ETHICS AND HEALTH POLICY
THE NUTS & BOLTS

A practical guide to health policy development and review for ethics committee and reference group members

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Nova Scotia Health Ethics Network

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ETHICS COMMITTEE / REFERENCE GROUP MEMBERS'
GUIDE TO HEALTH POLICY DEVELOPMENT AND REVIEW

I. Introduction

In the health domain, policy provides concrete direction as to how health organizations manage the crucially important social goods of health and health care. Policies direct how health care providers, staff and patients interact; how patients are cared for; and how, and to whom, limited health resources are delivered. According to Ruth Malone, this value-laden 'deciding for affected others' nature of policy making, and the significant implications of health policy development for persons and society as-a-whole, make it a moral endeavor and those that participate in it moral actors. Policies play a crucial role within a variety of health organizations, i.e., at the macro-level of government (e.g., provincial Departments of Health), the meso-level of health care organizations (e.g., provincial health authority and zones), and the micro-level of direct engagement and interaction between health care providers and patients/families.

The application of an 'ethics lens' and the critical appraisal that such analysis provides have the capacity to add-value to the development and review of policies within health organizations. In addition, the demonstration of the existence of a process for performing ethics reviews of policies is required for a health organization to be formally accredited by Accreditation Canada.

This users' guide focuses on assisting ethics committee and reference group members in the performance of their primary health policy work, i.e., the development and review of health policies that have strong ethics dimensions.

Examples of the topics/subjects of such health policies are: decision making about the use of potentially life-sustaining treatments/interventions, advance care planning, the disclosure of significant adverse events, organ donation after cardiac death, palliative sedation, conflicts of interest, informed choice/consent and business/financial planning related to the fair allocation of limited health resources.

The guide is organized into two main sections: II. Ethics-informed Health Policy Development, and III. Ethics Review of Health Policies. The latter has been the traditional purview of ethics committees since their inception in the 1960-70s. The former is an emerging role/function of ethics committees and reference groups, and reflects an increasing awareness and recognition of the value of applying an ethics lens to multiple stages of health policy development. In recent times, this has involved the active participation of ethics committee/reference group members in policy development working groups. Other important, constructive roles that ethics committee members may play in policy making include: 1) acting as consultant resource persons for individuals and groups who 'author' policies, and 2) direct engagement in the development and/or revision of the health organization's 'policy for policies', i.e., the administrative policy that sets out how and by whom policies are to be developed and reviewed within the organization.

In addition to the two main sections, the guide contains a glossary of health policy terms, an appendix list of references and resources to support ethics committee/reference group members in their policy work, and five other appendices which elaborate on and supplement various features of the guide.

It is recognized that NSHEN's other collaborating partners, i.e., Nova Scotia's health authority, the IWK Health Centre, and the Department of Health and Wellness, have different levels of resources/support for, and experience with, ethics-informed policy development and the ethics review of health policies. This guide is designed to take this diversity into meaningful account.

II. Ethics-informed Health Policy Development

- *Introduction*
- *Description of nine recommended policy development process steps*

Introduction

This section of the guide focuses on the pragmatic aspects of applying of an ethics lens to health policy development. It is intended to serve as a practical reference for policy makers and ethics committee/reference group members who engage in policy making/development.

A variety of common challenges and problems associated with traditional forms of health policy making has been identified in the literature. These include: lack of optimal lenses/standpoints; perils of traditional representation; conflation of 'is' with 'best'; exclusive focus on evidence; top-down obstruction; and inadequate follow-through. Descriptions of these particular challenges/problems are contained in Appendix B of the guide. In addition, the following key elements of socially-just policy making have been identified by NSHEN:

- Appropriately controlled, collaborative 'bottom-up' development
- Careful consideration of, and reflection on, relevant ethics principles and values
- Inclusiveness of appropriate, diverse stakeholders
- Meaningful attention to power differentials
- Engaged participation through deliberative dialogue
- Democratic decision making to resolve disputes
- Appropriate follow-through to the 'living' of developed policies

Conscious efforts have been made to: 1) incorporate the above key elements of socially-just policy making, and 2) constructively address the challenges/problems described in Appendix B in the policy development process recommended by NSHEN, which is described in the next section.

Description of Nine Recommended Policy Development Process Steps

Step One: Initiating the policy development process

In the policy development process recommended by NSHEN, initiation of the policy making process consists of three elements:

A. Identifying a possible need for policy development (or re-development)

Any individual or group who/that is appropriately positioned in the health organization (see definition of policy initiator) may identify a need for development or re-development of a particular health policy or may identify that the health organization could possibly benefit from such development. The policy initiator may consult the organization's Policy Coordinator (should one exist) or another individual who functions in this role within the organization. This provides a good mechanism for the policy initiator to identify whether another individual or group has been or is currently engaged in development of this particular or a relevantly similar policy within the organization. It is also helpful in identifying who or what entity within the organization would be the appropriate formal issuing authority.

B. Determining the policy's issuing authority and final approver

Before the policy development process begins, it is important to identify/determine the policy's formal issuing authority (see definition of issuing authority and final approver). This is the individual (or group) within the organization who signs off on initiation of the policy development process. In most but not all circumstances, the issuing authority and the final approver are the same which works to enhance

procedural clarity and to establish an optimal accountability loop for the policy's development.

C. Designating the policy's sponsor

Once a decision has been made to proceed with policy making, the issuing authority for the policy's development identifies and designates the policy's sponsor within the health organization, i.e., the portfolio(s), department(s) and/or standing committee(s) that is/are to be responsible for development and implementation of the policy. Typically, a lead person from within the sponsor is identified who will be directly involved in, and responsible for, the policy's development and implementation.

Step Two: Creating and maintaining an optimal policy development 'space'

A. Establishing a policy development working group

In the process recommended by NSHEN, the development of health policies with ethics dimensions takes place within a policy working group format. Under the direction of the appropriate issuing authority, the policy's sponsor, usually in collaboration with the Policy Coordinator or equivalent entity (if such exists within the health organization), strikes a policy development working group consisting of: participants from the identified primary/key stakeholder groups who will be directly affected by the policy (including those who will be the policy's end-users), appropriate resource persons/experts for the development of the policy's content and relevant organizational leads. Explicit attention is paid to the inclusion of members from disadvantaged social groups and low-in-the-hierarchy

occupational/organizational groups that may be particularly vulnerable to anticipated policy making outcomes. Although inclusion of diverse, relevant perspectives and standpoints is a crucial element of policy making, it is best to aim for a workable-sized working group of a maximum of a dozen members. An ideally sized group consists of eight to ten members.

B. Leveling non-constructive power dynamics

In the establishment and ongoing operational management of policy development working groups, it is important to pay meaningful attention to the leveling of non-constructive power imbalances among working group members. The policy's sponsor selects a chair-facilitator for the working group who is usually not the group's senior member within the organization's power structure. The chair is chosen for his/her demonstrated ability to facilitate dynamic group processes and not for her/his responsibility level in the organization and/or superior knowledge of the subject area.[1] If this facilitation capacity is not available within the working group, a non-voting, independent facilitator may be recruited and brought into the process.

A simple and symbolic way to reduce power imbalances is for the chair-facilitator, at the beginning of the working group's first meeting, to ask whether members are comfortable with addressing each other by first names. If all members indicate (by voice) their willingness to do so, the policy making dialogue proceeds on

[1] Note that this recommended chair-facilitator selection practice is different from the traditional way of organizing power within health organizations' committees and standing/working groups.

this basis. Another simple way to reduce power imbalances is to select and use a meeting table without traditional, authoritative seating positions.

C. Managing conflict

It is important for the working group's chair and members to set and maintain the conditions whereby 'best arguments' on all sides of a contentious policy issue may be collaboratively and safely developed. In such a policy making environment, conflict is not discouraged or suppressed. Rather, the focus of the dialogue is maintained on the collaborative development of arguments for and against policy positions, and not on 'the personal'. It is recognized that: 1) conflict is inevitable in policy making, particularly if the 'right' engaged stakeholders are at the decision making table, and 2) conflict among working group members often serves to generate creative ideas and innovative solutions that would not have surfaced without it. Within policy making processes, there is a danger in keeping legitimate primary/key stakeholders with known strong points of view out of policy working groups in an attempt to reduce conflict, as this may interfere with a balanced presentation of ideas and arguments. Furthermore, this type of intentional exclusion has the potential to motivate excluded persons to attempt to interfere with, or subvert, policy content at other levels of the stakeholder review and policy approval process.

D. Choosing a suitable meeting location

The policy's sponsor is encouraged to designate an appropriate meeting location for the working group's deliberations. The preferred meeting space for the development

of a health policy is a quiet, private, well lit, non-formal room with a round or oblong table that is appropriately-sized for the number of participating working group members.

Step Three: Gathering relevant information and evidence

Once a working group has been appropriately constituted and members have been briefed on the policy making process described in this section, one of the first tasks is to gather background information and evidence of relevance to the development of the policy. Given the usual presence of primary/key stakeholders/end-users and resource persons/experts, much of the relevant, operational-type information can usually be directly obtained from working group members. In the development of complex policies that are anticipated to change organizational practice and/or have a significant effect on patient care, it is important to research the content and scope of relevant, related policies and practices in other similarly-mandated health organizations across Canada (and, in some circumstances, internationally as well).[2] Other relevant information and evidence may be obtained through literature searches and the collective interviewing of resource persons who are not sitting as members of the policy working group. These various sources of collected information/evidence are subsequently reviewed, analyzed, and critically appraised by working group members during various stages of the policy making process.

[2] A note of caution here: although this type of valuable research can identify what some refer to as existing 'best practices', there may be a gap between 'what is' in terms of policy content and related practices and 'what should be'. This normative gap needs to be consciously considered and addressed by policy makers throughout the policy development process. In addition, it is important to acknowledge that established, highly regarded policies and practices in one jurisdiction may not work as well in another jurisdiction due to the context-dependent nature of many policies and practices.

Step Four: Identifying and considering relevant ethics principles and values

After the information gathering phase is underway or completed, the working group turns its attention to establishing 'the foundation' of the health policy under development. This is accomplished by identifying and reflecting on the principles and values that should inform the development of the policy's content. This goes beyond collective consideration of the core values, mission/vision and strategic directions of the health organization, and includes identification of, and reflection on, other ethics principles and values that are of particular relevance to the policy. For example, in the development of a policy for an organization's mental health program that involves the balancing of competing obligations to promote the liberty of very vulnerable patients and to ensure the safety of these patients and staff members, working group members could enter into a stimulating dialogue on the various relevant forms of the principle of justice. Putting this foundational principles and values work up-front assists in opening up the conversation and broadening the nature and scope of discourse around relevant policy issues. It also helps discourage the natural human tendency of participants to reinforce or move quickly toward fixed positions on policy-related issues.

Process values inform the development of the content of a health policy and are incorporated in a dynamic way into the policy's processes and procedures. Ideally, they are collaboratively-established by working group members prior to the development of specific policy content. This important preliminary work helps to

ensure that these values are consciously incorporated during the policy development phase. Examples of process values of relevance to health policy making are:

- Inclusiveness – ensuring that the legitimate interests of all relevant stakeholders are acknowledged and addressed within the policy.

- Procedural fairness – the incorporation of 'fair due process' which may, for example, involve the development and incorporation of a democratic dispute resolution process.

- Collaboration – creating the right conditions and 'space' that enable individuals and groups to act collectively and constructively in policy-related decision making.

- Accountability – ensuring that there are reliable, workable mechanisms for designated 'actors' to account, and be responsible, for their policy-related actions.

- Openness – incorporating mechanisms to ensure meaningful transparency of established decision making processes and the decisional outcomes of these processes.

- Consistency – ensuring that the policy's content is internally consistent and that the policy's procedures are congruent with the established guiding principles and values.

- Responsiveness – incorporating dynamic ways to respond to both predictable and unforeseen developments, and to individual policy-related concerns in a timely and responsible manner.

- Revisability – incorporating a process for review and critical appraisal that informs appropriate, constructive change(s) to policy content.

A health organization could choose to develop an appropriate, workable set of process values that are used in the development of all its policies and are incorporated into the organizations' decision and recommendation making frameworks.

Substantive principles and values are collaboratively established by policy makers to act/function as criteria for decision making and, as appropriate, the ranking of choices/options that are called for by a health policy. In ethics-rich, complex and/or practice-changing policies, the chosen substantive principles and values may be in conflict or tension and, as such, may give rise to competing obligations that require careful balancing by the policy's developers. Substantive principles and values are frequently components of frameworks that guide the process of reaching and making important, policy-related decisions and recommendations. An example of such a recommendation making framework is one that could be a developed as a component of a health organization's policy on the disclosure of significant adverse events. When faced with the occurrence of such events, appropriate decision makers (as defined by the policy) use a step-by-step framework to address the related issues and to decide among a number of possible options for the organization, e.g., non-disclosure, disclosure to potentially-affected persons and full public disclosure. A sample 'disclosure of significant adverse events recommendation making framework' developed by one of Nova Scotia's former health districts, with the assistance of the Ethics Collaborations Team of the Dalhousie University Department of Bioethics, is included in Appendix F.

It is important to define and clarify how these principles and values are to be used to inform decision making. The following are examples of substantive principles and values that could be identified for a health policy and incorporated into its decision making process and framework regarding the fair allocation of limited health resources:

- Health equity – '*a fair chance for all'* (WHO): the obligation to reduce disparities among individuals and groups of persons in their opportunities for good health and access to health care.

- Sustainability – take into meaningful account the sustainability of resources to meet the legitimate health care needs of individuals and all persons within a geographical area; entails the anticipation of future resource allocation challenges and trends in the changing/evolution of health care needs.

- Distributive justice – distribute benefits and burdens fairly/properly on the basis of legitimate health care needs and health resource availability.

- Formal justice – obligation to treat individuals and groups the same unless there is a demonstrable *re/evant* difference between/among them that justifies different treatment.

- Social justice – responsibility to identify, and reflect on, the particular disadvantages and vulnerabilities of individuals and groups of persons, and to determine ways to meaningfully attend to, and reduce, social injustice.

- Beneficence/nonmaleficence – obligation of health organizations and health care providers to benefit the health of, and reduce the harms accruing to, individuals and groups of persons.

- Efficiency – careful consideration of ways to efficiently deliver limited health resources and, in so doing, to effectively balance anticipated benefits and burdens.

Step Five: Building policy content

In the development of policy content, working group members are encouraged to adopt/use a 'deliberative dialogue' approach, which is characterized by the following key features/elements:

- Skilled facilitation (as available within the working group membership or as recruited from within the health organization)

- Use of effective, pragmatic power-leveling strategies

- Respectful discourse (reinforced by the chair-facilitator, as necessary)

- Meaningful attention to 'difference', including the active enabling of all voices, and, in particular, those of vulnerable and disadvantaged participants
- Encouragement of participants' adoption of an 'engaged participation' role and discouragement of 'traditional representation' (see below description)
- Attention to 'as you go' capacity and confidence building of the participants
- Openness of participants to reflective dialogue about diverse points of view and towards changing/altering personal starting positions
- Enabled development and presentation of 'best arguments'/reasons for all positions on substantive issues
- Readiness of participants to attempt to achieve and constructively work toward a meaningful consensus that 'all can live with' and support outside the working groups

Working group members are encouraged to consider adopting an 'engaged participation' role as they work together to build policy content. This involves asking/getting members to bring their life and vocational experiences to respectful, collective reflection and deliberation on issues of relevance to the policy. This role allows 'room/space' for the voluntary expression of affective (emotionally-based) responses to issues of importance to development of the policy. Such responses may be particularly appropriate and helpful in reaching a nuanced, combined intellectual and emotional understanding of relevant ethics issues from the perspectives of diverse and, in some cases, opposing standpoints. In addition to promoting engaged participation, group members are actively discouraged from assuming a representational role in policy making, e.g., where a nurse is expected to represent the interests of all nurses in the health organization. This traditional role often serves

to maintain the status quo and to protect the special interests of professional/vocational groups in non-constructive ways.

In this phase of policy making, working group members collaboratively develop policy content on a foundation of the previously established, relevant principles and values. Logistically, it typically involves the development of content sections in a step-wise fashion (see the glossary of health policy terms in Appendix A for descriptions of these policy sections). Typically, much of the substantive content of a policy is written into its *Policy* section. This is usually followed by a *Procedures* section that clearly outlines what actions are to be taken and by whom.

In the development of policies with robust ethics elements, working group members are encouraged and supported to present and argue for their points of view. It is the chair-facilitator's role to allow and embrace constructive disagreement. Working group members are enabled to collaboratively develop understandable versions of 'best arguments' for their positions, and to engage respectfully in dialogue with members who hold and argue for divergent positions. They should be open to changing their opinions on the basis of the arguments of others and should be prepared, as appropriate, to compromise in a constructive manner on the content of various sections of the policy. Of course, the development of these capacities in working group members takes time and effective mentoring and support from ethics consultants and those with experience in facilitating groups. Given the complexity of many health policies with strong ethics dimensions/elements, it is not uncommon for this policy content building phase to be an iterative one in which previously established content is progressively revised in a dynamic manner with the

emergence of new insights and subsequent decision points through the deliberative dialogue process.

It is the responsibility of the chair-facilitator to determine when a contentious issue has been adequately addressed and that all voices have been heard. In cases of disagreement, prolonging discussion may lead to a loss of focus on the policy making task at hand, personal divisiveness, and the progressive dropping-out (over time) of disillusioned and frustrated working group members. When the point of adequate deliberation on a contentious policy issue has been identified by the chair-facilitator, he or she determines whether a consensus (of the 'all can live with' and support outside of the group type) has been reached on how to handle this issue within the policy. If there is no such consensus, the chair stops the dialogue about the issue and may choose to initiate a formal dispute resolution process. Such dispute resolution processes are designed to establish decision making outcomes regarding policy content through a calm, orderly process based on democratic principles. Normally, dispute resolution processes allow for a separation in time between acrimonious debate about a policy issue and a final decision, and provide a mechanism for the formal, respectful recording of dissenting opinions. A sample dispute resolution process is contained in Appendix C.

Step Six: Secondary stakeholder review

Prior to the completion of a working draft for review by other relevant stakeholders, the policy's sponsor and chair-facilitator, in conjunction with members of the working group, collectively establish an inclusive list of appropriate secondary

stakeholders. These secondary stakeholders are standing groups/committees and individuals within the health organization and the community it serves who are positioned to apply 'lenses' to policy development that are typically broader than those of the primary stakeholders. In this process, the policy's sponsor and the chair-facilitator of the policy development working group send the working draft of the policy out (electronically, if possible) to the identified secondary stakeholders. After allowing a suitable, but not overly-long, period for submission of feedback, e.g., three weeks, the designated, administrative support person for the working group (if one exists) collates the stakeholder input and inserts the highlighted word-for-word comments into the working draft directly after the referenced policy sections. When this is complete, the working group reconvenes and carefully considers this collated stakeholder feedback through a renewed process of deliberative dialogue. Revisions are made to the working draft which the working group considers will: 1) add value, and/or 2) constructively address the legitimate concerns of secondary stakeholders. In the event of a decision to not incorporate a significant recommended revision(s), the chair-facilitator provides the written rationale for not making this revision(s) to the policy's sponsor and policy coordinator before, or at the time of, initiation of the formal approval phase of policy development.

In circumstances in which participants from a particular group of secondary stakeholders who will be directly affected by the policy have not responded or have responded to indicate significant concerns, it may be beneficial to obtain and/or clarify the group's input through targeted focus groups. In addition, if the policy aims

to create new organizational practice or to significantly change existing practice, it may be prudent to pilot the policy in an appropriate area prior to the formal approval phase of policy development. It is recommended that the 'most responsible' Vice-President(s) within the health organization authorize such policy pilots.

Step Seven: Stewardship through to policy approval

After the working group has carefully considered the secondary stakeholder feedback and the add-value revisions on this basis are completed, it is important to safeguard legitimately-generated policy content. Any suggested revisions to policy content arising from these organizational levels (outside of the formal approval phase) are considered and handled by the working group in the same manner as the other solicited secondary stakeholder feedback. Once the policy draft moves forward into its formal approval phase, any revisions to policy content that are required by the policy's formal approver are made/incorporated by the policy development working group (as the policy's legitimate author/steward) into the final policy document after appropriate communication and dialogue with the formal approver. One mechanism of achieving this for important, practice-changing policies is to arrange for the working group's chair-facilitator to attend a meeting of the formal approver, e.g., the executive management team, to discuss and answer questions about the policy. Through these pragmatic mechanisms, the working group stewards the policy throughout the development process and exerts an appropriate amount of control over its content up until formal approval.

Step Eight: Implementation

For those policies that are anticipated to significantly change or create new organizational practice, the policy's sponsor should give consideration to the establishment of an 'implementation plan working group' (see Appendix D). Ideally, this takes place prior to the final stages of the policy development. The implementation plan working group consists, at a minimum, of a member of the policy development working group, appropriate educators, a manager whose department/clinical unit will be affected by the policy, and appropriate resource persons, e.g., communications staff, technical support persons, human resources personnel, etc. This working group collaboratively establishes an implementation plan which, for complex policies, may include the planning and provision of a number of strategically-targeted educational sessions. In these sessions, which may be distributed by telehealth (as appropriate and available), key information about the new policy is provided to its end-users, and issues related to policy support and optimization of end-user adherence/compliance are addressed. These sessions are designed to be interactive and may include dynamic role-playing activities of relevance to the policy, e.g., the acting out by participants of an enhanced way of disclosing significant adverse events that is outlined in the *Procedure* section of a new policy on disclosure. In geographically large and diverse health zones, it may be helpful to videotape these sessions for eventual distribution as educational modules to relevant health service managers throughout the zone.

Step Nine: Evaluation

A new policy may be considered successfully implemented once there is evidence that it is being 'lived', i.e., it has appropriately influenced practice and is understood and accepted (and hopefully supported) by those working and receiving care within the health organization. One way of assessing the success of the development, implementation and organizational integration of the new policy is the performance of an appropriately-timed evaluation, the content of which is established by the policy's sponsor and the organization's policy coordinator (should one exist). This evaluation may include a planned or random assessment/audit of end-user adherence/compliance with the policy's procedures. Another feasible way is to use modern quality-management methodology to assess the level of understanding of, support for, and adherence with, the policy within the health organization. Such complementary approaches to policy evaluation can provide valuable insight into what works and what doesn't in the implemented policy. They also generate important post-implementation, experiential knowledge that should be used to inform regular and 'as needed' iterative revisions of the health policy.

Reference for this section:

Kirby J, Simpson C. An Innovative, Inclusive Process for Meso-level Health Policy Development. *Healthcare Ethics Forum* 2007; 19(2): 61-76.

III. Ethics Review of Health Policies

- *Introduction*
- *NSHEN sample template for the ethics review of health policies*
- *Description of the template's review elements*

Introduction

In this section of the guide, the focus is on providing ethics committee/reference group members with an informative, user-friendly tool to assist them in their ethics reviews of health policies. It describes a sample template that has been developed by NSHEN for potential use by ethics committees and reference groups in their performance of their ethics review work. The template consists of ten review elements which are designed to be considered as sequential steps/stages in a committee's/reference group's review of a health policy, while recognizing that the dialogue may move back and forth between these steps/stages. To enhance understanding of the individual steps, example considerations are listed beside each review element in the template, and each step is described in some detail in the text that follows.

This template is designed to be used, if so desired, as both a record of the committee's work and as an ethics review report. With this in mind, the version contained in Appendix E is 'editable' such that a designated committee/reference group member, e.g., the chair of the policy subcommittee/subgroup, could record the summary comments and collaboratively-established suggestions and recommendations of the committee/reference group in the blank boxes located below each review element. Once completed, this document could constitute the

official ethics review report of the committee/reference group to the policy developers and the official record of the ethics committee's/reference group's proceedings.

Of course, individual ethics committees/reference groups may wish to design and use their own review templates and/or to adopt some elements of the sample template in a hybridized version of their own. Some may choose to develop and use ethics review processes that do not utilize templates or frameworks. In any case, the development of an ethics review process for policies that meets the committee's/reference group's and health organization's particular needs, and which members are comfortable using, requires some time and experimentation.

For those committees/reference groups who decide to use the sample template, it is important to critically appraise this ethics review tool and, as appropriate, to share your experience with its use with NSHEN's other collaborating partners. Sample templates and frameworks are designed to be dynamic, 'living' tools that are revised and enhanced over time on the basis of pragmatic experience with their use and new developments in the field of health care ethics.

NSHEN Sample Template for the Ethics Review of Health Policies

Click here for an editable version of this template:

Review Elements	Example Considerations
1. Pre-review **preparation** by a designated Ethics Committee member(s) who presents this info to the other reviewers and facilitates relevant discussion: ➢ Research/gather information on the relevant policy topic(s)/issue(s)	E.g., research existing literature regarding 'organ donation after cardiac death' prior to review of your health organization's new DCD Policy E.g., obtain and review related policies from former provincial districts (as available), comparable national health care organizations and relevant centers of research and practice excellence

➢ Establish what are the relevant provincial/national 'best' policy practices ➢ Obtain information on the process used to develop the policy	E.g., assess compliance with your health organization's 'policy for policies' and the stewardship of policy content from early development to final approval by the policy development working group or other legitimate author
❖ … *(reviewers' comments)*	
2. Reflect (whole committee) on relevant **values:** ➢ Personal ➢ Professional ➢ Organizational	Which personal values and biases/influences are you bringing to this ethics review? Which health care professional values play a significant role in the policy? Insert your health organization's core values (e.g., as a permanent component of the template)
❖ …	
3. Identify and discuss the **ethics principles and values** that *should* inform the policy; which are the most important?	E.g., inclusiveness, collaboration, respect for persons/autonomy, beneficence, nonmaleficence (reduce harms), health equity, justice, transparency, accountability, sustainability
❖ …	
4. Identify the policy's **primary/key stakeholders**, i.e., those who will be directly affected by the policy including members of disadvantaged and vulnerable social groups; did participants from these stakeholder groups participate in the policy's development?; how will these stakeholders be positively and/or negatively affected by the policy?	E.g., 'care receivers'/patients, front line health care providers and staff, health service managers, persons living with disability, mental illness, etc. E.g., implementation of policy 'as is' will increase barriers to participation of those who…
❖ …	
5. Consider whether the policy's content is reflective of the best possible **balancing** of any identified competing:	E.g., the perspectives and interests of management inappropriately take

➢ Legitimate stakeholder interests ➢ Obligations arising from application of the ethics principles and values identified in step 3.	precedence over those of front line health care providers and patients E.g., individual autonomy is unnecessarily privileged over relevant health equity and social justice considerations?
❖ …	
6. Identify and discuss the ethics-related **strengths** of the policy	E.g., respects cultural diversity, pays meaningful attention to power differentials, policy content is reflective of appropriate stakeholder input
❖ …	
7. Identify and discuss the ethics-related **weaknesses** of the policy	E.g., inadequate Guiding Principles & Values and Definitions sections, relevant ethics concepts not well articulated and/or applied, contains significant procedural inconsistencies
❖ …	
8. Evaluate the appropriateness of the use of **language** as this relates to the policy's content, 'tone' and accessibility to end-users	E.g., too much 'ethics and legal speak' which requires ethics training and experience to understand; existing wording 'talks down' to end-users and/or is overly authoritative in tone
❖ …	
9. Would a formal **implementation** plan be helpful for this policy?; if one is available, evaluate its strengths and weaknesses	E.g., the proposed implementation plan does not make strategic use of the organization's health educators; the use of a policy education module and a 'train the trainers' approach could make good use of the organization's limited resources
❖ …	
10. Develop and record **suggestions and recommendations** for revision of the policy draft on the basis of the identified ethics concerns/questions; specify your reasons/rationales for	E.g., suggest incorporation of brief descriptions of the following relevant principles and values in the Guiding Principles and Values section; recommend making the policy more transparent and accountable in the

making these suggestions and recommendations	following ways…; suggest substitution of this policy wording "…" for that "…" because…
❖ …	

Descriptions of the templates' review elements

1. Pre-review **preparation** by a designated Ethics Committee member(s) who presents this info to the other reviewers and facilitates relevant discussion: ➢ Research/gather information on the relevant policy topic(s)/issue(s) ➢ Establish what are the relevant provincial/national 'best' policy practices ➢ Obtain information on the process used to develop the policy	E.g., research existing literature regarding 'organ donation after cardiac death' prior to review of your health organization's new DCD Policy E.g., obtain and review related policies from other provincial districts (sharing within NSHEN), comparable national health care organizations and relevant centers of research and practice excellence E.g., assess compliance with your health organization's 'policy for policies' and the stewardship of policy content from early development to final approval by the policy development working group or other legitimate author

In this preparation step, a member(s) of the ethics committee who has been pre-designated for the task (e.g., a member of the policy subcommittee or on an ad hoc basis) gathers information that he or she believes will be of value to the committee's formal review or the policy. This may include a review of the existing literature on the relevant topic(s) and issue(s). The information obtained could be shared with other committee members through a short presentation at the beginning of the review process and/or by the advanced sharing of selected key academic papers and relevant documents. It is often helpful in the case of complex policies that are likely to significantly change or create important new organizational practice to obtain and review established policies from other organizations and comparable national health organizations in order to establish what are considered to be current, relevant 'best policy practices'.

If possible, it may be constructive in this preparation step to investigate the process used to develop the policy to assess such factors as degree and type of stakeholder input, and the influence of those situated within the organization's power hierarchy on the developed content of the policy.

2. Reflect on relevant **values:** ➢ Personal ➢ Professional ➢ Organizational	Which personal values and biases/influences are you bringing to the ethics review? Which health care professional values play a significant role in the policy? Insert your health organization's core values (as a permanent component of the template)

When approaching the ethics review of health policies, individual committee members participating in the review should take some time to reflect on which of their own personal values they are bringing to the review. It is important for members to recognize that their personal values have likely been strongly influenced by cultural and social group factors, and that members of the dominant/privileged social group in a society tend to unconsciously consider the values of their own social group to be 'the norm'. It is also helpful for committee members to identify and reflect on where their personal values and influences have tended to lead them in terms of their views and positions on the policy's and related topic/subject area(s), and to recognize that patterned ways of thinking and acting may constitute a personal bias(es).

In addition, committee members should consider which sets of professional values will play a significant role in the making and eventual 'living' of the policy. Are there existing tensions between different sets of professional values within affected interdisciplinary health care teams whose members will be expected to follow in policy-related activities? Is it possible to anticipate that the policy procedural content (what the policy directs them to do) may conflict with the established codes of conduct and professional obligations of health care providers who will be the end-users of the policy?

It is also important for committee members to consider their health organization's core values and strategic directions in the context of review of the particular policy under consideration. For example, what should an organization's core values of 'collaboration' and 'accountability' *mean* in the particular organizational domain that the policy addresses?

3. Identify and discuss the **ethics principles and values** that *should* inform the policy; which are the most important?	E.g., inclusiveness, collaboration, respect for persons/autonomy, beneficence, nonmaleficence (reduce harms), health equity, justice, transparency, accountability, sustainability

In this review step, ethics committee members collaboratively identify and enter into a dialogue regarding the ethics principles and values that should inform the particular policy under consideration. It is helpful to first consider which process values should apply, i.e., the values that should guide/direct the development of the policy's content and be incorporated in a dynamic way into the policy's procedures and processes (see guide section II). The committee, as appropriate in the policy development context, should also identify and discuss any relevant substantive principles and values (see guide section II). Many health policies with strong ethics dimensions do/should make appropriate use of these. Substantive principles and values act as criteria for the making of important decisions and recommendations that are called for within the policy.

4. Identify the policy's **primary/key stakeholders**, i.e., those who will be directly affected by the policy including members of disadvantaged and vulnerable social groups; did participants from these stakeholder groups participate in the policy's development?; how will these stakeholders be positively and/or negatively affected by the policy?	E.g., 'care receivers'/patients, front line health care providers and staff, health service managers, persons living with disability, mental illness, etc. E.g., implementation of policy 'as is' will increase barriers to participation of those who…

Committee members identify the policy's primary stakeholders in this step/stage of the review, i.e., those persons who will be directly affected and impacted by the policy. The bottom of the organization's power hierarchy is often a useful place to start in the identification of primary stakeholders. In the case of health policies that involve the direct provision of care, 'the bottom' is usually populated by patients, health care providers and support staff. Other primary stakeholder groups which should be considered by committee members conducting an ethics review are members of historically marginalized and otherwise disadvantaged social groups which will be directly affected by the policy.

Once the primary stakeholders are identified, ethics committee members should collectively consider how these persons will be affected by the policy. Does the policy content as written appropriately address the interests and needs of these individuals? Are the positions, circumstances and conditions of the most vulnerable stakeholders enhanced or worsened by the policy? Are there ways not already addressed by the policy's developers that could work to constructively reduce the existing disadvantages of some of these stakeholders?

5. Consider whether the policy's content is reflective of the best	E.g., interests of management inappropriately take precedence over

possible **balancing** of any identified competing: ➢ Legitimate stakeholder interests ➢ Obligations arising from application of the ethics principles and values identified in step 3.	those of frontline health care providers and patients E.g., individual autonomy is unnecessarily privileged over relevant health equity and social justice considerations

In this step of the review, ethics committee members collaboratively identify potential conflicts between the legitimate interests of stakeholders and between the obligations that arise from the application of the principles and values (identified and discussed in step 3.), and consider how these can be optimally balanced within the provisions of the policy. For example, is it anticipated that the interests of affected patients will conflict with those of their health care providers and, if so, is there a way to respect and meaningfully attend to both, without unreasonably compromising either? In a policy that addresses the tension between the liberty interests (freedoms) of individuals and the safety of all societal members, are there ways to minimize potential collective harms/burdens while promoting and enhancing individual freedoms?

6. Identify and discuss the ethics-related **strengths** of the policy	E.g., respects cultural diversity, pays meaningful attention to power differentials, policy content is reflective of appropriate stakeholder input

It is important for ethics committee members to recognize the strengths of the health policies they review. Providing positive feedback to policy developers supports their important and generally under-appreciated work and helps to dispel the common misconception of ethics engagement in policy development as burdensome and non-constructive. Acknowledging strengths is also a good way to reinforce policy making that attends to relevant ethics considerations and to demonstrate the value of such ethics-informed policy development to the health organization.

7. Identify and discuss the ethics-related **weaknesses** of the policy	E.g., inadequate Guiding Principles and Values and Definitions sections, relevant ethics concepts not well articulated and/or applied, contains significant procedural inconsistencies

In this step of the review, the ethics-related weaknesses of the policy are identified and discussed by committee members. Once acknowledged and explored, it is important to describe these weaknesses, problems and deficiencies in a way that

will be accessible and understandable to the policy's developers. The use of judgmental, over-critical language should be avoided. It is often helpful in describing weaknesses to provide brief educational comments pertaining to, for example, related ethics concepts, any existing, relevant national ethics standards, etc.

8. Evaluate the appropriateness of the use of **language** as this relates to the policy's content, 'tone' and accessibility to end-users	E.g., too much 'ethics and legal speak' which requires ethics training and experience to understand; existing wording 'talks down' to end-users and/or is overly authoritative in tone

Ethics committee members consider and evaluate the use of language in the policy. Are ethics topics and concepts described in user-friendly ways that will enhance knowledge, understanding and frontline compliance with the policy?

9. Would a formal **implementation** plan be helpful for this policy?; if one is available, evaluate its strengths and weaknesses	E.g., the proposed implementation plan does not make strategic use of the organization's health educators; the use of a policy education module and a 'train the trainers' approach could make good use of the organization's limited resources

Health policies are translated from words to action through effective implementation. Although resource constraints often preclude this, many policies with rich ethics elements would benefit from the development of formal implementation plans which address the information-transfer and educational needs of end-users. As appropriate and possible, it is helpful for committee members to review any available implementation plans and to assess whether optimal provision has been made for ethics education components. If not, some relevant ethics education strategies could be recommended for the consideration of the policy's implementers.

10. Develop and record **suggestions and recommendations** for revision of the policy draft on the basis of the identified ethics concerns/questions; specify your reasons/rationales for making these suggestions and recommendations	E.g., suggest incorporation of brief descriptions of the following relevant principles and values in the Guiding Principles and Values section; recommend making the policy more transparent and accountable in the following ways; suggest substitution of this policy wording "…" for that "…" because…

Once the ethics considerations of steps 1. to 9. have been adequately addressed by the committee, it is important for a designated committee member (e.g., the chair of the policy subcommittee) to record the committee's collaboratively- developed suggestions and consensus recommendations for revision of the policy draft. It is important to be clear and concise in describing these. In order to achieve as much 'buy-in' as possible and to enhance the ethics capacity of the policy makers, the reasons/rationales for making these suggestions and recommendations should be recorded in the review report. While it is important to avoid taking over the writing role of policy developers and to be careful not to create such a perception, it is sometimes appropriate to suggest particular wording that relates to the specific ethics content of the policy as policy makers who lack ethics training and experience often lack the confidence to translate relevant ethics-related concepts into policy words.

In the case of ethics rich policies, as resources allow, the ethics committee may wish to consider extending an offer to the policy's developers of meeting with the whole committee or a group of its members, e.g., the policy subcommittee. The consideration of this option is of particular importance in those circumstances in which the committee has identified significant, ethics-related concerns with the policy draft during its formal review.

Appendices:

- *Glossary of health policy terms*
- *Common challenges/problems with traditional policy making processes*
- *Sample dispute resolution process*
- *Sample policy implementation plan template*
- *Sample ethics-informed 'Disclosure of Significant Adverse Events' Recommendation Making Framework*
- *References and resources*

Appendix A: Glossary of Health Policy Terms

Active voice: the preferred 'voice' for policy and most non-scientific writing: the (specific) subject of the sentence performs the action expressed in the verb. For example, "the attending health care provider initiates the decision making dialogue" as opposed to the passive voice version: "the decision making dialogue is initiated by the attending health care provider". The use of active voice reduces the number of "shoulds", "shalls" and "musts" in a health policy and adds clarity to what actions are to be taken and by whom. The use of the command verb "must" should be restricted to the content of policy procedures that warrant particularly strong emphases.

Policy coordinator: a person occupying a position within a (typically large) health organization whose responsibilities are: to coordinate the development and periodic review of the organization's policies; to arrange for newly developed policies to be reviewed by appropriate stakeholders and approved by senior management and/or the executive management team; and to organize and post approved policies (on the intranet, as possible) for easy access by their end-users within the organization.

Policy development working group: a group of individuals chosen by the policy's sponsor who meet to collaboratively develop the content of a new health policy. Membership typically includes participants from the policy's primary stakeholders and relevant resource persons and organizational leads.

Policy end-user: an individual whose vocational responsibilities fall within the scope of the policy and who makes (or should make) direct use of the health policy's procedures in the course of their normal work activities within a health organization.

Policy initiator: an individual or group within an organization who, within his/her scope of responsibilities, brings the apparent need for or potential value of

development of a particular health policy to the attention of the appropriate policy issuing authority.

Policy issuing authority and formal approver: depending on the anticipated content of the policy and relevant organizational context, this may be a standing committee, a director, a vice-president, the executive/senior management team (inclusive of the CEO or Deputy Minister) or the Board of Directors/Cabinet. The issuing authority and the formal approver are usually the same, which helps to open and close the policy development loop in a procedurally appropriate and accountable way.

Policy revision working group: a group of individuals chosen by the policy's sponsor who meet to revise an existing health policy on a regular (e.g., every three years) or on an ad hoc (as required) basis. Membership typically includes participants from the policy sponsor (which may consist of more than one portfolio/department/committee) and key stakeholders and resource persons.

Policy sections:

Preamble – a description of relevant background information that may enhance end-users' understanding of the policy and its situation within the health organization; sometimes this section is excluded from an organization's policy template and, in these circumstances, abbreviated background content may be included in the policy statement section.

Policy statement – a concise summary statement of the nature and purpose of the health policy.

Guiding Principles and Values – a description of the ethics principles and values that are to inform the policy (see below definitions of process values and substantive principles and values). In some circumstances, a Guiding Principles and Values section may be developed for a group of related health policies that have different procedural content. The guiding principles and values chosen for health policies may be different from and/or more inclusive than an organization's chosen core values, although an attempt is usually made to maintain appropriate alignment and consistency.

Definitions – a section of the policy which provides brief descriptions of key terms and concepts of relevance to the policy, and how they are to be specifically interpreted by end-users for purposes of adherence with the policy.

Procedure(s) – a straight forward, clear, concise description of what specific actions the policy calls for, and who (positions within the health organization) performs them.

Related Documents – a listing of the health organization's other existing policies, protocols and guidelines that are related to, or have a bearing on, the policy and its implementation.

References – a listing of published literature and resources used to develop the policy and/or to assist in the understanding of the policy's content.

Appendix(ces) – documents that complement policy content and/or appropriately expand on the scope of the policy.

Policy sponsor: the portfolio(s), department(s) and/or standing committee(s) within a health organization that is/are responsible for the development and implementation of the policy.

Primary stakeholders: persons who will be directly affected by the policy under development; typically in health organizations, 'care receivers'/patients, health care providers, health service managers and support staff are primary stakeholders in health policies that guide the direct provision of care. It is important to consider members of directly affected, disadvantaged social groups as primary stakeholders and potential members of policy working groups.

Process values: collaboratively-established values that inform the development of the content of a health policy and are incorporated in a dynamic way into the policy's procedures and processes. Examples of process values are inclusiveness, collaboration, accountability, transparency, consistency, procedural fairness and responsiveness (please see brief definitions of these process values in Section II of the guide).

Resource persons: persons who are in a position to support working groups in their deliberations. For example, ethics and health law consultants often participate as members of working groups that are tasked to develop or revise health policies with ethics and health law dimensions and/or are of a complex or organizational practice-changing nature.

Secondary stakeholders: standing groups/committees and individuals within the health organization and the community it serves who have a legitimate interest in the policy under development/review and who are positioned to apply 'lenses' to policy development that are typically broader than those of the primary stakeholders.

Substantive principles and values: principles and values that are collaboratively established by policy makers to act/function as criteria for decision making and, as appropriate, the ranking of choices/options that are called for by a health policy. In ethics-rich, complex and/or practice-changing policies, the chosen substantive

principles and values may be in conflict or tension and, as such, may give rise to competing obligations that require careful balancing by the policy's developers. Substantive principles and values are frequently components of frameworks that guide the process of reaching and making important, policy-related decisions and recommendations.

Appendix B:

Common Challenges/Problems with Traditional Policy Making Processes

Derived from:

Kirby J, Simpson C. An Innovative, Inclusive Process for Meso-level Health Policy Development. *Healthcare Ethics Forum* 2007; 19(2): 61-76.

This section provides brief descriptions of six identified, significant problems that policy makers commonly encounter in their use of traditional policy development processes within health organizations.

1. Lack of Optimal Lenses/Standpoints

Meso-level health policies are often developed by specific vocational and interest groups within health organizations. By their very nature, these groups tend to apply their own distinctive lenses to policy making and other organizational activities. Understandably and as might be expected, policies that result from this approach are typically shaped in explicit and implicit ways by influences and biases that are inherent to the particular group's ideology and practices. For example, policies regarding the same subject matter which are generated independently by an ethics committee and an office of risk management are sometimes quite divergent in their content and in the direction they provide to healthcare providers and support staff.

In addition to problems with the development of policies by specific vocational/interest groups, attempts to enhance the participation of identified core stakeholders in health policy making have generally fallen short. There has been considerable talk about stakeholder participation, while little effort goes in to

achieving this, especially when the relevant stakeholders are care-receivers/patients or members of the general public. Furthermore, policy making is too often characterized by the absence of meaningful input from those societal social groups that will be directly impacted by the policy under development, and, in particular, it is rare for members of disadvantaged groups, who are especially vulnerable to policy outcomes, to be given an opportunity to participate in the policy making processes of health organizations.

2. Perils of Traditional Representation

One potential problem with meso-level policy development arises from the over-privileging of a representational model of decision making. Typically, an individual is asked to engage in policy making as a representative of a particular professional or vocational group in the organization, e.g., a nurse is expected to represent all nurses. Unfortunately, this approach to policy making frequently translates, in practice, into a primary role of turf and status quo protection where members of policy making working groups consider the protection of the interests of their own professional/vocational groups to be their primary responsibility. This representational orientation often distracts policy makers from: 1) the recognition of a legitimate need for organizational change, and 2) the consideration of new, creative policy outcomes, where the effects on particular professional and vocational groups are different or unknown. The adoption of a representational paradigm for decision making may also contribute to the emergence of strident activism in some working group members, which has the potential to derail the policy making process

and to interfere with the building of constructive consensus around the relevant policy issues.

Representational engagement may reinforce the constraints imposed on meso-level policy making by the existing, hierarchical norms of health organizations. In traditional policy making, those with organizational power tend to exert it and those without such power tend to defer to authority. For example, there is a risk that physicians and senior administrators will unconsciously take over policy development and that the roles of other, less powerful participants and stakeholders get reduced to ones of meaningless representation.

3. Conflation of 'is' with 'best'

Another significant and under-examined problem/challenge encountered in meso-level policy development is the lack of awareness among policy makers of the potential difference (normative gap) between 'what is' in terms of existing policy-determined practices and 'what ought to be'. Typically and appropriately, those who are tasked to develop policies that will change organizational practice conduct research to establish the current scope of policy-determined practices across the country. This is often quite helpful early in the policy development process and can be an important component of the initial information gathering phase. Unfortunately, once such research is completed, there is a tendency for policy makers to consider the average practice and/or the current practice of well respected health organizations to be 'best'. This in turn tends to artificially constrain the choices open to policy makers, and allows policy development to proceed without much meaningful reflection and deliberation on 'what should be'. Of course, getting out in

front of the pack in policy development is considered by some to be risky. One response to this legitimate concern is that the taking of some reasonable and well anticipated risk is necessary in order to get it 'more right' and to assume a leadership policy making role for other health organizations

4. Exclusive Focus on Evidence

A potential challenge with policy making arises from the relatively new conception of policy making as an evidence-based process. This interest in evidence-based policy development has arisen (and could be considered a natural progression) from the late 20th century and early 21st century focus on evidence-based medicine and health care delivery. The usual argument of proponents of evidence-based policy making is that policy development will benefit from the application of rigorous, research-based methodologies and scientific tools. This makes sense. However, evidence-based policy making is only as good as the health evidence/knowledge which informs it. Unfortunately, health knowledge may be distorted by a variety of factors including: 1) the privileging of quantitative research findings over those generated by qualitative research methodologies; 2) the private capture of the public research process (by the frequently mandated requirement for public research monies to be partnered/matched with industry funding); 3) the blurring of academic and industry interests; 4) the pursuit of only that health knowledge that is anticipated to benefit industry shareholders; 5) the unjust exclusion of members of certain disadvantaged social groups from participation in research; 6) the lack of 'difference'-specific analysis of results; and 7) the presence of publication biases,

including the privileged publication of studies with positive results and the suppression of those with negative findings.

In addition to problems with obtaining accurate health knowledge about health matters of importance to the public good, an over-privileging of evidence in health policy development has the potential to distract policy makers from the moral dimensions of the work at hand. Although policy making always benefits from appropriate information/evidence gathering, it, in addition, frequently requires and/or benefits from reflection and respectful deliberation on the shared and/or conflicting ethics values and principles that do/should underlie health policies. This is an especially important component of developing policies with social justice implications, as when health policies under development are anticipated to have a selective and significant impact on members of disadvantaged social groups.

5. Top-down Obstruction

An all-too-frequently observed phenomenon that interferes with bottom-up policy making is that the legitimate developers of a policy lose control of its content after a draft is submitted for secondary stakeholder review. Typically, and especially with policies that aim to change/modify organizational practice, senior administration and executive members may decide to step in late in the game to shape a policy's content. This is frequently appropriate, as the standpoint and experience of those in leadership positions is crucial to an understanding of 'the big picture' and the broader context of health organizations. However, in some unfortunate circumstances, senior administration and executive members appear to be motivated by: 1) a desire to maintain the status quo and to slow down the rate of constructive

organizational change, 2) a preference/need for control, and/or 3) a lack of understanding of the demanding policy making work performed by those situated closer to the health care frontline. Such policy content revisions, which occur outside of the original policy working group format and dialogue, do not involve meaningful engagement with the policy's legitimate bottom-up developers, and often occur in an opaque, non-transparent manner.

6. Inadequate Follow-through

A common risk with meso-level policy making is the absence of adequate, up-front attention to the future implementation of the policy. Without thoughtful, pre-approval consideration of the policy's eventual implementation and related staff education needs (including the organizational resources required for such implementation/education), new policies might end up sitting and gathering dust 'on the shelf'. A lack of implementation follow-through poses a definite legal risk for the organization and those working in it, as it is difficult to defend the maintenance of older practices that are inconsistent with policies that have been formally approved by the health organization.

Appendix C: Sample Dispute Resolution Process

Preamble

Sometimes, in the process of striving for consensus on a decision of key importance to a policy development working group's mandate, an impasse is reached which makes the generation of a unanimously-supported decision or an 'all can live with' consensus regarding policy content impossible. With this in mind, it is recommended that working groups consider using a transparent, democratic impasse-resolution process when such impasses occur in the generation of key decisions regarding policy content. The following is a one such dispute resolution process:

Process steps

- The working group's chair-facilitator formally acknowledges that an impasse has been reached in the deliberations.

- At that time, further discussion of issues related to the particular piece of policy content ceases, and the chair steers the discussion for the remainder of the meeting to other issues of relevance to the working group's mandate.

- Working group members have the option of sharing additional, relevant information or comments related to the decision under consideration with other members between the meeting in which the impasse was acknowledged and the next. Any such additional information or comments are distributed to all working group members by e-mail.

- At the beginning of the next working group meeting, the chair provides a written summary of the issues and conflicting viewpoints/positions related to the reaching of the impasse. An opportunity is provided for members to clarify the content of the summary, but there is no further substantive discussion of the relevant issues.

- Working group groups are asked to vote in a transparent way on a statement provided by the chair which is designed to determine the majority member opinion regarding the decision under consideration. The majority vote determines the content of the relevant policy wording.

- Dissenters are provided the option of writing a dissenting opinion regarding the decision. This is contained in a Dissenting Opinions Appendix of the final report of the working group where it is located after the (above described) relevant summary of the issues and conflicting viewpoints/positions provided by the chair.

Appendix D: Sample Policy Implementation Plan Template

Preamble

This template is recommended for use in the implementation of organizational health policies that:

- are complex in nature
- will change organizational practice in significant ways
- would benefit from targeted stakeholder/end-user education
- have strong ethics and/or health law elements

Process

- As early as possible in the policy development process, the policy's sponsor strikes a Policy Implementation Plan Working Group**:**
    - Chair is chosen from the working group's members
    - Suggested membership components:
        - Policy sponsor
        - Educator(s)
        - Member of the relevant policy development working group
        - Health service manager
        - End-user(s)
        - Ethics and/or legal services support person(s), as appropriate
        - Other relevant resource persons, e.g., communications staff, technical support persons, human resources personnel, etc.

- The Policy Implementation Plan Working Group develops and organizes[3] a strategic implementation plan workshop and take-home print package and/or web-based resource kit:
    - Suggested workshop components:
        - Introduction
        - Description of key policy content
        - Presentation of relevant context(s) and case scenario(s)
        - Roll-plays by implementers/educators, as appropriate
        - Brainstorming re. 1) site-specific roll-out strategies and implementation plans; 2) anticipated challenges; and 3) resource requirements for effective implementation

      The health organization's Learning and Development staff may provide assistance with: 1) organization of the implementation plan workshop including advertising and arrangement for audiovisual equipment, and 2) workshop facilitation

[3] The health organization's Learning and Development staff may provide assistance with: 1) organization of the implementation plan workshop including advertising and the arrangement for audiovisual equipment, and 2) workshop facilitation.

- Suggested components of take-home print package and/or web-based resource kit (the latter for possible hyperlink to the electronically-posted policy):
    - Information regarding implementation and educational resource materials, e.g., references, audio-visual tapes, etc.
    - Description of recommended workshop components

Appendix E: Ethics-informed 'Disclosure of Significant Adverse Events' Recommendation Making Framework

Process Steps

1. Identify & assemble relevant stakeholders to form an ad hoc disclosure working group; consider inclusion of:
   - 1.1 Participants from vocational/organizational groups that will/could be directly affected
   - 1.2 Members of the public: citizens/'health care receivers' and, in particular, members of potentially affected disadvantaged social groups
   - 1.3 Relevant expert resource persons, e.g., ethics, health law, and communications supports
   - 1.4 Participants from the provincial Departments of Health and Health Promotion

2. Identify the legitimate decision makers and how recommendations will be reached by the working group, e.g.,
   - 2.1 Decision maker(s) for internal disclosure, e.g., most responsible VP(s) (established by the policy)
   - 2.2 Decision maker for external disclosure, e.g., CEO and/or LET (established by the policy)
   - 2.3 Recommendations reached by a consensus of working group members that 'all can live with'; if not possible, by transparent vote or secret ballot

3. Identify & reflect on:
   - 3.1 The ethics principles and values at play in disclosure of adverse events circumstances and the potential for conflict/tension between/among them

4. Confirm that the circumstances under consideration constitute an adverse event:
   - 4.1 Refer to the relevant policy definition, e.g., CPSI defn.: *an adverse event is an event which results in unintended harm to the patient, and is related to the care and/or the services provided to the patient rather than to the patient's underlying medical condition.*
   - 4.2 If not, should these circumstances be handled/treated as such for recommendation making purposes?

5. Consider all relevant information/evidence:
   - 5.1 Examine and discuss 'the context' from all relevant standpoints and perspectives, e.g., those of affected/potentially affected patients and their 'families', health care providers, the health care organization and the public

5.2 With the assistance of relevant, participating experts, determine the type, and best possible quantification, of risk to the potentially affected, e.g., evidence-based, theoretical, perceived, etc. with associated best-estimate percentages

6. Identify the possible disclosure options in the circumstances under consideration, e.g.,
   6.1 Non-disclosure
   6.2 Disclosure to the affected/potentially affected
   6.3 External disclosure, e.g., to other health organizations, the public, etc.

7. Through brainstorming and facilitated dialogue:
   7.1 Identify and discuss the benefits and burdens of the possible disclosure options, and to whom
   7.2 Assess alignment of the possible disclosure options with the step 3's ethics principles and values, e.g., respect for persons, patient welfare, justice (see Guiding Principles & Values section of the policy)

8. Choose the 'go forward' recommended disclosure option(s)
   8.1 Includes articulation of the ethics principles and values underlying the recommendation and how these were pragmatically applied by working group members

9. Develop and implement a comprehensive care and communication strategy including:
   9.1 Specific care plans for harmed and potentially harmed persons
   9.2 Attention to prevention of similar adverse events – necessary systems change, relevant education, etc.
   9.3 Optimal communication to patients/'families' and the public, as appropriate

10. Review the disclosure recommendation and monitor/evaluate the outcomes including:
    10.1 Checking for consistency with other disclosure recommendations
    10.2 Ensuring that 'lessons learned' inform future uses of the framework

Reference Guiding Principles & Values

A number of ethics principles and values should inform decision making regarding the disclosure of adverse events. It important to recognize and acknowledge that, in some circumstances/contexts, these principles and values, and the moral obligations that arise from them, will be in conflict/tension and, as such, will require careful balancing by decision/recommendation makers. The following are brief descriptions of some relevant ethics principles and values:

- Respect for persons
    - *Truth-telling* – a basic, widely accepted ethics principle and a key component of accountability, one of Capital Health's core values. Health care organizations and those working within them have a fundamental obligation to be honest and open in their communications with patients, their 'families'/substitute decision makers, and the public.

    - *Trust* – understood in the health care context as the reliance and related expectation that health care organizations and those working within them will act so as to put the interests of patients first. The earning and maintenance of the public's trust is an important moral obligation of health care organizations.

    - *Autonomy* – in the disclosure of adverse events context, this principle translates to the patient's 'right to (fully) know' about an adverse event that has affected or potentially affected him or her and to make informed choices about her/his future health care and treatment.

- Patient welfare
    - *Beneficence* – the obligation of health care organizations and those working within them to provide health benefits to patients/families and the public.

    - *Nonmaleficence* – the obligation to 'first, do not harm' or as little as possible, i.e., the responsibility of health care organizations and providers to mitigate/reduce burdens to patients and the public.

- Justice
    - *Traditional distributive justice* – social benefits (including health and health care) and burdens are to be fairly distributed/allocated.

    - *Formal justice* – like individuals and groups should be treated alike unless there is a demonstrable *relevant* difference between/among them that justifies different treatment.

    - *Social justice* – the obligation to engage participants from vulnerable social groups in health care decision making at the policy level (e.g., disadvantaged persons who may be affected by adverse events and their disclosure), and to demonstrate that policy and decision/recommendation outcomes have taken their interests into meaningful account.

    - *Procedural justice* – the requirement to collaboratively develop and follow fair due processes.

Appendix F: References and Resources

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