ANH Research Network, India 2019

Lucinda Manda-Taylor,

University of Malawi, College of Medicine

Introduction

- Who am I?
- Where do I come from?
- What do I do?
- Why am I here?

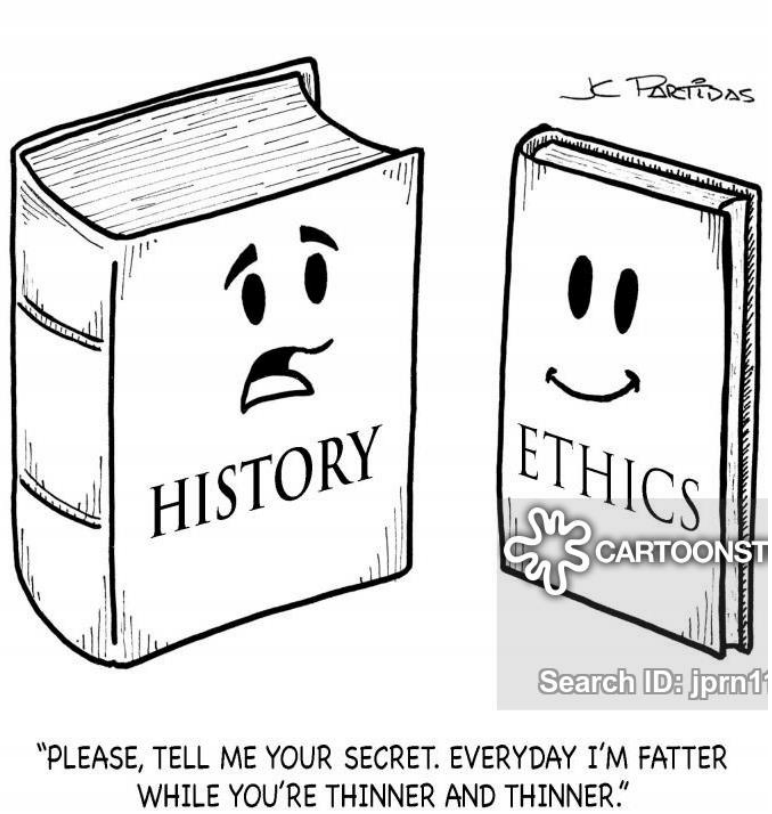
Doing ethics in research

- Everyone is expected to have **ethics** and to be ethical, and these **expectations** are not based on any specific training or expertise.
- Yet **normative ethics** as a discipline requires us to understand what it is that makes one action or state of affairs good, responsible or beneficial, in contrast to others that are bad, irresponsible or harmful?
- Key **ethical principles** and **approaches** for ethics-oriented research are important **signposts** for any researcher looking to do ethics in research.

Objectives

- Quick and easy exploration of the historical context of research ethics
- Discuss the basic ethical principles for international standards for research ethics

What can we learn about ethics from the past?



"PLEASE, TELL ME YOUR SECRET. EVERYDAY I'M FATTER WHILE YOU'RE THINNER AND THINNER."

- The history of politics, medicine and business is thick, rich and detailed.
- The history of ethics is thin, and brief!

A brief history of Human Research Ethics - 1

- ***Hippocratic Oath:***
  - ***….primum nil nocere …***
  - ("I will prescribe regimens for the good of my patients according to my ability and judgment and never do harm to anyone".

A brief history of Human Research Ethics – 2

- **Nuremberg Code (1947)**
  - As part of the verdict in the Nuremberg War Crime Trials of 23 German doctors, the court enumerated some rules for permissible medical experiments, now know as the Nuremberg Code:
    - *Voluntary consent*
    - *Benefits outweigh risks*
    - *Ability of the subject to terminate participation*

A brief history of Human Research Ethics - 3

- Declaration of Helsinki 1964 …
- Recommendation guiding doctors in biomedical research involving human subjects

  Concern for the interests of the participant must always prevail over the interests of science and society"

A brief history - 3

- Belmont Report (1979)
  - Tuskegee incident
  - In 1972 it was revealed that for over 40 years the US Public Health Service was performing studies on poor, black sharecroppers from Alabama and were denied treatment for syphilis without ever consenting.
  - Awareness created a scandal and demand for more stringent regulations for informed and voluntary participation in human research

What have we learned?

- Human experimentation can be traced back to several centuries.
- Atrocities in human subject experimentation set the basis for landmark statements and documents of principles of research.
- In any research the interests of science must never trump the interests of society.
- Written, informed consent is paramount for the good conduct of research

- Justice requires the fair treatment of human subjects in research.
- All research must be approved by an ethics committee
- Ethics committees must examine studies for acceptable balance of risk and benefit
- The principle of justice means the risk is distributed equally and benefits are accessible to everyone

Ethical Principles in Research

- There are numerous principles that have been enumerated that provide guidance for human research.
- For example, Childress and Beauchamp's seminal principles: Respect for persons, beneficence and justice
- Ezekiel Emmanuel's seminal benchmarks for ethical research (collaboration, social value etc.)
- While ethical requirements can and do vary across countries
- There is considerable consensus on the principles presented in the slides to follow

Three principles of Research Ethics

- Principles:
  - Respect for persons
  - Beneficence
  - Justice
- Concept of non-maleficence is complementary to beneficence:
  - To do good and no harm,
  - To maximize potential benefits
  - While minimizing risk

One: Respect for human beings

- Recognition that each human being has intrinsic value
- Making opportunity for human beings to exercise autonomy
- Respect requires prior knowledge for the culture, values, customs, beliefs and practices both individual and collective

Two: Beneficence

- Research must be of value to participants, their community or country
- Research must be designed to minimize risks
- In the health and development context, research should carry a commitment to support empowerment and participation
- Scientists have a commitment to a fiduciary relationship to stakeholders and the public to conduct engagement activities.

Three: Minimize harm in the study design

- Researchers do not intentionally seek to harm participants. Rather it is the risk of harm that researchers should aim to minimize.
- Types of harm can include:
  - Physical harm
  - Psychological harm
  - Social disadvantage
- The concept of minimal risk
  - US Federal Common Rule describes minimal risk as:
    - *"the 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."*

Identification and Interpretation of risk

- Risk assessment has been characterized in terms of four inter-related activities:
  - Hazard identification – consists of discovering adverse outcomes that are possible;
  - Exposure quantification – the process of determining how likely they are to occur under given circumstances;
  - Risk management and communication– comprises of risk characterization about what should be done.

Equipoise, Risk and Therapeutic Procedures

- Equipoise is a, "state of uncertainty as to the relative superiority of two treatments".
- Exposure to therapeutic risk may sometimes be acceptable if clinical equipoise exists

Placebo interventions as a comparator (vs. standard of care)

- A placebo should *only* be allowed if there are valid reasons to use it rather than an active standard of care drug.
- A placebo must satisfy one of these conditions:
  - Minimal risk
  - More than minimal risk but a direct benefit from te placebo
  - A minor increase over minimal risk but the study is likely to produce knowledge of vital importance to the subject's own disease

Four: Obtain informed consent

- Participants should understand that they are
  - Taking part in research;
  - What the research requires of them;
  - What possible discomforts they will experience;
  - Understand that they are volunteers;
  - Take part in research without being coerced or deceived;
  - Provide participants with the right to withdraw

Five: Research Integrity and Merit

- Research deemed to have merit is:
  - Well-justified (potential to benefit in form of new knowledge or improve well-being)
  - Meets relevant quality criteria (methodologically sound & appropriate to the research context)
  - Is conducted by persons or teams with sufficient experience and competence (beyond the academic qualifications, teams must have foundational knowledge of the culture, political situation, history and values in the relevant country)

Six: Justice

- Justice in procedural terms requires the following:
  - That ethics review processes involve methods that are fair and transparent
  - That established standards and procedures for reviewing protocols are in place
  - That the process be effectively independent

- Justice in research also connotes fairness and equity for all participants in research
- Fairness and Equity means
  - fair process for recruitments of research participants
  - No unfair burden of participation on particular groups
  - Fair distribution of and access to the benefits of participation in research

- The principle of justice thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge.

Conclusions & Take Home Message

- Doing ethics in research requires deliberate thought and consideration to do the right thing.
- Doing ethics requires putting people participating in research first.
- Doing ethics in research must appreciate the evolving nature of ethical issues and concerns with the growing development of new technologies and areas of research.


THANK
YOU