Informed Consent

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Overview

- Background
- Elements of informed consent
- Individual versus community informed consent

Why obtain informed consent?

- Informed consent shows respect for individual autonomy by allowing people to decide for themselves whether to enroll in research.

- Informed consent also helps people to protect their own interests and what matters to them.

How important is informed consent?

- Informed consent is an important condition for research, but may not be necessary in all cases.
  - E.g., emergency research
- Simply obtaining a subject's informed consent does not make research ethical.
  - It is one ethical condition among many.

Legal precedent for informed consent

- First recorded mention of consent was in 1767 in a British lawsuit.
- *Slater v. Baker & Stapleton*:
  - Two physicians were held liable for re-breaking a bone because:

    "It appears from the evidence of the surgeons that it was improper to disunite the callous without consent; this is the usage and law of surgeons…"

Precedent for informed consent in research

- Arguments for the importance of consent in research occurred before 1900.

- 1892-- Coley injected patients with cancer to induce artificial erysipelas. He describes how he began treatment with a patient who had a sarcoma and only “after some deliberation he consented” and injections began.

Battery

- Justice Cardozo in *Schloendorff v. Society of New York Hospitals* (1914):

  > "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."

- Informed consent developed from tort law prohibiting battery, or "nonconsensual touching".
- Informed consent law is distinct from contract law.

Precedent for informed consent

- 1946-49 Nuremberg Trial and formulation of the Nuremberg Code.

- Nuremberg Code contains “certain basic principles [that] must be observed in order to satisfy moral, ethical and legal concepts.”

- The first and longest principle is “The voluntary consent of the human subject is absolutely essential.”

Limitations of Nuremburg code

- Informed consent would not have made the Nazi experiments ethical.

- Another problem is that it is generally considered ethical to do research on people who cannot consent in some cases.
  - Pediatric research (contrast with Ethiopia)
  - Adults who cannot consent

Research and informed consent

- "[I]n order for a physician to avoid liability by engaging in drastic or experimental treatment, which exceeds the bounds of established medical standards, his patient must always be fully informed of the experimental nature of the treatment and the foreseeable consequences of that treatment…."

Ahern v. Veteran's Administration (1976)

Elements of informed consent

Valid informed consent requires:

1. Capacity to make autonomous decisions
2. Disclosure of relevant information
3. Understanding of this information
3. Voluntariness of decision
4. Indication of consent

1. Capacity

- A person with capacity has the ability to consider the available options and decide which option fits best with his or her values and interests.
- Who has capacity to give consent in research is determined by state law about who can give consent to the medical procedures.

Children and consent

- In most states in the U.S., children become capable to give consent at 18, with exceptions:
  - Treatment of sexually-transmitted infections or drug use, or
  - “Mature minors”.
- Consent should be obtained from parents; provisions should be made for obtaining assent from children.
- The age at which children become adults in other countries ranges from 14-21.

Capacity

- Adults with mental disorders or brain damage may also lack capacity for informed consent.
- The Federal regulations (45 C.F.R. 46.411) allow for consent to be obtained from a subject’s legally authorized representative.

2. Disclosure

- In order to respect an individual's autonomy, the information that person needs to make a decision should be disclosed to them.

What information should be disclosed?

- Even the most basic research protocol involves more information than any one individual could ever understand.

- So, how should we decide what to disclose?

Different legal standards

- Professional: What information do researchers usually provide?
- Reasonable person: What information would a reasonable person want?
- Individual: What information does this person want?

Discussion of different standards in *Canterbury v. Spence* (1972)

- Reliance on the custom of physicians
  - Could instantiate a code of silence among physicians
  - Doesn't respect patients' rights of self-determination
- Reasonable person standard
  - Respects patient autonomy
  - What if a patient didn't want information and would become distraught?
    - Place burden of proof on physician to show this
- Individual standard
  - Can't determine this after the fact except with patient testimony
  - Patients could manipulate this standard

State of the law

- States are almost evenly split between the professional & reasonable person standards.

- The reasonable person standard respects patient autonomy better than the professional standard, and is more practical than the individual patient standard.

What should be disclosed to research participants? (45CFR46.116 & 21CFR50.25)

- Statement of research
- Purpose and procedures
- Risks
- Benefits
- Extent of confidentiality
- Right to withdraw
- Alternatives
- What happens if there is research-related injury
- Who to contact for answers to questions

Legal limitation on disclosure

- Informed consent documents cannot include a waiver of any subject rights or a release of the researcher/sponsor from liability for negligence.
- Informed consent documents are different from contracts in this respect.

Criticisms of current disclosure practices

- Consent forms are often written at such a high level that they are difficult to understand.
- And if a consent form has too much information, it will be hard for people to focus on the information they need.
  - People do not make decisions by considering everything they know all at once.

Improving disclosure

- Instead, people choose between the available options.
- Therefore, it may help to focus informed consent on how research participation differs from the other options.
  - Concentrate discussion on a biopsy that is not part of clinical care rather than all the risks of clinically-indicated medications.

When is disclosure unnecessary?

- The Federal regulations (45 C.F.R. 46.116) recognize that informed consent is not always necessary, and permit waiver when:
  - Research involves minimal risk
  - Will not adversely affect subject's rights
  - Research cannot practicably be carried out otherwise
  - Subjects will get additional information after participation when appropriate

3. Understanding

- Understanding is processing of disclosed information.
- Before a person can make an informed choice, they have to understand the relevant information.
- Importantly, understanding is not recall.

Understanding in low-literacy populations

- In some contexts in the U.S. or internationally, some potential subjects may not be able to read the informed consent document.
- For populations that speak languages other than English, IRBs typically use translations and back-translations for informed consent forms.
- For research subjects who are not literate, researchers may need to use creative ways of disseminating information.

Creative ways of disseminating information

- Increasing use of decision aids in medicine, either web- or device-based.
- Rakai, Uganda:
  - Giving subjects tours of the laboratory to explain the research process, and
  - Communicating through theatre.

Photo courtesy of Ezekiel Emanuel.

4. Voluntariness

- When a person makes a free choice that is not forced upon them, they are making a voluntary decision.
  - No coercion
  - No undue influence

Can an offer to participate in research be coercive?

- Offers are proposals to make people better off.
- An offer to do something, therefore, is not coercive:
  - To be coerced, someone needs to threaten to make you *worse* off.
  - An offer gives someone more or better choices, and makes them *better* off in that respect.

When could research participation be coercive?

- If the offer is not really an offer:
  - What if a lab technician was asked by his boss to enroll in a research study she was conducting?
  - May be acceptable, if it is truly an offer.
  - Would not be acceptable if the boss threatened the employee with her displeasure or with termination of employment.

Voluntariness and bad situations

- A bad situation does not coerce someone into doing something.
  - To be coerced, *someone* needs to threaten to make you worse off.
  - In other words, unless there is a person or a moral agent who puts you in a bad situation, the fact that you are in a bad situation is not coercive.

Voluntariness

- People often talk about large payments for research participation undermining voluntariness.

- But offering someone money to be enrolled in research gives them more or better options, and is therefore not coercive.

Confusion about voluntariness

- Instead, large payments could be a problem because they confuse people and prevent them from making good decisions:
  - Large payments may be so enticing or attractive that they affect a research subject's capacity to carefully weigh the risks involved and *understand* the research.

U.S. regulations and voluntariness

- The U.S. regulations require that a subject understand that he or she has a right to withdraw from the research at any time.

5. Indication of consent

- The U.S. Regulations require that research subjects sign informed consent documents to authorize their participation in research.

Authorization

- The requirement can only be waived when:
  - There is no other record of the subject's participation, and there is a risk to subjects regarding confidentiality, or
  - Research is minimal risk, and does not involve procedures for which you would need written consent if done outside of research.

Cultural views on signatures

- Some cultures have differing views of signatures:
  - Once you have signed, you cannot withdraw from research, or
  - The Amish believe that verbal agreements are binding—requiring more, like a signature, is insulting.
- Probably cannot obtain waiver of the requirements for these concerns.

Authorization in low-literacy populations

- In some populations, many individuals may not be able sign informed consent documents.
  - Signature can be an “X” or a thumbprint.
  - However, an “X” may not identify that the right person signed the document.
    - Some institutions have a witness document separately that the correct person made the “X”.

For more on these issues, see:

Wendler D, Rackoff J. Informed consent and respecting autonomy--what's a signature got to do with it? IRB (2001) 23:3, 1-4.

Community versus individual consent

- U.S. law requires that the consent of a competent, adult research subject be obtained.

- In some cultures, however, this focus on the individual may seem to neglect the importance of community.

Informed consent and culture

- Although researchers must comply with applicable laws, they should also attempt to respect cultural practices so far as they can.
  - As long as these cultural practices are not unethical.
- Difficulties arise when cultural and language barriers intersect.
  - Use of unrelated translator may be very important.

Informed consent and culture

- Conducting research in countries with different cultures may not even be possible without taking into account differing cultural norms.

- In Mali, researchers have taken approaches to obtain community consent through a tiered model of consent.

Tiered consent

- A stepwise process:
  1. Approached the leaders of the community.
  2. Conducted group discussions with the heads of extended families.
  3. Then led group discussions with mothers of children who would be involved in the study.
  4. Finally, obtained consent from individual families.
     - Also approached mothers-in-law of pregnant women before obtaining consent from the women themselves.

Tiered consent model: Who decides?

- A tiered consent model means that other people have veto power over an individual's decision about whether to enroll in research.
- Also, before using this model in other cultures, their culture should be evaluated carefully.
  - One culture may include many different ideas, and changes over time.

Empirical data relevant to community consent

One solution: Look to empirical data for the relevant community.

- In a randomized study of anti-malarial treatments, 347 mothers giving parental consent were asked about the informed consent process.

- 94% reported making the decision about enrolling their child on their own.

Community consultation

- Community consultation differs from community consent.
- A model of community consultation could include:
  - Community discussions about the study well in advance of enrolling subjects.
    - In the U.S., many advocacy groups for breast cancer, HIV already involved in research.
  - Engagement with disenfranchised subgroups directly.
    - Sex workers represented on advisory boards in Vulindlela, South Africa.
  - But only individual consent for research participation.

Community consultation

- Benefits of community consultation:
  - Enables further communication of information about the research
  - Includes other stakeholders
  - Identifies concerns that may not come up in individual discussion
  - Starts a dialogue with the community that can continue as the research progresses

Conclusion

- Examining the history and elements of informed consent reveals many valid justifications for it.

- Obtaining individual informed consent becomes more complex, but no less important, in international research.

Conclusion

- As practiced, informed consent may overemphasize legal protection of institutions rather than the protection and respect of human subjects.
- Although reform is needed, informed consent has long been recognized as a critical component of medical care and medical research, and that is unlikely to change.