

## Issues in Nursing Research Ethics

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As the primary goal of conducting nursing research is to advance scientific knowledge in the field of health and nursing for improving patient care, inevitably patients will be involved as research subjects. When patients are invited to participate in clinical research while they are receiving health services, nurses have to assume responsibilities by taking up the dual roles of practitioner and scientist. As a practitioner, the patient's healing progress is the primary concern. As a scientist, the contribution to knowledge for the benefit of future patients is the primary concern. These concerns may not always run in tandem as the very nature of research is its element of uncertainty which necessitates gathering evidence to support its hypothesis or otherwise. The patients will be involved in a clinical trial which efficacy has yet to prove. While they are putting themselves at risk of varying extents, the research outcome will benefit future patients but not always the involving patients. In this regard, the crux of ethical considerations in nursing research involving patients will

be striking a balance between advocating for the patient's best interest as well as pursuing knowledge for improving future care. This implies that nurses have to take extra safeguards other than observing the general ethical norms for conducting research involving human subjects such as informed consent, confidentiality, privacy, beneficence and social utility. These safeguards have to take into account the illness vulnerability of patients that render them being dependent on health professionals, vulnerable patient groups such as the mentally incapacitated, the frail elderly, the terminally ill, patients with rare disease and ethnic minority, and the vulnerability of clinical venues where the studies take place. With reference to international research ethics guidelines and the universal norms of bioethics and human rights, this paper will explain the ethical norms for conducting nursing research in general and ethical safeguards in particular. Ethical Issues in conducting nursing research involving other disciplines and/or international collaborators will also be discussed.

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### Differentiation of research from clinical care

- Research activities should be regarded as a series of systematic enquiries which seek to expand knowledge and understanding.
- Enquires should be conducted in a manner which is free from bias, distortion and prejudice.

## Researcher's Responsibilities

- Assume direct responsibility for the intellectual and ethical quality of their work
- Avoid conflict of interest
- Demonstrate integrity and professionalism in using research funds
- Ensure the safety of everyone involved in the research work
- Respect intellectual property rights
- Accept that their research results will be subject to peer scrutiny and debate

## Some basic questions for ethical consideration...

- Does the study involve human subject?
- Who are they? Respect for autonomy, justice
- How are human data being treated? Privacy & confidentiality
- Is it an intervention study?
- What are the ethical safeguards for the subjects? Beneficence & nonmaleficence
- Has the study undergone ethical review?

## Consent & assumption of risk in genetic therapy, 1999

- Gelsinger, 18, had a genetic disorder that prevented his body from properly metabolizing ammonia, which could be managed well by diet and drugs
- He enrolled in a clinical trial at the University of Pennsylvania that was attempting to use gene therapy to correct the disorder. But rather than curing him the technique caused his death.
- The investigator had financial interests in the biotechnology company behind the project

Allegation: Breaching the duty of protection from harm, questionable informed consent, conflict of interest

## Korean researcher in stem cell fraud 09 January 06

In perhaps the biggest scientific scandal of recent times, South Korea's star scientist Woo Suk Hwang has retracted his landmark paper, published in the journal Science, in which he claimed to have created embryonic stem cells from adult humans. The latest news is a major blow for the prospect of using personalized stem cells to treat people with a variety of ailments, from spinal cord injuries to Parkinson's disease. Hwang first came under suspicion in November 2005 when, after over a year of denials, he admitted that he had used eggs donated by lab workers. He also acknowledged that some of the eggs used were bought, after first saying that they were all donated. Both violate ethics guidelines. His fraudulent research then came to light in December, when a former colleague alleged that some of the patient-specific stem-cell lines had been faked. It now appears that none of the stem-cell lines that Hwang claims to have created actually exist.

Allegation: Unethical procurement of egg, fabrication of data, and fraudulent report

## Ethical guidelines

- 1947 Nuremberg Code
- 1964 Declaration of Helsinki (2004 revision)
- 1978 Belmont Report
- 2005 UNESCO Universal Declaration on Bioethics and Human Rights
- Institutional Review Board
- Research Ethics Committee

## Declaration of Helsinki (with note of clarification, Tokyo 2004)

- Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects

## 2005 UNESCO Universal Declaration on Bioethics and Human Rights

### Article 3

- Human dignity, human rights and fundamental freedoms are to be fully respected.
- The interests and welfare of the individual should have priority over the sole interest of science or society.

## The Researcher-Subject relationship is different from the Nurse-Patient relationship

### Ethical Values in Patient-Nurse Relationship

Thinking of what is good for the patient  
Acting for the patient's best interest

Trust-based, covenantal

Autonomy-based, contractual

Respect the patient's right to informed consent  
Respect for privacy and confidentiality  
Treat the patient with equity

### Ethical Values in Researcher-Subject Relationship

Autonomy-based, contractual

- Social Utility
- Respect for person
- Beneficence
  - Favorable Risk/Benefit ratio
  - Maximize benefit & Minimize risk

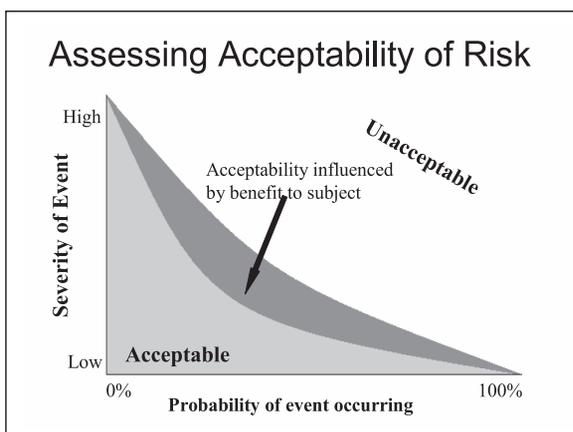
### Ethical issues at stake

- Therapeutic misconception
- Informed consent in question
  - Information to be comprehensive, including risks and possible benefits, alternatives to participating
  - The way information is presented, or the framing effect, to the subject
  - Who to obtain the consent
  - The patient's right to refuse and withdraw from the study at any time

The burden of responsibility rest on researcher:

### Benefit and Risk Assessment

- Benefit is defined as 'anything that is for the good of a person or thing'. It may be personal and direct or may be societal and indirect. It is appropriate to use both forms of benefit in making the judgment of risk/benefit ratio.
- Risk is defined as 'exposure to the chance of injury or loss'
- Injury is 'harm of any kind done or sustained'.
- It should be noted that no procedure is without risk, although the risks may be minimal.



GOOD AND HARM FROM RESEARCH				
	GOOD		HARM	
	Actual	Potential	Actual	Potential
Subject's Perspective	- Payment - Free Treatment - Duty to society	- Better treatment - Psychological relief	- Inconvenience - Known side effects of medication	- Lesser or no treatment - Physical harm - Psychological harm - Loss of clinical relationship - Loss of privacy
Society's Perspective	- Advance scholarship	- Better treatment identified	- Private space reduced - Over-reliance on vulnerable populations	- Subjects misused - Public confidence in research eroded - Money wasted

### The dual roles of clinician and scientist in conducting research which involves the patient as subject

Trust-based, covenantal

Autonomy-based, contractual

Autonomy-based, contractual

### Comparison of Clinical and Research Relationship

	CLINICAL	RESEARCH
Respect for Autonomy	Patient sets treatment goal	Subject offered choice to participate
Justification for Overriding Autonomy	Patient's best interests when competence is impaired	No justification to research on unwilling subjects
Beneficence	Do the best thing for the patient	Minimize risks
Justice	1) Fair access to health care 2) Fair distribution of health care resources	1) Fair access to participation 2) Fair distribution in groups 3) No group should have unfair research burden or benefit
Goal	Best treatment for individual patient	Benefit society by producing knowledge to benefit future patients
Patient/subject Motivation	Meet health care goals	1) Help society 2) Better treatment 3) Inducements to be subject (Money, free treatment etc.)
Clinician/Researcher Motivation	Help individual patients	Produce knowledge to help whole class of patients

### Minimizing Harm – Data Safety Monitoring Plans

- A plan for monitoring risk and acting on harm
- Reporting adverse events to Research Ethics Committee
- Plan for suspending research if harm is pervasive
- Plan for suspending research and offering the intervention to all subjects if the intervention is proven to work well

### Protection of Vulnerable Persons

- Children
- The Decisionally Impaired
  - Mentally Ill
  - Substance Abusers
  - Alzheimer's Disease
- Prisoners
- Emergency or Disaster care
- Minority Populations
- International Research

### Referrals for problems discovered through research

- Plan ahead
  - If studying something like suicidal thinking be prepared for immediate intervention
- Set trigger score for any tests used
  - Depression scale
- Researcher must be qualified to assess and refer
- The referral must be practical for the individual

### Issue of social utility & concern for individual's well-being

- The Tuskegee syphilis study (1932-1972) in African American men

### The Tuskegee Syphilis Study

- In 1932, the United States Public Health Service (USPHS) initiated the Tuskegee Syphilis Study to document the *natural history of syphilis*.
- The subjects of the investigation were 399 poor black sharecroppers from Macon County, Alabama, with latent syphilis and 201 men without the disease who served as controls.
- The physicians conducting the Study deceived the men, telling them that they were being *treated* for "bad blood."

### The Tuskegee Syphilis Study (cont'd)

- However, USPHS deliberately denied treatment to the men with syphilis and they went to extreme lengths to ensure that they would not receive therapy from any other sources.
- In exchange for their participation, the men received free meals, free medical examinations, and burial insurance.
- Published medical reports have estimated that between 28 and 100 men died as a result of their syphilis.

### Justification for limited research involving deception

1. Incomplete disclosure is truly necessary to accomplish the goals of the research
  2. No undisclosed risks to subjects that are more than minimal
  3. An adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them
- (Belmont Report, 1978)

### Declaration of Helsinki 2004 Article 30

- At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study

### Issue of Informed consent, privacy, confidentiality & concern for individual's well-being

- You are a member of a research team that is developing a family history tool to assist in identification of individuals and families at increased risk of cardiovascular disease. The study involves taking family histories, establishing the DNA sequences of 250 different genes using microarray technology, and gathering data on a wide variety of environmental factors. The DNA samples will be stored in your institution's DNA biobank.

You designed the study so that participants would not receive individual results, and this was stated in the consent form. You have recruited 5000 research subjects and collected their family histories and environmental exposures. You also have complete sequence data on all 250 genes. You are now in the process of analyzing the data and identifying risk factors.

Suddenly you realize that you have found an extremely strong connection involving specific alleles of two different genes (named Strbk1 and Strbk2) plus an environmental exposure. When both alleles are present in an individual and that same individual is exposed to the environmental risk factor caffeine, the result is almost always a massive stroke (usually fatal) at a very young age. Further, you realize that there is a simple remedy (avoidance of caffeine) that is very likely to prevent stroke in these individuals.

- You would like to warn the mutation carriers, and you have maintained a secure database linking their contact information with study number. However, participants were told that they would not receive any individual results, and the possibility of re-contact was not mentioned.

To inform the participants or not?  
If yes, How?

- While you are trying to decide what to do about the study results, you learn that researchers from another institution have requested access to the DNA samples for a different cardiovascular study. The consent form for your study said nothing about who has access to the DNA samples.

- For research involving the use of specimens or materials from a "data bank" (including discarded specimens), informed consent will not be required if all of the following conditions are met:
- (i) The organization in charge of the "data bank" agrees to the use of specimens in the "data bank" as proposed by the researcher;
- (ii) The organization withholds from the researcher all recorded information which allows the identification of the patients/subjects concerned;
- (iii) The specimens from the "data bank" will not be used for DNA work. (HK PolyU ethics guide, 2000)

### International Research

- Local Approval
- Informed Consent
  - Enrollment and maintenance
- Community Impact
- Local Standard of Care
- Community Input
- Community Involvement

### Special Ethical Consideration: Respect for Community

- Consider the effects of possible results on:
  - Community's self conception
  - Perceptions outside the community
  - Changes to health care delivery by implementing results
  - Potential problems implementing results
  - Effects on the entire community arising from individual participation

\*From: ICNE (2003). *Nursing Ethics* 10(2), pg. 125-126.