

**RECOMMENDATIONS FOR GUIDELINES ON PROCEDURES AND PROCESS
AND
EDUCATION AND TRAINING TO STRENGTHEN
BIOETHICS SERVICES IN VIRGINIA**

Virginia Bioethics Network

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PREAMBLE AND MISSION STATEMENT

The Virginia Bioethics Network (VBN) is an organization of institutional and individual members whose mission is to promote education in bioethics and to strengthen bioethics services in the healthcare institutions and organizations of the Commonwealth. To this end, the Board of Directors of the VBN desires to begin an eight month's process of consultation with its members and others about recommendations of guidelines for:

- 1) procedures and process for ethics committees and their activities; and
- 2) education and training for ethics committee members and ethics consultants.

An earlier draft of this document was discussed at the Annual Meeting of VBN on October 27-28, 1994, and the changes recommended at that meeting are incorporated in this document. At that meeting the Guidelines portion (as indicated by bold type) was approved by the VBN Board. The present document, or a revised version, will be "on the table" for discussion by each member institution and others during the next eight months. At the 1995 Annual Meeting, a final version should be ready for adoption by the VBN. The VBN desires the greatest degree of local and regional participation in shaping these recommendations.

The VBN makes these recommendations to the boards and professional staffs of healthcare institutions and organizations in Virginia. The authority to use or improve on the recommendations clearly lies within the boards of these organizations. Local and regional forms of self-regulation in providing bioethics services is preferable to regulations imposed by government or courts. However, since ethics committees are involved with patients' rights, healthcare organizations that neglect the issue of standards for bioethics services take a large risk.

The values underlying these guidelines concern:

- 1) insuring a fair and open process for ethics committees' deliberations; and

- 2) equipping ethics committee members and consultants with education and training for tasks that relate to improving quality in decisionmaking about ethical issues that arise in patient care.

Besides consultation about these recommendations with institutions and professionals in Virginia, the VBN will consult with the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), the Society for Bioethics Consultation, and other interested and involved groups.

The Procedure and Process Guidelines focus on the rights of patients and responsibilities of clinicians and healthcare organizations in reference to the activities of their ethics programs. The guidelines are framed to satisfy minimal requirements and allow for flexibility in implementation in large and small organizations.

The Education and Training Guidelines also are framed to satisfy minimal requirements and allow for flexibility and choice in implementation. The guidelines are goal-oriented statements and the methods to accomplish the goals are purposely not specified.

Specific examples are included to help organizations in deciding how to implement the guidelines. These examples need to be considered from the perspective of each organization and used in fulfilling the guidelines for that organization within a specific time frame. The examples may be used as an ideal toward which an organization can strive or as a menu from which certain parts can be selected to fulfill the guidelines. In the Education Guidelines section there are also some suggestions as to how an institution can ascertain whether the basic guidelines are being followed and evaluate its present position and progress in maintaining these guidelines.

GUIDELINES FOR PROCEDURE AND PROCESS

INTRODUCTION

A main purpose of these guidelines is to help assure fairness in the provision of bioethics services, which include education, policy development, and a process for ethics consultation. In reference to the latter service, there are many acceptable procedures for conducting ethics consultations and the VBN has no intention of limiting procedural options beyond recommending those elements of process essential for assuring fairness of whatever procedures are in place for ethics consultation. Therefore the guidelines will apply equally whether the focal point of an organization's bioethics consultation service is an ethics committee, a single consultant, or a consultation team. The method(s) used to fulfil the guidelines will vary from institution to institution and, in any particular institution, may not totally correspond to the examples which follow each guideline.

Keep in mind that the guidelines are general recommendations to be applied to all institutions, and that the method which each individual institution chooses to fulfil each guideline will, by necessity, vary with institutional type, size, and level of development of its ethics program.

Following each guideline is either a short discussion of the guideline or specific examples of recommendations which may be used to fulfil the goals stated in the guideline.

The following guidelines and examples represent two levels of information addressing implementation of procedure and process for institutional ethics programs. The guidelines

represent the more general level which is applicable to all healthcare institutions and organizations. The examples following each guideline represent the specific policy and procedural aspects of bioethics services which a number of bioethics programs have found reasonable and useful. These examples are however only that, examples, and are not meant to represent policies which must be adopted. If desired by particular healthcare institutions, the examples may be considered an ideal toward which an ethics program may strive.

Guideline I - An institutional ethics program should have its functions clearly defined by a mission statement and/or written policies.

Important bioethics service functions sponsored by institutional ethics programs include:

- 1) educating healthcare staff on bioethics issues;
- 2) assisting in policy development on bioethics issues;
- 3) organizing and carrying out community education on bioethics topics either individually or as a member of a bioethics network; and
- 4) assisting patients, patient's families, and healthcare staff in making and/or dealing with difficult ethical decisions relevant to patient care. The type and degree of commitment of an institutional ethics program to each of these functions should be addressed in the mission statement and/or specific policies.

Specific Example of Mission Statement - "Patients, their families and healthcare staff are frequently confronted with difficult ethical issues. In order to meet their needs for discussion and clarification of ethical issues, [name of institution] has established an institutional ethics program which sponsors certain bioethics services. These services include acting as a forum for discussion of ethical issues, education concerning ethical issues and problems, and the facilitation of ethical decisionmaking in specific cases. To further its goals the institutional ethics program will consult with patient's, patient's families, and staff; make institutional policy recommendations; and offer education on bioethics issues. The bioethics program will work to maximize options for those making difficult ethical decisions but will not seek to impose the moral preferences of its members on patients, patient's families or staff."

Guideline II - An institutional ethics program's structure and operating rules, as defined by the mission statement and specific policies, should assure fairness and accountability to those who use the bioethics services.

Specific Examples -

1. The ethics committee should be a multi-specialty committee with representatives from all of the important clinical areas of the institution. In addition one or more representatives from the community at large, who can reflect the community's values, should be afforded full membership on the committee. Attention to gender,

ethnic, and religious diversity in selecting members of the ethics committee is desirable.

2. The ethics committee should be an integral part of the structure of the institution and have a defined responsibility within this structure. The ethics committee's authority should be derived from the institutional entity (medical staff, administration or board of directors) to which it reports.
3. The ethics committee should have a specific schedule for regular meetings and have a defined written procedure for placing items on the agenda of the regular meetings. All committee members and staff members, who may wish to have an item placed on the agenda of the regular ethics committee meeting, should be aware of this procedure. Accurate minutes of all ethics committee meetings should be maintained.
4. The ethics committee should have a specific method for calling a special meeting of the committee for timely consideration of particular ethical issues. This method should be widely known and easily available to the healthcare and administrative staff. Consideration may be given to patients and families who wish to have specific issues discussed by the ethics committee.
5. The ethics committee should have specific policies concerning qualifications for membership, appointment procedure, time frame for appointments, methods and reasons for removal of a committee member prior to completion of his/her term (any method for removal of a committee member must minimally meet the same procedural standards as outlined in the policies of the committee or group which is directly responsible for the activities of the committee), and acquisition and disbursement of operating funds.
6. The ethics committee should have a specific and well defined procedure for consideration and development of institutional policies bearing upon the ethics of clinical care in the institution.

Guideline III. - An institutional ethics program which undertakes ethics consultation as a part of its bioethics services must assure that any ethics consultation proceeds in a manner which conforms to minimal standards of fairness and accountability.

Such minimal standards include defined methods for

- 1) access to consultation,
- 2) timely notice of consultation,
- 3) consultation process,

- 4) documentation of consultation, and
- 5) review (evaluation) of consultations.

Specific Examples

- 1) The ethics committee (or other appropriate body) should develop a protocol which addresses the entire process of ethics consultation and this protocol should be followed during all ethics consultations.
- 2) One member of an ethics consultation team or the single consultant should have completed all of the educational and training requirements to be specified as a "qualified consultant" (see Educational and Training Guidelines)
- 3) If ethics consultation is provided by more than one consultant, the consultation group or team should not consist entirely of persons with the same professional background. Possible exceptions and the acceptable reasons for the exceptions could be addressed in the ethics consultation protocol or in the rules and regulations of the ethics committee.
- 4) The ethics committee (or similar group) should be responsible for all ethics consultations and should review all consultations in a timely manner.
- 5) Ethics consultation should be focused on the clarification of options, education about the ethical issues represented by the options, and mediation where necessary. Specific moral advice as to a particular outcome should be avoided by the consultants, so that the appropriate decisionmakers can make the decision(s) that are most fitting for them. No ethics consultation should involve voting.
- 6) Any healthcare provider directly involved in a patient's care should be able to request a consultation without fear of intimidation or punishment. Likewise any patient, patient's surrogate or family member may request a consultation. The ethics committee or the administration should take steps to inform patients, families, and healthcare staff of the availability of ethics consultation.
- 7) The patient or the patient's surrogate and the patient's attending physician should be notified of a consultation request. (But also see example 12, below.) Only the patient or his/her surrogate has the authority to veto a consultation.
- 8) Strict attention to confidentiality should be maintained during the entire consultation process. This includes getting permission from the patient or surrogate prior to reading the patient's chart as well as fully explaining the consultation process to the patient or surrogate. (But also see example 12, below)

- 9) A good faith effort should be made to notify and invite to the consultation meeting the patient's treating physician(s), and all healthcare staff and family members involved in the patient's care, as well as any person with legal authority to make healthcare decisions for the patient.
- 10) When the consultation process involves a meeting of the participants in the case, the meeting should proceed with certain guidelines in place including: the appropriate decision makers are present, the consultant explains the purpose and parameters of the meeting, the goal of maintaining confidentiality is emphasized, each person present will be allowed to state his/her thoughts concerning the case, and limits concerning length of meeting, issues to be discussed, and goals of the meeting will be set at the beginning of the meeting.
- 11) All consultations shall be documented by a brief note in the patient's chart giving an overview of the issues and recommendations (if any) which the consultation process addressed. A complete record of each consultation including the ethics committee review and any available follow-up information should be kept by the bioethics service.
- 12) There should be an informal process for addressing and discussing ethics issues of importance to the clinical staff without instituting the formal process specified above. This informal process may be activated by one or more clinical staff members because of concerns about a specific clinical case and need not involve notification or participation of all parties mentioned above. However the case itself should only be discussed generally. Maintaining confidentiality concerning a case during this process is of utmost importance. Whether or not the names, specific aspects of the case, and information in the chart should be available to the ethics consultant(s) as a part of the informal process depends upon the nature of the inquiry, upon the culture of the institution and upon who is doing the consultation. This informal process should be considered an educational service.
- 13) If, in a particular case, complaints concerning the ethics consultation process or the ethics consultant(s) develop, there should be a mechanism in place for consideration of these complaints and for alternative consideration of the case, if needed.

Guideline IV. - A bioethics program should evaluate and review its services.

Specific Examples of Methods for Review

- 1) A bioethics service should appoint a member to periodically review the records of the service and report to the service as to possible methods for improvement.

- 2) A reviewer with no connection to the bioethics service or the institution should be employed to review the bioethics service at specified intervals. (Other VBN members can complete this review.)
- 3) A bioethics service may wish to undertake one or more surveys of staff members and/or patients and families to ascertain satisfaction levels with the activities of the service and suggestions for improvement.

RECOMMENDED GUIDELINES FOR EDUCATION AND TRAINING

ETHICS COMMITTEE MEMBERS

Membership in an institutional ethics committee requires a commitment to acquire and maintain a level of education needed to fulfil the obligations of a particular ethics committee as outlined in its mission and as understood by the patients, clinical staff, and administrative staff of the institution. Ethics committee functions include:

- 1) discussion and recommendations concerning institutional policy issues which bear on ethical clinical care,
 - 2) acting as a forum for discussion of specific ethical problems or dilemmas,
 - 3) sponsorship of an on-going educational program for the institutional staff, patients, and community, and
 - 4) sponsorship of an appropriate method for those patients, family members, and staff members with an ethical problem to receive help in addressing their problem.
- Research and networking activities are also functions of certain ethics committees.

Guideline I - Every ethics committee member should, within an appropriate time frame (e.g.,one year), have completed the education necessary for him/her to function as a knowledgeable and effective member of the committee based on the committee's stated mission and goals.

A. Education for ethics committee members should be aimed at providing a basic understanding of goals and activities of the particular ethics committee and its relationship to the parent institution and surrounding community.

B. Education for ethics committee members should lead to an understanding of acceptable processes for consideration of clinical ethics issues and problems as well as a basic knowledge of the parameters (legal and cultural) within which ethically appropriate decisions can be reached.

Specific Examples - The following are examples of educational subjects which may be used to fulfill Guideline I.

1. History of institutional ethics committees generally and of the ethics program in the particular institution.
2. Mission and scope of ethics committees generally and of the particular institution's ethics committee.
3. Methods of analyzing ethics problems.
4. Procedure and Process Guidelines affecting the operation of the ethics committee.
5. Specific ethical obligations in clinical care including disclosure, assessment of capacity, informed consent process, confidentiality, truthfulness.
6. Clinical ethical issues including refusal of treatment, forgoing life sustaining treatment, controversial reproductive choices, access and cost issues, death and dying issues, and others, including how diverse cultural and religious traditions affect decision making.
7. Legal issues bearing upon the ethical considerations of clinical care.

Evaluation of fulfillment of Guideline I

There are several techniques which may be used to evaluate whether Guideline I is being met. Which technique or method is appropriate for a specific ethics committee should be left for that committee -- in concert with the board of the institution or organization -- to decide. The most important factor in evaluating the education of ethics committee members is their demonstrated effectiveness in addressing the tasks of the committee. Possible methods for evaluation include:

1. Internal evaluation of adequacy of educational level of committee members in relation to assigned tasks.
2. Adherence to a specified educational curriculum.
3. Internal or external testing of knowledge.
4. Outside evaluation of educational curriculum and/or effectiveness of committee members.

ETHICS CONSULTANTS

A higher standard of education and training for those who are to be designated ethics consultants is necessary because of the challenging nature of the task as well as the high visibility and importance of this activity. A major error by a poorly informed ethics consultant may adversely affect a particular patient, one or more staff members, or the entire institution.

Guideline II.

All ethics consultants, prior to accepting primary responsibility for ethics consultation, should meet requirements adopted by the parent institution. These requirements should include those educational and training elements which assure that the ethics consultant fully understands the ethics consultation process in the particular institution, is comfortable in the clinical setting, and has the requisite knowledge of clinical ethics and health care law.

Specific Examples - The following are examples of educational and training activities which may be used to fulfil Guideline II.

1. Fulfil Guideline I with added attention to ethics consultation.
2. Course or courses focused on the clinical setting and its language.
3. One or more basic or advanced clinical ethics courses.
4. Lectures, or courses focused on principles and practice of ethics consultation including consideration of history, different models, evaluation techniques, and relationship to other professional endeavors.
5. Involvement in real or mock consultations as a trainee or participant/observer, with supervision from consultants with experience.
6. Training sessions devoted to skills in communication and group leadership, individual and group dynamics, mediation, and self- awareness.

Evaluation of fulfillment of Guideline II.

Evaluation of ethics consultation and the educational and training activities associated with it is at an early stage of development and is therefore difficult. Nevertheless each institution should attempt to evaluate this activity in some manner which seems appropriate in reference to the goals of consultation in the institution. One or more of the following examples of evaluation methods may be used to evaluate specific ethics consultants or ethics consultation generally.

1. Internal or external testing of the knowledge and/or level of expertise of the ethics consultant.
2. Internal review of each ethics consultation and the consultant's knowledge and ability in relation to the consultation. This can be done by the ethics committee or another designated body.
3. Observation of ethics consultant by external evaluators with recognized experience in ethics consultation.

4. Surveys of levels of satisfaction with ethics consultants or of their effectiveness in relation to specific desired processes.
5. Acceptance of demonstrated competence in another institution.

Guideline III. - All persons who are designated as faculty for the education and training necessary to fulfil Guidelines I and II should have knowledge and/or training in the area which he/she will teach and have demonstrated his/her ability to teach in this area.

Recommendations for Teaching Faculty:

- A. For an initial orientation of new ethics committee members: It is recommended that someone conducting this teaching have:
 1. At least one year's experience as an ethics committee member or chairperson;
 2. Attended and evaluated two prior orientations;
 3. Assisted with one prior orientation; and
 4. Completed at least the education to fulfil Guideline I.
- B. For teaching required to fulfil Guideline I for education of ethics committee members: It is recommended that each faculty member for this activity have:
 1. At least two years' experience as an ethics committee member or chairperson;
 2. Completed the recommended education and training for ethics committee members in Guideline II; and
 3. Assisted in the teaching of the education to fulfil Guideline I for ethics committee members at least once.
 4. The legal component of this educational activity should be taught or supervised by an attorney admitted to the bar in Virginia or on the faculty of an accredited law school in Virginia.
- C. For the teaching needed to fulfil Guideline II for education for ethics committee members and consultants: It is recommended that each faculty member for this activity have:
 1. At least two years' experience as an ethics committee member or chairperson;
 2. Completed the education required for Guideline II for ethics committee members and consultants;

3. Provided ethics consultation effectively in a health care institution or organization; and
 4. Assisted in the teaching designed to fulfil Guidelines I and II at least once;
 5. The legal component of this educational activity should be taught or supervised by an attorney admitted to the bar in Virginia or on the faculty of an accredited law school in Virginia.
- D. For the teaching of pathophysiology and medical terminology associated with fulfilling Guideline II: It is recommended that each faculty member for this activity have:
1. Either the MD or RN degree; and
 2. Either assisted in the teaching of this material at least once, or demonstrated skill in teaching persons who are not clinicians.

Notes:

1. The resources of VBN will be made available to member institutions, both to consult on the application of these recommendations to the unique situation of an individual institution, and to assist, where possible, in the development of appropriate training for ethics committee members and ethics consultants.
2. The VBN makes these recommendations recognizing that they will be flexibly used. For example, it initially may be desirable to "grandfather" some committee members, ethics consultants, and/or faculty members, in recognition of the work which they have been doing prior to the adoption of standards for bioethics services. Also, institutions have sufficient discretion to permit exceptions to standards for persons who present education and training equivalent, although not identical, to the standards.