Privacy and Research Ethics

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Full Disclosure

Conflict of Interest: No
Full Disclosure

Conflict of Interest: No

Bias: Probably
Full Disclosure

Conflict of Interest: No

Bias: Probably

“Bias has been defined as any systematic error in the design, conduct or analysis of a study that results in a mistaken estimate of an exposure’s effect on the risk of disease.”

Full Disclosure

Conflict of Interest: No

Bias: Probably

Inference: Yes

Full Disclosure

Conflict of Interest: No

Bias: Probably

Inference: Yes

Disclaimer: All of the material in this presentation, and the opinions expressed here in, are mine (T. Christie) and they do not represent the views of Horizon Health Network, any of the Universities with which I am affiliated, or any other institution. And that’s a damn shame!
Bertrand Russell 1872-1970

• “The whole problem with the world is that fools and fanatics are always so certain of themselves, and wiser people so full of doubts.”
Thomas Hobbes 1588-1679

• “The very rationality of right actions is the ground for our obligation to perform them.”
• Never retract, never explain, never apologize -- get the thing done and let them howl!
• Question:
  – “What do you get when you cross the Godfather with a Philosopher?”
• Answer:
  – “An offer you can’t understand.”
Outline

1. History of Evidence Based Medicine
2. History of Research Ethics
3. History of Informed Consent: Treatment, Research and Privacy
4. Privacy Guidelines
5. 10 Privacy Principles
Learning Objectives

1. To understand the connection between the history of Evidence Based Medicine, Research Ethics and Informed Consent to the current REB review processes and requirements.
2. To understand the Privacy considerations set out in the TCPS
3. To understand the 10 Privacy Principles.
• Standard of Disclosure for Informed Consent
  – Treatment = The amount of information that a reasonable person in that patient’s position would want to know.
  – Research = Full and frank disclosure of all risks, even theoretical
  – Privacy = Collection, Use and Disclosure.
History of Evidence Based Medicine
Historical Reasons for Treatment

• “When I qualified in medicine in 1937, new treatments were almost always introduced on the grounds that in the hands of professor A or in the hands of a consultant at one of the leading teaching hospitals, the results in a small series of patients had been superior to those recorded by professor B.”

First Published RCT

- Medical Research Council trial of Streptomycin in Pulmonary Tuberculosis in 1948.

John Snow 1813-1858

- London Sept 1854, 600 people died from cholera in a condensed area of the city.
- Registrar General was William Farr who thought cholera was caused by miasma (bad air).
- John Snow thought it was through contaminated water.
John Snow 1813-1858

- To prove his theory Snow conducted ‘shoe leather epidemiology.’

- He went from house to house counting deaths from cholera and determined the water supply for each house.
John Snow 1813-1858

- Southwark and Vauxhall Companies got water from the Thames: 315 deaths per 10,000 households

- Lambeth Company got water from upstream in Thames: 38 deaths per 10,000 households.

Ambroise Paré (1510-1590)

• “At length my oil lacked and I was constrained to apply in its place a digestive made of yolks and eggs, oil of roses and turpentine. That night I could not sleep at my ease, fearing that by lack of cauterization I would find the wounded upon which I had not used the said oil, dead from the poison. I raised myself early to visit them, when beyond my hope...
Ambroise Paré (1510-1590)

- I found those to whom I had applied the digestive medicament feeling but little pain, their wounds neither swollen nor inflamed, and having slept through the night. The others to whom I had applied the boiling oil were feverish with much pain and swelling about their wounds. Then I determined never again to burn thus so cruelly the poor wounded.”

James Lind 1716-1794

• “I took 12 patients in the scurvy on board the Salisbury at sea. The cases were as similar as I could have them… they lay together in one place and had one diet common to them all. Two of these were ordered a quart of cider per day… Two others took 25 gutts of elixir vitriol… Two others took two spoonfuls of vinegar… Two were put under a course of sea water…"
Two others had two oranges and one lemon given them each day… Two others took the bigness of nutmeg. The most sudden and visible good effects were perceived from the use of oranges and lemons, one of those who had taken them being at the end of 6 days fit for duty… The other… was appointed nurse to the rest of the sick.”

Ignatz Semmelweis (1809-1894)

- 1846 Hypothesized that obstetricians were the vectors for puerperal fever.

- Instituted hand washing after conducting autopsies.

- Mortality rate declined from 90.2/1000 live births to 12.7/1000 after hand washing implemented.
EBM & Knowledge Translation

- 50 years after Lind study the Admiralty added lemon juice to ships.

- 30 years for Semmelweis findings to be accepted.
History of Research Ethics
Mengele Case Study

• “Mengele was a doctor who became mad because of the power he was given. Nobody ever questioned him - why did this one die? Why did that one perish? The patients did not count. He professed to do what he did in the name of science, but it was a madness on his part ..."
Nuremberg Code 1946

1. Consent
   – Legal Capacity
   – Voluntary
   – Understanding
2. Social Value
3. Based on Animal Studies
4. Avoid Unnecessary Risks
5. Risk of Death Unacceptable
6. Proportional Risk Benefit Assessment
7. Safeguards
8. Qualified Investigators
9. Voluntary Withdrawal at any time
10. Clear stopping rules
The Nuremberg Code was a reaction to the research related crimes committed during World War II.

- It emphasized the importance of Informed Consent and prohibited any form of research on any person who could not give consent for him or herself.

- This is a prioritizing, in the research community, of the principle of respect for persons (autonomy).
Specific Cases Post World War II in Canada and the United States
Tuskegee Syphilis Study 1932-1972

- Tuskegee Study of Untreated Syphilis in the Negro Male (1932-1972)
- 1932—399 Black males with syphilis and 200 disease free controls were selected and followed.
- 1932—current treatments for syphilis were toxic, dangerous and of questionable effectiveness.
Tuskegee Syphilis Study 1932-1972

• Hypothesis: Is it better not to be treated with these remedies?

• 1947—penicillin was discovered to be a safe and effective treatment for syphilis.

• “Individuals enrolled in the Tuskegee Syphilis Study did not give informed consent and were not informed of their diagnosis; instead they were told they had “bad blood” and could receive free medical treatment, rides to the clinic, meals and burial insurance incase of death in return for participating.”
Tuskegee Syphilis Study 1932-1972

• “Rather than treat all syphilitic subjects with penicillin and close the study… the Tuskegee scientists withheld penicillin and information about penicillin, purely to continue to study how the disease spreads and kills. Participants were also prevented from accessing syphilis treatment programs that were available to other people in the area.”
Tuskegee Syphilis Study 1932-1972

• Tuskegee Summary
  – The research participants in this case were chosen because they were vulnerable, i.e., uneducated and black.
    • (vulnerable subjects)
  – They were not informed that they were participating in research.
    • (No difference between treatment and research)
  – They were denied effective treatment, when it became available, because the researchers felt the goals of research were more important than individual interests.
    • (New information became available that could influence their decision to participate but they were denied this information.)
Jewish Chronic Disease Hospital - 1963

• “There were intradermal injections of live human cancer cells into 22 chronically ill, debilitated non-cancer patients in 1963 without their consent… to learn if foreign cancer cells would live longer in debilitated non-cancer patients than in patients debilitated by cancer.”

• “The subjects were not told that the injection contained cancer cells, because the physicians “did not wish to stir up an unnecessary anxieties in the patients” who had “phobia and ignorance” about cancer.”

• http://www.rbs2.com/humres.htm
Jewish Chronic Disease Hospital Case Summary:

- The research subjects were not informed that they were participating in research, they thought they were receiving normal medical care.
  - (Difference between research and treatment)
- Subjects were not informed that they were being injected with live cancer cells because the investigators did not want refusals based on “irrational fears and phobias about cancer.”
  - (Lack of informed consent and intentional withholding of information.)
History of Informed Consent

- “[Dr. Hopp] is an orthopedic surgeon practicing in Lethbridge, Alberta. He had performed a disc operation on [Mr. Lepp], having first obtained his formal signed consent.”

- “A myelogram had disclosed a block in the spinal canal and the [Dr. Hopp] had removed a portion of the disc between the third and fourth lumbar vertebrae (the operation is known as a hemilaminectomy). An X-ray confirmed that the blockage had been removed.”

• “Subsequently with [Mr. Lepp] not improving as expected, it was determined that a blockage still existed and [Dr. Hopp] referred [Mr. Lepp] to a neurologist in Calgary who discovered a complete blockage between the third and fourth vertebrae.”

• “A Calgary neurosurgeon was called in who performed an extensive decompressive laminectomy from the second to the fifth lumbar vertebrae. This operation, involving considerable exploring, revealed a large chunk of extruded disc material between the third and fourth lumbar vertebrae, and it was removed.”

- “The Court of Appeal, by a majority, allowed the appeal, holding that the consent given to the operation was not an informed consent and hence there was an unlawful invasion of [Mr. Lepp’s] bodily security, a battery or assault.”
The Decision

• “Whether there was informed consent was the main issue argued in this Court. It is an issue that comes before this Court for the first time. The term “informed consent”, frequently used in American cases, reflects the fact that although there is, generally, prior consent by a patient to a proposed surgery or therapy, this does not immunize a surgeon or physician from liability for battery or for negligence if he has failed in a duty to disclose risks of the surgery or treatment, known or which should be known to him, and which are unknown to the patient. The underlying principle is the right of a patient to decide what, if anything, should be done with is body.”
The Decision

• “It follows, therefore, that a patient’s consent, whether to surgery or to therapy, will give protection to his surgeon or physician only if the patient has been sufficiently informed to enable him to make a choice whether or not to submit to the surgery or therapy. The issue of informed consent is at bottom a question whether there is a duty of disclosure, a duty by the surgeon or physician to provide information and, if so, the extend or scope of that duty.”
The Decision

• “In summary, the decided cases appear to indicate that, in obtaining the consent of a patient for the performance upon him of a surgical operation a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation. However, having said that, it should be added that the scope of the duty of disclosure and whether or not it has been breached are matters which must be decided in relation to the circumstances of each particular case.”
Reibl v. Hughes 1980

• March 18, 1970 Mr. Reibl, then 44-years-old, Polish Immigrant, and Worked for Ford Motor Company.

• He underwent serious surgery to remove an occlusion in his left internal carotid artery, which was restricting more than 15% of the blood flow.

• The procedure was elective, there was no emergency that demanded immediate attention. Although if left untreated he would be at high risk for serious adverse outcomes: stroke, paralysis, etc.

• During or immediately after surgery, Mr. Reibl suffered a stroke which resulted in unilateral paralysis, impotence, and total permanent disablement.

• The surgery was performed competently.
FACTS

• Mr. Reibl was under the mistaken impression that the surgery would relieve his headaches. FALSE

• That the risk of stroke was greater without surgery than with the surgery. TRUE

• He was not aware of the risk of stroke, paralysis, or death as a result of the surgery. TRUE

• He was only 18-months from retirement and a lifetime pension. TRUE [but not considered relevant by surgeon.]
“In answering the patient’s query about the possibility of stroke, the surgeon did not inform him of his chance of being paralyzed ... but stressed that the chances of paralysis were greater if the patient did not undergo surgery. The patient testified that he would have forgone elective surgery until a lifetime retirement pension had vested in a year and a half, and would have opted for a shorter, normal life rather than a longer one as a cripple.”

Reibl v. Hughes 1980

• “Merely because **medical evidence** established the reasonableness of a recommended operation did not mean that a **reasonable person in the patient’s position** would necessarily agree to it if proper disclosure had been made of the risks attendant upon it, balanced by those against it.”

Reibl v. Hughes 1980

- Ultimately, the Supreme Court of Canada decided that a “reasonable person” in Mr. Reibl’s position 1.5 years from a full life-time pension would have chosen to have elective surgery after he collected his pension if he was sufficiently informed of the risks.
“In my opinion, a reasonable person in the plaintiff’s position would, on a balance of probabilities, have opted against surgery rather than undergoing it at this particular time.”

- On the “Balance of Probabilities”
- Not “Beyond a Reasonable Doubt”
- Not “Clear and Convincing Evidence”
Summary

- Informed Consent Cases would be heard in negligence (duty, breach, and damage) not battery

- The standard for disclosure is an objective/subjective standard (reasonable person in the patient’s position)
Arndt v. Smith [1997]
Arndt v. Smith [1997]

- Mrs. Arndt sued her physician Dr. Smith for costs associated with raising her daughter who was congenitally injured by chickenpox that Mrs. Arndt contracted during her pregnancy.
Arndt v. Smith [1997]

• Mrs. Arndt argued that had Dr. Smith properly informed her of the risk to her fetus, she would have terminated the pregnancy and avoided the damages she suffered.
• (Calculus of Negligence: Duty, Breach and Damage)
• Dr. Smith claimed that Mrs. Arndt would not have terminated her pregnancy even if she would have been fully informed and thus, the damages Mrs. Arndt suffered were not caused by Dr. Smith's failure to inform.
Arndt v. Smith [1997]

• Basically the court upheld the Reibl v Hughes (1980) decision by considering what a reasonable person in Mrs. Arndt’s position would do. They found:
  – Mrs. Arndt had a desire for children
  – Mrs. Arndt was suspicious of mainstream medicine and initially refused an ultrasound
  – A second trimester abortion carried additional risks
  – A second trimester abortion would have required approval by a committee
  – The risks posed by chickenpox were remote
  – An abortion would not have been recommended by her physician
Arndt v. Smith [1997]

• The SSC found that a on the balance of probabilities, “a reasonable person in Mrs. Arndt’s position” would not have terminated her pregnancy and thus, the costs Mrs. Arndt has incurred were not caused by Dr. Smith’s failure to disclose.
Informed Consent and Research Ethics
Halushka v University of Saskatchewan

- On August 21, 1961, Walter Halushka went to the employment office at the University of Saskatchewan to find a job. Although there were no jobs available he was informed, by the employment office, that the University Hospital was recruiting participants for a scientific study and that the remuneration was $50. He was informed that the test would take about two hours and that it was “safe and there was nothing to worry about.”
“Doctor Wyant explained to me that a new drug was to be tried out on the Wednesday following. He told me that electrodes would be put in both arms, legs and head and that he assured me that it was a perfectly safe test it had been conducted many times before.”

The actual test was called “The Heart and Blood Circulation Response under General Anaesthesia.” The drug was called “Fluoromar” and had not been previously used or tested by the University Hospital.
• At 11:32 am, the doctors inserted a catheter through a vein in Halushka’s arm and advanced it to his heart, at which point the anaesthetic agent was administered.

• At 12:25 pm Mr. Halushka suffered a complete cardiac arrest.
  – “took immediate steps to resuscitate the respondent’s heart by manual massage. To reach the heart an incision was made from the breastbone to the line of the arm-pit and two of the ribs were pulled apart. A vasopressor was administered as well as a urea, a drug used to combat swelling of the brain. After one minute and thirty seconds the respondent’s heart began to function again.”
“In ordinary medical practice the consent given by a patient to a physician or surgeon, to be effective, must be an “informed” consent freely given. It is the duty of the physician to give a fair and reasonable explanation of the proposed treatment including the probable effect and any special or unusual risks…”
Halushka v University of Saskatchewan

• “In my opinion the duty imposed on those engaged in medical research... to those who offer themselves as subject for experimentation, as the respondent did here, is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient.”

• “The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.”
Halushka v University of Saskatchewan

• Halushka Summary

  – Mr. Halushka was not informed that the catheter would be advanced to his heart, he was not informed that this drug had not been previously tested, and he was not informed of any of the risks associated with the drug. The investigators believed that disclosing this information would prevent people from volunteering in the study. (Absence of informed consent and intentional withholding of information.)

  – This case highlights the difference between the duties owed to patients involved in treatment and those owed to subjects involved in research. (Difference between the ethical norms that guide treatment and research.)
Weiss v. Solomon


- “The duty to inform of the risks was greater in the case of an experiment than for necessary surgery. All risks, rare or remote and even potential ones had to be disclosed. The doctor in charge of the program could not discharge this obligation by a written declaration by the patient that he had had chances to ask questions…”
Consent and Privacy Considerations
“Consent to treatment and informed consent have long played a prominent part in health law’s development at common law and through professional and legislative regulation. However, consent as it relates to the collection, use and disclosure of patients’ personal health information is a separate and distinct concept from consent to treatment…”

• “With implied consent, the patient never comes out and tells the health care provider that personal health information may be collected, used or disclosed. Instead, surrounding circumstances reasonably permit the conclusion that the patient would agree if asked directly…”

• “…express consent occurs when patients agree to the collection, use and disclosure of their personal health information.”
TCPS Privacy Guidelines
Two Goals of REB Review:

1) Provide necessary protection to research participants.
   - Respect for persons
   - Concern for welfare
   - Justice

2) Serve the legitimate requirements of research.
Concern for Welfare

• “Other contributing factors to welfare are privacy and the control of information about the person…”

• “Concern for Welfare means that researchers and REBs should aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research.”
Privacy

• “Where researchers seek to collect, use, share and access different types of information or data about participants, they are expected to determine whether the information or data proposed in research may reasonably be expected to identify an individual.”
• “Information is identifiable if it, alone or when combined with other available information, may reasonably be expected to identify an individual.”
• “The term ‘personal information’ generally denotes identifiable information about an individual.”
Types of Information

1. Directly identifying information
2. Indirectly identifying information
3. Coded information
4. Anonymized information
5. Anonymous information
Privacy Concerns

1. Initial collection of information
2. Use and analysis of information
3. Dissemination of findings
4. Storage and retention of information
5. Disposal of records or devices that store information
Privacy

• “Where it is not feasible to use anonymous or anonymized data for research… the ethical duty of confidentiality and the use of appropriate measures to safeguard information become paramount.”
10. Privacy Principles

1. Accountability
   • Contact person

2. Identifying Purposes
   • Purposes for which info is collected, used, disclosed

3. Consent
   • Implied or express

4. Limiting Collection
   • Limit to what is needed to achieve goal.

5. Limiting Use and Disclosures
   • Limit use to identified purposes

6. Accuracy
   • Identify limitations to this

7. Safeguards
   • Technological, administrative, and physical

8. Openness
   • Policies regarding information practices

9. Access
   • Patients/participants

10. Challenging Compliance
    • Complaint procedure
Summary

1. History of Evidence Based Medicine
2. History of Research Ethics
3. History of Informed Consent: Treatment, Research and Privacy
4. Privacy Guidelines
5. 10 Privacy Principles
Take Home Message

• Standard of Disclosure for Informed Consent
  – Treatment = The amount of information that a reasonable person in that patient’s position would want to know.
  – Research = Full and frank disclosure of all risks, even theoretical
  – Privacy = Collection, Use and Disclosure.