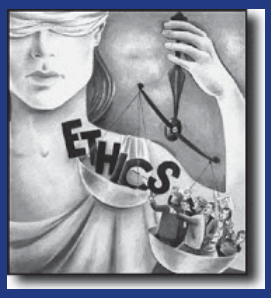
Ethics of Radiation Protection in Medicine



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First IRPA North American Workshop on the
Ethics of Radiological Protection
Baltimore, Maryland, USA
17-18 July 2014

Disclosures

- Financial: None
- Views: My own based on:
  - experience at Mayo Clinic,
  - participation in consensus organizations,
  - review of literature.

Radiation in Medicine

- Patients exposed to radiation:
  - Research
  - Practice
- Occupational radiation exposure (not addressed in this paper)

Radiation in Medicine

- Day 1 – Anna Ludwig Roentgen's ring:

Radiation in Medical Research

1949 Nuremberg Code:

–The first principle of which is that voluntary consent of human research subjects is required prior to participation in research.

Radiation in Medical Research

Informed Consent:

1932- U.S. Navy required that subjects for proposed experiments be “informed volunteers.”

1950s- Committee on Medical Research (subsequently NIH) decreed “where risks are involved, volunteers only should be utilized as subjects and these only after signed statements have been obtained.” [for normals rather than patient-subjects]

Radiation in Medical Research

1964 Declaration of Helsinki: World Medical Association recommendations - guide to physicians conducting biomedical human use research.

- Included the principal of consent and expanded that principal to issues of coercion and study of individuals who are legally incompetent.
- IAEA (BSS): human radiation exposure in medical research is not justified unless :
- a) in accordance with the provisions of the Helsinki Declaration,
- b)follows the guidelines of Council for International Organizations of Medical Sciences and World Health Organization, and
- c) subject to advice of an Ethical Review Committee (e.g. IRB) and to applicable national and local regulations.

Radiation in Medical Research

1974 Belmont Report: U.S. National Research Act creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

–Identified the primary ethical principles that would become the basis for the conduct of biomedical and behavioral research – The Belmont Report.

Belmont Report Ethical Principles

Respect for persons

-Dignity and freedom of every person

-Informed consent from all potential research subjects or their legally authorized representatives

Beneficence

-Researchers maximize benefits and minimize harm

-Research related risks must be reasonable in light of expected benefits

Belmont Report Ethical Principles -continued

Justice

-Equitable selection, recruitment and fair treatment of research subjects

Autonomy

-Patients' right to information

-Patients' right to accept or reject treatment

National Bioethics Advisory Commission

• Established by President Clinton in 1995 to address allegations of unethical practices in government-sponsored research experiments involving human subjects from 1944 to 1994.

This investigation was stimulated by reports criticizing experiments in concentration camps (freezing, infectious diseases, methods of killing)

•Also the result of the widely publicized Tuskegee Study by USPHS.

Institutional Review Board

•A central protection for research participants is the guarantee that someone other than the investigator will assess the risks of the proposed research.

No one should participate in research unless independent review concludes that the risks are reasonable in relation to the potential benefits.

•In US, IRB is principle structure responsible for conducting such reviews.

Radiation in Medical Research

- Radiation, e.g. x-rays or nuclear scans, may be used to measure the effect of an experimental agent or procedure, e.g. new therapeutic drug, placement of catheter.
- There is no specific dose limits for these protocols, but the radiation is applied as a "routine" diagnostic test (standard of practice). Cannot combine "experimental" radiation with "experimental" agent.
- Assumption: human subject receives no benefit; radiation must be justified & optimized.
- If radiation is experimental, it must be justified but not necessarily optimized e.g. new radiopharmaceutical.

Radiation in Medical Research

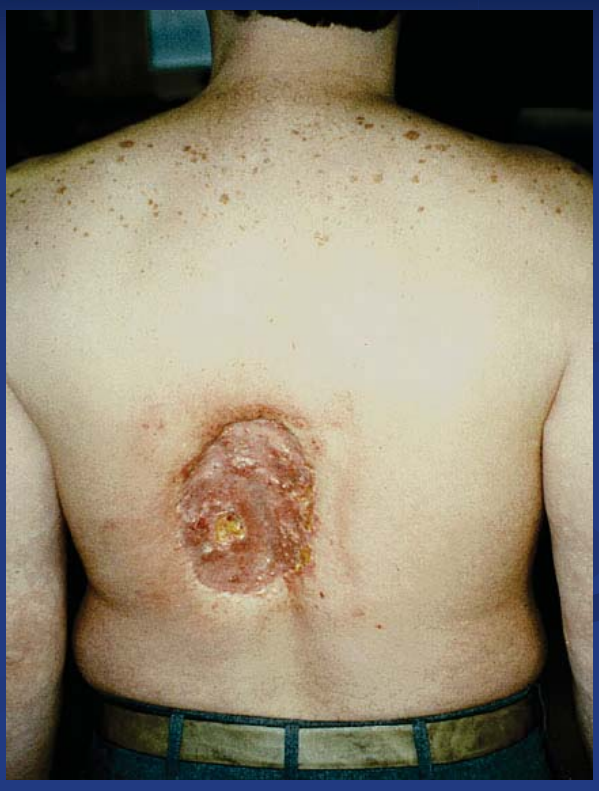
- FDA Regulation on Use of Radioactive Drugs in Research: Describes the conditions under which radioactive drug research may be conducted (21 CFR Part 361).

Example of Major Benefit from Radiation in Research

- Development of angioplasty:
  - Benefits:
    - Eliminates risk from open heart surgery.
    - Rapidly reopens heart arteries in patients having heart attacks.
    - Opens heart arteries in patients with blocked arteries likely to result in heart attack.
  - Risks:
    - Predicted radiation doses from a few mSv to a few Gy
      - Deterministic: skin burns
      - Stochastic: low risk of cancer (up to ~ 1% increase)

Example of Major Benefit from Radiation in Research

- Development of angioplasty:
  - Complications:
    - 10s of Gy in some early patients.



Example of Major Benefit from Radiation in Research

- Development of angioplasty:
  - Results:
    - This procedure has since become standard therapy for heart attacks around the world.
    - Combined with drug eluting stents, patients live years to decades longer without open heart surgery.

Dilemmas in Research

- How to communicate radiation procedures?
- How to communicate radiation risk?
- Industry protocols that demand radiation procedures, e.g. extra CT to measure tumor growth.

Radiation in Medical Research

- How to communicate procedure?

"The essential fatty acid that will be infused into your body will be labeled with a radioactive substance called tritium. The amount of tritiated octadecatrienoic acid perfused through microdialysis tubing into your subclavian artery will be 0.1 uCi/ml up to a total of 2.0 uCi."

Radiation in Medical Research

- How to communicate risk?

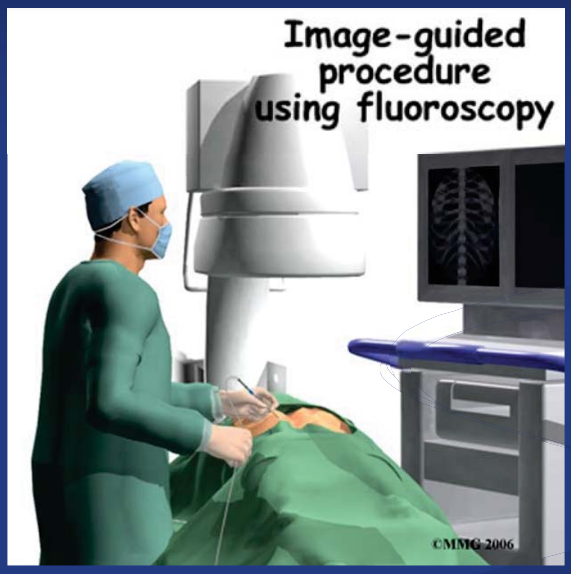
  "I understand that I will be injected with either 1 or 100 uCi of the radioactive compound used in this study. The radiation dose that I will receive from this study includes either 2.2 mrem mrem (mrem is a measure of the radiation dose) or 220 mrem to my urinary bladder. The rest of my body will receive a radiation dose that is less that the daily dose that I receive from natural background radiation (radiation that I receive from cosmic rays, radioactive materials present in the earth's crust and radioactive materials normally present in my body). Although unlikely, this increases my risk of developing bladder cancer."

Radiation in Medical Research

- Or:

I understand that I will be injected with a small amount of radioactive drug as a result of my participation in this study. The amount of radiation I will receive is well below the level that results in significant risk of harmful effects.

Radiation in Medical Practice



Principles of Medical Ethics in Radiation Practice

- The Four Principles*
  - Autonomy (right to make own choice)
  - Beneficence (acting in best interest of patient)
  - Non-Maleficence ("above all, do no harm")
  - Justice (emphasizes fairness and equality among individuals)

*The Four Principles, originally devised by Beauchamp and Childress in their textbook *Principles of Biomedical Ethics* (Oxford University Press, 2001), are considered by many as the standard theoretical framework from which to analyze ethical situations in medicine.

Principles of Medical Ethics in Radiation Practice

- By definition:
  - Intentional exposure to potential harmful agent.
  - Exposure results in direct benefit to patient.
- Principles of Protection (ICRP 103)
  - Justification (cornerstone of ICRP and IAEA ethical philosophy; sanctions a utilitarian ethic, i.e. to maximize benefits to the majority of people vs. egalitarian ethic, i.e. equal protection of all people).
  - Optimization (optimize protection and economics).

Principles of Medical Ethics in Radiation Practice

- Principles of Protection (ICRP 103)
  - Justification of a procedure:
    - Professional bodies and regulators.
  - Justification of use in a patient:
    - Decision made by healthcare provider.
    - Procedure will result in benefit to patient.
    - Avoid unnecessary exposures in diagnostic and interventional procedures.
    - Avoid unnecessary exposure of healthy tissues in radiation therapy.

Principles of Medical Ethics in Radiation Practice

- Essentially individual patient centered
- Beneficence, non-maleficence, and justice defined in terms of individual patient:
  - How does patient define "good"?
  - How does patient define "harm"?
  - Justice ensures that each patient has access to equivalent goods based solely on need.

Dilemmas in Practice

- Patient release following thyroid therapy with I-131:
  - Without consent, members of public receive radiation exposure from patients who were treated and released (not hospitalized). This benefits:
    - General public (very successful method to treat thyroid disease).
    - Reduces cost (benefits patient and payer).
    - Improves well being of many patients.
  - Patients expected to follow instructions designed to minimize public exposure but no enforcement.
    - Patient may become ill on auto journey home and stays in hotel against instructions of physician.

Dilemmas in Practice

- Patient release following thyroid therapy with I-131:

Release Limits

Country	Activity (MBq)
USA*	1200
UK	800
Australia	600
Japan	500
Germany	75

*May be exceeded if dose estimate to public does not exceed 5 mSv

Summary

- Research in which human subjects are exposed to radiation must be conducted in accordance with requirements of:
  - Declaration of Helsinki
  - IAEA
  - WHO
  - ICRP

Summary

- In United States must satisfy (Belmont):
  - Respect for person (dignity, informed consent),
  - Beneficence (maximize benefits, minimize harm),
  - Justice (fairness),
  - Autonomy (patients' right to information and to accept or reject treatment).

Summary

- Radiation procedures and individual patient/subject exposures must be:
  - Justified (a utilitarian ethic)
  - Optimized (a utilitarian ethic that considers dose, social values, and economics)

Summary

- The Four Ethical Principles for Practice
  - Autonomy (right to make own choice)
  - Beneficence (acting in best interest of patient)
  - Non-Maleficence ("above all, do no harm")
  - Justice (emphasizes fairness and equality among individuals)

THE END