



National Radiation Oncology Research Needs Assessment

EXECUTIVE SUMMARY



*Improving Cancer Care
Through Research and Education*

August 2012

Conducted by

crescendo
CONSULTING GROUP, LLC

 **YALE NEW HAVEN
HEALTH**
Yale New Haven Health System Center for
Healthcare Solutions



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Introduction

*I*n addition to grappling with the implications of the Patient Protection and Affordable Care Act (PPACA), healthcare providers and organizations will face continued pressure to increase quality of care while reining in ever increasing costs to provide that care. These demands underscore the need to develop new ideas, capital, and clinical research studies able to address these challenges.

The Radiation Oncology Institute (ROI) was developed in 2006 with a mission to “enhance and promote the critical role of radiation therapy in the treatment of cancer by supporting research and education about the life-saving and quality-of-life benefits of radiation therapy.”¹

“As one of its first initiatives, the ROI’s Research Committee commissioned a comprehensive study to identify research priorities for the field of radiation oncology. The results of this comprehensive research needs assessment may be useful not only for directing the initiatives of ROI itself but also for other funding agencies that seek to support research of high significance with the potential to have an impact on practice.”²

ROI selected the Yale New Haven Health System Center for Healthcare Solutions (YNHHS-CHS) and Crescendo Consulting Group to conduct the ROI National Research Needs Assessment. This executive summary provides an overview of the assessment which was comprised of two research phases with an overall objective to better understand the gaps that currently exist in evidence and knowledge about the specialty. Phase 1 was completed in January 2011 and provided the basis for the Phase 2 research.

PHASE 1 RESEARCH

Phase 1 Research included discussions with ROI leadership; stakeholder interviews with many of the nation's leaders in the field of radiation oncology; focused discussions with diverse stakeholder groups; and a broad-based electronic survey. Each of these sources contributed unique information to the process and, together, forged an understanding of leading research issues among diverse segments of the radiation oncology field. The multi-phase research resulted in more than 1,150 annotations and 275 proposed research questions and culminated with 107 research questions across the ten research categories that would be further evaluated and prioritized in Phase 2. Several Phase 1 themes emerged.

A NEED FOR MORE EVIDENCE

In Phase 1, the most frequently cited category of issues in radiation therapy was “Improving the efficacy of radiotherapy.” Respondents indicated that research is needed to compare the effectiveness of different approaches intended to improve the efficacy of radiation treatment, including technological advances and other novel strategies, such as radiosensitizers. Comments from participants illustrated a profound frustration regarding the increasing need for evidence-based results and the lack of comparative effectiveness research, compounded by the current lack of funding and infrastructure to conduct the necessary research. This struggle was also seen in the participants’ often interchangeable use of “comparative effectiveness” and “clinical efficacy”.

CHALLENGING ENVIRONMENTAL CONDITIONS

The participants agreed that in addition to national demographic and budgetary challenges, the environmental challenges include:

- Increased regulatory focus and publicity on safety and efficiency
- Tying reimbursement to quality measures
- Improving consistency of Radiation Oncology’s role in patient referral patterns, treatment and follow-up
- Maintaining practitioner satisfaction and effectiveness amid changes in the field and the unknown future of healthcare reform

SCOPE OF PRACTICE

Issues related to scope of practice also emerged early as a major theme. Variability in the scope of treatment and follow-up, as well as in treatment across hospital- and clinic-based practices, was noted as a particular challenge. Lack of follow-up and out-referral may be prompted by multiple factors including:

- Patient referral patterns from primary care physicians and/or other cancer specialists
- Limited means to follow patients after radiation therapy has been completed
- Lack of coordination regarding the management of non-radiation medical problems
- Inefficient screening for cancer in patients who may be better served by receiving radiation treatment

RESEARCH CATEGORIES AND QUESTIONS

In addition to being designed to engage the RO community, leadership and stakeholders, objectives of Phase 1 were to develop: 1) a set of research categories and 2) a broad-based list of research questions to be evaluated and prioritized in Phase 2.

Based on discussions with ROI leaders and a citation review early in Phase 1, ten initial research categories were identified. Most of the more than 1,150 annotations and 275 proposed research questions were able to be summarized in the ten categories listed below:

- Improving the Alignment of Reimbursement with Patient Outcomes
- Improving the Efficacy of Radiotherapy
- Fundamental Science of Cancer and Radiation Biology
- Improving the Geometric Accuracy and Reliability of the Delivery of Radiation Therapy
- New Research Trial Designs
- Quality Assurance; Safety Protocols
- The Scope of Practice of Radiation Oncology Relative to Other Specialties
- Radiation Oncology Structure, Processes and Operations
- Shared Decision-Making and Patient Involvement
- Toxicity and Improving Tissue Tolerance

These initial categories framed the research environment and facilitated the grouping of research questions so that they could be analyzed and prioritized.

Phase 1 research culminated with 107 research questions across the ten research categories.

PHASE 2 RESEARCH OVERVIEW

A central goal of the Phase 2 research was to evaluate and prioritize the 107 research questions from Phase 1. Several methodologies were used to accomplish this goal:

- **Delphi Panel – Rounds One and Two.** The Delphi Panel (comprised of national leaders in the field of radiation oncology and other select stakeholders) was used in two iterations to refine the list of 107 questions down to 30. Panelists evaluated each research question based on the dual criteria of (1) the impact on patients and (2) the ability to fill critical gaps within the Radiation Oncology specialty. Detailed discussion of the methodology and results are contained later in this report.
- **Phase 2 Survey.** The 30 questions from the Delphi Panel were evaluated in a quantitative survey disseminated to more than 1,000 ASTRO members. The survey sample was chosen at random from more than 6,300 total members. Respondents closely mirrored the full membership based on profession, professional activity, geographic region and gender.
- **Town Hall Style Meeting.** About one-half of the 30 questions emerging from the Delphi Rounds 1 and 2 were included in the town hall style discussion held in Richmond, Virginia, in early April 2011. The meeting was attended by over 30 cancer survivors and their families. It provided an important avenue for patient feedback and insight. This document also includes the report drafted after the town hall meeting.
- **ROI Board Criteria Prioritization.** During an ROI Board meeting held prior to the Delphi Panel Round 3 meeting, the Board established three sets of rating criteria that were to be used to finalize the Research Priorities and were consistent with the project goals:
 - A. Patient and public needs:** These criteria have been used throughout the research process and are implicit in the current ratings. All of the current questions meet these criteria. The criteria do not need to be prioritized further at this point.
 - B. Strategic “fit” with ROI:** These criteria can be used to assess the research topics in relation to ROI’s organizational goals.
 - C. Implementation feasibility:** These criteria are used to assess the degree to which the research need can be realistically implemented.

The ROI Board was asked to prioritize the “fit and feasibility” criteria. The most important criteria were used by the Delphi panel and the ROI Research Committee to finalize the research priorities.

- **Delphi Panel Round 3 Meeting.** The Delphi Round 3 utilized the quantitative and qualitative research results from the town hall meeting, and the criteria and scenarios developed by the ROI Board to finalize the Research Priorities and to test whether the priority of specific needs may change based on different future scenarios. The output provided a consensus opinion to the ROI Research Committee about the prioritized list of research needs.
- **ROI Research Committee Recommendations.** The six consensus topics were assigned to the ROI Research Committee members, who engaged colleagues to draft a research priority profile that includes:
 - A.** Background and Description of Topic
 - B.** Strategic Importance and Implications for RO and ROI
 - C.** Potential Projects

Where helpful, a selected bibliography and potential timeline are also included. A half-day colloquium was held to review competing priorities and establish a blueprint for the ROI research pipeline based upon a mix of project sizes, timelines and required resources.

SUMMARY OBSERVATIONS

The ROI Research Committee developed the prioritized list of six research areas. The final list of top priorities, or “consensus topics”, includes six high priority areas.

1. IDENTIFY AND DEVELOP COMMUNICATION STRATEGIES TO IMPROVE PATIENTS’ AND OTHERS UNDERSTANDING OF RT

Background and Description of Topic. Increasingly, medical decision-making has moved from a physician-driven model, wherein medical professionals were tasked with delivering a complete patient care plan, toward a “shared decision model”. However, the increasing complexity of cancer care, generally, and radiotherapy, specifically, preclude ready understanding of the therapeutic balance between toxicity and tumor control for many radiation-eligible patients.

In scenarios where radiotherapy provides equivalent oncologic outcomes with competing interventions (e.g., surgery, chemotherapy), relatively complex toxicity profile data must be carefully explained in an unbiased, yet understandable, way. Furthermore, specific patient cohorts (e.g. socioeconomically disadvantaged patients, ethnic minorities, elderly patients) may have identifiable barriers to understanding the potential benefits of radiotherapy. Finally, as the shared decision making process now often occurs in the context of a multidisciplinary medical model, it becomes apparent that referring physicians and oncologic colleagues may present opportunities to improve decision making processes through greater education regarding radiotherapy indication(s), survival, local control, quality of life, or economic profiles.

Strategic Importance. Extant literature reveals a substantial knowledge gap in the optimal method for shared decision making (SDM) in radiotherapy, with few rigorously constructed protocols. Consequently, this has been identified as a high priority area from the Research Needs Assessment. Specifically, the committee was charged with Question 68 (revised and combined with Q62 & Q54):

Identify communication and dissemination of information strategies (including web-based modalities) that focus on enhancing patients’ and physicians’ understanding and awareness of radiotherapy and its pros and cons including those related to quality of life issues, relative to alternative treatment options.

The following stakeholders are identified as potential “targets” for efforts designed to improve patient and physician awareness of radiotherapy risk benefit profiles:

- Current and potential radiotherapy patients, with a special emphasis on sub-populations at risk for impaired SDM
- Associated medical decision-assisting communities
- Non-radiation oncology physicians

Potential Projects. The ROI supports projects to identify communication, and dissemination of information strategies that focus on enhancing patients’ and physicians’ understanding and awareness of radiotherapy and its risks and benefits including those related to quality of life issues, relative to alternative treatment options.

Special emphasis is placed on interventional projects that address communication needs and/or knowledge gaps in non-radiation oncology physicians, patients and survivors and sub-populations at risk for impaired SDM. The focus on research should be balanced with practical solutions that can change behavior. Potential projects fall into two large categories and are not mutually exclusive.

- **Communications tools and processes that enhance physician decision making**
- **Communications tools and processes that enhance patient decision making**

2. ESTABLISH GENERAL QUALITY INDICATORS FOR RADIATION ONCOLOGY TREATMENT

Background and Description of Topic. The strategic importance of QA and safety received renewed impetus recently with a series of *New York Times* articles detailing the misuse of radiation in both therapy and diagnostic applications, as reviewed in Hendee and Herman.³ Those events, along with recently published data showing that facilities fail the RTOG QA IMRT test phantom irradiation test at a discouraging rate (28% for the head and neck cohort, as reprinted in Hendee and Herman³, have created a sense of urgency to both improving the current QA efforts and also to implementing QI (quality improvement efforts) that guard against similar problems. These efforts, along with the results of a workshop which generated 13 specific recommendations for improving the safety of radiation oncology, were recently summarized by Hendee and Herman.³ Other recent editorials have focused on this issue.^{4,5}

Scientists and clinicians in radiation oncology have long understood the need for safety, and there is a rich resource of established procedures to ensure the delivery of safe radiotherapy (including many relevant AAPM task force publications). Nevertheless, as Hendee and Herman point out by their workshop summary, much urgent work remains to be done to improve quality in radiotherapy. Any RFP on this topic must be considered within the wider framework of the evolution in quality assurance/quality improvement programs. Several quality indicators, or key areas of work in this topic were considered that could lead to improvements in quality improvement programs.

Strategic Importance. A major theme of quality programs, going back at least to Denning, is that variance in a process should be controlled. However, we are currently lacking quality metrics that capture the quality of the planning and delivery process for individual patients. To that end, we focus here on new metrics of quality care relating to contouring, IMRT treatment planning, and geometric setup accuracy. Denning believes that the creation and validation of simple metrics is feasible, and could then be used as standard reporting tools that facilitate quantitative summaries and continuing quality improvements.

An overarching commitment to quality and safety in RO is now not only urgent for reasons of public relations and public perception, but is also important on the merits of problems uncovered by professional practitioners and thought leaders. Despite our focus on quality metrics, a burning question in the general quality of IMRT delivery is raised by the published Radiological Physics Center data. It is therefore important that this issue be addressed by the professional Radiation Oncology community with some urgency.

Potential Projects. In looking at this research area in more detail, four potential projects were identified. Core questions underlying the potential projects are listed below:

- **Is IMRT delivery really unreliable? If so, why?** The fail rate of 28% in irradiation of the RPC phantom for H&N IMRT treatment plans is still as yet unexplained. Although many causes for this shocking number are offered in informal discussions, general knowledge suggests that there has been no Root Cause Analysis of these errors. It is important to note that the pass criteria are liberal: generally, 93% of the measurement points should be within plus or minus 7% of the expected doses. This is significantly wider than any published criteria for accept-

able dose deviations. The NCI themselves are unlikely to fund this, ostensibly as they focus on changes to treatment likely to result in better outcomes, rather than improvements in standards of quality assurance. The actual causes may be systematic problems with delivery machines, treatment planning systems, or common problems in delivery that are not as yet appreciated. In discussions with David Followill, PhD, Head of the RPC, he agrees that funding for a joint project between the RPC and collaborating institutions where the measurements would be done would be highly beneficial.

- **When is an IMRT treatment plan a high-quality plan?** IMRT treatment planning remains a highly trial-and-error and time consuming process. At least two research groups have shown that one can systematically understand obtainable target volume dosimetric characteristics based on straightforward geometrical considerations (e.g., the closeness of the rectum to the prostate; size of the target volume, etc.). If such data could be distilled into usable charts, it could save an enormous amount of effort lost to fruitless efforts to marginally improve treatment plans. On the other hand, not being within expected bounds of such criteria could signal when continuing treatment planning efforts might be worthwhile. Some simple checks, such as continuously trying to minimize the mean dose to the contra-lateral parotid gland in H&N irradiation, could be effective at catching errors that can affect patient outcomes. Efforts by McNutt et al. at Johns Hopkins⁶ and Kevin Moore at Washington University have already been made.
- **Are target volume contours consistent with standards?** Developing a standard method for comparing patient-specific physician contours to contour atlases could significantly decrease the known wide variability in treatment plan design methodology. Consensus target volumes have been defined for several treatment sites using software developed by Washington University in St. Louis. Deformable image registration methods could be used to map contours to standard human reference images, with corresponding simple metrics indicating how 'standard' the fields are.
- **Is geometrical setup accuracy within expected bounds?** Some method for reviewing setup precision would be highly desirable as a standard setup accuracy metric. For example, post- or pre-shift-pre-Tx volumetric imaging could be fed to a software tool that would

estimate the needed shift (compared to the CT-sim plan and contours) using deformable image registration techniques. The average deviation from either the actual shift or the residual shift if no action is taken would be a definite measure of the quality of geometrical deliver. If such metrics became available, reporting on this information could significantly enhance knowledge of plan delivery quality.

3. DEVELOP A REGISTRY AND ESSENTIAL COMPONENTS

Background and Description of Topic. Although randomized clinical trials provide the highest level of evidence to support treatment strategy, they suffer from certain limitations including the high cost of conducting them, the amount of time required to complete such trials and the potential lack of generalizability due to strict eligibility criteria in some trials. In addition, the rapid pace of new technology development and adaptation in the community has outstripped the pace that can be supported by randomized clinical trials; therefore, there is a strong need for obtaining population-based comparative effectiveness data to compare different treatment techniques. Therefore, a high priority area that has been identified from the National Radiation Oncology Research Needs Assessment is to “develop a radiation oncology registry and related components.”

In the last few years, there has been rapid development and adaptation of new technologies in the specialty. These technologies include IMRT, IGRT, SBRT and proton beam therapy. Their clinical adaptation has been mainly based on studies showing dosimetric advantages favoring these new modalities. However, their clinical effectiveness, benefit to patients (in survival and quality of life) as well as costs are not known. These knowledge gaps, unfortunately, will not be adequately addressed by randomized clinical trials (except perhaps for proton) due to their present wide adaptation in clinical practice. Another knowledge gap is the lack of a radiation oncology specific database. Although large population database such as the SEERs database exists, they do not adequately address the questions above. In addition, they do not capture patient reported outcomes (PRO). Therefore, developing a comprehensive radiation oncology specific database with details of radiation treatment information as well as PRO is crucial to address the above knowledge gaps.

Strategic Importance. A major intent of the ROI is to “support objective research about Radiation Oncology to demonstrate the value, safety, efficiency and cost effectiveness of radiation therapy.” This means supporting research that demonstrates the value of novel technologies in radiation therapy. Developing a radiation oncology registry and maintaining it will address the ROI strategic criteria by helping to fill in the knowledge gaps described above. In summary, the NROR project is highly significant as it has the potential to provide significant benefit to a large population of cancer patients in a cost effective way.

Potential Projects. The National Radiation Oncology Registry (NROR) project to date has generated the following:

- **Data dictionaries:** A comprehensive taxonomy and data dictionary for the collection of physician, patient, tumor, treatment and outcomes data for patients with intact prostate cancer treated with various forms of radiotherapy has been compiled.
- **Information Technology (IT) Infrastructure:** The IT infrastructure committee has generated a recommendation for NROR architecture V2.0.
- **Institutional questionnaire:** The committee has identified intact prostate cancer as the first tumor site for data collection into the registry and has generated a draft questionnaire to identify the institutions to form the pilot network for initiating the data collection.

Building from this foundation, potential projects may include the following:

- **Completion of the IT infrastructure for the registry, expansion of data collection to other tumor sites and maintenance of the database.** All these aspects are critical for the registry to exist. The current design of the IT infrastructure can be highly cost effective as it involves collaborations between vendors and NROR appointees. The approach is feasible provided that NROR receives targeted vendor support to develop oncologic applications for data deposit and gateway applications for web transfer.
- **Thought should also be put into designing effective and user-friendly linkages to other national registries (existing and new) for data comparison with non-RT treatment modalities.** In addition, adequate resource for registry updates and maintenance is crucial for registry success. Finally, rapid expansion to other tumor sites once the prostate pilot study is completed is critical if the registry is to benefit a larger patient population.

4. CONDUCT COMPARATIVE EFFECTIVENESS STUDIES THAT CONSIDER EFFICACY, TOXICITY (INCLUDING QUALITY OF LIFE) AND OTHER OUTCOMES

Background and Description of Topic. Various study designs can compare the benefits and harm of competing approaches in cancer treatment, including randomized clinical trials, pragmatic clinical trials, adaptive trials, and prospective or retrospective observational research studies. An intervention is efficacious when it provides the intended benefit in a specific population. An intervention is effective when it provides benefit to patients in the context of routine clinical practice. The essence of radiotherapy efficacy and effectiveness research is to understand what health interventions work, for which patients, and under what conditions.

Comparative effectiveness research (CER) is particularly relevant to radiation oncology, a field characterized by medical technology innovations that have led to measurable improvements in survival and quality of life. As summarized by the 2009 consensus report by the Institute of Medicine, “the purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.” Increasing national attention has focused on radiotherapy technological advances that have been quickly adopted with few studies investigating whether they represent an incremental improvement in patient outcomes.

Given the large pool of possible CER questions, the ROI supports CER evidence generation to identify treatments that consistently improve health outcomes compared to alternatives; patient subpopulations that consistently benefit from treatments; and treatments which consistently produce similar health outcomes. In the case of treatments of similar effectiveness, care decisions should be based on minimizing treatment costs.

Strategic Importance. ROI encourages efficacy and effectiveness research that examines survival (defined as overall survival and disease specific survival) and quality of life (defined as disease-specific and overall QOL). As local-regional cancer control with maximal normal tissue preservation is a defining role for radiotherapy, ROI particularly encourages research that examines the impact of local-regional cancer control on survival, toxicity/side effects and quality of life. Other intermediate outcomes, such as the following (and others), are also important: Surrogate disease response outcomes; second malignancies; patient reported outcomes; and disease specific QOL.

Based on the ROI Delphi research prioritization process, ROI has identified four main topic areas as CER priorities for radiation oncology:

- Outcomes of invasive vs. non-invasive approaches to definitive treatment for prevalent cancers. The Delphi process highlighted radiotherapy vs. surgery for early stage non-small cell lung cancer (NSCLC).
- Outcomes of competing radiotherapy modalities for prevalent cancers. The ROI particularly encourages CER focused on proton therapy versus intensity-modulated radiotherapy. The ROI also encourages CER aimed involving the following modalities: Intensity modulated radiotherapy (IMRT), to include conventional IMRT and volumetric arc therapy; image guided-IMRT (IG-IMRT); brachytherapy (BRT); stereotactic body radiotherapy (SBRT), to include linac, helical, robotic and others; and proton beam therapy (PBT).
- Outcomes of alternative approaches to management of oligometastatic disease.
- Outcomes of hypofractionation for prevalent disease.

Potential Projects. ROI currently encourages prospective clinical trials in areas consistent with those listed below.

- **Examine outcomes of invasive vs. non-invasive approaches to definitive treatment for prevalent cancers.** ROI encourages prospective randomized clinical trials to evaluate the efficacy and effectiveness of alternative treatments for early stage non-small cell lung cancer. One example of such a trial is RTOG 1021, a Randomized Phase III Study of Sublobar Resection (+/- Brachytherapy) versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer. ROI recognizes that randomization may be challenging when comparing invasive vs. non-invasive treatments, because patients and clinicians may have strong treatment preferences. Therefore, ROI encourages high quality observational research to examine the effectiveness of alternative approaches. Research could include prospective cohort studies (i.e. National Radiation Oncology Registry) or retrospective studies using large clinical databases (i.e. SEER-Medicare, National Cancer Database (NCDB) or National Cancer Care Network (NCCN) Oncology Outcomes database). Studies should carefully examine and adjust for confounding between treatments and prognostic factors.

- **Examine outcomes of competing radiotherapy modalities for prevalent cancers.** ROI encourages prospective randomized clinical trials, prospective cohort studies, and retrospective studies to evaluate the comparative effectiveness of competing radiotherapy modalities for prevalent cancers. The ROI supports the National Radiation Oncology Registry's effort to establish a pilot registry in prostate cancer. In addition, the ROI supports retrospective studies using large clinical databases, but recognizes the challenges in identifying modalities and secondary outcomes like toxicity in these databases.
- **Examine outcomes of alternative approaches to oligometastatic disease.** ROI encourages prospective clinical trials to evaluate the efficacy and effectiveness of alternative treatments for oligometastatic disease. One example of such a trial is RTOG 0631, a Phase II/III Study of Image-Guided Radiosurgery/SBRT for Localized Spine Metastasis. ROI emphasizes the importance of evaluating survival and overall and disease specific quality of life endpoints in prospective studies of oligometastatic disease.
- **Examine outcomes of hypofractionation for prevalent diseases.** ROI encourages clinical trials and observational studies to evaluate the efficacy and effectiveness of hypofractionation for prostate and breast cancer.

5. IDENTIFY BEST PRACTICES FOR MANAGEMENT OF RADIATION TOXICITY AND OTHER ISSUES IN CANCER SURVIVORSHIP

Background and Description of Topic. More than half of the 1.4 million Americans diagnosed with cancer receive radiation therapy and many of them experience transient side effects of therapy. The severity and type of side effects is dependent on the cancer type, radiation techniques, complementary cancer therapies and the patients' general health. The management of treatment related symptoms often involves the empiric administration of palliative medications or physical therapies that have limited evidence about their relative effectiveness. Furthermore, there is growing concern that the severity of acute radiation side effects may have a substantial impact on a patient's recovery and risk of late effects of therapy.⁷

As a result of the successful cure of countless patients with cancer, there is a growing survivorship population. Survivors of cancer face unique physical, psychological and social challenges that require a long term strategy to minimize a negative

impact on the quantity and quality of their lives. In 1986, the National Coalition for Cancer Survivorship was founded to deal with the full spectrum of survivorship issues related to living with, through, and beyond a cancer diagnosis. In 1996, the NCI established the Office of Cancer Survivorship (OCS) to direct and support research and education on the topic of cancer survivorship. Despite this focus there remains a significant knowledge gap on the specific impact of radiation therapy on many long term cancer survivors. Furthermore, the role of radiation oncologists in the ongoing follow-up and management of problems related to cancer therapy needs to be more clearly defined. Engagement of radiation oncologists in the long term care of patients will inform other healthcare providers of the proper diagnosis and management of late sequelae of radiation therapy.

Strategic Importance. Radiation oncologists need be fully engaged in the management of side effects during and after radiation therapy. As we are involved in the weekly assessment and management of patients under our care, it is necessary to understand the biological and physiological adverse responses to therapy and the physical and pharmacological principals of management. Successful management of acute radiation therapy reactions not only may contribute to better quality of life but could improve patient outcomes through better compliance with all cancer therapies.

Radiation oncologists have a unique opportunity to establish a long term relationship with their patients and support their lifelong health objectives. It is critical to have an understanding of the impact of radiation therapy on a patient's function years following successful therapy and cure.

Potential Projects. The management of acute side effects of radiation therapy is as much a matter of culture as it is of evidence.

- Initially, it may be worthwhile to compile and categorize symptom management strategies and prioritize them by effectiveness and the levels of evidence that support them. Publishing these symptom management techniques in a format readily available to radiation oncology physicians, nurses and patients will allow expedient treatment of treatment related side effects. A "WIKI" type webpage may be suitable for making this information universally available. Ideally, interventional clinical trials testing supportive therapies and other symptom management strategies will help identify effective strategies that minimize the side effects of therapy.

- One important aspect of cancer survivorship is the ongoing collection of late effect data as well as economic and psychosocial consequences related to a cancer history. There is an opportunity to engage cancer survivors through web channels and/or social media to collect data on social and clinical outcomes to better inform future decisions about treatment options.

6. ASSESS THE VALUE OF RT/RO

Background and Description of Topic. As a percentage of GDP, health care spending growth is projected to outpace the Social Security and Defense programs over the next 20 years. Oncology spending represents 5% of US medical spending; rise in the past decade is largely secondary to anti-neoplastic agents. Radiation Oncology accounts for a small portion of oncology spending but has seen substantial cost growth secondary to technology innovation. The IOM, NCI, ASTRO, and ROI have called for generation of evidence to demonstrate the comparative effectiveness of technologies and interventions in radiation oncology.

Strategic Importance and Implications for RO and ROI.

The ROI supports studies that examine the comparative value of radiotherapy because such studies have the potential to generate the evidence needed to improve cancer outcomes while slowing the growth of health care spending.

Potential Projects. To examine the comparative value of radiotherapy, three main topics areas are proposed:

- **Examine CEA of alternative radiotherapy modalities.** Conduct cost-effectiveness analyses of alternative radiotherapy modalities (e.g. 3DCRT, IMRT, Helical, Robotic, Brachytherapy, Proton Beam Therapy) across prevalent disease sites. Rationale: New and expensive radiotherapy technologies have been introduced without evidence indicating incremental benefits compared to alternatives. The ROI encourages research studying the cost-effectiveness of radiotherapy modalities.
- **Examine HRQOL, utilities and CEA of alternative approaches (e.g. radiotherapy, surgery, combined modality therapy) for local-regional control and function preservation across prevalent disease sites.** Establish HRQOL and utilities (e.g. preferences for health states) for local-regional control and function preservation across prevalent disease sites. Rationale: Local-regional cancer control with maximal normal tissue preservation is a defining role for radiotherapy. Improvements in radiotherapy technique and delivery as part of combined modality therapy or novel hypofractionated treatment approaches may lead to equivalent or improved survival outcomes while maximally preserving function and HRQOL. To establish the value of function preserving treatment associated with definitive radiotherapy, the ROI encourages research to examine patient HRQOL and utilities after definitive treatment. Based on this work, CEA analysis can be conducted to compare radiotherapy or combined modality treatment to alternative approaches for definitive cancer care. Examples include patient HRQOL and utilities after definitive radiotherapy for early stage NSCLC, after breast conservation for breast cancer, after definitive treatment for prostate cancer, after bladder preserving therapy for muscle invasive urothelial carcinoma of the bladder, and others.
- **Examine productivity loss associated with definitive cancer care.** Examine productivity loss associated with alternative approaches to definitive cancer care. Rationale: Productivity outcomes are important to characterize the impact of cancer in the workplace and show the effects of treatment on productivity. The analysis of lost productivity is complementary to conventional CEA. Productivity loss can be categorized as absenteeism (being absent from work) or presenteeism (being present at work but working at a reduced capacity). Presenteeism may account for a larger proportion of losses than absenteeism. The cost of lost productivity may be several times greater than direct medical costs and may be minimized by advances in radiotherapy technique and delivery. The ROI encourages studies that compare productivity loss for patients and their caregivers during and after alternative modalities of treatment for cancer.

ENDNOTES

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Mission

The Radiation Oncology Institute (ROI) will enhance and promote the critical role of radiation therapy in the treatment of cancer by supporting research and education about the life-saving and quality-of-life benefits of radiation therapy.



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