

Exploration of an ethically justified response to drug undersupply: Values and recommendations discussion paper



May 27, 2013

BC Drug Undersupply Ethics Working Group

Request for Feedback Section Revised October 21, 2013

This document is circulated for discussion and feedback.

PROJECT TEAM

The document is offered on behalf of the BC Drug Undersupply Ethics Working Group:

Anita Ho, Providence Health Care & UBC Centre for Applied Ethics

Bashir Jiwani, Fraser Health

Duncan Steele, Fraser Health

Evelyn Pollock, Vancouver Island Health Authority

Judy Nicol, Interior Health Authority

Lori d'Agincourt-Canning, Provincial Health Services Authority

Michael Leisinger, Northern Health Authority

Paddy Rodney, UBC School of Nursing

Terry Anderson, Vancouver Coastal Health Authority

AUTHORS

Bashir Jiwani, Ethicist and Director, Fraser Health Ethics Services and Diversity Services, Surrey, BC

Lori d'Agincourt-Canning, Ethicist, B.C. Children's & Women's Health Centre, & Clinical Assistant Professor, UBC, Vancouver, BC

Anita Ho, Director, Ethics Services, Providence Health Care & Assistant Professor, Centre for Applied Ethics, UBC Centre for Applied Ethics, Vancouver, BC

Paddy Rodney, Associate Professor, School of Nursing, UBC, Vancouver, BC
Duncan Steele, Coordinator of Ethics Services and Diversity Services, Fraser Health, Surrey, BC

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FEEDBACK

Feedback is welcome to ethics.services@fraserhealth.ca. A webform for feedback is also available at <http://fluidsurveys.com/surveys/susan-rink/drug-undersupply-feedback/>

OCTOBER 2013 UPDATE

AS PART OF THE INITIAL PHASE OF CONSULTATION, THE MAY 27, 2013 EDITION OF THIS PAPER WAS SHARED WITH THE DIRECTORS OF PHARMACY IN BRITISH COLUMBIA, THE PROVINCIAL SUPPLY CHAIN WORKING GROUP, AND PHARMACEUTICAL SERVICES DIVISION – BC MINISTRY OF HEALTH (AMONG OTHERS). A CONSISTENT COMMENT WE RECEIVED WAS THAT IT IS IMPORTANT FOR THOSE REVIEWING THIS DOCUMENT TO BE AWARE OF THE EXISTING WORK IN THE DIRECTION OF THE RECOMMENDATIONS MADE IN THE DISCUSSION PAPER. TO THIS END, WE HAVE UPDATED THE REQUEST FOR FEEDBACK SECTION WITH THE DIRECT FEEDBACK FROM THE BC MINISTRY OF HEALTH AND REFLECTIONS FROM ADDITIONAL FEEDBACK WE HAVE RECEIVED FROM OTHER STAKEHOLDERS CONSULTED. THE BODY OF THE DOCUMENT REMAINS UNEDITED. WE ARE GRATEFUL FOR THE FEEDBACK WE HAVE RECEIVED TO DATE.

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Executive Summary

When decisions are made on behalf of citizens, the integrity of the entire community is at stake. The importance of this is heightened when these decisions concern goods of the highest order - human life and well being. Decisions made in the context of drug shortages are thus of great significance to the individuals who are directly affected by them and to the community as a whole.



Purpose

Broadly, this report is intended to provide practical advice for those individuals affected by drug shortages to consider.

Intended Audience

The report is intended for individuals and teams who are part of the health system and must make choices in responding to drug shortages at some level. Although political and geographic contexts do impact the way that drug undersupply is responded to in different jurisdictions, much of the analysis and many of the recommendations will have relevance across boundaries.

In its current form, the report sets out recommendations broadly for health system leaders in British Columbia. It is anticipated that through the consultation process, specific accountability for each of the recommendations will be clarified.

Current Draft

THIS REPORT IS CIRCULATED FOR DISCUSSION AND FEEDBACK. It is being shared widely to generate discussion and to solicit feedback. The authors will review feedback received and prepare a revised, final version of the document for submission to those leaders directly impacted by the recommendations.

A feedback form is provided at the end of the document that we would appreciate you complete and send to ethics.services@fraserhealth.ca. A web version of the feedback form is also available at <http://fluidsurveys.com/surveys/susan-rink/drug-undersupply-feedback/>

When To Use The Report

The report calls for a systematic response to the reality of drug undersupply, beginning with prevention and running through to evaluation and system learning. However, our hope is that elements of the analysis and recommendations will be useful to different groups at various stages of the phenomenon.

How To Use The Report

Different audiences will likely find different sections relevant and beneficial. (The table below sets out what audiences might be interested in which sections of the document.)

	Values	System Integration, Decision Structure and Process	System Learning and Follow-Up	Undersupply Prevention	Resource Allocation Criteria, Structure and Process	Resource Preservation and Stockpiling	Communication about Resource Allocation during Drug Shortage	Facts About the Context
Clinician	X		X		X	X	X	X
Clinical Leader	X	X	X		X	X	X	X
Administrative Leader	X	X	X	X	X	X	X	X
Policy Maker	X	X	X	X	X	X	X	X
Member of the community	X		X				X	X

Background

In 2012, British Columbians, along with citizens across Canada and the United States, were faced with a shortage of injectable opioids. This experience highlighted the issue of drug shortages in the health system and the need to respond to these shortages, including making difficult resource allocation decisions, in an ethically justified way.

What is becoming evident is that drug shortages are increasingly a chronic rather than acute issue. We are also aware that some efforts are underway at various levels to develop response strategies.

Responding to a request from Health Shared Services British Columbia (HSSBC), a small group of ethicists and ethics leaders representing BC's health regions and the academic community have undertaken an exploration of how health system leaders might respond to the reality of drug shortages. This document reports on the analysis and offers recommendations for health system leaders.

The method used for this analysis requires engagement with key stakeholders to ensure that decisions are based on the best information available and a well-justified evaluation of the relevant values. The recommendations provided here should be seen as preliminary and available for critical assessment. The next step in the process will be to undertake a consultation to obtain feedback. After this, the authors will engage the feedback and offer final recommendations to health system leaders.

Summary of Recommendations

The report provides analysis and recommendations under high-level themes of issues that emerge in the drug undersupply context.

The recommendations are formulated as *ought* statements. The authors are suggesting that, based on the facts in the context and the values identified, health system leaders should take the following actions. Put another way, we are arguing that if we are to live up to the values identified in the drug undersupply context, health system leaders will have to make decisions along the lines of the recommendations offered.

Readers will notice that many of the recommendations are related to each other and that in some cases there is overlap between the recommendations. That these areas of work are connected will not be surprising. The primary reason for the overlap is that some recommendations are subsections of other broader recommendations, but because of their importance we believe they should be set out in more detail on their own. For example, the Report calls for the establishment of a decision-making structure that includes a body responsible for guiding resource allocation decisions. Because each of these is sufficiently complex, each has been set out in a separate recommendation.

The analysis and recommendations are based on an understanding of the values that should guide decisions. The first recommendation is that these values are accepted. We conclude this section with a summary of the recommendations found in the report.

What Should Matter (Values)

Health system leaders ought to establish that decision-making relevant to responding to drug undersupply will be guided by the following list of values:

- *Accountability*
- *Effectiveness*
- *Equity*
- *Excellence in clinical and administrative practice*
- *Fiduciary Responsibility*
- *Inclusiveness*
- *Integrity*
- *Respect/ Transparency/ Procedural Fairness*
- *Solidarity*
- *Stewardship*
- *Sustainability*
- *Timeliness*
- *Trust*

System Integration, Decision Structure and Process

Health system leaders ought to...

- *Set the expectation of decision transparency within the system.*
- *Establish a clear information gathering and decision-making process*
- *Ensure that a clear evidence-informed and values-based decision-making process is established.*
- *Establish a drug undersupply communications strategic planning structure.*

System Learning and Follow-Up

Health system leaders ought to...

- *Ensure that individual institutions and programs conduct evaluation and outcome assessments of practice changes enacted in response to the drug shortage.*
- *Commission a large-scale quality review (similar to the Cochrane Report) to inform decisions made for dealing with the present drug undersupply.*

- *Create and/or participate in opportunities for knowledge transfer at multiple levels related to drug undersupply.*

Undersupply Prevention

Health system leaders ought to...

- *Work with the BC Ministry of Health to advocate for the creation of an inter-provincial working group to develop a Canadian drug shortage response plan.*
- *Work with the BC Ministry of Health to create a pan-Canadian group to develop a clear and shared understanding of the Canadian drug supply context.*
- *Advocate that the inter-provincial working group consider the question of having government participate in the manufacturing of drugs.*

Resource Allocation Criteria, Structure and Process

Health system leaders ought to...

- *Establish that patient need is the principal criterion used to make allocation decisions at the meso and micro levels.*
- *Establish that judgments of deservedness must not enter into allocation decisions.*
- *Establish a provincial body to oversee meso level allocation decisions and establish micro level allocation criteria regarding drugs in short supply.*
- *Require health regions to create local multidisciplinary resource allocation committees as one of the structures required to respond to drug undersupply.*

Resource Preservation and Stockpiling

Health system leaders ought to...

- *Urge regions to refrain from stockpiling drugs in undersupply.*
- *Mandate the provincial drug resource allocation body to make decisions about drug conservation and distribution.*
- *Ensure formal structures and processes are established in every region for overseeing safe and effective therapeutic alternatives and changes to clinical practice standards during a shortage.*

- *Indicate that providing sub-optimal but still useful amounts of a drug ought to be permitted.*

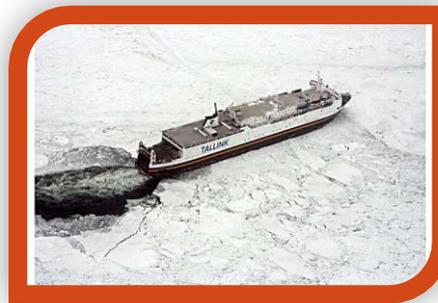
Communication about Resource Allocation during Drug Shortage

Health system leaders ought to establish a dedicated provincial resource allocation communications strategic planning committee.

The committee ought to implement and evaluate and follow-up on the communications strategic plan.

Introduction

In February 2012, Sandoz Canada announced that it would be scaling back its production of drugs and would not be able to meet its delivery targets. To manage the drug shortage, Health Shared Services British Columbia (HSSBC) established a provincial working group including representatives from the BC Ministry of Health, each of BC's health authorities, and various health professional associations and colleges. As part of this effort, a core group of the BC Provincial Forum for Clinical Ethics Support and Coordination was invited to develop a framework for allocating scarce injectable narcotics during periods of undersupply. The core group, called the BC Drug Undersupply Ethics Working Group, was led by Fraser Health Ethics Services and used that department's ethics-based system-level decision process.¹



This work was received well and the ethics core group was asked to offer broad direction on the allocation of drugs during periods of undersupply. **This report represents the BC Drug Undersupply Ethics Working Group's analysis and recommendations.**

The main reason for doing an ethics analysis in the healthcare context is to safeguard the system's integrity. Organization and system leaders are stewards of public resources and have an obligation to ensure that decisions made on behalf of those to whom they are accountable align with the values of these stakeholders.

Accordingly, an ethically justified response to the allocation of drugs during periods of undersupply cannot be limited to the narrow choices of which individuals or groups should benefit (and which should not). This is because there are many other values-informed decisions that are relevant to the issue.

¹ Jiwani, B. (2011). *Good Decisions: A guide to system-level decision-making*. Surrey, British Columbia: Retrieved from <http://www.incorporatingethics.ca/the-process.php>

We ask that health system leaders approach the question of how to ethically respond to drug undersupply in the health system holistically, and not only in terms of how to allocate scarce pharmaceutical resources.

An ethically justified decision is based on a) a clear understanding of the facts and b) a well-reasoned analysis of guiding values (what matters most).²

This report is not intended as the final analysis of how to respond to drug undersupply. The purpose of this document is to articulate the ethics core group's initial thinking with a view to having stakeholders review and provide critical comment and feedback.³

We ask that health system leaders understand this report as a document aimed at supporting discussion among the various individuals and groups affected in the system.

We ask that health system leaders participate in the consultation effort by distributing the document widely and supporting the feedback methods identified.

The report provides a high level summary of the broad context, identifies the key values that should guide system response to drug undersupply, and provides initial recommendations in key areas about which decisions should be made. A response form can be found at the end of this document. The form sets out the questions about which those consulted (and their teams) will be asked to reflect, deliberate, and provide feedback.

² In as complicated a context as the drug chain, no one individual or group will have sufficient insight about the facts on the ground or how values should be specified in every sub context. To achieve this ethical justification, a dialogical process across the broad context needs to be facilitated. This process will have to be sophisticated and nuanced so as to ensure it enables the right kinds of engagement about the right questions with the right background information.

³ Submission of this document is intended to be part of a rich consultation exercise, parties of which are sketched out later in the document.

The core group will accept feedback, review it and offer responses and final recommendations. At that stage a final report will be prepared and submitted to the specific leaders who will be identified in the recommendations.

What Should Matter (Values)

The ethical justification of a policy recommendation depends in large part on what the recommendation considers important, the value trade-offs it makes, and how well these tradeoffs are justified. This requires articulating what considerations should matter.



In this section we identify (in alphabetical order) the value themes that have emerged, offer definitions for each, and suggest how these themes are specified in the drug undersupply context.⁴ (A description of the process used to arrive at these is appended to the document.)

The values are then picked up in the remaining sections of the report where they are analyzed and balanced to arrive at specific recommendations.

Health system leaders ought to establish that decision-making relevant to responding to drug undersupply will be guided by the following list of values:

- ***Accountability***
- ***Effectiveness***
- ***Equity***
- ***Excellence in clinical and administrative practice***
- ***Fiduciary Responsibility***
- ***Inclusiveness***
- ***Integrity***
- ***Respect/ Transparency/ Procedural Fairness***

⁴ This is a lengthy section simply because the context is complex and there is a lot at stake in the drug supply management question. The value specifications (detailed descriptions of what is important) listed are from *Good Decisions* (Jiwani, B. 2011), while the description of their application has emerged from the method of analysis (described in Appendix A). It is important to note that each value may fit more than one theme as the value themes themselves often overlap.

- *Solidarity*
- *Stewardship*
- *Sustainability*
- *Timeliness*
- *Trust*

Accountability

This value describes the answerability of an individual or group to another individual or group for the kind and quality of decisions made or actions taken.⁵

In the context of drug undersupply...

- Stakeholders on the national, provincial, and health authority levels should
 - Work in good faith together to find common solutions
 - Take responsibility for making decisions and following through on corresponding actions
 - Communicate each decision and action, so meso/micro partners can understand their own roles and accountability
- There should be clarity about who is responsible for what decisions and actions in responding to drug shortages and managing the drug chain (nationally, provincially, health authority)
- Health system leaders should work with appropriate partners who have the ability to affect necessary change
- Health system leaders should demonstrate that we are doing the best we can with the resources we have

⁵ Accountability can be to a supervisor or sponsor organization (e.g. to a professional association as part of one's professional mandate). It can also be to an individual or group to whom one has a fiduciary responsibility (e.g. as a group's representative at a meeting or to a community of people one accepts a duty to serve.)

Effectiveness

This value refers to the extent to which an intervention meets the objectives it is designed to achieve.⁶

In the context of drug undersupply...

- The care and treatment needs of all patients should be met
- Patients who need drugs should be provided those drugs in a manner that effectively addresses their health issue
- Patients should receive care in the most appropriate setting possible
- There should be clarity about decision-making processes and responsibilities
- There should be clarity about what information is to be communicated, how information will flow, and the role of different care providers in communicating messages
- We should maintain excellence in infection control and public health practice
- Undersupply response frameworks should be easy to understand and use
- People should be aware of and understand how to use such frameworks
- We should protect our population from possible negative effects of drug shortages
- People should not be physically harmed by the effects of drug shortages

Equity

This captures the idea that a resource should be distributed based on need as opposed to other criteria such as ability to pay, social status, etc.⁷

In the context of drug undersupply...

⁶ This requires having a clear and shared understanding of the objectives for a given intervention strategy. In many cases, true objectives can be hard to measure and sometimes this leads to focusing on objectives that are easily measured. This could be a serious mistake where the measurable is given priority over the important.

⁷ Equity can mean equal distribution if everyone has the same need or unequal distribution if the needs of some are greater than the needs of others. How need is defined and measured will depend on the objectives the resource is meant to achieve.

- Distribution of drugs across the country should be based on need
- Only relevant differences, determined through a process of deliberation, should distinguish what medication people across the country get access to
- Those living in rural settings should have similar access to drugs as those living in urban centres
- Everyone should use the same standards to determine when to conserve drugs anticipated to be in short supply (consistency)
- Drug undersupply policies should not reinforce marginalization of vulnerable people (social justice)

Excellence in clinical and administrative practice

This value calls for performing an action or delivering a service to the highest standard - or maximally achieving the objectives of a strategy. This includes how the action is done and the outcome it achieves.⁸

In the context of drug undersupply...

- The health system should provide the highest standard of care possible given resource limitations
- Drug substitutions should meet the standards of therapeutic equivalence (bioequivalence and pharmaceutical equivalence)
- Where the standard of therapeutic equivalence cannot be met, care providers should be aware of negative side effects of substitute drugs and minimize these
- Unsafe practices should be prevented from creeping into daily practice
- Sound clinical judgment should be exercised in responding to drug shortages

⁸ This includes how the action is done and the outcome it achieves. In health care it requires constantly improving quality of service to better meet patient needs. It implies growth and capacity building of human resources, which requires ongoing learning, research and training.

Fiduciary Responsibility

This refers to the special relationship that certain individuals, usually professionals, have to those who are vulnerable and who put their trust in the professional to assist them in some manner. In health care, patients are much less powerful than healthcare professionals.⁹ Fidelity is about maintaining the trust patients put in their care providers to advance patient interests ahead of their own.

In the context of drug undersupply...

- We should meet the needs of immediate sufferers to whom a fiduciary duty of care is owed

Inclusiveness

This is the commitment to ensuring that room is created for all relevant perspectives to be involved in a decision or action. It requires identifying and overcoming barriers to participation that would prevent such participation unjustifiably.¹⁰

In the context of drug undersupply...

- Attention should be paid to patients across the continuum of care
 - The needs of all sectors of a region should be considered in the broad response strategy (e.g. acute care/institution based care should not outweigh considerations in community)
 - An exclusively urban-centred approach should be avoided

⁹ This power imbalance is at least three-fold: patients are usually ill, whereas caregivers are not; they are usually not in surroundings they are accustomed to or comfortable in, whereas health care professionals are; and most of all, they lack the expert knowledge and resources required to meet their healthcare goals - which health care professionals have. Patients must put themselves in the hands of their health care providers and trust that the care providers will help them to achieve the patient's goals. This puts health care professionals in a conflict of interest where the conflict lies between meeting their personal interests and the needs of their patients.

¹⁰ Barriers can include language, power, financial resources, time, access to decision corridors, prejudice, and even style of discussion and debate.

- Difficulties encountered in Northern, rural and remote parts of BC should be addressed
- All relevant areas of professional practice should be included in the dialogue process
- The needs of all stakeholders should inform the response policies, processes and guidelines
 - All levels of health care should be aware of triage criteria to be used
 - All those affected by a drug shortage should be supported through it
 - Stakeholders should know they can provide feedback on policies, practices and guidelines

Respect/ Transparency/ Procedural Fairness

This complex of values is based on the notion of respect for individual autonomy and self-determination. This is the idea that individuals capable of understanding and appreciating the consequences of decisions that impact them should have their values inform such decisions. At the system-level, this leads to the importance of making decisions and the rationale behind them visible to those affected by them - transparency. This also leads to the value of procedural fairness - ensuring that decision processes are transparent and accessible to stakeholders, where these stakeholders have a way of influencing the values that decisions are based upon.¹¹

This understanding aligns with active citizen engagement in system-level decisions within the public domain.

In the context of drug undersupply...

- All stakeholders should be fully informed of the decision-making criteria used and actions taken on an ongoing basis in a transparent manner
- There should be transparent, regular, ongoing communication with those impacted during a period of undersupply

¹¹ Poor transparency can lead to poor decisions, unfair suffering by those impacted, reinforcement of bad decision-making practices, lack of trust for leadership and understanding of the system, and missed opportunities for moral growth.

- All those impacted by a decision should be made aware of it, including (but not limited to)
 - Senior system leaders
 - Administrative and clinical leaders
 - Clinical staff
 - Patients and Families
 - Members of the public
- Those who disagree with decisions should have a way of challenging them
- Clinicians should be informed of decisions that affect their practice and the reasoning behind these decisions

Solidarity

Within a healthcare context, solidarity is a commitment to the health and well-being of all members of the community and to working together to achieve shared interests.¹²

In the context of drug undersupply...

- Access to healthcare, including drugs, should be seen as an essential public good
- We should seek to build healthy relationships between the various stakeholders who must partner to find a solution
- We should stand together with others locally and globally
- We should avoid a blame-allocation culture
- A shared commitment to coordination between facilities, regions and provinces should be sought

Stewardship

This value calls for careful management and distribution of community resources. It involves using resources effectively to meet the intended goals with minimal waste, allocating resources in a manner that is fair to all those who need them, and that is

¹² Within a healthcare context it is a commitment to the health and well-being of all members of the community and to working together to achieve shared interests.

sensitive to broader questions of justice in society. Stewardship also requires ensuring the long-term sustainability of the resources.

In the context of drug undersupply...

- Scarce resources should be used fairly
- Human resources should be maximized
- Hoarding (or inappropriate stockpiling) should be prevented
- Waste of scarce resources (human, financial, capital, etc.) should be minimized
- Public healthcare organizations should maximize their purchasing power
- Opportunities to reduce the cost/expense of purchasing drug should be maximized
- Assuming therapeutic equivalence, the least costly drugs should be used wherever possible
- Approaches at national, provincial and regional levels should be coordinated
- Decisions should be made with an understanding of the complexity of our systems and where there may be gaps

Sustainability

This value concerns the viability of a system over a long period of time. It calls for decisions that ensure the system's existence is not threatened and that it will be able to continue to meet its objectives into the future.¹³

In the context of drug undersupply...

- Health system leaders should put in place a long-term plan at national, provincial, and regional levels to address drug shortages
- The plan should be well thought out to minimize the need for reacting to emergency shortages on an *ad hoc* basis

¹³ It requires being clear about what the system's objectives are, and what might threaten its ability to meet these objectives. It also requires clarity within an organization about whether the desired sustainability is about a specific strategy, service, program, or the organization itself.

- The health system should be prepared for catastrophic events that we have good reason to expect
- We should not seek 'Band-Aid' solutions for political gain or expedience
- Our solutions should ensure long-term management of resources (including human, financial, and material resources)
- We should seek solutions that do not force us to compromise our values in the long term (including public safety, public good, trust, etc.)

Timeliness

This value speaks to the importance of ensuring interventions are undertaken when they are maximally able to achieve intended goals.¹⁴

In the context of drug undersupply...

- Relevant sections of the drug undersupply response framework should be used at the time when they are intended
- Communication should be done well in advance of any decisions needing to be made

Trust

This refers to a commitment to create relationships where parties can be counted on to act consistently and according to justified values. Central to any trusting relationship is honesty, open communication and transparency.¹⁵

In the context of drug undersupply...

- Leaders should seek to enhance trust and collaboration across all levels, disciplines and practice contexts

¹⁴ Interventions can include practical efforts to bring about change, facilitate decisions and communication, and the proper use of tools.

¹⁵ In order to trust someone, one needs to know that they will be treated with respect. They will not be deceived and that one will be forthcoming with important, relevant information in a manner that is respectful to the relationship.

- Trust should be built between the various stakeholder groups, with particular attention to key relationships including between:
 - Administrators and clinicians
 - Pharmacy and nursing staff
 - The public and the system - specifically as concern resource allocation decisions
 - Public services and private industry
 - Different levels of government
 - Federal to provincial
 - Provincial to ministry
 - Ministry to Health Authorities
 - Ministry to municipal
 - Public services and the media
- System-level decisions should be made in a way that builds confidence of those affected by them in the decisions taken

Having laid out the key values at stake in the drug undersupply context, we now go on to suggest what we believe are the implications of these values for various specific dimensions of the drug undersupply context.

System Integration, Decision Structure and Process



The set of strategies described here should live up to the values of accountability, inclusiveness, procedural fairness, and trust.

Accountability and transparency (part of procedural fairness) create the responsibility for key stakeholders to work with appropriate partners to affect necessary change. Learning from past experience, preparing for the future, and responding to drug shortages during a state of drug undersupply will all require coordinated effort.

Thus, it will be very important to have system integration strategies in place.^{16,17} The framework for this integration will need to be established in the current state of the system and include contingency plans for responding to widespread, acute drug shortages such as that experienced in 2012.

Health system leaders ought to set the expectation of decision transparency within the system.

There should be an expectation that key decision-makers at local, regional and provincial levels are responsible for informing the public about decisions made in response to the drug shortage. This includes being transparent about the reasons why certain decisions were made.

Health system leaders ought to establish a clear information gathering and decision-making structure and accountability map for addressing drug shortages.

¹⁶ Gibson, JL, et al. (2012). Ethical Framework for Resource Allocation During a Drug Supply Shortage. *Healthcare Quarterly*, 15(3), 26-35.

¹⁷ Singleton, R, et al. (2013). From Framework to the Frontline: Designing a Structure and Process for Drug Supply Shortage Planning. *Healthcare Management Forum*, 26, 41-45.

Appropriate regional and provincial authorities should work collaboratively with leaders of the relevant bodies affected to put into place the appropriate structure for guiding drug undersupply response efforts during all of these stages.¹⁸

Health system leaders will need to determine the overall governing structure, and which additional structures will be required to respond to various tasks outlined below. These structures may include existing bodies or committees (such as Emergency Operations Committees during a period of severe shortage) or novel approaches (such as task-specific inter-regional shared work teams).

The form the structures take should...

- Describe the leadership chain and identify a clear accountability matrix for who is responsible, and who is accountable for what type and level of decision during each stage of the undersupply. The appropriate role of all relevant players should be understood by those involved.
- Include all relevant elements of the system impacted, across the geography of the system and the continuum of care.
- Ensure that groups of individuals who are most vulnerable in the context can be identified.
- Link to higher levels of authority at the national level.
- Identify responsibility for decisions related to:
 - System learning and follow up
 - Communication
 - Resource allocation
 - Changes in clinical practice standards
- Enable funneling of just in time information to the decision-makers.

¹⁸ Singleton R, et al. (2013) usefully describe the structure established by Eastern Health (serving Newfoundland and Labrador).

Because of the importance of resource allocation decision-making and communication related to allocation, more detailed discussion and specification of these recommendations is provided below.

Health system leaders ought to ensure that a clear evidence-informed and values-based decision-making process is established.

In addition to defining the individuals and bodies that should be involved and establishing parameters for their relationships, the way these groups should come together and make decisions should also be set out.

- In general, the structure should call for regular meetings at each of the relevant levels in the context.
- There should be regular, inter-sectorial, inter-professional rounds at each relevant level of the accountability matrix.
- Decision-makers should ensure that a systematic method of analysis is used to work through each important issue encountered. The issue-specific decision process should include:¹⁹
 1. Agreement about the actual issue in question and the problem needing to be solved
 2. Clarification of the relevant facts, and data gathering where missing information can be obtained
 3. Agreement on what should matter most in responding to the issue (including a process of reviewing values identified in this document)
 4. Discussion of possible responses
 5. Analysis to determine which response best aligns with what should matter most
 6. Making a preliminary decision
 7. Articulation on paper of the decision and its rationale
 8. A consultation plan for whose perspective will be considered before a final decision is taken

¹⁹ Jiwani, B. (2011). *Good Decisions: A guide to system-level decision-making*. Surrey, British Columbia: Retrieved from <http://www.incorporatingethics.ca/the-process.php>

9. A feedback strategy for what kind of feedback will be welcomed and how those affected can offer this feedback
10. A communication plan for who needs to be made aware of the decision and its rationale
11. An implementation plan for how the decision will be carried out
12. A support plan for assisting those who will face difficulty as a result of the decision
13. An evaluation plan for how information about the impact of the decision (and whether it did what it was intended to achieve) will be collected and analyzed
14. A decision review plan for how feedback will be synthesized and existing decisions reviewed against what is being heard

Health system leaders ought to establish a drug undersupply communications strategic planning structure.

Effective communication that lives up to the above values and responds to the various dimensions of the decision process will be crucial to bring people together and to effectively respond to drug shortages.

This communications strategic planning structure may be stand alone or embedded within the broader drug shortage response structure.

The particular values that should guide the communication strategies developed and implemented in responding to drug supply shortage include accountability, effectiveness, excellence, inclusiveness, procedural fairness, solidarity, timeliness, and trust.

The structure should ensure communication strategies are developed for the following areas:

- Current and timely sharing of the status of drug availability and pending undersupply
- The overall drug undersupply response plan, relevant policies and rationale
- System learning and follow up
- Resource allocation during a drug shortage
- Changes in clinical practice standards during a drug shortage

The structure should also:

- Ensure timely sharing of information and rationale for any decisions made

- Ensure information about available supplies of a potentially unavailable product and about alternative therapies is shared among the facilities
- Include regular, non-blaming communications
- Communicate the dangers of stockpiling
- Proactively establish communication lines before acute, widespread drug shortages become reality
- Contribute to the prevention of reactionary decision making
- Make space to consider the development and sharing of support tools for clinicians and administrators

System Learning and Follow-Up

Having now had some experience with drug undersupply, system stewards have an obligation to review existing experience as well as future experience, and to learn from these. This also aligns with the plan, do, study, act philosophy of quality improvement.



The values that should guide systems learning and follow-up after response to a drug shortage include accountability, clinical excellence, solidarity, transparency and trust.

During a drug shortage, some harm is likely to be unavoidable. Learning from experience, both locally and nationally, is the best way to provide better care and reduce harm in the event of a future drug shortage. The results from follow-up evaluation will enable improvements in system response, including better coordination between planning and response activities, at local, regional, provincial and national levels. Also, providing open and honest information and evaluating the effect of decisions on patients, families and providers is consistent with the principles of respect and best practice, and enhances the public's trust in those making health care decisions.

Health system leaders ought to ensure that individual institutions and programs conduct evaluation and outcome assessments of practice changes enacted in response to the drug shortage.

In order to foster learning from decisions made during the drug shortage, health system leaders should set the expectation that institutions and health authorities:

- Undertake follow-up research to evaluate processes and outcomes
- Gather follow-up information from health care providers, patients, and families
- Continue to monitor and share incidents

This review should include the use of therapeutic alternatives.

Evidence should be sought from multiple sources and involve both quantitative and qualitative measures (including perspectives of staff and patients) to evaluate fully the impact of changes made.

Health system leaders ought to commission a large-scale quality review (similar to the Cochrane Report) to inform decisions made for dealing with the present drug undersupply.

This recommendation will best enable decision-makers to take what was learned during the drug shortage and apply this to future decisions concerning resource allocation at local, regional, provincial and national levels.

Health system leaders ought to create and/or participate in opportunities for knowledge transfer at multiple levels related to drug undersupply.

This could be in partnership with appropriate provincial bodies. The goal of such efforts should be to help improve practice for others faced with making difficult allocation decisions during a drug shortage. Opportunities should range from local to international initiatives.

Undersupply Prevention

Between and within every level of the drug supply chain (from the source of raw material to the end user) there are multiple complexities, including incentives and responsibilities, that impact behaviour.



The multiple contexts and relations can create crucial gaps in knowledge and communication. Preventing the undersupply of medically necessary drugs in BC, including the work of identifying and addressing these gaps, will require collaboration across regional, provincial and national jurisdictions.²⁰

Based on the values of accountability, effectiveness, excellence, procedural fairness, solidarity, stewardship, sustainability, and trust, the following recommendations emerge for health system leaders.

Health system leaders ought to work with the BC Ministry of Health to advocate for the creation of an inter-provincial working group to develop a Canadian drug shortage response plan.

Under the broad parameters of the *Canada Health Act* provincial governments are ultimately responsible for deciding which drugs are covered under provincial drug plans and contracting with manufacturers to ensure a steady supply of essential drugs.²¹ Even so, provinces can pool their resources and experiences to develop a shared response to drug shortages. It is crucial that clinicians be involved with this work to elaborate on the

²⁰ We recognize that some of this work is already underway. This section is meant to offer additional reflections about the parameters of these efforts, for example with respect to focus, structure.

²¹ Ordre des pharmaciens du Québec, Collège des Médecins du Québec, et al. (2012). *Drug shortages: A public health issue that demands a coordinated response*.

specifics of health contexts and provide a valuable perspective as those who will provide the direct care of vulnerable patients.

This working group should seek limited partnership with industry. This is because the values driving industry will not necessarily align with the values that should underpin this process (e.g. protecting our population from negative effects of shortages, not allowing people to be physically harmed by the effects of shortages, or treating necessary drugs as an essential public good).

Industry partners should be involved to the extent necessary for the working group to understand the capacity, ability, and interest from different companies to do the work and/or provide the products within the parameters outlined by the working group.

Health system leaders ought to work with the BC Ministry of Health to create a pan-Canadian group to develop a clear and shared understanding of the Canadian drug supply context.

Because provincial health ministries are tasked with choosing which drugs are paid for under provincial coverage plans, this group should receive funding from the provinces. Its membership should include individuals who gained expertise and knowledge during the Sandoz drug shortage. The group's focus should be to outline how the different provinces (and, with a secondary importance, how other countries):

- Track drug shortages, communicate prior to and during shortages, predict shortages
- Purchase drugs
- Decide which drugs to cover through provincial funding programs

The group should report to the inter-provincial working group.

The group should also have the mandate to:

- Compile a list of which drugs have been in short supply in general (and what type of shortage: chronic, cyclical, etc.)
- Compile a separate list of which drugs in short supply are low-cost/low-profit generics that could be alternately sourced
- Report on the price of these drugs (including generics) paid by other countries.

Funding a group to gather this knowledge now, rather than during the next acute, widespread shortage, will provide a foundation for future drug-related decisions (i.e.

purchasing, contracts, safety assessments, etc.) which, if used, will undoubtedly benefit the populations we serve.

Existing research also indicates that Canadian provinces currently pay more than the Organisation for Economic Co-operation and Development (OECD) averages for generic drugs.²² As with any purchasing done with public funds and aimed at the public good, we should strive for maximizing the value of our investment.

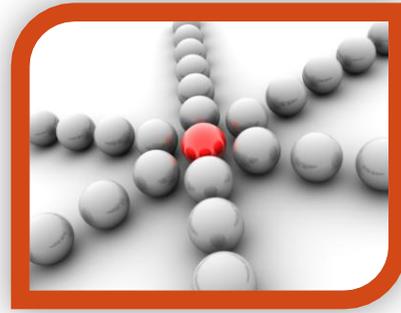
Possible concerns with this recommendation include the political will required to follow-through with supporting the group's work initially and over time, the challenge of keeping the information collected current and ensuring the data is used to inform policy decisions.

Health system leaders ought to advocate that the inter-provincial working group consider the question of having government participate in the manufacturing of drugs.

Some reports have indicated the profit margin for some generics are so slim that private producers may not have the incentive to continue manufacturing them. Manufacturing of certain generic drugs by a provincial, pan-provincial, or federal initiative (i.e. Crown corporation) could fall within the core function of Crown corporations: to provide essential services to the public that would otherwise not be economically viable as private enterprises. This would live up to the values of providing a secure source of necessary drugs, efficient use of healthcare financial resources, and many others. We suggest that this issue should be raised and analyzed by the working group.

²² Law, M. (2013). Money left on the table: Generic drug prices in Canada. *Healthcare Policy*, 8(3), 17-25. doi: 10.12927.hcpol.2013.23208

Resource Allocation Criteria, Structure and Process



Resource allocation in healthcare is very complex. The practice involves multiple levels and several questions at each level. Resource allocation decisions in drug allocation context are even more complicated for a variety of reasons; not least of which is the complexity of the drug supply chain. (See the section below on Facts About the Context for a description of the resource allocation environment in health care.)

Ethical practice requires that health care providers maintain the integrity of their practice at each level of resource allocation, advocate for resources at each level, and address the interactivity of action at each level.^{23,24,25,26,27}

²³ By recognizing the interactivity of ethical practice at each level we can work on policy action to advocate for all levels while still maintaining the integrity of our practice at each level. For example, in addressing inadequate pain relief for home care clients who are having difficulty accessing opioids at the micro level, we could ensure that we use best practices for pain management with our individual clients and their families, advocate for better discharge planning processes between institutions and home care organizations at the meso level, and at the macro level engage with our health regions to address the need for better home care pharmaceutical and other support services provincially and nationally.

²⁴ From the highest level of generality (macro) to the most specific (micro), each level sets limits on and constrains decision making at a lower level. For example, government macro allocation decisions about how to work with industry to regulate the production of drugs will impact the types and quantities of drugs available to individual programs and institutions. In turn, the amount of a drug that a program has access to will impact the choices needed to be made about which individuals can and should receive what medications.

²⁵ Adapted from Rodney, P., Harrigan, M.L, Jiwani. B., Burgess, M., & Phillips, J.C. (2013). A further landscape: Ethics in health care organizations and health/health care policy. In Storch, J., Rodney, P., & Starzomski, R. (Eds.) *Toward a moral horizon: Nursing ethics for leadership and practice* (2nd ed.). Toronto: Pearson-Prentice Hall.

Health system leaders ought to establish that patient need is the principal criterion used to make allocation decisions at the meso and micro levels.

Whether at the meso or micro level, the primary criterion in determining which programs or individuals should receive a drug in short supply is need. This is based on the values of effectiveness, excellence, stewardship and trust.

Health system leaders ought to establish that judgments of deservedness must not enter into allocation decisions.

There are criteria that should never enter into resource allocation decisions. For example, the following characteristics are not relevant to determine who should receive injectable opioids: the behavioural cause of a patient's pain and suffering; where they are receiving care along in the continuum of care; where they live in the region or province; their race, religion, linguistic background, ethnicity, ability to pay for the opioids, socioeconomic status, or past history of/and or current substance use.

In every drug allocation context, there will likely be marginalized populations at risk of having one or more of the above characteristics used to judge their suitability to receive drug resources. Effectiveness and fiduciary responsibility require that these situations are identified and vigilantly guarded against.

As part of the broader structure identified in the section on system integration, health system leaders ought to establish a provincial body to oversee meso level allocation decisions and establish micro level allocation criteria regarding drugs in short supply.

Drugs in short supply may have to be allocated across programs with significantly different patient populations. For example, injectable opioids were needed for patients in surgical units, medical units, and palliative care units. Determining need and weighing

²⁶ Rodney is indebted to Dr. Michael McDonald, Founding Director of the W, Maurice Young Centre for Applied Ethics at the University of British Columbia, for his articulation of these relationships between levels.

²⁷ Pellegrino, E. (1979). *Humanism and the physician*. University of Tennessee Press.

which patient population's needs are greater requires careful analysis, further refinement of the understanding of need and possibly the use of additional criteria.²⁸

This provincial resource allocation body may or may not be one of the broader groups established to oversee responses to drug shortages generally. Regardless, it should be a partnership between the health regions and relevant partners including the provincial Ministry of Health.

The body assigned this work should be mandated to:

- Understand the particular types of trade-offs required by the particular drug in undersupply
- Develop standardized, needs-based criteria to govern meso level decisions that the shortage requires the system to make
- Make recommendations/decisions for allocating the specific drugs in undersupply at the meso level
- Set out needs-based criteria for allocation of the drugs at the micro level
- Establish and oversee implementation plans for these decisions

In addition, the body should:

- Ensure coordination between planning, response and assessment activities at provincial, regional and local levels
- Ensure everyone uses the same standards to determine when to conserve
- Ensure consistent and ongoing communication to prevent reactionary decision-making about drug shortage. This includes clear and honest messaging about the dangers of stockpiling
- Oversee sharing of resources to ensure that drugs available in one location are not being stored while need elsewhere is unmet

²⁸ Jiwani B., et al. (2012, March). Criteria for allocating injectable opioids during a period of undersupply. Approved by the Health Shared Services British Columbia Board of Directors, March 8, 2012. Version 4.1

- Conserve drugs most critical for unique contexts and stockpile only for urgent/predictable problems
- Ensure all resources, such as drugs about to expire, are not wasted

In order to maximize the resources available for micro-level allocation, proactive and responsive meso and macro level strategizing is essential. In other words, at the meso level we must make sure that health care agencies and health regions communicate effectively to prevent, ameliorate, and respond to shortages of resources in a collaborative manner; working with the input of practice based experts and striving for equity within and across practice sites. At the macro level provincial and federal authorities as well as professional associations ought to be monitoring the state of resources nationally and internationally, working with evidence-based guidelines to anticipate health care related needs at the population level.

Health system leaders ought to require health regions to create local multidisciplinary resource allocation committees as one of the structures required to respond to drug undersupply.

Once the criteria for allocating resources at the micro level have been established by the provincial group and have been communicated widely, clinicians at the point of care will require support in understanding and applying the criteria, and in responding to challenges by those who disagree with the application of the criteria in a particular context.²⁹

These local committees should be charged with the responsibility for supporting necessary allocation decisions within relevant local contexts.

The local committees should:

- Include interdisciplinary representatives from relevant clinical areas
- Maintain communication channels with administrative, professional, and public stakeholders

²⁹ Rosoff, PM (2012) offers an interesting example of such a drug shortage allocation committee.

- Be clear that their key goal is to serve those patients with the greatest need
- Interpret and promote resource allocation guidelines
- Make allocation decisions in situations of particular conflict and/or uncertainty
- Gather ongoing feedback about the substance and process of allocation decision making so as to promote current and future best practices

In some cases, the broad allocation criteria at a provincial level may require further nuancing and balancing at the local level. For example, in cases where patients are not limited in their ability to participate in decision-making about their care, it may be appropriate to bring patients into the conversations about the difficult choices that have to be made and to respect their wishes to forego a necessary drug to allow other to benefit. Such considerations will likely have to be determined at the local level and overseen by the local resource allocation committee.

Resource Preservation and Stockpiling

To continue to meet their fiduciary responsibility to patients during drug shortages, individuals, teams and institutions must confront questions of appropriate standards of clinical practice and drug supply management.



The values implicated in these issues include effectiveness, excellence in clinical and administrative practice, procedural fairness, stewardship, sustainability and trust.

It is worth noting both that rural and urban contexts will have particular problems that will require different responses and that health authorities in BC increasingly have established methods in place to deal with their unique needs.

Health system leaders ought to urge regions to refrain from stockpiling drugs in undersupply.

Inventory management creates difficulties during a drug shortage and because of this, stockpiling (hoarding) in advance of or during the shortage can occur. Yet, stockpiling causes two distinct problems: (1) it can exacerbate the shortage when health systems drain the supply chain and (2) divert unneeded supplies away from other health systems with patients in need.³⁰

In the context of drug undersupply, stewardship means that:

³⁰ Fox, E., Birt, A., James, K., Kokko, H., Salverson, S., & Soflin, D. (2009). ASHP guidelines on managing drug product shortages in hospitals and health systems. *American Journal of Health-System Pharmacy*, 66, 1399-1406. doi: 10.2146/ajhp090026

- Institutions and professional groups across all practice contexts (acute, community, rehab and long-term care) conserve drugs only for predictable and certain urgent contingencies
- Institutions and professional groups at all levels should refrain from hoarding

Health system leaders ought to mandate the provincial drug resource allocation body to make decisions about drug conservation and distribution.

The resource allocation body should ensure that:

- Decision-making regarding conservation of drugs is a collaborative and inclusive process, recognizing that different regions of the province will experience drug shortages differently and have different needs.
- Decisions made about conservation and distribution of drugs do not favour one region over another
- There is the widest possible consultation with those affected by the decisions (clinicians and the public) in planning for a drug shortage and no particular group is excluded from decision-making
- Decision-makers consider whether their decision(s) has a disproportionate impact on particular groups of people and whether this is justified
- Decision-makers recognize that the needs for predictable urgent/emergent situations will vary from urban to rural settings

In addition, the drug allocation body should put policies in place to preserve and compound drugs and should establish policies and standardized procedures that mitigate drug waste.

Health system leaders ought to ensure formal structures and processes are established in every region for overseeing safe and effective therapeutic alternatives and changes to clinical practice standards during a shortage.

The strategy should...

- Enable decisions to be made as quickly as possible.
- Ensure decisions about alternative agents are made in collaboration with medical, nursing, and pharmacy representatives
- Require approval from the appropriate medical committees
- Ensure monitoring of outcomes and quality review are in place when therapeutic alternatives are used (in order to ascertain potential negative effects)

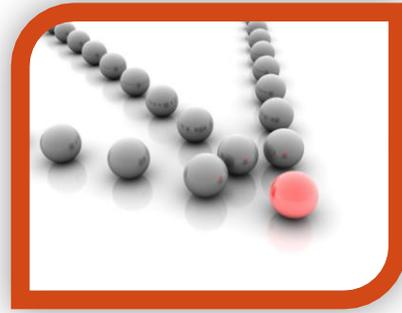
- Ensure an education strategy is developed and put into place to provide clinical programs information about best practices concerning use of alternative drugs and/or strategies to deal with the drug shortage
- Ensure a communication strategy is developed and implemented (as per the recommendations on communication section of this document)
- Ensure medical order sets and auto-quantity delivery systems should be updated to reflect decisions

Providing sub-optimal but still useful amounts of a drug ought to be permitted.

It is better to give a sub-optimal (but still useful) amount of drugs to more people than an optimal amount of drugs to fewer people. Health care professionals may object to the idea of providing less than the best care for their patients but if doing less gives more patients the chance of a better outcome it is justified.

Communication About Resource Allocation During Drug Shortage

Because of the crucial importance of communication during a drug shortage, we have set out several recommendations concerning the handling of communication especially at such a stage.



These recommendations are meant to act as a guide for decision-makers to consider if faced with drug undersupply and the difficult task of allocating scarce resources for patients in the most safe and fair means possible. An ethical approach to resource allocation requires an ongoing and effective communication strategy at each point of the decision-making planning process.

As part of the broader drug undersupply communications planning structure, health system leaders ought to establish a dedicated provincial resource allocation communications strategic planning committee.

The committee's mandate should be to develop a strategic plan for coordinating information gathering, dissemination and feedback processes.

Communication and engagement should run across all practice contexts (acute, community, rehab, and long-term care) and at each level to identify safe and effective treatment alternatives for patients.

A participatory approach to decision-making, rather than rigid hierarchies should be emphasized.

Patients and families ought to be engaged in the decision process. Broader public engagement strategies should also be developed and employed to create space for citizen voices in the conversation.

The committee ought to implement a communications strategic plan.

Once a plan is in place, providers' roles and responsibilities ought to be established in order to ensure transparency and accountability at each point of care.

All health care providers must be informed of the situation (context) and the reasoning behind decisions that are made.

Instructions on appropriate roles of different care providers and their responsibilities for delivering messages about the plan will ensure a streamlined approach to the communication strategy.

Instructions and education sessions on how to implement the plan ought to be provided to appropriate health care providers.

Communities should be informed about the situation and response plan, including the work undertaken to pursue the most ethically justified system response through public forums.

The communication strategies should be sensitive to the cultural and linguistic context within which the communication is being delivered.

A constant flow of information throughout health care services must be established. Exchange of information, including updates and reporting barriers/challenges to the plan, must flow between management, front line staff, and patients/families on an ongoing and consistent basis.

Interdisciplinary ethics rounds can be hosted at the regional level to review progress.

A central office can be identified to provide ongoing updates across the provinces and act as the point of contact with suppliers/ distributors/ providers.

Engagement must be established at the Federal level in order to effect change.

The committee ought to evaluate and follow-up on the communications strategic plan.

Continual communication on drug shortage updates and assessment of the decisions and actions must be reflected upon before, during, and after the response plan is in place.

Those who disagree with decisions that are made ought to have a way of communicating their concerns and challenge the decisions through the establishment of meso and micro level appeals processes.

We should strive to improve best practices. This can be accomplished by ensuring a feedback loop is in place that includes communications from diverse perspectives on their assessment of drug supply and response plan (i.e. medical outcomes, patient meaning, staff morale).

The committee should establish regular health-authority wide updates on an ongoing and consistent basis via email, newsletters, and teleconference and/or face-to-face meetings.

Regular public updates should be provided to address drug supply status through traditional and social media. A public forum for discussing the assessment and continual status updates on an ongoing basis should also be offered.

The plan must be translated at every level of health care service and followed-up through a feedback mechanism in order to evaluate the plan on an ongoing basis. This approach will enable a clear, thorough, and ongoing communication strategy to effectively manage and implement the response plan as well as aim to engender patient, provider and public trust in our system of health care as a whole.

Emergency situations, such as the case of drug undersupply, present many barriers to the establishment of clear, effective and ongoing communication strategies within complex health care settings. Some concerns with this approach include the ability to effectively:

- 1) Involve all appropriate stakeholders in the decision-making process;
- 2) Provide adequate education for patients, families, and the public, that will allow communities to understand the types of decisions that sometimes need to be made in these difficult situations;
- 3) Collaborate across multi-disciplinary boundaries given time and staffing resource constraints;
- 4) Adapt communication strategies across various health institutions and authorities that are accountable to their own sets of individual policies;
- 5) Balance both our obligation to provide a transparent translation of information with the need for sensitivity at times of uncertainty and unknowns.

These potential barriers to effectively implement communication plans are legitimate concerns that need to be carefully considered. To address these concerns:

- 1) Strategizing a communication plan in advance of an urgent situation of drug undersupply can help to avoid the potential problems identified above. Therefore, identification of stakeholder groups to involve in decision-making and appointing communications planning committees for emergency situations are activities that ought to be established immediately.

- 2) Clarifying policies and providing education on how to communicate with stakeholders and the public at large can help to prepare for time-sensitive information dissemination and avoid reactionary decision-making.
- 3) Preparing strategies to improve coordination of communication across multi-disciplinary boundaries within and across institutions, as well as relationship building between health authorities, can be a continual practice across our entire system of health care in British Columbia.

Facts About the Context (The Descriptive Landscape)



This section provides a description of key elements of the context against which the recommendations here are made. The justification of the recommendations will depend in part on the accuracy of these descriptions. It is important to ensure that we have a shared and well-justified understanding of descriptive context because if those guided by policies based on these recommendations disagree with the descriptive assumptions about the context, they may believe the policies are unjustified and not comply.

The reality of drug undersupply

- Drug undersupply is a real, serious and complex problem.
- The drugs often in undersupply play a role in saving life, relieving suffering, and/or preventing disease.
- Responsibility for the situation does not rest with any single individual or group.
- Securing drugs from other companies can take weeks to months.
- Many of the drugs used in the health system are single source.
- There are many stakeholders in the drug supply chain.
- The system is complex and interlocking.
- Solutions to the broad issue of securing a reliable drug supply will be complex and require the involvement and collaboration of multiple parties and addressing all dimensions - from issues in manufacturing and supply to demand and dispensation.

Duration of drug shortages

- According to HealthProCanada data for the period January to December 2012³¹,

³¹ Personal communication with Linda Morris, Director, Pharmacy Services, Lower Mainland Pharmacy Services.

- The overall average of monthly medians to resolving a drug undersupply in Canada is 109.6 days - up from 72.8 days for the same period in 2011
- The yearly median was 107.0 days (compared to 74.0 days in 2011)
- The overall average of monthly hospital specific medians was 135.5 days (compared to 66.5 days in 2011)
- The yearly hospital specific median was 117.0 days (compared to 62.0 days in 2011)
- The overall average of monthly single source (not necessarily innovator) medians was 158.5 days (compared to 88.6 days in 2011)
- The yearly single source median was 149.0 days (compared to 86.0 days in 2011)
- The average of monthly medians for innovator drugs in 2012 was 264.8 days (compared to 82.3 days in 2011)
- The yearly median for innovator drugs in 2012 was 237.0 days (compared to 74.0 days in 2011)
- According to the FDA:³²
 - It takes 105 days to resolve the shortage of a medically necessary drug
 - The overall median period for a drug shortage is 62.5 days
 - For innovator products the period is 57 days
 - For generic drugs the period is 71.5 days
- Many shortages last more than a year
- Announced dates of availability return by manufacturers are not always met.

Severity of drug shortages³³

- Drug shortages are a historical problem, but their severity has quadrupled since 2006

³² U.S. Department of Health and Human Services, U.S. Food and Drug Administration. (2011). *A review of FDA's approach to medical product shortages*.

³³ *Ordre des pharmaciens du Québec, Collège des médecins du Québec, Association des pharmaciens des établissements de santé du Québec, Association Québécoise des pharmaciens propriétaires. (2012). Drug shortages: A public health issue that demands a coordinated response.*

- In 2011, the FDA counted 250 shortages, which represents a 40% increase over the previous year
- Reporting of drug undersupply varies because manufacturers are only required to notify voluntarily and for medically necessary drugs
- In Quebec, shortages of drugs covered by the public insurance plan for which substitutes are available reported that...
 - In 2006, there were 33 drug shortages
 - In 2009, there were 80
 - In 2011, there were 207.

Kinds of drugs affected

- Increasingly, drugs in undersupply are used to treat and/or prevent serious health issues for which no alternative available.³⁴
 - According to the FDA, of 127 shortages between January 2010 and August 2011:
 - 93% were for medically necessary drugs
 - 41% were for medically necessary that were sole source.
- Few companies manufacture sterile injectable drugs because they are complex. According to the FDA:^{35, 36}
 - In 2008, 35% all reported shortages in US were for sterile injectable drugs
 - In 2009, this rose to 46%
 - In 2010, 74% all reported shortages in US were for sterile injectable drugs.
- Generic drugs are affected much more than brand-name drugs.
 - According to HealthProCanada data for the period January to December 2012³⁷

³⁴ FDA, 2011.

³⁵ Morrison A. *Drug Supply Disruptions* [Environmental Scan Issue 18]. (2011). Ottawa: Canadian Agency for Drugs and Technologies in Health.

³⁶ FDA, 2011.

³⁷ Personal communication with Linda Morris, Director, Pharmacy Services, Lower Mainland Pharmacy Services.

- The yearly median for 2012 (January to December) for generic drugs was 105.0 (compared to 72.0) in the previous year.
- The overall average of monthly medians for generic drugs in 2012 was 107.5 days (compared to 72.3 days in 2011)
- According to the IMS Institute Health Informatics:³⁸
 - 83% of drug shortages in 2011 affected generics
 - 50% drugs in shortage were produced by just one or two manufacturers.
- According to a 2011 FDA report:³⁹
 - 50% of drugs in undersupply were generic
 - 43% were innovator drugs
 - 7% of products were both generic and innovative.
- Cancer drugs are also affected by undersupply.
 - According to the IMS Report, 16% of drugs in shortage were oncology drugs
 - According to the FDA report, of 127 shortages from January 2010 to August 2011, 28% were for oncology drugs.
 - Antibiotics are also affected.
 - According to the IMS Report, 15% of shortages were for antibiotics.
 - According to the FDA report, of 127 shortages from January 2010 to August 2011, 13% were for antibiotics.

2012 Sandoz experience

- Sandoz makes approximately 230 products, of which 130 drugs are single source.
- For various reasons, Sandoz was unable to provide the pharmaceutical products expected.
- These led to drug shortages for some time.
- The production of some drugs was discontinued, while for others production was put on hold.
- The impact was felt across Canada and the US.

³⁸ IMS Institute for Healthcare Informatics. (2011, November). *Drug shortages: A closer look at products, suppliers and volume volatility*. Parsippany: NJ.

³⁹ FDA, 2011.

- In BC:
 - Manual counts were conducted and inventory taken at all sites.
 - Drugs were shared between sites in several cases.
 - Usage levels were difficult to assess.
 - Emergency Operating Committees were set up at health regions and the Ministry of Health for communicating and providing guidance.
 - Primarily injectable narcotics were affected, used for:
 - Pain management in various contexts
 - Surgery and post-op
 - Medical Patients
 - Palliative Care

Causes of Drug Undersupply

- Business or economic decisions impact the availability of drugs. Examples of such decisions include:
 - The decision to pursue generic versus brand name drugs
 - Consolidation of manufacturing companies
 - Decisions to limit or discontinue production of certain drugs
 - Company closures
 - Decisions to pursue drugs which maximize profit
 - Distributor limitations
 - Management practices to make inventory control efficient
 - Exclusive agreements between supply chain entities
 - Purchasing beyond immediate need and stockpiling practices (e.g. in response to rumored shortages)
 - Reconfiguration of manufacturing and production processes
- Manufacturing quality issues also impact drug availability, especially factors such as:
 - Quality control breakdowns
 - Non-compliance with standards
 - Labeling issues
 - Recalls
- Shortages of active ingredients or components also impact drug availability. These can include:
 - Scarcity of raw materials
 - Having only single sources of raw material
 - Source countries (e.g. China & India) not meeting raw material production standards

- Natural disasters or political unrest in source countries.
- Changes in demand, such as increases and volatility, also impact availability. These can be due to:
 - Policies of inventory control that create little room for adapting to change
 - Clinical practice shifts
 - Monopsony practices (single buyer - many sellers)
 - Changes in international demand
- Drug shortage can also be caused by legislative changes or delays in processing approvals by regulatory bodies at various levels:
 - Local (Health Canada regulations)
 - International (e.g. FDA - this was the issue in the Sandoz case)
- Market failure is also a cause of drug undersupply.⁴⁰ Examples include:
 - Inflexibilities in the health care market (in areas where health care is distributed in the market)
 - Inadequate supply of drugs do not always reduce demand
 - Prices cannot be raised if they are pre-negotiated
 - New manufacturers cannot quickly enter the market
 - Drug alternatives are not always available, effective or well-tolerated

Impact of Drug shortages

Drug shortages have a considerable impact on individuals, systems and communities. This section lists some of the impacts according to broad categories. It is important to recognize that many impacts cross categories of individuals and groups and so may fit in multiple places.

- Drug shortages impact the health of those for whom these drugs are intended. Possible and reported impacts when patients are deprived of needed drugs include:
 - Death

⁴⁰ Hoffman, S. (2012). *The Drugs Stop Here: A Public Health Framework to Address the Drug Shortage Crisis*. Food and Drug Journal 67, no. 1. Case Legal Studies Research Paper No. 2012-4. Available at SSRN: <http://ssrn.com/abstract=2001660>

- Hospitalization
- Longer institution stays
- Greater illness (disease progression, new symptoms and problems)
- Greater suffering
- Infections
- Loss of control over symptoms
- Side-effects from new medications
- Iatrogenic suffering from adverse events
- Shortages impact the quality of care and access to necessary services. For example through:
 - Increases in near misses, adverse events and medical errors
 - Compromise or postponement of medical interventions
 - Unmet standards of practice
 - Violation, change, or delay of research protocols
 - Patients having to go to multiple pharmacies to get medications (which leads to increased distribution of patient information and increased chance of drug interactions)
 - Generation of secondary shortages
 - Jeopardizing of research studies
- Shortages can result in financial impacts on the system. These include:
 - Higher cost of replacement drugs
 - Cost of drugs purchased outside supply agreements
 - Time invested in sourcing and procuring alternates
 - Time for preparing alternate care plans
 - Cost of additional therapies
 - Medical care for visits due to change in treatment plan
 - Time for management of supply chain management
 - Cost of postponing interventions, surgeries, etc.
 - Costs of management of compensation for accidents
- Drug shortages have a significant impact on the health system.
- These impacts concern all parts of the system - those under public control and those in the private system.
- Not all of these are visible.
- Some of the system-level impacts include:
 - Deterioration of the relationships between physicians, pharmacists, nurses, and institutions
 - Diversion of healthcare resources, management time, expertise from other areas to manage the problem

- Exacerbation of inequalities of access to services and treatments
- Greater moral distress for all from having to make more difficult choices
- Staff misuse of drugs
- Trust the public has of the system - specifically related to the handling of drug shortages and in general
- Hoarding (inappropriate stockpiling) of drugs for fear of undersupply, leading to unfair and/or inefficient distribution
- A positive impact of the shortage experience is the effort underway to examine the drug supply process from multiple perspectives and by multiple stakeholders.

Vulnerable populations⁴¹

- There are a number of groups who may be potentially vulnerable during an episode of drug undersupply, depending on the undersupply context. These include:
 - Infants and children
 - Elderly patients
 - Socio-economically disadvantaged individuals and groups
 - Non-competent adults and people with diminishing or fluctuating cognitive capabilities
 - People with diminishing or fluctuating physical capabilities
 - Chronic disease sufferers
 - Women
 - Aboriginal populations
 - Substance users
 - Patients with mental illness
 - Non-English speakers
 - People with non-traditional sexual orientations

⁴¹ This can be a difficult list to encounter, especially as being mentioned on the list might be perceived to indicate a position of weakness. Notwithstanding this discomfort, we assert that it is true that in various contexts groups mentioned in this list are vulnerable to having their interests subjugated and presented in a manner not of their choosing.

Structure of Resource Allocation

Decisions about the allocation of drugs happen at multiple levels.⁴² This is most easily recognizable at the micro level where allocation decisions and policies determine the distribution of resources to individuals. The question raised here is, when we have a shortage of a drug within a given unit or program, who should receive the drug and who should not?

Meso-level practice involves decisions and policy within an institution, program or community. At this level, the resource in question is important in various programs or communities of practice. The question is, how much of a scarce drug should go to each of the various programs, institutions and communities who need it?

At the broadest level within a system, the macro-level, practice involves decisions and policy involving broader public policy issues and includes the allocation of general resources. Decisions made by federal, provincial, and territorial governments about funding, priorities and relationships are examples of macro decisions.

Resource allocation decisions at each of these levels can be divided into three decision points: a) which criteria will be used to choose between candidate options; b) who will use these criteria; and c) through what process will the criteria be applied and decisions made and implemented.

Stakeholders

- Stakeholders in the system include:
 - Industry
 - Government bodies
 - Distributors
 - Public agencies
 - Private clinics e.g. surgical
 - Veterinary clinics (who use anesthesia agents)

⁴² Adapted from Yeo, M., Rodney, P., Moorhouse, A., and Khan, P. 2010. Justice. In M. Yeo, A. Moorhouse, P. Khan, & P. Rodney (Eds.), *Concepts and cases in nursing ethics* (3rd ed., pp. 293–316). Peterborough, ON: Broadview Press.

- Complex relationships between national, international pharmaceutical industry, regulation and health care provision
- In periods of drug undersupply there may be tension between the interests of stakeholders at various levels, for example with meso and micro allocation interests

Decision-making influence, authority and the law

- No clear line of accountability for the drug supply between industry, governments and health authorities currently exists
- Professional associations can influence practice of members but do not have authority to intervene with supply chain stakeholders
- No regulation is in place that requires industry to give notice of product discontinuation or interruption of supply - this makes shortage prevention and risk management measures hard or even impossible
- Manufacturers must make submissions for Notifiable Changes to a drug manufacturing process - delays in process of submission lead to delays in production⁴³

Drug supply chain elements

- The drug supply chain is complex. The following is a rough summary of elements in the chain:
 - Raw material production (production, packaging & distribution)
 - Drug Production (purchase and procurement of raw materials, production from raw materials, packaging (including labeling), shipping to distributors - sometimes to pharmacies & health institutions)
 - Wholesale Distribution (purchase & procurement, storage, inventory management, distribution to pharmacies & health institutions)
 - Pharmacies (purchase, storage, inventory management, supplying to patients, facilitation of payment/reimbursement of insurers)
 - Regulators (create standards that manufacturers must meet)

⁴³ Ordre des pharmaciens du Québec, Collège des médecins du Québec, Association des pharmaciens des établissements de santé du Québec, Association Québécoise des pharmaciens propriétaires. (2012). *Drug shortages: A public health issue that demands a coordinated response*.

- Private pharmacies sometimes have different sources of drugs

Change strategies

- Auditing makes a difference to compliance
- Practice regulations work in normal times, not in times of shortage

Request for Feedback

We appreciate your taking the time to provide feedback on this document. You may do so by completing this form and emailing it to ethics.services@fraserhealth.ca or completing the web version of the form at <http://fluidsurveys.com/surveys/susan-rink/drug-undersupply-feedback/>

The feedback form is divided into two sections: general questions about the document and recommendation-specific feedback.

GENERAL FEEDACK

What would make this document easier to use?

What additional tools or resources would assist with responding to drug undersupply efforts?

Who do you recommend should be consulted about these recommendations?

Is there any general feedback you would like to offer?

<u>RECOMMENDATION-SPECIFIC FEEDACK</u>	<i>To whom should this section be directed?</i>	<i>What additional issues should be addressed for this section?</i>	<i>Do you have any critical feedback about this section?</i>
<p><i>What Should Matter (Values)</i></p> <p><i>Health system leaders ought to establish that decision-making relevant to responding to drug undersupply will be guided by the following list of values:</i></p> <ul style="list-style-type: none"> • <i>Accountability</i> • <i>Effectiveness</i> • <i>Equity</i> • <i>Excellence in clinical and administrative practice</i> • <i>Fiduciary Responsibility</i> • <i>Inclusiveness</i> • <i>Integrity</i> • <i>Respect/ Transparency/ Procedural Fairness</i> • <i>Solidarity</i> • <i>Stewardship</i> • <i>Sustainability</i> • <i>Timeliness</i> • <i>Trust</i> 			

<u>RECOMMENDATION-SPECIFIC FEEDACK</u>	<i>To whom should this section be directed?</i>	<i>What additional issues should be addressed for this section?</i>	<i>Do you have any critical feedback about this section?</i>
<p><i>System Integration, Decision Structure and Process</i></p> <p><i>Health system leaders ought to...</i></p> <ul style="list-style-type: none"> • <i>Set the expectation of decision transparency within the system.</i> • <i>Establish a clear information gathering and decision-making process</i> <p><i>BCMoH UPDATE: In June 2012, the House of Commons Standing Committee on Health (HESA) tabled its Ninth Report entitled: Drug Supply in Canada: A Multi-Stakeholder Responsibility. Central to its report and recommendations, HESA called on the Government of Canada to work with key stakeholders across the Canadian drug supply system to anticipate, mitigate and manage drug shortages in Canada.</i></p> <p><i>The Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) was assembled in August, 2012. The MSSC includes representatives of industry associations, federal, provincial and territorial governments, and health professional associations, coming together to address drug shortages in a collaborative and coordinated manner.</i></p> <ul style="list-style-type: none"> • <i>Ensure that a clear evidence-informed and values-based decision-making process is established.</i> • <i>Establish a drug undersupply communications strategic planning structure.</i> <p><i>BCMoH UPDATE: Under MSSC, recently developed tools include:</i></p> <ul style="list-style-type: none"> o <i>Protocol for the Notification and Communication of Drug Shortages released September 13, 2013 (establishes process and principles for the notification and communication of drug shortage information);</i> o <i>Multi-Stakeholder Toolkit released September 13, 2013 (clarifies the roles and responsibilities of key players across the drug supply chain and identifies tools and strategies to address drug shortages);</i> o <i>The list of stakeholders involved (Health Care Associations, P/T Health Ministries, Industry Associations, group purchasing organizations, distributors, P/T Drug Shortages Task Team, Federal Health Portfolio, CADTH);</i> o <i>Contracting and Procurement Best Practices Tool, currently being developed, which will identify the best practices in each step of the drug supply chain that would prevent, mitigate and manage the supply of drugs; and</i> o <i>Revisions to the Canadian Drug Shortages Database managed by Rx&D (www.drugshortages.ca).</i> 			

<u>RECOMMENDATION-SPECIFIC FEEDACK</u>	<i>To whom should this section be directed?</i>	<i>What additional issues should be addressed for this section?</i>	<i>Do you have any critical feedback about this section?</i>
<p>System Learning and Follow-Up</p> <p>Health system leaders ought to...</p> <ul style="list-style-type: none"> • Ensure that individual institutions and programs conduct evaluation and outcome assessments of practice changes enacted in response to the drug shortage. • Commission a large-scale quality review (similar to the Cochrane Report) to inform decisions made for dealing with the present drug undersupply. • Create and/or participate in opportunities for knowledge transfer at multiple levels related to drug undersupply. 			
<p>Undersupply Prevention</p> <p>Health system leaders ought to...</p> <ul style="list-style-type: none"> • Work with the BC Ministry of Health to advocate for the creation of an inter-provincial working group to develop a Canadian drug shortage response plan. • Work with the BC Ministry of Health to create a pan-Canadian group to develop a clear and shared understanding of the Canadian drug supply context. • Advocate that the inter-provincial working group consider the question of having government participate in the manufacturing of drugs. • <p>BCMoH UPDATE: The BC Pharmaceutical Supply Chain Working Group (PSCWG) has been established. The purpose of the PSCWG is to provide a forum for communication between the Health Authority Pharmacies including Provincial Health Services Authority (PHSA) Agencies and Emergency and Health Services Commission, Health Shared Services BC (HSSBC), HealthPRO and the Pharmaceutical Services Division, Ministry of Health for supply chain issues of common concern. The group provides recommendations for proactive provincial management of supply chain issue communication and processes.</p>			

<u>RECOMMENDATION-SPECIFIC FEEDACK</u>	<i>To whom should this section be directed?</i>	<i>What additional issues should be addressed for this section?</i>	<i>Do you have any critical feedback about this section?</i>
<p>Resource Allocation Criteria, Structure and Process</p> <p><i>Health system leaders ought to...</i></p> <ul style="list-style-type: none"> • <i>Establish that patient need is the principal criterion used to make allocation decisions at the meso and micro levels.</i> • <i>Establish that judgments of deservedness must not enter into allocation decisions.</i> • <i>Establish a provincial body to oversee meso level allocation decisions and establish micro level allocation criteria regarding drugs in short supply.</i> • <i>Require health regions to create local multidisciplinary resource allocation committees as one of the structures required to respond to drug undersupply.</i> 			
<p>Resource Preservation and Stockpiling</p> <p><i>Health system leaders ought to...</i></p> <ul style="list-style-type: none"> • <i>Urge regions to refrain from stockpiling drugs in undersupply.</i> • <i>Mandate the provincial drug resource allocation body to make decisions about drug conservation and distribution.</i> • <i>Ensure formal structures and processes are established in every region for overseeing safe and effective therapeutic alternatives and changes to clinical practice standards during a shortage.</i> • <i>Indicate that providing sub-optimal but still useful amounts of a drug ought to be permitted.</i> <p>UPDATE: Through work of contracts (Group Purchasing Organizations and provincial shared services organizations like Health Shared Services BC) and MSSC, work is being done to urge industry (manufacturers and wholesalers) to be more transparent about potential and actual drug shortages and to put in a system of allocation to all purchasers to ensure stockpiling does not happen.</p>			

<u>RECOMMENDATION-SPECIFIC FEEDACK</u>	<i>To whom should this section be directed?</i>	<i>What additional issues should be addressed for this section?</i>	<i>Do you have any critical feedback about this section?</i>
<p><i>Communication about Resource Allocation during Drug Shortage</i></p> <ul style="list-style-type: none"> • <i>Health system leaders ought to establish a dedicated provincial resource allocation communications strategic planning committee.</i> • <i>The committee ought to implement and evaluate and follow-up on the communications strategic plan.</i> 			

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Appendix 1: Method of Analysis

The BC Drug Undersupply Ethics Working Group (the Working Group) undertook the following key steps in the process to arrive at this document:

- A meeting of relevant experts to begin to establish a shared understanding of the descriptive context was held on May 8, 2012. All of the health regions in BC, the Ministry of Health, and the BC College of Pharmacists were invited to send representatives.
- Members of the Working Group met on May 18, 2012 to review the discussion, add to it and begin the process of articulating the values that should guide the various types of recommendations the group might make.
- At that stage the core team also identified the various dimensions for which the report should include recommendations. The Working Group allocated responsibility for each of the sections and began drafting the document.
- In June of 2012, members of the Working Group participated on a panel together with colleagues from the Joint Centre for Bioethics at the University of Toronto in an Experts Symposium on the Pharmaceutical Crisis.
- In June of 2012, a member of the Working Group participated in a Consensus Conference hosted by Emory University to explore a response to drug shortages.
- Over the next year, several individual members of the Working Group prepared drafts of various sections of the Report. The lead author then compiled and integrated these sections in an iterative process of drafting and review.
- During this time we have benefitted from the publication of work by our colleagues led by the Joint Centre for Bioethics at the University of Toronto (see Gibson et al. 2012) and more recently from Eastern Health (see Singleton et al, 2013).
- In February of 2012, members of the Working Group were Co-Applicants on a CIHR Meetings grant to host a national workshop on ethics and drug supply shortages to be held in June 2013. This grant application was successful. The workshop will be held in Banff, Alberta on May 29, 2013. The findings from this workshop and a survey that was created to inform the workshop will both be used as inputs into the consultation process.