Impact of New Technology Diffusion on Medicare Expenditures

July 20, 2015

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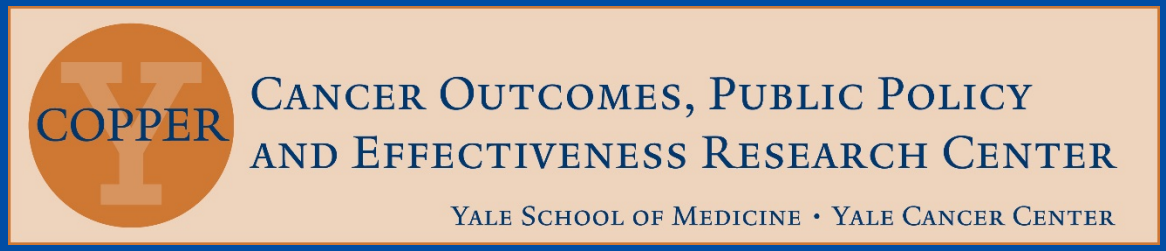


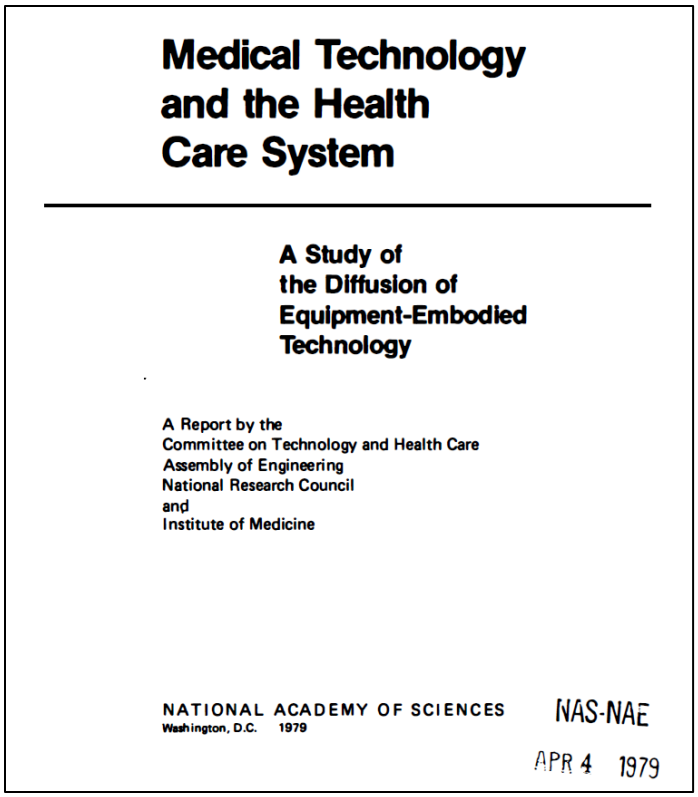
Disclosures

- Research gift to my institution: 21st Century Oncology LLC

Outline

1) Context
   - Why are we here?
2) History of recent technology diffusion for radiation oncology
   - Intensity modulated radiation therapy (IMRT)
   - Proton radiotherapy
3) What factors influence radiation technology diffusion?
   - What is the typical pattern of adoption? Who are the stakeholders in radiation technology adoption?
   - What can we learn and predict about IMRT and Proton therapy?
4) What is the cost of new radiation technology adoption to Medicare?
5) How to move forward

Context: Why are we here? We've been here before...



Medical Technology and the Health Care System

A Study of the Diffusion of Equipment-Embodied Technology

A Report by the
Committee on Technology and Health Care
Assembly of Engineering
National Research Council
and
Institute of Medicine

NATIONAL ACADEMY OF SCIENCES
Washington, D.C. 1979

NAS-NAE
APR 4 1979

1979 Institute of Medicine Panel

Of all the problems which constitute the medical care "crisis," none receives more attention than the consistently and rapidly escalating costs of personal health services, especially those associated with hospital care. Two decades ago, health expenditures totaled less than 5 percent of the nation's Gross National Product; today, Americans devote over 8.5 percent of GNP to health. The cost of a day of hospital care grew by more than 1,000 percent from 1950 to the present, while general consumer prices rose only 125 percent. In the public sector, the health share of the federal budget has risen from half a percent 20 years ago to more than 8 percent. With consumption of services increasingly freed from direct financial liability through the vehicle of insurance, and with the supply of services functioning with only limited regulation and controls, there is no clear end in sight to the problem of medical cost inflation.[1]

National Research Council. *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology*. Washington DC: The National Academies Press. 1979.

Money can be better spent. We can do better.

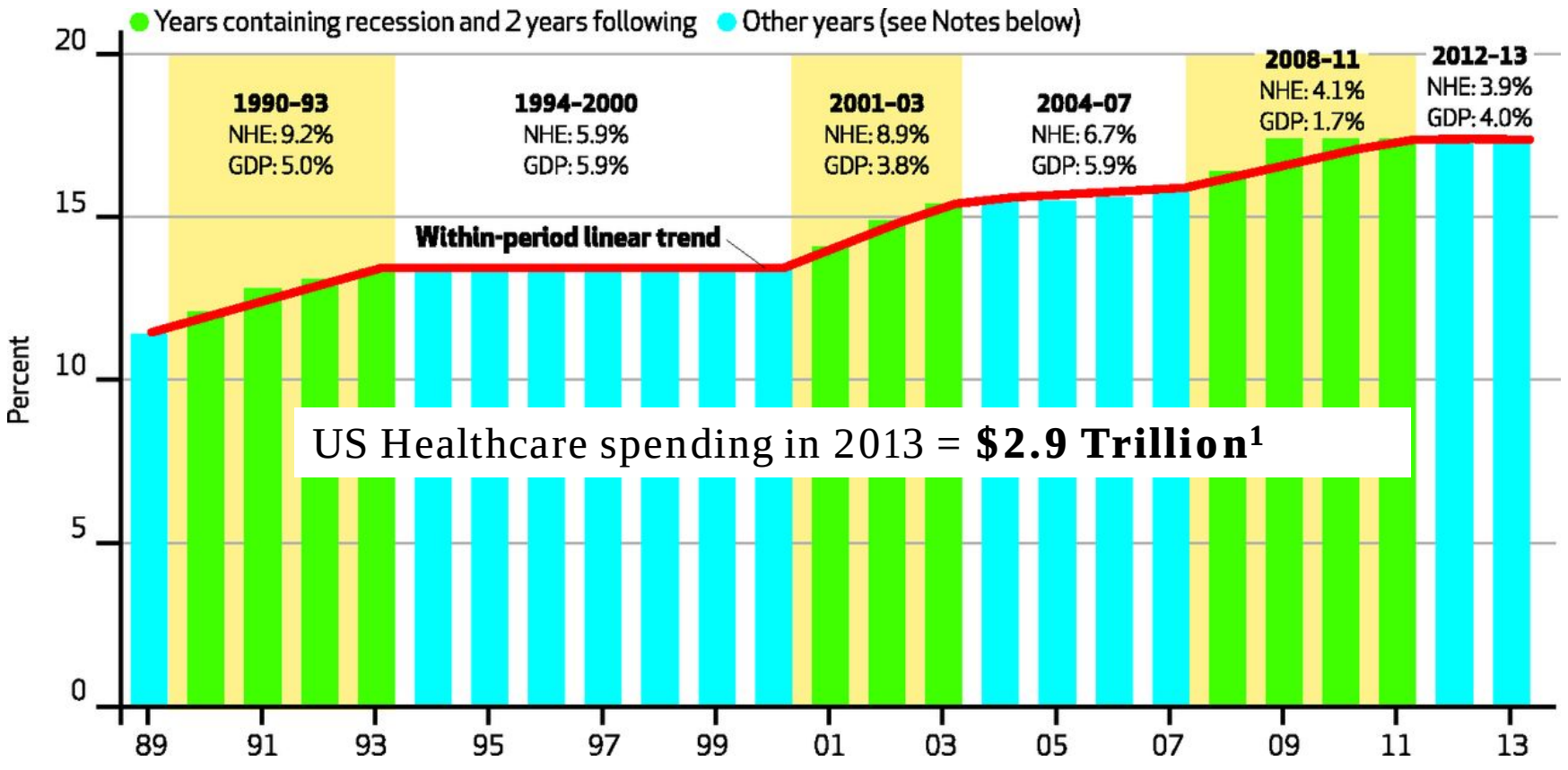
[W]e spent 4 billion dollars for new technology [for Medicare patients in 1976] and we do not know if it did any good, much less how much. . . .

. . . If we had continued providing hospital services to the aged, as they were in 1967, then we could have spent that 4 billion dollars last year [to] . . . have

- Brought *all* aged persons above the poverty line [with at least 3.3 million currently living below it]; or
- Provided the rent to raise 2 million elderly from substandard to standard housing units;

National Research Council. *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology*. Washington DC: The National Academies Press. 1979.

Here we are in 2015– the stakes to society are even greater



National Health Expenditure Accounts (http://www.cms.hhs.gov)
Hartman M, et al. Health Aff. 2014.

The personal "financial toxicity" of health care is arguably ***even greater*** in 2015

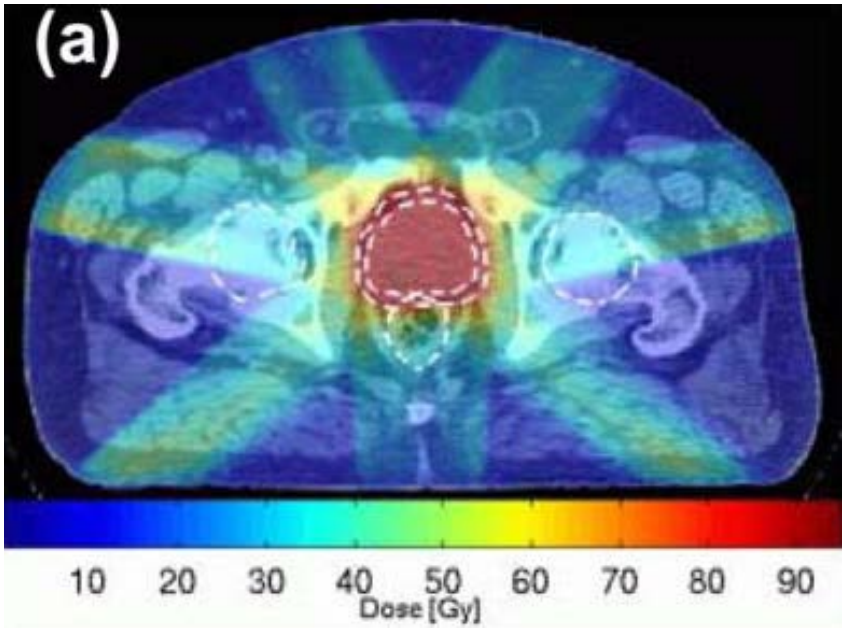
- Financial burden among cancer survivors impacts their quality of life[2,3]
  - So even a treatment is just as safe physically, it can impact patients through its cost
- Therefore, rejecting low-value or overly expensive treatments and technology is a top priority for medicine
  - ABIM Choosing Wisely campaign[4]

That is the context of this talk. What are two examples of radiation technology diffusion?

[1]CDC/National Center for Health Statistics
[2]Zafar SY, et al. J Oncol Pract. 2015;11:145-50.
[3]Zafar SY, et al. Oncology (Williston Park). 2013;27:80-1.
[4]http://www.choosingwisely.org

2) History of recent technology diffusion for radiation oncology

Intensity modulated radiation therapy (IMRT): A method of optimally shaping radiation dose by varying the intensity across a photon radiation beam through the use of complex radiation dose planning and specially equipped linear accelerators



Trofimov A, Nguyen PL, Coen JJ, et al. Radiotherapy treatment of early-stage prostate cancer with IMRT and protons: a treatment planning comparison. Int J Radiat Oncol Biol Phys. 2007;69:444-53.

A brief history of IMRT

1988 Anders Brahme publishes first paper on algebraic inverse radiation dose planning (a key theoretical step in the creation of IMRT)

1995 Main planning and delivery techniques worked out and early treatments delivered

2000 All major companies offering IMRT capable machines and software

2002 Medicare approves primary CPT code for IMRT delivery (77418)**

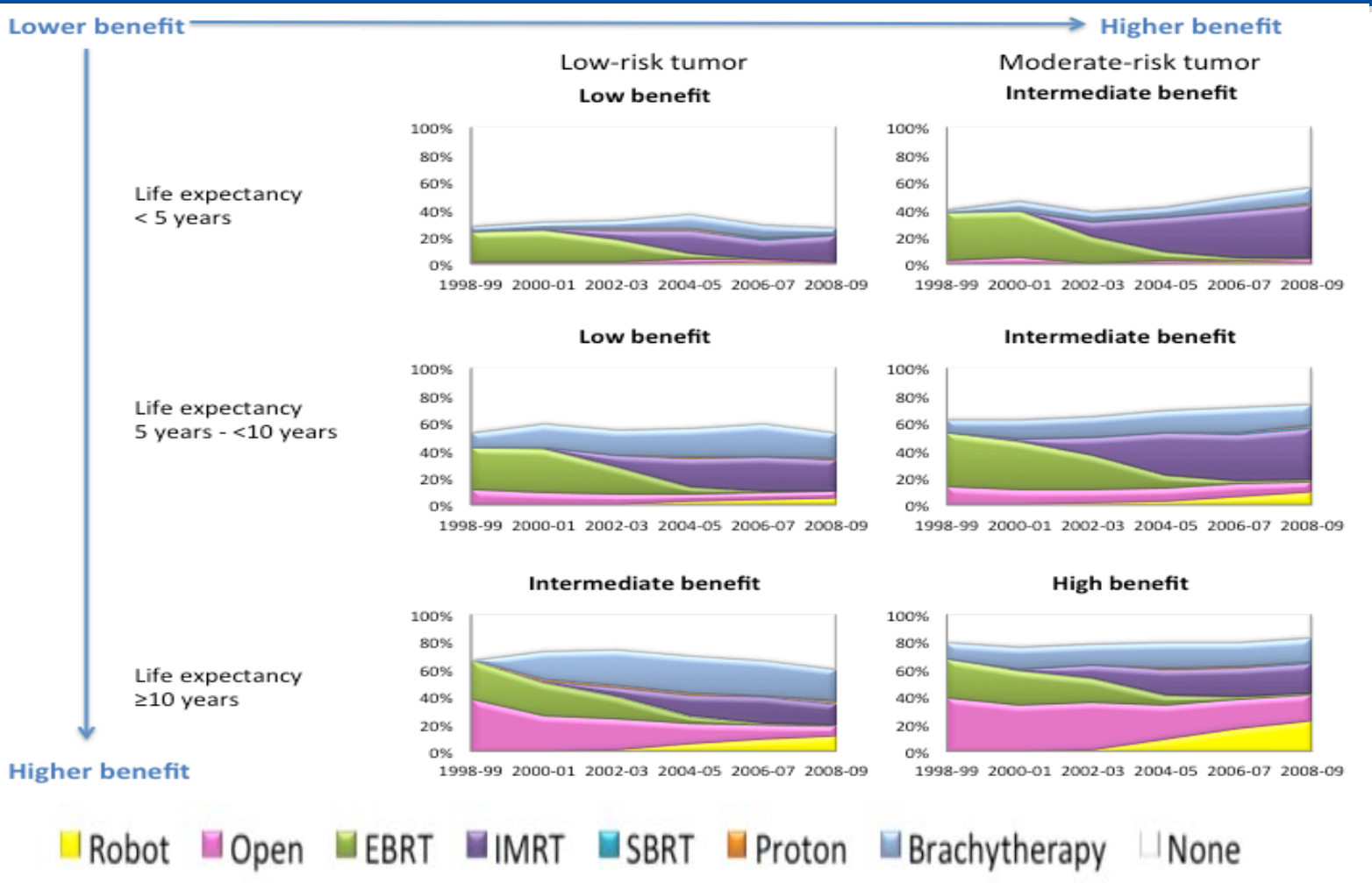
IMRT then rapidly adopted...

1994

2002

Thanks to Steve Webb – Emeritus Professor – Institute of Cancer Research and Royal Marsden Hospital Joint Department of Physics, UK

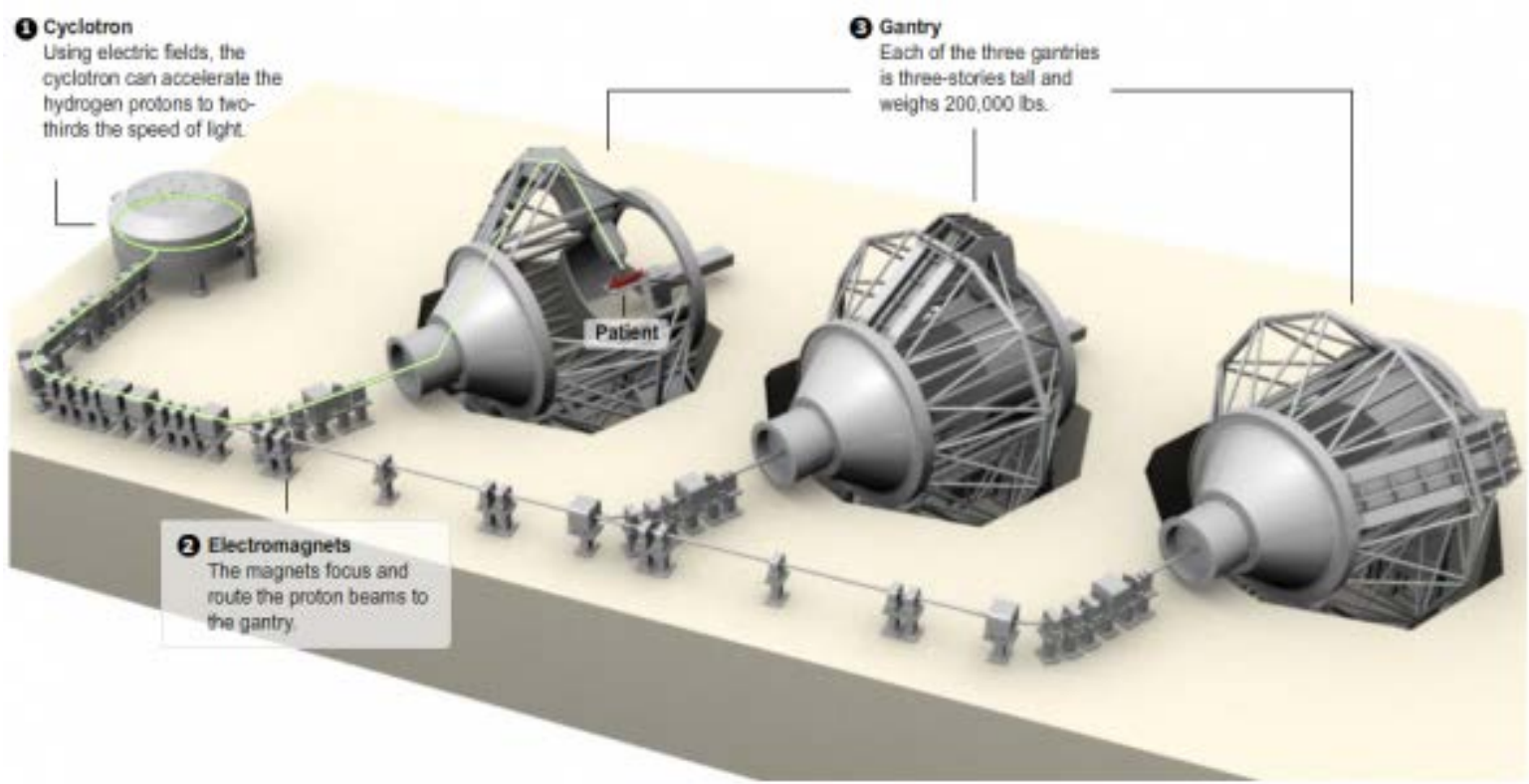
Example: IMRT rapidly replaced 3D conformal radiotherapy for prostate cancer



Raldow AC, et al. Dissemination of new technologies: cost and temporal trends in curative therapy for prostate cancer. Unpublished. (Yale COPPER Center)

What is proton beam radiotherapy?

- Minimizes entry and exit radiotherapy dose
- Very technologically complex and resource intensive



Pollack, A. Hospitals look to nuclear tool to fight cancer. The New York Times. December 26, 2007

A Brief History of Proton Therapy

- First postulated to treat cancer in 1946 by Robert Wilson
- 1954 First patient treated at Berkeley Radiation Laboratory
- 1988 Proton therapy approved by FDA for treatment of cancer
- 1990 Loma Linda University opens first hospital based proton clinic

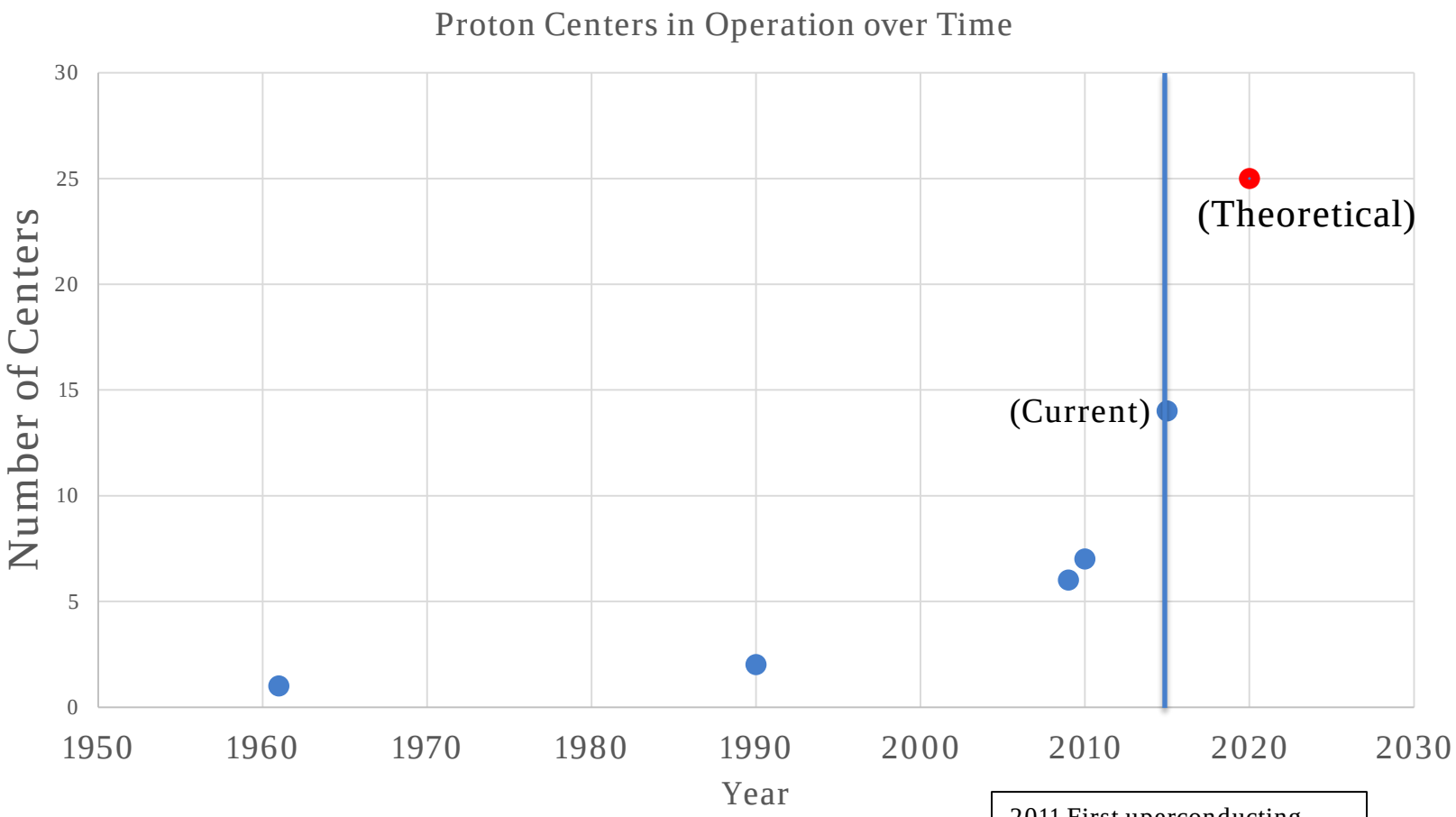
Proton beam radiation - 2009

Yu JB, et al. J Natl Canc Inst. 2013;105:25-32.

Proton beam radiation - 2015

From: http://www.proton-therapy.org/map.htm

Proton beam therapy – rate of adoption



Summary

- IMRT diffusion has been rapid and relatively complete
- Proton radiotherapy diffusion is just beginning and accelerating

- Both technologies are ***theoretically safer***, but have a relative lack of evidence supporting their use in many clinical situations where it is already being applied
  - Though some applications have much evidence to support its use (for example, IMRT for head and neck cancers[1], proton radiotherapy for pediatric cancers or chordoma[2])

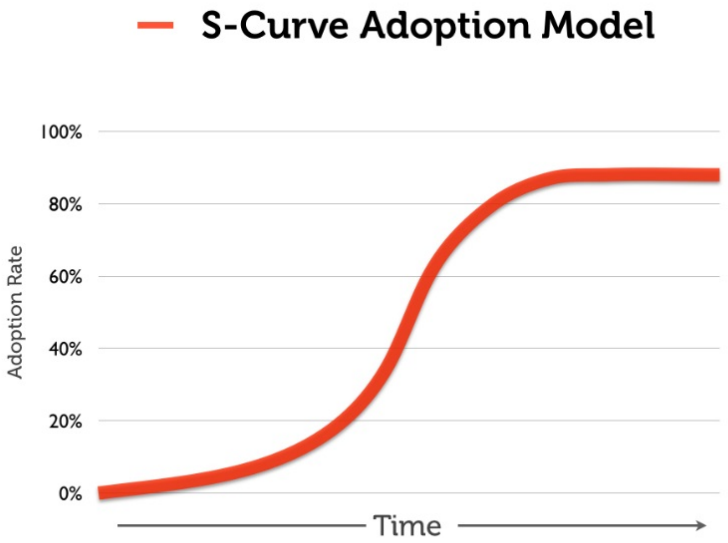
- **Why was diffusion different for IMRT vs. Proton therapy? Let's dig deeper.**

[1]Nutting CM et al. Lancet Oncol. 2011;12:127-36.
[2]Allen AM, et al. An evidence based review of proton beam therapy: the report of ASTRO's emerging technology committee. Radiother Oncol. 2012;103:8-11.

3) What factors influence radiation technology diffusion?

Much has been written regarding the factors generally influencing technology diffusion

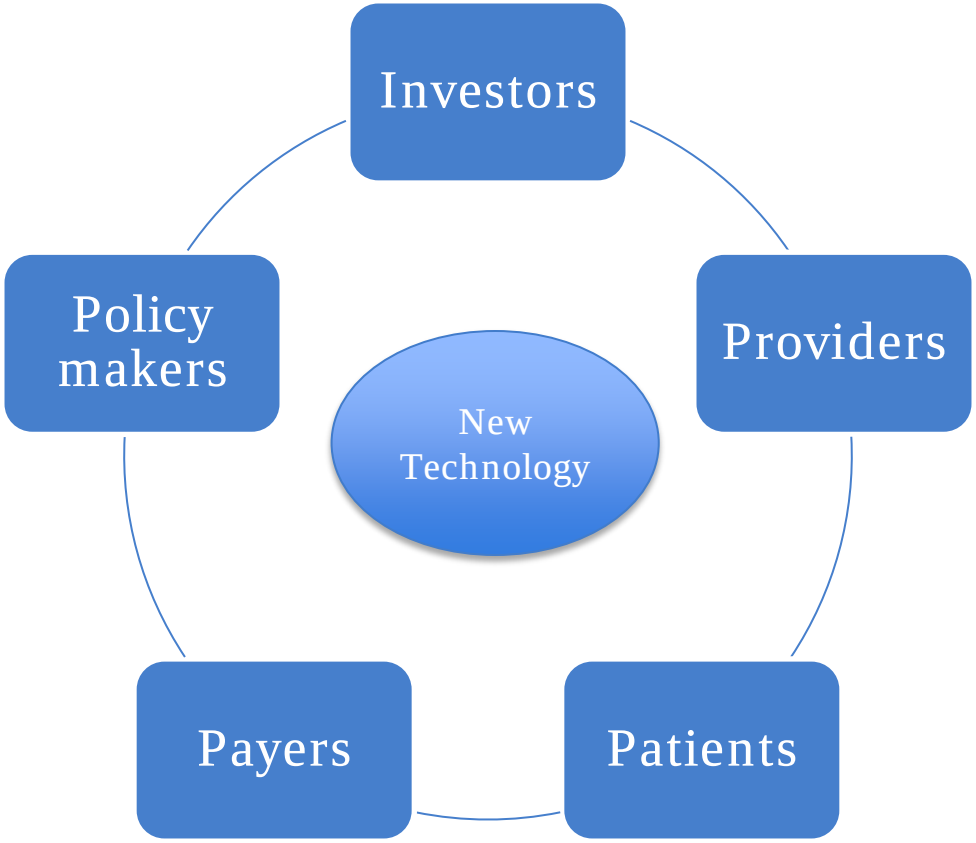
- Perception of "extra benefit"
- Competition advantage
- Capital cost
- Skills and knowledge required
- Evidence supporting the technology
- Stability of need (i.e. patients)
- Return on investment



Technology adoption when it occurs is thought to largely mimic an "S curve"

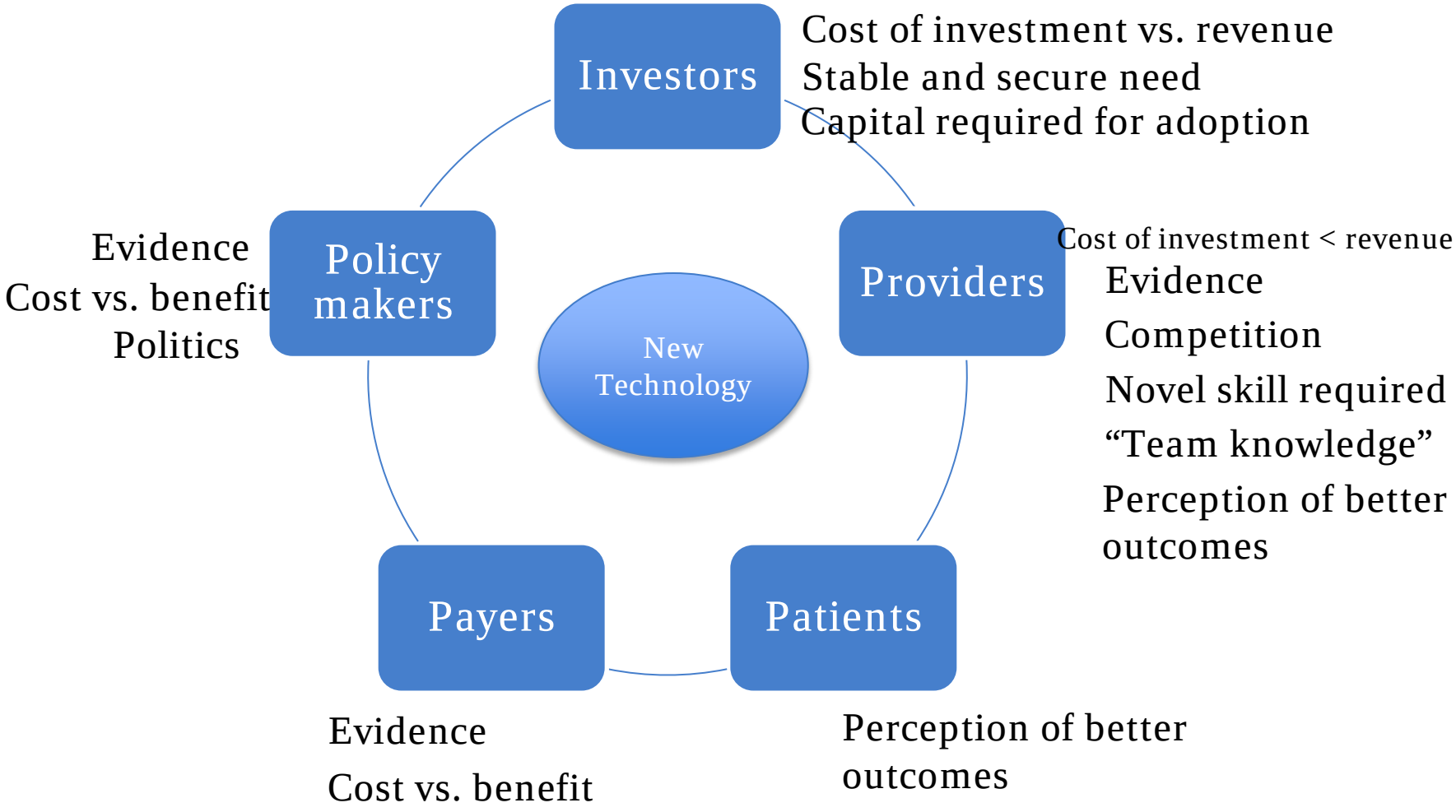
Dirksen CD et al. Health Policy. 1996;37:91-104.
Hall BH and Khan B. *New Economy Handbook: Hall and Khan*. November 2002.
Geroski PA. Centre for Economic Policy Research. Discussion Paper No. 2146. May 1999.

Stakeholders in radiation oncology technology

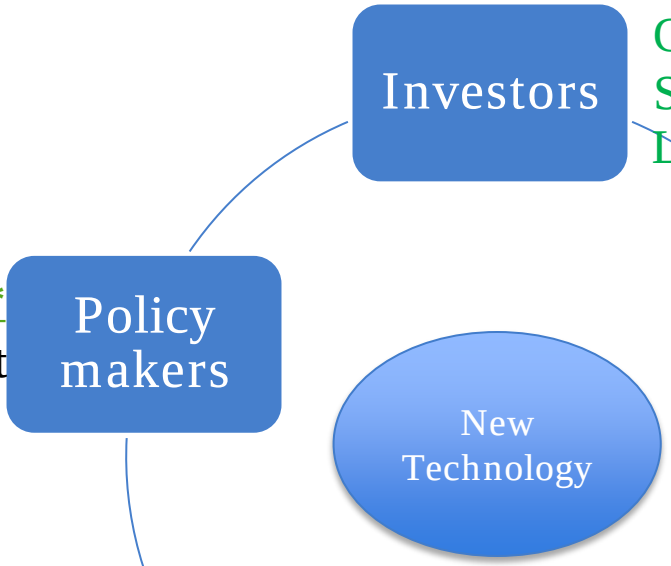


Wallner PE et al. Front Radiat Ther Oncol. 2011;43:60-78

Combining influencing factors and stakeholders



IMRT adoption – Factors influencing stakeholders are largely favorable



Cost of investment < revenue
Stable and secure patient stream
Low capital required for adoption

Cost of investment << revenue
Evidence*
High competition[1]
Skill readily obtained
Good existing levels of "Team knowledge"
Perception of better outcomes[1]

Evidence*
Cost vs. benefit

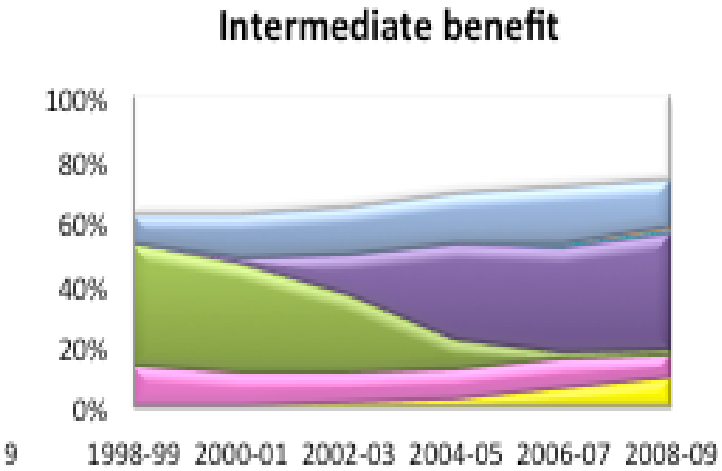
*>6,000 manuscripts in pubmed.org with search term "IMRT", including 538 clinical trial publications

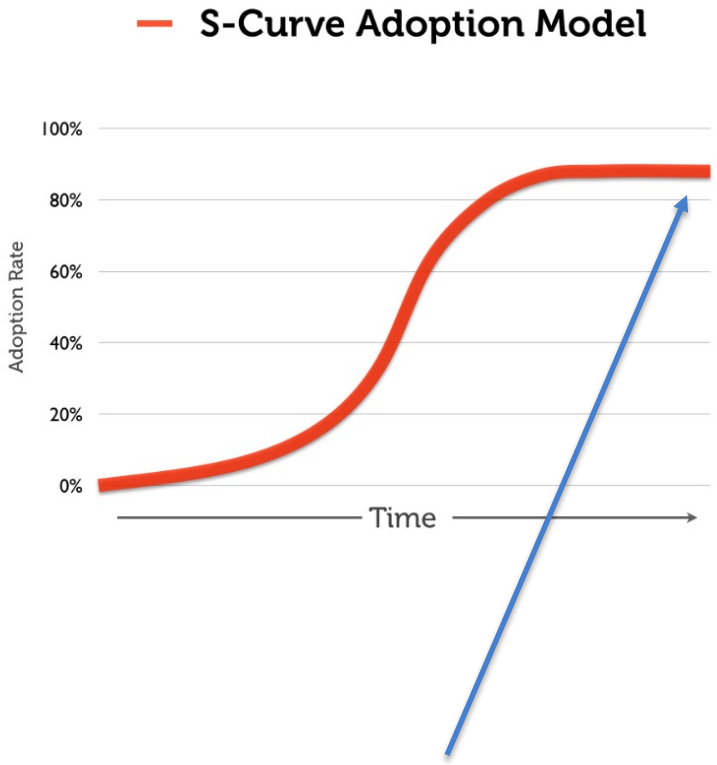
Evidence*
Cost vs benefit

Perception of better outcomes

[1]Mell et al. Cancer. 2005;104:1296-1303

As a result, IMRT rapidly adopted





IMRT in present day

Proton adoption – Factors influencing stakeholders are mixed

Investors

Cost of investment vs. revenue?
Stable and secure patient stream?
High capital costs → getting cheaper

Evidence
Cost vs. benefit?

Policy makers

Providers

Cost of investment >> revenue
Evidence?
Competition +/-
Significant novel skill required
"Team knowledge" sparse
Perception of better outcomes

New Technology

THE WALL STREET JOURNAL.
Big Bets on Proton Therapy Face Uncertain Future

Payers

Patients

Evidence?
Cost percieved to be greater than benefit

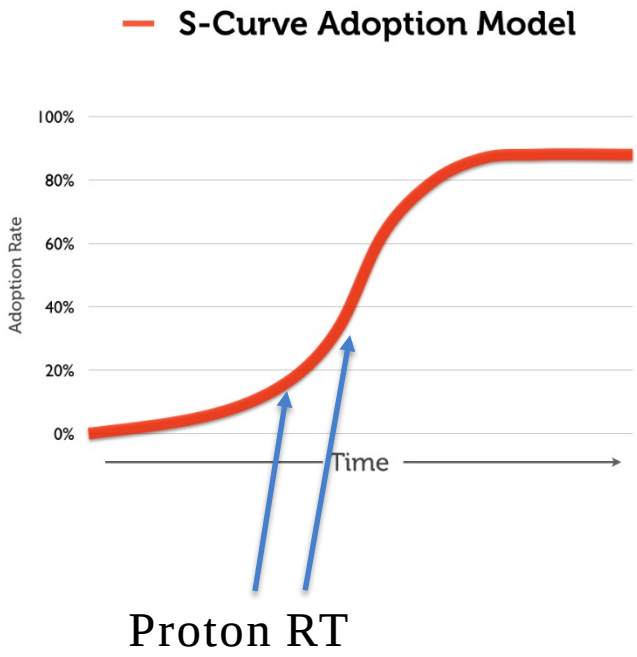
Perception of better outcomes

Beck, M. *Big Bets on Proton Therapy Face Uncertain Future*. The Wall Street Journal. May 26, 2015

As a result, proton beam therapy less rapidly adopted

But poised for rapid growth if:

- ✓ *Capital costs decrease
- ✓ *Competition increases
- *Reimbursement stabilizes
- ✓ *Practitioners become familiar with proton beam therapy
- *Evidence grows



4) What is the cost of this new technology adoption to Medicare?

Both technologies are ***reimbursed more*** than older technology and that cost is passed on to payers and/or patients

Prostate cancer example:

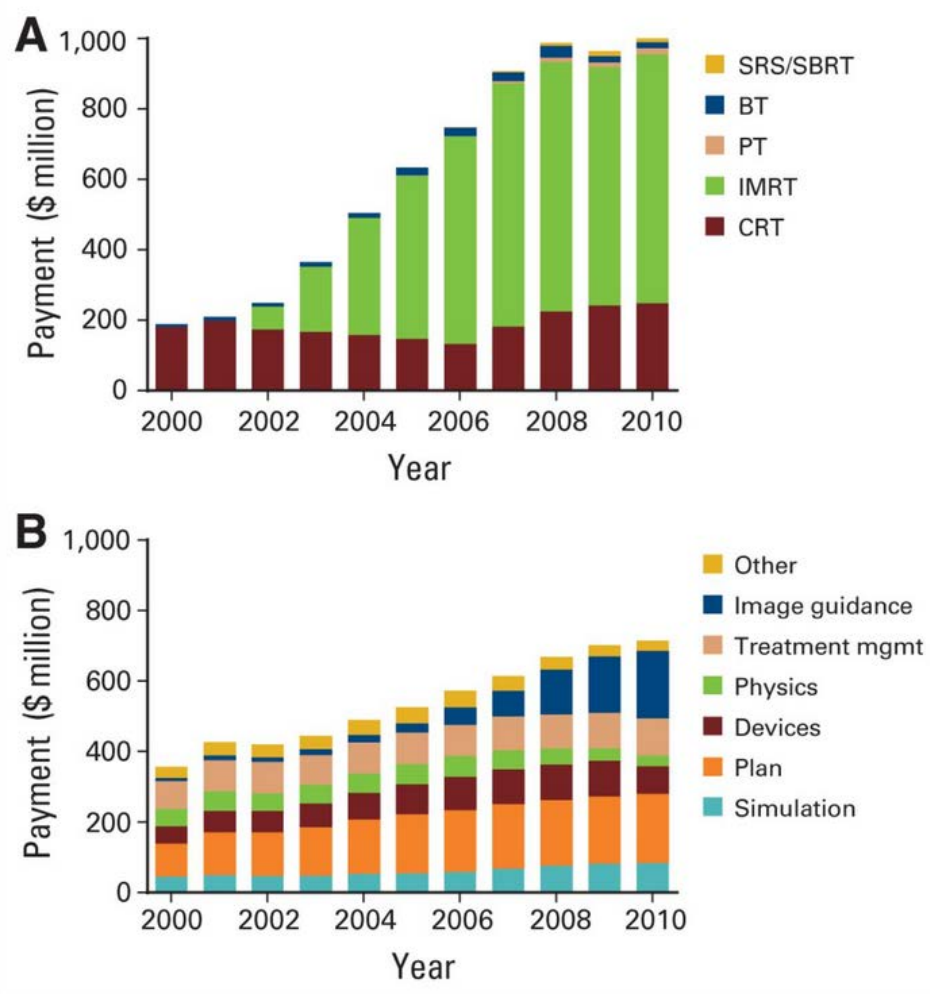
- Cost of 3DCRT: $20,588[1]
- Cost of IMRT: $31,574[1]
- Cost of PRT: $13,753 more than IMRT[2]

- For prostate cancer in 2005, **IMRT cost Medicare $282 million** (compared to older external beam radiotherapy)[1]
- Proton radiotherapy has the **potential** to cost Medicare hundreds of millions of dollars for prostate cancer beyond IMRT

  (26,647 men with prostate cancer treated with IMRT in 2008-2009[2] x $13,753 = $372 million)

[1]Nguyen PL et al. J Clin Oncol. 2011;29:1517-24.
[2]Yu JB et al. J Natl Canc Inst. 2013; 105:25-32.

IMRT was responsible for the increasing cost of radiation therapy to Medicare 2002-2008



Shen X, Showalter TN, et al. J Oncol Pract. 2014;10:e201-7

IMRT treatment was the only code in the top 20 of all CPT category I codes not an evaluation and management code in 2008

Konski A. The War on Cancer: Progress at What Price? JCO. 2011;29:1503-1504.

But… It's important to note that some change occurring: The cost of IMRT is decreasing

Reimbursement decreasing

	Facility Price of IMRT delivery (CPT 77418)*
2002	$490-$619.77
2006	$553-$750.51
2008	$599.11
2012	$475.85
2014	$395.13
2015	Significant decrease!

Unlike for medications, Medicare can set the price of treatment!

*National Payment Amount listed for 2008-Present, and a range for all carriers/MACs for 2002 and 2006

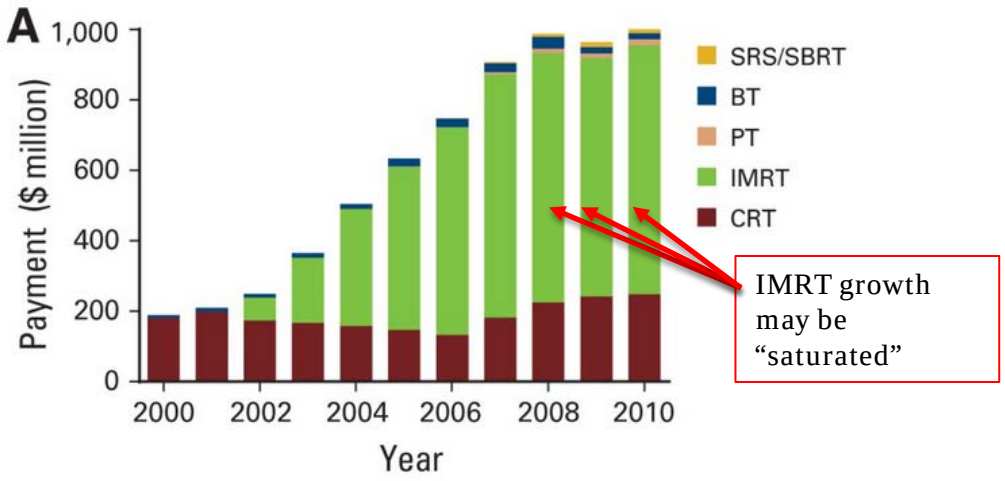
Computational costs decreasing as well

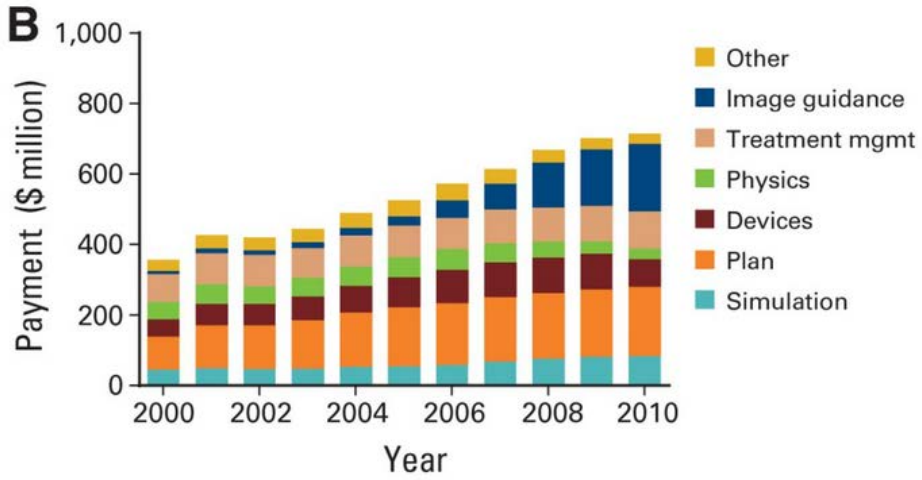
1994
($1,000/GB)

2002
($3/GB)

2015
($.01/1 GB)
Cloud storage

Further… IMRT growth stopped (The S curve has plateaued?)





For Medicare, the % of all external beam treatments:

IMRT = 78.5% in 2006

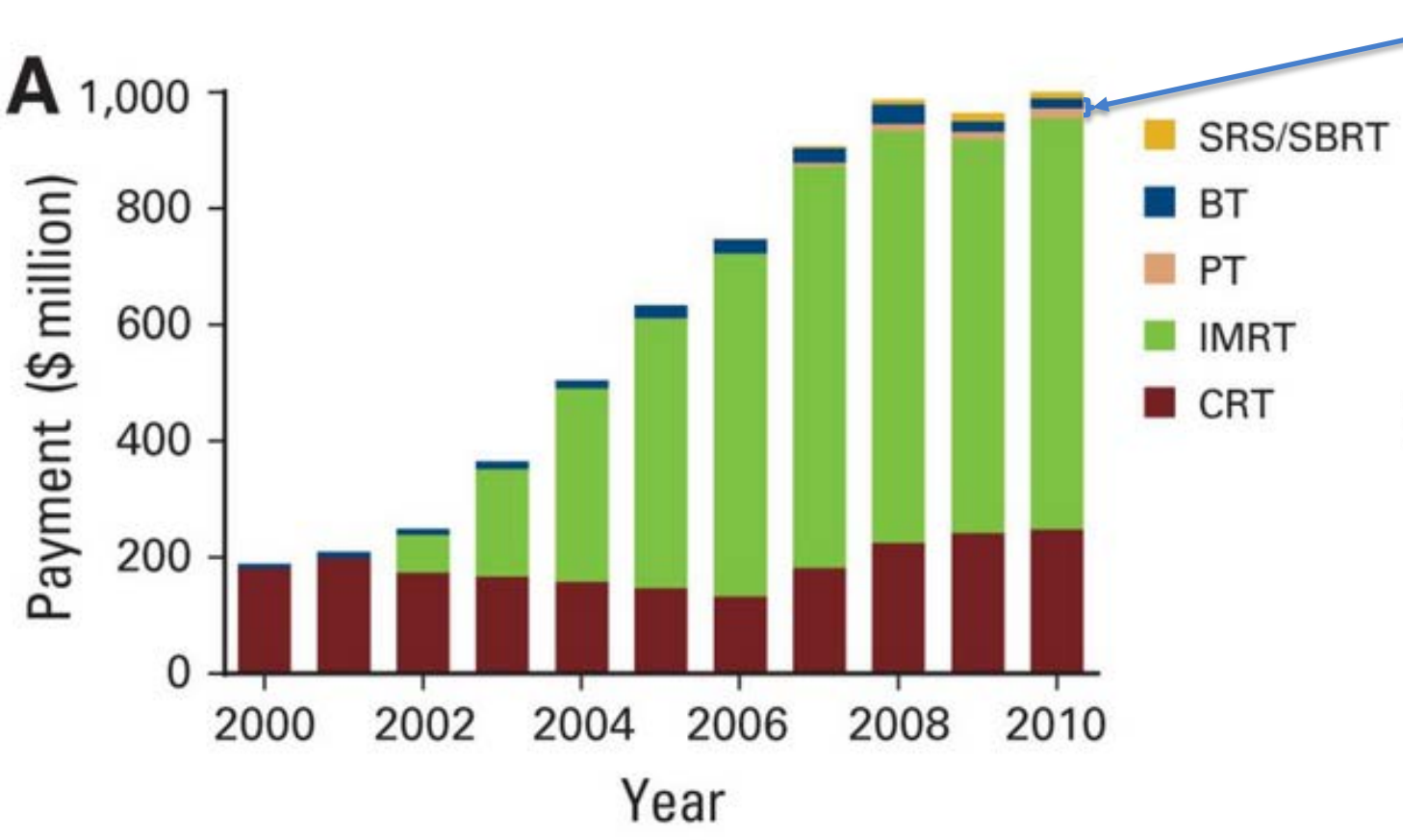
IMRT = 69.8% in 2010[1]

Consistent with findings from Michigan that the % of treatments delivered as IMRT has generally plateaued[2]

[2]Shen X, et al. Radiation oncology services in the modern eral: Evolving patterns of usage and payments in the office setting for Medicare Patients from 2000 to 2010. J Oncol Pract. 2014;10:e201-7

[1]Shumway DA, et al. J Oncol Pract. 2015;11:e373-e379.

What will happen to the cost of proton radiotherapy?



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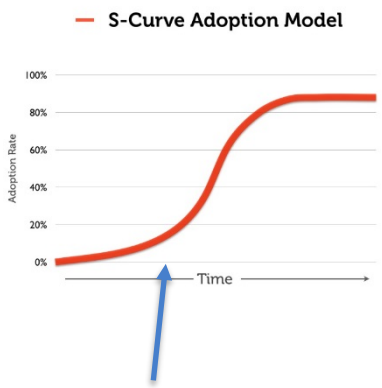


Stay tuned...

Shen X, Showalter TN, et al. J Oncol Pract. 2014;10:e201-7

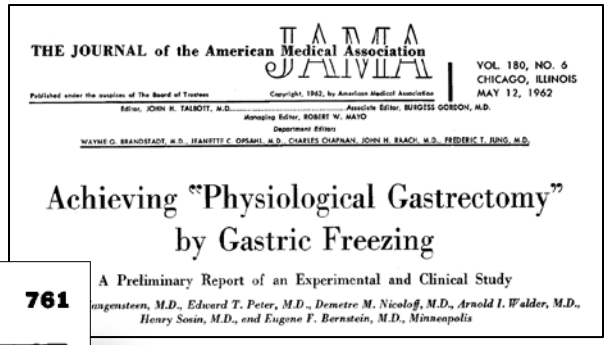
5) Where do we go from here?

- How can we avoid inefficient use of healthcare dollars for expensive new technologies that may or may not be beneficial?

- First, one cautionary example…

Gastric freezing for stomach ulcers

- Invented in 1959 to treat bleeding ulcers non-surgically
- 1,500 machines in use by 1963



THE JOURNAL of the American Medical Association

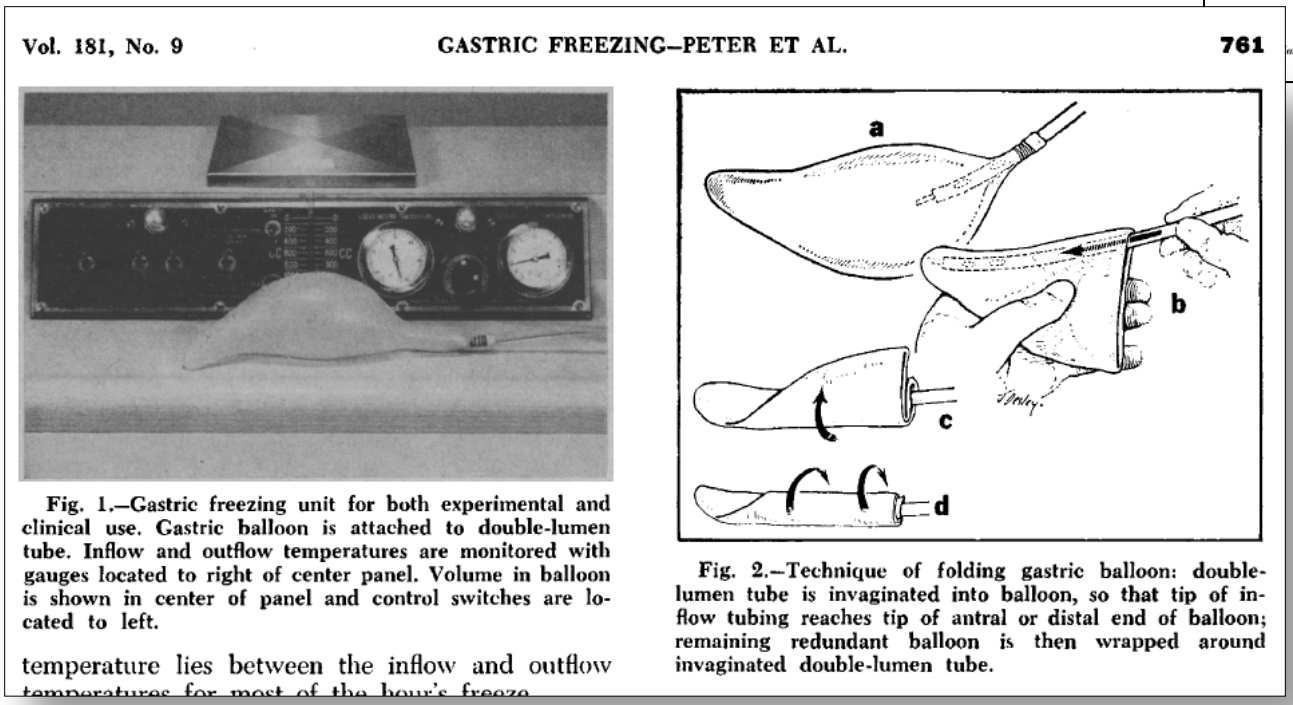
JAMA

VOL. 180, NO. 6
CHICAGO, ILLINOIS
MAY 12, 1962

Achieving "Physiological Gastrectomy" by Gastric Freezing

A Preliminary Report of an Experimental and Clinical Study

ngensteen, M.D., Edward T. Peter, M.D., Demetre M. Nicoloff, M.D., Arnold I. Walder, M.D., Henry Sosin, M.D., and Eugene F. Bernstein, M.D., Minneapolis



Vol. 181, No. 9 GASTRIC FREEZING—PETER ET AL. 761

Fig. 1.—Gastric freezing unit for both experimental and clinical use. Gastric balloon is attached to double-lumen tube. Inflow and outflow temperatures are monitored with gauges located to right of center panel. Volume in balloon is shown in center of panel and control switches are located to left.

temperature lies between the inflow and outflow

Fig. 2.—Technique of folding gastric balloon: double-lumen tube is invaginated into balloon, so that tip of inflow tubing reaches tip of antral or distal end of balloon; remaining redundant balloon is then wrapped around invaginated double-lumen tube.

Peter ET, et al. JAMA. 1962;181(9):760-764.

Gastric freezing– rapid abandonment as evidence mounts

- As the treatment is adopted, reports of complications grow
  - "What was developed and promoted as a last, safe resort before surgery was by this time not only evidently risky and questionably efficacious, but also being indiscriminately applied by some."
- By 1966 treatment is largely abandoned

National Research Council. *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology*. Washington DC: The National Academies Press. 1979.

Gastric freezing – what can we learn?

- Not a crackpot scheme – the inventor, Dr. Wangensteen was a respected surgeon and researcher
  - Academic faculty - he received no fees for services – so was not driven by obvious financial gain
  - Treatment based on animal studies and early reports were very favorable
  - Earnest enthusiasm perhaps the only “vice”*

What can we do to prevent history from repeating?

National Research Council. *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology*. Washington DC: The National Academies Press. 1979.

What can we do to not repeat the past? #1

1979 Recommendation[3]

"Funding of large-scale technological development projects by the federal government is a reasonable approach.."

Further, "on again off-again federal commitments to development in that area".. Have had "catastrophic effects".

2015 Recommendation

Though 40-60% of all cancer patients require radiation therapy[1], only 1.6% of NIH Cancer funding went to radiation related research in 2013[2]

Greatly increase and stabilize NIH funding for radiation oncology specific research

Need funding not only for new technology assessment, but for the innovative integration of radiobiology knowledge[1]

[1]Brown, JM and Adler JR. Is equipment development stifling innovation in radiation oncology? Int J Radiat Oncol Biol Phys. 2015;92:713-714.
[2]Steinberg M, et al. Int J Radiat Oncol Biol Phys. 2013;86:234-240.
[3]National Research Council. *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology*. Washington DC: The National Academies Press. 1979.

What can we do to not repeat the past? #2

1979 Recommendation[1]

Technology regulation must be weighed against ensuring access to the technology and encouraging innovation

"If third-party payers were required to reimburse for procedures conducted on their beneficiaries as part of an evaluative study.. ..then a major cost of [comparative and evidence generating] studies would be covered."

2015 Recommendation

Coverage with evidence development (CED) needs to be applied to all radiation technology

<u>All patients</u> undergoing treatment with a new radiation technology should be enrolled in a study

[1]National Research Council. *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology*. Washington DC: The National Academies Press. 1979.

What can we do to not repeat the past? #3

1979 Recommendation[2]

Because of the cost, potential ethical issues, time, and rapidly changing nature of technology, "clinical investigators.. ..often resort to other methods of evidence generation" than randomized clinical trials.

"These compromises are *not necessarily detrimental.* Judgment is needed to assess the loss of information content against the gains in technical and economic feasibility."

2015 Recommendation

Incorporate other forms of comparative effectiveness research in evidence creation

Enable and utilize a learning healthcare system[1] to provide insights and evidence

[1]Institute of Medicine Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington DC: The National Academies Press. 2013.

[2]National Research Council. *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology*. Washington DC: The National Academies Press. 1979.

“Those who cannot remember the past are condemned to repeat it.”

-George Santayana (1905)

Thank You!

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