

**College of Nursing
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Curriculum on International Research Ethics (CIRE)**

**Beverly J. McElmurry, EdD, FAAN
Program Director**

**Susan J. Misner, RN, MS
Program Coordinator**

**Teresa Savage, RN, PhD
Research Assistant Professor**

**Elissa Dresden, RN, ND
Post Doctoral Trainee**

For further information:
Beverly J. McElmurry, EdD, FAAN
UIC College of Nursing
845 S. Damen Ave., Room 1158
Chicago, IL 60612
(312) 996-0621 – (312) 996-8945 FAX
melmurr@uic.edu

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With the emergence of a global perspective in research, students, practitioners and academic professionals are faced with ethical decision making in unfamiliar settings. These encounters create the need for development of skills to assist researchers in making decisions under conditions of uncertainty. The CIRE covers content areas the authors judged essential for the beginning international researcher. This content is presented in four modules:

- Module I Health Care and Professional Practice Ethics
- Module II Perspectives on Research Ethics
- Module III Concepts of Culture
- Module IV Concepts of Community/Communitarian Ethics

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College of Nursing, University of Illinois at Chicago
MINORITY INTERNATIONAL RESEARCH TRAINING (MIRT) PROGRAM
Curriculum on International Research Ethics (CIRE)

Module I: Health Care and Professional Practice Ethics
Susan J. Misner RN, MS

Overview

As professionals, health care clinicians and researchers are granted public trust to maintain a high quality of services within standard guidelines. While scientific knowledge supports health services, health research also is affected by values in the cultural and/or clinical practice setting. At times, professional values may differ from dominant cultural norms or among health clinicians and researchers. With increased awareness of global influences on health, it is essential to consider the ethics of professional practice in planning and conducting health research in international settings.

Competencies

Upon completing review of this module, the learner will be aware of the concepts and critiques of different types of ethical theories. The learner will consider various ethical approaches to health care and ethical concepts related to global health issues and research. Basic professional practice ethics will be deliberated in the context of health research in international settings. A comparison of key foci for various professional codes of ethics, including nursing ethics, will be accomplished.

Objectives

By completing review of this section, the learner will:

- Review strategies for determining the strengths and limitations of ethical systems
- Compare bioethics and social ethics from the perspective of international health
- Identify current ethical issues pertaining to globalization of health and research
- Examine the relationship of professional practice ethics and international health research
- Consider the central tenets of ethical codes for a specific professional group
- Critique different approaches for assuring ethical conduct in professional practice

Key Ideas and Concepts/Definitions

- Ethics
- Morality
- Common morality
- Personhood
- Conscience
- Deontology
- Teleology
- Virtue ethics
- Bioethics
- Principles
- Casuistry
- Relativism
- Social contract
- Justice
- Human rights
- Globalization
- Professional ethics
- Codes of ethics
- Moral community
- Nursing ethics
- Ethic of care

Ethics, Morality, and Health Research

“Scientific statements of facts and revelations, indeed, cannot produce ethical directives. However, ethical directives can be made rational and coherent by logical thinking and empirical knowledge” (Einstein, 1953).

Ethics is the term that encompasses a variety of approaches to the understanding and examination of moral living. **Morality** is the distinction and content of right and wrong. **Common morality** is considered as a consensus, widely shared and stable, about socially approved human behavior and values. Common morality is based on social codes or rules which can be erroneous and incomplete. Thus, morality can be viewed as the end result of ethical deliberation about problems that need decisions and require action. Ethical decision making requires the precision of science and an intuitive application as art.

In health care, conflicts about morality may arise during the development of scientific knowledge and during application of learned knowledge in clinical practice. Differences in the concepts of health and morality interface among individuals or groups of people, for example, between a health professional and a patient, or among health researchers and a cultural or community group. When ethical dilemmas occur, knowledge of ethical theories and strategies for their evaluation can provide health professionals and researchers with insights and skills to use toward collaborative resolution.

Ethical Theory and Moral Concepts.

Based on various philosophical perspectives, there are a number of different approaches to the study of ethics, including the development of **ethical theories** about the nature and role of morality. These include:

<p style="text-align: center;">NORMATIVE ETHICS (First Order):</p>	<p style="text-align: center;">NON-NORMATIVE ETHICS (Second Order)</p>
<p>Includes the defense of moral theory and general moral positions, or judgments on specific moral issues; e.g., cloning.</p> <p>Provides conclusions and theories, which in themselves are substantive ethical statements.</p> <p>Gives guidance for norms to determine the rightness or wrongness of individual and/or social behavior</p> <p>Overlaps with practical ethics, including professional ethics, social etiquette, and theological codes.</p> <p>Asks, “What rules will be used to deem conduct as morally acceptable and why?”</p>	<p>Descriptive ethics :</p> <p>Investigates moral behavior and beliefs.</p> <p>Asks, “ What are the moral traditions, practices, and decisions across different cultural groups?”</p> <p>Metaethics:</p> <p>Analyzes the language, concepts, and reasoning of ethical discourse.</p> <p>Investigates the meaning of moral language (epistemology) and the justification of ethical theories and judgments.</p> <p>Asks “Is social morality objective or subjective, relative or non-relative, and rational or emotive?” (p. 5) (Beauchamp and Childress, 1994).</p>

Certain moral concepts are common across different approaches to ethics, though these may be assigned varying importance and attention by specific ethical theories. By considering these questions/concepts, attempts are made to answer the overall question: **What is ethical?** These ideas include:

- What is the behavior under consideration?
- What is the motive for the behavior?
- What can be anticipated as consequences of the behavior?
- What is the character of the actor(s) based on predictable trends of actions over time?

Consider the following example:

A researcher was interested in conducting a study comparing a new health care product to an existing product that was in use in the USA at the time. The existing product was considered to be the standard of care in the USA. Because neither product was available for use in a specific developing country, the researcher proposed conducting a double blind clinical trial to test the effectiveness of the new product in that developing country setting. The researcher claimed that one benefit of the research would be the new product's availability in the developing country during the study period, with the potential of saving lives during that time. However, due to costs, neither product would be made available in the developing country following the study period, regardless of the determined level of effectiveness. The researcher worked for a corporation that hoped to market the new product in the USA as a competing treatment, perhaps with increased effectiveness, to the existing product.

Questions for Reflection (Please refer to the research example described above):

- What is the nature of the moral behavior in this situation?
- Can the character of the researcher be described related to this proposed research?
- If this research is granted approval, what are the possible beneficial versus detrimental consequences and to whom?
- Can the motive for this research be determined and, if so, is it useful to consider the motive in determining the ethical merit of this proposed study?

Other important moral concepts with relevance for health care include **personhood** and **conscience**. Regarding personhood, a central assumption of ethical thought is that interactions with persons (i.e., Homo sapiens) are unique. While the description of persons may seem obvious, colloquial statements such as “I want to be treated like a person” are a reminder of the normative significance of “humanity” and “humaneness.” Of course, as public debate about both beginning and end of life ethical decisions has illustrated, the concept of personhood does not have simplistic agreement in our society.

Conscience is a person's sense of his or her own propensity for behaviors that are required for personal moral integrity. Conscience is self-directed, in that one's own evaluation cannot

compel another human being's sense of moral duty. An interesting question about conscience may be posed: "Is the right to act (or not to act) on a conscientious conviction provided or morally required by the presence of that conviction?" The debate on the moral status of capital punishment is an example of conflicting conscience choices and associated views about requirements for action.

Moral codes are guidelines that require review of actions. Moral codes also provide guidance to evaluate the impact of one's actions on self and others, thereby making social cooperation possible. Frequently, moral codes share the characteristics of being prescriptive (provide guidelines on how to act morally), universal (applicable to varied situations, people, cultures) and overriding (invoke a value or ideal that prevails over other values and ideals).

"A key issue is whether moral codes and standards are best regarded as theories and propositions with a truth value, analogous to scientific... theories, or as systems of norms or rules that lack truth value, analogous to codes of etiquette... For if a moral code is a theory, and if it and its component standards have truth-values, then they are potential objects of epistemic [i.e., knowable] justification. That is, there is at least the possibility of finding evidence or an argument that would support the truth of some of them. But if a moral code is a system of rules, and if rules and codes of rules lack truth-values, then there is no possibility of supporting their truth" (p. 1081) (Copp, 2001).

However, whether viewed as theories or as a system of norms, moral codes may be evaluated for their methods of justification and for their logic. There are criteria to evaluate the construction of ethical theories and propositions. Some of these include:

- Clarity – Is the language precise?
- Coherence – Are the concepts consistent?
- Completeness – Does it comprehensively address different moral values?
- Simplicity – Is the theory as simple as the subject permits?
- Explanatory Power – Does it provide sufficient insight?
- Justificatory Power – Are beliefs grounded in a reasoned and justifiable logic?
- Output Power - Will new ideas be generated by the theory?
- Practicability – Are requirements realistic in the theory's expectations? (p. 46-47) (Beauchamp and Childress, 1994).

Selected Classical Ethical Theories: Advantages and Disadvantages.

Deontological systems of philosophy employ concepts about the inherent rightness or wrongness of actions, characters, or motives. Based on sets of principles, theories of deontology consider the fundamental morality of acts as obligatory (e.g., actions permissible to do and forbidden to omit). The notion of duty, with implicit rights, is primary in deontology. Examples of deontological theories include natural law, divine command theory, and ethical rationalism (Rae, 1995).

Criticisms of deontology center on the assumption about human capacities to discern “goodness,” including duty and obligation. Also, there is theoretical incongruence in deontology when mandates conflict in theological scripture, etc., or in principle-based interpretations of “right.” These approaches reflect a **non-consequentialist** posture in ethical discourse. In this view, the results of decisions and behaviors are not the primary concern. Rather, the application of a set of guidelines leads to the question: Which principles are relevant for the moral purpose?

Human rights may be viewed as essential human obligations. Frequently, these rights are considered to be evolved from deontological theory.

Particularly in international settings and among diverse cultural groups, a critical challenge to health care ethics is the need to resolve competing claims of ethical obligations to basic humanity. For instance, issues in the development and use of emerging technologies, such as new pharmaceuticals and cloning, have yet to be resolved.

Teleological systems, within a **consequentialist** approach, are based on the belief that moral justification stems from the results of human behavior. From this perspective, duty and obligation are derivative, since moral goodness is determined by the consequences of ethical decisions and actions.

Utilitarianism is the main form of teleology. The theory assumes that the best moral choice is the action tending toward the “greatest good for the greatest number.” The premise of utilitarianism is that human behavior should benefit the interests of those affected (i.e., the principle of utility).

Another teleological form of ethics is “**ethical egoism**,” advancing the notion that self-interest is the only consequence (i.e., outcome of ethical decisions) that is moral. Primarily, this approach has been studied as it applies to individual ethical actions. However, the theory also has merit to evaluate the moral choices of communities and countries.

In contrast to ethical egoism, utilitarian philosophy justifies impartiality to the consequences of actions. From this view, individual self-sacrifice may be necessary to achieve the greatest benefit for others. Yet, a problem with this premise is that morally praiseworthy, but ethically heroic actions could become obligatory under utilitarian justification.

One example illustrative of this dilemma is the prescriptive mandate in moral codes for whistle-blowing of unethical professional behavior. Since whistle-blowing frequently has been observed to result in significant adverse effects for the ethical agent, these specific mandates have been labeled as demanding unreasonable heroism, which in itself is criticized as unethical.

Thus, consequentialist approaches suffer from the classic skepticism about “the means being justified by the end.” In addition, these approaches do not settle disputes about how the

consequences of moral choice are to be defined and measured. In other words – what kind of results are good and for whom?

Aretaic ethics (e.g., virtue theory) has a focus on the moral character of a person versus the morality of a specific act. In contrast to deontological and teleological approaches, **virtue ethics** has an emphasis on the moral agent's general characteristics rather than particular actions. The following are key elements of this perspective:

- A moral virtue is reflected over time in a person's predictable ethical choices, actions, and motives, particularly the person's state of mind and feelings.
- Strong moral character [however that may be determined] is the goal of ethical persons.
- Development of moral character is preferable to expecting adherence to moral norms (e.g., codes and regulations), since these rules are difficult to impose.
- Rather than imposed compliance with external rules, one's commitment to moral ideals, with a desire for ethical behavior, is more trustworthy to assure right conduct (Rae, 1995).

Critiques of virtue ethics express concern that the moral character of an agent (e.g., health professional) is not adequate to assure moral protections. In part, this concern rests with potential flaws of personal conscience and moral reasoning that may result in erroneous actions – virtuous persons may make mistakes. Also, theories of virtue ethics are limited by the claim that morality rests solely in the actions of a moral person. The question arises, “Is virtuous character sufficient to assure ethical decisions and conduct?”

*To support strong moral character in ethical behavior, the notion of the “**moral community**” has been proposed. Moral behavior may be enhanced by creating a climate or environment that supports virtuous character.*

Questions for Reflection:

- What characteristics do you value in health care professionals?
- How might colleagues in a health care environment strive to be a “moral community?”
- Can you think of a health care situation in which persons defined moral conduct by different results or outcomes?

Bioethics and International Health Issues

Bioethics is the critical evaluation of moral aspects for decisions in health care and the life sciences. Bioethics attends to a wide range of questions and disciplines - from abstract, speculative discourse to specific and practical issues. Besides traditional medical ethics (i.e., biomedical ethics), current areas of scholarly and popular discussion in bioethics include topics such as economics, molecular biology, and public policy.

Bioethics, as a discipline in itself, has become a model for public dialogue about a range of values and controversial issues. Yet at times, bioethics is limited by debate that is too abstract for clinical relevance. In addition, bioethics may be plagued by seemingly unanswerable questions and risks susceptibility to shifting public sentiment.

For many years, in medicine and in health care, ethicists have embraced a “**principled approach**” to ethical decision making. **Principles** may be defined as generalizations that instructively guide moral actions. The generality of principles (versus the greater specificity of rules) is considered a strength by advocates of this approach. Claims are made that this generality provides flexibility for judgments that are an inherent responsibility in moral life. Selected guidelines (i.e., principles) are justified by common morality and medical tradition. Critiques have labeled this approach to ethics as “**principlism**,” claiming that principles have vague delineations and are unranked in moral significance. Multiple principles may be in conflict with each other. Another problem with principlism is that it stems from coherence in “common morality,” which is fallible.

Widely cited throughout literature on biomedical ethics, Beauchamp and Childress (1994) claim four clusters of principles. While principled ethics does not limit principles to these four clusters, this specific group has received broad application as well as criticism within the life science disciplines. These are:

1. **Respect for autonomy** (a norm of respecting the decision making capacities of autonomous persons.
2. **Non-maleficence** (a norm of avoiding the causation of harm)
3. **Beneficence** (a group of norms for providing benefits and balancing benefits against risks and costs)
4. **Justice** (a group of norms for distributing benefits, risk, and costs fairly). (p. 38)”

From these four general guidelines, derivative rules, especially codes of behavior within health care, have been developed with greater clarity in specific areas. Examples of these rules include privacy/confidentiality and informed consent.

Criticisms of the principled approach have evolved over time, particularly from health professionals attempting its application in clinical settings. Summarized below, problems ensue with the principled approach to ethical decision making when:

- Differences exist in the relevant principles affirmed
- Varied emphasis for application of principles occurs (either across different but comparable case situations or among different ethical actors involved in one specific case)
- Arbitrary or intuitive prioritization of relevant principles is specified (e.g., binding versus flexible; rank of significance)
- Rules derived from principles tend to be proscriptive (guidance on what NOT TO DO), whereas principles are meant to be prescriptive (guidance on what TO DO)

- Moral knowledge is treated as general whereas moral knowledge is fundamentally particular (e.g., principles may point out distinctions in moral quandaries across specific cases but do not provide particularistic instruction to address the moral differences)
- Credence is given to the importance of moral character but no focus is provided for development of moral virtues. Knowledge of ethical principles may not correlate with virtuous action.
- Principles are derived from the common morality, respecting communal values and traditions, but the philosophical emphasis is individualism.
- Moral reasoning deteriorates to principled reasoning. There is a risk between:
 - 1) Adherence to the principles at the cost of the moral outcome (i.e., the application of the principles becomes the ultimate goal of ethical deliberation irrespective of the case result [Means justify the end]) and
 - 2) Maximal priority on the principle of utility, emphasizing “greatest good” as priority over other potentially relevant principles.

Despite these limitations and critiques, the principled approach has been the predominant philosophical basis for applied bioethics. Principle-based ethics is used by most members of ethics committees in clinical settings. Bioethical principles are often cited in professional codes of ethics in the USA and abroad. This approach has been widely accepted and, primarily, is the basis for human subjects protection in USA federal regulations and for some international organizations as well (See <http://www.biol.tsukuba.ac.jp/~macer/Declarations.html>).

Casuistry (i.e. case-based moral reasoning) has been revived as a method to apply practical ethics in specific cases. It relies on the in-depth understanding of particular situations, using a set of moral norms considered to be more or less beyond dispute (Bedau, 2001). Formerly, casuistry was disparaged as an inadequate means of moral reasoning due to reliance on intuition. However, recent applications of case-based ethical analysis are in response to the rigid application of grand theories of good or right. In casuistry, morality is addressed from a wide variety of conditions requiring insightful judgments. Case situations are used for moral instruction about courses of action to be taken. Yet, critiques maintain that casuistry is a slippery slope toward justifying any action as permissible given the right circumstances (i.e. **relativism**). However, this critique is countered with the position that principlism also balances competing values in essentially an intuitive process. In addition, the specification of circumstances for applying moral principles may lead to rationales approximating, “it depends.”

In the United States, the principle of autonomy (self-determination) and the rule of veracity (truth telling) has led to the standard of informed consent for treatment, implying full awareness of medical diagnosis. This standard has been invoked regardless of ultimate prognosis related to a person’s health status and/or health condition (e.g., cancer). Thus, patients and family members, as well as health professionals would expect, in most situations, full disclosure of medical diagnosis.

However, in some countries, the diagnosis of most forms of cancer and some other conditions may mean a definitive terminal prognosis, at times due to late identification or inaccessibility to treatment In these settings,

where communal living among extended family members often is the norm, health decisions are family based. Hope is valued as a means of continued survival and hopelessness is to be avoided. On this basis, while invoking the principle of non-maleficence, disclosure of a terminal prognosis, or even a medical diagnosis, may be withheld from the index patient, both at the request of family members and on the basis of ethical and clinical judgment of health professionals.

Questions for reflection:

- Are there limits to the application of ethical principles, such as truth-telling, or are these ethical standards to be applied without compromise?
- Are any principles of moral reasoning universal across cultural settings? If so, which ones?
- By review of international case situations such as the one described above, what lessons in ethics are applicable for clinical practice in the USA?

“The internationalization of bioethical theory is being driven by global pandemics, a global pharmaceutical industry, and the globalization of biomedical science “(p. 445) (Baker, 1999). It is not clear that principlism in bioethics will survive in the global health arena. Particularly following global crises, a different perspective may be required to meet the moral considerations for international bioethics in coming years (Moreno, 2001).

Baker (1999) has proposed that a framework for international bioethics should include the following characteristics:

- 1) Sensitive to cultural differences
- 2) Capable of justifying moral judgments across cultures and eras
- 3) Moral judgments extend to individuals and their actions
- 4) Moral judgments extend to institutions and their actions.

Challenges for international bioethics. In the context of dramatically shifting world events, there are many challenges for bioethics in international settings. Following past travesties and more recent controversies about the ethics of international research, there is increasing concern regarding the protection of human subjects. Also, health care ethicists must help to clarify the role of scientists and the health personnel in many situations, for example, addressing potential bio-terrorism.

Global disparities in health across countries must be eliminated, beginning with the need for proportionate allocation of research resources based on global burden of disease. Also, the application of emerging technologies, such as genetics, has taxed the capacities of ethical review processes in both developed and developing countries. While profound, these moral challenges present both health clinicians and researchers with a critical role in the expanding public dialogue and developing decisions in public health and social policy.

Social Ethics in Health Care

In 1939, Bernal discussed the social function of science.

"Science implies a unified and coordinated and, above all, conscious control of the whole of social life...Science, conscious of its purpose, can in the long run become a major force for social change...The greater part of disease in the world today is due directly or indirectly to lack of food and good living conditions. All these are plainly remediable evils, and no one can feel that science has been properly applied to human life until they are swept off the face of the earth." (p.409, 410).

Social ethics addresses moral decisions in the organization of human relationships, including the development of social policy. Much of social philosophy, and thus, social ethics, is based in social contract theory, first developed by authors such as Thomas Hobbes, John Locke, and Jean-Jacques Rousseau.

Social contract theories. Traditionally, this set of theories assumes that persons of free choice can and will make reasoned decisions in order to cooperate with one another (e.g., contractual agreement). Otherwise, life for all persons would be chaotic. The concept of the state (i.e., government) is justified through this appeal. From this perspective, professional persons gain their status by entering into a social contract (e.g., a public trust) with inherent rights and correlative duties. Public dialogue about patients' and human rights (e.g., the right to health care, the right to voluntary participation in research) usually is based on the concept of free, (i.e., autonomous) choice. Thus, social contract theories incorporate expectations that individuals who benefit from common self-interests will cooperate freely with corresponding social obligations (e.g., compliance with traffic laws, allocation of tax dollars to fund health research).

The primary critique of social contract theories pertains to the assumption that humans are free, equally independent, and socially isolated, if not mutually disinterested in the welfare of others. Rather than being free and unconstrained, a person's ethical decisions, moral character, and actions may be viewed as the result of social context and political influences. Indeed, some theorists argue that human good is only achieved through communal dialogue, requiring that persons exist as members of communities in order to achieve morally reasoned choice.

A common dilemma for health researchers working in low-income communities or developing countries is consideration about offering incentives to research subjects. Examples of research incentives include payments for an individual subject's time or payment to the community leadership or institutions. Included among justifications for offering incentives to research participants are: 1) costs incurred (e.g., lost work time, parking fees, child care, meeting space) and 2) exchange of specific expertise (e.g., knowledge of symptoms; knowledge of the local community). However, the practice of paying incentives has been criticized as constraining free choice or as coercive. From this viewpoint, the realities of some individual's life conditions may influence their choice toward accepting an incentive. Thus, incentives may constrain a prospective subject's choice to decline participation. Also, in particular settings, like small villages, the receipt of research incentives by

participating residents, but not others, may disadvantage those not selected or deciding not to participate.

Questions for Reflection:

- Besides finances, what other influences on voluntary research participation may exist?
- What social influences effect political policy regarding patients' rights?

Social Justice. Simply stated, justice is fairness. However, the application of this concept is very complex across many areas of ethical decision making. The concept of justice is addressed by ethical theories in several ways, ranging from a teleological focus on utility (i.e., what is "just" ultimately is that which benefits the most persons) to a relational focus (e.g., fairness is what enhances relationships between persons, communities, and countries). In health care, discussions about justice usually apply to **distributive justice** (i.e., fairness in allocation of society's benefits and burdens, such as health care and health care costs). Distributive justice is differentiated from **retributive justice** (i.e., criminal punishment or revenge) and **rectificatory justice** (i.e., compensatory measures for breaches in cooperation). Justice is also distinguished from **generosity**, which implies allocation of benefits to an individual beyond those deemed to be warranted.

Currently, public discussions of social justice in health care are taking place in the context of overarching, broad commentaries about science and morality. First, inquiries have been raised about the dualistic notion of good prevailing over evil versus more pluralistic notions of truth and justice. Illustrative questions arise:

When does the imposition of a prevailing view about "goodness" constitute injustice to others (e.g., Marketing by USA companies of tobacco products to other countries)?

"Is any act fair and just if it occurs between presumably consenting, cooperating persons (e.g., bride sales; euthanasia)?

To what extent does science inform decisions about justice (e.g., research on the rationing of health care)?

Internationally, many factors influence concepts of justice, including scientific standards of "good practice" in the context of impoverished resources. For example, the realities of maternity care and occupational health in some countries include a severely limited supply of surgical gloves for protection against blood borne pathogens. Indeed, the explicit notion of "fair and impartial" (e.g., objectivity) has been challenged anew. Regarding objectivity, critics believe that humans live interdependently versus independently. Rather, most persons do not make observations and decisions, either moral or scientific, in isolation from social influences. Claims have been made that truth and justice might be determined more rationally by resolving disparate viewpoints, thereby more closely approximating reality and ideal fairness.

From this critical standpoint, social scientists may be misguided if their efforts are limited to objective descriptions about social problems. Instead of merely observing social problems, some authors have claimed, social science and scientists have an ethical responsibility to generate new knowledge while simultaneously addressing practical concerns in a collaborative process with concerned persons – or to learn about social systems while changing them (Lewin, 1946; Rapaport, 1970).

A final criticism of many ethical theories is that concepts of justice have frequently focused on the scarcity model (e.g., fair distribution of **limited** social resources or material goods). Rather, critics claim, true justice involves an obligation of society to strive for adequate rather than to share inadequate levels of material goods and social services that may be required for the pursuit of happiness. Young (1990) also claims that justice compels addressing the way that social institutions limit or support life conditions. Thus, justice commands the use of existing resources to create conditions in which each person can determine and develop the capacities that fit their life choices and actions.

Concepts addressed by different theories of justice include:

- Liberty (e.g., freedom, autonomy)
- Equality (e.g., equals treated equally)
- Rights (e.g., entitlement to self-determination)
- Desert (e.g., what is deserved or fairly due and warranted)
- Reciprocity (e.g., mutual obligation)

Thus, some concepts of justice attempt to describe fair allocation of social benefits and burdens, based on individualistic rights or just due. Other concepts of justice mandate the use of differential wealth in ways that have the greatest good for those persons with the least. Finally, some theorists claim that common control over means of production can abolish differences in social benefits and burdens, ending the scarcity of necessary material goods.

Questions for reflection:

- In the past, scientists that engaged in unethical, even criminal behavior, have been subject to punishment under the law. When health researchers fail to meet the standards for the “responsible conduct of science,” what is their social responsibility?
- In international research, how can individual researchers from the USA foster reciprocity between themselves and their colleagues in a host country?
- Controversy about fairness to private enterprise versus the availability of knowledge for the common good have arisen following proposals to legally patent identified human genes. What do you think and feel about this issue?

Globalization and Health Research

“The next society will be a knowledge society. Knowledge will be its key resource... [Knowledge] will be borderless....” (p.2) (Drucker, 2001).

Increased global mobility, including the new wave of immigration to the USA and world travel for pleasure and business, has highlighted concerns for global health. Some of these issues can be framed as ethical concerns in the health field, including concerns about justice, obligation, relationships, and the common good.

For example, within the USA, stark differences exist in health status across ethnic and income groups of the country's population. This situation has resulted in research foci of the National Institutes of Health on causal influences and means to remedy these disparities. Additionally, across developed and developing countries, global challenges include the need to address existing disparities in population health, including the discrepancies in allocation of research resources to improve economic and health conditions.

Internationally, issues that have raised ethical concerns about global health include:

- 1) The resurgence of uncontrollable infectious diseases,
- 2) Environmental contamination,
- 3) Availability of health knowledge via internet technologies,
- 4) International collaboration during natural disasters,
- 5) Global marketing of health products and services,
- 6) Threats related to weapons of war,
- 7) Cross-national health research, including pharmaceutical studies.

Fundamental questions arise: "Is globalization good for health? Is health necessary for global stability and improvement?"

One report of the World Health Organization (WHO) concluded that global economic investment in health will save lives (i.e., 8 million lives) and also produce significant economic gain (i.e., \$360 billion annual gain over 15 years). Economic growth does not inevitably improve population health status. However, improvement of health may depend on economic investment, especially investment in close to client (e.g., at the community level) health services. The WHO report concluded that improved health is a critical requirement for economic development, especially in poor countries (Commission on Macroeconomics, 2001).

Also, in a 2001 analysis of global public goods and health, Kaul and Faust concluded:

In a globalizing world, the national (private) interests of countries are sometimes best served through international cooperation with others. Even though some goods are privately produced, it may be efficient to enable producers to keep the public interest in mind. The public interest would include not only the effective demands of the rich, but also the urgent needs of the poor" (p. 872-873).

Burden of disease. Wide disparities in health status exist among different cultural groups within country borders and across different national boundaries. In the past, research investment has not been proportionate to these disparate health conditions. Webber and Kremer (2001)

summarized global health research and development (R&D). In 1992, while 50% of research dollars were undertaken by private industry, less than 5% was allocated for diseases effecting less developed countries. Also, citing Pecoul's 1999 report, the authors state, "Of 1223 new chemical entities marketed worldwide between 1975-1996, only 13 were developed specifically for tropical diseases."

While classic epidemiologic rates of mortality and morbidity have been used in the past to report global health statistics, more recent methods have been developed to better reflect comparable health conditions across cultural groups and national borders.

*One method applied recently is the **Disability-Adjusted Life Year (DALY)**, which is used to measure burden of disease. DALY's express the years of life lost, resulting from premature death and years of a person's life spent with a disability. The indicator adjusts for different severity levels of the disability. One DALY is one year of healthy life lost. **Disease burden can be defined as the level of difference between a population's actual health status and a selected reference status (e.g., average life expectancy at birth for a standardized model population).***

Using DALY's as the method of analysis, the *World Health Report, 1999*, determined that a significant portion of the global burden of disease rests in avoidable conditions, particularly infections diseases. Also, maternal mortality risks are unacceptably high and concentrated in developing countries, among the three major causes of disease burden. This situation persists in spite of known interventions for maternal conditions (i.e., obstructed labor, sepsis, and unsafe abortion) that were among the ten leading causes of death and disability among women aged 15 to 44 years.

WHO proposed the model of Primary Health Care (PHC) as an approach to address local community and global health. Espousing the values of accessibility, affordability, and acceptability of health care to patients and communities, the PHC model integrates collaboration across social sectors (e.g., education and health). PHC also incorporates an expanded role for health personnel as collaborators with other societal members in affecting the social influences that determine the health of persons, communities, and countries.

Collaborative research among international researchers is needed to address these global health disparities. Yet, ethical concerns arise in the conduct of international research, particularly in developing countries. Abdool Karim (2001) discussed some of these issues:

"...a prime factor in the decision to participate in clinical trials can be the belief among those eligible that participation will result in better medical treatment... Language creates additional constraints, such as when there are no local words for 'placebo' and 'randomization.' One way of enhancing informed participation...is through researcher-community partnership...To achieve and sustain such community-based approaches,

funding agencies need to be made cognizant of such models and to set aside funds for this purpose" (p.1)

Professional Ethics

Characteristics of a Profession. Many occupational groups claim a “professional” identity for their members and some groups endorse a “code of ethics” as evidence of their professionalism. However, forms of occupational control, within either professional and other work groups, may influence the manner in which ethical standards function.

In the past, defined traits of a professional group were based on the analysis of education in the health care field (Flexner, 1915). The essence of professional practice centered on key common values and behaviors. Traditionally, some elements considered critical to professional practice include:

- Independent thinking applied to understanding and resolving problems
- Development of ongoing, systematic knowledge
- Transfer of knowledge and techniques through education using specialized symbols
- Autonomous decision-making with responsibility, and therefore, inherent risk
- Code of ethics with ideal of service for social good
- Public trust with social contract for self-governance

From a somewhat different perspective, a profession may be distinguished from occupational or apprenticeship pursuits by identifying:

- Public approval for a competitive and defended jurisdiction
- Abstract knowledge applied for practical benefit
- Monopolistic boundaries created and maintained for the practice culture
- Status and prestige associated with acquired knowledge

One view of professionalism is that of a self-limiting group with power for enhancing the moral behavior of group members or for penalizing unethical behavior. The “collegial” form of self-policing in professional ethics assumes an altruism among members of the group. Noted examples of the service ideal exist within health and other professions. However, too often, gross failures of self-policing within professions lead to tragic consequences, with child abuse by some members of the clergy being a recently reported and highly publicized example. The occurrence of the human radiation experiments is an example in health research (Advisory Committee on Human Radiation Experiments, 1995).

A different form of occupational control with ethical significance occurs when a professional is employed by a consumer of their professional services (e.g., a nurse employed by a hospital). In this situation, there is a risk of narrowing autonomy for professional ethics. An employer may consider ethical and practice standards of a professional group (e.g., professional codes of ethics) as secondary to workplace expectations. Such a situation may lead to incongruence between the realities of the employment situation and the ideals of professional practice.

One past example of this has been the health care conditions in some nursing homes, especially those institutions that accepted patients with psychiatric conditions without meeting professional standards for the care of those with mental illness.

Another example: A health professional objected to the protocols of a proposed research study. However, administrators of the employing institution were in favor of the study's approval, since great public prestige and notoriety were associated with participation as a research site for the study.

In yet another situation, professional ethics are influenced by a "third party" (e.g., government policy or insurance). In this case, decision making is constrained for the receiver of services and the professional provider. The "middle man" control limits professional autonomy and, perhaps subsequently, ethical responsibility for meeting professional standards of practice.

Classically, this situation may be illustrated by pre-approval or non-approval of reimbursement for health services by case managers of private health insurance.

An extreme example of this situation is health professional practice during time of war. If conditions are beyond control of the professional, ethical responsibility for maintaining professional practice standards take into account available resources and levels of personal risk.

Professional Codes of Ethics. Professional associations have accepted the role of identifying and espousing the key values of their members based on the social contract and public trust. This role includes activities such as ongoing reform of the profession, serving as a vehicle for communicating professional standards, and integrating the ethics of the profession into the values of society at large. The method commonly used by professional organizations to communicate ethical standards to professional members and to society is the "code of ethics."

Codes of ethics are not without criticism. While purporting to protect the public trust, codes of ethics may insulate a profession against unwanted outside control. Another criticism of professional codes is the very fact that these standards are determined by members of the professions themselves rather than representatives of the persons served by the profession. However, professional autonomy is not inconsistent with the public good simply because it represents professional self-interest. The primary issue confronting professional self-regulation through codes of ethics is whether the professional values are serving the public well or, alternatively, serving too well by overriding the public interest and common morality.

Therefore, a quandary exists regarding professional ethics:

- It is assumed that the core values of a profession are justified by appeal to common moral norms.
- Yet, professional values may supercede common morality when in conflict

- Thus, a fundamental question arises: Does professional status limit or enhance ethical decision making?

While differences are distinct across the codes of ethics for various professional groups, there are specific values frequently found in common. At least two moral issues commonly identified in professional codes are:

- 1) Confidentiality: Maintain confidences despite vital interest to others.
- 2) Loyalty: Exhibit allegiance to either an employer or to the broader community

Questions for Reflection:

- Do you believe that professional codes of ethics enhance your professional ethics by increasing your accountability?
- Do professional codes place an unreasonable burden on professionals to achieve ethical standards and create public expectations that are not based in the reality of daily practice?

Ethics of Professional Practice and Health Research. Professional groups strive to establish standards of practice that ensure high quality of services to the public. Professional codes of ethics are guidelines that attempt to assure the moral behavior of professionals within acceptable ethical conduct and defined standards of professional practice. To maintain scientific integrity, research studies investigating health issues must be designed to comply with basic standards of professional practice, including ethical behavior. For health professionals who conduct research, the role of researcher may coincide and/or conflict with the role of health care provider. This blurring of the clinical and research roles of health professionals may create dilemmas for the health professional and confusion or even risk for the health care recipient or research subject. In health research, professional practice standards, codes of ethics, and guidelines for scientific integrity must all interact with sound practices of scientific inquiry. These strategies are designed to protect human subjects while assuring their safe and quality health care in the context of knowledge development.

Question for Reflection:

What's wrong with this picture?

A senior surgical resident is seeing patients in an outpatient setting. The resident is evaluating the health problems of a 48 year old woman who is experiencing serious dysfunctional uterine bleeding. The nurse assists the resident in the evaluation of the patient and observes the resident spending a significant amount of time reviewing and explaining the indications and procedures of a hysterectomy to her. Later, after the woman had left the clinic, the nurse inquires in regard to the woman's decision about treatment. The resident indicates personal relief that the woman decided to have the surgery, since the resident needed additional experience with the surgical procedure and is a co-investigator on a research study related to hysterectomies.

Professional Authorship Issues

Dissemination of research findings is a responsibility of professionals who have completed research investigations. With competitive pressure for publication and the complexity of multiple team contributors to collaborative, multiple site research investigations, issues of authorship confront participants on the research teams. Ethical issues relevant to discussions of research authorship include veracity (i.e., truthfulness), duty (i.e., accountability/responsibility), and justice (i.e., fairness).

Many problems involved in decisions about authorship center on **research quality**. Dissemination of research results depends on participation of qualified professionals who make an intellectual contribution to the actual development of the research report.

*Therefore, science relies to some extent on trust for accuracy of scientific content; **truthfulness** is essential for the evaluation of scientific merit.*

In addition, authors are **accountable** for the integrity of the content in their published report and they accept public responsibility related to that content. At times, with multiple aspects of complex research designs, involving multiple sites and team members across international settings, this accountability can be daunting.

A second issue that is important when determining authorship is **fair credit** for research contributions. The issue of credit may become volatile due to high stakes for academic careers and conflicting perceptions about individual contributions. Further complexities arise from the multiple stages involved in the course of research:

- 1) Creative conceptualization early in the research process,
- 2) Planning the research design, implementation and analysis,
- 3) Synthesis/interpretation and drawing conclusions, and
- 4) Actual writing of the research report.

Different participants in research investigations may have varying strengths related to each phase of the study; yet, recognition may be warranted for any “substantive” contribution at any particular phase –early or late in the process.

Issues of credit can be blurred further by the formal and informal roles related to the research study. In some cases, consultants and employed staff members may have distinct responsibilities for limited aspects of the research. **However, under circumstances of substantive contribution to the overall research study, authorship credit is warranted for these research team members, provided they accept accountability for the content of the research report.** However, when these conditions are not met, yet team members or others have made a significant contribution to advancing the research, public acknowledgment rather than authorship may be deemed appropriate.

Various guidelines for determination of authorship have been proposed, including those from Erlen and colleagues (1997). These include:

- “Learn from others experience
- Involve the entire team in the discussion
- Establish guidelines early
- Define the roles of each member of the research team
- Set rules for assignment of authorship order
- Develop general guidelines for author responsibilities
- Address conflict resolution” (p. 262-270).

However, as has been established, decisions based on rules raise questions about the circumstances when those rules will apply. Because of these difficulties, alternative guidelines exist for decisions about authorship, including:

- 1) Alphabetical listing of those identified for authorship credit and responsibility,
- 2) Single authorship only, and
- 3) All inclusive listing of contributors (distinguished from authors) to the research process is reported in the publication.

In a commentary in the New England Journal of Medicine, Kaissirer and Angell (1991) cited the criteria of the International Committee of Medical Journal Editors:

“Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met” (p. 1511).

Question for Reflections:

- What criteria do you believe to be important for determining authorship of research publications?

Professional Ethics in Nursing

The history of nursing is rooted in religious and militaristic hierarchy. During many periods of historical development, the role of nursing in health care also has been tied to medicine. Despite concerted efforts in recent years to establish professional autonomy, the discipline of nursing continues to be encompassed within the “medical sciences” in many public forums.

However, ethical issues underlie attempts to identify the philosophical foundations that distinguish the nursing profession. Traditionally, nursing has meant the care of persons, individually or in groups, during illness or for promotion of health, in the context of their relationships and other environmental influences (Meleis & Trangenstein, 1994). Yet, while remaining true to the fundamental concepts of health and environment, contemporary nursing authors have tried to focus the ideological values that define the experiences identified with professional nurses and their services (Gadow, 1980).

Issues of ethical concern have a significant presence in scholarly nursing literature, including the journal, *Nursing Ethics: An International Journal for Health Care Professionals*. Ranging from dilemmas about patient safety to reporting of scientific misconduct in nursing, ethical issues constitute important concerns for nursing clinical practice and research. However, in recent years, two predominant, but not mutually exclusive values have prevailed in discourse about nursing ethics: **Advocacy and Care**.

Advocacy can be defined as support, assistance, encouragement and protection. In nursing, advocacy has been conceptualized as:

“existential... the nurse’s participation with the patient in determining the unique meaning which the experience of health, illness, suffering, or dying is to have for that individual” (p. 81) (Gadow, 1980). *However, more commonly in nursing and broadly in health care, advocacy has meant the professional obligation to protect the rights of health care consumers – primarily patients* (Bernal, 1992).

The advocacy model places nurses in the role of ardently supporting the rights of patients and negotiating for those rights within health care systems. The ideology of advocacy for patients has been incorporated into the American Nurses Association’s Code of Ethics. Specifically, this has been interpreted as a nurse’s professional duty to identify and take measures to correct health care practices that do not meet clinical, ethical, or legal standards.

Frequently, the advocacy model in nursing ethics articulates several assumptions:

- Patients are vulnerable and their rights require protection
- Patients will accept nurses as advocating on their behalf
- Nurses are in a unique professional position for the advocacy role
- Nurses have the capacities to advocate on behalf of the patient
- Professional autonomy is a necessary condition for exercising the advocacy role.

While widely embraced throughout nursing, the adequacy of this ethical theory for application in nurse’s clinical practice has been challenged. In particular, critics observe that the protection of patients’ rights and standards for practice is embraced, at least theoretically, by most professions in the health field rather than being unique to nursing. Also, the nursing profession’s claim to an advocacy role has been viewed as confrontational (Benjamin, 2001). And the associated stance for professional autonomy – in this case, greater protection for nurse’s independent decision making - has been criticized as professional self interest (Bernal, 1992).

Perhaps most problematic for advocacy as a nursing ethic is the condition of independent autonomy in professional practice. Nurses are often subject to the form of occupational control resulting from their employment situations. Thus, patient advocacy is the primary professional and ethical responsibility for nurses; however nurses may have primary occupational responsibility to their employers – creating the reality of practical conflicts, if not ethical and moral dilemmas. Yet, advocating for the rights of patients remains a standard of ethical practice

within nursing and nurses are held accountable for maintaining this standard in their professional practice.

Ethic of care. Stemming from the work of feminist ethicists, many nursing theorists have embraced the concepts associated with the “ethic of care” (Gilligan, 1982; Noddings, 1984).

The basic premise of this theory is that ethical dilemmas arise from conflicts relating to relationships and responsibilities rather than arising from conflicts about justice over competing rights. This perspective acknowledges a moral sentiment for an “affective” as well as cognitive dimension. Caring is informed concern with encompassing involvement that is more than benevolence, sympathy, or even compassion. This ethical theory describes the concept of receptivity – a flexible responsiveness to another’s reality. The recognition of this reality becomes the guide to resolving ethical dilemmas and courses of moral action.

From this perspective, social and global institutions must be reconceptualized to enable caring relations among people. The “ethic of care” claims values of inclusion, protection from harm, love, trust, attention, and interdependence (Benjamin, 2001).

In summary, key concepts in the ethic of care include:

- Moral dilemmas are conflicts of responsibility versus rights
- Solutions to ethical conflicts are based in relationship strengthening
- The concept of self is integral to relationships and social meaning
- Appeals to justice or rights are based in domination or subordination

In focusing on relational responsibility, caring as a “virtue” incorporates mutuality and an appreciation for perceived life context. Caring theorists are among those challenging the benefit of rationality, claiming that belief in objectivity ignores fundamental aspects of human life and posits ideals unattainable by human beings. Choice is seen as socially constructed and consent occurs in the context of social conditions. Self is conceived as mind over body versus body over mind. Significance in relationships rests not with formal equality but informal inequality. An important aspect in feminist ethics is the notion that gender differences exist in moral perspectives, whether biologically based or socially constructed, but these differences are compatible and of equal worth.

Concerns regarding limitations for applying the ethic of care to health issues include:

- 1) Will this theory impose self sacrifice?
- 2) How will needs of particular individuals be equitably met?
- 3) Does addressing specific situational foci meet the need for social structure?
- 4) Will personal solutions be encouraged over institutional and social change?
- 5) Does acknowledging gender based differences affect moral imperatives?
- 6) Can caring strengthen moral virtue across cultural contexts?

Caring has been called the “essence of nursing.” Claiming more than mere kindness, nursing theorists have described caring in a professional role as requiring commitment, knowledge, and practice. In response to the limitations of more classical ethical theories, many nurses embraced

the ethic of care as a constructive concept for approaching ethical dilemmas perceived in their professional role.

Concepts such as empathy have long been incorporated into professional education in nursing, independent of a nursing student's gender. While not unique to nursing, or to any profession or discipline, caring is valued by nurses as an important component of human relationships. Yet, even nurses who value caring as a professional virtue recognize occupational constraints on their professional actions and functions. Rather than fostering the role of caring interactions, if not advocacy, such occupational constraints may limit adherence with ideals of caring relationship with patients. Indeed, in the context of hierarchical disapproval, the fear of occupational reprisals, such as termination of employment, may strongly encourage nurses to remain silent about ethical concerns for patients, while they weigh the very real meaning of caring for both patients and for themselves.

Autonomy. Nursing has recognized the value of self-determination for patients. In this sense, autonomy is an ethical principle applied to the ethics of patients' rights. However, in professional discourse about ethics in nursing, autonomy also has been discussed as it applies to professional integrity and jurisdiction. The question is often posed: "Are nurses entitled, if not required, to act upon their own professional judgment in patient situations of ethical concern?" Others might ask, "Are nurses sufficiently independent from the risk of occupational reprisal to enable autonomous professional decisions and actions that are consistent with patients' best interests?" Many nurses care strongly about their right to ethical decision making. However, in the public discourse about health care, it remains a matter of debate whether autonomy for nurses will be viewed as professional self-interest or a matter of public interest necessary for protection of the public good.

Implied in this discussion is the preparedness of nurses to accept responsibility for their professional and ethical decisions. Whether as independently functioning professionals or as members of a collaborative professional team, nurses and their patients will experience the results of moral decisions and actions. Nurses must acquire the skills necessary to participate in ethical decisions as informed and capable professionals.

As the World Health Organization's model of Primary Health care has espoused, health care decisions, including ethical decisions, occur across many sectors of society. Nurses and others are moral agents and members of local and global communities. Through collaborative participation in health care and health research, nurses may contribute to health and social policy decisions that improve health care and reflect ethical considerations.

Questions for Reflection:

- What has been your experience with ethical decisions by professional colleagues?
- How can nurses structure their professional practice to assure integrity of ethical decisions?
- What can nursing research contribute to ethical decisions in health care?

Additional Activities:

- Review the American Nursing Association’s Code of Ethics
- Compare a Code of Ethics for another discipline, either within or outside of health field.
- Read the World Health Organization’s Declaration of Alma Alta [about Primary Health Care]
- Describe your own important moral beliefs and write a short paragraph about how these influence your ethical choices in nursing and health care.

Additional Resources

Note: Please refer to Reference List.

- ANA Position papers.
- Position papers of nursing specialty organizations: e.g., www.apna.org/position “Position statement on the use of seclusion and restraint.”
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College of Nursing, University of Illinois at Chicago
MINORITY INTERNATIONAL RESEARCH TRAINING (MIRT) PROGRAM
Curriculum on International Research Ethics (CIRE)

Module II: Perspectives on Research Ethics
Teresa Savage, RN, PhD

Overview

To maintain public trust in the research enterprise, researchers must demonstrate the responsible conduct of research. With an increasing need for international research in health, it is critical to develop strategies to educate researchers in the responsible conduct of research and human subjects protection during global collaboration.

Competencies

This module will help the learner define human subjects research, describe critical elements that must be present in order for research to be conducted ethically, and to define scientific integrity. In order to do this, the learner should be familiar with regulations that govern research in their own country as well as in international settings.

Objectives

By the completion of this section, the learner will:

- Define human subjects research
- Describe critical elements that must be present in order for research to be conducted ethically.
- Define scientific integrity.
- List and describe the tenets of the most frequently cited codes governing research ethics.
- Describe the U.S. system for research oversight. Students should obtain forms from their own institution and speak with someone serving on an IRB about research oversight in the U.S.
- Identify differences in the conduct and oversight of research in international settings.

Key Ideas and Concepts/Definitions

- Bioethics
- Clinical research
- Codes and regulations
- Ethical principles and theories
- Ethics
- Historical perspective
- Human subject
- Institutional Review Board (IRB)
- Minimal risk
- Primary health care research
- Standard of care
- Research
- Research oversight
- Therapeutic misconception
- Vulnerable populations

Bioethics – the field of applied ethics focusing on medicine, health care, and the human condition.

Clinical research – systematic investigations, usually involving human subjects, leading to the discovery of new knowledge and/or support or refutation of a testable hypothesis.

Codes and regulations – many countries have specific codes and/or regulations to govern research; many of the codes and regulations were derived from the Nuremberg Code, a set of statements resulting from the revelations of research atrocities during World War II discovered during the trials of the Nazi doctors who conducted the experiments. References for resources of various codes and regulations are in the reference list.

Ethical principles and theories – There are four overarching principles: Autonomy, beneficence, non-maleficence, and justice. Other principles such as veracity and fidelity are embedded in the four major principles. Briefly defined, autonomy means self-rule. It is based on respect for others. One makes decisions for oneself and those decisions are honored by others out of respect for the individual. Autonomy is paramount in ethical decision-making for people in the Western world, especially the U.S. Beneficence means to do good; non-maleficence means to prevent harm. Who decides what is good or harmful is key. Justice has many definitions, but in bioethics, justice usually refers to distributive justice, the fair allocation of the benefits and burdens of society. Allocation of resources in society is a justice issue. The major ethical perspectives in bioethics are utilitarianism, deontology, ethics of caring, and virtue ethics. Utilitarianism deals with maximizing the good for the greatest number. Recruitment of a large number of people for a vaccine study, and accepting that a small percentage will be harmed directly by the experimental vaccine, is an example of a utilitarian approach to human subject research. Deontology, by contrast, is a non-consequentialistic approach and follows a rule or judges an act as good or bad regardless of the outcome. A deontologist might decide that to cause harm to anyone through the testing of a vaccine is never acceptable. The ethics of caring is described as a contrast to the way some people perform moral reasoning. Moral reasoning is the identification of the problem, then application of the ethical principles in an abstract, objective way. The “ethics of caring” was coined to describe the process used by some people, often women, in which the context of the problem was key, and preservation of relationships and relief of burden, even to the point of self-sacrifice, was the desired outcome. Virtue ethics is the individual’s reliance on their moral upbringing to behave in an ethical fashion.

Ethics - basic principles governing moral life (Beauchamp & Walters, 1982). While some philosophers would claim that there are universal rights and wrongs (Kant, 1959) others would say that ethics is relative and dependent upon the situation and context (Fletcher, 1966). Research conducted in various settings and countries would be expected to conform to globally accepted guidelines of ethics, yet there may be some variation and interpretation of those rules. This module will introduce the learner to the “standards” of the responsible and ethical conduct of research while acknowledging the points of controversy.

Historical perspective - Students in the health care professions are probably aware of the ugly history of experiments on unwilling human subjects during World War II. One of the Nuremberg Trials was held to prosecute doctors who conducted the experiments and performed

medicalized killing of prisoners in concentration camps. The Nuremberg Code was developed to describe what conditions should be present before research is conducted on human subjects. Other rules and codes (World Medical Association, Declaration of Helsinki; Belmont Report (Common Rule); the Councils for International Organizations of Medical Sciences, International Ethical Guidelines for Biomedical Research Involving Human Subjects, for example) have been proposed and adopted by different groups. Each code or guideline lists conditions that should be met before research is conducted with human subjects. In brief, the proposed research should have scientific merit, should be designed in such a way as to minimize potential harm to the subjects and maximize potential benefits and accrual of knowledge that can be used to improve the human condition. The proposed investigation cannot be conducted without human subjects, and the recruitment plan provides for equitable and respectful recruitment of subjects. Data are kept confidential and are appropriately analyzed and interpreted. The investigator is qualified to conduct the study and will train and supervise research personnel. Appropriate approval and oversight of research has been obtained and is on-going while research is underway. Subjects are aware of the approval and oversight, and can contact the responsible oversight body. Students who wish more detail can see attached information on the NIH Human Subjects Protection website or consult one of the references on the attached list. (Additional links to other website, e.g. Tuskegee, Willowbrook, Human Radiation Experiments, etc.)

Human subject – a living person; data, which may include personal identifying information is collected through interaction, intervention, or observation for research purposes (Common Rule, 1991)

Institutional Review Board (IRB) – group of local community members charged with approving and monitoring research conducted by investigators at their institution; IRB can also be assembled by a private company hired by an institution to provide review, approval, and monitoring of the institution's research; Canada refers to these groups as Research Ethics Committees (REC), other countries may have other names e.g. ethics committees, review committees

Minimal risk – probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and psychological examination or tests (Common Rule, 1991)

Primary health care research – systematic investigations, usually with persons or communities, focused on gaining generalizable knowledge in the area of primary health care; Primary Health Care (PHC) emphasizes essential health services that are accessible, affordable, and acceptable to community residents. PHC delivery encourages partnerships between community residents and health professionals to achieve health goals. PHC stresses community participation, transfer of appropriate technology, public education for health, decentralization and coordination of services across geographic sectors, and the integration of health improvement with overall social, economic, and environmental development. PHC strategies are characterized by the processes of self-learning, self-determination, self-care, and self-reliance on the part of stakeholders.

Standard of care – the accepted community approach in assessment and management of a given health condition

Research – systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (Common Rule, 1991)

Research oversight – designated bodies, such as Institution Review Boards, or research ethics committees, to review research proposals and monitor approved studies for the expressed purpose of ensuring human subject protection

Therapeutic misconception – the impression by a potential research subject that participation in the research will result in a direct benefit to the subject; the purpose of many studies is to determine the safety and side effects of a given intervention, not to provide a benefit to the subject in the study

Vulnerable populations – Codes for research ethics identify special populations, such as pregnant women, fetuses, children, prisoners, people who lack decision-making capacity, economically disadvantaged persons, and students and employees of the research institution, who require special protections if they are to participate in human subjects research

Fundamentals in Research

The research begins with a researchable question and a sound research design that results in a meritorious project.

Questions to Consider:

- Is this study appropriate to the intended population?
- Do participants have anything to gain or lose if they agree to be included in the study?
- Why are these particular participants (or this particular community) being recruited for this study?

Research is the systematic investigation of a phenomenon of interest for the purposes of describing or testing the phenomenon, thereby developing or contributing to generalizable knowledge. There are several different research methodologies, such as quantitative research, qualitative research, or epidemiological research. Examples of each type of research will be presented throughout this module. Each methodology poses different ethical challenges. One aspect of designing the study that the investigators must consider is the benefit/risk assessment. The investigators must estimate the potential benefit to society in relation to the potential risks to the subjects. The subjects must have enough information to perform their own benefit/risk analysis before deciding to participate in the study.

Questions to Consider:

- Is there possibility for a direct benefit to the subject for participation?
- Is information being presented in a manner that the subject can understand?
- Is it presented without coercion or undue influence?
- Does the subject have the opportunity to consult with others who are usually involved in the subject's decision-making process?

- Does the subject understand the purpose(s) and procedure(s) of the study?

Each potential subject should evaluate whether the benefit of participation outweighs the risks. The dominant culture in the U.S. values the autonomy of people to make their own decisions; other cultures in the U.S. and other countries may value the benefit to the community over the benefit to any single individual. Regardless, each person must decide that there is no direct benefit but the knowledge gained may help others.

The recruitment process should be equitable and non-coercive. For quantitative research, such as a clinical trial, subjects in the desired population should have an equal chance of being selected to participate. Commonly, in pilot studies where subjects must follow complex directions or complete standardized tests, U.S. researchers limit their selection of subjects to English-speaking only. The National Institutes of Health insists that every effort be made include people whose native language is not English.

Questions to Consider:

- Does the subject have a fair opportunity to be selected to participate in the study?
- Is the recruitment process respectful, non-coercive, and sensitive to the community?

Autonomy again predominates in the recruitment process, so that a person's privacy is protected and there is equity in the opportunity to participate in research. Other cultures and countries may require that there be a "go-between" or "gatekeeper" to gain access to certain groups. Some groups may be inaccessible, such as married women in societies where consent of their husbands or a community leader is required.

Questions to Consider:

- What does a researcher do when a woman wants to participate but her husband does not want her to participate? Or if she does not want to participate but her husband wants her to?

The consent process should be culturally appropriate and comprehensible by potential subjects. In some countries, written documentation may be waived, however, under U.S. regulations researchers must obtain approval from the appropriate oversight committee to waive written consent. In some groups or societies, consent of someone other than the subject may be required but consent of the subject is always required. In the U.S., people who lack decisional capacity, such as minors and people with dementia or other cognitive disabilities, can participate only with their assent and the permission of a legally authorized representative (specified by state statute, usually parent, spouse, or legal guardian).

Questions to consider:

- Is the consent process consistent with the subject's culture and usual consent process?
- Are there others whose consent should be obtained prior to subject's consent being sought?
- When should a waiver of documentation of informed consent be requested?
- What is the difference between **assent** and **consent**?

Assent is the affirmative agreement, rather than the lack of objection. **Consent** is the legal term indicating that the person has agreed to participate in the study. **Informed consent** means that

the person has the capacity to make a decision, has been informed and comprehends the information so that he/she can arrive at a decision. A person can revoke consent during the study, and must be informed of the consequences of that revocation.

In U.S. regulations, only adults with decision-making capacity (also referred to as competent adults) can give informed consent. Parents or other legally authorized representatives may give permission for another person, a child or a person who lacks decision-making capacity, depending upon state law and institutional policies. Assent is required from children (unless there is a possibility of direct benefit, such as clinical trials for cancer treatment) and from adults who lack decisional capacity. Adults who lack capacity may have intellectual disabilities congenitally or from brain injury, dementia, or other neurologic condition. If the adult cannot give assent, research would only be permitted under special circumstances.

Example #1: A researcher wants to study the changing level of consciousness in persons in coma. The person in coma is unable to consent, or give assent, yet there may be value studying their responses as they come out of coma. There may be local or national laws identifying who can consent for persons in a coma; the researcher must learn what is the prevailing custom or law.

Example #2: Another researcher may be interested in the use of medication to treat ischemic stroke. The person experiencing an ischemic stroke may be incapacitated and unable to communicate, therefore unable to consent or give assent to experimental treatment, yet the treatment's efficacy cannot be determined without administration at the time of the incapacitation.

Example #3: A researcher plans to study the use of condoms by adolescents, and may plan to interview adolescents who come to a community center. Traditionally, parental permission would be required, as well as the assent of the adolescent. In order to obtain honest responses, the researcher wants to conduct the interviews anonymously, waive documentation of informed consent so there is no link to the subject's interview and the subject's name. The researcher must justify to the oversight committee why it is for the protection of the adolescent to forgo written consent, and to forgo parental permission. It is extremely important that the researcher design the study in a culturally appropriate way to protect the rights of potential subjects and to demonstrate respect for individuals, their culture, and their laws.

There is the possibility of confusion when treatment is being studied in the research process. Patients who are invited to be study participants may assume that the research is being conducted to offer them a benefit. When they have the impression that the research offers them the hope of benefit, it is called the **therapeutic misconception**.

Questions to Consider:

- Does the individual understand if there is NO direct benefit possible from participation in this study?
- Is randomization explained in a way that the participant can understand?

Some studies have the potential to benefit subjects, but are being conducted to gain knowledge. That knowledge may eventually bring about a benefit, but will not benefit the subjects in the earlier studies. People who join studies in the belief that the study will help them have a therapeutic misconception. The informed consent process should include assessment of the individuals's understanding of the purpose of the study and the potential for benefit to the subject.

Example #1: A pharmaceutical company wishes to study an experimental drug for the treatment of psoriasis. The first human subject phase involves identifying people with psoriasis and excluding those people with other conditions that could confound the results (such as liver dysfunction, blood dyscrasias, or any other condition identified in animal studies). The purpose of the study is to learn the possible side effects of the medication. Any potential benefit is a secondary finding in the study. Subjects who enroll, however, may believe that the purpose of the study is to learn if the medication improves their condition (**therapeutic misconception**). Researchers must stress to the subjects that the purpose is to learn side effects of the medication. What is learned from the study may benefit people with psoriasis in the future.

Subjects should receive feedback from their participation. This may be in the form of learning the results of a study, as well as how to access appropriate post-study treatment, if needed. In the above example, people who participated in the psoriasis study may be informed when the drug is available. In some studies involving life-limiting or life-threatening illnesses, there is debate over whether studies should be conducted with populations who may not have access to the treatment once approved for marketing. Researchers in developed countries who conduct studies in the developing countries should have a plan for making their efficacious interventions available after conclusion of the research.

Questions to Consider:

- Does the subject understand that the research study is intended to generate generalizable knowledge, but may not provide any information that is immediately useful for the subject?
- Should the oversight committee insist that the researcher make the treatment, if efficacious, available in an affordable arrangement, to the population on which it was tested?

Researchers share their results through peer-reviewed publications and presentations at professional conferences. Many researchers may arrange to present their results back to the subjects from the study and the community in which the subjects belong. In the recruitment process, the researcher may have been asked to provide specific tangibles to the community in order to gain access to the community to recruit subjects. The tangibles may be in the form of direct payment to community leaders, a promise of sharing results, and a promise of continuing the experimental intervention if it is found to be beneficial. The tangibles, however, may not be so influential that the subjects are otherwise induced to participate, when they may not have participated without the tangibles (incentives). It is critical that the researcher understand the culture of the population of potential subjects so that the tangibles are appropriate. For example, offering a child money equivalent to \$500 for participation in a study would be considered

coercive. The excessive amount would entice the child to participate, and likely would entice the parent to have the child participate even if the risks were high if the parent needed the money. The incentive should not be so great as to induce participation of an individual who was not otherwise inclined to participate. The oversight committee is one group that assesses the appropriateness of the research incentives or compensation. There may be other people or groups in the community who expect compensation for access to potential study participants. Although in the U.S. this would be regarded as “finder’s fees” and has been denounced as unethical, it is present in other countries and usually the research cannot be conducted without these transactions.

Research Oversight

Protection of human subjects – In the U.S., the National Institutes of Health (NIH) permits local institutions to review and approve, according to federal regulations, research conducted by their employees. In the past these institutions have obtained Multiple Project Assurance or MPA. A Single Project Assurance (SPA) means that the researcher must go directly to NIH for approval of a study. In 2000, NIH replaced the MPA and SPA with a Federal-Wide Assurance (FWA), one for domestic research and one for international research. “...each legally separate institution must obtain its own FWA, and assurances approved under this process would cover all of the institution’s federally supported human research” (National Bioethics Advisory Commission, 2001, Vol. I, p. 80). U.S. researchers, under the FWA, may use their institutions existing IRB, use an IRB of another institution, or use an independent IRB. Foreign institutions are permitted to abide by the World Medical Associations Declaration of Helsinki, the U.S. Belmont Report, or other relevant international research guidelines as an alternative to U.S. regulations. No matter the configuration of the research oversight body, all personnel are required to complete training on the relevant guidelines or regulations pertinent to the protection of human subjects.

Institutional Review Board (IRB) (U.S. and local in host country)

The IRB is an officially sanctioned committee convened for the purpose of protecting human subjects. These committees consist of professionals and lay community members who review applications of research proposals prepared by the investigator. The proposals describe the purpose, procedures, possible risks and benefits, recruitment methods, compensations, consent process, and any other pertinent aspects of a study that could pose a risk to the subject. (Some committees also review the proposals for scientific merit if the proposals have not been reviewed by another group for that purpose.)

In an international setting, there may be numerous groups that must review and approve the proposal prior to permitting the researcher to conduct the study. The researcher in a foreign country must learn the appropriate channels to follow. In the U.S., a research proposal is reviewed by various groups prior to its implementation. One of the first groups is the potential funder who convenes a study section to review the proposal for scientific merit. Proposals lacking merit are unlikely to get funded. The next group to review the proposal is the IRB. The IRB reviews the proposal for measures to protect human subjects while providing a benefit to society. The IRB follows regulations based on the Belmont Report, or Common Rule. When the researcher documents the plan for conducting the study, and the plan meets with the IRB’s approval, the research is approved. The researcher must notify the IRB and funder of any

adverse events, and must apply for continuing approval at the interval required by the IRB. Some institutions may conduct periodic audits of consents, recruitment methods, and data collection and storage. Other regulatory bodies, such as the Food and Drug Administration, may require certain documentation and may monitor the study.

In other countries, there may be a national organization overseeing human subject research, or the responsibility may be at the local level. Research ethics committees are convened to review and approve research in their jurisdiction. The country may subscribe to the tenets of the Declaration of Helsinki, the International Conference on Harmonization of Technical Requirement for Registration of Pharmaceuticals for Human Use, Guidelines for Good Clinical Practice, the Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Review of Epidemiological Studies, International Ethical Guidelines for Biomedical Research Involving Human Research (Brody, 1998), the National Bioethics Advisory Commission Ethical and policy issues in international research, or the Clinical trials in developing countries (2001). It behooves the student to be familiar with the ethical policies governing research oversight in the host country (see appendix for references or websites).

Scientific Integrity

Misconduct and reporting of misconduct – There are various forms of scientific misconduct. The most obvious misconduct would be the falsification of data. Researchers may omit data or invent data that will skew the results in the desired direction. Sloppiness in any aspect of the research process can result in misconduct. Not protecting the rights of human subjects is also considered scientific misconduct. Enrolling subjects who do not meet the inclusion/exclusion criteria, not withdrawing subjects when they request withdrawal, not informing subjects of the risks or overemphasizing the potential benefits are all examples of scientific misconduct. The oversight committee must often rely on the research team to maintain their integrity or to report instances of misconduct. The oversight committee depends on reports generated by the principal investigator on the progress of the research, and may have the authority to examine data, review consent documents, or meet subjects. The auditing and monitoring procedures are probably the weakest piece of the oversight process, as they require manpower and resources beyond most committees.

Clinicians who are conducting research may be faced with ethical issues in the clinical setting. A nurse researcher may question the care a patient is receiving, or may believe it would be in the patient's best interests to intervene as a clinician, rather than a researcher.

Example #1: A nurse researcher in an African country is recruiting subjects to participate in her study on sexually transmitted disease transmission. She is present when a pregnant woman comes to the clinic in distress. The woman is complaining of severe pain and is bleeding heavily. The researcher, who is also a midwife, suspects an abruption of the placenta. There is no physician present and the only local midwife is assisting another woman in delivery of twins. Does the nurse researcher provide direct treatment to the woman in distress?

Example #2: A student is assisting a researcher in data collection. She is taking blood pressure measurements in a clinic and conducting a brief interview with the subjects. She learns from one female subject that the woman has been beaten by her husband that morning, and the student believes the woman requires medical attention for possible fractured ribs. With the woman's permission, the student asks the clinic nurse to see the woman, but is informed that the woman is married to a tribal leader and it would be unwise to treat her. What should the student do?

Questions to Consider:

- What do nurses (nurse faculty) consider scientific misconduct? (Falsification of data, plagiarism, breaches of research ethics?)
- What do they do in their setting if they suspect scientific misconduct?
- How should nurse researchers address clinical ethical issues in their role as researchers?

Other Ethical Issues for Nurse Researchers

In addition to overseeing the scientific conduct of the research being conducted, the nurse researcher has other ethical issues to address. As indicated above, there are issues of boundaries between the nurse as a researcher and as a clinician. As a knowledgeable clinician who has access to information within the clinical setting, the nurse researcher may feel obligated to advocate on the part of the patient when the patient may be harmed. As previously stated, however, the assessment of harm is relative and contextual. The nurse researcher may need to carefully consider potential situations and what resources are available to her to resolve ethical issues in her setting.

Another ethical issue the researcher must address is the order of authorship in any publications resulting from her research. There are no clearly agreed-upon guidelines for inclusion or order of authors. Various health care disciplines have different perspectives and “rules of thumb,” such as the chair of the researcher's department is listed as the last author on every publication, or the person who had the research idea is the first author. No matter what decisions are made, it is advisable to negotiate any authorship. A person in the community who facilitates the research through access to patients or navigation through the approval process may insist on authorship. The researcher may use a specific journal's guidelines or the published guidelines of a professional group, if available, as a resource in the negotiation process.

Vulnerable Populations (as defined by Belmont Report)

Historically, certain groups of people have been exploited or ignored in the research enterprise. Concern about harm to the fetus, especially after the thalidomide experience where infants were born with various forms of phocomelia (deformity or absence of limbs), virtually prohibited all research on pregnant women and fetuses. Children were also prohibited, even after it was clear that one could not extrapolate findings from adult studies and apply them to children. Other groups were considered vulnerable, such as prisoners, or students and employees of the research institution. The element of coercion could not be eliminated for these groups. People who lack decisional capacity, such as the poor, residents in facilities for the mentally ill or mentally retarded, or the elderly with dementia, are viewed as vulnerable and in need of added protections. There are regulations for pregnant women and fetuses, children, and prisoners that were adopted by all of the federal agencies funding research. A consensus was not reached on regulations for

people lacking decisional capacity, so it rests on the individual research oversight body to build in protections for these groups.

Questions to Consider:

- What other groups may be considered vulnerable participants in research?
- How do researchers adapt the research process when they believe they should/must include participants from vulnerable populations?

Primary Health Care and Research

The researcher should perform an assessment of community benefit /risk if a study is conducted. What does the community have to gain or what could the community lose as a result of this study being conducted?

Questions to Consider:

- How does the researcher (an outsider) gather the information about the potential benefits/risks to the community?
- How is the information presented to the community?
- Who are the decision-makers in the community—the leaders, the potential subjects, others?

The researcher must be knowledgeable about the community in order to recruit respectfully and appropriately in the community.

Questions to Consider:

- What is culturally appropriate?
- Whose permission must be obtained before subjects can be approached?
- How does the researcher respond if one adult gives permission for another adult to participate, for example, a husband giving or refusing permission for his wife to participate, regardless of her wishes?

In the U.S., consent of a competent adult participant is required. In other countries, however, it may be necessary and culturally appropriate to get consent from the adult and others, such as a spouse, tribal elder, or community leader.

Questions to consider:

- Do all cultures and communities view documentation of consent the same as the U.S.?
- How does a researcher satisfy regulations if subjects refuse to sign the consent form?

Some communities in developing countries are selected because the researchers want to test their treatment in comparison to no treatment. There may be a number of conditions in which there is no curative treatment. The community standard may be palliative treatment. However, in the developed country, there may be an approved treatment that has become the standard of care. The developing country does not have the approved treatment, because of lack of resources (cost is prohibitive, appropriate trained personnel are not available). The issue of community standard is raised.

Questions to Consider:

- What is the community standard, in terms of treatment of a particular condition?

It has been proposed that researchers have an obligation to provide access to beneficial treatment to the community of the research subjects after the conclusion of the study. Some sponsors of research specifically select certain communities who do not have the same standards of care as the U.S. so that they can study their intervention compared to no treatment.

Example #1: Researchers wanted to study their preparation of artificial surfactant, a lubricant-like substance, used to treat lung immaturity in preterm newborns. Every nursery in the U.S. uses a form of surfactant in preterm newborns meeting certain criteria. A country in South America does not use surfactant as the standard. Therefore the sponsor proposed randomizing infants to a treatment or control group in which the treatment group received surfactant and the control group received a placebo, which is consistent with the usual treatment. The outcome for infants receiving the usual treatment was death. Critics of this plan thought that the sponsors should provide all pre-term newborns with surfactant. They could compare the use of their product with another formulation of surfactant. Since the lack of use of surfactant resulted in death of the infants, although the lack of use was the community standard of care, critics believed it was unethical to withhold surfactant treatment. Proponents of the sponsor's plan to withhold surfactant to the control group argued that fewer subjects would be needed with a randomized double-blind placebo trial, the study could be conducted more quickly, and fewer infants would die in the long term if their product's efficacy was known. Again critics observed that having more than one company produce surfactant was not a reasonable trade-off for allowing preventable deaths to occur during the research process. [At the time this was written, the study had not been approved.]

Feedback to the Community

Much research is devoted to discovering efficacious treatments or interventions for health conditions in humans. Again, historically, researchers from developed countries have conducted studies in developing countries because of the lack of restrictive research regulations or the rapidity in which studies can gain approval and be conducted. One can view this as exploitative or it could be seen as efficient if new treatments or interventions can be made available more quickly. However, if the benefits of the research are not available to the subjects after the research is completed, the exploitative view seems appropriate.

Questions to Consider:

- What was the community promised?
- Should the researcher share the results if there is the possibility of harm to anyone in the community?
- In the U.S. the researcher is viewed as the owner of the research data, but is this a universal view?
- If the researcher gathers personal identifiable information, can the researcher remove the data from the country, or does the data belong to the subjects/community?

- Does the researcher have an obligation to work with the study population to address issues of accessibility, affordability, sustainability of study's intervention, if beneficial?
- Should the community expect that beneficial interventions will be available upon completion of the study?
- Is it ethical to provide an intervention, determine that it is beneficial, then discontinue its availability?
- Should some arrangements be made to provide access to the intervention to the community after completion of the study?

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Appendix A

Clinical trial example

Research is the systematic investigation of a phenomenon of interest for the purposes of describing or testing the phenomenon, thereby developing or contributing to generalizable knowledge. To conduct research, the investigator must employ a methodology that is appropriate to the research question and develop a sound research design that is likely to yield useful information. Even before designing the project, the investigator refines the research question through searching the literature and consulting experts or other informants to support the need for and significance of the study. In order for a study to be ethical, a number of questions should be answered affirmatively: Is the phenomenon of interest important? For example, an investigator may want to know whether or not an experimental drug is a better treatment for an infection than another drug that is considered the standard of care. The investigator believes that the experimental Drug X will have fewer side effects, should cure the infection in a shorter period of time, and costs less than the standard drug. The investigator's beliefs are the hypotheses of the study when stated this way:

H1: Drug X has fewer side effects than the standard drug (standard drug has 5 side effects, which are.....)

H2: Drug X cures the infection in a shorter time than the standard drug (standard drug cures infection in 14-21 days).

H3: Drug X costs less than the standard drug (standard drug costs \$10/dose; \$280/14 day course; \$420 for 21 day course).

The study is designed in a way to test the two drugs with a sample of subjects drawn from the same population (people with a certain type of infection). The sample size is large enough and is selected in such a way to control for bias. The most common way to control for bias is to assign subjects into either an experimental group, where they will receive Drug X, or the control group, where they will receive the standard drug. Both the investigators dealing directly with the subjects and the subjects themselves will not know to which group they have been assigned. The drugs are prepared in such a way as to appear identical. This "blinding" controls any bias that the investigator or subjects may have toward either drug. Subjects must be willing to be randomly assigned to either group. When the desired sample size is reached and all data collected, the investigator uses appropriate methods of analysis to determine the results of the study. Through statistical analysis, the investigator judges whether or not the hypotheses were supported. Did subjects taking Drug X experience few side effects than subjects taking the standard drug? Did subjects taking Drug X have their infection cured in a shorter time than subjects taking the standard drug? Is the cost for treating infections in the group taking Drug X lower than the group taking the standard drug? Whether or not the hypotheses are supported or refuted, generalizable knowledge has been gained. It is just as important to know that Drug X is not the better drug as it is to know that it is the better drug.

International considerations: Does the specific type of infection occur in this host country? Is the "standard treatment" available in this host country? Could the people in the potential subject pool obtain and afford the standard treatment? Will the experimental drug be available and affordable to the community after the study is completed? Is the consent process comprehensible to the potential subject pool? Are there cultural considerations related to the infection, or treatment that would affect subject participation? Are the procedures understandable and able to

be followed by the potential subject pool? Are the compensations, if any, appropriate and non-coercive to the potential subject pool? Is treatment and monetary compensation available if subjects are harmed by their participation in this study?

Ethical Conditions To Conduct Human Subjects Research

Research quality

The above example is simplified and is missing some important pieces. Is this study scientifically sound? Why is this important? In order for research to be useful, it must be acquired in such a way as to be valid and reliable, credible and trustworthy. Research that is not scientifically sound leads to inaccurate and misleading findings, and shows disrespect for the subjects asked to participate. The least amount of harm poor research can do is waste time and resources; the worst is to jeopardize the lives of humans during the research study or as a result of applying its faulty results.

Another missing piece in the example is a discussion of recruitment of subjects, the informed consent process, and the monitoring of the safety of subjects during the study. Subjects should be recruited in such a way that those who meet the inclusion criteria, which in this example would be that they had a certain type of infection, have an equal chance of being included in the study, that they would be willingly randomized to the experimental or control group, and that there is no undue influence on them to participate if they do not want to participate. They should be informed that they may withdraw from the study at any time, it will not jeopardize their medical treatment, or under what conditions the investigator may withdraw them from the study or cancel the study. If the subject participation includes spending a great deal of time having tests done, completing questionnaires, or staying in the hospital, they may be given monetary compensation for their time and efforts. The compensation, however, should not be so great as to influence them to be in the study if they would not otherwise participate.

The subjects should receive information about the study and be asked if they would participate without being coerced. Some believe that if the subject's treating physician presents the information, the subject may agree, thinking that the physician would not ask if the study would not benefit the subject. This assumption on the subject's part is called a "therapeutic misconception," and it means that the subject assumes the study will be of benefit, even if the investigator indicates that the subject may not benefit. In the Drug X example, both groups received a medication that would benefit them by treating their infection. The experiment was to see which drug worked faster, caused fewer side effects, and was less costly. However, in some drug experiments, the experimental drug may not benefit the subject at all, and may even be harmful. In cancer treatment, new drugs may be given and compared to the standard of care. Drug AB may be given to subjects with a brain tumor, and compared to subjects who get the standard treatment for brain tumors. In comparing medication to treat stiff, non-pliable lungs in critically ill subjects, one group may get an experimental drug and the other group get a placebo, or an inert drug that has no medicinal value. Although both groups would agree to be randomized and are informed that they may receive the active, experimental drug or the inactive placebo, subjects may believe that they will benefit from being in the study. It is the responsibility of the investigator to clearly communicate with the subjects to ensure they make an informed decision about their participation.

International considerations: Is there equity in recruiting subjects? Are people from a particular segment of society more likely to be recruited or eliminated? Are subjects who predominately speak a certain language eliminated because of the research team's lack of fluency in that certain language? Is the information, such as randomization and blinding, presented to potential subjects in a comprehensible way?

The investigator has an ethical responsibility to only conduct research for which he or she is qualified, or to have a research team with all the appropriate skills and talents to conduct the study. Subjects are recruited in a respectful and equitable way. Risks are minimized and data is kept in a way to protect the confidentiality of the subjects. Subjects are informed that the study has been approved by the local institutional review board (IRB) for the investigator's institution (and, possibly, other institutions as well), and is given written information on how to contact the investigator and IRB (if written information is culturally appropriate). How does one tell "good" research from "bad" research? Review the tenets of the Nuremberg Code (summarized in II of above outline) and see if the research adheres to these tenets. Research ethics is a branch of applied ethics pertaining to the planning, implementing, monitoring, evaluating and reporting of research.

Fundamental Research Ethics In Conducting Research With Humans

Risk/benefit assessment

Again, the Drug X example is simplified and did not capture all the nuances of research ethics in a research study. The investigator must estimate the risk/benefit ratio in order to justify exposing a subject to any risk. Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research is not greater than the risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Which of the following studies would be considered minimal risk?

Study A. Participants are asked to participate in a study where someone takes their blood pressure

Study B. Participants are asked to agree to randomization into one of two groups—experimental and control (placebo). The experimental group will receive an active drug not yet approved by the Food and Drug Administration (FDA) and the control group will receive an inactive substance that has a physical appearance identical to the experimental drug.

Study C. Participants are asked to complete questionnaires that ask personal information about a socially stigmatizing condition.

Three assessments of benefit and risk occur. The investigator assesses the potential benefit to the participants and the potential benefit of the generalizable knowledge if the study is completed. Those benefits are weighed against the known risks and possible unforeseen harms. The investigator offers the rationale for why the benefits outweigh the risks, and provides this rationale to the IRB or local research oversight body. The IRB makes a judgment about the risk/benefit ratio and decides whether or not additional protections of subjects would be indicated if the research were approved. The final assessment occurs when potential participants

consider the benefits and risks, as they see them, and decide whether or not to participate in the study.

Recruitment Process

The recruitment process has been discussed in the Drug X example. The Drug X study is considered a quantitative study as data from two groups are statistically compared and a statistically significant difference between groups is sought. Participants were recruited using criteria for inclusion or exclusion as a way to control for potential unexplained variance in the findings. Conditions which might confound results, such as having two types of infections or taking multiple medications are criteria used to judge exclusion from a study. Recruitment was conducted in local clinics and other ambulatory settings, where health care providers were informed of the study and participant eligibility criteria. Individuals interested in participation contacted the research team to obtain more information about the study. In qualitative research, recruitment may consist of the investigator contacting specific persons to invite them to participate based on their position, role, or ability to inform on a particular topic. The “snowball technique” for recruitment occurs when a current participant refers a friend or colleague to the investigator for information about the study. The recruitment technique must be appropriate to the research. Suppose the researcher posted an advertisement in a local establishment that read “Wanted: Research subjects. \$500 for participation in the entire study. Call Dr. Doe at 555-5555.” Would you be inclined to call? Is the \$500 coercive? If an individual would not otherwise participate in the study, the \$500 is considered coercive. The judgment on whether a certain compensation amount is coercive is a topic that is frequently debated at IRB meetings. The investigator must justify compensation for the time and effort of participants. At times the IRB may require the investigator to change the amount offered.

Consent Process

The concept of informed consent, written or verbal agreement to participate, is the bedrock of research ethics. In democratic societies, autonomy, self-rule, and self-determination are greatly valued. Before participants join a study, they must be fully informed of the purpose of the study, the procedures, any alternatives to participation, the potential risks and benefits, expected duration of the study, how to withdraw from the research and the consequences of withdrawal, how confidentiality will be maintained, and who to contact for information about the study or about their rights as research subjects. If the study involves greater than minimal risk, subjects should be informed of what medical treatment and/or compensation is available and where they can get more information. Subjects are reminded that participation is strictly voluntary. All of these elements must be included in the consent process. The investigator must provide this information in an understandable format, such as the subject’s native language, free of jargon and at an appropriate level for the population’s educational level. The process may need to occur over several meetings, or days prior to the intervention. Are there times when it would be inappropriate to obtain consent from the subjects? For example: During labor, a woman may be asked to participate in a study on circumcision. How might the timing affect her ability to give informed consent? The woman may be under the influence of medication, or may be significantly uncomfortable so that she could not attend to the information about the study. In the Drug X study, the subjects were given information by their healthcare provider once they were determined by the provider to be eligible for the study. The subject then contacted the investigator and learned about the study. Prior to signing the consent form, the investigator

reviewed the information and asked the subjects to summarize in their own words what the study is about, procedures, risks, benefits, etc. When the investigator is satisfied that the subject has the capacity to make an informed decision, and understands what was shared in the consent process, the subject can then be enrolled in the study. If the subject is required to make multiple visits, each time the subject comes back or is contacted, the investigator affirms that they wish to continue in the study. At any time, the subject may withdraw. If the withdrawal could cause harm to the subject, they are informed from the start and provisions are made to minimize harm from withdrawal in the study. In the Drug X study, if Subject #5 decided to withdraw, the investigator breaks the “blinding” of Subject #5’s group assignment and learns that #5 was in the experimental group. The investigator tells the subject that he was taking the experimental drug and he should now see his health care provider to obtain the standard drug for treatment of his infection. With Subject #5’s permission, the investigator may share data on Subject #5 with his health care provider.

International Considerations: Is a community leader’s approval required prior to approaching any community members for inclusion in the study? If an adult woman is being recruited, is it culturally appropriate to obtain her husband’s consent, or the consent of another family member as well as the woman’s consent? Would it be impossible to conduct the study without the consent of others besides the subject? How might this requirement bias the study?

Nursing Research

Specific challenges are faced by nurses conducting research in international settings while fulfilling their role within the hierarchy of a Western health care institution. For instance, conflict can occur between the role of the caregiver and the role of the researcher. Further, potential conflicts are raised by requirements that U.S. nursing researchers must follow U.S. regulations as well as conform to the host country standards. Where does the student turn for assistance in resolving ethical problems in such a situation? Here are a few examples of ethical problems to consider:

Patient who tests seropositive for HIV

A 35 year old woman presents at the clinic for evaluation of a persistent cough and night sweats. A blood test is taken and she is positive for HIV. The nurse asks her if she will ask her husband to come in for testing. The woman refuses to discuss her diagnosis with her husband because she has been with another man and if her husband is not positive, he will know that she was not a virgin when they married. The treatment for HIV is not available, or affordable, so she cannot see any reason for telling him. The nurse is aware of a clinical trial (a quantitative study) being conducted in their clinic and believes the woman may be eligible, as well as her husband, if he tests positive. Should she tell the woman about the study and persuade her to tell her husband to get tested?

Suppose that an epidemiological study was being conducted in country and the study required recording of identifying information about people with HIV. Should the above woman’s data be included, whether or not she consents? She refuses to sign a consent form.

Patient with advanced cancer

A 60 year old man is hospitalized with jaundice, ascites, and presumed liver dysfunction. He is diagnosed with terminal liver cancer. His son and daughter are told the diagnosis by the physician, but they ask that the patient not be told, and this request is consistent with the physician's experience. A nurse researcher is conducting a qualitative study on palliative care and wants to recruit the patient and family in her study. Does she need the physician's permission to talk to the patient? Does she need the family's permission to talk to the patient? Should the nurse not consider recruiting this patient since he does not know his diagnosis? Should the nurse conduct the study with this patient if the family gives consent but asks that the patient not be asked for consent since he could learn his terminal diagnosis during the consenting process?

Incentives and Undue Influence

A nurse researcher is conducting a study of contraceptive practices. She is recruiting women whose partners use condoms and she is providing a cash incentive for participation. Women who learn of the cash incentive desire to be in the study, but do not meet the eligibility requirements, i.e., their partners do not use condoms. They falsify their answers so they appear to meet the eligibility criteria, however, one woman tells the student working with the nurse researcher about the ruse. What is the student's responsibility? Is it unethical to offer an incentive that would induce participation in a subject who would not otherwise participate?

Epidemiological Studies

A midwife is doing a study in a community regarding childbirth practices. In recruiting subjects for interviews, the midwife learns that a young girl who is pregnant has been - and is being - beaten by her father. The girl reveals that she will kill herself if the beatings do not stop. What is the ethical obligation of the midwife/researcher to this girl?

Possible scientific misconduct

As a student, you are observing all aspects of a study—recruitment, consenting, and data collection. You discover that there are many apparent errors in recording the data, as the written data does not correspond with what you observed while the data were being collected. When you ask about the discrepancy, you are told that it would be considered impolite to record the information in front of the patient, so the data collector is relying on memory. She assures you that it is not important to record the data precisely. You ask the researcher about this practice, and she angrily dismisses the data collector who denies making any errors. The data collector is unemployed, the researcher has no one to collect her data, and study is suspended. Was this the most appropriate action you could have taken? What else could you have done?

Access to community for a fee

The nurse researcher from another country has obtained approvals from all the appropriate groups to conduct his study on attitudes toward people with disabilities. After he has recruited subjects to participate in a focus group, he learns that one of the community leaders insists that he pay a "fee" for administrative services before proceeding. The "fee" is \$1,500. The study is funded by a private organization in the researcher's home country. There are no discretionary funds budgeted, but the researcher reasons that he could make some adjustments in his planned expenses and pay the "fee." He does not think he can divulge paying this fee to the funder as he

believes it is tantamount to extortion, but he has invested too much at this point to drop his study. And he is aware that this type of request is not uncommon in poorer countries. Should the researcher pay the fee? Is it unethical to conceal it from his funder?

Truth-telling in recruitment

A nurse researcher plans to study infant positioning during sleep. In this community, most infants sleep in bed with their mothers on soft mattresses. The nurse believes this places the infants at risk for breathing obstruction, and wants to learn whether or not this is true. She points out the change from putting infants face down to face up in the last decade in the U.S. The community leaders are interested in learning this as well, but tell the researcher that she may not tell the mothers what she is actually studying. They say it suggests to the mothers that they are responsible if their infants die, and that's unacceptable. They agree to permit the researcher to study infant positioning, but she must tell the mothers that she is looking at something else other than infant mortality. Her study has merit and may help change practices to decrease infant mortality in this community. Should she lie to the mothers as the community leaders request, or find another site to conduct the study?

College of Nursing, University of Illinois at Chicago
MINORITY INTERNATIONAL RESEARCH TRAINING (MIRT) PROGRAM
Curriculum on International Research Ethics (CIRE)

Module III: Concepts of Culture
Sue Misner, RN, MS

Overview

Many views exist about the meaning of culture. Diverse cultural perspectives have important implications for health research. In international health research, sensitive awareness and accurate knowledge of culture is critical.

Competencies

The “Concepts of Culture” module of CIRE will help the learner obtain knowledge of cultural influences important in international research. Various definitions of culture will be identified. Key concepts about culture will be reviewed. Important differences in ways that culture may be considered for international research will be described. Learners will have an opportunity to review case situations.

Objectives

By the completion of this section, the learner will

- Identify various definitions of culture
- Define key concepts related to culture
- Recognize past ethical influences of health research on culture.
- Describe some contemporary influences of culture on the ethics of health research.
- Consider the role of international health research for cross-cultural leadership in ethics and human rights.

Key Ideas and Concepts/Definitions:

- Culture
- Ethnicity
- Race
- Diversity
- Culture shock
- Cultural internationalism
- Cross-cultural leadership

Definitions of Culture

The term “culture” has many meanings, varying from a notion of “the arts” to a “general interpretation of experience and knowledge that is used to explain or guide behavior.” Consider the following definitions of culture:

- A high degree of taste and refinement formed by aesthetic and intellectual training.
- Complex whole which includes knowledge, belief, art, morals, law, custom, and any other capabilities and habits acquired by man as a member of society.
- Culture refers to the common lifestyles, languages, behavior patterns, traditions, and beliefs that are learned and passed from one generation to the next.
- Culture is what guides people in their thinking, feeling, and acting, and serves as an emotional road map or plan of action in their struggle for survival.
- Culture is a state of being – a process rather than a person, place, or thing; a verb rather than a noun. ...Culture gives meaning to people's lives and is symbolically represented through language and interaction." (Arvizu, 2000).

Perceptions of culture influence individual and collective views of the world and approaches to knowledge development. The interaction of social customs, community values, and knowledge traditions will influence and be influenced by scientific research.

Ethnicity and race

Ethnicity refers to common group identification by race, nationality, religion, language, geography, or familial relations. Race is a classification of social determination that at times refers to mankind as a whole, as in the "human race," but more generally distinguishes group membership based on some physical characteristic or set of physical characteristics.

In conversation and in writing, including health literature, the terms culture, ethnicity, and race may be used in ways that carry the same meaning. This confusion may compromise the soundness of information about the health status and practices among groups of people. The lack of clarity also threatens the validity of research findings. For example, identification as "Hispanic" may have different meaning for the culture and health of a Latina woman who is an American citizen with Mexican parents of Native American descent versus a female citizen of Argentina with German and Spanish ancestral heritage.

As a classification for health research, race has received controversial scrutiny. Two issues focus the problematic nature of racial classification for determining health risk: 1) The confounding of research by uncontrolled environmental or non-genetic factors, and 2) The confusion of genotype (i.e., genetic characteristics) and phenotype (expression of genes in physical characteristics or symptoms) of disease.

The ambiguity of racial and ethnic classifications leads to assumptions of group homogeneity for heterogeneous cultures. Racial classification may lead to stereotyping based on erroneous assumptions about biologic traits, diverting efforts to address social influences on health. However, at the same time, the use of race as a social classification may help to identify disparities in health status influenced by discriminatory cultural practices (Goodman, 2000).

Diversity

Globalization, including changing demographics in the United States, continues to influence the health sectors of most countries. For health policy decisions, social and political demands from

groups previously marginalized continue to result in programs that strive for increased diversity of persons involved in health decision-making.

Issues of language require much more than mere literal translation and idiomatic awareness of colloquial terms. Researchers must be aware of the symbolic meaning of specific terms and the reference for local beliefs and values that words and phrases may hold within cultural groups. Differences in language meaning may be significant between the researcher's own cultural experience and the experience of the cultural group of research focus.

For example, the term "poverty," and terms commonly used in the U.S. as synonyms for "poverty," may hold various meanings in different cultural settings. In the past, some local U.S. urban groups have objected to descriptors such as "poverty" and "the poor" as demeaning labels that inadequately represented the true spirit of a community or group of people. These objections are centered in perspectives about differences between economic resources and personal resources.

However, English language terms suggested as alternatives for "poor," such as "low-income status," may not fully capture the essence of living conditions in all cultural settings. For instance, both in the USA and in other countries, some persons may have no annual income at all. In other settings, limited economic resources may be accompanied by class stigma, discrimination, access to political power, and available health care that may indeed be associated with very real constraints on life choices and, consequently, hopelessness. As Paulo Freire, the Brazilian educational philosopher once stated, "There is poverty and then there is misery" (Presentation, University of Illinois at Chicago, Undated).

Health science researchers in cross-cultural and international settings must have a keen sensitivity to language terms that have potential for emotional and/or political meaning. Much dialogue may be required during all phases of research activities to assess the nuances of these meanings and to find language terms that are acceptable to research participants.

Examples of **definitions of diversity** include:

The range of human perspectives, backgrounds, and experiences as reflected in characteristics such as age, class, ethnic origin, gender, nationality, physical and learning ability, race, religion, sexual orientation, and veteran's status. Other dimensions of diversity include but are not limited to, education, marital status, employment and geographic background, as well as cultural beliefs, and practices...

"The recognition of variation among people related to their cultural heritage, racial and ethnic identification, and gender and class experiences." (Arvizu, 2000).

Internationally, there is concern about the disparate health status among diverse population groups, both within and across national boundaries. Recently, health researchers internationally

have raised concerns about the disproportionate focus of large amounts of research funds spent globally on health concerns that impact only limited population groups.

Cultural Internationalism

While the term **internationalism** may be considered as an idea or movement seeking to reform the nature of relations among nations through cross-national cooperation and interchange, the term "cultural internationalism" has a more specific meaning. **Cultural internationalism** “entails a variety of activities undertaken to link countries and peoples through the exchange of ideas and persons, through scholarly cooperation, or through efforts at facilitating cross national understanding” (p3) (Iriye, A. 1997).

However, as identified in the National Bioethics Advisory Commission reports, concerns have emerged in poorer nations of the world that the pursuit of health research places a disproportionate burden of risk on subjects in developing countries. Some health advocates have claimed that the level of risk by subjects in poor countries constitutes an unethical burden. The term “**cultural imperialism**” has been applied to situations purported to breach ethical standards considering subject risk versus the eventual benefit, to either individual subjects or groups in developing countries compared to developed countries.

Cross-Cultural Leadership

“**Cross-cultural**” refers to different cultures within a country or between one cultural group and another. **Cross-national research** refers to research conducted in more than one country. Cross-national work may not be cross-cultural if the two nations are similar in the phenomenon of interest. Cross-national research is often cross-cultural, but cross-cultural research may or may not be cross-national (p. 17) (Corless, I.B. et al. 2001).

In cross-cultural research, the cultural context may influence implementation of the concepts of scientific integrity. For instance, in many research situations, informed consent is documented very clearly stating the research participant’s awareness of potential risks and benefits. Failure to obtain a written consent, documenting voluntary and informed participation, often would be considered unethical.

However, in some settings, cultural norms may discourage written documentation of consent. For example, in some cultural situations, participants may be extremely offended that verbal agreement is not accepted as a matter of trust. In other research environments, confidentiality of any written document may be compromised – perhaps due to political or familial control. Yet another exception for written documentation of consent may occur when individual participants have low literacy levels, risking offense when asked to make a “mark.”

The settings do not constitute waiver of voluntary participation and informed consent, but merely the documentation of these standards for the protection of human subjects.

For international research in health, the research team usually will include scientists from multiple countries. Yet, the responsibility for leadership or the principal investigator role for the international research often may be assigned to a single individual within a specific country.

Cross-cultural leadership in international health research has a goal of mutually beneficial and shared leadership responsibilities among scientists and individuals from multiple nations or cultural groups. Research designs may be developed to identify coinciding or collaborative investigations that lead to multiple leadership roles, including principal investigator status for multiple scientists from participating countries. Representation in leadership across cultural perspectives is thought to strengthen the overall relevance and potential contribution of research investigations.

Influence Of The Ethics Of Health Research On Culture

Historical Case Example - the Nazi Nurses.

Stemming originally from efforts to apply Mendelian genetics principles between 1910 and 1940, the field of eugenics was an effort in the biological development of so-called improved human beings. Eugenacists were scientists advocating the application of eugenics concepts in human reproduction with perceived “good” versus “bad” genes. Eugenacists in the United States brought political pressure for laws to separate races, restrict immigration, and to sterilize persons deemed to have “bad” genes.

Components of the USA eugenics movement eventually were applied to the Nazi program considered “euthanasia” of handicapped and mentally ill children and adults, and eventually the Holocaust (Corless, I.B., et al. 2001).

In Germany, during the years of Nazi power, nurses and doctors actively participated in the killing of thousands of persons deemed to have a “life not worthy of life.” During these killings, professionals acted in consort with colleagues rather than singly in isolation. Today, the explanation for this behavior may seem to elude us, but at the time, many of the health provider participants in these killings joined in the belief that their actions were either necessary or even merciful. While some may have perceived the threat of adverse outcome to themselves or their family members, others held to an ideology, based on eugenics, or to the principles of obedience to authority.

Influence Of Cultural Practices On Health Research

Contemporary example – Female circumcision

“Just because certain practices have existed for centuries, are widespread, and are widely accepted in some cultures does not make them ethically justifiable” (Best, K. 2001).

Numerous international groups advocating for health have ruled that the cultural practice of female genital cutting or female circumcision causes unacceptable harm. The lists of immediate and long-term complications are very long. In some countries, health practitioners have suggested that some of the complications of the female circumcision procedure are due to procedures by untrained personnel. Suggestions have been put forward that cultural tradition could be maintained and health complications diminished if the genital cutting procedure were altered or performed in

sterile settings by properly trained health providers. However, this proposed “scientific” approach has continued to be deemed unacceptable by global health and women’s rights advocacy groups.

Processes For Learning About Culture And Cultural Groups

Cultural awareness may be considered as obtaining information about the daily customs, food, religious, and other common practices of a group of people. The concept of **cultural competence** has been proposed to be the acquisition of a minimal amount of relevant information about another person’s culture to achieve effective cross-cultural communication. However, **cultural sensitivity** implies the capacity for an ongoing and caring manner of increasing insight about the meaning of culture for another individual’s or group’s daily practice and life.

Numerous strategies have been proposed for the study of culture and cultural groups, including study of language and arts/humanities. One model for the study of a culture’s basic values envisions ten basic message systems as listed below:

- 1) Language
- 2) Temporality (e.g. attitudes toward time, routine, and schedule)
- 3) Territoriality (e.g. space, property)
- 4) Exploitation (e.g. methods of control, use and sharing of resources)
- 5) Association (e.g. family, kin, community)
- 6) Subsistence (e.g. work, division of labor) Gender (e.g. differing modes of speech, dress, conduct)
- 7) Learning (e.g. observation, modeling, instruction, concepts of “truth”)
- 8) Play (e.g. humor, games)
- 9) Defense (e.g. health practices, social conflicts, beliefs)

(Adapted from Hall, E. T. 1973. *The Silent Language*. Garden City, N. Y: Doubleday).

Other models of learning how to adapt to international experiences include the concepts of **country shock and culture shock** (Storti, 2001). With country shock, the required changes for adaptation may not be specifically related to any cultural differences. In international work, much flexibility and effort may be required simply adjusting to changes in climate, available consumer items, routines, responsibilities, and familiar faces. In some international settings, community infrastructures may be unreliable, with electricity, transportation, communication, and even water supply being fragile.

With culture shock, cultural differences are centered on many deeply held beliefs, expectations, and views about the norms of good human behavior. These differences may lead to “confusion, misunderstanding, and misinterpretation “ (p.25) (Storti, 2001). Craig Storti describes two different situations that may occur:

- 1) The behavior of a person or persons from the local but different culture results in confusion, frustration, or other dismay by the newcomer, or
- 2) The behavior of the newcomer results in confusion, etc. in the local person or group.

For example, a researcher from the United States may be frustrated by the lack of medical supplies, etc., in an international setting. However, a partnering scientist from a host country with universal health care may be dismayed by the USA health policy described by the researcher: Each individual patient in the USA receiving treatment must demonstrate a system of payment for their fees for health services.

Questions for Reflections and Optional Activities:

- Some international leaders have suggested different goals for cross-national collaboration: 1) the vision of a global community, or 2) avoidance of nationalistic excess. What do you think is the value for collaborative international health research activities?
- Does “internationalism” constitute an “ism” in the sense of an ideological viewpoint/philosophy about world order?
- Based on your personal experience, how do you view culture and what beliefs do you hold that you think are culturally based?
- Optional case for ethics review:

ROAD ACCIDENT

(Adapted from www.hf.uib.no/i/Filosofisk/seahen/volume2.pdf)

As a student, you have been assigned to the Emergency Room at a local hospital to conduct observations related to your research on domestic violence situations. However, during your observation period, two persons of middle age are brought into the hospital with injuries resulting from traffic accidents. After immediate assessment, it is determined that major surgery, if successful, can restore the full function of the first victim. It is also assessed the second victim should have limited recovery with a major operation. Both are made aware of the expected outcomes of surgery and agree to comply with follow up treatments and medications. Both wish to be treated. However, it is uncertain whether the local hospital can manage successful operations on both victims in adequate time.

What is your view about the best manner to proceed?

What is the ethical basis for your decisions?

If it became known that one of the victims had attempted suicide and that became a factor in the decisions of hospital personnel, what would your viewpoints be in regard to this change in the situation.

Additional Resources And Activities:

Case example: *Bioethics on NBC's ER – When East Meets West: Cultural Norms Collide with Personal Autonomy in the ER.*

http://www.ajobonline.com/er_bioethics.php?task=view&articleID=429

Case example: *Examination and treatment of a women with impending abortion*

<http://www.hf.uib.no/i//Filosofisk/seahen/volume2.pdf>

Article: Starfield, B. (2000). Is US health really the best in the world? *JAMA*, 284(4), 483-485.

Article: Corless, I.B., Nicholas, P.K. & Nokes, K.M. (2001). Issues in cross-cultural quality-of-life research. *Journal of Nursing Scholarship*, 33(1), 15-20.

Book: DeVita, P.R. & Armstrong, J.D. (2001). *Distant mirrors: America as a foreign culture.* Stamford, CN: Wadsworth/Thomson Learning.

Website: Image Archive on the American Eugenics Movement

<http://vector.cshl.org/eugenics>

Website: Nurses' Participation in the "Euthanasia" Programs of Nazi Germany.

<http://www.interlog.com/~mighty/essays/nurses.htm>

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College of Nursing, University of Illinois at Chicago
MINORITY INTERNATIONAL RESEARCH TRAINING (MIRT) PROGRAM
Curriculum on International Research Ethics (CIRE)

Module IV: Concepts of Community/Communitarian Ethics

Elissa Dresden, RN, RN

Beverly J. McElmurry, EdD, FAAN

Overview

Exploring community influences and perspectives on ethics enriches the students understanding of research ethics, particularly in cross-cultural and cross-national settings. The conduct of international nursing research will benefit from an overview of communitarian ethics as an example of community perspectives. This module provides an orientation to community decision-making and participation in research.

Competencies

The “Concepts of Community” module (CIRE) will present the learner with a community-focused framework for examining research questions and methodologies in international research.

Objectives

By the completion of this section, the learner will:

- Describe a communitarian approach in international research.
- Understand how communitarian ethical perspectives may relate to one’s experience in the MIRT program.
- Analyze a selected case study from a communitarian perspective
- Compare an ethical perspective on the community to existing national and international research ethics guidelines.

Key Ideas and Concepts/Definitions

- Community
- Social ethics
- Social justice
- Distributive justice
- Participation
- Communitarianism
- Social constructionism

Introduction

In the last decade, scientists and ethicists have suggested that the existing research ethics guidelines and Western principled approach do not adequately address the role and influence of the community when conducting research (Callahan, 1994; Murray, 1994; Emanuel, 1995; Tukala, 2001; Zion, 1995; Bastian, 2001). Particularly in developing countries and across cultures, where a community may play a very different and significant role than what has been considered from the Western bioethical guidelines, many examples have arisen that reflect the

need to protect communities in research (Emanuel & Weijer, 2001, Zion, 1995; Callahan, 1994; Murray, 1994). In the United States, we believe in the primacy of autonomy and are accustomed to clearly examining any risks posed to individuals as a result of research. However, there has not been a firmly developed and accepted framework from which to understand what risks a community may face as a result of participation in research. Thus, it is crucial that the researcher who is planning to conduct international and cross-cultural studies appreciate the potential roles and responsibilities that a community may have in order to be a considerate, ethical professional. This is particularly important if the researcher has been largely educated and socialized in a perspective that has influenced the existing research ethics guidelines. This is considered by some to be called the Liberal Individualist approach (Meadowcraft, 1996; Arblaster, 1984).

In this approach, the individual is central as a rational self, able to make decisions and choices. Some of the philosophers who are considered to be the “heart” of the liberal tradition include Hobbes, Locke, Rousseau, and Smith. The liberal approach has been instrumental in the “design and workings of certain social and political institutions in modern democratic societies – for instance in the procedures of representative institutions, the regulation (or absence of regulation) of labor markets, in systems of punishment and legal authority, and so on” (Frazer, 1999, p. 18). It is partially this tradition that has significantly contributed to the development of several guidelines including the Nuremberg Code, the Belmont Report, and the Declaration of Helsinki. As is noted below, some of the guidelines have been responsive to the need to include a “community” component as researchers worldwide bring to light ethical dilemmas and circumstances. There is some acknowledgement that ethical reasoning “must include attention to social practices rather than only abstract moral propositions” (Marshall, Koenig, Grifhorst & Van Ewijk, 1998). A community-focused perspective allows for such attention to social practices.

There are many ideas and definitions of “community” and other key concepts relevant to this topic. For our purposes, we examine the communitarian definitions of terms and how they apply to international research ethics. This material is organized into several sections. The first section presents a definition of a few key concepts. Following this, justification is provided for using a communitarian or community-focused approach when conducting ethical research. We provide links and references to several established research ethics guidelines and outline how a communitarian perspective provides a necessary complement for thinking about the guidelines in our work with communities? The concept of “community consent” is developed in detail and highlighted with a case study. Finally, we consider practical applications for the MIRT scholar with reality-based case studies and situations s/he may experience.

I. Key Concepts

In this section we examine several key concepts and identify the importance of understanding a communitarian approach to international research ethics. While other ethical frameworks do recognize the significance of community, communitarians place it as central and irreducible. This approach is further viewed against the backdrop of several existing research ethics guidelines in order to highlight the significance of a community-focused approach to research ethics.

Community

Definitions of “community” can be found in the areas of sociology, philosophy, the health sciences, psychology and cultural studies. Several scholars have conducted behavioral research to help define this term (Dworkin, 1993; Bellah, 1995/6; MacQueen, K.M., McLellan E., Metzger D.S., Kegeles S., Strauss R.P., Scotti R., Blanchard L., & Trotter R.T, 2001) with findings that have not led to a cohesive and accepted definition. For our purposes, we focus on how the communitarians examine this term and its implications for research. However, this term is often not defined, and authors tend to rely on the reader to have already understood what “community” means.

From the communitarian perspective, it is important to situate community as not simply an aggregation, or population, but as a particular kind of shared and coherent relationship, beyond the household and family, where there are boundaries, such that membership rests on acceptance by existing members, and there are distinctions between insiders and outsiders. A community is not simply a state or market institution. Often community is reliant on being in a particular locality, or geographic setting. However, some consider this unnecessary, as there can be linguistic, religious and other communities that do not share a locality. The communitarians suggest that these are “partial communities”, (Frazer, p.73) that do not meet the full, multi-layered definition of community. Selznick states, “A group is a community to the extent that it encompasses a broad range of activities and interests, and to the extent that participation implicates the whole person rather than segmental interests or activities”(1992, p. 359). There is some disagreement in this as one communitarian scholar defines community simply when “we care about each other’s well being” and when “the community can lay moral claims on its members” (Etzioni, 1993, 31).

For most, the characteristics central to community include:

- Mutuality,
- Plurality,
- Autonomy,
- Participation,
- Historicity,
- Emphasis on identity,
- Integration,
- Interdependence, and
- Reciprocity.

There is a sense of belonging and a sharing of history. Communitarians look to the community for moral guidance and promise (Selznick, 1996), and consider that “individuals are realized only in and through communities, and that strong, healthy, morally vigorous communities are the prerequisite for strong, healthy, morally vigorous individuals” (Bellah, 1995/6). Such a community encourages enhanced responsibility and social justice. It is important to note that for the communitarians, the community encourages moral responsibility, thus, for example, a group based on oppression and human rights abuses would not be viewed as a community. In other words, if a group is formed on values of hate, oppression and human rights abuses, the communitarians would not see that as congruent with their definition of a community, as such an

oppressed group or society is not able to produce morally vigorous individuals with moral agency.

For the researcher, it is difficult to empirically validate a community, as there are neither definitive measures nor definitions. For example, a group of people may have a “community leader”, but an outsider cannot know for sure if this leader appropriately and adequately represents the “community” as defined by the community members. However, working in collaboration and equal partnership with self identified members of a community can provide the researcher with perspectives and information on why a particular group constitutes a community with shared values, norms and beliefs.

Communitarianism

A review of the history, politics and philosophies of communitarianism is well beyond the scope of this document. We have included an expanded reference list from which to pursue further interests. For our purposes, communitarianism can be defined as a view that emphasizes the centrality of contextual influences on the individual and sees the community as non-reducible, or as more than the sum of it’s parts.

Communitarians place much value on community and tradition. The focus is not on the individual as such, but on the social individual, or the community of which the individual is a member. In other words, what we are depends upon many factors such as tradition, culture, interpersonal relations, and family. This is congruent with a notion of “embeddedness”, in which individuals are couched in multiple contextual layers that play important roles in the development and identity of that individual. They do not believe that the individual, as such, stands or should stand in a disembedded and direct relationship with state and society.

Social Constructionism

This view is complementary with the process of social constructionism, a process of making, building, or constructing things as part of understanding the thing, or construct in question, whether that be an individual, institution or philosophy. Communitarians stress that values, roles, individuals, institutions, and philosophies are in some sense socially constructed (Frazer, 1999; Selznick, 1996). For example, a communitarian may consider that “the way to do ethics is not to try to deduce and apply universally valid fundamental principles, but to interpret and refine values that are immanent in the ways of the lives of really living groups – societies, communities. This way, ethical principles can be accepted and owned by social actors” (Frazer, 1999, p. 21).

From 1932 to 1972 the Public Health Service conducted the Tuskegee Syphilis study. The research team included nurses from the area, familiar with the people, culture and issues central to that time and place.

We would like you to watch the video “Miss Evers Boys” (HBO Home Video ISBN # 0-7831-1090-1) in order to understand how nurses become embedded in a socially constructed situation. In other words, how the nurses acquiesced to a research community that violated their rights during Tuskegee. Often, the social construction of the role of nurses through education, practice

and research creates this response to situations. Nurses face issues as they try to socially construct new perspectives on their roles.

Questions to examine after viewing the video are:

- What were some of the factors involved in why the nurse remained with the Tuskegee project?
- What choices did Nurse Evers have?
- What does it mean to be a "product of one's time?"
- Can you think of other historical or current situations where the ethical practice of nurses is constrained by factors that are similar?

Beyond the social constructions of ideas, communitarians place significance on the social commitment of "we, the community". A community member, by definition, participates in the community. These philosophers consider that the emphasis should move from rights to duties, and that the "duties and responsibilities of citizens to each other and to the community should balance individual rights (Frazer, 1999, p. 37). For communitarians, there is a common good toward which the community strives. They regard the community as a setting that promotes social justice and individual moral development.

Social Justice

There is no single, accepted definition of social justice. There exist among the definitions some similarities and differences. Definitions of social justice also differ depending upon the time and place, as social issues and conditions change with history and culture. Most definitions of social justice include ideas of equitable and fair access to resources and opportunities. In addition, the object, or purpose of social justice as well as the form, or process involves the good of others. Social justice is considered to be reactive, responding to specific unjust social conditions and working to alleviate the core causes of these conditions. For example, a group may work together to reduce or eliminate the number of community members who are homeless. On a surface level, the group can work to develop homeless shelters. To reach the root causes of the homelessness, however, issues of employment, affordable housing, job training and other methods may be developed.

From a community-focused perspective, social justice is both a basic value and a desired goal. As an individual can strive to be virtuous, so can a community or society. Groups working toward social justice often focus on systems and institutions rather than individuals. They are interested in equalizing the opportunities within the society. For communitarians, the individual and group participation toward this goal is key. The goal can be thought of as the promotion, production and protection of the common or public good. In this sense the public good is required for a just society.

Distributive Justice

Distributive justice also does not have a commonly accepted definition. It can be viewed as the relationship between the whole to its parts insofar as resources are distributed. In other words, it is the process of equitably sharing in what has been produced together. The various definitions include some economic conditions. For communitarians, there is a community or societal

obligation to the disadvantaged to fairly and appropriately distribute social goods such as wealth, opportunity and liberty. When there is inequality in income and wealth, a distributive justice approach would seek to fairly and appropriately distribute the resources. In addition, unequal distribution is permitted if it improves the position of the worst-off social group. Everyone has a say in decisions and no segment of the community is unfairly burdened with the harms of research.

Social Ethics

This is an area of ethics that generally examines issues significant to the society. It integrates philosophy, religious social teachings, and the social sciences into the study of values and morality in society. Some current topics include: abortion, slavery, euthanasia, and cloning.

II. The Concept Of Community And The Existing Guidelines

As a researcher in the United States, one is oriented to key national and international ethics guidelines. The U.S. based researcher not only learns these guidelines, but is obligated to follow them, particularly the national guidelines. Each guideline is a product of its time and place, and while there may be ongoing revisions, it is important to note the context in which the guideline was created. For example, the Nuremberg Code (1948) was created largely as a response by the international community to crimes against research subjects committed by medical researchers during World War II. The World Medical Association issued the Declaration of Helsinki in 1964, this document built upon the Nuremberg Code and added significant regulations for medicine. In 1993, the Council of International Organizations of Medical Sciences in collaboration with the World Health Organization created a guideline that supplemented the Declaration of Helsinki. This document was the first to specify the concern of providing protection to research subjects in developing countries. In the United States, researchers are guided by the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). This report is based upon three principles: justice, beneficence, and respect for persons (autonomy). Particularly in the United States, the orientation of bioethics corresponds to the Western emphases on individualism and autonomy (Callahan, 1994; Emanuel, 1995; Childress, 2000; Beauchamp & Childress, 1994).

There have been many criticisms of the existing ethical research guidelines. In particular, some critics have called for “the need for bioethics to develop a richer understanding of its societal dimension” (Callahan, 1994, p.28). This notion is especially prevalent around discussions of autonomy and informed consent. For example, in communities where persons other than the research subject make decisions, the existing guidelines are not helpful. Bastian (2001) states that “a meaningful role for the community in determining what is essential to enhance people’s health and their ability to exercise their rights is long overdue, both at global and local levels” (p. 1421).

Some scholars have examined the “principled approach” and suggested that the concept of community could be added as a fourth principle, (Emanuel & Weijer, 2001) or the principles could be interpreted within a communitarian rather than solely an individualistic framework (Childress, 2000). Using the second approach, the principles of beneficence, respect for persons

and justice would be re-examined with a communitarian lens, paying close attention to notions of embeddedness and other key components of communitarianism.

Beneficence

For example, in addition to balancing risks and benefits to individual subjects, one would pay close attention to the potential for harm to particular communities. Due to the involvement in research, some communities may be viewed as “diseased” or tainted and thus become the subjects of discrimination and harm. Recent developments in genetic patterns of disease inheritance speak to this potential trend. If a research team in a community is known to be conducting HIV/AIDS research, they may stigmatize the community in which they work, even if they are focusing on prevention and education.

Justice

Looking at justice from a communitarian perspective involves moving beyond the tasks of fairly selecting subjects and distributing benefits of research. As noted above, principles of social and distributive justice play key roles when examining an ethical approach. Using a community-focused approach, the researcher can explore in-depth what are some of the issues related to justice when conducting research in a community. Participation, in this view, includes just and equitable involvement by communities in the design and evaluation of the research. This view of participation highlights the duties-centered approach of communitarianism whereas “community activism forges civil bonds, and promotes individuals’ and groups’ independence from state bureaucracies” (Frazer, 1999, p. 41). While the literature generally speaks to political participation in civil society, there are implications for community-based research, in that this notion of participation involves more than what many of the existing guidelines suggest.

The National Bioethics Advisory Commission examined “Ethical and Policy Issues in International Research”, (2001) and has offered many suggestions that fit within a communitarian approach to research ethics. The Commission recommends community involvement in research design. This requires close attention to various contextual considerations in the design and implementation of research, and recognizing the roles of others in the consent process. Furthermore, the participation of the community contributes to determining whether the research is relevant and responsive to the community concerns. For example, clinical trial research may be conducted in a community that, following the study, has little or no access to the pharmaceuticals that were used in the intervention.

In such resource-poor settings, some ethicists have raised concerns about communities considered vulnerable groups, such as the homeless, the incarcerated, and children. For example, the protection of communities in research can be realized by equating communities with vulnerable groups. The Tuskegee Syphilis Study had a community of 400 poor, undereducated men who did not receive treatment for syphilis so that researchers could determine the course of untreated disease. While not all communities are vulnerable groups and vice versa, it can be useful at times to consider this approach, particularly when working with communities for whom Western scientific approaches are largely unknown. However, it is important to understand the difference between forming a relationship with a community based on partnership as opposed to a custodial one, focused solely on protection.

Respect for persons (Autonomy)

For communitarians, the principle of respect for persons would broaden to include these persons as members of a community, not merely as isolated individuals. Additionally, this can be developed into a notion of respect for communities, so that the researcher has “an obligation to respect the values and interests of the community in research, and, whenever possible, to protect the community from harms” (Emanuel & Weijer, 2001, p. 10). This can be considered an addendum to the principle of respect for persons, or the addition of a fourth principle.

Communitarians believe that a community is more than the sum of individual values and interests. They posit that the community has values and interests in and of its self. There are examples worldwide where, aside from governmental authority, the decision making for certain matters resides mainly at the community level. In these instances the community, rather than the individual, is prime. However, if the views of the community conflict with existing ethical guidelines, such as the Belmont Report principles, the principles will not be superseded by this respect for communities. For example, respect for communities cannot be justified to perpetuate oppressive community structures such as domestic violence and child labor.

Several international research ethics guidelines now include recommendations on how, when and why to involve communities during various aspects of the research process (Council for International Organizations of Medical Sciences, National Bioethics Advisory Commission, 2001). This is particularly true where vulnerable or disadvantaged communities, in both developed and developing communities are concerned. However, obtaining community consent and involvement is not a simple process, and may involve political representational issues and cultural clashes. For example, how is a representative chosen and exactly who does s/he represent? As a researcher from the “outside”, obtaining this information often takes time, patience, and partnership. In addition, a researcher may be confronted with community consents that are not consistent with ethical guidelines, particularly in the areas of gender and coercion. An example may be when research subjects consent solely because of the community leader’s opinion and do not believe that they have the choice to withdraw or refuse to participate. The community consent process is not a single encounter, and the researcher should continue to involve and work in partnership with community representatives through the entire process.

Case Study 1

A nurse researcher is interested in access to a community that is non-Western and is based on oral tradition and patriarchal collectivism. The area of research is identifying customs and norms that contribute to HIV/AIDS and sexually transmitted infection risks. After working with the community for several months in malaria control, the researcher feels that s/he has identified a “cultural broker” – someone who is helping the researcher to be accepted by the community. Some time passes, and the researcher presents the research purpose and objectives to the community leader. The community leader states that he is prepared to allow the researcher to conduct the study only if 1) no women and children are included; 2) the researcher can list what benefits the community will receive from their involvement; and 3) he, the community leader, reviews and approves the final list of research subjects. The cultural broker, who

is a woman, tells the researcher that this community leader is too old and traditional and soon another will be elected, and so it is okay to collect data from women.

Questions for Reflection:

- What does community consent mean in this context?
- What does informed consent mean in this context?
- What are some options available to the researcher?

There are many advantages to the researcher in considering a community-oriented approach. An understanding of community influences on individuals and decision-making helps to explain the values and norms of the research subjects. Emanuel and Weijer (2001) state, “An individual’s actions, desires, and goals are only comprehensible, and for that matter possible, within the context of a larger community” (p. 7). Particularly if the community and/or culture are quite different from the researcher, an examination into the “embeddedness” of the individual subject allows for an enriched, multi-layered view that does not atomize, or reduce the subject. However, this does not mean that conflicts will not arise.

Conflicts can arise for a variety of reasons. If the community representatives are considered to be unjust and oppressive, tensions can arise when the research team attempts to include them as partners and collaborators. The concept “community” can be too elusive and vague for researchers who want to know if they are working with a “true” community or not. When certain community practices are in direct opposition to the researchers’ values, the researchers may be closed to understanding different influences and how it relates to the study. Communitarian perspectives are often accused of being too relativistic. Since the core values are community, tradition, family and participation rather than absolute values, critics argue that practices such as female genital circumcision, torture, child labor, and others can be justified using this perspective. However, communitarians do not consider that whatever the community sanctioned and accepted, as practices are equal to the ideal or even a morally acceptable situation.

In sum, Emanuel and Weijer (2001) identify five broad themes for the protections of communities. These are: 1) Consultation in protocol development; 2) Information disclosure and informed consent; 3) Involvement in research conduct; 4) Access to data and samples; and 5) Dissemination and publication of results (p. 15-16). Some of these protections assume certain “types” of communities – how representative and cohesive they are in addition to other characteristics. As a researcher entering a new and foreign community for a short amount of time, it may not be possible to gain such a coherent and complete assessment. However, the information and understanding that is gained will lead to more valid findings (Costello & Zumla, 2000; Tollman, 2001; Marshall, Thomasma, & Bergsma, 1994; Benatar & Singer, 2000).

Questions for Reflection:

- Could an individual give consent to disclosure of information, and yet the study would violate the right of the collective, or community, to privacy? (Gostin, 1991)

- What harm could come to a community by participating in a study that examines behavioral risk factors for HIV/AIDS?
- What are some ways to determine if there is a need for community consent in addition to individual consent?
- What is an example of your own belief about autonomy that has influenced your clinical and research practice?
- Are ethical principles absolute and universal, or are they relative to the culture in which they exist? (Crigger, 2001)
- Does a community have the authority to give or withhold consent to approach its members?
- Should individual consent prevail over community consent in certain cases, and vice versa?

III. Practical Applications

In this module the reader has been oriented to the importance of considering research ethics from a community-focused approach, with the communitarian philosophy highlighted as a case example. For the MIRT Scholar traveling abroad there are many things to consider when preparing to conduct research in international settings. This section recommends concrete steps to prepare for the international experience and uses real-life examples based upon previous Scholar and Faculty Mentor's experiences in addition to feedback from host sites.

While it may not be known in which particular community one will be working, it is possible to begin to study the various cultures and communities prior to leaving. For the researcher interested in conducting appropriate community-based research, some areas to focus upon include:

- Ethnic and racial composition
- Religious beliefs and practices
- Formal and informal political structures
- Oral vs. written traditional structures
- Gender issues
- Existing national ethical codes of conduct
- Ethical dilemmas in the national popular press
- Recent changes or trends in international ethics guidelines

Most of this information should be available on the Internet and in comprehensive libraries. While useful, this preparation does not replace the steps that need to take place once the Scholar has arrived in country. These may include:

- Reviewing the University and Ministry of Health ethical guidelines
- Speaking with community members about previous experiences with "research"
- Recognizing that there may be large diversity within one culture/community and thus speaking with people in different positions and roles

- Asking community members, with which one has a respectful connection, about what they consider a “community” to be, how is it represented and decisions made
- Working in partnership to develop an appropriate and timely dissemination plan
- Speaking with a variety of community members, once rapport has been established, about what consent and autonomy means to them and their neighbors

In addition to reviewing the country’s experiences and perspectives around community ethics, it is important for the MIRT Scholar to examine their community values and ethical norms. One’s family, political and social system, religion, culture, and age and life experience may influence this. When we are confronted with a belief system different from our own, it can be very challenging. Understanding what has gone into “constructing” our ethics and values will help us to communicate our differences and work toward common meanings.

A final case study is presented below. Discussion around this case study will be continued in a group setting with the Faculty Mentor and other Scholars. This example, while modified from the real experience, is directly drawn from a MIRT experience (Mogotlane, 2002) and the discussion is relevant to what you may encounter.

Case Study 2

Soon after arriving in a new country, a group of American nursing student researchers begin working with American and host site faculty in a rural village. The entire research team (local and international) is unfamiliar with the customs and norms of this particular village. The Americans are very excited to be in such a new and foreign environment and feel more like tourists than researchers. They begin to take photographs of people, their homes, their children and the general surroundings. The host site faculty does not ask them to stop, as it seems that the villagers are enjoying the photo sessions. During this visit they learn about the importance of the village leader, how it is because of him that they have been granted permission for the study. While he is not available on this particular visit, his house is pointed out to the team. Before the team returns to the city, they decide to drive by his house, as it is very beautiful and unique. The team drives up the private drive in their unknown vehicle and quickly takes several photos. Then they leave toward the city, without making any contact with whomever may have been present at the leader’s home. Some time passes and a message is sent to the University where the host site faculty works. This message is from the village leader and it states that they are no longer allowed to work in this village and that they should return all data that has been collected.

Questions for reflection:

- What does community consent mean in this example?
- What could the role of a “cultural broker” have been in this setting?
- What are some reasons why the taking of photos of a private dwelling might be threatening for a village leader?
- What could be done to resolve this so that they might continue their research?

- What were the priorities of the research team during this visit and how does that relate to professionalism?
- What would you have done in this example?

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