

# Ethics of Radiation Protection in Medicine



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# 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 principle of consent and expanded that principle 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?

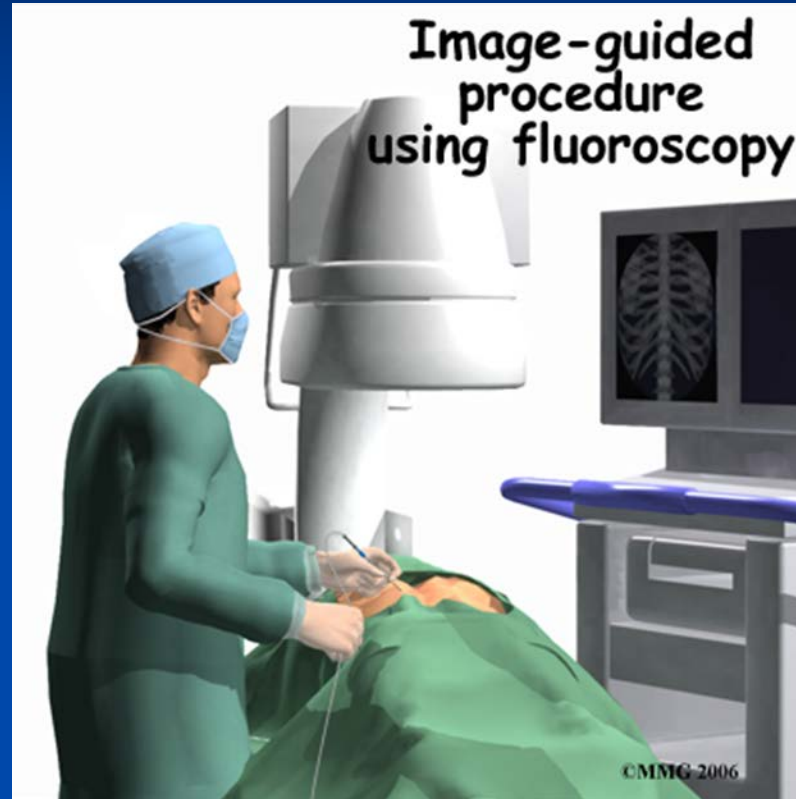
“I understand that I will be injected with either 1 or 100 uCi of the radioactive compound used in this study. The radiation dose that I will receive from this study includes either 2.2 mrem mrem (mrem is a measure of the radiation dose) or 220 mrem to my urinary bladder. The rest of my body will receive a radiation dose that is less than 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

<u>Country</u>	<u>Activity (MBq)</u>
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)

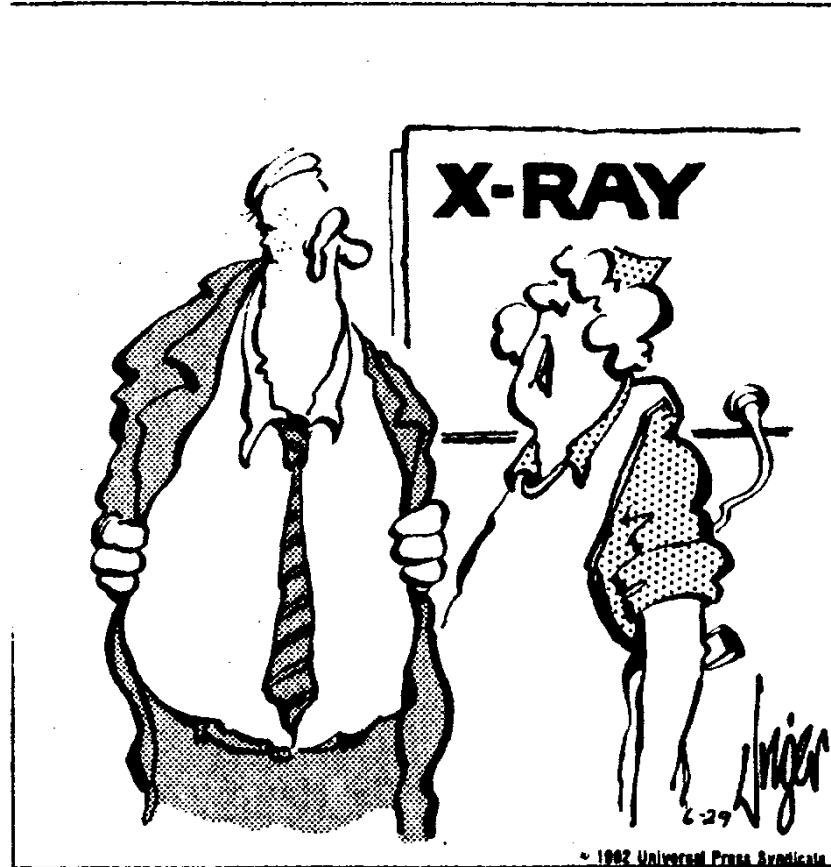


# Summary

- 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

Herman



"Don't bother undressing.  
I'll turn up the power."