Decision-making Framework for Drug Shortage Planning, Response and Recovery

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Executive Summary

Preparation for and response to a shortage of drugs, or other essential resources, raises numerous ethical issues and questions. Planners and decisions makers need ethics resources and supports. This document offers an ethics decision-making framework and ethics resources.

The four Regional Health Authorities (RHAs) and the Department of Health and Community Services (DHCS) collaborate to provide ethics services and support through the Provincial Health Ethics Network Newfoundland Labrador (PHENNL). This template is offered to all partners of PHENNL.

Structure and Network (Section 1) is established to ensure participation and involvement within each RHA and within the province. The following resource groups are part of the network: Provincial Drug Shortage Resource Group, Ethics Resource Group for Drug Shortage, Regional Health Authority Drug Shortage Core Team, Regional Health Authority Clinical Resource Group, Drug Shortage Rapid Response Resource Teams, and Community Representatives Network for Drug Shortage.

The Ethics Decision Making Framework (Section 2) provides a set of values to guide the discussions and processes to ensure an ethically balanced decision regarding care and policies. The framework allows for consistency throughout the province over time.

Decision-making Tables (Section 3) has two tools to guide discussion, consider relevant values, ensure an ethical process, and maintain a record of decisions. **Section 3. a**, the Ethics Framework Values Table can be used by any of the committees or groups. **Section 3. b,** the Triage Logue is a tool to assist participants in a Triage Forum.

The Ethics Consultation Service (Section 4) has been in place for over a decade and it has been used throughout the province. It is designed to respond to requests for discussion and provide recommendations on specific issues or policies. Ethics facilitators work with ethicists and caucus the right mix of people to have a balanced discussion within the timelines available. Information is available at http://www.easternhealth.ca/WebInWeb.aspx?d=4&id=919&p=918

Communications (Section 5) are essential to utilizing the ethics service and resources within the health care system and in the broader community. Communications professionals will advise and support the internal and external communications for the RHAs and DHCS. Each partner will develop its own Communication Plan. The available RHA Communications Plans are available in Section 5.

The flexibility and benefit of the Ethics Framework and Ethics Service will be tested as issues emerge, urgency intensifies, priorities shift and new information becomes available prior to and during a time of drug shortage. These changing conditions will challenge leaders and decision makers to continually reinforce and hold their core values intact.

Section 1: Structure

The Regional Health Authorities (RHAs) and the Department of Health and Community Services (DHCS) have internal processes in place to monitor, plan and respond to the drug shortages. The structures described below facilitate communication and collaboration among the RHAs and DHCS.

Provincial Drug Shortage Resource Group

Purpose
To monitor the status of the drug shortage and related issues within the province, maintain the communications, and collaborate as needed to respond to the drug shortage.

Membership
- Three representatives from each RHA. (One clinical leader, one pharmacy representative, and one administrative leader).
- Representatives from DHCS.
- Two representatives from the Ethics Resource Group.
- Other as deemed necessary.

Co-Chairs
- Two VP representatives.

Other Attendees
- Members of the four RHA Drug Shortage Core Teams may attend.
- Other invitees.

Ethics Resource Group for Drug Shortage

Purpose
To develop and maintain the expertise needed to provide competent and consistent ethics advice and support to the RHAs, DHCS and others within the health care system of Newfoundland and Labrador for planning, response and recovery from the drug shortage.

Membership
- The professional Ethicists that work within PHENNL.
- The Ethics Lead for each RHA, or Ethics Designate to the RHA Drug Shortage Core Team.
- Others as deemed necessary.

Chair
- Director of PHENNL.

Other Attendees
- As invited to share expertise and receive information.

Regional Health Authority Drug Shortage Core Teams

Purpose
To monitor the status of the drug shortage and related issues within the region, and provide advice and assistance for planning, response and recovery from the drug shortage.

Membership
(determined by respective RHAs. Alternates will be provided.)

- VP Clinical Leaders
- Physician Leader
- All Hazards Lead
- Pharmacy Leader
- Ethics Lead
- Communications
- Human Resources
- Quality and Risk Management
- Leadership from Departments and Programs likely impacted by the drug shortage.

Co-Chairs

- VP Representatives, and
- Director, All Hazards and Emergency Management

Other Attendees

- As invited to share expertise and receive information

Drug Shortage Clinical Resource Group

Purpose
To be a resource for decision-making regarding utilization of drugs in short supply. The Clinical Resource Group members are selected because of their clinical and administrative roles related to services, utilization and management of drugs in short supply. The Clinical Resource Group members will represent their respective service areas and give leadership to identification of medically necessary treatment and procedures and inclusion criteria for allocation of drugs in short supply.

Membership

- RHA representatives on the Provincial Drug Shortage Resource Group
- Regional Health Authority Drug Shortage Core Team
- RHA Ethics Lead or designate
- Directors (or designate) from Programs and Departments impacted by the drug shortage
- Clinical Directors, Chiefs or designates with expertise relevant to specific classes of drugs.
- Others as deemed necessary

Group members will be updated regularly regarding availability and concerns regarding the status of specific drugs and classes of drugs in short supply.

The Clinical Resource Group may consult with the Ethics Resource Group or request a Triage Forum to discuss matters that could not be resolved by the established clinical criteria.

Drug Shortage Triage Forum

Purpose
To provide opportunity for discussion and decision-making based on clinical and ethical criteria relevant to a critical drug shortage where established criteria have not been able to determine who will receive a drug in limited supply.

The Drug Shortage Triage Forum is similar to the regular Ethics Consultations, except that participants are recruited based on their administrative or clinical roles and their expertise, and neither patients nor their representatives would participate in the Triage Forum.

Participants in a Triage Forum would ideally not be responsible for the clinical care of current patients being considered for triage. They should be relieved of their clinical duties to participate in the Triage Team. This will help to avoid conflicts of interest (i.e. advocacy for one's patients).

Triage Forum Participants
- One Clinical Leader from each area presenting patients for triage regarding the specific drug.
- One Pharmacy Leader.
- One Vice President.
- One Ethicist.
- Clinician experts from outside the area presenting patients for triage.

Teleconferences may be used for Triage Forum meetings.

Chair
VP member of the RHA utilizing the Triage Forum functions as Chair for the Forum.
The Chairperson:
- Facilitates the discussion and decision-making process.
- Supports consistent, fair and principled decisions regarding allocation of drugs in limited supply, using the best available clinical facts, application of the clinical triage criteria and ethics framework.
- Facilitates the discussion to bring about a consensus decision.
- Administers a secret ballot vote if consensus cannot be reached.
- Administers a random draw if a decision cannot be reached by consensus or vote.
- Documents the decisions of the Triage Forum (including reasons, referencing the ethical framework and criteria).

- Supports the communication of decisions to attending physician/ward/unit/and others who need to be informed of the decisions.
- Manages any required follow up.
- Reports on the decision from the Triage Forum to all members of the Provincial Drug Shortage Resource Group for communication throughout the RHAs and DHCS.
- Report significant challenges and issues to the Provincial Drug Shortage Resource Group for further discussion and follow up.
- Participate in periodic quality review processes.

Community Representative Network for Drug Shortage ***(This will be fleshed out as decisions are made.)***

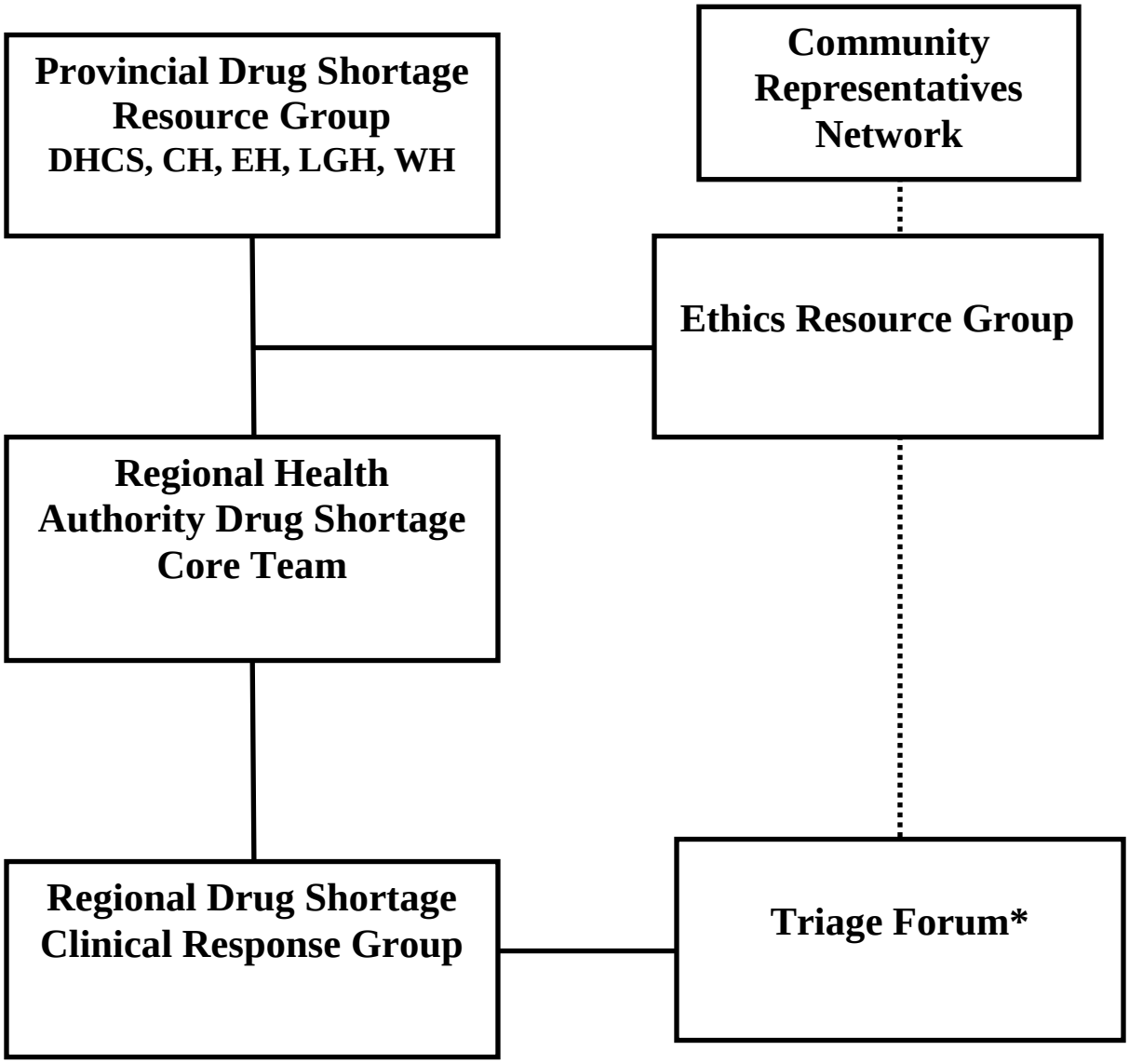
Purpose
To provide community perspectives on ethics activities related to drug shortage planning and response.

Membership
- From each RHA within NL

Attendance
- Scheduled meetings
- Meetings likely by teleconference

Chair
- Director or delegate from PHENNL

Drug Shortage Organizational Chart



*** A Triage Forum or an ethics consultation can be arranged to respond to issues presented by anyone within the provincial structure and network.**

Section 2
Ethics Decision-making Framework

Background and Purpose

Pharmacies across Canada were informed in late February 2012 by Sandoz Canada that production capacity at the Quebec plant will be reduced for the next 12 to 18 months. This will cause a shortage of some drugs including some critical injectable medications.

Leaders in health care organizations must now anticipate a shortage of some medications and prepare to respond to the situations that may arise.

The following is an ethics decision-making framework to assist during the course of planning for or responding to the drug shortage.

The ethical issues and challenges pertinent to the drug shortage are essentially the ethics of resource allocation. This Framework draws on other work regarding allocation of limited resources and our Ethics Framework to Pandemic Planning, Response and Recovery (2009).

The purpose of this framework is to provide health care decision makers with a tool to ensure appropriate consideration of their organizations' Vision and Core Values. It will also ensure consideration of other relevant factors as they make decisions regarding the redistribution of drug supplies and adjustment of services. It is also a resource for the overall response to the large-scale drug supply shortage. The framework includes appropriate considerations at the micro, meso and macro levels of the health care system.
Micro level focus is on individual patient, within the circle of care.
Meso level focus is on operational focus, within the domain of departments, programs, and the organization.
Macro level focus is on the bigger system, with focus and concern for provincial, national and broader health care system.

This Framework does not intend to displace the role and responsibility of individual health care professionals' clinical judgments, their fiduciary duties to their patients, their responsibility to be good stewards of resources, or compliant with organizational, professional or legislated roles and obligations.

The ethical issues to be faced in managing this drug shortage can be best approached using an established format that is based on a set of values that have been agreed upon in related ethics activities such as the Values Exploration (2006 -2007), and Statement of Rights and Responsibilities (2010 -2011). These included broad consultations with staff and community representatives.

Values and Principles Framework

The values essential to this drug shortage situation are organized in three categories: Substantive Values, Guiding Principles for Allocation of Drugs in Short Supply[1], and Procedural Values.

Substantive Values are basic convictions that give meaning and direction to the things deemed important. It is because of core values that we can identify what is important to us as individuals, groups, and society. Values are based upon beliefs and attitudes. They involve what is desirable, and help us know whether we are working in the right direction to bring about what we really want.

Guiding Principles are values based perspectives intended to guide thinking and discussion to ensure the important ethical matters are considered in the decisions to be made. In this case, the Guiding Principles are articulated to specifically address issues and decisions about allocating drugs in short supply.

Procedural Values lay out the directions and parameters for decision-making processes. They typically give direction regarding who should be involved, how evidence is considered, and who should know about the decisions.

Ethics and values based decision making strives to consider the relevance of all identified values. It should not focus on one value only as justification for a decision. Considered together, and in the spirit of Accountability for Reasonableness, the decision-makers ought to be able to explain to reasonable people the extent to which any, and all, values are considered in making a particular choice and selecting one option over another.

Substantive Values

The group of **substantive values** provides a set of independent principles that serve as the basic starting points from which an ethical decisions can be made can be made about allocation of drug in short supply or adjustments to medical services.

Compassion

Deep awareness of the suffering of others coupled with the wish to relieve it. Suffering can be physical, emotional, social, or spiritual. Finding ways to support those who suffer, regardless of age or stage of life, is of prime concern.

When making drug allocation decisions based on compassion, decision-making should consider

- Are other drugs and support being appropriately used?
- Are we maintaining appropriate palliative care?

[1] Adapted from the Ontario Ministry of Health and Long Term Care (MOHLTC) Drug Shortage Technical Advisory Group. *Ethical Framework on Resource Allocation During the Drug Supply Shortage.* Version 1.0, March 20, 2012

- Can short-term measures and options be used until more long term solutions can be found?
- Are we acknowledging the suffering and providing appropriate relief and support?

Example: Regard for relief of suffering and comfort to the dying is a cherished element in providing care. An individual who is terminally ill ought to be considered for a drug in short supply that cannot be effectively replaced.

Communal Beneficence

Do as much good as we can for as many as we can with the resources we have available. Beneficence in this context is somewhat different from the typical understanding of the best interest of the individual. Here it includes the benefit to the broader community by making best use of the limited drug allocations to ensure safe and effective care while reducing pain and suffering as well as maintenance of standards and best practices.

When considering communal beneficence in making decisions regarding use of drugs, decisions makers should ask:

- Have we identified those in most need who are likely to benefit from the drug?
- Have we considered all alternative drugs and treatments?
- Have we considered the risks and benefits of using the limited drug and alternatives?
- Have we decided what can be offered to individual patients who are being denied a drug?
- Have health care professionals, patients and others been educated about the risk, benefits and options available?
- Are we providing the most appropriate available care in the most appropriate available setting?

Example: In this context, some who may have received drugs will not receive them while in short supply because the likelihood of more benefit to others is more justifiable.

Solidarity

A collaborative and partnership approach that sets aside typical concerns of self-interest or territoriality among health care professionals, services, sectors, or organizations.

Solidarity can be considered by decision makers when they ask:

- Are we ensuring timely, open, and honest communication within our organization and with other stakeholders?
- Are we ensuring sharing of resources, particularly limited drugs?
- Are we coordinating health care delivery, transfer of patients, and deployment of human and material resources to alleviate the burden on strained parts of the system?
- Are we supporting ethically sound decisions and plans of other organizations?

Example: Territoriality between programs, departments and divisions, and between health care organizations and sectors needs to be overcome with good communication

and sense of common purpose in order to provide equitable care across jurisdictions. Collaborative networks, committees, and working groups help achieve solidarity.

Equity

All patients have an equal claim to receive the health care they need under normal conditions. During this time of drug shortage, however, difficult decisions may need to be made regarding which health services to maintain and which to defer. Decisions may also have to be made regarding care options for individual patients. Decision makers will be forced to decide, with available evidence considered, on the option that ensures the greatest number of people stay healthy. Efforts must be made to ensure no individual, group, institution or organization has disproportionate burden, and that alternative relief and support are provided to the extent possible. The decisions must consider the interest of everyone.

Decision-makers should strive to:

- Preserve as much equity as possible between the interests of patients who need access to drugs in limited supply.
- Ensure clinically irrelevant matters do not influence decisions, e.g. social status, culture, or life style.
- Ensure procedural fairness in decision-making.

Example: In a time of crisis when there is a shortage of a drug needed by several, the criteria to decide who will receive the limited supply drug must be based on equity. People in the same category must be treated the same, and selection must not be based on factors that are prejudicial or gives one an unfair advantage over another. Equity also requires that other care and appropriate support be provided to the one who is denied access to the limited supply drug.

Reciprocity

Reciprocity requires that society support those who face a disproportionate burden in protecting the public good, and take steps to minimize burdens as much as possible. Measures to protect the public good are likely to impose a disproportionate burden on some health care workers, patients, and their families.

Decision-makers and institutions are responsible for:

- Easing the burdens of health care workers, patients, and patient's families in their hospitals and in coordination with other health care organizations.
- Ensuring the safety and well-being of their workers, especially when there are increased workloads, and redeploying staff in areas beyond the usual scope of practice.

Examples: The provision of equipment and supports to staff that may be exposed to greater than usual risks or demands in performing their duties.

Anticipate the challenges that may come and take steps to prevent exhaustion and fatigue for Pharmacy Staff and others who provide services essential to the drug shortage situation.

Trust

Trust is an essential component of the relationships among clinicians and patients, staff and their organizations, the public and health care providers or organizations, and among organizations within a health system. Decision-makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during a time of large scale limited drug supply. Trust is enhanced by upholding such process values as transparency.

Decision-makers should:

- Take steps to build trust with stakeholders during the planning phase and not wait until it is becomes a crisis.
- Ensure decision-making processes are ethical and transparent to those affected stakeholders.
- Communicate in a timely fashion about decisions made, lessons learned, and adjustment needed to effectively respond to the drug shortage.

Example: Early engagement with stakeholders may go some distance to justify their confidence in decision-makers' trustworthiness. In part, the value of trust is respected and promoted by consistently following an ethics framework.

Stewardship

Those entrusted with leadership and decision-making roles should be guided by responsible stewardship. Inherent in stewardship are the notions of trust, ethical behaviour, and good decision making. This implies that decisions regarding limited resources, in this case drug shortages, are intended to maintaining the health care system to effectively respond to the most serious and urgent cases.

During the time of wide spread drug shortage decision makers, as good stewards are responsible for

- Prioritizing access to limited supply drugs based on urgency and severity of need.
- Adjusting services to preserve the limited supply of high demand drugs.
- Monitoring developments in other areas to predict demand as well as alternatives to scarce drugs.
- Making adjustments based on new information regarding drug utilization or access, as well clinical evidence.

Example: An organization's decision to stockpile medications based on the speculation that they may be needed later must be balanced with the burden of care being delayed or denied.

Guiding Principles for Allocation of Drugs in Limited Supply

These principles will provide the basis of discussion and reasoning to move toward decisions regarding the use of drugs in short supply. These guiding principles are presented in chronological sequence to facilitate decisions that may need to be made from the time of initial planning and preparation to the eventuality of a crisis. Effective communications are essential to the implementation of these guiding principles.

1. Efficient utilization.
When risk of a drug shortage is discovered, the first initiative must be to conserve the existing supply. Early efforts to procure new access and supply must be pursued as well. Initiatives to postpone or reduce elective procedures and treatments must be considered.

Conserve

- Inventory of available drugs and those known to be accessible if needed.
- Review prescribing practices.
- Reduce drug wastage, using safe processes.
- Use evidence based alternatives drugs and treatments.
- Use lower dosage where evidence supports similar clinical efficiency.
- Delay research initiatives requiring use of drugs in short supply.
- Regularly reassess patient medical needs and adjust drug doing as appropriate.

Procure

- Investigate and procure alternative sources.
- Collaborating with partner organizations to identify alternative supplies.
- Collaborate and cooperate with partners to consider internal adjustments to improve efficiencies.

Postpone

- Delay may be necessary if conservation and procurement efforts are inadequate to balance supply and demand.
- The first considerations for postponement must be non-medically necessary elective procedures and treatments that require use of drugs in short supply for which there is no alternative, e.g. cosmetic surgery.
- If above measures are inadequate then there must be postponement or reduction in medically necessary elective procures and treatments.
- Criteria for "medically necessary" elective procedures and treatment as well as prioritizing procedures must be defined by local experts and stakeholders in reference to the Values articulated in this Framework.

2. Triage
When efforts identified by Guiding Principle 1 (Efficient Utilization) have been inadequate to balance the supply and demand of a drug in short supply then decisions are made to optimize the therapeutic benefit. The order of priority is as follows:

I. 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**.

II. 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 they are sub-optimal**.

III. 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 this drug could have **severe, adverse health consequences**,
- and where **no therapeutic alternatives exist**.

IV. Patients whose medical needs are non-urgent or emergent.

When implementing Guiding Principle 2 (Triage), it is important to continue with Guiding Principle 1 (Efficient Utilization) initiatives, as well as maintain a therapeutic relationship with patients, and provide ongoing support.

Clinical experts from within respective programs and regions are expected to develop reference criteria to assist with triage decision making. The reference criteria should include lists of medically necessary and non-medically necessary treatments and procedures as well as inclusion and exclusion criteria to receive drugs in short supply. Forms are provided in **Appendix A** of this section to assist with development of reference criteria.

A Procedure for Drug Shortage Triage Decision-making is described in Appendix B of this Section. The procedure includes a rapid response Triage Forum process to assist with complex issues pertaining to the drug shortage and with Triage related to specific drugs or classes of drugs that are likely to be in short supply.

3. Fair Access

When situation arise where a decision must be made between patients in the same level of priority and there is no further clinical reason to give priority of one over the other (s) then the decision must be fair to all. The decision must not consider factors not clinically relevant such as race, religion, social status, life style. When all decision-making efforts have not been able to select from those equal in a category, the Chair of the Triage Forum would administer a random draw. Two witnesses who are not part of the team should be present for the draw.

Procedural Values

The more fair, informed, open (transparent), accountable and responsive to necessary revision the decision making process is, the more likely it is to result in a good, if not perfect, decision. The **procedural values** provide continual tests against which an ethical decision making process should be measured. These values attempt to ensure that every

stage of the process in reaching a final decision on an ethical issue is transparent and justifiable to all parties that have a stake in the outcome. The five procedural values, from EH Pandemic Framework (2009), are applicable to guide decision makers arrive at good decisions by a fair process.

Reasonable

Decisions should be based on reasons (i.e., evidence, principles, and values) that stakeholders can agree are relevant to meeting the needs in the time of large-scale drug shortage. The decisions should be made by people who are credible and accountable.

Decision makers should consider:

- Do we have the best available evidence on the matters we are discussing?
- What principles and substantive values influence discussions and decisions?
- Will our reasons for this decision make sense to stakeholders?
- Can we defend our decision to those who will disagree with our decision?

Example: Decision-makers should provide a rationale for prioritizing particular patients for specific short supply medications and for limiting access to elective procedures and treatments.

Transparent

The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.

Decision makers should consider:

Who are the stakeholders in this issue?

- How will we communicate the decisions to stakeholders?
- Who will create a record of events and decisions or a resource of information that can be consulted by the public or other interested parties?

Example: A communication plan developed in advance or early to ensure that information can be effectively disseminated to affected stakeholders and that stakeholders know where to go for needed information.

Inclusive

Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision making process.

Decision makers should consider:

- How have we informed stakeholders about the issue and allowed for input to the decision making process?
- Whose interests are being served by the decision?
- Who is at the decision making table and who has been consulted?
- Are those most affected by the policy or decision involved in the process? If not, can their exclusion be justified?
- How are clients and the community represented?

- Is there competent representation for those who cannot speak for themselves?

Examples: Decision making related to staff deployment should include the input of affected staff. Decisions to suspend elective surgeries should include professionals such as physicians and nurses who work in the operating rooms, as well as some community representatives.

Responsive

There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.

Decision makers should consider:

- What opportunities are there to revisit policies and decisions once new information relevant to the question(s) emerges?
- How does this new information influence the policy and decision?
- Should there be a specific time to review the issue or decision?

Example: If elective procedures and treatments are cancelled or postponed, there should be a formal mechanism for stakeholders to voice any concerns they may have with the decision.

Accountability

There should be mechanisms in place to ensure that decision-makers are answerable for their actions and inactions. Defense of actions and inactions should be grounded in the substantive values, guiding principles and procedural values proposed above.

Decision makers should consider:

- How is the process of making a specific decision or sequence of decisions accountable to the public?
- How is it accountable to those involved in the process?
- How is it accountable to those most affected by the decision?
- Do we have an efficient communication plan to provide relevant and timely information within the health care system and within the community?

Example: If a decision is made to suspend specific elective procedures and treatments, then there should be a communication plan that informs stakeholders, including the public about the decision, the context, the process and principles that led to the decision.

The principles and values are foundational to the ethics framework. Individuals and groups involved in preparation and response to a large-scale drug shortage can consider the above values and principles to ensure an ethically appropriate decision. Under ideal circumstances, each value will be given equal consideration in relation to the others in its grouping. In a crisis such as drug shortage, however, this might not be possible in all cases involving ethical choices and it should be acknowledged that these values could come into conflict with one another. In difficult cases and situations an ethics consultation can be arranged.

An Ethics Framework Values Table (Section 3) is provided below to assist decision-makers in their discussions.

Conclusion

A large scale and long-term drug shortage could place an immense demand on the health care system, and many will be impacted. Should the situation worsen those in leadership and decision-making roles will feel the burden of their responsibilities. They will feel the burden most intensely when they have to make big decisions without the luxury of time, ample evidence, or broad consultation. This framework is a solid starting point for balancing positive health care outcomes with ethics in the face of such situations.

Appendix A

Drug Shortage Clinical Services Triage Form

The Purpose of this form is to record the advice provided from the clinician experts in respective programs and regions to assist with decision making in times of short drug supply.

Regional Health Authority:	Program / Facility:
Participants in developing criteria Print Name	Position

Consider Triage, order of priority, pages 12 – 13.

Medically Necessary Treatments and Procedures

Inclusion Criteria for consideration to receive a drug in short supply.

Appendix B

Protocol for Drug Shortage Decision-making Triage Forum

Triage Forum

Triage is challenging both clinically and emotionally; those responsible for assessing patients and making triage decisions must have proper support in allocating scarce, life-saving resources. In addition, the RHAs have an ethical obligation to ensure that resource allocation decisions consistently reflect relevant values and principles, and the decisions are not made idiosyncratically. In Newfoundland and Labrador the RHAs and DHCS will collaborate to support triage decision making. The structure and process to support evidence-based and ethical decision-making allocation of drugs in short supply is described above in Section 1. The components of the structure are:

- The Provincial Drug Shortage Resource Team oversees the establishment, orientation and maintenance of the structure and process for decision making to plan for, respond to and recover from a widespread drug shortage. Groups, committees, teams and networks are established throughout the regions and the province.
- Regional Health Authority Drug Shortage Core Teams monitor the status of the drug shortage and related issues within the region, and provides advice and assistance for planning, response and recovery from the drug shortage.
- Regional Health Authority Drug Shortage Clinical Resource Group provide the clinical and administrative expertise to assist decision-making regarding clinical services and operations in the respective regions.
- Triage Forums are established as a rapid response process when and as needed to facilitate triage decision-making.
- The Ethics Resource Group provides ethics expertise to the RHAs and DHCS.
- The Community Representatives Network is established to ensure participation and involvement from the broader community. It connects to the structure through the ethics resource group.

As the shortage of a particular drug or class of drugs becomes more critical, membership for a Triage Forum can be selected from the RHA Drug Shortage Clinical Resource Group to ensure adequate preparation and availability of the individuals competent to participate in triage decision-making relevant to the patients and the drug in short supply.

Drug Shortage Triage Forum Decision-making

Depending on the circumstances, members of the rapid response Triage Forum may meet at regular intervals throughout the day and/or as needed to review current availability and utilization, and make decisions regarding treatments and procedures pertaining to a particular drug or class of drugs.

The Triage Forum will consider the following questions for each patient presented for consideration to receive the drug in short supply.

1. What is the clinical status of the patient, and what is his or her triage priority?

If two or more patients are determined to be equal in triage priority then the goals of treatment are considered.

2. Into which category is the goal of treatment for each patient?
   Life saving
   Pain management
   Treatment of illness

I. Life-saving treatments and interventions are the first priority during triage. (Guiding Principles, Appendix B, page 12). When there are two or more patients who need a drug in short supply as a life-saving treatment or intervention, and all other things being equal, a decision can be based on **age**.

Justification and Explanation: The age rationale is described as fair innings or life cycle principle. The established and acceptable rationale is that "Death seems more tragic when a child or young adult dies than an elderly person - not because the lives of older people are less valuable, but because the younger person has not had the opportunity to live and develop through all stages of life" (Emanuel & Wertheimer 2006). The "fair innings" or "life-cycle principle" recognizes this intuition and supports prioritizing resources to those who are at an earlier stage in the life-cycle in comparison to those at a later stage of the life-cycle. This principle does not favor younger persons over older persons in absolute terms, but rather those in an earlier phase in the life-cycle relative to other patients with the same prognosis. For example, a 32 year-old would not get priority over a 35 year-old, but a 20 year-old may get priority over a 65 year-old as these patients would be at different stages in their life-cycle. This principle supports the value of *Equity* by enabling younger persons to have the same life opportunities older persons have had; it also supports the value of *Stewardship* as saving the life of the 20 year-old may result in a net gain of roughly 55 years (if they live an average lifespan) while saving the life of a 65 year old may result in a net gain of only about 10 years. (See Emanuel & Wertheimer 2006; Gostin 2006; Sztajnkrycer, Madsen, & Baez 2006).

Age as determinant in life-saving triage gives priority to children. This reflects:

- Society's overall regard for the protection of children from harm and pain.
- The dosages are smaller and allow for broader distribution.
- Sickness and suffering of children has an impact on others, thus treatment for children has more positive impact by reducing the distress of parents and others involved with the child. This is not to minimize the regard for loved ones at any age.

II. Pain and Symptom Management is second only to Life Sustaining Treatment. Triage decisions regarding patients who require drugs in short supply for pain and symptom management should consider severity and potential to manage patient's pain, terminal patients with severe pain, and the patient's ability to cope with pain.

Justification and Explanations: Health care professionals are challenged to gauge severity of pain in ways that allow comparisons between individuals. Using the best clinical skills available and considering coping skills and supports the participants in the triage discussions will make their best efforts to allocate the drug in short supply to the determined to be in most need based on the severity of pain, lack of treatment alternatives and ability to cope. *Compassion* and *stewardship* are the values that support such decisions. *Trust* and *solidarity* support the health care professionals whose clinical judgments contribute to making difficult triage decisions. Consideration must also be given to individuals who are terminally ill. The broadly held regard for death *with dignity,* as well as *compassion* are foundational values to support consideration of terminally ill patients as candidates to receive drugs in short supply.

III. Treatment of Illness receives priority after **I. Life Saving** and **II. Pain and Symptom Management**. Triage Forum discussions to decide which patients should receive a drug in short supply as treatment of illness should be evidence based and consider the anticipated outcomes.

Justification and Explanation: Evidence based usage ensures the drug is proven to be effective for the treatment of the patient's condition. Off-label usages must give way to evidence based usage. Anticipation that treatment will likely result in improvement in long term life expectancy and / or quality of life should give way to unlikely improvement in life-expectancy and / or quality of life. Equity and communal beneficence are foundational values to these considerations.

IV. Fair Access. When situations arise where a decision must be made between patients in the same level of priority and there is no further clinical reason to give priority of one over the other (s) then the decision must be fair to all. The decision must not consider factors not clinically relevant such as race, religion, social status, life style. The Triage Forum would administer a random draw if all other efforts have not been able to select from all who are equal in a category. Two witnesses should be present for the draw who are not part of the team.

Deliberation Process

Ideally, the Triage Forum shall make decisions by consensus. If consensus cannot be reached in a reasonable amount of time, then all the Forum members will cast a secret ballot. The vote of the majority is the decision of the Forum. In the event that voting does not produce a decision then the decision shall be made by a transparent and unbiased process of random selection, to ensure fairness (Tabery & Mackett 2008). An impartial and random selection among objectively equal candidates is a fair means to do this. The Chair of Triage Forum would administer the random draw. The draw would be in the presence of the Forum members and two witnesses who are not part of the team.

Any resource allocation decision that reflects a substantive change in policy/process or deviation from the criteria above must be referred to the Provincial Drug Shortage Resource Group. If time allows the Provincial Group would be involved prior to the

decision. In urgent cases where a decision has to be made, then the Triage Team must report the changes to the Provincial Drug Shortage Resource Group.

Conflicts of Interest

The Drug Shortage Triage Resource Teams will attempt to make their decisions based on the criteria above, blinded to the identities of eligible patients competing for the drugs in limited supply (for this reason, patient names are not included with information provided). However, Triage Team members must excuse themselves from any cases that involve known:

- Relatives (by birth or marriage) or friends.
- Close professional colleagues.
- Any situation in which they feel they have, or they may be reasonably perceived as having, a bias that predetermines their analysis (i.e. they cannot judge based on the above criteria).

Communication of Decisions

The Triage Forum Chair will take the lead in communicating the drug allocation decisions and reasons for their decisions to the referring physicians/units/wards in a timely manner. When patients are provided drugs in short supply they are advised that there will be close monitoring and their eligibility for access to the drug in short supply will be reassessed regularly. Patients who cannot access a drug in short supply or who are discontinued on a drug in short supply will be provided with care appropriate to the situation with a goal to reduce harm and provide comfort and support.

A senior clinician from the Triage Forum will arrange for the communication with the family. They will communicate directly or arrange for another competent person to directly communicate the decision.

Communications with families regarding decisions will be supported by other professionals such as chaplains, social workers or others deemed appropriate to the needs of the families.

The recipients of bad news often want to have explanations of the decision-making process, the rationale for the decisions, and the identity of the decision makers. In a spirit of openness and transparency such requests will be accommodated to the extent possible. Individuals recruited for a Triage Forum must be advised that their identity may be disclosed to families subsequent to the deliberations. The specifics of the discussion are not reported.

Evaluation and Revisions

The proper authority within DHCS and/or RHAs is responsible for gathering the most recent information regarding shortages of drugs.

Each RHA has a structure and process to ensure regular updates. The updates should include:

- current drugs in short supply, or likely to be in short supply;
- demands for specific drugs in short supply within the RHA;

- recent and emerging information about the drug shortage;
- consistency of the decisions and application of the Drug Shortage Triage Protocol and Criteria;
- documentation and communication processes;
- outcomes of decisions based on the Framework and Triage Protocol;
- challenges of the Framework and Triage Protocol;
- recommended changes to the Framework and Triage Protocol to adapt to changing realities;

Changes to this protocol may be warranted based on this evaluation process.
Any changes must be authorized by the Provincial Drug Shortage Resource Group.

The RHA representatives on the Provincial Drug Shortage Resource Group are responsible for reporting on the activities of the Triage Forums to the RHAs.

Documentation
The Drug Shortage Rapid Response Triage Forum Chairs are responsible for documenting the deliberations and decisions of their assembled Drug Shortage Triage Forum. Each RHA shall keep a logue of each Drug Shortage Triage Forum meeting regarding patients within the RHA. The logue records:

- Date and location of meeting, including teleconferencing;
- Rapid Response Triage Forum participants present;
- Patients reviewed (identified by MCP #);
- Which patients were approved for the drug in short supply, which were not;
- Reasons for approving eligible patients (using criteria above);
- Reasons for not approving ineligible patients (using criteria above).

The form provided below in Section 3. b **(Triage Logue)** can be used as the Logue entry.

A copy of material entered in the RHA Drug Shortage Triage logues will be forwarded to the proper authorities in the RHA and DHCS.

The logues will be accessible only to those approved by RHA VPs or DHCS designates to the Provincial Drug Shortage Resource Group.

Decisions pertaining to individual patients will be entered in the patient's Health Record.

Section 3. a Ethics Framework Values Table

Ethics Framework Values Table is a tool that decision makers can use to ensure their discussions give adequate consideration of relevant values from the framework. Use of the table provides a record of the ethics considerations regarding significant matters. It prompts steps essential to verify an ethical process.

Issue			
Ethics question(s)			
Participants in Discussion:			
Consulted in preparation for the discussion			
Substantive Values	**Relevant**		**Notes / Comments**
Compassion Deep awareness of the suffering of others coupled with the wish to relieve it.	**Yes**	**No**	
Communal Beneficence Do as much good as we can for as many as we can with the resources we have available.	**Yes**	**No**	
Solidarity A collaborative and partnership approach among health care professionals, services, sectors, or organizations.	**Yes**	**No**	
Equity All patients have an equal claim to receive the health care they need under normal conditions. Decisions regarding which health services and care options for individual patients must give adequate consideration to the needs of everyone	**Yes**	**No**	
Reciprocity Supports for those who face a disproportionate burden in protecting the public good, and take steps to minimize burdens as much as possible.	**Yes**	**No**	

Trust Trust is an essential component of managing difficult situations. Communications, accountability and transparency are essential.	**Yes**	**No**	
Stewardship Decisions are intended to maintaining the health care system to effectively respond to the most serious and urgent cases.	**Yes**	**No**	
Guiding Principles for Allocation of Drugs in Limited Supply			
1. Efficient utilization. When risk of a drug shortage is discovered the first initiative must be to conserve the existing supply. Early efforts to procure new access and supply must be pursued as well. Initiatives to postpone or reduce elective procedures and treatments must be considered.	**Yes**	**No**	
Conserve	**Yes**	**No**	
Procure	**Yes**	**No**	
Postpone	**Yes**	**No**	
2. Triage When efforts identified in Stage 1 have been inadequate decisions are made to optimize the therapeutic benefit.	**Yes**	**No**	
I. 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**.	**Yes**	**No**	
II. 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 they are sub-optimal**.	**Yes**	**No**	
III. 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 this drug could have **severe, adverse health consequences**, ➢ and where **no therapeutic alternatives exist**.	**Yes**	**No**	
IV. Patients whose medical needs are non-urgent or emergent.	**Yes**	**No**	

3. Fair Access When situation arise where a decision must be made between patients in the same level of priority and there is no further clinical reason to give priority of one over the other (s) then the decision must be fair to all. The decision must not consider factors not clinically relevant such as race, religion, social status, life style.	**Yes**	**No**	
Random Draw: Procedure for fair access	**Yes**	**No**	
Witnesses: two who have not participated in Triage Forum.			

Procedural Values	**Evidence of this Value**
Reasonable Decisions should be based on evidence, principles, and values by people who are credible and accountable.	
Transparent The process must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible	
Inclusive Decisions should be made explicitly with stakeholder views in mind and opportunities for their engagement.	
Responsive There should be opportunities to revisit and revise decisions as new information emerges.	
Accountability Decision-makers are answerable for their actions and inactions.	

Recommendation:

Communication Plan:

Signature: _____ Date: _____

Section 3. b Triage Logue

This Triage Logue is a tool to assist participants in a Triage Forum. It ensures discussions give adequate consideration of relevant values from the framework and follows the Protocol for Drug Shortage Decision-making Triage. Use of the Logue provides a record of the ethics considerations, discussions, and decisions. It prompts steps essential to verify an ethical process.

Chair		
Date		
Location		
Patient MCP numbers only	Approved	Not Approved

Specific Drug in short supply			
Participants in Discussion:			
Name	**Position**	**Name**	**Position**

Consulted in preparation for the discussion			
Name	**Position**	**Name**	**Position**

Substantive Values	**Relevant**		**Notes / Comments**
Compassion Deep awareness of the suffering of others coupled with the wish to relieve it.	**Yes**	**No**	
Communal Beneficence Do as much good as we can for as many as we can with the resources we have available.	**Yes**	**No**	
Solidarity A collaborative and partnership approach among health care professionals, services, sectors, or organizations.	**Yes**	**No**	
Equity All patients have an equal claim to receive the health care they need under normal conditions. Decisions regarding which health services and care options for individual patients must give adequate consideration to the needs of everyone	**Yes**	**No**	
Reciprocity Supports for those who face a disproportionate burden in protecting the public good, and take steps to minimize burdens as much as possible.	**Yes**	**No**	
Trust Trust is an essential component of managing difficult situations. Communications, accountability and transparency are essential.	**Yes**	**No**	
Stewardship Decisions are intended to maintaining the health care system to effectively respond to the most serious and urgent cases.	**Yes**	**No**	

Guiding Principles for Allocation of Drugs in Limited Supply			
1. Efficient utilization. When risk of a drug shortage is discovered the first initiative must be to conserve the existing supply. Early efforts to procure new access and supply must be pursued as well. Initiatives to postpone or reduce elective procedures and treatments must be considered.	**Yes**	**No**	
Conserve	**Yes**	**No**	
Procure	**Yes**	**No**	
Postpone	**Yes**	**No**	
2. Triage When efforts identified in Stage 1 have been inadequate decisions are made to optimize the therapeutic benefit.	**Yes**	**No**	
I. 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**.	**Yes**	**No**	
II. 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 they are sub-optimal**.	**Yes**	**No**	
III. 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 this drug could have **severe, adverse health consequences**, ➢ and where **no therapeutic alternatives exist**.	**Yes**	**No**	
V. Patients whose medical needs are non-urgent or emergent.	**Yes**	**No**	
3. Fair Access A decision must be made between patients in the same level of priority. There are no further clinical reasons to give priority of one over the other (s) then the decision must be fair to all. The decision must not consider factors not clinically relevant such as race, religion, social status, life style.	**Yes**	**No**	

Random Draw: Procedure for fair access	**Yes**	**No**	
Names of Witnesses: two who have not participated in Triage Forum.	**1.** **2.**		

Procedural Values	**Evidence of this Value**
Reasonable Decisions should be based on evidence, principles, and values by people who are credible and accountable.	
Transparent The process must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible	
Inclusive Decisions should be made explicitly with stakeholder views in mind and opportunities for their engagement.	
Responsive There should be opportunities to revisit and revise decisions as new information emerges.	
Accountability Decision-makers are answerable for their actions and inactions.	

Recommendation:

Communication Plan:

Triage Forum Chair Signature: _____ Date: _____

Section 4
Ethics Consultation Service

A. Preamble

The Ethics Consultation Service provides the opportunity for open and frank discussion of ethical issues related to clinical cases, operations, policies and systems within the Regional Health Authorities (RHA) and the Department of Health and Community Services (DHCS). The consultations often result in secondary positive outcomes of mediation and debriefing. The Service is not for the purpose of discussing or reviewing medical or legal issues, except as they relate to the ethical dimension of the case.

The Ethics Consultation Service has grown out of the experience and increased interest in clinical ethics as a result of developments in medical science and technology, changing standards of care, and the desire to have more collaborative decision making in health care. The examination of systemic issues, policies and procedures, and broader organizational issues has led to increased interest in and demand for ethics consultations on administrative matters as well as clinical issues.

The ethics consultation process is intended to be a resource to health care providers, administrators and managers, clients, families and the community. The process supports the right of the clients and substitute decision-makers to make informed health care decisions. As a consultative service it is available to assist physicians and health care professionals by providing advice on complex matters and issues. It does not replace roles or responsibilities of physicians or any health care professionals in providing care. It aims to provide a safe environment and non-judgmental process for open and honest discussion among interested and involved parties. The Ethics Consultation Service aims to provide a timely response to requests for ethics consultations. This service and process presumes the right to privacy and the obligation to confidentiality for all participants. The richness of this process lies in the openness and free discussion that it fosters. A summary of the discussions and recommendations are recorded and kept on file. When deemed appropriate case specific clinical consults are documented in the clients' health records. In some cases the follow up includes policy review and development, or educational activities.

B. THE GOAL of the ETHICS CONSULTATION SERVICE

The goal of the Ethics Consultation Service and Process is to aid in making ethical decisions regarding clinical cases, operations, policies and processes within the health care system in the province.

C. THE STRUCTURE

The Ethics Consultation Service is administered through the Pastoral Care and Ethics Department of Eastern Health. Facilitators for the service are recruited from within the Department and other interested individuals throughout the RHAs and DHCS.

Facilitators for the Ethics Consultation Service are aligned with specific ethics committees, portfolios, or RHAs. Ethics Committee members may be invited to become facilitators or facilitators may be appointed to an Ethics Committee. Efforts are made to ensure each committee has at least two ethics facilitators.

Facilitators are provided educational opportunities in health care ethics and facilitation skills.

The professional ethicists for the service are ethics faculty members with the Faculty of Medicine, Memorial University. Occasionally other ethicists may be recruited to assist with specific consultations.

Ethics consultation activities are reported to the Provincial Health Ethics Network Advisory Committee (PHENNLAC)' and the ethics committee connected to the site or service area where the case arose.

D. The CONSULTATION PROCESS

An Ethics Consultation can be requested by anyone: client, member of the general public, RHA or DHCS employee, volunteer, or other health care professional. The request for an ethics consultation may be presented in writing or verbally. The request must include all the information needed to complete the Request for an Ethics Consultation Form.

The request for an ethics consultation may be received by any of the following

- Director of Pastoral Care and Ethics / Director of PHENNL
- Managers and Coordinators, Pastoral Care and Ethics Department
- Ethics Lead for RHAs and DHCS.
- Administrative Assistant, Pastoral Care and Ethics Department / PHENNL
- Ethics Consultation Facilitators
- Ethicists

Copies of a Request for an Ethics Consultation Form are available from the Pastoral Care and Ethics Department offices, managers, RHA and DHCS Ethics Leads, and from the RHA intranet and internet sites. The individual who receives the Request for an Ethics Consultation should advice the Office of the Director of the request.

Sometimes an issue might not be presented as a request for an ethics consultation but an expression of concern about a situation to an individual who recognizes the ethical dimension of the situation and articulates or presents the issue identified. A consultation to discuss the issue may be arranged to assist participants better understand the issues.

The request mobilizes a process that may move through three phases: the preliminary phase; the discussion phase; and the wrap-up phase.

Provincial Health Ethics Network Newfoundland Labrador
Ethics Consultation Service

Request for an Ethics Consultation

This form is used to collect information from the individual or group requesting the Ethics Consultation and others with information needed to respond to the request for an ethics consultation. This form may be completed by the one requesting the consultation or the one who receives the request may collect the information. The required information can be forwarded in an e-mail.

Individual requesting Consult	
Name	
Position	
Telephone Number	
Pager Number	
E-mail	
Date	
Details of the Specific Issue for Ethical Consultation	
Location RHA/Site / Portfolio / Unit	
Program / Department	
Description (add another page if needed)	
How soon does this consultation need to be completed. Explain if immediate or urgent attention is requested.	

Identify who needs to attend and contact information.	Name	Position	Tele or E-mail

Forward the completed form to

Eastern Health
Office of the Director of PHENNL
Phone: (709) 777-8940
Fax: (709) 777-7612

Central Health
Phone: (709) 257-5226
Fax: (709) 257-4613

Labrador-Grenfell Health
Phone: (709) 897-3103
Fax: (709) 896-6766

Western Health
Phone: (709) 634-4350
Fax: (709) 634-4591

Section 5: Communications Plans
(Being developed by Communications Staff in the RHAs and DHCS).

Section 6:
Guidelines on Specific Issues
B. Expired Drugs

Guidelines on the Use of Expired Drugs
August 08, 2012

These Guidelines are intended to give direction on the use of medications and pharmaceuticals in short supply after the manufacturers expiration date. They are based on the Decision-making Framework for Drug Shortage Planning, Response and Recovery (PHENNL, 2012). They fit into the context of the Guiding Principles for Allocation of Drugs in Short Supply (p. 12).

Guidelines

1. Use of expired drugs should only be considered when efforts to manage the drug shortage by conservation, procurement and postponement have been inadequate to meet the demand, and there are not alternatives that have not expired.

2. Expired drugs may be considered as an option for treatment within the Drug Shortage Triage phase* only.

3. Expired drugs may be offered as treatment under the following conditions:
    a. Clinical experts (pharmacists and physicians) are satisfied that the likely benefits outweigh identified risks to the patient.

    b. Applicable parties, such as RHA Leadership and insurers, have been consulted and provided the rationale of using expired drugs in the context of Drug Shortage Triage.

    c. The patient or substitute decision maker has been informed of the risks and benefits of using an expired drug, and has provided explicit consent to use the expired drug.

4. Expired drugs may be offered in the sequence of the Drug Shortage Triage priority categories.

5. Expired drugs will be discontinued as soon as a non-expired supply or suitable alternative is available.

* *The Drug Shortage Triage phase is implemented when efforts to manage the drug shortage through conservation, procurement and postponement have been inadequate to balance the supply and demand of a drug in short supply then decisions are made to optimize the therapeutic benefit. Decisions must be made about who will and who will not receive the drug in short supply.*

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