the 74 unique events, 39 of these infusions involved the drug fluorouracil.

Seven of the 70 reports of "over-infusions" described events where the elastomeric AIP delivered the drug less than 10% faster than expected, which is within the normal performance specified by Baxter.

**Literature Review**

An extensive literature search for articles on the performance of elastomeric devices was conducted with the help of a librarian, but only four relevant articles were found. The three original research studies were conducted in controlled laboratory conditions, and showed a variation in flow rate even in ideal conditions\(^ {13, 14}\) and that these variations are further magnified in non-ideal conditions such as hyperbaric chambers.\(^ {15}\) The fourth article\(^ {16}\) was a literature review outlining the factors affecting the flow rate of a disposable device (elastomeric, spring-powered and vacuum), which in combination could result in a flow accuracy that is 40% faster or slower than expected.
In addition to finding very few articles on the laboratory performance of the pumps, no studies could be found that evaluated the performance of pumps while they were being used by actual patients.

**Discussions with the Manufacturer**

Results of the survey showed that Baxter Corporation is the dominant manufacturer of these pumps in Canada (96%). Baxter’s educational materials for elastomeric devices were therefore collected and reviewed. Very little information is available in the public domain. The research team therefore contacted Baxter directly and arranged several face-to-face meetings and teleconferences to gain more information about their product.

Representatives from the company discussed four factors affecting the flow rate accuracy of intravenous infusions: diluent type, capillary temperature, head height, and reservoir filling volume (Table 6).

**Table 6 - Factors affecting the flow rate accuracy of elastomeric AIPs, as provided by Baxter**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Departure from calibration setting</th>
<th>Difference in flow rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent Type</td>
<td>Normal saline instead of D5W</td>
<td>+10%</td>
</tr>
<tr>
<td>Capillary Temperature</td>
<td>Per increase of 1°C above 33°C</td>
<td>+2.3%</td>
</tr>
<tr>
<td></td>
<td>Per decrease of 1°C below 33°C</td>
<td>-2.3%</td>
</tr>
<tr>
<td>Head Height</td>
<td>Per inch that the elastomeric reservoir is positioned above the access point</td>
<td>+0.5%</td>
</tr>
<tr>
<td></td>
<td>Per inch that the elastomeric reservoir is positioned below the access point</td>
<td>-0.5%</td>
</tr>
<tr>
<td>Reservoir Filling Volume</td>
<td>Underfilled</td>
<td>Increase in flow rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(no numerical data provided)</td>
</tr>
<tr>
<td></td>
<td>Overfilled</td>
<td>Decrease in flow rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(no numerical data provided)</td>
</tr>
</tbody>
</table>

It should be noted that the percentage changes in flow rate listed in Table 6 are in addition to the ±10% range that the manufacturer considers acceptable for typical (or “nominal”) infusions. These factors can be additive (i.e., all supporting an increase or decrease in flow rate) or they can offset each other. In the worst-case scenario where all of the factors are additive, it is possible for a patient
to receive their drug significantly faster or slower than expected. For example, Table 7 shows a hypothetical clinical situation and its associated increase in flow rate.

**Table 7 - Calculation of a hypothetical increase in flow rate**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Departure from calibration setting</th>
<th>Example(s) of why such a departure might occur</th>
<th>Difference in flow rate</th>
<th>Cumulative difference in flow rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accepted range of deviation</td>
<td>None</td>
<td>- physical properties of the device</td>
<td>+ 10.0%</td>
<td>+10.0%</td>
</tr>
<tr>
<td>in ideal conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diluent Type</td>
<td>Normal saline instead of D5W</td>
<td>- patient’s protocol calls for normal saline</td>
<td>+10.0%</td>
<td>+20.0%</td>
</tr>
<tr>
<td>Capillary Temperature</td>
<td>Increase of 5°C above 33°C</td>
<td>- patient uses a heat blanket</td>
<td>(+2.3%)×5 = +11.5%</td>
<td>+31.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- patient goes sunbathing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head Height</td>
<td>Elastomeric reservoir is positioned 10 inches above the access point</td>
<td>- patient places the device on a nightstand while sleeping</td>
<td>(+0.5%)×10 = +5.0%</td>
<td>+36.5%</td>
</tr>
</tbody>
</table>

As shown in Table 7, modest deviations from the nominal settings can result in a flow rate increase of 36.5%. Even greater increases in flow rate are possible, as the example above does not consider deviations in fill volume since no numerical data on the resulting change in flow rate were provided by the manufacturer. It is thus quite plausible that flow rate deviations of ±40% or worse are possible.16

**Review of Educational Materials**

Most cancer treatment facilities and/or provincial agencies have their own educational materials for elastomeric pumps. The team was interested in how staff and patients are educated on the use of these pumps, so field study participants and members of the CAPCA Systemic Therapy Safety Committee were asked to share their materials. It was immediately evident that the content of these materials varied significantly. Further, few mentioned the factors that Baxter has identified as affecting flow rate accuracy. Also, most educational materials, whether from the manufacturer or the cancer treatment facility, were a one-size-fits-all approach, where the same materials are used for pharmacy technicians, pharmacists and nurses. However, each of these clinicians has a very different role to play in the preparation and administration of the devices and would likely benefit from customized information.
Summary

- The survey, field study and MAUDE database analyses revealed a significant number of over- and under-infusions of chemotherapy with elastomeric AIPs.

- Discussions with manufacturer have clarified that elastomeric AIPs are only ±10% accurate under ideal conditions, there are at least four additive factors that predictably affect flow rate. Therefore, a flow rate increase or decrease of 40% or more is plausible.

- Information on these performance factors is not readily available in the public domain nor is it well understood by front line staff.

- Many incident reports included infusion rates that were within the expected parameters of the device, highlighting the fact that users do not seem to be aware of the pumps’ performance limitations.

- There is an absence of research on the topic of in vivo and in vitro elastomeric AIP performance.

Recommendations

- Elastomeric AIPs are a simple way of preventing massive flow rate errors that can occur with electronic programmable AIPs such as in the fluorouracil incident. However several factors (diluent type, head height, temperature, underfilling, and diameter of vascular access device) can lead to a significant variance in flow rate. Improved education is required to ensure that the pumps infuse as close to the nominal rate as possible.

  - Education materials should be user-specific so that pharmacy staff, nurses and patients are aware of the factors affecting pump performance; the points relevant to their role in preparing, administering and using the device; and how to recognize when a pump is not performing according to specifications (details in Appendix H). These have been shared with Baxter Canada, who have collaborated to develop new product information documents (see Appendix I for drafts).

  - Ordering physicians should be made aware of the strengths and weaknesses of these devices.

  - Manufacturers of elastomeric devices should place development efforts on the continued performance improvement of these products.

- Research on pump in vivo performance with a variety of drugs, as patients carry out daily tasks would help establish the actual performance and incident rates of these pumps.

- If infrastructure is available to fully implement and adequately maintain smart pumps with dose error reduction systems, this technology should be considered as a means of improving safety and accuracy of ambulatory infusion pumps.

1.2 Elastomeric AIP selection errors
**HAZARD SCORE: 24**

Different models of elastomeric AIPs resemble each other in size, shape and colour, even though they deliver medication at significantly different rates (Figure 3). Since cancer programs often use elastomeric devices for several chemotherapy regimens, multiple models may be required to fulfill different infusion rate requirements. If more than one device type is stocked, there is a risk that pharmacy staff may select the incorrect device for filling and therefore administer the patient’s drug at a faster or slower rate than prescribed. Incidents where the wrong device was selected have occurred in several sites in Canada, sometimes with negative patient outcomes. There were 10 such incidents reported in the survey.

![Figure 3. Different models of Baxter elastomeric AIPs](image)

**RECOMMENDATIONS**

- The variety of models of elastomeric AIPs at each cancer treatment facility should be minimized through the simplification and standardization of protocols.

- Models of elastomeric AIPs with different flow rates should be stored separately from each other in pharmacy areas to prevent selection errors (see Appendix G for detailed education recommendations).

- In education materials for pharmacy staff, emphasis should be placed on processes for identifying correct devices, and on the impact of device selection errors.

- Education for nurses should include procedures for ensuring that the correct device has been chosen and filled by pharmacy.

- Pump manufacturers should work to better differentiate different models of pumps through improved use of colour, shape and labeling.

- If infrastructure is available to fully implement and adequately maintain smart pumps with dose error reduction systems, this technology should be considered as a means of improving safety and accuracy of ambulatory infusion pumps.17
1.3 Homecare and AIPs

**HAZARD SCORE: 16**

In some health regions, electronic and/or elastomeric AIPs are connected to the patient in the cancer treatment facility and then monitored and disconnected by homecare nurses in the patient’s home. During the field studies, the team became aware of incidents involving homecare. For example, one nurse taught a patient to disconnect their electronic AIP for showering. The patient did so and acquired a central line blockage. Another nurse did not recognize that a critical incident had occurred with an elastomeric AIP and threw it out without notifying anyone. The patient suffered renal failure that was at first attributed to other causes.

These incidents highlighted the issue of homecare and AIPs as a concern. However, it is in fact just one small component of the larger issue of cancer care and homecare, which follows different models within and between provinces. Given the significant scope of the issue, the study’s steering committee felt that it merited its own focused research study and was therefore not explored in detail.

**RECOMMENDATIONS**

- More research is needed on how to ensure the safety of chemotherapy patients in homecare environments.
- Cancer treatment clinics should ensure clear information is provided to patients on how to recognize a pump error and what to do when one occurs (see Appendix G).
- Findings from this study need to be communicated to provincial home care programs for knowledge transfer so that strategies to improve care for cancer patients can be implemented.

1.4 Access devices used with elastomeric AIPs

**HAZARD SCORE: 16**

Different access devices can be used in the administration of chemotherapy via AIPs. A peripherally inserted central catheter (PICC) is a device that is inserted via a peripheral vein and threaded through to the superior vena cava. A port-a-cath™ (also known as a “port”) is a device that is surgically inserted beneath the skin and connected to a vein with a catheter, which usually terminates in the superior vena cava, just before the right atrium of the heart. Both of these devices can be connected to an elastomeric device.

There was little consistency between and sometimes within centres as to which device was used with elastomeric AIPs. The impact on pump performance is unknown, but the issue was observed frequently. There is currently no national standard or established research evidence for determining the type of access device required to meet patients’ needs; to prevent harm to veins or tissue; and to manage care appropriately over time. Clinicians, therefore, must currently rely on their professional judgment or the available resources at their site. This is an issue that therefore needs attention from the oncology community to ensure safe and consistent care.
RECOMMENDATIONS

- More research is needed to determine the impact of different access devices on elastomeric AIP performance and to determine a standard of care.

2 Orders and Labels

Chemotherapy can be ordered in a variety of ways, from free-form prescription pads, to pre-printed order templates, to computerized prescriber order entry (CPOE). Chemotherapy orders often must change in conjunction with the patient’s condition. All IV chemotherapy is labeled by the mixing pharmacy with information about the patient and the order. This section concerns issues with these elements of the chemotherapy system.

2.1 Change Orders

HAZARD SCORE: 36

A cancer patient’s condition is dynamic, and their chemotherapy treatment plan must be adaptable. A chemotherapy order modification is referred to as a “change order”: a patient-specific customization made to the standard order information (i.e., additions, omissions or modifications), or a change to the patient’s initial treatment plan. To prepare and administer chemotherapy accurately, a change order must be communicated quickly to pharmacists, pharmacy technicians, unit clerks and treatment nurses. However, in the field studies this communication was observed to not always be timely or accurate.

To better understand how change orders are communicated and to identify potential risks, a literature review of articles relating to change orders for chemotherapy was conducted. The field study observations were further analyzed to understand the workflows, tools and patient safety risks associated with the communication of change orders. Flow maps were developed for each of the field study sites, illustrating how chemotherapy order information is communicated between stakeholders. Preprinted orders (PPOs) collected from the field study sites were also analyzed to identify features that may help or hinder the efficient and accurate communication of change orders. Four commonly used chemotherapy protocols were selected for analysis as well as those PPOs involved in change order incidents at the sites. Then safety issues identified in flow maps and sample PPOs were further analyzed using structural hierarchies.

No research on communication of change orders in chemotherapy could be found, although a few studies suggest that change orders are common contributors to incidents, and that PPOs play a critical role in change order communication.

Nine types of change orders were identified in the field study data analysis (Table 8). Further analysis led to the identification of factors that contribute to the likelihood of last-minute change

---

2 One cancer treatment facility was excluded from this analysis since chemotherapy was administered but not ordered at this site.
orders (Table 9) as well as the issues that may hinder successful communication of change orders (Table 10).

**Table 8. Categories of chemotherapy change orders**

<table>
<thead>
<tr>
<th>Treatment delay</th>
<th>Modifications of the chemotherapy drug doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustments of the pre-requisites for proceeding with the treatment</td>
<td>Addition of laboratory orders</td>
</tr>
<tr>
<td>Addition/omission of pre-medications</td>
<td>Additional doctor’s appointment</td>
</tr>
<tr>
<td>Modification to the standard hydration order</td>
<td>Special notes by the prescriber</td>
</tr>
<tr>
<td>Addition/omission of chemotherapy agents</td>
<td></td>
</tr>
</tbody>
</table>
### Table 9. Factors that may increase chances of last-minute change orders

<table>
<thead>
<tr>
<th>Issue</th>
<th>Description</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemotherapy ordered before the patient's blood test results are reviewed</strong></td>
<td>Test results are key to determining if the patient should receive treatment or if doses should be adjusted. If the oncologist orders a treatment prior to reviewing the patient’s blood test results, there is a higher chance that the order will be changed.</td>
<td>Following a multi-day model of patient scheduling, blood tests are conducted at least one day before the physician visit. Clinicians therefore have more recent data on the patient’s condition before examining them, and chemotherapy orders are less likely to be changed (see Section 4.1).</td>
</tr>
<tr>
<td><strong>No nursing assessment prior to physician assessment</strong></td>
<td>Accurate toxicity assessment is essential for physicians to develop an effective treatment plan. Nurses have been found to be more effective than physicians at collecting toxicity related information from patients. Our field study data also supports this finding.</td>
<td>Oncology nurses should assess patients before chemotherapy orders are submitted to pharmacy.</td>
</tr>
<tr>
<td><strong>Long delay between patient’s clinic visit and ordering, treatment</strong></td>
<td>At one site there was up to a three-week delay between the patient’s clinic visit and chemotherapy ordering. The patient’s condition may change between the clinic and treatment visits.</td>
<td>Whenever possible, physicians should order chemotherapy treatments immediately after examining their patients, and treatment should take place as soon as possible thereafter.</td>
</tr>
<tr>
<td>Issue</td>
<td>Description</td>
<td>Recommendation</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Existing PPOs do not have designated space for documenting change orders</strong></td>
<td>The format of all of the evaluated PPOs made it difficult to decipher change orders (Figure 5 and Figure 6). Changes could therefore be easily missed or misinterpreted by other care providers.</td>
<td>Designated space should be provided on PPOs for change order communication. Refer to supplemental report <em>Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.</em></td>
</tr>
<tr>
<td><strong>PPOs are often used for multiple cycles</strong></td>
<td>Many PPOs are designed to be used for multiple cycles. Since the patient’s condition is likely to change over the course of treatment, orders can become cluttered and/or confusing. Differentiating which change order applies to which cycle also becomes challenging (Figure 6).</td>
<td>PPOs should be designed and used for one cycle only. Refer to supplemental report <em>Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.</em></td>
</tr>
</tbody>
</table>
| **Inherent limitations of paper orders**                            | Handwriting legibility is an issue with any paper order. Multiple stakeholders require access to an order, often at the same time, so photocopies, faxes and carbonless copies are commonly used. If an order is changed, informing all stakeholders and removing outdated copies is a challenge. All the study sites relied heavily on ad hoc phone calls and face-to-face conversations to communicate change orders few had formal processes for documenting them. | Institutions should develop appropriate policies and procedures to:  
  • Keep written track of changes made to an order  
  • Visually flag orders that have been or likely to be changed  
  • Immediately alert all relevant stakeholders in writing when a change is or likely to be made to an order  
  See Figure 7 and Figure 8 for examples from the field studies. |
### Unrealized potential of CPOE

Computerized prescriber order entry (CPOE) systems can overcome many limitations of PPOs. Handwriting is not an issue, multiple users can access an order at once, it can automatically keep a history of changes made to an order, and automatically alert all stakeholders that a change has been made.

Nevertheless, the two CPOE study sites had systems that did not provide this functionality and they therefore encountered similar problems as at the PPO sites.

At minimum, a CPOE system should include the following functionality:

- Prescriber can attach notes to each order in a format that allows other clinicians to easily notice and understand.
- Automatically alert users if an order is non-standard.
- Automatically notify the clerks, clinic, pharmacy and nursing if a change has been made to an order.
- Automatically keep track of all the changes made to an order, including when, why and by who the change was made.

### Same-day patient scheduling model

In centres where the same-day model is employed, the physician orders the drugs before seeing blood work results (Section 4.1). A nurse or pharmacist must therefore check blood work on the day of treatment and make a decision to proceed or to request a change order from the physician. Meanwhile the patient is waiting. Pharmacies therefore have very limited time for dispensing.

The multi-day scheduling model may help address issues with change order communication. See Section 4.1.

---

**Figure 4. Laboratory tests and a doctor’s appointment added to a PPO**
Improving the Safety of Chemotherapy in Canada: Full Report and Recommendations

Figure 5. An order with multiple changes to premedications

Figure 6. An order with changes made to chemotherapy doses and required test results. Order is designed for two cycles, so these changes could be interpreted as being for Cycle 11 or Cycle 12, or both.
Figure 7. One pharmacy’s "chemotherapy work card" which highlights a dose change in the second cycle. Copies of the drug preparation labels are affixed and changes are highlighted with a yellow line and instructions.

Figure 8. The yellow form used by one site to flag an order that has an unresolved issue such as an unconfirmed change order. When pharmacy sees that the order has been flagged, they can process other orders while waiting for the issue to be resolved.
**RECOMMENDATIONS**

- To improve the collection of toxicity information, oncology nurses should assess patients before chemotherapy orders are submitted to pharmacy.

- The multi-day scheduling model should be employed whenever possible (see Section 4.1):
  - To reduce the likelihood of change orders.
  - To relieve pressure and inefficiencies in the pharmacy department, thus reducing errors and wasted drugs.

- To improve the quality of change order communication, PPOs should be designed according to recommendations in *Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.* Specifically, they should:
  - Ideally, be used for one cycle only.
  - Have designated space for change order communication.

- CPOE has the potential to reduce some types of errors. At a minimum, CPOE systems should provide the following functionality for managing change orders:
  - Prescriber can attach notes to each order in a format that allows other clinicians to easily notice and understand.
  - Automatically alert users if an order is non-standard.
  - Automatically notify the clerks, clinic, pharmacy and nursing if a change has been made to an order.
  - Automatically keep track of all the changes made to an order, including when, who and why the change was made.

- Institutions should develop appropriate policies and procedures to:
  - Keep written track of changes made to an order.
  - Visually flag orders that have been or likely to be changed.
  - Immediately alert all relevant stakeholders when a change is or likely to be made to an order (see Figure 7 Figure 8 for examples from the field studies).

**2.2 Pre-printed orders: reuse of forms, handwriting, usability, flexibility**

**HAZARD SCORE: 24**

Pre-printed orders (PPOs) are protocol-specific paper templates for ordering chemotherapy regimens and according to the survey, are the most commonly used ordering tool in Canada. They help simplify and standardize the ordering process because much of the basic information is already pre-filled; the physician simply has to complete the patient-specific details. In the field studies,
however, the designs of most PPOs were observed to be problematic in that they are reused for multiple cycles, are difficult to read, and are not very intuitive or flexible.

Computerized Physician Order Entry (CPOE) is often considered the best and safest approach to ordering medication. Oncology specific systems with built in clinical decision support can reduce the risk of improper dosing and inaccurate body surface area and drug dose calculations. However, successful implementation requires significant resources and coordination, and is not an immediate possibility for many cancer care sites. For the many sites who are striving to implement pre-printed orders (PPO) as a strategy of moving away from handwritten orders, a focus of this study has been PPO design.

A major project was undertaken to create guidelines and supportive tools for the development of chemotherapy PPOs. The full project report is available as a supplementary document entitled *Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.* It provides guidance to cancer treatment facilities on the process for creating and evaluating PPOs, as well as the essential contents and design elements. A summary of the process used to develop the guidelines is presented below.

**Literature Review and Environment Scan**

Multiple search strategies were used to capture articles relevant to PPOs in chemotherapy, general medicine as well as the general form design literature. Websites of key medication safety organizations as well as the general web were searched for articles related to PPOs and standard order sets.

Forty-six relevant articles were identified. Four themes emerged from their review:

1. Chemotherapy PPOs are superior to blank free-form order sheets in terms of efficiency and patient safety.\(^{18, 21-23}\)

2. Most of the existing guidelines and studies on chemotherapy orders and PPOs are concerned with content, expressions and nomenclature on chemotherapy orders, and some recommendations conflict with each other.\(^{24-32, 30}\)

3. The general form design literature is thin, and its recommendations cannot be directly applied to the design of ambulatory chemotherapy PPOs.

4. Limited guidance exists on how to design PPOs for maximum patient safety.\(^{33, 34}\)

**In-depth Analysis of Field Study Observations**

The field study observations were further analyzed to understand the workflows, tools and patient safety risks associated with the use of PPOs in ambulatory chemotherapy. Sample PPOs from the field study sites were analyzed in terms of their usability and utility. Patient safety issues related to content, design and use of PPOs were identified and are as follows:

- Inconsistent content, format and layout of PPOs
  - PPOs did not always include type and volume of diluents or the frequency of the chemotherapy cycle.
None of the PPOs showed infusion flow rates in mL/hr even though all of the general infusion pumps required nurses to program flow rates in mL/hr (see Section 2.3).

None of the PPOs showed safe dosing ranges for chemotherapy agents to prevent wrong dose errors.

Design issues included: confusing formatting of protocol options; insufficient distinction between different types of information; and inefficient use of text alignment.

- Use of “no‐carbon‐required” (NCR) paper
  - These forms are printed at a central location and distributed manually. Therefore, users tend to hoard PPOs to avoid the hassle of ordering more PPOs from the central location. When new versions of PPOs are released, it is very challenging to ensure that all older versions are destroyed.
  - Orders produced by NCR paper are not very legible, because the colours used to differentiate copies from each other (e.g., pink) turn into grey when faxed, scanned or photocopied, thus reducing contrast with the text.

- Absence of tall man lettering to visually differentiate look‐alike, sound‐alike (LASA) chemotherapy drug names
  - Although tall man is commonly recommended as a medication safety strategy that can be applied to chemotherapy, none of the PPOs evaluated used this method.

**Development Process for Guidelines and Sample PPOs**

Using the above results, a human factors expert assembled a list of best practices that could be applied to ambulatory chemotherapy PPOs. The resulting guidelines were compiled into two categories: (1) contents and (2) design of PPOs.

For each guideline, benefits, examples, and issues were documented. Those guidelines from the literature that conflicted with human factors principles, field study observations, or with each other, were noted.

Three oncology pharmacists, an oncology nurse, two medical oncologists and one radiation oncologist formed a clinical advisory group. They participated in two focus group sessions on the design and content guidelines, respectively. The objective was to achieve a unanimous decision on the retention or rejection of each draft guideline.

Seven senior graphic designers and two faculty members from the Graphic Design Department at the Ontario College of Art and Design (OCAD) then joined the group to contribute their expertise in typography, visual arts and page layout. The interdisciplinary group collaborated on five iterations of designing, prototyping, and evaluating three commonly used chemotherapy protocols. In the fourth iteration, a group of 20 oncologists, oncology pharmacists, pharmacy technicians, clerks, and oncology nurses from across Canada provided feedback on the prototypes. The fifth and final revision included an update based on the ISMP’s newly released guidelines for standard order sets.
Once the guidelines and redesigned PPOs were finalized, a final document was developed, which includes:

- The ideal PPO design process for cancer treatment facilities
- Design and content guidelines, divided into themes
- Priority levels for each guideline
- A checklist tool for evaluating a centres’ existing PPOs against the key guidelines
- Graphical illustrations of issues that the guidelines address
- Customizable, downloadable PPO templates compatible with Microsoft Word or Adobe InDesign

**RECOMMENDATIONS**

- Sites that use paper for chemotherapy ordering (including sites with CPOE where paper is still used for some orders) should follow the recommendations outlined in the supplemental report *Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.*
- To ensure current versions are always used, PPOs should be centrally managed and available electronically online or on the treatment centre's intranet. Orders should be printed on a per-patient basis.
- The foundation of effective PPOs is well-designed, standardized protocols. It is impossible to design a PPO that is easy to use and understand if the protocol itself is complex and difficult to follow. The same is true for CPOE. Thus, protocols should be examined to determine whether they can be simplified.

### 2.3 Large volume general purpose infusion pump programming errors and labeling

**HAZARD SCORE: 18**

Patients receive the majority of their treatment in the cancer treatment facility via large volume general purpose infusion pumps. Most pumps require nurses to enter an infusion flow rate in mL/hr. However, none of the sites’ drug labels or physicians’ orders showed infusion rates in the unit required to program infusion pumps. Consequently, nurses had to perform a complex calculation to convert the dose ordered in milligrams over duration into the flow rate in mL/hr to administer medications via infusion pumps, which in one study was found to be done incorrectly 42% of the time. Although potentially critical, these errors are more easily detected than with ambulatory pumps because the nurses are close to the bedside during the entire infusion, hence the relatively low hazard score.
**RECOMMENDATIONS**

- Flow rate (in the same units as the pump, e.g., mL/hr) should be included on pharmacy-generated chemotherapy labels and/or preprinted orders for infusions administered via large volume infusion pumps, as well as AIPs.42
  - For sites where overfilling is employed (when drug volumes are added to the existing total volume of the IV bag, rather than the removal of the same volume of fluid as is to be injected), approximate flow rates should be used.

- If infrastructure is available to fully implement and adequately maintain smart pumps with dose error reduction systems, this technology should be considered as a means of improving safety at the bedside for large volume infusions.17

**2.4 Free-form orders**

**HAZARD SCORE: 16**

When there is no pre-printed order for a specific protocol, prescribers must use free-form orders or blank prescription pads. This ordering method is fairly common: it was reportedly used by 35% of survey respondents for at least some regimens.

The following safety issues may result from the use of free-form orders:

- The lack of structure means prescribers can complete the order in whatever sequence or layout they choose. Given the complexity of chemotherapy protocols, these contents may be challenging for pharmacists or nurses to interpret.

- Changes to the orders can be especially difficult to notice if the prescription is used for multiple cycles.

- There are no standards or reminders to limit and guide the prescribers. They may order medications at a dose outside the reasonable range for the drug, or omit parts of the order.

- Illegible handwriting is especially problematic when compared to PPOs because the prescriber must handwrite all the information. The possibility of an interpretation error increases especially with LASA drug names (e.g., carboplatin and cisplatin).

**RECOMMENDATIONS**

- Preprinted orders should be developed for all commonly used protocols and free-form orders should be avoided.

- Chemotherapy regimens and protocols should be standardized at the provincial level, should be as simple as possible, and associated tools such as preprinted orders and/or CPOE regimens should be provided to prescribers.

**3 Pharmacy Practices**

A variety of practices were observed across sites for workspace organization, mixing processes, or double-checks in the biological safety cabinets (BSCs), and some practices were inherently more
error-prone than others. This finding is of concern because many mixing errors are often undetectable once the drug leaves the BSC. However, many of the observed practices were not in violation of Canadian and international policies and standards, and that each pharmacy staff member seemed to have confidence that their own organizational technique was safe.

3.1 Organization of materials and work processes in biological safety cabinets

HAZARD SCORE: 48

One of the field study sites only permits a single preparation to be mixed in the BSC at a time, as is mandated by the provincial cancer organization policy. The other sites do not have any policy or practice standards on the maximum number of drugs in the BSC and multiple drugs for multiple patients were often observed in the BSC at once (Figure 9). A risk with this approach is that the wrong drug vial could be selected and injected into the diluent bag, and if the correct vial is then shown to the pharmacist, the error would subsequently go undetected.

Drug labeling procedures also vary between centres. At one centre, the label is half-adhered to the diluent bag (Figure 10) and only fully adhered by the technician once the drug has been injected. At another centre, the technician adheres a temporary handwritten label to the bag and the computer-generated label is adhered by the pharmacist outside the clean room once the double-check has been conducted. However, at other sites, labels are stored in physically distinct locations from their associated preparation supplies such as the diluent bag (Figure 9), introducing an opportunity for a
label to be applied to the incorrect bag after mixing has occurred. Once this error is made, it could easily remain undetected despite independent checks.

Mixing errors missed in pharmacy would also be less detectable by the patient and/or care team because the impact of these errors could be consistent with common toxicity reactions to chemotherapy. If these errors are in fact occurring and going undetected in hospital pharmacies, they would also go undetected in research studies that use methods such as retrospective chart reviews and self-reports, which are commonly employed when establishing error rates, leading us to believe that mixing errors are under-reported in the literature.

**RECOMMENDATIONS**

- Research examining the quality of mixed chemotherapy bags through techniques such as high-performance liquid chromatography (HPLC) is necessary to establish the mixing error rate in Canadian chemotherapy pharmacies.

- Consistent with international standards, only one chemotherapy preparation should enter the biological safety cabinet (BSC) at a time. This can be achieved if materials for each preparation are staged ahead of time in a single bin or Ziploc bag: diluent bag, drug vials, syringes and label/mixing instructions. Bins/bags can be stacked together on a cart or table next to the BSC but only one bin/bag should enter the BSC at a time. Other creative solutions may be required when space or resource restrictions prevent the use of a cart.

- Labels and/or mixing instructions should be paired at all times with their associated preparation supplies and final prepared product.
• Standardized mixing instructions should be created, preferably through an automated process when the prescription is handled by pharmacy. Handwritten mixing instructions are prone to error and misinterpretation.

• Consideration should be given to having separate mixing and administration labels so that only information relevant is shown to each user group (pharmacy staff & nurses).

• As a final safety measure, consider weighing diluent bags prior to and after mixing to confirm the correct volumes have been injected. Anecdotal evidence from colleagues suggests that this method catches major volume errors.

• Other options for mixing and/or verification such as robotics, outsourcing and spectroscopy should be explored.

3.2 No double-check of reconstitution

**HAZARD SCORE: 32**

Some chemotherapy drugs must be reconstituted prior to mixing, whereby diluent is added to the drug vial and agitated to form the final solution. Although independent checks (involving a second person, usually a pharmacist) of final preparations were required by all sites, at four of the six field study sites, no independent check of drug reconstitution was observed. Thus, if the pharmacy technician were to dilute the solute incorrectly, there would be no mechanism to detect this error once the drug had been injected into the diluent bag. Depending on the concentration of the drug mixed, the patient could receive a significant overdose or underdose. Many of the policies and standards we reviewed do not specify an independent check of diluent type and/or volume. Those sites requiring a check did not specifically require a check of diluent type, only volume.

**RECOMMENDATION**

• A second individual (ideally a pharmacist) should check that the correct diluent type and volume have been drawn up in the syringe for reconstitution. They should be examined prior to adding to the solute, as opposed to using techniques such as the “syringe pullback” method. These checks should be in addition to any existing checks of post-constituted volumes of chemotherapy.

3.3 Exposure to hazardous drugs

**HAZARD SCORE: 16**

At the majority of cancer treatment facilities, medication infusion bags are spiked by nurses next to the patient’s bed or chair. Staff and patients can be exposed to hazardous drugs as the bags containing these drugs are typically hung at eye level and protective eyewear is not worn. Nursing staff in some centres were observed to not always follow best practice in handling and disposal of chemotherapy bags, for example, not wearing gloves when disposing of empty bags. It is possible that they were not aware of the hazards these practices posed to their health, or that there were systemic barriers to safe practice such as time pressure or lack of appropriate tools. Some centres have changed their processes so that infusion bags are spiked and primed in the BSC prior to injecting the chemotherapy, thus reducing the risk of nursing exposure.
RECOMMENDATIONS

- To protect nurses and patients from exposure to hazardous drugs, chemotherapy bags should be spiked and primed in the BSC prior to mixing. Alternatively centres should employ the use of closed system drug transfer devices.\textsuperscript{65}

- Centres should provide staff with regular education and tools to help them follow established guidelines on safe handling of hazardous drugs (e.g., \textsuperscript{46}).

4 Additional Issues

In the analysis of the above eleven issues, two further safety themes emerged: patient scheduling models and simplification and standardization.

4.1 Patient Scheduling Models

Delivering chemotherapy involves three major tasks: a) conducting blood tests; b) assessing the patient; and c) treating the patient. How these tasks are scheduled is a key driver of the way cancer treatment facilities operate.

Observations from the field studies revealed two general scheduling models: the same-day model and the multi-day model. In centres that follow the same-day model, blood tests are completed and reviewed by a clinician in the morning, and treatment is administered in the afternoon of the same day (Figure 11). In centres that follow a multi-day model, blood tests may be done up to two days before the treatment, and the patient is assessed by a physician the day before the treatment (Figure 12). The three key elements to the multi-day model are:

1. The ordering physician has access to blood test results at the time of chemotherapy ordering, and
2. Treatment takes place soon after chemotherapy orders are written, but
3. Treatment takes place at least one day after the orders are written so that pharmacy and nursing have time to prepare.

It should be noted that in all centres operating on the multi-day model, exceptions are made for patients based on factors such as travel distance and mobility.

The rationale for the use of the same-day model is that it minimizes disruption to the patient by keeping their number of visits to a minimum.
FIGURE 11. EXAMPLE SEQUENCE OF EVENTS FOR DELIVERING CHEMOTHERAPY USING THE SAME-DAY SCHEDULING MODEL

**Multi-Day Model (3-day version)**

<table>
<thead>
<tr>
<th>Two days before treatment day</th>
<th>One day before treatment day</th>
<th>Treatment Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient checks in</td>
<td>Lab draws blood</td>
<td>Lab processes blood</td>
</tr>
<tr>
<td>Patient checks in</td>
<td>Physician reviews blood test results</td>
<td>Physician assesses patient</td>
</tr>
<tr>
<td>Pharmacy reviews order</td>
<td>Pharmacy checks mixed drugs</td>
<td>Nurse reviews the order</td>
</tr>
<tr>
<td>Nurse calls in patient</td>
<td>Patient receives treatment</td>
<td></td>
</tr>
</tbody>
</table>

**FIGURE 12. EXAMPLE SEQUENCE OF EVENTS FOR DELIVERING CHEMOTHERAPY USING THE MULTI-DAY SCHEDULING MODEL (RECOMMENDED)**

Analysis
To better understand the impact of the same-day model on patient safety, the issues hierarchies of the two field study sites operating on the same-day model were further analyzed. Hazards resulting directly from the same-day model were highlighted (Appendix J).

**Results**

The analysis revealed that although the same-day model may seem more consistent with patient-centered care, there are issues that permeate through all areas of the chemotherapy treatment facility that impact patient experience and safety:

- Patients’ waiting times on the day of treatment tend to be very long. Long waiting time has been identified as the worst aspect of receiving care in ambulatory oncology clinics.  

- Many patients arrive early in the morning hoping to get through the processes faster. This creates extreme peaks and valleys in patient volume and staff workload.

- Pharmacy receives a large number of orders at once and staff feel pressured to process the orders as fast as they can.

- When a change order is placed, the order is further delayed from getting to the pharmacy, and the pharmacy staff is further pressured to work quickly.

- Staff are more vulnerable to human errors because their cognitive resources are taxed by stress, interruptions and distractions (Figure 13).

**NURSES CANNOT PREPARE THE SUPPLIES AND MEDICATIONS IN ADVANCE. THE PRESSURE TO COPE WITH FLUCTUATING AND UNCERTAIN WORKLOAD MAKES THEM VULNERABLE TO HUMAN ERROR (**

- Figure 14).

- Since patient volumes are unpredictable, it is a challenge to staff the unit appropriately.
FIGURE 13. POTENTIAL ISSUES AND HUMAN ERRORS IN PHARMACY RESULTING FROM THE SAME-DAY MODEL
In comparison, centres using a multi-day model experience the following benefits:

- Treatments can be scheduled evenly throughout the day with fewer peaks and valleys in patient volume.
- Patients spend less time waiting at each of their visits.
- Orders can be prioritized depending on the length of treatment and pharmacy preparation time.
- Nursing and pharmacy resources can be more efficiently planned and utilized.
- The work environment can be less chaotic and stressful.
- Blood test results can be reviewed thoroughly by multiple stakeholders since they are conducted at least one day before the treatment. At one site following a multi-day model, all of physicians, nurses and pharmacists review blood test results.
• Sufficient time is possible for communication between disciplines for order clarifications and/or change orders (see Section 2.1).

RECOMMENDATIONS

• Patients’ perspectives on pros and cons of scheduling models have not yet been studied, and little guidance exists in the literature on the impact on patients, health care providers, or to the system when switching to a multi-day model, or how to successfully migrate to a multi-day model. Thus, further investigation is required.

• Given the many issues stemming from the same-day model, centres should evaluate the impact of implementing a multi-day model, and where and when it is appropriate, should strive for an implementation of this scheduling approach. Those who do are encouraged to share their experience, ideally by publishing their results in a peer-reviewed journal:
  o The ordering physician has access to blood test results at the time of chemotherapy ordering, and
  o Treatment takes place soon after chemotherapy orders are written, but
  o Treatment takes place at least one day after the orders are written so that pharmacy and nursing have time to prepare (Figure 12).

• Policies and procedures should be established to identify for whom same-day treatment may be preferable (e.g., patients with mobility problems; those who must travel a great distance; or those for whom the model poses financial, emotional or other stressors).

4.2 Simplification and Standardization

There are a variety of strategies for reducing human error, many of which are recommended in the sections above. However, a common theme emerged from these recommendations: the simplification and standardization of work processes. This error reduction strategy is well known in aviation safety as well as patient safety because it reduces the number of decision points required by human operators, and thus their reliance on memory.

The following are examples of how simplification and standardization could provide significant safety benefits in IV ambulatory chemotherapy:

• **Drug protocols:** National, provincial or local cancer/health authorities could simplify the number of protocols available for ordering as well as simplifying the protocols themselves.

• **Ordering tools:** The tools used for ordering (PPOs, CPOE) could be standardized at the national, provincial or local cancer/health authority level so that no matter where an oncology care provider practices, the system is the same or similar.

• **Dosing:** If doses could be simplified or standardized, processes downstream would be simpler and therefore less error-prone.

• **Overfilling of IV bags:** Some centres withdraw the same volume of IV fluid as is injected with chemotherapy (unless this volume is below a minimum threshold). However, other centres add the drug volume to the IV bag without withdrawing fluid (unless the total volume exceeds the bag manufacturers’ guidelines). Although overfilling reduces the number
of punctures made to the IV bag and therefore the potential contamination, standardized volumes results in simpler workflows for nurses, especially when calculating infusion rates.

- **Prescriber workflows:** When prescribers have idiosyncratic processes (e.g., in their preference for protocols, calculation algorithms such as body surface area (BSA) and creatinine clearance (CrCr), and requirements for who checks what and when), inefficiencies and confusion result. Teams should collaborate to create standardized work processes that are simple for everyone.

- **Other workflows:** Workflows in areas such as scheduling and mixing were observed to have unnecessary inefficiencies and complexities. Making these simple benefits everyone.

**RECOMMENDATION**

- Simplification and standardization at the highest possible level of the healthcare system in terms of protocols, ordering tools, dosing, and workflows, will result in the greatest safety and efficiency gains. Collaboration between provincial health organizations, cancer treatment facilities and individual cancer care providers is required.
CONCLUSIONS

The first aim of this study was to identify the current practices for ordering, preparing, labeling, verifying & administering ambulatory IV chemotherapy in Canada. Through the survey and field studies, a very high awareness of the fluorouracil incident and its associated report\(^1\) was found among cancer care providers illustrating one of the many benefits of incident disclosure. Many centres have made changes to practice as a result of this report, including a major migration away from electronic AIPs to elastomeric AIPs. The most common tool for ordering chemotherapy was preprinted paper orders. A very wide variety of practices and organizational cultures were observed in the field studies, but two commonalities existed across sites: complexity and efficiency pressure.

The second aim of the study was to identify sources of risk in a wide variety of environments. Through analysis of the survey and field study data, 37 unique safety issues were identified. Eleven of these were chosen for future study and were organized into three themes: elastomeric AIPs and access devices; orders and labels; and pharmacy practices. The additional themes of patient scheduling models and simplification and standardization were uncovered during the analysis of those eleven issues.

The final aim of the study was to recommend strategies to reduce risks with the identified safety issues. Recommendations relating to the four themes are provided in this report. They take a variety of forms, from staff education, to improved forms design, to changes in mixing workflow, and standardization and simplification of chemotherapy protocols. These recommendations are currently being reviewed and will be incorporated into Accreditation Canada standards, as appropriate.

A number of future research topics have arisen from this work. Research on in vivo performance of elastomeric AIPs, homecare and chemotherapy treatment, and especially, the quality and safety of mixed IV chemotherapy bags would serve to better understand and improve the safety issues in IV chemotherapy.

The findings from this research will be distributed widely across Canada through the CAPCA network. Documents and tools will be available for download from [www.capca.ca](http://www.capca.ca).
REFERENCES


12. FDA. Manufacturer and User Facility Device Experience (MAUDE).


35. FDA. Name differentiation project, 2002.


37. The Joint Commission. National Patient Safety Goal: Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs. .


44. Standards of practice for oncology pharmacy in Canada: Version 1: Canadian Association for Pharmacy in Oncology (CAPhO), 2004.


APPENDIX A: EXCERPT FROM EXAMPLE PROCESS DESCRIPTION

Process steps that differ between oncologists are noted in blue.

Clinic

Day before clinic visit (3 days prior to treatment, T-3)

- Secretaries from the treatment area refer to the Green Book List in scheduling system to determine whose chemo charts need to be pulled and sent to clinic.
- Clerks from the clinic area also refer to the Green Book List to determine whose hospital charts need to be pulled.
- Clerks marry the hospital chart with its respective chemo chart (hereinafter referred to as the ‘merged chart’) and file them at the clinic reception desk

Day of clinic visit (T-2)

- Patient arrives for clinic visit
  - Patient checks in at the hospital’s main admitting desk
    - Shows health card and is “arrived” in scheduling system
    - Patient-specific face sheet and armband label print automatically at the clinic reception desk
  - Patient checks in at the clinic reception desk where the clinic receptionist affixes their armband and sends them to the waiting room
  - Clinic receptionist paperclips the face sheet to the merged chart and takes it to the clinic to signal to the clinic LPNs that the patient has arrived

- Clinic LPN prepares patient for clinic
  - Organizes merged charts by oncologist
  - Takes merged chart to the waiting room to call a patient once an exam room is free
  - Weighs patient and documents this on the face sheet
  - Escorts patient to the exam room and leaves their merged chart in the box outside the room

- Oncologist assesses patient
  - Reviews merged chart prior to entering the exam room and reviews information on CPOE system as necessary
    - Method 1: Patient has bloodwork done prior to the clinic visit so less follow-up activity is required.
    - Method 2: Patient has bloodwork done after the clinic visit so that blood doesn’t have to be drawn again should additional tests be required.
  - Assesses and examines patient
o Fills in face sheet with requirements for:
  - Next clinic visit
  - Lab tests
  - Diagnostics/exams

• Clinic LPN and clinic receptionist process bloodwork requests
  o Clinic LPN enters bloodwork requests into CPOE system
    • Labels for the blood vials will print automatically at the clinic reception desk
  o Clinic LPN takes face sheet to clinic receptionist
  o Clinic receptionist schedules next clinic visit based on the oncologist’s instructions on the face sheet, and updates the patient’s appointment card
  o Clinic receptionist paperclips the labels and appointment card to the face sheet and passes these to the LPNs responsible for blood draw

• Blood draw LPN calls patient from waiting room
  o Asks the patient for their DOB and verifies this against their armband
  o Draws blood and affixes the labels to the vials
  o Returns patient’s appointment card to them
  o Records time spent with patient in nursing workload system

• Treatment visit is scheduled
  o Clinic LPN calls the secretaries in treatment area to tell them the patient’s name, protocol, planned start date, etc.
  o Secretaries use their own learned knowledge of the protocol and the order (handwritten or preprinted) to schedule the treatment visit
  o Secretaries begin coordinating the patient’s calendar with treatment details, administration of oral medications, etc.

Movement and Checking of Charts

(Note that the tasks described in this section occur anytime during T-2, T-1 and treatment day, and do not necessarily occur in this order. The order in which the tasks are completed is dependent on the oncologist and the timing of the other tasks.)

• Porter transports the charts from clinic to the Charge Nurse in treatment area

• Charge Nurse reviews patient’s chart
  o Creates a ‘To Do’ list for each oncologist
    • Method 1: Adheres a sticky note to the patient’s chart to remind the oncologist what needs to be done (e.g., “check lab results,” “needs proceed,” “needs prescription,” etc.) when they order
    • Method 2: Adheres a sticky note to the patient’s chart to remind him/herself what to tell the oncologist when they enter orders together in the afternoon
    • Method 3: Adheres a sticky note to the patient’s chart to remind him/herself if she needs to contact the oncologist to make any changes to the order
  o Checks whether bloodwork has populated CPOE system, and if so, reviews it
• Occasionally calls patients to do a toxicity assessment over the phone
  o Gives charts to secretaries

• Secretary reviews patient’s chart
  o Checks chart for completeness
  o Transcribes available lab results from CPOE system (hospital patients) or faxed results (non-hospital patients) into the patient’s chart

• Oncologist carries out follow-up activity from clinic visit (immediately following clinic visit, later in the day, or at the very end of the day)
  o Enters requisitions for X-rays and other diagnostics in CPOE system
  o Dictates notes in dictation room and leaves merged chart to be picked up by porter (who takes the green charts to be re-filed in clinic and brings the chemo charts upstairs)
  o Writes new orders for new patients and makes any necessary adjustments for repeat patients’ orders
    ▪ Method 1: Write orders by hand and personally enter all drug details into CPOE system
    ▪ Method 2: Write orders by hand and enter chemo details into CPOE system, while pharmacist enters other drug details into CPOE system
    ▪ Method 3: Write orders in personal electronic order system and personally enter all drug details into CPOE system
  o Oncologist authorizes “proceed” of orders
    ▪ Method 1: Oncologist authorizes proceed only if they have personally reviewed the bloodwork
    ▪ Method 2: Oncologist allows a nurse to authorize the proceed given that the labs values are within the parameters as specified by the oncologist

• Charge nurse checks that order is complete
  o Checks that handwritten orders have been entered into CPOE system correctly and that all orders are complete
  o Checks that proceed has been authorized
  o Reviews bloodwork
  o Separates charts according to patients’ treatment rooms

  o
### APPENDIX B: EXAMPLE PROCESS MAPS

**Chemotherapy Administration**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Prepare patient and chemotherapy set up.</td>
</tr>
<tr>
<td>2.</td>
<td>Ensure accurate drug concentration and dosing.</td>
</tr>
</tbody>
</table>

**Example Process**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Receive prescription.</td>
</tr>
<tr>
<td>2.</td>
<td>Verify patient identification.</td>
</tr>
<tr>
<td>3.</td>
<td>Prepare chemotherapy solution.</td>
</tr>
<tr>
<td>4.</td>
<td>Administer chemotherapy.</td>
</tr>
<tr>
<td>5.</td>
<td>Monitor patient for adverse effects.</td>
</tr>
<tr>
<td>6.</td>
<td>Dispose of used equipment.</td>
</tr>
</tbody>
</table>

---

**Injection Administration**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Prepare injection site.</td>
</tr>
<tr>
<td>2.</td>
<td>Administer injection.</td>
</tr>
</tbody>
</table>

**Example Process**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Receive prescription.</td>
</tr>
<tr>
<td>2.</td>
<td>Verify patient identification.</td>
</tr>
<tr>
<td>3.</td>
<td>Prepare injection solution.</td>
</tr>
<tr>
<td>5.</td>
<td>Monitor patient for adverse effects.</td>
</tr>
<tr>
<td>6.</td>
<td>Dispose of used equipment.</td>
</tr>
</tbody>
</table>
### APPENDIX C: EXCERPT FROM EXAMPLE DATA REPOSITORY

<table>
<thead>
<tr>
<th>Task</th>
<th>Done</th>
<th>Who</th>
<th>Where</th>
<th>When</th>
<th>How</th>
<th>Comments/Concerns</th>
<th>Comment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrive patient in clinic</td>
<td>1</td>
<td>Clerk</td>
<td>Hospital reception</td>
<td>When patient arrives for clinic visit</td>
<td>Clerk checks patient’s health card and &quot;arrives&quot; them in scheduling system. Patient-specific face sheet and armband label will print automatically at the clinic reception desk.</td>
<td>There is no ID check prior to affixing the armband. If two patients with similar or the same name are being seen around the same time, the armband could be affixed to the wrong patient.</td>
<td>Unsure of the purpose of the armbands in clinic since they are not checked (except for occasionally prior to the bl</td>
</tr>
<tr>
<td>Obtain patient height and weight</td>
<td>1</td>
<td>LPN</td>
<td>Clinic</td>
<td>Before the patient is brought into the exam room</td>
<td>When patient arrives for clinic visit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX E: ANALYSIS OF INCIDENTS REPORTED IN SURVEY

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong drug/dose/patient</td>
<td>“placed the wrong pump on the wrong pt”</td>
<td>21</td>
</tr>
<tr>
<td>Medication administered to incorrect patient</td>
<td>“A patient was ordered 5 days worth of VAD to be delivered in one day”</td>
<td>5</td>
</tr>
<tr>
<td>Medication ordering error</td>
<td>“problems with pharmacists incorrectly calculating drug volumes in pumps”</td>
<td>7</td>
</tr>
<tr>
<td>Mixing error</td>
<td>“at least two incidents where... infusors have emptied much faster/sooner than they were supposed to and patients were very ill as a result”</td>
<td>9</td>
</tr>
<tr>
<td>Medication infused too quickly or too slowly</td>
<td>“Misprogrammed pump, resulting in Herceptin being infused too quickly.”</td>
<td>67</td>
</tr>
</tbody>
</table>

3. Note that examples are exact quotes from respondents; errors in spelling were not corrected.
4. Ambulatory infusion pump.
5. Elastomeric pumps, sometimes referred to as “baby bottle” pumps or “infusors”, are disposable, fixed-rate, non-electric pumps used for a one-time administration of intravenous medications.
<table>
<thead>
<tr>
<th>Issue</th>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong elastomeric pump filled and administered</td>
<td>“Incorrect elastometric infuser selected. The result was that the patient received a 7 day infusion in 2 days.”</td>
<td>10</td>
</tr>
<tr>
<td>Infusion pump incident- pump type not specified</td>
<td>“5-FU being delivered over a short period of time instead of over 46 hours patient developed severe mucositis but survived.”</td>
<td>10</td>
</tr>
<tr>
<td>Medication not infused</td>
<td>“5-FU being delivered over a short period of time instead of over 46 hours patient developed severe mucositis but survived.”</td>
<td>47</td>
</tr>
<tr>
<td>Line kink with elastomeric pump</td>
<td>“tubing may kink on an elastomeric infuser which prevents the drug from infusing over the perscribed time.”</td>
<td>10</td>
</tr>
<tr>
<td>Electronic AIP not started</td>
<td>“at least one incident of a nurse forgetting to start a CADD pump.”</td>
<td>6</td>
</tr>
<tr>
<td>Tubing not unclamped</td>
<td>“Numerous cases of pump was not unclamped and patient returned without any drug infusing.”</td>
<td>31</td>
</tr>
<tr>
<td>Lines and leaks</td>
<td>“one patient’s port-a-cath dislodged at night and pt did not call nurse on call”</td>
<td>8</td>
</tr>
<tr>
<td>Leak</td>
<td>“leak directly from the baby bottle when the nurse went to hook the patient up, the nurse was exposed to 5FU”</td>
<td>39</td>
</tr>
<tr>
<td>Other</td>
<td>“low battery beeping, battery replaced.”</td>
<td>3</td>
</tr>
<tr>
<td>Other electronic AIP issue</td>
<td>“pump failing to run and an error message given”</td>
<td>6</td>
</tr>
<tr>
<td>Mechanical failure of electronic AIP</td>
<td>“patient cut the tubing line while gardening with her gardening scissors”</td>
<td>14</td>
</tr>
<tr>
<td>Extravasation</td>
<td>“Patient’s have returned with extravasation from 5FU baby bottles”</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>213</td>
</tr>
</tbody>
</table>
## APPENDIX F: ALL SAFETY ISSUES IDENTIFIED IN SURVEY AND FIELD STUDIES

<table>
<thead>
<tr>
<th>#</th>
<th>Safety Issue (potential error/hazard)</th>
<th>Data source(s)</th>
<th>Description of potential impact</th>
<th>Evidence of near miss or incident?</th>
<th>Severity</th>
<th>Probability</th>
<th>Detectability</th>
<th>Hazard score</th>
<th>Explored in study?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Elastomeric infusor malfunction (delivers too quick/slow)</td>
<td>3 sites, survey</td>
<td>Chemo delivered at wrong rate</td>
<td>Y</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>64</td>
<td>Y</td>
</tr>
<tr>
<td>2</td>
<td>Labels and bags are not married to each other until after mixing, and there is no identification on the bag. Wrong label could be applied to a bag of mixed medication.</td>
<td>3 sites</td>
<td>Patient receives incorrect drug/dose</td>
<td>N</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>48</td>
<td>Y</td>
</tr>
<tr>
<td>3</td>
<td>No formal structure for communicating changes to orders. Changes therefore not received/prepared by pharmacy</td>
<td>4 sites</td>
<td>Patient receives incorrect drug/dose</td>
<td>Y</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>36</td>
<td>Y</td>
</tr>
<tr>
<td>4</td>
<td>Multiple drugs are stored in the biological safety cabinet during mixing. Technician could draw up wrong drug but hold up the correct vial for the pharmacist check</td>
<td>5 sites</td>
<td>Patient receives incorrect drug/dose</td>
<td>N</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>32</td>
<td>Y</td>
</tr>
<tr>
<td>5</td>
<td>No independent double check of chemo reconstitution. If error occurs, no one is there to catch it.</td>
<td>2 sites</td>
<td>Patient receives incorrect drug/dose</td>
<td>N</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>32</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>6: Handwritten changes made to pre-printed order forms missed by nursing or pharmacy.</td>
<td>1 site</td>
<td>Patient receives incorrect drug/dose</td>
<td>Y</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>24</td>
<td>Y</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>7</td>
<td>7: Wrong elastomeric infusor is selected because multiple different infusor sizes are stocked in pharmacy area.</td>
<td>2 sites, survey</td>
<td>Chemo delivered at wrong rate</td>
<td>Y</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>24</td>
<td>Y</td>
</tr>
<tr>
<td>8</td>
<td>8: Formatting of order forms (pre-printed or CPOE) confusing making ordering errors possible</td>
<td>3 sites</td>
<td>Patient receives incorrect drug/dose</td>
<td>Y</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>24</td>
<td>Y</td>
</tr>
<tr>
<td>9</td>
<td>9: Nurses program an incorrect infusion rate into the general purpose pump because they have nothing to verify the rate against on the drug label or order and there are no hard or soft limits on the pump</td>
<td>6 sites, survey</td>
<td>Chemo delivered at wrong rate</td>
<td>N</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>18</td>
<td>Y</td>
</tr>
<tr>
<td>10</td>
<td>10: PICC line kink (using Infusor)</td>
<td>2 sites, survey</td>
<td>Chemo delivery not at constant rate</td>
<td>Y</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Y</td>
</tr>
<tr>
<td>11</td>
<td>11: Use of free-form order forms have no guidance or boundaries for drugs, doses, hydration etc.</td>
<td>3 sites, survey</td>
<td>Patient receives incorrect drug/dose</td>
<td>N</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>16</td>
<td>Y</td>
</tr>
<tr>
<td>12</td>
<td>12: CPOE does not default to using updated BSA</td>
<td>1 site</td>
<td>Patient receives incorrect dose</td>
<td>Y</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>16</td>
<td>Y</td>
</tr>
<tr>
<td>13</td>
<td>13: Tubing leaks with elastomeric and electronic AIPs</td>
<td>Survey</td>
<td>Exposure to cytotoxins</td>
<td>Y</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Y</td>
</tr>
<tr>
<td>14</td>
<td>14: Chemo bags not wiped down in pharmacy</td>
<td>1 site</td>
<td>Exposure to cytotoxins</td>
<td>N</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Y</td>
</tr>
<tr>
<td>15</td>
<td>15: Spiking of chemo bags occurs at patient bedside and leaks/drips can occur</td>
<td>1 site</td>
<td>Exposure to cytotoxins</td>
<td>N</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Y</td>
</tr>
<tr>
<td>16</td>
<td>Homecare teaches patient to self-care</td>
<td>1 site</td>
<td>Patient's treatment is disrupted or they self-diagnose or self-treat</td>
<td>Y</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>16</td>
<td>Y</td>
</tr>
<tr>
<td>17</td>
<td>Preprinted order sheets used for multiple cycles and handwritten changes to orders can go unnoticed</td>
<td>4 sites</td>
<td>Patient receives incorrect drug/dose</td>
<td>Y</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>18</td>
<td>Elastomeric infusor malfunction - leak</td>
<td>1 site</td>
<td>Exposure to cytotoxins</td>
<td>Y</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>19</td>
<td>Patient side effects not identified in clinic or treatment area</td>
<td>1 site</td>
<td>Patient receives incorrect dose</td>
<td>Y</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>20</td>
<td>Chemotherapy preparation cards used for multiple treatments in same cycle- details change and amendments are made by hand on scrap paper. Changes can go unnoticed</td>
<td>1 site</td>
<td>Patient receives incorrect drug/dose</td>
<td>Y</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>21</td>
<td>No verification of BSA</td>
<td>1 site</td>
<td>Patient receives incorrect dose</td>
<td>Y</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>22</td>
<td>Bloodwork is only checked once/by one person</td>
<td>1 site</td>
<td>Patient receives incorrect drug/dose</td>
<td>Y</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>23</td>
<td>Yellow carbon copy of order given to pharmacy is difficult to read</td>
<td>1 site</td>
<td>Patient receives incorrect dose</td>
<td>Y</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>24</td>
<td>Electronic AIP programming error</td>
<td>3 sites, survey</td>
<td>Chemo delivered at wrong rate</td>
<td>Y</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>25</td>
<td>Wrong volume of drug calculated (manually on calculator)</td>
<td>1 site</td>
<td>Patient receives incorrect dose</td>
<td>N</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>No.</td>
<td>Issue Description</td>
<td>Location</td>
<td>Result</td>
<td>Impact</td>
<td>Severity</td>
<td>Risk Factor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------</td>
<td>--------</td>
<td>--------</td>
<td>----------</td>
<td>-------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Mixing instructions transcribed incorrectly on to recipe card in pharmacy</td>
<td>1 site</td>
<td>Patient receives incorrect dose</td>
<td>N</td>
<td>4</td>
<td>2</td>
<td>8</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Drug-patient mix up: wrong drug given to nurse/delivered to patient room/wrong armband applied to patient at checkin/patient ID not checked during admin</td>
<td>4 sites, survey</td>
<td>Patient receives wrong drug</td>
<td>Y</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>28</td>
<td>Chemo appointment scheduled incorrectly</td>
<td>2 sites</td>
<td>Chemo not delivered at appropriate time</td>
<td>Y</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>29</td>
<td>Tubing not unclamped</td>
<td>Survey</td>
<td>Delay in treatment/underdose</td>
<td>Y</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>30</td>
<td>Hydration does not automatically repopulate the pharmacy system after the first treatment</td>
<td>1 site</td>
<td>Patient does not receive hydration</td>
<td>Y</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>31</td>
<td>There is no restriction on the choice of regimen. Oncologist may select an inappropriate treatment plan.</td>
<td>2 sites</td>
<td>Patient receives inappropriate treatment</td>
<td>N</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>32</td>
<td>Electronic medication administration record not signed off at end of shift</td>
<td>1 site</td>
<td>Ordered medication documented as not administered and subsequent treatment decisions affected</td>
<td>Y</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>N</td>
</tr>
<tr>
<td>33</td>
<td>Electronic AIP - forgot to start pump</td>
<td>Survey</td>
<td>Delay in treatment</td>
<td>Y</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>N</td>
</tr>
<tr>
<td>34</td>
<td>Nurses must leave patient unattended in the treatment room without anyone close by</td>
<td>1 site</td>
<td>Patient could have a reaction the the drugs with no one there to respond</td>
<td>N</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>N</td>
</tr>
<tr>
<td>Case</td>
<td>Description</td>
<td>Sites</td>
<td>Patient misses dose of oral medication (non-chemo)</td>
<td>Y</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>N</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------</td>
<td>-----------------------------------------------</td>
<td>----</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>35</td>
<td>Oral (non-chemo) prescriptions handwritten on IV chemo order sheets. Prescriptions missed by nurses.</td>
<td>1</td>
<td></td>
<td>Y</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>N</td>
</tr>
<tr>
<td>36</td>
<td>Wrong pre-printed order printed off website</td>
<td>1</td>
<td>Patient receives incorrect treatment</td>
<td>N</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>N</td>
</tr>
<tr>
<td>37</td>
<td>Order is not completely transcribed into electronic order system</td>
<td>1</td>
<td>Patient does not receive drug</td>
<td>N</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>N</td>
</tr>
</tbody>
</table>
## APPENDIX G: TABLE OF RECOMMENDATIONS

<table>
<thead>
<tr>
<th>1</th>
<th>Elastomeric Ambulatory Infusion Pumps (AIPs) and Access Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong></td>
<td><strong>Unexplained elastomeric AIP malfunctions</strong></td>
</tr>
</tbody>
</table>
| 1.1.1 | • Elastomeric AIPs are a simple way of preventing massive flow rate errors that can occur with electronic programmable AIPs such as in the fluorouracil incident. However several factors (diluent type, head height, temperature, underfilling, and diameter of vascular access device) can lead to a significant variance in flow rate. Improved education is required to ensure that the pumps infuse as close to the nominal rate as possible.  
  
o Education materials should be user-specific so that pharmacy staff, nurses and patients are aware of the factors affecting pump performance; the points relevant to their role in preparing, administering and using the device; and how to recognize when a pump is not performing according to specifications (details in Appendix H). These have been shared with Baxter Canada, who have collaborated to develop new product information documents (see Appendix I for drafts).  
  
o Ordering physicians should be made aware of the strengths and weaknesses of these devices.  
  
o Manufacturers of elastomeric devices should place development efforts on the continued performance improvement of these products. |
<p>| 1.1.2 | • Research on pump in vivo performance as patients carry out daily tasks with a variety of drugs would help establish the actual performance and incident rates of these pumps. |
| 1.1.3 | • If infrastructure is available to fully implement and adequately maintain smart pumps with dose error reduction systems, this technology should be considered as a means of improving safety and accuracy of ambulatory infusion pumps.(^{17}) |</p>
<table>
<thead>
<tr>
<th>1.2</th>
<th>Elastomeric AIP selection errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2.1</td>
<td>• The variety of models of elastomeric AIPs at each cancer treatment facility should be minimized through the simplification and standardization of protocols.</td>
</tr>
<tr>
<td>1.2.2</td>
<td>• Models of elastomeric AIPs with different flow rates should be stored separately from each other in pharmacy areas to prevent selection errors (see Appendix G for detailed education recommendations).</td>
</tr>
<tr>
<td>1.2.3</td>
<td>• In education materials for pharmacy staff, emphasis should be placed on processes for identifying correct devices, and on the impact of device selection errors.</td>
</tr>
<tr>
<td>1.2.4</td>
<td>• Education for nurses should include procedures for ensuring that the correct device has been chosen and filled by pharmacy.</td>
</tr>
<tr>
<td>1.2.5</td>
<td>• Pump manufacturers should work to better differentiate different models of pumps through improved use of colour, shape and labeling.</td>
</tr>
<tr>
<td>1.2.6</td>
<td>• If infrastructure is available to fully implement and adequately maintain smart pumps with dose error reduction systems, this technology should be considered as a means of improving safety and accuracy of ambulatory infusion pumps.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.3</th>
<th>Homecare and ambulatory devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.1</td>
<td>• More research is needed on how to ensure the safety of chemotherapy patients in homecare environments.</td>
</tr>
<tr>
<td>1.3.2</td>
<td>• Cancer treatment clinics should ensure clear information is provided to patients on how to recognize a pump error and what to do when one occurs (see Appendix G).</td>
</tr>
<tr>
<td>1.3.3</td>
<td>• Findings from this study need to be communicated to provincial home care programs for knowledge transfer so that strategies to improve care for cancer patients can be implemented.</td>
</tr>
<tr>
<td>1.3.4</td>
<td>• Findings from this study need to be communicated to provincial home care programs for knowledge transfer so that strategies to improve care for cancer patients can be implemented.</td>
</tr>
<tr>
<td>1.4</td>
<td>Access devices used with elastomeric AIPs</td>
</tr>
<tr>
<td>-----</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>1.4.1</td>
<td>• More research is needed to determine the impact of different access devices on elastomeric AIP performance and to determine a standard of care.</td>
</tr>
</tbody>
</table>
## Orders and Labels

### 2.1 Change orders

<table>
<thead>
<tr>
<th>2.1.1</th>
<th>• To improve the collection of toxicity information, oncology nurses should assess patients before chemotherapy orders are submitted to pharmacy.</th>
</tr>
</thead>
</table>
| 2.1.2 | • The multi-day scheduling model should be employed whenever possible (see Section 4.1):
  |   o To reduce the likelihood of change orders.  
  |   o To relieve pressure and inefficiencies in the pharmacy department, thus reducing errors and wasted drugs. |
| 2.1.3 | • To improve the quality of change order communication, PPOs should be designed according to recommendations in *Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.* Specifically, they should:
  |   o Ideally, be used for one cycle only.  
  |   o Have designated space for change order communication. |
| 2.1.4 | • CPOE has the potential to reduce some types of errors. At a minimum, CPOE systems should provide the following functionality for managing change orders:
  |   o Prescriber can attach notes to each order in a format that allows other clinicians to easily notice and understand.  
  |   o Automatically alert users if an order is non-standard.  
  |   o Automatically notify the clerks, clinic, pharmacy and nursing if a change has been made to an order.  
  |   o Automatically keep track of all the changes made to an order, including when, who and why the change was made. |
| 2.1.6 | • Institutions should develop appropriate policies and procedures to:
  |   o Keep written track of changes made to an order.  
  |   o Visually flag orders that have been or likely to be changed.  
  |   o Immediately alert all relevant stakeholders when a change is or likely to be made to an order (see Figure 7 Figure 8 for examples from the field studies). |
### 2.2 Pre-printed orders: reuse of forms, handwriting, usability, flexibility

| 2.2.1 | Sites that use paper for chemotherapy ordering (including sites with CPOE where paper is still used for some orders) should follow the recommendations outlined in the supplemental report *Guidelines for Developing Ambulatory Chemotherapy Preprinted Orders.*

| 2.2.2 | To ensure current versions are always used, PPOs should be centrally managed and available electronically online or on the treatment centre's intranet. Orders should be printed on a per-patient basis.

| 2.2.3 | The foundation of effective PPOs is well-designed, standardized protocols. It is impossible to design a PPO that is easy to use and understand if the protocol itself is complex and difficult to follow. The same is true for CPOE. Thus, protocols should be examined to determine whether they can be simplified.

### 2.3 Large volume general purpose infusion pump programming errors and labeling

| 2.3.1 | Flow rate (in the same units as the pump, e.g., mL/hr) should be included on pharmacy-generated chemotherapy labels and/or preprinted orders for infusions administered via large volume infusion pumps, as well as AIPs.

|  | For sites where overfilling is employed (when drug volumes are added to the existing total volume of the IV bag, rather than the removal of the same volume of fluid as is to be injected), approximate flow rates should be used.

| 2.3.2 | If infrastructure is available to fully implement and adequately maintain smart pumps with dose error reduction systems, this technology should be considered as a means of improving safety at the bedside for large volume infusions.

### 2.4 Free-form orders

| 2.4.1 | Preprinted orders should be developed for all commonly used protocols and free-form orders should be avoided.

| 2.4.2 | Chemotherapy regimens and protocols should be standardized at the provincial level, should be as simple as possible, and associated tools such as preprinted orders and/or CPOE regimens should be provided to prescribers.
### Pharmacy Practices

#### 3.1 Lack of standard practice in biological safety cabinet (BSC) organization and processes

| 3.1.1 | • Research examining the quality of mixed chemotherapy bags through techniques such as high-performance liquid chromatography (HPLC) is necessary to establish the mixing error rate in Canadian chemotherapy pharmacies. |
| 3.1.2 | • Consistent with international standards, only one chemotherapy preparation should enter the biological safety cabinet (BSC) at a time. This can be achieved if materials for each preparation are staged ahead of time in a single bin or Ziploc bag: diluent bag, drug vials, syringes and label/mixing instructions. Bins/bags can be stacked together on a cart or table next to the BSC but only one bin/bag should enter the BSC at a time. Other creative solutions may be applicable when space or resource restrictions prevent the use of a cart. |
| 3.1.3 | • Labels and/or mixing instructions should be paired at all times with their associated preparation supplies and final prepared product. |
| 3.1.4 | • Standardized mixing instructions should be created, preferably through an automated process when the prescription is handled by pharmacy. Handwritten mixing instructions are prone to error and misinterpretation. |
| 3.1.5 | • Consideration should be given to having separate mixing and administration labels so that only information relevant is shown to each user group (pharmacy staff & nurses). |
| 3.1.6 | • As a final safety measure, consider weighing diluent bags prior to and after mixing to confirm the correct volumes have been injected. Anecdotal evidence from colleagues suggests that this method catches major volume errors. |
| 3.1.7 | • Other options for mixing and/or verification such as robotics, outsourcing and spectroscopy should be explored. |

#### 3.2 No double-check of reconstitution

| 3.2.1 | • A second individual (ideally a pharmacist) should check that the correct diluent type and volume have been drawn up in the syringe for reconstitution. They should be examined prior to adding to the solute, as opposed to using techniques such as the “syringe pullback” method. These checks should be in addition to any existing checks of post-constituted volumes of chemotherapy. |
| 3.3.2 | Centres should provide staff with regular education and tools to help them follow established guidelines on safe handling of hazardous drugs (e.g.⁴⁶). |
## Other Issues

### Patient scheduling models

4.1.1 Patients’ perspectives on pros and cons of scheduling models have not yet been studied, and little guidance exists in the literature on the impact on patients, health care providers, or to the system when switching to a multi-day model. Thus, further investigation is required.

4.1.2 Given the many issues stemming from the same-day model, centres should evaluate the impact of implementing a multi-day model, and where and when it is appropriate, should strive for an implementation of this scheduling approach. Those who do are encouraged to share their experience, ideally by publishing their results in a peer-reviewed journal:

- The ordering physician has access to blood test results at the time of chemotherapy ordering, and
- Treatment takes place soon after chemotherapy orders are written, but
- Treatment takes place at least one day after the orders are written so that pharmacy and nursing have time to prepare (Figure 12).

4.1.3 Policies and procedures should be established to identify for whom same-day treatment may be preferable (e.g., patients with mobility problems; those who must travel a great distance; or those for whom the model poses financial, emotional or other stressors).

### Simplification and standardization

4.2.1 Simplification and standardization at the highest possible level of the healthcare system in terms of protocols, ordering tools,
dosing, and workflows, will result in the greatest safety and efficiency gains. Collaboration between provincial health organizations, cancer treatment facilities and individual cancer care providers is required.
### APPENDIX H: EDUCATION TOPICS FOR THE SAFE USE OF ELASTOMERIC AIPS

**Table 12 – Education topics for patients**

<table>
<thead>
<tr>
<th>Topic to include in educational materials</th>
<th>Reason(s) for recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>How the device works</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>Keep the pump in a carrying pouch or pocket where it won’t fall out</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>Effect of temperature on flow rate accuracy</td>
<td>- an increase of 1°C from the calibrating temperature of 33°C will increase the flow rate by 2.3%</td>
</tr>
<tr>
<td>Keep the device out of extreme temperatures</td>
<td>- a decrease of 1°C from the calibrating temperature of 33°C will decrease the flow rate by 2.3%</td>
</tr>
<tr>
<td>Keep the device out of direct sunlight</td>
<td></td>
</tr>
<tr>
<td>Ensure that the flow restrictor is taped directly on the skin</td>
<td></td>
</tr>
<tr>
<td>Keep the catheter dry</td>
<td>- keeping the catheter dry requires modifications to the patient’s daily activities (e.g., showering, swimming, etc.)</td>
</tr>
<tr>
<td>Keep the device at the same height as the access point</td>
<td>- the flow rate will increase by 0.5% for every inch that the elastomeric reservoir is positioned above the access point</td>
</tr>
<tr>
<td></td>
<td>- the flow rate will decrease by 0.5% for every inch that the elastomeric reservoir is positioned below the access point</td>
</tr>
<tr>
<td>How to check the progress of infusion</td>
<td>- during the field studies patients often noted that they didn’t know how to check the progress of their infusion as the graduated markings on the shell</td>
</tr>
<tr>
<td>When to contact a healthcare provider</td>
<td>- during the field studies it was observed that some cancer treatment facilities had formalized procedures for contacting a healthcare provider should problems arise, while other centres did not</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>How to tell if the device is leaking</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>If there is a very slow leak, it will leave a white powdery residue under the dressing or at any of the connection points which can irritate the skin</td>
<td></td>
</tr>
<tr>
<td>What to do if the device leaks</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>FAQ</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>How do I have a bath/shower? Can the device get wet or should it be placed on a ledge outside of the bath/shower?</td>
<td></td>
</tr>
<tr>
<td>Can I sleep with the device in the bed (e.g. under my pillow) or should the device be placed on a bedside table or on the floor?</td>
<td></td>
</tr>
<tr>
<td>Can I exercise with the device on?</td>
<td></td>
</tr>
<tr>
<td>Is it safe to have my pet near the device?</td>
<td></td>
</tr>
<tr>
<td>Is it safe to be in warmer areas (e.g., when cooking, sunbathing or using an electric blanket)?</td>
<td></td>
</tr>
<tr>
<td>Is it safe to be in colder areas (e.g., during winter sports)?</td>
<td></td>
</tr>
<tr>
<td>Can I travel on planes with the device?</td>
<td></td>
</tr>
<tr>
<td>What do I do if the device begins leaking?</td>
<td></td>
</tr>
</tbody>
</table>
Table 13 – Education topics for Nurses

<table>
<thead>
<tr>
<th>Topic to include in educational materials</th>
<th>Reason(s) for recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Points to be reviewed with patients</td>
<td>- in the field studies it was observed that nurses are typically the ones that educate patients on the device</td>
</tr>
<tr>
<td>Magnitude of the effects of temperature and head height on flow rate accuracy</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>How flow rate changes during the duration of the infusion</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>How to differentiate between device models, and verify that the correct model has been selected and filled by the pharmacy</td>
<td>- in the field studies and survey device selection errors were noted. Nurses have an opportunity to detect errors before they reach the patient.</td>
</tr>
<tr>
<td>How to connect the elastomeric device to the patient’s access device</td>
<td>- in the survey there were 31 adverse events described where the tubing was not unclamped, preventing delivery of the drug to the patient</td>
</tr>
<tr>
<td>How to choose the correct catheter diameter</td>
<td>- the diameter of the catheter is a factor known to affect flow rate accuracy</td>
</tr>
<tr>
<td>How to force prime should air bubbles in the tubing cause low or no flow</td>
<td>- during the field studies, nurses were often observed flicking the tubing to remove air bubbles, but this may not be sufficient to fully clear the line of air, which would have a negative impact if infused into the patient</td>
</tr>
</tbody>
</table>
Table 14 – Education topics for pharmacists and pharmacy technicians

<table>
<thead>
<tr>
<th>Topic to include in educational materials</th>
<th>Reason(s) for recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>How the device works and expected flow rate accuracy under &quot;nominal&quot; conditions (+/- 10%)</td>
<td>- in the survey there were at least 27 adverse events described that involved an elastomeric AIP infusing too quickly or slowly</td>
</tr>
<tr>
<td></td>
<td>- in the field studies it was observed that pharmacists are often the ones responsible for introducing a device to a cancer treatment facility and are the main sources of information for other clinicians</td>
</tr>
<tr>
<td></td>
<td>- in the FDA MAUDE database analysis 7 of the 74 reported “adverse events” described events where the device infused within +10% of the expected infusion time, a range of error accepted by the manufacturer</td>
</tr>
<tr>
<td>Changes in flow rate accuracy when operating conditions vary from the calibrating conditions (D5W, 33°C, 22 gauge diameter access, elastomeric reservoir at same height as luer lock, appropriate filling volume)</td>
<td>- these factors have the potential to greatly affect flow rate</td>
</tr>
<tr>
<td></td>
<td>- In the field studies, survey, incident analysis, and review of education, staff did not seem to be fully aware of these factors</td>
</tr>
<tr>
<td>Effect of diluent type on flow rate accuracy (+10% when NS is used instead of D5W)</td>
<td></td>
</tr>
<tr>
<td>Effect of temperature on flow rate accuracy (+/-2.3% per degree Celsius above/below calibrating temperature)</td>
<td></td>
</tr>
<tr>
<td>Effect of drug viscosity on flow rate accuracy (which is affected by device temperature, drug temperature, and drug concentration)</td>
<td></td>
</tr>
<tr>
<td>Effect of head height on flow rate accuracy (+/-0.5% per inch that the elastomeric reservoir is above/below the distal end luer lock)</td>
<td></td>
</tr>
<tr>
<td>Effect of overfill/underfill on flow rate accuracy</td>
<td></td>
</tr>
<tr>
<td>Effect of tubing diameter and length on flow rate accuracy</td>
<td>- tubing diameter and length are factors known to affect flow rate accuracy</td>
</tr>
<tr>
<td>Clinical significance of variations in flow rate (i.e., effect of over-infusions and under-infusions)</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Effect of intermittent radiation on flow rate accuracy</td>
<td>- expert clinical recommendation</td>
</tr>
<tr>
<td>How to differentiate between device models, and verify that the correct model has been chosen and filled</td>
<td>- in the survey there were 10 adverse events described related to the selection of an incorrect device model</td>
</tr>
<tr>
<td>Proper storage techniques</td>
<td>- the manufacturer’s product guide [13] states that: the device must be stored in an area away from direct sunlight or extremes of temperature to prevent device malfunction</td>
</tr>
<tr>
<td>Different models should be stored in physically separate areas</td>
<td>- in the survey there were 10 adverse events described related to the selection of an incorrect device model. Storage of different models in physically distinct areas may help with selection errors.</td>
</tr>
<tr>
<td>Storage bins should be clearly labeled with the Infusor model information (SV vs. LV, flow rate)</td>
<td>- during the field studies, it was observed that different models of the device were often stored together</td>
</tr>
<tr>
<td>- different models of pumps often resemble each other in size, shape and colour</td>
<td></td>
</tr>
<tr>
<td>Proper filling techniques</td>
<td>- the manufacturer’s product guide [13] states that: the device should be filled slowly while in the vertical position, the area around the port should be wiped down after filling, and the luer cap should be screwed on securely after filling</td>
</tr>
<tr>
<td>Fill slowly</td>
<td>- errors in filling may be missed once the device leaves the biological safety cabinet</td>
</tr>
<tr>
<td>Ensure device is in vertical position</td>
<td></td>
</tr>
<tr>
<td>Wipe around the filling port after filling the device</td>
<td></td>
</tr>
<tr>
<td>Ensure luer cap is screwed on securely</td>
<td></td>
</tr>
<tr>
<td>How to determine what size of Infusor and rate of infusion should be used</td>
<td>- expert clinical recommendation</td>
</tr>
</tbody>
</table>
| Choice of infusion device is determined, in part, by the dose being given (determines volume), as well as the length of time of infusion (determines
<table>
<thead>
<tr>
<th>Rate</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>2mL/h device filled to 96mL</td>
<td>vs. 5mL/h device filled to 240mL</td>
</tr>
</tbody>
</table>

E.g., using a 2mL/h device filled to a volume of 96mL vs. a 5mL/h device filled to a volume of 240mL.
Printed versions of the educational materials are available from your Baxter Canada representative. Electronic versions can also be downloaded from www.capca.ca.
BAXTER ELASTOMERIC PUMPS INTERMATE

CONSIDER THESE 5 CONDITIONS

The following factors will further impact delivery time
Ensure that patients are provided and instructed on accompanying patient guide

CLINICAL INFORMATION

1 TEMPERATURE
The intermate flow rate is most accurate at 21.1°C or 70°F. Flow rate will decrease ~ 2.3% per 1°C decrease in temperature. Flow rate will increase ~ 2.3% per 1°C increase in temperature.

2 VISCOSITY
The intermate flow rate is most accurate with a diluent solution of 0.9% Sodium Chloride (NaCl). An intermate filled with 5% Dextrose as a diluent will flow ~10% slower than labelled rate.

3 ACCESS
To ensure an accurate flow rate, the access system should be 18 GAUGE or larger when using an intermate.

4 FILL VOLUME
Intermate flow rate is most accurate when filled to the labelled nominal volume. Intermates flow faster than labelled flow rate if UNDER-FILLED (filled to < 81% of optimal fill volume).

5 PUMP HEIGHT
Flow rate is most accurate when the balloon reservoir and the Luer Lock Connector are at the same height. Flow rate can decrease ~ 0.5% per 2.5 cm if the balloon reservoir is below the Luer Lock Connector. Flow rate can increase ~ 0.5% per 2.5 cm if the balloon reservoir is above the Luer Lock Connector.

PRACTICAL GUIDANCE

Keep intermate at a constant temperature during infusion. Do NOT expose intermate to extreme heat or forced re-warming. If intermate is refrigerated, remove it from the refrigerator and allow the device to reach room temperature prior to use. Ensure that the intermate remains close to the body and at room temperature (approx. 21.1°C or 70°F) while in use.

The viscosity of the solution may be affected by the temperature of the solution (diluor or diluent), and the concentration of the solution thereby impacting the flow rate.

A catheter smaller than 18 gauge will decrease the labelled flow rate. Ensure that patient's catheter port is patient before connecting intermate.

Intermates flow faster if underfilled. Use aseptic technique throughout the infusing process. In context of a surgical procedure, do not place the intermate into a sterile field. The fluid path is sterile whereas the outside of the device is not.

Once connected to the patient's catheter port, instruct the patient to keep the top of the intermate as close to the level of the Luer Lock Connector as possible. Provide a carrying case to assist patients in meeting this requirement.

1 Winged Luer Cap protects the opening and stops the flow of medication.
2 Luer Lock Connector at the end of the tubing attaches the infusion/intermate to the catheter/port.
3 Flow Restrictor controls the flow rate of the medication.
4 Tubing is kink-resistant and carries the medication from the device into the patient's body.

Balloon Reservoir holds the medication.
Progression Lines mark the horizontal or vertical on the plastic housing. These show you the progress of the infusion.
Fill Port Cap protects the infusion/intermate device.
Plastic Housing.
Slidr Clamp.

*THERE ARE EXCEPTIONS FOR SOME CODES. PLEASE REFER TO THE INSTRUCTIONS FOR USE FOR ADDITIONAL INFORMATION.

Baxter Corporation 4 Robert Speck Plaza Suite 700 Mississauga, Ontario L4Z 5Y4 Canada
Baxter Corporation 6500 West 95th Street, Suite 100 Minnetonka, Minnesota 55343 USA
Copyright 2016 Baxter Corporation. All rights reserved. MDPI-010-1012
How is medication delivered by the Infusor/Intermate?

- The device is filled with medication prescribed by your physician.
- The product immediately starts delivering medication once it is connected to your catheter/port and will continue until it is empty or disconnected.
- As the elastomeric “balloon” consistently deflates it will gently push medication through your IV tubing and into your catheter/port.

How should I carry it?

- The Luer Lock Connector (refer to Diagram 1) should always be taped to your skin at approximately the same level as the top of the device (ie. Fill Port Cap - refer to Diagram 1) of the Infusor/Intermate in order to maintain an accurate flow rate.
- Carry the device using the carrying case/pouch provided by your health care provider.

Diagram 1

1. **Winged Luer Cap** protects the opening and stops the flow of medication.
2. **Luer Lock Connector** at the end of the tubing attaches the Infusor/Intermate to the catheter/port.
3. **Flow Restrictor** controls the infusion rate of the medication.
4. **Tubing** is kink-resistant and carries the medication from the device into your body.
5. **Balloon Reservoir** holds the medication.
6. **Progression Lines** may be horizontal or vertical on the plastic housing. These show the progress of the infusion.
7. **Fill Port Cap** protects the Infusor/Intermate device.
8. **Plastic Housing.**
9. **Slide Clamp.**
Monitoring Infusion Progress

- Since the Infusor/Intermate delivers medication at a slow rate the elastomeric “balloon” reservoir will appear to be shrinking over several hours or days.
- Ensure that the IV tubing is not clamped or kinked.
- Utilize progression lines on the Infusor/Intermate housing to monitor infusion progress over time.
- Infusion is complete when the “balloon” is completely deflated and all eight indicator bumps (four on either side) on the inside of the device are clearly visible (refer to Diagram 2).

Diagram 2

1. Indicator Bumps
2. Progression Lines
Diagram 3

Infusion Progression - LV5 (2C1009KP)
Delivering accurate infusion. Continuously.

12 HRS INFUSED

24 HRS INFUSED

36 HRS INFUSED
Diagram 4

Infusion Progression - LV1.5 (2C1087KP)
Delivering accurate infusion. Continuously.

2 DAYS INFUSED

4 DAYS INFUSED

6 DAYS INFUSED
Contact your Healthcare Provider if:

- Patient name or medication is incorrect on the medication label.
- The expiration date on the label has passed.
- The medication does not appear to be flowing as expected (i.e. size of elastomeric “balloon” is not changing as expected).
- The Infusor/Internate is leaking.
- Medication comes in contact with your skin:
  - Immediately wash the area with water and soap. Place the device in the plastic bag provided (or any other plastic bag) and return to your healthcare provider.
  - The elastomeric “balloon” has burst.
  - Luer Lock Connector becomes un-taped from your skin (Infusor only).

Consider these conditions that can affect flow rate

**Temperature:**
- If using an Infusor, ensure Luer Lock Connector is taped to your skin.
- Ensure device remains at room temperature.
- Do not expose device to extreme heat/cold.

**Pump Height:**
- Ensure the top of the device is carried as close as possible to the same level as your catheter/port (where Luer Lock Connector is taped to your skin).
FAQ:

**Bathing**
- The Infusor/Internate device should not be submerged or exposed to a direct stream of water.
- Place the Infusor/Internate in a plastic bag OR on a flat surface outside the shower/bath.

**Sleeping**
- Place the Infusor/Internate at approximately the same level to where the device connects to your catheter/port.
- The device can be placed on its side under your pillow.

**Exercise**
- It is acceptable to exercise with the Infusor/Internate as long as the product remains close to room temperature and is not exposed to water. Follow your healthcare provider guidelines.

**Pets**
- The device is safe to use around pets, but ensure that it is protected from chewing and playing.

**Environment**
- The Infusor/Internate can be utilized during everyday activities (e.g. cooking) as long as the device is in a location where it can remain at room temperature and is not exposed to extreme heat/cold.
- Keep device out of direct sunlight.

**Travel**
- It is safe to travel on planes that have pressurized cabins.

*If you have any questions about what you’ve read here, please contact us at 1-888-719-9955.*
Who will answer my questions?

- Health Care Provider:

- Telephone:

- Special instructions:
What I experienced at home with my Infusor/Intermate:

- Infusion start date: [Blank] Time: [Blank]
- Infusion expected end date: [Blank] Time: [Blank]
- Infusion actual end date: [Blank] Time: [Blank]

- Date: [Blank]
- Important notes: [Blank]

- Date: [Blank]
- Important notes: [Blank]

- Date: [Blank]
- Important notes: [Blank]

Please remember to share your experience at home with your Healthcare Provider.
Making a Meaningful Difference in Patients’ Lives.
Portfolio Overview:

Baxter Elastomeric Pumps are non-electronic medication pumps designed to provide ambulatory infusion therapy. Medication is delivered to the patient as the elastomeric “balloon” consistently deflates and gently pushes solution through the IV tubing and into the catheter/port.

The elastomeric technology promotes patient recovery and improves patient quality of life by allowing ambulatory treatment without the inconvenience of programming, power sources or alarms.

Baxter offers two different Elastomeric Pumps that operate using the same base technology:

Infusors:

- Offer duration infusion times from 12 hours to 7 days.
- Designed for ambulatory infusion of: Infusional Chemotherapy, Pain Management & Chelation Therapy.
- Available in a variety of volumes and flow rates.
- Multi-rate and Patient Control Module (PCM) formats available.
- SV infusors (other than SV1 – 2C1701KP) flow within ±12.5% of the labelled flow rate.
- LV & SV1 Infusors flow within ±10% of the labelled flow rate.

*Please refer to Package Insert or the ‘Consider These 5 Conditions’ section of this booklet, as some environmental factors can affect the accuracy of the above flow rate parameters.

Infumates:

- Offer duration infusion times from 30 minutes to 5 hours.
- Designed for ambulatory infusion of: Antibiotic & Antiviral medications.
- Available in a variety of volumes and flow rates.
- Flow within ±15% of the labelled flow rate.

*Please refer to Package Insert or the ‘Consider These 5 Conditions’ section of this booklet, as some environmental factors can affect the accuracy of the above flow rate parameters.

Small Volume (SV) Devices: Small Elastomeric Reservoirs that can hold 105 to 130 ml of solution.

Large Volume (LV) Devices: Large Elastomeric Reservoirs that can hold 275 to 300 ml of solution.

Extra Large Volume (XLV) Devices: Extra large Elastomeric Reservoirs that can hold 550 ml of solution.

Indications:

- Infusional Chemotherapy
- Pain Management
  - Continuous Peripheral Nerve Block (CPNB)
  - Continuous Wound Infusion (CWI)
- Antibiotic/Antiviral Therapy (i.e. Cystic Fibrosis, Osteomyelitis, HIV)
- Iron Chelation

Administration Routes:

- Intravenous (IV)
- Intra-arterial
- Subcutaneous
- Epidural

* Baxter Elastomeric Pumps are safe to use on all central access lines, including PICCs.

Pump Features & Benefits:

- Ambulatory Design – No Cords, Outlets, Batteries or IV Poles
- Lightweight & discreet design
- Single-use disposable
- Latex-Free
- Silent Operation
- No programming required
- Built-in flow regulator eliminates rate manipulation
- Easy to Use

The Baxter Elastomeric Pump offers patients a medication delivery system that is comfortable, portable and adaptable to both their therapy and lifestyle needs.
### The Infusor System

<table>
<thead>
<tr>
<th>Bottle Type</th>
<th>Code</th>
<th>Description</th>
<th>Nominal + Residual Volume</th>
<th>Nominal Flow Rate</th>
<th>Nominal Delivery Time</th>
<th>Maximum Volume</th>
<th>Units / Case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>JACKSON DEVICES [SMALL VOLUME]</strong></td>
<td>2C107K0JP</td>
<td>Single Day Infuser</td>
<td>60 ml + 1 ml</td>
<td>5 ml / hr</td>
<td>12 hours</td>
<td>65 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C107K1JP</td>
<td>Two Day Infuser</td>
<td>96 ml + 2 ml</td>
<td>2 ml / hr</td>
<td>2 days</td>
<td>105 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C108K3JP</td>
<td>Infusion for Doxorubicin</td>
<td>48 ml + 1.5 ml</td>
<td>1 ml / hr</td>
<td>2.5 days</td>
<td>65 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C108K5JP</td>
<td>Multi-Clay Infuser</td>
<td>96 ml + 3 ml</td>
<td>0.5 ml / hr</td>
<td>5 days</td>
<td>65 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C108K8JP</td>
<td>Seven Day Infuser</td>
<td>84 ml + 2.5 ml</td>
<td>0.5 ml / hr</td>
<td>7 days</td>
<td>95 ml</td>
<td>12</td>
</tr>
<tr>
<td><strong>SMALL VOLUME INFUSORS</strong></td>
<td>2C110K0P</td>
<td>Infusion SV 2</td>
<td>96 ml + 1 ml</td>
<td>2 ml / hr</td>
<td>2 days</td>
<td>130 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C110K1P</td>
<td>Infusion SV 1</td>
<td>95 ml + 1 ml</td>
<td>1 ml / hr</td>
<td>4 days</td>
<td>130 ml</td>
<td>12</td>
</tr>
<tr>
<td><strong>MULTI-RATE INFUSORS</strong></td>
<td>2C115K4P</td>
<td>Infusion 1, 2, 3</td>
<td>96 ml + 1 ml</td>
<td>1, 2, 3 ml / hr</td>
<td>96-48-32 hours</td>
<td>130 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C115K6P</td>
<td>Infusion 2, 3, 5</td>
<td>240 ml + 3 ml</td>
<td>2, 3, 5 ml / hr</td>
<td>120-80-48 hours</td>
<td>300 ml</td>
<td>12</td>
</tr>
<tr>
<td><strong>REGIONAL ANAESTHESIA MULTI-RATE INFUSOR WITH PREATTACHED PATIENT CONTROL MODULE</strong></td>
<td>2C1811K</td>
<td>Infusion L 5, 7, 12</td>
<td>240 ml + 3 ml</td>
<td>5, 7, 12 ml / hr</td>
<td>48, 34, 20 hours</td>
<td>300 ml</td>
<td>6</td>
</tr>
<tr>
<td><strong>LARGE VOLUME INFUSORS</strong></td>
<td>2C108K0P</td>
<td>Infusion L 10</td>
<td>240 ml + 3 ml</td>
<td>10 ml / hr</td>
<td>1 day</td>
<td>300 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C115K6P</td>
<td>Infusion L 7</td>
<td>272 ml + 3 ml</td>
<td>7 ml / hr</td>
<td>39 hours</td>
<td>300 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C108K8P</td>
<td>Infusion L 5</td>
<td>240 ml + 3 ml</td>
<td>5 ml / hr</td>
<td>48 hours</td>
<td>300 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C108K4P</td>
<td>Infusion L 2</td>
<td>240 ml + 3 ml</td>
<td>2 ml / hr</td>
<td>5 days</td>
<td>300 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C108K7P</td>
<td>Infusion L 1</td>
<td>252 ml + 3 ml</td>
<td>1.5 ml / hr</td>
<td>7 days</td>
<td>300 ml</td>
<td>12</td>
</tr>
<tr>
<td><strong>BASAL / BOLUS INFUSORS</strong></td>
<td>2C108K5P</td>
<td>Basal / Bolus Infusor**</td>
<td>1.5 ml</td>
<td>Basal 0.5 ml</td>
<td>Maximum 5 days</td>
<td>65 ml</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2C108K6P</td>
<td>Basal / Bolus Infusor**</td>
<td>2.5 ml</td>
<td>Bolus 2 ml</td>
<td>Maximum 2 days</td>
<td>96 ml</td>
<td>6</td>
</tr>
</tbody>
</table>

** Must be used with Patient Control Module

**Diagram 1**

1. **Winged Luer Cap** protects the opening and stops the flow of medication.
2. **Luer Lock Connector** at the end of the tubing attaches the Infusor/Intermate to the catheter/Port.
3. **Flow Restrictor** controls the infusion rate of the medication.
4. **Tubing** is kink-resistant and carries the medication from the device into the patient’s body.
5. **Balloon Reservoir** holds the medication.
6. **Progression Lines** may be horizontal or vertical on the plastic housing. These show you the progress of the infusion.
7. **Fill Port Cap** protects the Infusor/Intermate device.
8. **Plastic Housing**
The Internate® System

<table>
<thead>
<tr>
<th>Bottle Top Colour</th>
<th>Code</th>
<th>Description</th>
<th>Nominal + Residual Volume</th>
<th>Nominal Flow Rate</th>
<th>Nominal Delivery Time</th>
<th>Maximum Volume</th>
<th>Units / Cages</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMALL VOLUME INTERMATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2C1734K</td>
<td></td>
<td>Internate SV 200</td>
<td>100 ml + 1 ml</td>
<td>200 ml / hr</td>
<td>30 minutes</td>
<td>105 ml</td>
<td>48</td>
</tr>
<tr>
<td>2C1732K</td>
<td></td>
<td>Internate SV 100</td>
<td>100 ml + 1 ml</td>
<td>100 ml / hr</td>
<td>1 hour</td>
<td>105 ml</td>
<td>48</td>
</tr>
<tr>
<td>2C1730K</td>
<td></td>
<td>Internate SV 50</td>
<td>100 ml + 1 ml</td>
<td>50 ml / hr</td>
<td>2 hours</td>
<td>105 ml</td>
<td>48</td>
</tr>
<tr>
<td>LARGE VOLUME INTERMATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2C1744K</td>
<td></td>
<td>Internate LV 250</td>
<td>250 ml + 3 ml</td>
<td>250 ml / hr</td>
<td>1 hour</td>
<td>275 ml</td>
<td>24</td>
</tr>
<tr>
<td>2C1742K</td>
<td></td>
<td>Internate LV 100</td>
<td>250 ml + 3 ml</td>
<td>100 ml / hr</td>
<td>2.5 hours</td>
<td>275 ml</td>
<td>24</td>
</tr>
<tr>
<td>2C1740K</td>
<td></td>
<td>Internate LV 50</td>
<td>250 ml + 3 ml</td>
<td>50 ml / hr</td>
<td>5 hours</td>
<td>275 ml</td>
<td>24</td>
</tr>
<tr>
<td>EXTRA LARGE VOLUME INTERMATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2C1064K</td>
<td></td>
<td>Internate XLY</td>
<td>500 ml + 5 ml</td>
<td>250 ml / hr</td>
<td>2 hours</td>
<td>550 ml</td>
<td>12</td>
</tr>
<tr>
<td>2C1100</td>
<td></td>
<td>Ball Bag</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6</td>
</tr>
</tbody>
</table>

Diagram 2

1. **Winged Luer Cap** protects the opening and stops the flow of medication.
2. **Luer Lock Connector** at the end of the tubing attaches the infusor/intermate to the catheter/port.
3. **Flow Restrictor** controls the infusion rate of the medication.
4. **Tubing** is kink-resistant and carries the medication from the device into the patient’s body.
5. **Balloon Reservoir** holds the medication.
6. **Progression Lines** may be horizontal or vertical on the plastic housing. These show you the progress of the infusion.
7. **Fill Port Cap** protects the Infusor/Intermate device.
8. **Plastic Housing**.
9. **Slide Clamp**.
The Infusor System

**The following factors will further impact delivery time**

*Ensure that patients are provided and instructed on accompanying patient guide*

<table>
<thead>
<tr>
<th>CLINICAL INFORMATION</th>
<th>PRACTICAL GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. TEMPERATURE</strong></td>
<td>Keep Luer Lock Connector at a constant temperature during infusion.</td>
</tr>
<tr>
<td>The Infusor flow rate is most accurate at 33.3°C or 92°F.*</td>
<td>Do NOT expose infusor to extreme heat or forced re-warming.</td>
</tr>
<tr>
<td>Flow rate will decrease ~ 2.3% per 1°C decrease in temperature.</td>
<td>If Infusor is refrigerated, remove it from the refrigerator and allow the device to reach room temperature prior to use.</td>
</tr>
<tr>
<td>Flow rate will increase ~ 2.3% per 1°C increase in temperature.</td>
<td><em>How to achieve the correct temperature during infusion:</em></td>
</tr>
<tr>
<td><em>Half Day Infusor (2C1073KJP), LV10 Infusor (2C1063KP) and LV1.6 (2C1087KP)</em> Infusor are designed to operate at optimum flow rate when Luer Lock Connector is at 31.1°C or 68°F.</td>
<td>A temperature of 33.3°C or 92°F is achieved when the Luer Lock Connector is taped to a central (i.e. torso) location on the patient’s skin.*</td>
</tr>
<tr>
<td><strong>2. VISCOSITY</strong></td>
<td>A temperature of 31.1°C or 68°F is achieved when the Luer Lock Connector is taped to a peripheral (i.e. limbs) location on the patient’s skin.*</td>
</tr>
<tr>
<td>The Infusor flow rate is most accurate with a diluent solution of 5% Dextrose.</td>
<td>The viscosity of the solution may be affected by the temperature of the solution (drug &amp;/or diluent), and the concentration of the solution thereby impacting the flow rate.</td>
</tr>
<tr>
<td>An Infusor filled with 0.9% Sodium Chloride (NaCl) as a diluent will flow ~10% faster than labelled rate.</td>
<td><strong>3. ACCESS</strong></td>
</tr>
<tr>
<td>To ensure an accurate flow rate, the access system should be <strong>22 GAUGE</strong> or larger when using an Infusor.</td>
<td>A catheter smaller than 22 gauge will decrease the labelled flow rate.</td>
</tr>
<tr>
<td><strong>4. FILL VOLUME</strong></td>
<td>Ensure that patient’s catheter is patent before connecting Infusor.</td>
</tr>
<tr>
<td>Infusor flow rate is most accurate when filled to the labelled nominal volume.</td>
<td>Infusors flow faster if underfilled.</td>
</tr>
<tr>
<td>Infusor flow is faster than labelled flow rate if UNDERFILLED (filled to &lt; 81% of optimal fill volume).</td>
<td>Use aseptic technique throughout the filling process.</td>
</tr>
<tr>
<td><strong>5. PUMP HEIGHT</strong></td>
<td>In context of a surgical procedure, do not place the infusors into a sterile field. The fluid path is sterile whereas the outside of the device is not.</td>
</tr>
<tr>
<td>Flow rate is most accurate when the balloon reservoir and the Luer Lock Connector are at the same height.</td>
<td>Once connected to the patient’s catheter/port, instruct the patient to keep the top of the Infusor as close to the level of the Luer Lock Connector as possible.</td>
</tr>
<tr>
<td>Flow rate can decrease ~ 0.5% per 2.5 cm if the balloon reservoir is below the Luer Lock Connector.</td>
<td>Provide a carrying case to assist patients in meeting this requirement.</td>
</tr>
<tr>
<td>Flow rate can increase ~ 0.5% per 2.5 cm if the balloon reservoir is above the Luer Lock Connector.</td>
<td></td>
</tr>
</tbody>
</table>
# The Internate System

**CONSIDER THESE 5 CONDITIONS**

The following factors will further impact delivery time

*Ensure that patients are provided and instructed on accompanying patient guide*

<table>
<thead>
<tr>
<th>CLINICAL INFORMATION</th>
<th>PRACTICAL GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 TEMPERATURE</strong></td>
<td>Keep Internate at a constant temperature during infusion. Do NOT expose Internate to extreme heat or forced re-warming. If Internate is refrigerated, remove it from the refrigerator and allow the device to reach room temperature prior to use. Ensure that the Internate remains close to the body and at room temperature (approx. 21.1°C or 70°F) while in use.</td>
</tr>
<tr>
<td>The Internate flow rate is most accurate at 21.1°C or 70°F. Flow rate will decrease ~ 2.3% per 1°C decrease in temperature. Flow rate will increase ~ 2.3% per 1°C increase in temperature.</td>
<td></td>
</tr>
<tr>
<td><strong>2 VISCOSITY</strong></td>
<td>The viscosity of the solution may be affected by the temperature of the solution (drug &amp;/or diluent), and the concentration of the solution thereby impacting the flow rate.</td>
</tr>
<tr>
<td>The Internate flow rate is most accurate with a diluent solution of 0.9% Sodium Chloride (NaCl). An Internate filled with 5% Dextrose as a diluent will flow ~10% slower than labelled rate.</td>
<td></td>
</tr>
<tr>
<td><strong>3 ACCESS</strong></td>
<td>A catheter smaller than 18 gauge will decrease the labelled flow rate. Ensure that patient’s catheter/port is patent before connecting Internate.</td>
</tr>
<tr>
<td>To ensure an accurate flow rate, the access system should be 18 GAUGE or larger when using an Internate.</td>
<td></td>
</tr>
<tr>
<td><strong>4 FILL VOLUME</strong></td>
<td>Internates flow faster if underfilled. Use aseptic technique throughout the filling process. In context of a surgical procedure, do not place the Internate into a sterile field. The fluid path is sterile whereas the outside of the device is not.</td>
</tr>
<tr>
<td>Internate flow rate is most accurate when filled to the labelled nominal volume. Internate flow faster than labelled flow rate if UNDERFILLED (filled to &lt; 81% of optimal fill volume).</td>
<td></td>
</tr>
<tr>
<td><strong>5 PUMP HEIGHT</strong></td>
<td>Once connected to the patient’s catheter/port, instruct the patient to keep the top of the Internate as close to the level of the Luer Lock Connector as possible. Provide a carrying case to assist patients in meeting this requirement.</td>
</tr>
<tr>
<td>Flow rate is most accurate when the balloon reservoir and the Luer Lock Connector are at the same height. Flow rate can decrease ~ 0.5% per 2.5 cm if the balloon reservoir is below the Luer Lock Connector. Flow rate can increase ~ 0.5% per 2.5 cm if the balloon reservoir is above the Luer Lock Connector.</td>
<td></td>
</tr>
</tbody>
</table>
Pharmacy:

1) Jackson Device Filling Instructions:

1. Ensure Winged Luer Cap is fastened to distal end of tubing. Remove paper tubing tape from the Jackson Device tubing.

2. Draw up required drug and diluent syringes. Remove all the air from the syringes.

3. Remove Fill Port Cap retaining it for later use. Beginning with the diluent filled syringe, gently insert the tip of the syringe into the Fill Port and turn clockwise to lock. (Do not attach a needle to the syringe as this will damage the Fill Port.)

4. Place the end of syringe plunger on work surface. Keeping the unit vertical, grasp syringe barrel and push slowly downward on the syringe to gradually force fluid into the Elastomer Reservoir. Do not grasp the Jackson Device Housing during filling.

5. Remove the syringe from the Fill Port. Replace the Fill Port Cap and lock by twisting in a counter clockwise direction.

6. Remove the Winged Luer Cap retaining it for later use. This will allow the solution to move through the tubing and purge air from the system. Allow three drops of diluent to fall onto a 70% alcohol swab to visually confirm that the contents of the Jackson Device are flowing.

7. If the device is flowing, attach the Winged Luer Cap. Continue filling the device (step 2-6) until all required solution has been added. Upon removal of the final syringe, replace the Fill Port Cap and lock by twisting in a counter clockwise direction. If the Jackson Device is not flowing follow steps 8-11.

8. Attach a luer adaptor or stopcock to the Jackson Device Luer Lock Connector.

9. Attach a 10 ml syringe to the other side of the stopcock or luer adaptor. Ensure the stopcock is in the 'open' position.

10. Pull back syringe plunger to create suction. Continue to apply suction to the distal end until fluid is observed in the syringe.

11. Visually confirm that the contents of the Jackson Device are flowing and that the tubing is clear of air before use. Replace Winged Luer Cap.

*Caution: Gently lock syringe or Fill Port Cap. Overtightening can result in damage to Fill Port. Use aseptic technique throughout the procedure.
Pharmacy:

2) Infuser SV & LV Filling Instructions:

1. Draw up require drug and diluent in syringes. Ensure Winged Luer Cap is fastened to distal end of tubing (Luer Lock Connector).

2. Remove paper tubing tape from the Infuser tubing. Ensure Winged Luer Cap is fastened to distal end of tubing (Luer Lock Connector).

3. Remove Fill Port Cap, retaining it for later use. Beginning with the diluent filled syringe, gently insert the tip of the syringe into the Fill Port and turn clockwise to lock.** (Do not attach a needle to the syringe as this will damage the Fill Port.)

4. Place end of syringe plunger on work surface. Keeping the unit vertical, grasp syringe barrel and push slowly downward on the syringe to gradually force fluid into the Elastomeric Reservoir. Do not grasp the infuser device Housing during filling.

5. Remove the syringe from the Fill Port. Replace the Fill Port Cap and lock by twisting in a counter clockwise direction.**

6. Remove the Winged Luer Cap from the distal end of the tubing and retain for later use. This will allow the solution to move through the tubing end purge air from the system. Allow three drops of diluent to fall onto a 70% alcohol swab to visually confirm that the Infuser is flowing. Re-attach the Winged Luer Cap.

7. If the Infuser is flowing, re-attach the Winged Luer Cap and go to step 12. If the Infuser is not flowing, follow steps 8-11.

8. Remove Winged Luer Cap retaining it for later use. Luer lock a syringe tip connector or stopcock to the distal end of the Infuser tubing.

9. Luer lock a 10 ml syringe to the syringe tip connector or stopcock. Ensure the stopcock is in the ‘open’ position.

10. Pull back syringe plunger to create suction until fluid is observed in the syringe. Once fluid is observed close the stopcock, then, remove the syringe. Remove the syringe tip connector or the stopcock from the tubing.

11. Allow three drops of diluent to fall onto a 70% alcohol swab to visually confirm that the Infuser is flowing. Re-attach Winged Luer Cap.

12. Remove Fill Port Cap retaining it for later use. Insert tip of drug filled syringe into Fill Port and turn clockwise to lock.**

13. Place end of syringe plunger on work surface. Keeping the unit vertical, grasp syringe barrel and push slowly downward on the syringe to gradually force fluid into the Elastomeric Reservoir. Repeat with remaining syringes until all required solution has been added.

14. Upon removal of the final syringe, replace the Fill Port Cap and lock by twisting in a counter clockwise direction.** Wind the tubing around the top of the infuser, securing it in place.

*Caution: Gently lock syringe or Fill Port Cap. Overtightening can result in damage to Fill Port. Use aseptic technique throughout the procedure.
Pharmacy:

3) Multi-rate Infusor Filling Instructions:

1. Remove the Fill Port Cap and retain for later use.

2. Remove all air from a 60 ml syringe.

3. Insert tip of filled syringe into Fill Port and turn gently to lock.*

4. Place the end of syringe plunger on work surface. Keeping the unit vertical, grasp syringe barrel or flanges and push slowly downward on the syringe to gradually force fluid into the Elastomeric Reservoir. Do not grasp the Multirate Infusor device Housing during filling. To fill the Multirate Infusor to the desired volume, steps 2-4 may need to be repeated.

5. After the Multirate System is filled, remove syringe.

6. Replace the Fill Port Cap.*

7. Remove the Winged Luer Cap and retain for later use.

8. Insert the Rate Adjustment Tool into the Multirate Infusor Control Module. Using the Rate Adjustment Tool, change the rate to the lowest labelled rate to initiate priming. Medication will automatically begin to purge air from the system. Visually confirm flow of fluid. If the Multirate Infusor is not flowing, follow steps A – D of the Force prime procedure.

9. Using the Rate Adjustment Tool, turn counter-clockwise to change the rate to the middle labelled rate to continue priming the Multirate Infusor. Visually confirm flow of fluid. If the Multirate Infusor is not flowing follow steps A – D of the Force prime procedure.

10. Using the Rate Adjustment Tool, change rate to the highest labelled rate to continue priming the Multirate Infusor. When priming is complete, visually confirm flow of fluid and adjust the Multirate Infusor System to prescribed flow rate. Adjustment tool should be removed after the clinician has set the flow rate as it is not intended to be provided to the patient. Replace the Winged Luer Cap.

Force Prime Procedure:

A. Attach a luer adaptor or stopcock to the Multirate Infusor Luer Lock Connector.

B. Attach a 10 mL syringe to the other side of luer adaptor (or stopcock).

C. Pull back syringe plunger to create suction.

D. Visually confirm flow of fluid from Luer Lock Connector before using Multirate Infusor System. Ensure all air is purged from the delivery tubing. Replace the Winged Luer Cap.

*Caution: Gently lock syringe or Fill Port Cap. Overtightening can result in damage to Fill Port. Use aseptic technique throughout the procedure.
Pharmacy:

4) Regional Analgesia Infusor Filling Instructions:

1. Do not remove PCM shipping tab until system is primed. Confirm that the flow rate module setting is at 0.

2. Ensure all air is removed from syringe or filling device.

3. Remove the Fill Port Cap and retain for later use.

4. Insert the tip of the filled syringe or filling device into the Fill Port and turn to lock.*

5. Place end of syringe plunger on work surface. Keeping the unit vertical, grasp syringe barrel or flanges and push slowly downward on the syringe to gradually force fluid into the Elastomeric Reservoir. Do not grasp the Regional Analgesia Infusor device housing during filling. To fill the Regional Analgesia Infusor to the desired volume, steps 3-5 may need to be repeated.

6. After the Regional Analgesia Infusor system is filled, remove the syringe or filling device.

7. Replace the Fill Port Cap.*

8. Remove the Winged Luer Cap and retain for later use.

9. Remove the Rate Adjustment Tool from the Regional Analgesia Infusor System tubing and insert into the Multirate Control Module. Using the Rate Adjustment Tool, change the rate to the lowest-labelled rate to initiate priming. Medication will automatically begin to purge air from the system. Visually confirm fluid is past the Y connector. If the Regional Analgesia Infusor is not flowing follow steps A – D of the Force prime procedure.

10. Using the Rate Adjustment Tool, turn counter-clockwise to change the rate to middle labelled rate to continue priming the Regional Analgesia Infusor. Visually confirm flow of fluid. If the Regional Analgesia Infusor is not flowing follow steps A – D of the Force prime procedure.

11. Using the Rate Adjustment Tool, change the rate to the highest labelled rate to continue priming of the Multirate Infusor. Visually confirm flow of fluid. If the Regional Analgesia Infusor is not flowing follow steps A – D of the Force prime procedure.

12. Change the flow rate of the flow control module to “0” with the rate adjustment tool.

13. Observe air and fluid flow into unclamped tubing and PCM through clear base. Visually confirm all air is purged through delivery tubing and fluid is flowing from distal end luer lock. Force prime PCM if fluid is not flowing from PCM.

**Pharmacy:**

4) Regional Analgesia Infusor Filling Instructions (continued):

**A.** Remove PCM Shipping Tab from PCM before connecting device to patient. Pull up on Shipping Tab to remove. Do not push down on Shipping Tab. Failure to remove Shipping Tab will cause continuous infusion through PCM line and patient may receive higher than intended basal dose of medication.

**B.** To force prime the Multirate module: First, close the Slide clamp, and attach a luer adaptor or stopcock to the Regional Analgesia Infusor Luer Lock Connector. To force prime PCM: First, set the Flow Control Module to “0”, and attach a luer adaptor or stopcock to Luer Lock Connector.

**C.** Pull back syringe plunger to create suction until fluid flow is visually confirmed into PCM reservoir when force priming the PCM.

**D.** Visually confirm flow of fluid from Luer Lock Connector before using Multirate Infusor System. Ensure all air is purged from the delivery tubing. Replace Winged Luer Cap. If Multirate module is primed, open the Slide Clamp.

---

*Caution: Gently lock syringe or Fill Port Cap. Overtightening can result in damage to Fill Port. Use aseptic technique throughout the procedure.*
Pharmacy:

5) SV & LV Intermate Filling Instructions:

1. Close the Slide Clamp.

2. With the delivery tubing in place, remove the Fill Port Cap and retain for later use.

3. Draw up required diluent and drug syringes. Expel all air from syringes. Do not attach a needle to the syringes or you will damage the Fill Port.

4. Gently insert the syringe tip into the Fill Port and turn it clockwise to lock.*

5. Use steady downward pressure on the syringe flanges or the syringe barrel. The steady downward pressure on the syringe will gradually push fluid into the Elastomeric Reservoir. Steps 3-5 may need to be repeated.

6. After the Intermate is filled, remove the syringe.

7. Gently twist the syringe counter-clockwise to separate from the Intermate.

8. Lock the Port Cap onto the Fill Port by carefully twisting in a clockwise direction.*

9. To prime the delivery tubing, remove the Winged Luer Cap. Note: Failure to prime set at time of filling may result in flow rate difficulties.

10. Open the Slide Clamp and let the delivery tubing prime. Visually confirm the flow of medication in the tubing and expel the air before use.

11. After the delivery tubing has primed, make certain the Slide Clamp is in the ‘closed’ position.

12. Reattach the Winged Luer Cap.

*Caution: Gently lock syringe or Fill Port Cap. Overtightening can result in damage to Fill Port. Use aseptic technique throughout the procedure.
Volume:

The flow rate of Baxter Elastomeric Pumps is most accurate when filled to the labeled nominal volume.
- Infusors and Intermates flow faster than labeled flow rate if underfilled (filled to < 81% of nominal fill volume).
- Nominal flow rate is achieved by utilizing the fill volumes listed in the Directions for use.

Solution Viscosity:

**Infusors:**
- The Infusor flow rate is most accurate with a diluent solution of 5% Dextrose.
- An Infusor filled with 0.9% Sodium Chloride (NaCl) will flow ~10% faster than labeled rate.

**Intermates:**
- The Intermate flow rate is most accurate with a diluent solution of 0.9% Sodium Chloride (NaCl).
- An Intermate filled with 5% Dextrose will flow ~10% slower than labeled rate.

Storage Instructions:

The Infusor/Intermate may need to be stored either in the refrigerator or at room temperature depending upon the medication being administered.

When stored in a refrigerator please ensure that the Infusor/Intermate is brought to room temperature before use. Do not use any external heat source to bring the Infusor/Intermate to room temperature.

**Refrigerator Storage:**
- Ensure the area of the refrigerator where you store the Infusor/Intermate is clean and separate from food products.
- Keep the Infusor/Intermate within the plastic pouch provided or a zip loc bag when storing in a refrigerator.

**Room Temperature Storage:**
- Ensure storage area is clean.
- Keep out of direct sunlight.
- Keep away from extreme heat sources such as an oven or heater.
Nursing:
Connecting the Device:

Connecting the Infusor or Internate to the catheter/port:

1. **REMOVE THE WINGED LUER CAP FROM THE END OF THE INFUSOR OR INTERMATE TUBING.** Check to make sure that liquid has moved to the end of the tubing.

2. Replace the Winged Luer Cap.

3. **Flush the IV line as per institution protocol.** Make sure that the patient’s catheter is clamped, then remove and discard the catheter end cap.

4. While still holding the IV line, pick up the Infusor/Internate tubing, remove the Winged Luer Cap and connect the device tubing to the catheter with a quarter clockwise turn. Tape the Luer Lock Connector securely to the patient’s skin (Infusor only).

5. **Store the Winged Luer Cap in the bag the Infusor/Internate came in.** (You may need it later).

6. **REMEMBER, undamp the catheter** and open any clamp on the device so that the fluid can start flowing.

7. Place the Infusor or Internate either in its carrying bag, in a beltbag or pocket where it won’t fall out or get damaged. Ensure the top of the device is carried as close to the level of the Luer Lock Connector as possible.

How Should the Device be Carried?

- The Luer Lock Connector (refer to Diagram 1) should always be taped to the patient’s skin at approximately the same level as the top of the device (i.e. Fill Port Cap – refer to Diagram 1) of the Infusor/Internate in order to maintain a consistent flow rate.
- Flow rate is most accurate when the Elastomeric Reservoir and the Luer Lock Connector are at the same height.
- Flow rate can **decrease** 0.5% per 2.5 cm if the Elastomeric Reservoir is below the Luer Lock Connector.
- Flow rate can **increase** 0.5% per 2.5 cm if the Elastomeric Reservoir is above the Luer Lock Connector.
- Provide a carrying case to assist patients in keeping the top of the device as close to the level of the Luer Lock Connector as possible.
Monitoring Infusion Progress

- Since the Infusor/InfusorMate delivers medication at a slow rate the elastomeric “balloon” reservoir will appear to be shrinking over several hours or days.
- Ensure that the IV tubing is not clamped or kinked.
- Utilize progression lines on the Infusor/InfusorMate housing to monitor infusion progress over time.
- Infusion is complete when the “balloon” is completely deflated and all eight indicator bumps (four on either side of balloon) on the inside of the device are clearly visible (refer to Diagram 3).

Diagram 3

1. Indicator Bumps
2. Progression Lines
Diagram 4

Infusion Progression - LV5 (2C1009KP)
Delivering accurate infusion. Continuously.

12 HRS INFUSED

24 HRS INFUSED

36 HRS INFUSED
Diagram 5

Infusion Progression - LV1.5 (2C1087KP)
Delivering accurate infusion. Continuously.

2 DAYS INFUSED

4 DAYS INFUSED

6 DAYS INFUSED
Patient FAQ’s:

**Bathing**
- The Infusor/Intermate device should not be submerged or exposed to a direct stream of water.
- Place the Infusor/Intermate in a plastic bag OR on a flat surface outside the shower/bath.

**Sleeping**
- Place the Infusor/Intermate at approximately the same level to where the device connects to your catheter/port.
- The device can be placed on its side under your pillow.

**Exercise**
- It is acceptable to exercise with the Infusor/Intermate as long as the product remains close to room temperature and is not exposed to water. Follow your healthcare provider guidelines.

**Pets**
- The device is safe to use around pets, but ensure that it is protected from chewing and playing.

**Environment**
- The Infusor/Intermate can be utilized during everyday activities (e.g. cooking) as long as the device is in a location where it can remain at room temperature and is not exposed to extreme heat/cold.
- Keep device out of direct sunlight.

**Travel**
- It is safe to travel on planes that have pressurized cabins.

*If you have any questions about what you’ve read here, please contact us at 1-888-719-9955.*
Making a Meaningful Difference in Patients’ Lives.
APPENDIX J: ISSUES HIERARCHIES FOR SITES USING THE SAME-DAY MODEL OF PATIENT SCHEDULING

Figure 15. Legend for issues hierarchies
FIGURE 16. ISSUES HIERARCHY OF SITE A FOLLOWING THE SAME-DAY MODEL
Figure 17. Issues hierarchy of Site B following the same-day model.