ABSTRACT: 2013 ELAM Institutional Action Project Poster Symposium

Project Title: Upstate Proton Therapy Center at University of Rochester Medical Center

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Collaborators: George Uschold, Eric T. Gommel, Richard Cowen, and Michael Schell

Background, Challenge or Opportunity:

Proton therapy offers unique clinical advantages due to the physical characteristics of proton particles. As protons travel, only a small amount of radiation dose is delivered along its path, and most of the dose can be delivered at a precise distance in tissue, called the "Bragg Peak." As a consequence, much more healthy tissue can be spared of radiation, and deep targets can receive a higher dose of radiation. Proponents cite fewer side effects and better quality of life as the main advantages over conventional radiotherapy. Very little scatter and no exit dose of proton radiation can reduce delayed radiation effects, such as second malignancy, coronary artery disease, fibrosis and organ dysfunction.

The first-generation proton machines utilize a single cyclotron unit to feed 4 treatment machines costing well over $150 to $200 million and a football-field size space. Smaller proton systems are in development with smaller space need, and the cost of $25 - $30 million per machine, thus offers a unique opportunity to consider a proton center. There are currently 10 operating proton centers, 14 under construction and 22 under development.

Purpose/Objectives:

The primary objective of this project is to assess the feasibility of establishing a proton therapy center at URMC including:

1. Developing a Pro Forma business plan including the development, construction, and operating costs for treating patients in the greater Rochester region.
2. Conducting a technology and cost assessment of current proton vendors to select the right machine for our needs.
3. Developing a plan to build and operate a Center of Excellence in Proton Therapy that will be the premier destination for cancer care in upstate New York (NY). The facility will be recognized for innovative and advanced technology, clinical excellence, translational research, and outcomes research.

Methods/Approach:

1. The team attended the National Proton Conference to update the current proton therapy market place in the context of health care reform. The conference provided an overview of clinical trials, current studies, and the economics of proton therapy involving providers and insurers.
2. The team conducted a market analysis of the cancer patient population that could benefit from proton treatment in upstate NY, and assessed the challenges of planning, developing, and operating a successful proton center.
3. The team will propose a proton center plan through a regional proton center partnership. The plan will combine multi-institution proton clinical care with a research center, which will build upon the expertise of radiation biology, translational research, and cancer survivorship of the Department of Radiation Oncology at UR.

Outcomes and Evaluation:

The business analysis reveals that a single room proton center is feasible and financially viable with the potential for further growth in upstate NY. The developmental plan and the Pro Forma will be presented to the URMC CEO Strategic Group for further evaluation.

Upstate Proton Therapy Center

University of Rochester Medical Center, James P. Wilmot Cancer Center (JPWCC)

ELAM Fellow: Yuhchyau Chen, MD, PhD, University of Rochester **Mentor**: Mark Taubman, MD, Dean of UR SMD

Collaborators: George Uschold, D Ed, Eric T. Gommel, MBA, Richard Cowen, MBA, and Michael Schell, PhD

Background, Challenge or Opportunity

Proton therapy is a form of charged particle radiotherapy. It offers unique clinical advantages due to the physical characteristics of proton particles. As protons travel, only a small amount of radiation dose is delivered along its path, and most of the dose can be delivered at a precise distance in tissue, called the "Bragg Peak." As a consequence, much more healthy tissue can be spared of radiation, and deep targets can receive a higher dose of radiation. Proponents cite fewer side effects and better quality of life as the main advantages over conventional radiotherapy. Very little scatter and no exit dose of proton radiation can reduce delayed radiation effects, such as second malignancy, coronary artery disease, fibrosis and organ dysfunction.

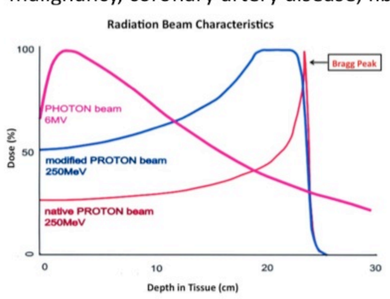


Figure 1. *Beam characteristics: proton vs. photon. Proton beam Bragg Peak is Shown .*

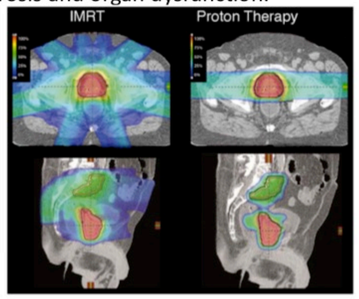
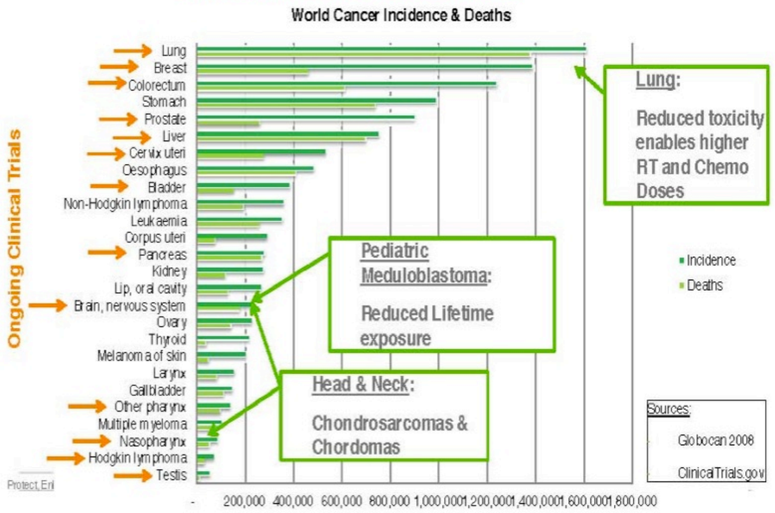


Figure 2. *Radiation dose intensity map of proton vs. IMRT photon for the treatment of prostate cancer. Note much less radiation to the surrounding normal structures by proton therapy.*

The first-generation proton machines utilize a single cyclotron unit to feed 4 treatment machines costing well over $150 to $200 million and a football-field size space. Smaller proton systems are in development with smaller space need, and the cost of $25 - $30 million per machine, thus offers a unique opportunity to consider a proton treatment center.

Figure 3. Ongoing Proton Clinical Trials (in orange arrows)



Purpose/Objectives

The primary objective of this project is to assess the feasibility of establishing a proton therapy center at the James P. Wilmot Cancer Center at URMC including the following:

1. Conducting market analyses, insurance and provider analyses, and the impact of health care reform to develop a Pro Forma Business Plan, that will include the development, construction, and operating costs for treating patients in the greater Rochester region.
2. Conducting a technology and cost assessment of current proton vendors to select the right technology and machine for our needs.
3. Developing a plan to build and operate a Center of Excellence in Proton Therapy that will be the premier destination for cancer care in upstate New York (NY). The facility will be recognized for innovative and advanced technology, clinical excellence, translational research, and outcomes research.

Outcomes and Interpretation of Results

1. There are currently many operating charged particle (including protons) radiotherapy centers worldwide, and an increasing global interest in developing more centers. There are 10 operating proton centers, 14 under construction and 22 under development in U.S. (Fig. 4)

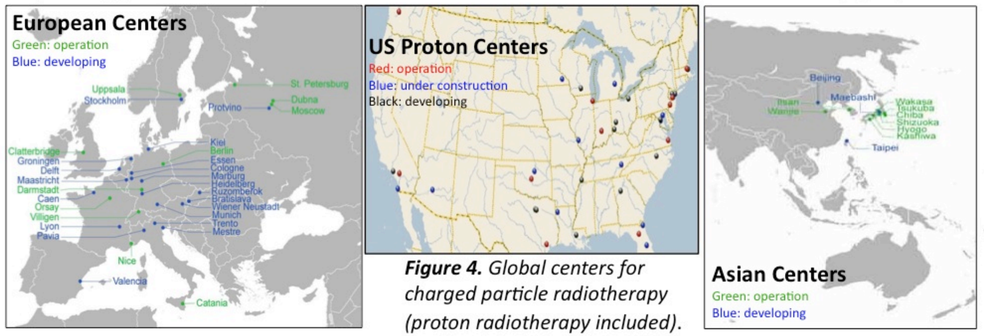


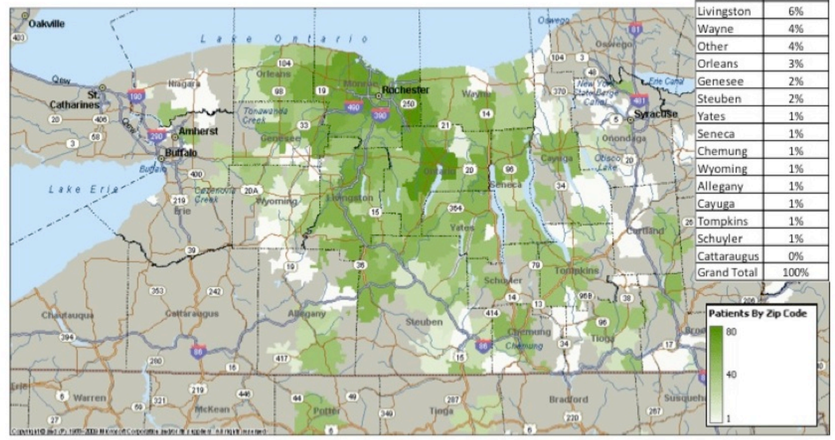
Figure 4. *Global centers for charged particle radiotherapy (proton radiotherapy included).*

2. There are many ongoing clinical trials assessing efficacy and cost-effectiveness of proton (and other charged particle) radiotherapy (Fig. 3).
3. Market analyses (population data and URMC radiation treatment database, 2012) of potential patient population for proton therapy in the Rochester & 16 county regions reveal an estimated 300-400 patients/year for the proposed upstate proton center (Figs. 5 & 6).
4. Technology assessment reveals that 'pencil beam scanning' proton offers higher conformity than the classical 'passive scattering' proton. It does not requite patient-specific and field-specific hardware and the risk of generating harmful neutron is greatly reduced. A built-in Cone-Beam CT will reduce the sensitivity to organ motion for 'pencil beam scanning' protons.
5. The Pro Forma business plan reveals that the single room design (either one or two rooms, pending capital investment) of a proton facility centered at Rochester is feasible and financially viable with a potential for further growth in upstate NY. A developmental plan (Fig. 7) and the Pro Forma will be presented to the URMC CEO Strategic Group for an evaluation.

Impact: The Upstate Proton Center at URMC will provide the leading edge cancer treatment technology to serve patients in upstate NY. It is vital to health care economy of NY state.

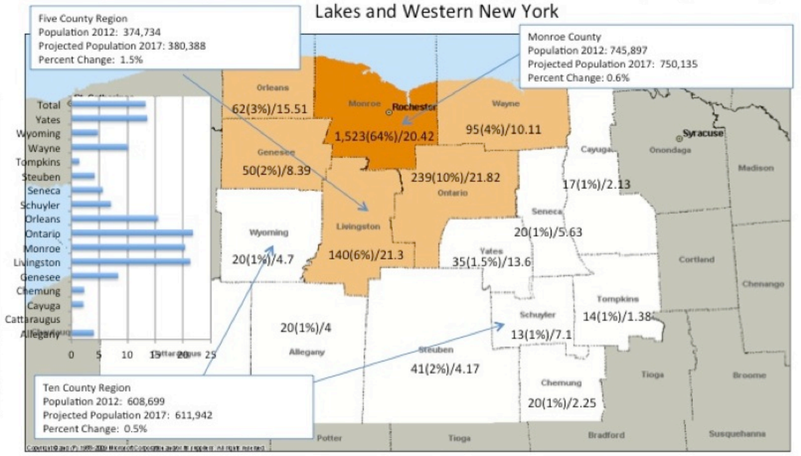
Presented at the 2013 ELAM® Leaders Forum

Figure 5. **Radiation Oncology Patients By Zip Code (2012 data)**



Counties	Percentage
Monroe	63%
Ontario	10%
Livingston	6%
Wayne	4%
Other	4%
Orleans	3%
Genesee	2%
Steuben	2%
Yates	1%
Seneca	1%
Chemung	1%
Wyoming	1%
Allegany	1%
Cayuga	1%
Tompkins	1%
Schuyler	1%
Cattaraugus	0%
Grand Total	100%

Figure 6. Population Projections Monroe County, Five County and Ten County Region of Finger Lakes and Western New York



Growth in the five county region is three times that of Monroe County and the ten county region fueled by out migration of residents to Ontario and Livingston counties.

Pts treated at UR Rad Onc/yr (% of UR Rad Onc excluding 200 Pluta patients)/ Pts per 10,000 population in each county-----> "410" potential proton patients from all 16 counties/year

Figure 7. *A Gantt Chart showing the timeline for the development, construction, and operation of either one-room or two-room, single room proton center at JPWCC*