

**Ethical Framework for Resource Allocation During the
Drug Supply Shortage**

Version 1.0

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1. Introduction

On March 7, 2012, the Ontario Ministry of Health & Long-Term Care (MOHLTC) struck a Drug Shortage Technical Advisory Group to provide technical expertise and broad stakeholder input on plans to respond to possible drug supply shortages resulting from production and distribution issues at the Sandoz Canada plant. As part of this effort, the MOHLTC requested ethics input from the University of Toronto Joint Centre for Bioethics (JCB). An ethics working group was struck to develop an ethical framework to guide: i) redistribution of drug supplies across the province based on need, and ii) service modification in the event of drug shortages affecting service delivery.

Starting on March 12th, the ethics working group met daily by teleconference: i) to review the ethics literature on drug shortages and related ethics frameworks for managing supply shortages on a system level (e.g., Fraser Health, Ontario Pandemic Influenza Plan); ii) to share intelligence about the real and potential impacts of a drug supply shortage in different health sectors through each member's own institutional and inter-professional networks; and ultimately, iii) to build deliberative consensus on ethical principles 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 developed iteratively over a one week period in consultation with the multi-stakeholder and inter-professional members of the MOHLTC's Drug Shortage Technical Advisory Group, with other members of the ethics community, and with clinical colleagues. Due to the urgency of the drug shortage, there was limited time for comprehensive stakeholder feedback. As a result, the ethical framework should be considered a dynamic document that will evolve over time in response to stakeholder feedback.

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. Individuals are encouraged to consult with their appropriate regulatory body for additional guidance on operationalization. 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 Ontario 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.

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 the Sandoz drug supply shortage are outlined below. These ethical principles are not exhaustive of all principles that might guide our typical practice, but rather these are the ethical principles that are most relevant to the situation we find ourselves in, 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
- 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
- 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 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 at the Local Health Integration Network (LHIN) level, within and 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

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 LHIN partners and governments 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 for 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.

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.

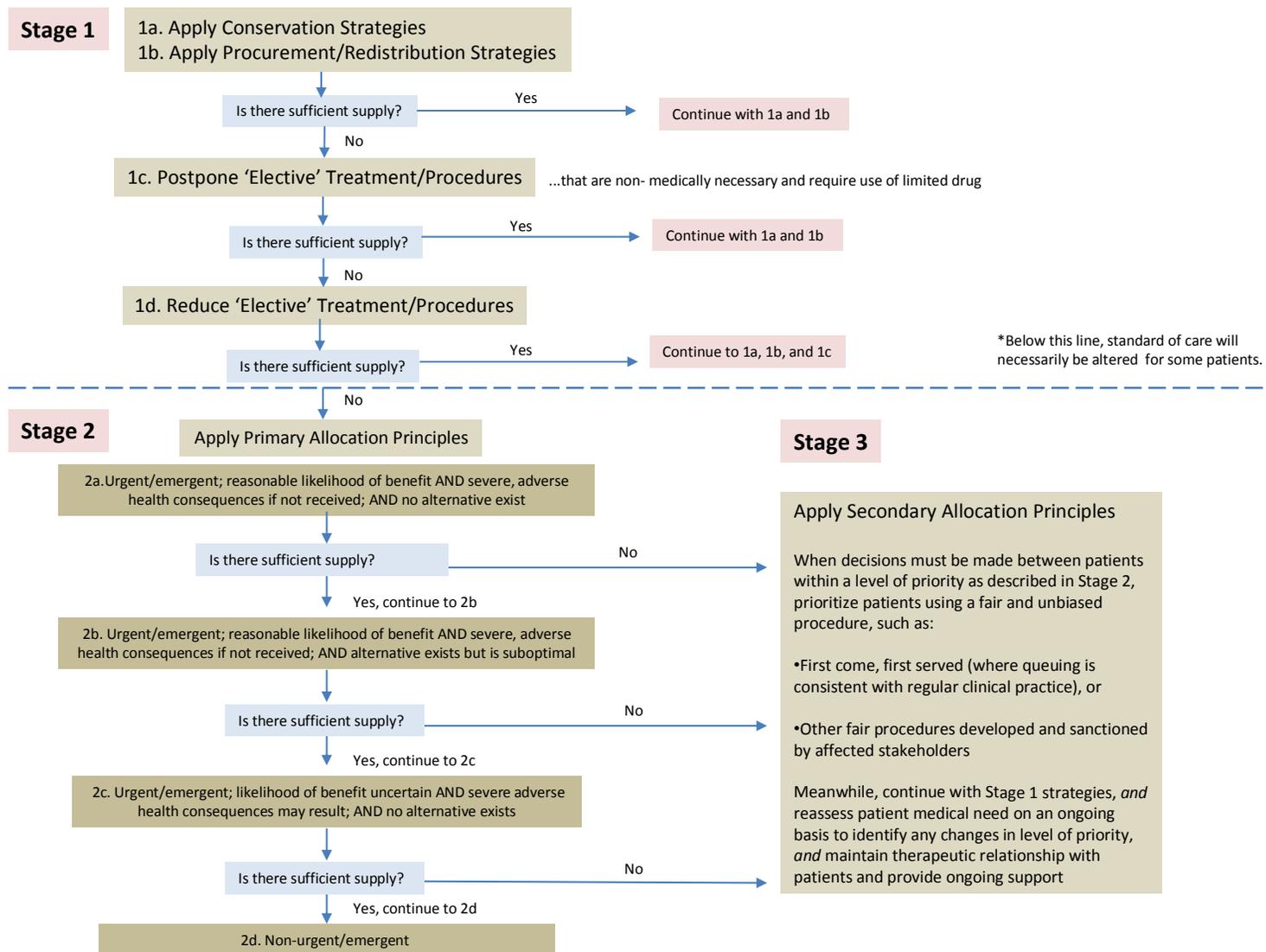
4. Fair Process Principles:

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 Ontario health system – 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](#)).

Appendix 1. Allocation Flowchart



5. Ethics Working Group

The ethics working group is comprised of ethicists affiliated with the University of Toronto Joint Centre for Bioethics (JCB) and/or the Regional Bioethics Group (RBG), including:

- Sally Bean (Sunnybrook Health Sciences Centre/JCB)
- Paula Chidwick (William Osler Health System/RBG)
- Jennifer Gibson (Chair - JCB)
- Dianne Godkin (Credit Valley and Trillium Health Centre/JCB/RBG)
- Robert Sibbald (London Health Sciences Centre/RBG)
- Frank Wagner (Toronto Central CCAC/JCB)

Ethics working group members were selected for their ethics expertise, the diversity of their experience in different health settings (including community care), and their proactivity in reaching out to the JCB to explore collaboration on this pressing issue.

6. Drug Shortage Technical Advisory Group

The Drug Shortage Technical Advisory Group is composed of key technical experts who provide advice to the Ministry of Health and Long-Term Care on the response to the drug shortage, and who represent the following organizations:

- Association of Municipal Emergency Medical Services of Ontario
- Calea
- Canadian Society of Hospital Pharmacists
- Centre for Addiction and Mental Health
- EHS Medical Advisory Committee
- Institute for Safe Medication Practices Canada
- Lakeridge Health
- Local Health Integration Networks
- London Health Sciences Centre
- Medbuy
- Mount Sinai Hospital
- Ontario Association of Community Care Access Centres
- Ontario Base Hospital Medical Advisory Committee
- Ontario Hospital Association
- Ontario Long-Term Care Physicians

- Ontario Medical Association
- Ontario Pharmacists' Association
- Rouge Valley Health System
- Sick Kids Hospital
- St Michael's Hospital
- University of Toronto Joint Centre for Bioethics