

Equipoise and Proton Beam Therapy

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Agenda

Definition of equipoise

Relevant ethics

History of equipoise

Grounds for equipoise

Equipoise and protons

A Definition of Equipoise

“the state of uncertainty or lack of **grounded** preference concerning which of two treatments options is **preferable**”

A Definition of Ethics

“The rules or standards governing the conduct of a person or the members of the profession.”

Principles of Biomedical Ethics

Respect for Autonomy

Non-maleficence

Beneficence

Justice

Medical Professionalism

Expert knowledge

Self-regulation

Fiduciary responsibility

“those attitudes and behaviors that serve to maintain patient interest above physician self-interest”

The Ethics of Science

Ask a Question

Do Background Research

Construct a Hypothesis

Test Your Hypothesis

Analyze Your Data

Communicate Your Results

The Ethics of Clinical Research

Belmont Report

Respect for Persons

Beneficence

Justice

Patient Care

Autonomy

Non-maleficence

Beneficence

Justice

Science

Hypothesis

Blinding/Masking

Placebo

Randomization

Clinical Research

Beneficence

Respect for Persons

Justice

Equipoise

Of Mice but Not Men

“The randomized clinical trial requires doctors to act simultaneously as physicians and scientists. This puts them in a difficult and sometimes untenable ethical position.”



Carlos Gutierrez

Chaiten Volcano May 2, 2008

A Definition of Equipoise

“the state of uncertainty or lack of **grounded** preference concerning which of two treatments options is **preferable**”

Whose Equipoise?

- Individual physician (Fried)
- MD community (Freedman)
- Patient/Subject

Fried's Equipoise (FE)

- Concern of research vs care
- Physician is the moral locus
- “Genuine uncertainty”
- FE used to justify lack of consent
- Interpreted as absolute uncertainty

Freedman's Equipoise

- Fried's E = "theoretical E"
- Impossibly demanding
- Freedman redefines E
- Moral locus is medical community
- Calls this "clinical equipoise" (CE)

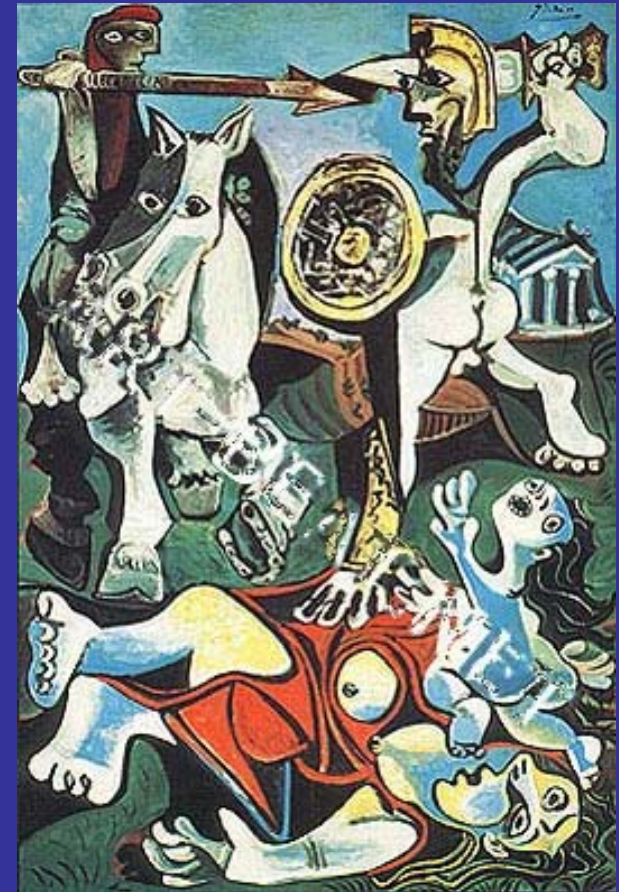
Rehabilitating Equipoise

- FE=fiduciary duty to patient
- CE=standard for social approval
- Not competing concepts
- Complementary, both required

The Irrelevance of Equipoise

- Rejects FE and CE
- Only the subject/patient important
- Subject equipoise not required
- Informed, free, unexploited consent

Grounds for Equipoise



Grounds for Equipoise

Physician perspective

- Evidence-based medicine
- “Early adopters”
- Idiosyncratic grounds

Grounds for Equipoise

Patients/Subjects

- Shared decision making
- Idiosyncratic
- Advocacy

Proton Advocacy

“The laws of physics prove
beyond a shadow of a doubt
that proton radiation is better”

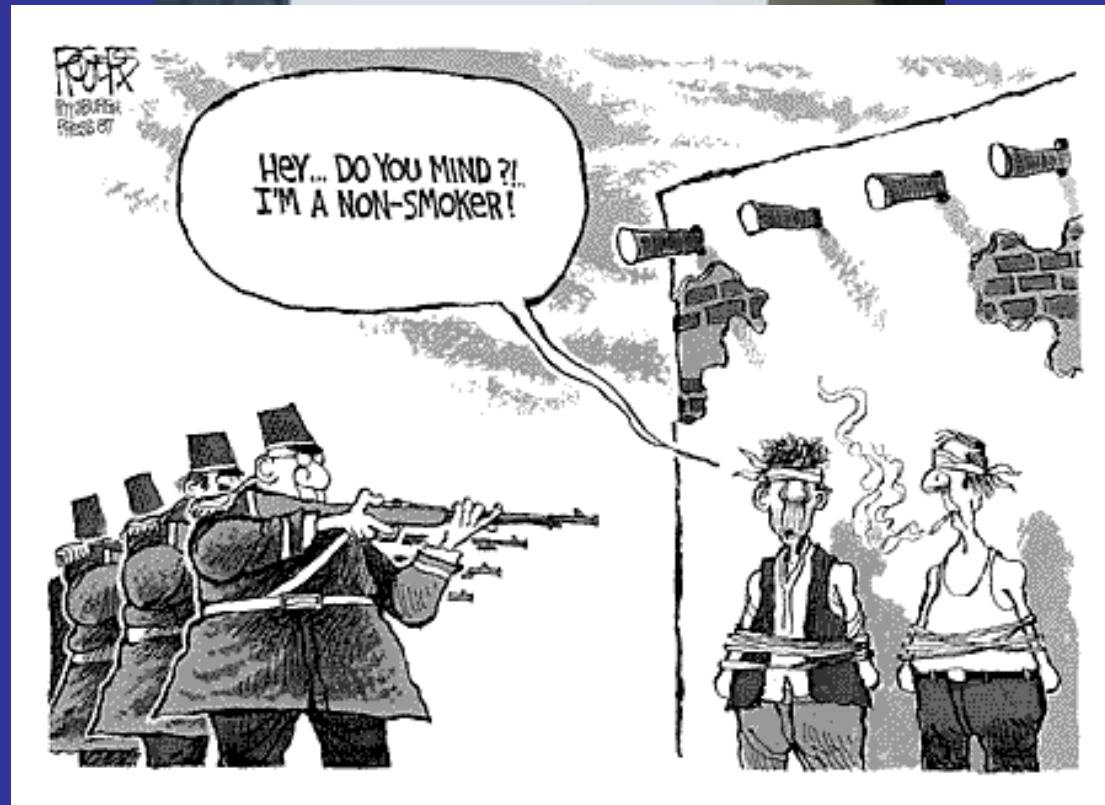
Robert Marckini
Founder ProtonBOB
Forbes, March 2009

Proton Equipoise

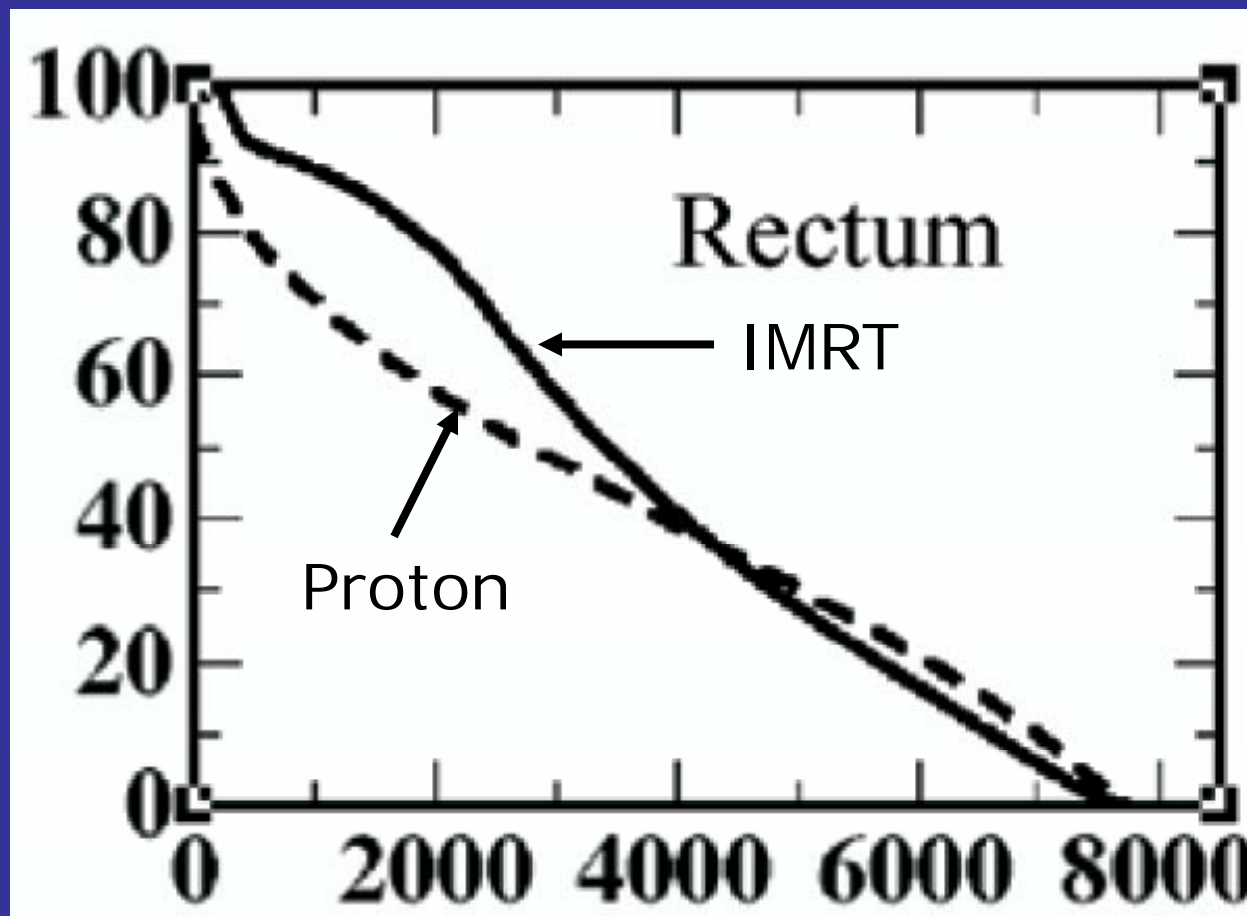
Proton Therapy

- Not a placebo
- High level evidence lacking
- Scarce Resource
- Expensive
- Evolving technology

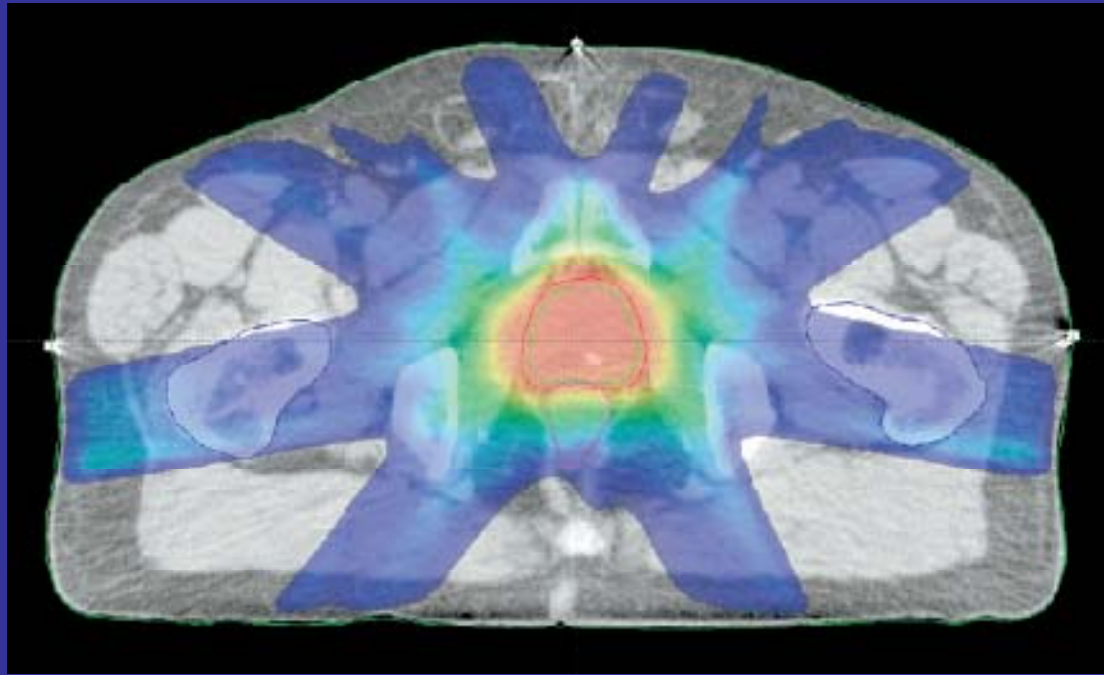
Context Matters



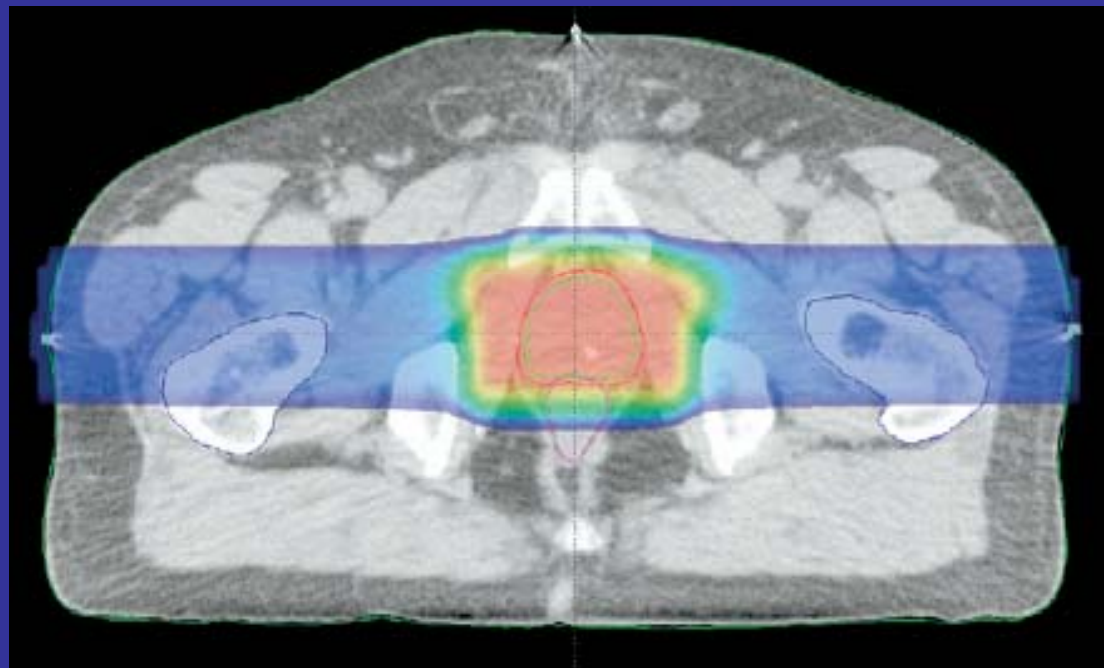
DVH Idolatry



“The proton therapy plan was better at sparing the rectum at doses of less than 50 Gy. However, above 50 Gy, IMRT was better at sparing the rectum.”



IMRT



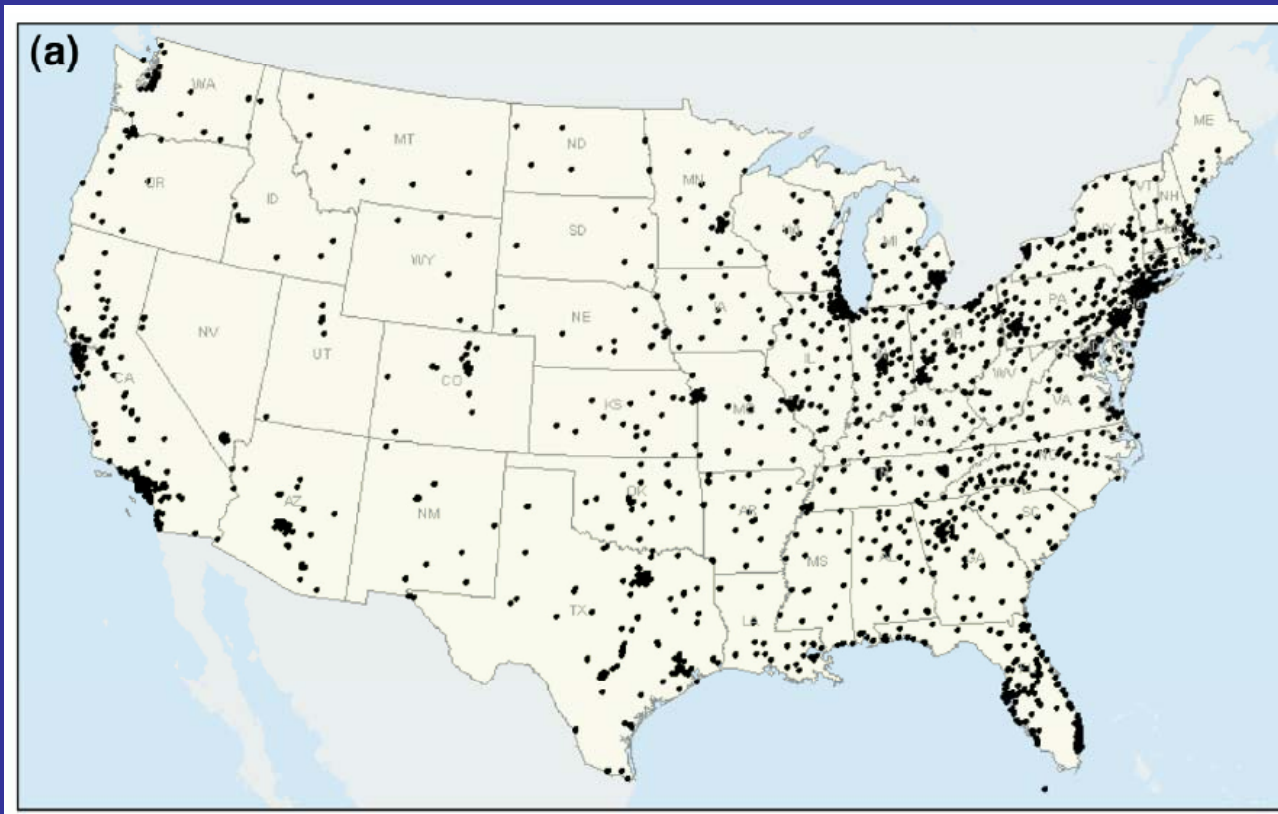
Prot

Proton Equipoise

“current or imminent conflict in the clinical community over what treatment is preferred for patients in a defined population.”

“honest, professional disagreement”

Protons: A Scarce Resource



2,246 photon
<10 proton

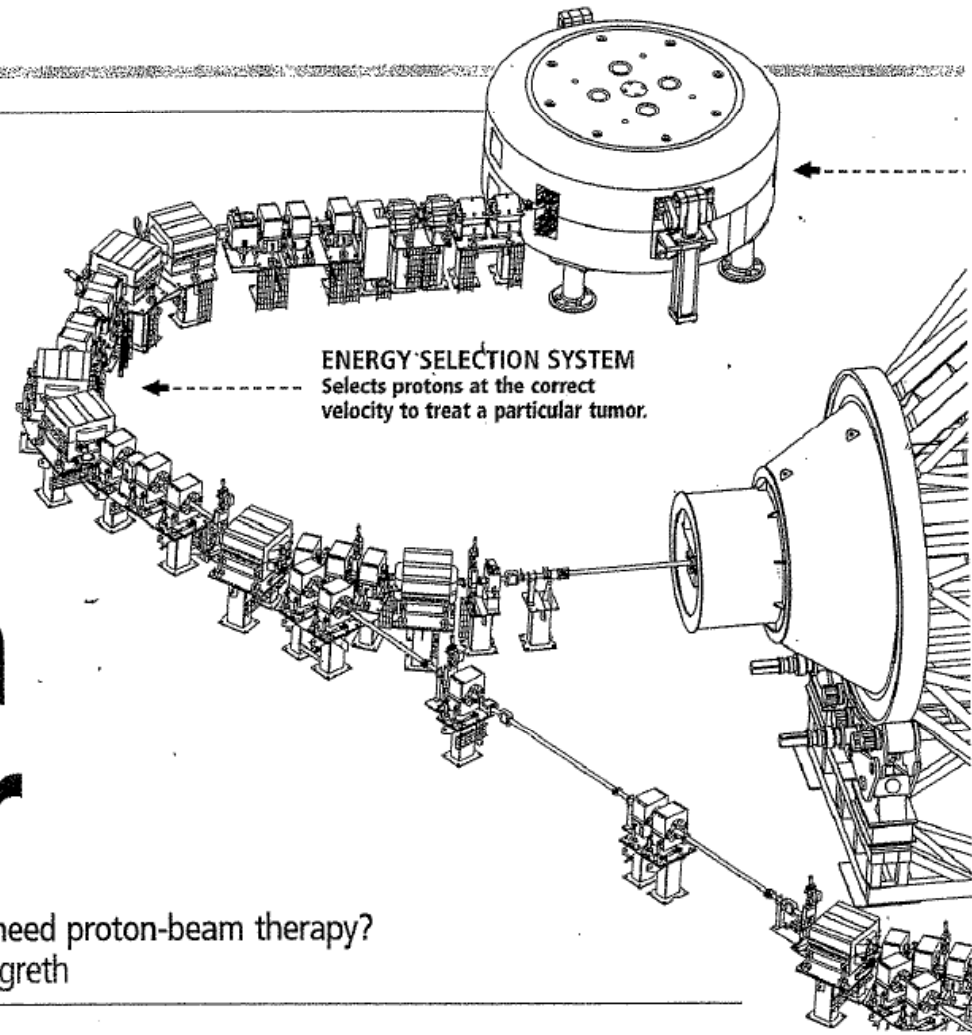
Proton Therapy is Expensive

HEALTH

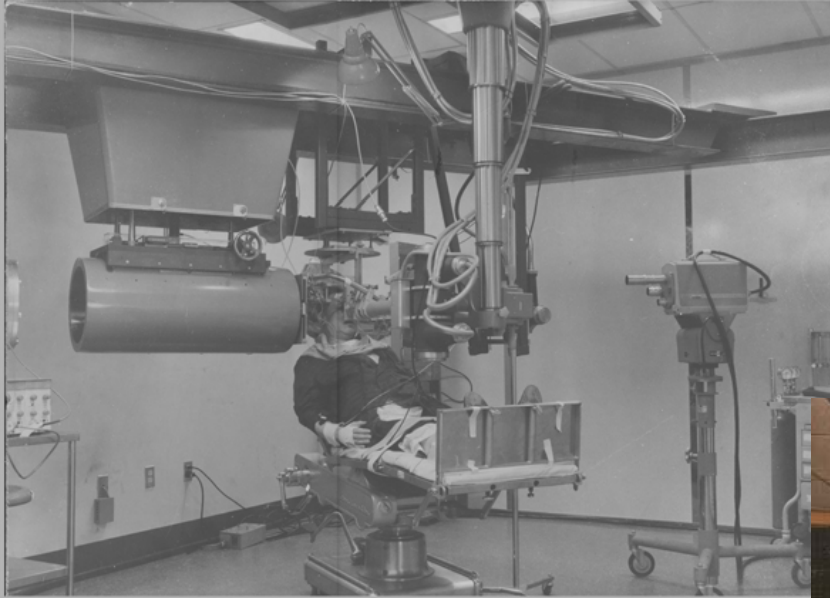
RADIATION THERAPY

The \$150 Million Zapper

Does every cancer patient really need proton-beam therapy?
By David Whelan and Robert Langreth



Proton Technology is Evolving



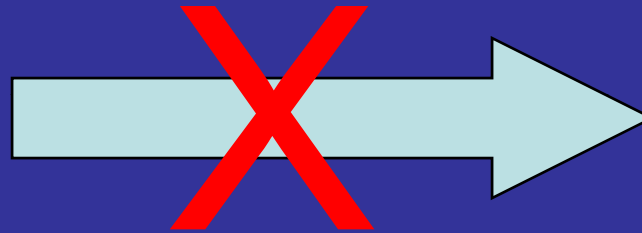


Undisclosed location July 6, 2008

Ignore Individual Equipoise?

“...it may be inappropriate to ask clinicians and their patients to be the principal gatekeepers of developments in practice.”

Equipoise



RCT

It's the hypothesis, stupid!

Will equipoise be disturbed?

Proton Advantage

“...given that protons are a limited and expensive resource, it is important to identify the indications for which protons would probably have the greatest advantage—presumably largely for situations in which current therapies are inadequate.”

Proton Payment

“With very few exceptions, there is little clinical reason to argue against the use of protons for almost any patient or disease site. However, treatments that offer only marginal advantages over X-rays will not long be reimbursed...”