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Special Article

Developing a national radiation oncology registry: From acorns to oaks

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Abstract

Purpose: The National Radiation Oncology Registry (NROR) is a collaborative initiative of the Radiation Oncology Institute and the American Society of Radiation Oncology, with input and guidance from other major stakeholders in oncology. The overarching mission of the NROR is to improve the care of cancer patients by capturing reliable information on treatment delivery and health outcomes.

Methods: The NROR will collect patient-specific radiotherapy data electronically to allow for rapid comparison of the many competing treatment modalities and account for effectiveness, outcome, utilization, quality, safety, and cost. It will provide benchmark data and quality improvement tools for individual practitioners. The NROR steering committee has determined that prostate cancer provides an appropriate model to test the concept and the data capturing software in a limited number of sites. The NROR pilot project will begin with this disease-gathering treatment and outcomes data from a limited number of treatment sites across the range of practice; once feasibility is proven, it will scale up to more sites and diseases.

Results: When the NROR is fully implemented, all radiotherapy facilities, along with their radiation oncologists, will be solicited to participate in it. With the broader participation of the radiation oncology community, NROR has the potential to serve as a resource for determining national patterns of care, gaps in treatment quality, comparative effectiveness, and hypothesis generation to identify new linkages between therapeutic processes and outcomes.

Conflicts of interest: None.

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Conclusions: The NROR will benefit radiation oncologists and other care providers, payors, vendors, policy-makers, and, most importantly, cancer patients by capturing reliable information on population-based radiation treatment delivery.

Introduction

The last decade has seen rapid technical developments in the field of radiation oncology. Techniques such as 3-dimensional radiation therapy, intensity-modulated radiation therapy, and image-guided radiotherapy have become the standard of care for the treatment of a wide variety of disease sites.[1] More recently, much interest has been generated for proton therapy, which may allow for improved local control and survival with less morbidity but at a substantial increase in treatment delivery cost. As is often the case with new technologies, most of these changes in radiation oncology practice have occurred without systematic collection of high quality evidence of improved outcomes.[2] No clear evidence exists to prove that their widespread use in real-world care settings is ultimately as beneficial as initial testing and clinical use in academic centers or controlled clinical trials would suggest.[3] In addition, the value of one technology over another or any of the non-radiotherapeutic alternatives has not been determined. Incremental technological advancements, along with increased drug costs, have driven up the cost of cancer care to unsustainable levels.[4] As a result, emerging payment reforms will increase the importance of practicing medicine with better outcomes at lower costs. Thus, there is an urgent need to obtain population-based comparative effectiveness data on all radiotherapy techniques.

To address the need for accurate, comprehensive, and clinically rich data, to determine national patterns of care, outcomes, and gaps in treatment quality, and to compare the effectiveness of different treatment modalities, we propose establishing the National Radiation Oncology Registry (NROR). The NROR is a collaborative initiative of the Radiation Oncology Institute and the American Society for Radiation Oncology (ASTRO) with input and guidance from other major stakeholders in oncology. The NROR will collect patient-specific radiotherapy data electronically to allow for rapid comparison between the many competing treatment modalities for effectiveness, outcome, utilization, quality, safety, and cost. It will provide benchmark data and quality improvement tools for individual practitioners.

The most rigorous type of outcome evaluation and the highest level of evidence can only be derived from randomized controlled trials (RCTs). The greatest strength of RCTs lies in their internal validity and the extent to which we can trust that the causal relationship between treatment and outcome is due to the treatment being studied. However, because RCTs take years to conduct, are expensive to run, and tend to be conducted at a small number of academic institutions, their practicality is limited. Furthermore, it is not always clear that these RCTs can be applied to patients treated in standard-care facilities. Patients in such settings are more heterogeneous, may have greater comorbidities or advanced age, may be of lower socioeconomic status, and may have different outcomes from the subgroups studied in RCTs.[5] Pragmatic clinical trials, which are intended to address many of these limitations, can in some cases be faster and less expensive than traditional RCTs; however, pragmatic trials are operationally complex and have yet to be applied in radiation oncology settings.[6]

While traditional explanatory clinical trials test the efficacy of an intervention in select patients and in a controlled setting, population-based studies evaluate the effectiveness of real-world clinical practice. Population-based studies are intended to include nationally representative samples and may permit access to data from a large number of cancer patients treated over time. These studies have generally been drawn from large administrative and claims-based observational databases, such as the Surveillance, Epidemiology, and End Results (SEER) program established by the National Cancer Institute (NCI) in 1973[7] and the Health Care Financing Administration (the agency which oversees Medicare, now called the Center for Medicare and Medicaid Services). Currently, SEER collects data from regional cancer registries that cover 26% of the US population. These data include information on cancer incidence, patient demographics, clinical and treatment factors, and survival. Although the SEER database has many strengths, including its large size, long follow-up, and excellent identification of cancer incidents in a population that reasonably resembles that of the United States overall, key limitations include lack of detailed clinical and treatment information. Not only does SEER lack adequate information on radiation dose and technique to allow for detailed analyses of different radiation approaches, recent studies have suggested that at least some SEER registries under-ascertain the very fact of radiation therapy receipt.[8,9] In any case, both SEER alone and SEER-Medicare databases have been used to describe patterns of care,[5-7,10] access to care,[11] quality of care,[12] treatment complications,[13] and treatment effectiveness[14-18] relating to radiation therapy.

A more detailed source of observational data regarding radiation therapy techniques is the American College of Radiology (ACR) Quality Research in Radiation Oncology (QRRO) project, which was founded over 35 years ago. QRRO (formerly Patterns of Care) conducts national surveys that determine the structure, process, and outcome of care; they emphasize practice setting, use of new

technologies, and other factors likely to influence outcomes. They use sophisticated statistical techniques to compute national averages on each survey item. These national averages are a benchmark of clinical quality assurance in radiation oncology for national practice as well as for participating institutions. We envision that the NROR will broaden the scope of studies conducted by QRRO by providing population-based evidence on how different treatment modalities influence outcomes for selected cancer patients. Additionally, the model discussed in more detail below will compliment the QRRO program that abstracts data from manual and random chart audits to a program that captures comprehensive data from electronic medical record systems for entire patient cohorts in participating practices.

In addition to the concerns already noted, such analyses have been limited by the usual analytical issues regarding observational data, such as selection bias and confounding factors, migration of patients into and out of catchment areas, and the lack of patient-reported outcomes (PRO). Accurate diagnosis, disease-free survival, toxicity, PRO, and quality of life are particularly important when one attempts to compare the effectiveness of several different treatment modalities, all of which may cure the patient but some of which may do so with measurably less toxicity. Other outcome-related measures such as associated treatment costs and health care utilization are equally important.

In 1992, the Center for Disease Control established the National Cancer Registry Program,[19] which aimed for the development of PBCR (population-based cancer registries) in every state; this goal has been achieved. Although most PBCRs get information primarily via manual abstraction from patient hospital records, such databases have many limitations.

- Data may not be of sufficient quality to provide accurate and unbiased estimates.
- Data are affected by changes in disease classification and coding over time.
- With improving survival rates, individuals suffering from multiple cancers are becoming more and more common. Approximately 16% of new cancers in the United States are second or higher order cancers in the same individual.
- Pathologists often have divergent cancer diagnoses.
- Patients from rural or underserved regions can die with undiagnosed cancer and without ever visiting a health care facility.
- The scope and detail of data collected is broad, and little radiotherapy-related data are collected.
- Data collection, aggregation, and analysis often take many months to years.

Some of these issues have been addressed by national registry organizations through the use of common definitions and coding, quality-control procedures, and staff training. However, the existing cancer registries remain an underused resource for comparative effectiveness and outcome research, in part because they were not designed to support this type of research and do not include some of the necessary data elements. The rapid introduction of advanced radiation technologies further challenges the existing system.

Thus, those cancer registries currently in existence do not have the detail needed to accurately and effectively assess radiation therapies. In order to address the limitations of existing data collection programs, we propose to develop a radiation oncology-specific registry that prospectively captures patient and disease characteristics, radiation therapy details, information on other therapeutic and diagnostic interventions, clinician-reported outcomes (CROs), and PROs and provides access to this information in near real time.

National Radiation Oncology Registry

The overarching mission of the NROR is to improve the care of cancer patients by collecting reliable information on treatment delivery and health outcomes. Unfortunately, real-world data are often variable; therefore, our goal is to build an infrastructure that minimizes the possibility of incomplete and inaccurate data collection.[20,21] The NROR is designed to collect patient-specific data electronically to allow for rapid comparison of the effectiveness, outcome, utilization, quality, safety, and cost between the many competing treatment modalities. One of the design specifications of the NROR, which distinguishes it from other registries, is the collection of PRO data. Based on the needs and goals of the patient, treatment-related changes in PRO can influence the clinical decision-making process. For example, there are a variety of treatment options for prostate cancer, including surgery (open or robotic prostatectomy), brachytherapy, external-beam radiotherapy (ranging from expensive proton therapy to relatively inexpensive 3-dimensional conformal therapy), and hormone therapy. Additionally, because prostate cancer is very slow growing, "active surveillance" is another option, particularly in elderly men with low-risk disease. Each of these management options comes with a different set of risks, such as incontinence, impaired bowel and bladder function, sexual dysfunction, and anxiety that may affect the quality of life of both patients and their partners.[22] Therefore, incorporating the collection or measurement of PROs into longitudinal, prospective, comparative effectiveness research studies will provide a more detailed evaluation of these options.

To incorporate rapidly evolving information as it is developed, an open-source database with detailed de-identified information about patients, their treatment, and their health outcomes that also ensures the confidentiality

of their health information will be deployed. These data sets will offer a potentially valuable source of information on patterns of care, quality improvement, and treatment effectiveness. They will also enable researchers to more rapidly and efficiently answer questions regarding interventions and the processes associated with improved outcomes for cancer and other conditions. The NROR will improve the methodology for collecting prospective data not only from existing radiation therapy-electronic medical records (RT-EMR) but also from other records (eg, hospital records) and for entering patients into an electronic clinical database to generate new evidence on the comparative effectiveness of different modalities of radiotherapy treatments and population-based outcome data.

The global objectives of the NROR are to do the following:

1. Elucidate national patterns of care, gaps in treatment quality, comparative effectiveness, and hypothesis generation to identify new linkages between processes of care and outcomes.
2. Provide benchmark data and quality improvement tools to individual practitioners to benefit quality improvement, to maintain certification, and to accredit individuals and practices.
3. Produce information available to clinicians and patients at the point-of-care to support informed decision making.
4. Improve health care outcomes and also potentially lower the cost of care to benefit not only individual patients but also the overall health care system.
5. Automatically abstract and aggregate registry data elements from RT-EMR, patient portals, medical record systems, institutional databases, cancer registries, and radiation treatment planning systems.
6. Collect longitudinal CRO and PRO data for outcome studies.
7. Harmonize data elements with the NCI's common data element (CDE) browser,[23] which will make the development of shared protocols with insurance administrative databases, the National Cancer Data Base, and SEER possible and make the information included in the NROR more comprehensive.
8. Establish an unprecedented scalable registry infrastructure for rapid and automated abstraction of radiotherapy-related information from RT-EMR, radiation treatment planning systems, and patient portals. This abstraction will allow the NROR to collect data concerning a very large cohort of patients treated with radiotherapy and to compare outcomes, such as surgery, chemotherapy, and combined therapies, across treatment modalities.
9. Develop novel methods for conducting efficient and valid comparative effectiveness research in radiation oncology.

Because we recognize that achieving all of the aforementioned objectives at once would be extremely difficult, we will develop NROR in phases. The first phase will be restricted to one disease site, a narrow and focused study question, a limited number of data elements, and a limited number of representative institutions. Even though the adoption of electronic medical records and treatment planning systems is almost universal in the field of radiation oncology, the actual electronic extraction and aggregation of data from these systems is fraught with technical, administrative, and other challenges. The design specifications of the information technology infrastructure for NROR is intended to ensure that we can overcome technical challenges and automate the process of registry data abstraction and aggregation from participating facilities and patients themselves.

Design characteristics of NROR

The Effective Health Care Program of the Agency for Healthcare Research and Quality has developed a user's guide for developing registries to evaluate patient outcomes. According to this user's guide, patient registries are a valuable complement to RCTs for determining real-world outcomes in medical practice. These can be used to evaluate outcomes for diverse purposes, ranging from the natural history of a disease, to patterns of practice, to the safety and effectiveness of competing treatment modalities. The Effective Health Care Program recommends that each registry should be designed with respect to its major focus. The NROR will have the following design characteristics.

Scope

The NROR is a health services registry. Its purpose is to determine the clinical effectiveness and value of competing modalities of radiation therapy, to measure or monitor toxicities, to track clinical outcomes, and to measure quality of care, including conducting studies to measure and improve the practice of radiotherapy. Data will be collected to assess radiotherapy trends within a broad range of care settings and to describe cancer control rates, survival, and morbidity. Furthermore, harmonizing common data elements with the CDE browser and linking to other registries and databases should ultimately allow us to compare the effectiveness of radiotherapy with other treatment options or modalities.

Governance

The development and maintenance of NROR is governed by the Registry Steering Committee, which is made up of radiation oncologists, medical physicists,

statisticians, health services researchers, population scientists, patients and patient advocates, vendor representatives, and medical informaticists. The steering committee will ensure the following:

- Outcomes are clinically meaningful and relevant.
- Operational definitions of outcomes are clearly defined.
- Appropriate personnel and facilities are available, including facilities for secure storage of electronic data.
- Adequate fiscal resources are available for smooth operations and long-term sustainability of the NROR.
- Individuals responsible for the integrity of computerized data are identified and have the training and experience to perform the assigned tasks.
- Registry quality assurance, legal, regulatory, and data integrity programs are in place and properly resourced.

The steering committee currently oversees 2 subcommittees that are responsible for the development of the NROR infrastructure. As the NROR matures, other committees, such as Executive, Data Monitoring and Quality Assurance, Research/Publications, Statistics, Stakeholder Advisory, Recruitment, Marketing-Communications, Government-Payer Relations, Business Development-Strategy, and Ethics will be constituted. The current committees are described below.

Data dictionary committee

This committee is tasked to develop data nomenclature, common taxonomy, and data elements and their definitions. We anticipate that the use of agreed-upon terminology derived from standards will save significant time and resources by lessening ambiguities along the continuum from data collection to data entry to data analyses. A well-maintained data dictionary, together with an open-source information technology infrastructure, has the potential to effectively serve the myriad of research, clinical, and societal needs encountered on a daily basis for years to come. The NCI-sponsored Common Data Element Dictionary[23] provides a unique source to standardize the terminology used in clinical trials and to promote the uniform collection of study data. Unfortunately, the existing CDE terminology is not adequate for data collection in radiation oncology. The DDC will overcome this problem by creating a collectively determined and comprehensive taxonomy and data dictionary for the compilation of treatment and health research quality of life data on patients treated with radiotherapy. The DDC will ensure that the NROR taxonomy and data dictionary conforms to the NCI goal of maintaining a common nomenclature across modalities and diseases whenever possible to provide consistent common data element terminology.

The membership of this committee is comprised of health services researchers, technical experts from the Integrating the Healthcare Enterprise in Radiation Oncology initiative, and subject experts identified by ASTRO. The DDC will ensure the following:

- A plan is developed to identify and capture all the necessary aspects that can be collected from the outset (eg, demographics, patient-tumor characteristics, and treatment details).
- A data and coding dictionary is maintained to provide explicit definitions and describe coding.
- A process is established to document new data elements and modifications to the existing data elements.
- A quality assurance plan is created to address data editing and verification.
- A mechanism is put in place to ensure that applicable stakeholders, such as vendors and participating facilities, have the means to participate in data standards development and adequate time to adapt and implement ratified standards.

Information technology infrastructure committee

This committee will develop and manage an information technology infrastructure for data collection. It will establish an electronic data collection infrastructure to link existing radiation oncology electronic medical records and to transmit, archive, and remotely manage CRO and PRO data. Its first task will be to carefully evaluate existing technologies and information technology (IT) infrastructures to avoid de novo development of an infrastructure for the NROR. The IT infrastructure will facilitate the transfer of information from the clinical systems to a database model designed for efficient aggregate analysis at the institutional, regional, or national level. This analytical database will fulfill all security and privacy considerations and maintain redundancy to ensure no data loss. Web-based access will provide for communication among various users (eg, patients, radiation oncologists, data managers, and support staff). In recognition that data collection is integral to the clinical process, recommendations for clinical workflows that facilitate collection of the structured data defined by the Data Dictionary Committee will be identified. The system design architecture will support the following:

- The Internet as a platform for standards-based health information technology (HIT) applications delivered as modular and interoperable applications and services.

- Proposals for the "meaningful use" of electronic health record technology as defined by the Office of the National Coordinator for Health Information Technology.
- The ability of each participating institution to access information generated from their clinic for self-analysis.
- Tools and services that empower patients to manage their cancer survivorship effectively.
- Health Insurance Portability and Accountability Act-compliant security, confidentiality, and privacy to protect patient, practice, provider, and clinician data.
- A modern database infrastructure, including federated database models to meet system requirements.
- Open standards, open protocols, and open application programming interfaces, which allow for computable data exchange and interoperation between applications, devices, and platforms.
- Certification requirements for platforms and applications, such as those anticipated by the federal government.

Pilot project

The steering committee has determined that prostate cancer provides an appropriate model to test the concept and the data capturing software in a limited number of sites. Prostate cancer is common, has great public health and economic consequences, and was identified by the Institute of Medicine as the area of oncology most in need of comparative effectiveness research. The steering committee will designate a clinical investigator to oversee a pilot project to gather treatment and outcomes data from a limited number of treatment sites across a range of practices; once feasibility is proven, the project will scale up to more sites and diseases.

NROR stakeholders

Relevant stakeholders must be identified and engaged from the very beginning, as they have important input into the type and scope of data collected by the NROR. Ultimately, they may be users of the data, or they may play an important role in disseminating the results from the registry. Some stakeholders may provide incentives for physicians to aggregate their patient data in the registry, which may help assure the long-term sustainability of the registry. Therefore, stakeholder input will be a critical consideration in the design and operation of the NROR.

The primary stakeholder group is the patient community. The fundamental purpose of the NROR is to improve outcomes for our patients. Operationally, the stakeholder group is comprised of the Radiation Oncology Institute, ASTRO, NCI-designated clinical trial groups, the American Board of Radiology, the ACR, and RT-EMR vendors. These stakeholders are responsible for the creation and long-term sustainability of the NROR. The other stakeholders for the NROR include the following: regulatory authorities (the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration, and state agencies); radiation oncologists; health care service providers; patient advocacy groups; health care payors; the National Institutes of Health/NCI; representatives from the surgical, medical oncology, and palliative care specialties; and any other entity that would benefit from knowledge of the data (or would be impacted by the results) but is not instrumental in establishing and maintaining the NROR.

Patient enrollment and retention strategies

The goal of the NROR is to collect population-based radiotherapy data. In the first phase, data collection will be restricted to a small group of institutions and a single disease site (prostate cancer). However, the design and implementation of the IT infrastructure will be scalable to a much larger population and multiple disease sites. The scope of questions that could be addressed through NROR is quite broad. Appropriate scientific approaches for risk adjustment will be used to address other confounding factors for given registry study questions. The NROR will ensure that registry participants are similar to the target population and selection bias will be minimized to the extent feasible. Eligibility (in terms of inclusion and exclusion criteria) will be confirmed upon patient enrollment. Registry participants will be appropriately trained to ask about complaints or adverse events in a manner that is clear and specific (eg, solicited versus unsolicited). Finally, special attention will be directed to enrollment of vulnerable populations, minority groups, and other patient populations that are often underrepresented in clinical research.

Privacy and ethics issues

Health information is widely regarded by patients as a confidential communication between them and their health care providers. Furthermore, a patient's identifiable health information is protected by the federal privacy regulations resulting from the Health Insurance Portability and Accountability Act of 1996. These legal requirements may influence registry decisions involving the selection of data elements and verification procedures. The NROR infrastructure will ensure that each registry application is fully compliant with legal requirements in the United States. Finally, procedures will be established to assure that facilities participating in the NROR meet with institutional review board guidelines. The NROR will adhere to the fundamental principles for the ethical conduct of scientific research involving human subjects. According to the Belmont Report, each scientific study

must demonstrate respect for persons (as autonomous agent; self-determination), beneficence (do good; do no harm; protect from harm), and justice (fairness; equitable distribution of benefits and burdens; equal treatment).

Data collection, quality assurance, and safety

The NROR data include both PROs and CROs. These data elements are specific to each registry study question and are determined by the radiation oncology content experts. All data elements will be abstracted electronically from RT-EMR and clinician-patient electronic portals. The NROR will ensure that data are reasonably complete and accurate. Automatic data range and consistency checks will ensure data integrity. Adequate efforts will be expended to assure that the appropriate patients have been systematically enrolled and followed in an unbiased way. Concerted effort will be made to include vulnerable and minority populations in the registry.

Legal, administrative, and regulatory issues

We anticipate that there will be substantial barriers to direct access and collection of facility EMR data as well as data derived from web-based PRO entry portals. A model whereby a third party has access to such data and can "pull" it or have data "pushed" on request is novel in medicine. It is likely that radiation oncology practices, including their physicians, administrators, and legal and regulatory representatives, will express discomfort with this paradigm. Thus, the NROR must develop supportive materials in the form of technical white papers, demonstrable precedent models, exemplary consent forms, and other assurances that the collected data will be duly protected, de-identified, and managed in accordance with institutional and governmental regulatory guidelines. It will also be critical that ASTRO, as the representative professional organization, directly help develop this supportive material and endorse the NROR model. Consequently, we anticipate that there will be greater participation in the NROR and that the time frame from solicitation to participation will be minimized.

Long-term sustainability and funding plan

Long-term sustainability of the NROR will ultimately depend on how well we are able to recruit and retain radiation oncologists and patients. We will develop well-planned strategies that will secure an appropriate balance between participation burden and reward. The pilot project will help us determine acceptable data burden and audit requirements. We anticipate that a successful pilot will also allow the NROR to obtain further seed funding from federal funding sources and third-party payors. If participation in this registry supports CMS Physician Quality Reporting System (PQRS) payments, the ASTRO PAAROT program (Performance Assessment for the Advancement of Radiation Oncology Treatment), ASTRO-ACR Practice Accreditation program, and American Board of Radiology Maintenance of Certification requirements, we could reasonably solicit direct participation from the radiation oncologist and their institutions. In addition, NROR data requirements are likely, over time, to align with those from statutory regulatory programs, such as the Health Information Technology for Economic and Clinical Health Act and "Meaningful Use." Finally, if future technological validation will hinge upon coverage with evidence of the determination process, the NROR could serve as a vehicle for aggregation of experience with the new technology. Support from equipment manufacturers and third-party payors would be a reasonable request, particularly if the new technology will be reimbursed by the CMS during the assessment phase. We must also clearly articulate the value of the registry to private payors; Medicaid, the Department of Veterans Affairs, and other health plans, as well as the Food and Drug Administration, for whom the NROR may support both pre-market and post-market evaluation requirements. As a general principle, the sustainability of the NROR will depend on ongoing efforts to engage these and other organizations so that the work can be designed to simultaneously address as many interests as possible.

Summary

By capturing reliable information on population-based treatment delivery and health outcomes, the National Radiation Oncology Registry will be of great benefit to treating physicians and other care providers, payors, vendors, policy-makers, and, most importantly, cancer patients. A pilot registry will test the concepts and processes necessary to create and sustain such a registry using prostate cancer as a model. The pilot will utilize a phased approach toward data collection, including paper-based and web-based forms; however, the eventual goal will be to automate data collection from multiple data sources, such as radiation oncology management information systems, general (mainly hospital-based) electronic health records, radiation treatment planning systems, and patient portals. For the project to have long-term sustainability, we will engage and seek counsel and support from a broad range of stakeholders.

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