

**Ethical Framework for Resource Allocation  
During Drug Supply Issues  
Affecting Saskatchewan<sup>1,2</sup>**

**Version 1.0  
June 19, 2012**

<sup>1</sup> Based on the Ontario Ethical Framework for Resource Allocation During the Drug Supply Shortage.

<sup>2</sup> Modified and used with permission from Jennifer Gibson, Ph.D., Director of Partnerships & Strategy at the Joint Centre for Bioethics at the University of Toronto, 30 March 2012.

# Ethical Framework for Resource Allocation During Drug Supply Issues Affecting Saskatchewan

## 1. **Introduction:**

In February 2012 Sandoz Canada, a Canadian drug manufacturer, communicated its decision to discontinue certain products and slow the production of many common injectable products produced at its Quebec plant. As Sandoz Canada produces approximately 50% of the injectable drugs used in Canada, this action resulted in immediate and ongoing supply disruptions of critical medications in Saskatchewan.

The Ministry, Health Canada, Regional Health Authorities (RHAs) and the Saskatchewan Cancer Agency have taken steps to monitor the province's drug supplies and continue to work together to reduce the potential impact this drug shortage has on patient care. While the health regions and cancer agency are currently managing the situation, it is important to be prepared to respond with an appropriate ethics framework should it be needed.

The Joint Centre for Bioethics (JCB) at the University of Toronto had prepared the "Ethical Framework for Resource Allocation during the Drug Supply Shortage" and permission was obtained from Dr Jennifer Gibson, Chair of the JCB, to modify and apply the value-based framework in Saskatchewan. The ethical principles underpinning the framework are based on Daniels, N. & Sabin, J. *Accountability for reasonableness* and Gibson, J. et al. *Priority setting in hospitals: fairness, inclusiveness, and the problem of institutional power relations*. Such resource allocation models promote value setting that is inclusive, transparent and reflexive.

Ethics consultation on the framework and its adaptation to Saskatchewan was provided to the Ministry by Dr. Qaiser Fahim (Bioethicist Saskatoon Health Region/Saskatchewan Cancer Agency) and Joy Mendel (Bioethicist St. Paul's Hospital/Catholic Health Association of Saskatchewan). The input of Senior Medical Officers (SMOs) of each health region in Saskatchewan, several RHA pharmacists, and public representatives from the Drug Advisory Committee of Saskatchewan was sought by the Ministry. During discussions between the bioethicists and the Ministry the comments received were reviewed and incorporated. The general consensus from the feedback indicated acceptance of the Ontario "Ethical Framework for Resource Allocation during the Drug Supply Shortage" including the values as defined. The Ministry's Drug Shortage Technical Advisory Group, SMOs, and public representatives then reviewed and provided further comments on the Saskatchewan ethical framework document which were considered by the Ministry and the bioethicists.

The ethical framework is intended to provide high-level guidance only as a shared foundation for decision-making and deliberation within and across health sectors, health institutions, and health professionals in response to the drug supply shortage. The framework will need to be operationalized further to accommodate the particularities of local context and may also need to be supplemented with specific guidelines customized to particular drug classes, patient populations, or care settings. The ethical framework is not intended to supersede the clinical judgment of healthcare professionals, the fiduciary duty to individual patients in their care, or their role as stewards of finite healthcare resources, nor does it replace or displace the permissions and constraints of applicable

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Saskatchewan legislation.

## **Purpose of this document:**

The purpose of this document is to propose an ethical framework to guide decision-making about redistribution of drug supplies and modification of health services in response to a large-scale drug supply shortage. The ethical framework is grounded in six overarching ethical principles (section 2) that establish the parameters of an ethical approach to managing a drug supply shortage of this scale. These overarching principles are further specified as allocation principles (section 3) to aid in setting priorities for access to drugs in short supply and as fair process principles (section 4) to enable constructive stakeholder engagement in identifying solutions to this priority setting challenge.

The ethical framework should be considered a dynamic document that will evolve over time.

## 2. **Overarching Ethical Principles:**

When resources are scarce, tough decisions must often be made about how to meet health needs ethically within resource constraints. Key ethical principles that will be relevant in responding to a large-scale drug supply shortage are outlined below. These ethical principles are not exhaustive of all principles that might guide typical practice, but rather these are the ethical principles that are most relevant to the situation, where difficult decisions need to be made about how drugs in short supply will be allocated to meet patients' needs and about whether health services will need to be modified in response to the drug shortage.

### **Beneficence:**

Maintain highest quality of safe and effective care within resource constraints by:

- Ensuring standard of care and best practices whenever possible
- Minimizing pain and suffering of individuals
- Using alternative drugs or treatments where evidence suggests similar clinical efficacy
- Informing and educating health providers about benefits, risks and appropriate use of alternative treatments, including risk mitigation strategies
- Informing and educating stakeholders about this ethical framework
- Enabling individuals to receive care in the most appropriate setting

### **Solidarity:**

Build, preserve and strengthen inter-professional, inter-institutional, inter-sectoral, and where appropriate, inter-provincial/territorial collaborations and partnerships by:

- Embracing a shared commitment to the well-being of patients regardless of care setting or geographic location
- Establishing, encouraging, and enabling open lines of communication and coordination amongst health professionals, health institutions, and health sectors
- Encouraging sharing of resources across health sectors, health institutions, and, where appropriate, provinces/territories with an emphasis on collaborative

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relationships.

- Supporting each other's allocation decisions consistent with the ethical framework

### **Utility:**

Maximize the greatest possible good for the greatest possible number of individuals by:

- Distributing drugs in short supply to those in most need and most likely to benefit
- Sharing drugs within and across institutions/sectors

### **Equity:**

Promote just/fair access to resources by:

- Ensuring burdens are not borne disproportionately by any patient, patient group, health sector, or institution
- Using allocation processes for distribution of drugs and modification of services that do not arbitrarily disadvantage any particular patient, patient group, health sector, or institution
- Not discriminating between patients based on factors not relevant to their clinical situation (e.g., social status)

### **Stewardship:**

Use available resources carefully and responsibly by:

- Ensuring drug utilization is consistent with available evidence of clinical efficacy
- Postponing elective procedures/treatments that require use of drugs that are in limited supply
- Prioritizing access to scarce drugs based on urgency and severity of need
- Monitoring drug utilization and distribution to facilitate mid-course corrections as needed

### **Trust:**

Foster and maintain public, patient, and health care provider confidence in the health system by:

- Communicating in a clear and timely fashion
- Making decisions in an open, inclusive and transparent way with clearly defined decision-making authority and accountability at all levels
- Evaluating health system response to capture short and long-term lessons learned

## **3. Allocation Principles:**

The following proposed allocation principles are understood to apply generally across drug classes and contexts. They provide a basis for discussion to inform decision-making across health institutions, health sectors, and provinces/territories, and among health providers. See Appendix 1 for an allocation flowchart.

### **Stage 1:**

Implement strategies to preserve standard of care and best practices to the greatest extent possible within available drug supply.

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## When there is risk of drug shortage,

### 1a. Conserve existing supply of drugs using strategies such as:

- Developing an inventory of available drugs across care settings based on available supply and criticality of need and/or demand
- Reviewing current drug prescribing practices based on available evidence of clinical efficacy
- Reducing wastage of drugs (e.g., where evidence does not support or is weak for clinical efficacy and where it can be done safely)
- Using alternative drugs or treatments where evidence suggests similar clinical efficacy to the drug in short supply
- Using lower dosages where evidence suggests similar clinical efficacy to the drug in short supply
- Reassessing patient medical need on an ongoing basis and adjust drug dosing or Stage 2 priority allocation level as appropriate
- Delaying enrolment in research studies using drugs in short supply

### 1b. Access new supply of drugs by:

- Collaborating with other health regions and the government to identify and procure alternative sources
- Redistributing drugs between care settings in coordination with key stakeholders in accordance with the ethical framework

### *And if these strategies are insufficient ...*

- ### 1c. Postpone all non-medically necessary elective procedures/treatments (e.g., cosmetic surgery) that require the use of drugs in short supply (i.e., for which there is no treatment alternative)

### *And if this strategy is insufficient ...*

- ### 1d. Postpone or reduce those medically necessary elective procedures/treatments that require the use of drugs in short supply (i.e., for which there is no treatment alternative). "Medically necessary" is a context-specific concept that will need to be defined by local stakeholders and experts.

## **Stage 2:**

Apply Primary Allocation Principles to Optimize Therapeutic Benefit.

When Stage 1 strategies are insufficient to meet the need/or a drug(s) in short supply, give priority access in rank order to:

- ### 2a. Patients whose medical needs are urgent or emergent for whom there is reasonable likelihood of benefit from the drug in short supply *and* where not receiving this drug would have severe, adverse health consequences *and* where no therapeutic alternatives exist. "Likelihood of benefit" and "severe, adverse health consequences" are context-specific concepts that will need to be defined by local stakeholders and experts.

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- 2b. Patients whose medical needs are urgent or emergent for whom there is reasonable likelihood of benefit from the drug in short supply *and* where not receiving this drug would have severe, adverse health consequences, and where therapeutic alternatives do exist but are sub-optimal
- 2c. Patients whose medical needs are urgent or emergent for whom likelihood of benefit from the drug in short supply is uncertain (e.g., variable evidence) *and* where not receiving the drug may have severe, adverse health consequences *and* where no therapeutic alternatives exist
- 2d. Patients whose medical needs are not urgent or emergent

### *Meanwhile ...*

- Continue with Stage 1 strategies, and
- Reassess patients' medical needs on an ongoing basis to identify any changes in level of priority, and
- Maintain therapeutic relationship with patients and provide ongoing support.

### **Stage 3:**

#### Apply Secondary Allocation Principles to Ensure Fair Access to Needed Care

When decisions must be made between patients within a level of priority as described in Stage 2, prioritize patients using a fair and unbiased procedure that does not discriminate between patients based on factors not relevant to their clinical situation (e.g., race, social value, sex, age) such as:

- First come, first served (where queuing is consistent with regular clinical practice), or
- Other procedure that is developed and sanctioned by affected stakeholders (e.g., dividing dose among more than one patient, random selection)

### *Meanwhile ...*

- Continue with Stage 1 strategies, and
- Reassess patients' medical needs on an ongoing basis to identify any changes in level of priority, and
- Maintain therapeutic relationship with patients and provide ongoing support.

## **4. Fair Process Principles:**

Allocation decisions about limited resources, whether under normal circumstances or in a crisis, entail making difficult choices that may have a profound impact on how patient needs are met or not met. While making the right decision is important, making the decision in the right way may be even more important, that is, decision-makers need to be concerned with not just what decisions are made, but how they are made. Experience with priority setting in other contexts underscores the importance of a fair process in allocating scarce resources. A fair deliberative process will be essential in specifying and operationalizing the allocation principles (outlined above) within and across health institutions. Key stakeholders of the

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Saskatchewan health system such as patients, health care providers, and members of the public will be more likely to accept allocation decisions about drugs in short supply or about modification in health service delivery if the decision-making processes are and are perceived to be fair. Fair processes are characterized by adherence to the following principles:

- **Relevance:** Decisions should be made on the basis of reasons (i.e., evidence, principles and values) that are relevant under the circumstances and made by people who are credible and accountable.
- **Publicity:** Decisions are made using an open and transparent process that enables affected stakeholders to appreciate and understand the rationale for allocation decisions.
- **Revision:** Decisions are revisited and revised as new information emerges, and stakeholders have opportunities to voice any concerns about decisions (i.e., formal mechanisms to bring forward new information, to appeal or raise concerns about particular allocation decisions, and to resolve disputes).
- **Empowerment:** Decisions are made explicitly with stakeholder views in mind and stakeholders have meaningful and effective opportunities to participate in and/or inform the decision-making process.
- **Enforcement:** There are mechanisms to ensure that these fair process principles are sustained throughout the response. (Daniels, N. Accountability for reasonableness. *BMJ* 2000, 321: 1300-1301; Gibson et al., Priority setting in hospitals: fairness, inclusiveness, and the problem of institutional power relations. *Social Science & Medicine* 2005; 61:2355-2362. Also, Ontario Health Plan for an Influenza Pandemic).

### **5. Drug Shortage Ethical Framework Ethics Working Group:**

- Dr. Qaiser Fahim, Bioethicist Saskatoon Health Region (SHR)/Saskatchewan Cancer Agency (SCA)– Chair SHR/SCA Ethics Committee
- Joy Mendel, Bioethicist St. Paul’s Hospital/Catholic Health Association of Saskatchewan - SHR/SCA Ethics Committee
- SHR/SCA Ethics Committee

### **6. Drug Shortage Ethical Framework Consultation Group:**

- Kevin Wilson, Executive Director, Drug Plan & Extended Benefits Branch, Saskatchewan Ministry of Health
- Tracey Smith, Director, Pharmaceutical Services, Drug Plan & Extended Benefits Branch, Saskatchewan Ministry of Health
- Dr. Brian Laursen, Medical Advisor, Saskatchewan Ministry of Health

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- Saskatchewan Senior Medical Officers Committee:

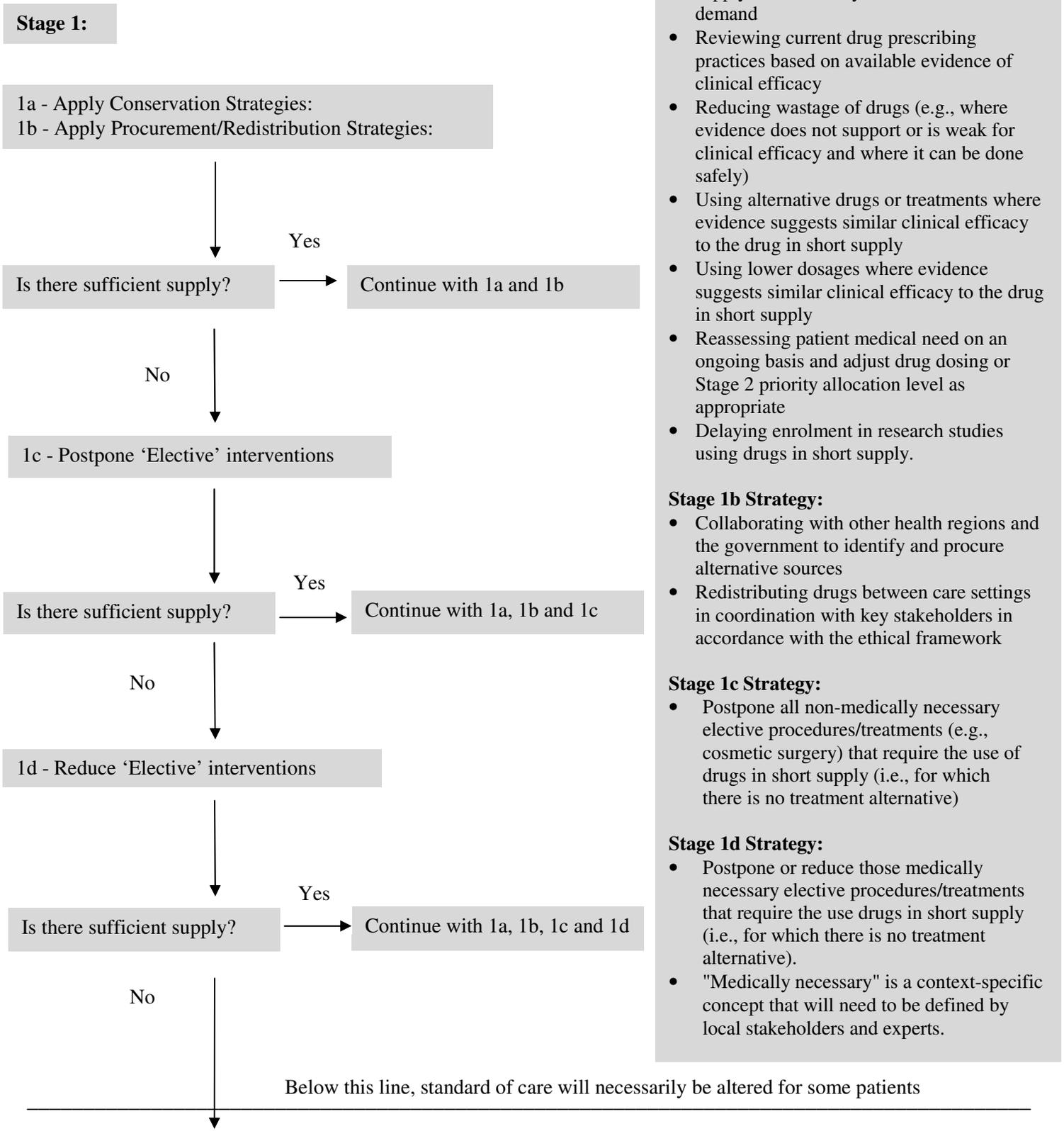
Michael Bishop	Steven Britton	David Ledding	Joy Dobson
David Stoll	Brian Geller	Cecil Hammond	Brenda Hookenson
I Radevski	Alain Lenferna	Bruce Murray	Fauzi Ramadan
Grant Stoneham	Jordan Wingate	Edmund Royeppen	Colum Smith
Karen Shaw	Barb Porter		
  
- Drug Advisory Committee of Saskatchewan Public Representatives:

Namarta Kochar	Allen Lefebvre
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- Regional Health Authority/Saskatchewan Cancer Agency - Drug Shortage Technical Advisory Group:

Corry MacWilliam	Dave Sereda	Bernie Schwartz	Barry Lyons
Melanie Bogdan	Dale Rodenbush, Chaela Barry	Dawn Calder, Kelly Babcock	Janet Harding, Leah Heilman
Karen Kaptein	Darryl Boehm	Shannan Neubauer	Susan Kozey
Dale West	Terry Safnuk		

# Ethical Framework for Resource Allocation During Drug Supply Issues Affecting Saskatchewan

## Appendix 1: Allocation Flowchart



- Stage 1a Strategy:**
- Developing an inventory of available drugs across care settings based on available supply and criticality of need and/or demand
  - Reviewing current drug prescribing practices based on available evidence of clinical efficacy
  - Reducing wastage of drugs (e.g., where evidence does not support or is weak for clinical efficacy and where it can be done safely)
  - Using alternative drugs or treatments where evidence suggests similar clinical efficacy to the drug in short supply
  - Using lower dosages where evidence suggests similar clinical efficacy to the drug in short supply
  - Reassessing patient medical need on an ongoing basis and adjust drug dosing or Stage 2 priority allocation level as appropriate
  - Delaying enrolment in research studies using drugs in short supply.
- Stage 1b Strategy:**
- Collaborating with other health regions and the government to identify and procure alternative sources
  - Redistributing drugs between care settings in coordination with key stakeholders in accordance with the ethical framework
- Stage 1c Strategy:**
- Postpone all non-medically necessary elective procedures/treatments (e.g., cosmetic surgery) that require the use of drugs in short supply (i.e., for which there is no treatment alternative)
- Stage 1d Strategy:**
- Postpone or reduce those medically necessary elective procedures/treatments that require the use of drugs in short supply (i.e., for which there is no treatment alternative).
  - "Medically necessary" is a context-specific concept that will need to be defined by local stakeholders and experts.

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