ข้อคำนึงทางจริยธรรมในการวิจัยในกลุ่มประชากรซ่อนเร้น

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Scope

- What is hidden or hard-to-reach population?
- What is professional ethics?
- What is research ethics?

2

Hidden population

A **population** is "**hidden**" when no sampling frame exists and public acknowledgment of membership in. the **population** is potentially threatening. Accessing such **populations** is difficult because standard probability. sampling methods produce low response rates and responses that lack candor.

Douglas D. Heckathorn, University of Connecticut



Two characteristics

- No sampling frame exists
 - Size and boundaries are unknown
- Strong privacy concerns
 - Leading individuals to refuse to cooperate
 - Leading individuals to give unreliable answers to protect their privacy

Examples:

Groups at risk of contracting HIV

Persons who inject drugs

Persons who use drugs



Douglas D. Heckathorn, University of Connecticut

People who are sometimes categorized as being hard-toreach or hidden

Those being under social pressure of the broader community

Those living in faith based communities

Those who fear of confrontation with legal authorities

Illiterates

Those who have no interest to be found or contacted

Migrants

Newly arrived residents

Over-researched people

Those living in remote physical and geographical location

Those living in vulnerable social and economic situation



Shaghaghi A, Bhopal RS, Sheikh A. Approaches to Recruiting 'Hard-To-Reach' Populations into Re-search: A Review of the Literature. *Health Promot Perspect.* 2011;1(2):86-94. Published 2011 Dec 20. doi:10.5681/hpp.2011.009

The Colombo Plan Asian Centre for Certification and Education of Addiction Professionals Training Series

Curriculum 8

Ethics for Addiction Professionals

MODULE 2—FOUNDATIONS FOR ETHICAL THINKING

Ethics Definitions

- An agreed-on set of morals, values, and professional conduct standards accepted by a community, group, or culture
- A social, religious, or civil code of behavior considered correct, especially that of a particular group, profession, or individual

Source: World English dictionary. (2003). Retrieved October 15, 2011, from http://www.world-english.org/dictionary.htm

Ethics Definitions (continued)

- Standards that govern the conduct of a person
- A "human reflecting self-consciously on the act of being a moral being," which implies a process of self-reflection and awareness of how to behave as a moral being that may be based in law, individual belief systems, religion, or a mixture of all three

Sources: NAADAC. (2011). NAADAC code of ethics. Retrieved October 15, 2011, from http://www.naadac.org/resources/codeofethics and http://www.naadac.org/resources/185-pr11



A Final Ethics Definition

Basic Beliefs

+ Value Systems

+ Developmental Age

= Ethics

Individuals, organizations, and countries have "developmental ages"

Source: Prevention Think Tank. (2008). Prevention ethics 2020. Wheaton, MD Author.



Many Professional Organizations Have Codes of Ethics

- Guidelines for ethical behavior and decision-making for professionals in:
 - Family counseling
 - Social work
 - Law
 - Psychiatry
 - Health care
 - SUD prevention and treatment



Elements of All Professional Codes

- Various codes have similarities and differences, but they all focus on:
 - Protecting clients by identifying counselor scope of competency
 - Doing no harm by acting responsibly and avoiding exploitation
 - Protecting confidentiality and privacy
 - Maintaining the integrity of the profession



Limitations of Counselor Codes of Ethics

- Codes can lack clarity
- A code can conflict with another code, personal values, organizational practice, or local laws and regulations
- Codes are usually reactive rather than proactive
- A code may not be adaptable to another cultural setting



Professional Ethical Judgment

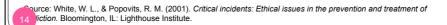
- No code of ethics can substitute for:
 - Active knowledge of codes and laws
 - Established deliberative process
 - Creative approach to securing supervision and guidance





Problematic Assumptions

- SUD staff assume:
 - Workers have personal standards of morality and ethical conduct that ensure ethical conduct
 - Workers have common sense
- How could these assumptions cause ethical problems?



Problematic Assumptions (continued)

- SUD staff assume:
 - All workers have been trained in ethical issues through their professional and academic training
 - Programs can depend on workers to know and follow ethical codes based on their professional certification or licensure
- How could these assumptions cause ethical problems?



Problematic Assumptions (continued)

- SUD staff assume:
 - Only counseling staff need to be concerned about ethical dilemmas
 - Ethical dilemmas are personal/professional issues, not program issues
- How could these assumptions cause ethical problems?



Problematic Assumptions (continued)

- SUD staff assume:
 - Because workers who violate ethical principles are bad people, they should be excluded from the program or profession
 - Because all supervisors place emphasis on ethics, ethical compliance of supervisees is ensured
- How could these assumptions cause ethical problems?



Problematic Assumptions (continued)

- SUD staff assume:
 - If supervisors don't hear about ethical conflicts, there must not be any, because counselors would tell them if they encountered a difficult ethical issue
- How could this assumption cause ethical problems?



Definition of Code of Ethics

• "an explicitly defined set of beliefs, values and standards that guide organizational members in the conduct of activities in pursuit of the agency's mission"

 $Source: White, W. L., \& Popovits, R. M. (2001). \textit{Critical incidents: Ethical issues in the prevention and treatment of addiction}, p. 13. \\ Bloomington, IL: Lighthouse Institute.$



Functions and Purposes of a Code for Professional Practice

- Identify values for members of the organization to strive for as they perform their duties
- Set boundaries for both appropriate and inappropriate behavior
- Provide guidelines for staff facing difficult situations encountered in the course of work performance



Functions and Purposes of a Code for Professional Practice (continued)

- Communicate a framework for defining and monitoring relationship boundaries of all types
- Provide guidelines for day-to-day decision-making by all staff and volunteers in the organization





Functions and Purposes of a Code for Professional Practice (continued)

- Protect integrity and reputation of individual members of organization (including paid and volunteer staff) and the organization itself
- Establish high standards of ethical and professional conduct within the culture of the organization



External Purpose of a Code for Professional Practice

- Protect health and safety of clients, while promoting quality of services provided to them
- Enhance public safety





NAADAC: General Areas of Professional Conduct (continued)

- Introduction
- I. The Counseling Relationship
- II. Evaluation, Assessment, and Interpretation of Client Data
- III. Confidentiality/Privileged Communication and Privacy



NAADAC: General Areas of Professional Conduct (continued)

- IV. Professional Responsibility
- V. Working in a Culturally Diverse World
- VI. Workplace Standards
- VII. Supervision and Consultation



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NAADAC: General Areas of Professional Conduct (continued)

- VIII. Resolving Ethical Issues
- IX. Communication and Published Works
- X. Policy and Political Involvement





Values

- Values:
 - Basic beliefs that an individual thinks to be true
 - The bases on which an individual makes a decision regarding good or bad, right or wrong, most important or least important
- Values can also be:
 - Cultural, guiding social behavior
 - Organizational, guiding business or other professional behavior



Small-Group Exercise

- Develop a list of values that you think would be particularly important as bases for an SUD code of professional ethics
- Consider personal, cultural, organizational values
- Write list on newsprint
- Be prepared to describe how each value is relevant to SUD treatment



Universal Values

- Autonomy: Enhance freedom of personal identity
- Beneficence: Help others
- Competence: Be knowledgeable and skilled
- Conscientious Refusal: Disobey illegal or unethical directives





Universal Values (continued)

- Discretion: Respect confidentiality and privacy
- Diligence: Work hard
- Fidelity: Don't break promises
- Gratitude: "Giving back," or passing good along to others



Universal Values (continued)

- Honesty and Candor: Tell the truth
- Justice: Be fair, distribute by merit
- Loyalty: Don't abandon
- Non-maleficence: Don't hurt anyone

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Universal Values (continued)

- Obedience: Obey legal and ethically permissible directives
- Restitution: Make amends to persons injured





Universal Values (continued)

- Stewardship: Use resources judiciously
- Self-interest: Protect yourself
- Self-improvement: Be the best that you can be



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Interactive Presentation: Relationship Between Ethics & Law

- Law presents minimum standards of behavior in a professional field
- Ethics provides the ideal for use in decision-making



Ethics and Legal Action Choices

- A course of action could be:
 - Ethical and legal
 - Ethical and illegal, as in the case of breaking an unjust law
 - Ethical and neither legal nor illegal, as in a case where no law applies

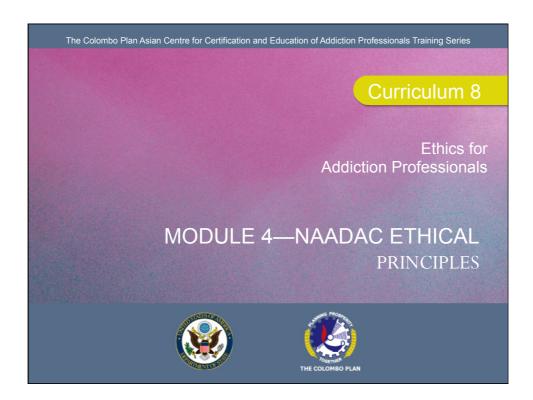
Source: White, W. L., & Popovits, R. M. (2001). Critical incidents: Ethical issues in the prevention and treatment of addiction. Bloomington, IL: Lighthouse Institute.



Additional Action Choices

- A course of action could also be:
 - Unethical and legal, in a case of complying with an unjust law
 - Unethical and illegal, in the case of breaking an unjust law
 - Unethical and neither legal nor illegal, as in a case of committing an unethical act that is not legally prohibited

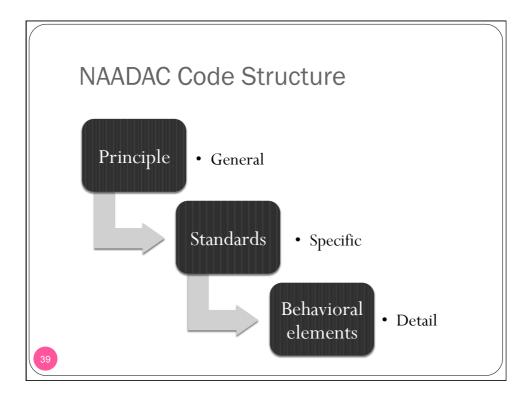




NAADAC Principles I´III

- Principle I: The counseling relationship
- Principle II: Evaluation, assessment, and interpretation of client data
- Principle III: Confidentiality/privileged communication and privacy

Source: NAADAC. (2011, March 28). NAADAC Code of Ethics. Retrieved January 20, 2012, from http://www.naadac.org/resources/codeofethics



NAADAC Code Introduction: Key Points

 NAADAC recognizes that addiction professionals live and work in many diverse communities and has established a set of ethical best practices that apply to universal ethical deliberation



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NAADAC Code Introduction: Key Points

- The code is designed as a statement of the values of the profession *and* as a guide for making clinical decisions
- NAADAC recognizes and encourages the notion that personal and professional ethics cannot be dealt with as separate domains



NAADAC Code Introduction: Key Points

- The ability to do good is based on an underlying concern for the well-being of others:
 - Recognition that we are all stakeholders in each other's lives
 —the well-being of each is intimately bound to the well-being
 of all
 - When the happiness of some is based on the unhappiness of others, the stage is set for the misery of all



NAADAC Code Introduction: Key Points

- Addiction professionals must act in such a way that they would:
 - Have no embarrassment if their behavior became a matter of public knowledge
 - Have no difficulty defending their actions before any competent authority





Principle 1: The Counseling Relationship

- Addiction professionals are:
 - Responsible for safeguarding the counseling relationship and protecting vulnerable clients
 - Responsible to the larger society
- Even in their personal lives, addiction professionals should try to foster self-sufficiency and healthy self-esteem in others



Principle 1: The Counseling Relationship: Five Standards

- Client welfare
- Client self-determination
- Dual relationships
- Group standards
- Preventing harm





Principle II—Evaluation, Assessment, and Interpretation of Client Data

- Ethical practice of assessment:
 - Takes into account the client's personal and cultural background
 - Ensures that the assessment process promotes the well-being of individual clients or groups
 - Ensures that counselors' recommendations are based on reliable assessment instruments



Principle II—Evaluation, Assessment, and Interpretation of Client Data: 12 Standards

- Scope of competency
- Informed consent
- Screening
- Basis for assessment
- Release of assessment results
- Release of data to qualified professionals



Principle II—Evaluation, Assessment, and Interpretation of Client Data: 12 Standards

- Diagnosis of mental health disorders
- Unsupervised assessments
- Assessment security
- Outdated assessment results
- Cultural sensitivity diagnosis
- Social prejudice



NAADAC Principles IV-V

- Principles IV and V in the NAADAC Code of Ethics address:
 - Professional responsibility
 - Working in a culturally diverse world



Principle IV: Professional Responsibility

- Ideally, addiction professionals:
 - Act with objectivity and integrity
 - Maintain highest standards in services provided
 - Recognize that effectiveness in the profession is based on the ability to be worthy of trust
 - Have reflected on the ethical implications of clinical decisions



"A More Than Ordinarily Responsible Life"

- The addiction professional must live a more than ordinarily responsible life, including:
 - Recognizing that even in a life well lived, harm might be done to others by words and actions
 - Admitting error when he or she becomes aware that any word or action has done harm
 - Doing what is possible to repair the harm except when to do so would cause greater harm



Principle IV—Professional Responsibility: Four Standards

- Counselor Attributes
- Legal and Ethical Standards
- Records and Data
- Interprofessional Relationships



Principle V: Working in a Culturally Diverse World

 Addiction professionals must understand the significance of the role that ethnicity and culture play in an individual's perceptions and how he or she lives in the world



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Potential Case Study Issues

- Issues that could be addressed in a cultural conflict case study:
 - A program facing religious or language barriers in the community
 - Serving a client from a very different cultural background
 - A program with non-diverse staff members
 - Making (or not making) accommodations for a client with a disability



Principle VI—Workplace Standards

- Competency of counselors and other staff members
- Obtaining supervision
- Issues of the working environment



Principle VII—Supervision and Consultation

- Staff development
- Supervisor competency
- Appropriate supervisor—supervisee relationships



Principle VIII—Resolving Ethical Issues

- Possible conflicts between law and ethical standards
- Dealing with colleagues who are impaired or behaving in an unethical manner



Principle IX—Communication and Published Works

- Respecting the limits of present knowledge in public statements
- Acknowledging the contributions of others to written works
- Responsibility to follow copyright laws



Principle X—Policy and Political Involvement

- Obligations to society
- Participating in community activities
- Social and political action



International Guidelines for Research Ethics

Historical Aspects

- 1932 (2475) US. > Tuskegee Syphilis Study until 1972 (2515)
- 1939 (2482) > Nazi Experiments during WWII until 1945 (2488)
- 1944 (2487) US. > Human Radiation Experiment

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Ethical Declarations & Guidelines: Historical Perspective

Guidelines	Source	Year and Revision
Nuremberg Code	Nuremberg Military Tribunal Decision	1947 (2490)
Declarations of Helsinki	World Medical Association	1964 (2507), 1975, 1983, 1989, 1996, 2000
Belmont Report	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	1979 (2522)
International Ethical Guidelines for Biomedical Research Involving Human Subjects	Council for International Organizations of Medical Sciences (CIOMS)	Proposed in 1982 (2525) Revised in 1993, 2002

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Ethical Declarations & Guidelines: Historical Perspective

Guidelines	Source	Year and Revision
Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products	World Health Organization	1995 (2538)
Operational Guidelines for Ethics Committees That Review Biomedical Research	World Health Organization	2000 (2543)
The Ethics of Research Related to Healthcare in Developing Countries	Nuffield Council on Bioethics	2001 (2544)
Surveying and Evaluating Ethical Review Practice	World Health Organization	2002 (2545)
3		

Nuremberg Code 10 issues to which physicians must conform when carry on experiment on human; related to • human's right : voluntary consent, freedom to withdraw at anytime • human experiment : unavoidable • merit of experiment : based on scientific evidence, expecting to yield fruitful result • quality of researcher : experienced researcher, considerate, careful, faithful, well prepared

Declaration of Helsinki (by WMA)

Adopted by the 18th WMA General Assembly, Helsinki, 1964

Amended in

Tokyo, 1975 Venice, 1983 Hong Kong, 1989 Somerset West, Republic of South Africa, 1996 Edinburgh, 2000



Declaration of Helsinki (by WMA)

Introduction

- -Duty of MD. To promote and safeguard health of people.
- -MD shall act only in the patient's interest when providing medical card.
- -Consideration related to well-being of the human subject should take precedence over the interest of science and society.
- -MD's care should be challenged through research for their effectiveness, efficacy, accessibility and quality.
- -Be aware of different types of patients.



Basic Principles of Medical Research

- Duty to protect life, health, privacy and dignity of human subject.
- Based on scientific, knowledge, adequate lab.
- Protocol should be submitted for consideration.
- Should be conducted by qualified personnel.
- Assessment of predicable risk and foreseeable benefits.



Basic Principles of Medical Research (Con't)

- Population involved the research get benefit.
- Respect privacy, confidentiality and willingness.
- Participant adequately informed.
- Cautious on vulnerable group.
- Author should report only accurate results.



Belmont Report 1979 (2522)

"Ethics Principles and Guidelines for the Protection of Human Subject of Research"

Part A

Boundaries Between Practice and Research

- · Research: biomedical and behavioral research
- Terms "experiment" and "research" not clearly defined
- Practice: to provide diagnosis, prevention, therapy



Belmont Report 1979 (2522)

"Ethics Principles and Guidelines for the Protection of Human Subject of Research"

Part B

Basic Ethical Principles

- 1) respect for person
- Acknowledge autonomy
- to protect those with diminished autonomy
- 2) beneficence
- · do not harm
- maximize possible benefits and minimize possible harms



Continue...

Belmont Report 1979 (2522)

"Ethics Principles and Guidelines for the Protection of Human Subject of Research"

Part B

Basic Ethical Principles

3) Justice : Who ought to receive the benefits of

research and bear its burdens?

Injustice occurs when some benefit to which a person is entitled is denied or when some burden is imposed unduly.

"The poor always take risks while the rich get benefit"

Belmont Report 1979 (2522)

The accepted formulation: just ways to distribute burdens and benefits.

Issues to be considered are: to each person

- 1) an equal share
- 2) according to individual need
- 3) according to individual effort
- 4) according to society contribution
- 5) according to merit



Belmont Report 1979 (2522)

Application of Belmont Report

I Informed Consent

- information
- comprehensive
- voluntariness

II Assessment of Risks & Benefit

III Selection of Subject



Council for International Organizations of Medical Sciences (CIOMS)

An international NGO, founded under support of WHO and UNESCO in 1949 and proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects in 1982

With cooperation with Global Programe on AIDS had developed two sets of guidelines

1991: International guidelines for Ethics Review of Epidemic Logical Studies

1993: International Ethical Guidelines for Biomedical Research Involving Human Subjects



Council for International Organizations of Medical Sciences (CIOMS)

The revised guideline of 2002, circulated

Research can be ethically justifiable only if it is carried out in ways that respect and are morally acceptable within the communities in which the research is carried out.



Nuffield Council on Bioethics

A report on The Ethics of Research Related to Health Care in Developing Countries (2001)

The purpose of this report is to examine the ethical issues raised when research is carried out in developing countries and funded by sponsors from developed countries.



Background

- Inequalities in resources between developed and developing countries – exploited by sponsored.
 - All countries should set priorities related to their provision of health care.



Important Guidelines for Researcher

- Ethical framework
- Setting priorities for research
- Consent
- Standards of care
- Social and cultural issue
- After research project is completed



Ethical Framework - based on four principles

- Duty to alleviate sufferings
- To show respect for persons e.g. sensitive to cultural differences
- Not to exploit the vulnerable
- Context of social, cultural and economics need to be taken into account



Setting priorities for research

If no clear picture of the priorities

- Difficult for government and sponsors to collaborate in addressing them.
- Difficult to carry out its own research which should be beneficial to the country.
 - Unable to determine which research is appropriate.
 - Research proposal should be reviewed by ethics committee of the host and sponsoring country.



Consent

In some culture it is accepted to obtain agreement from the particular community or senior family member, but genuine consent is a must.



Standard of care

Participants of the control group should be offered a universal standard of care for the disease being studied.

If it is inappropriate at least is the best intervention currently available.



Social and Cultural Issues

Means of informing potential participants is very important.

If this fails it also may fail to maximize the benefit of the research to the community.



After research project is completed

- Consider providing services to the control group.
- The effective intervention should be made available to whom it could benefit.



