Research Ethics in Real World Research

Dr Leslie Gelling
Reader in Research Ethics
Anglia Ruskin University
Cambridge, UK
At last! An Ethics Committee that will listen to reason..!
Plan

1. Why do we take research ethics so seriously?

2. What principles should guide researchers in the ethical conduct of research?

3. Do Research Ethics Committees still have a place in research in the 21st century?
1. Why do we take research ethics so seriously?
The Cycle of Harm

Unethical event

Response

Harm
1. Uncontrolled experimentation

- 500BC  Hippocrates
- 210AD  Galen
- 1543   Andreas Vesalius
- 1620   Sir Francis Bacon
- 1628   Sir William Harvey
- 1721   Newgate Prison

2. Pre-WWII (1800 - 1939)
Dr Albert Neisser

The Royal Prussian Minister of Religious, Educational and Medical Affairs

Directive to all medical directors of university hospitals, polyclinics, and other hospitals

I. I advise the medical directors of university hospitals, polyclinics, and other hospitals that all medical interventions for other than diagnostic, healing, and immunization purposes, regardless of other legal or moral authorization, are excluded under all circumstances, if

(1) the human subject is a minor or not competent due to other reasons;

(2) the human subject has not given his unambiguous consent;

(3) the consent is not preceded by a proper explanation of the possible negative consequences of the intervention.

II. At the same time I determine that

(1) interventions of this kind are to be only performed by the medical director himself or with his special authorization;

(2) in all cases of these interventions the fulfillment of the requirements of I (1-3) and II (1), as well as all further circumstances of the case, are documented in the medical record.

III. The existing instructions about medical interventions for diagnostic, healing, and immunization purposes are not affected by these instructions.

Berlin, 29 December 1900
The Minister for Religious ec. Affairs
Studt
1. The voluntary consent of the human subject is absolutely essential.
2. Pre-WWII (1800 - 1939)
3. WWII (1939 - 1947)
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
- Written in 1960 but not published until 1967
- 78 examples of research in the NHS undertaken without informed consent
- Research undertaken for career development
- Pappworth told to be quiet … but refused
Declaration of Helsinki 1964

“In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject’s freely given informed consent, preferably in writing.”
2. Pre-WWII (1800 - 1939)

3. WWII (1939 - 1947)

4. Post WWII (1947 - 1964)

5. Recent events (1964 - 2019)
<table>
<thead>
<tr>
<th>Year</th>
<th>Event/Outcome</th>
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<tbody>
<tr>
<td>1988 – 1995</td>
<td>Tissue and organs collected from around 850 children without consent</td>
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<tr>
<td>1999</td>
<td>Public Inquiry</td>
</tr>
<tr>
<td>2001</td>
<td>Redfern Report</td>
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<td>2004</td>
<td>Human Tissue Act</td>
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**Alder Hey**

A pathologist secretly removed and stockpiled the body parts of hundreds of babies and children without their parents' consent, a medical tribunal heard today.

Around 850 babies' organs were harvested by Professor Dick van Velzen during the six years that he was the head of foetal and infant pathology at Liverpool's Alder Hey children's hospital, the General Medical Council (GMC) heard.
2. Pre-WWII (1800 - 1939)
3. WWII (1939 - 1947)
4. Post WWII (1947 - 1964)
5. Recent events (1964 - 2019)
6. The future (2019 - )
Why do we take research ethics so seriously?

Research Ethics in Real World Research
2. What principles should guide researchers in the ethical conduct of research?
Ethical principles underpinning research

Ethical principles in healthcare research

Date of acceptance: January 21 1999.

Ethical principles underpin decision making in the research process. This article considers the seven ethical principles that are most frequently highlighted in the literature. Although the principles will be considered individually, they are not mutually exclusive, and the article demonstrates that they are closely linked.

Introduction

Ethical principles form the foundations for decision making within the many stages of the research process. This article will consider the seven ethical principles that are most frequently highlighted in the literature: 1986). Beneficence is characterised as an active state as opposed to non-maleficence which is a passive state. This suggests that non-maleficence is an extension of beneficence. However, it is necessary to separate these two ethical principles because they may conflict (Faden and Beauchamp 1986).
Principles

- Beneficence and Non-maleficence
- Autonomy
- Fidelity
- Confidentiality
- Justice
- Veracity
Beneficence and Non-maleficence

“Beneficence places an obligation on the researcher to weigh or balance the potential benefits against the potential risks.”

“The ethical principle of non-maleficence is based on the assumption that no harm should come to the patient or research subject as a result of participating in a study.”

(Gelling 1999)
Risk v Benefit

1. When might it be ethical for individuals to be invited to participate in research where the possible risks could outweigh the possible benefits?

2. Who decides when a risk might be acceptable?
Types of harm

• Physical harm
• Psychological harm
• Social harm
• Economic harm
No risk of harm
Temporary discomfort
Unusual levels of temporary discomfort
Risk of permanent harm
Certainty of permanent harm
My friends, as a result of our experimentation, we have just lost a dear and valued colleague....

On the other hand, we have just gained a publication.
Fidelity

“Fidelity is the research principle concerned with building trust between the researcher and the research subject. The research subject will entrust himself or herself to the researcher who subsequently has an obligation to safeguard the subject and their welfare in the research situation.”

(Gelling 1999)
Justice

“This research principle requires the researcher to be fair to the research subjects.”

(Gelling 1999)

Are there any groups in Society who cannot or should not be involved in research?
Veracity

“The research principle of veracity highlights the obligation of the researcher to tell the truth about the research study.”

(Gelling 1999)
"To create the ethical principle of confidentiality it is necessary that two conditions exist. First, one person must undertake not to disclose information considered to be secret. Second, a different person must disclose to the first person information that they consider to be secret."

(Gelling 1999)
Autonomy

“Personal rule of self by adequate understanding while remaining free from controlling influences by others and from personal limitations that prevent choice.”

(Faden and Beauchamp 1986)
OF COURSE THE DEATH WAS STUDY-RELATED. HE WAS READING THE PATIENT INFORMATION SHEET WHEN THE BUS HIT HIM.
What principles should guide researchers in the ethical conduct of research?

Research Ethics in Real World Research
3. Do Research Ethics Committees still have a place in research in the 21st century?
“There now. We get our wish of continuing our work unimpeded, and they get their wish of being in a position of direct oversight at all times.”
The Future

1. Move to a principled approach to ethical review
2. Greater collaboration
3. Greater involvement of service users in the ethical review process
Research Ethics in Real World Research
Thank you

leslie.gelling@aru.ac.uk

@Leslie_Gelling

a.r.u.