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Minimum Data Elements for Radiation Oncology

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Special Article

Minimum Data Elements for Radiation Oncology: An American Society for Radiation Oncology Consensus Paper

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Abstract

Purpose: In recent years, the American Society for Radiation Oncology (ASTRO) has received requests for a standard list of data elements from other societies, database architects, Electronic Health Record vendors and, most recently, the pharmaceutical industry. These requests point to a growing interest in capturing radiation oncology data within registries and for quality measurement, interoperability initiatives, and research. Identifying a short and consistent list will lead to improved care coordination, a reduction in data entry by practice staff, and a more complete view of the holistic approach required for cancer treatment.

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Methods and Materials: The task force formulated recommendations based on analysis from radiation specific data elements currently in use in registries, accreditation programs, incident learning systems, and electronic health records. The draft manuscript was peer reviewed by 8 reviewers and ASTRO legal counsel and was revised accordingly and posted on the ASTRO website for public comment in April 2019 for 2 weeks. The final document was approved by the ASTRO Board of Directors in June 2019.
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Introduction

Background

There is an increasing interest in leveraging data in the oncology space as demonstrated in the scientific and lay press, including in a recent *New York Times* article, "New Cancer Treatments Lie Hidden Under Mountains of Paperwork."[1] There is high variation in documentation of radiation therapy–specific data, and sharing between information systems is often done manually rather than automatically, leading to a potential breakdown of efficiency and accuracy. Identifying a standard set of data elements is an important step in promoting data capture and transfer in radiation oncology. The American Society for Radiation Oncology (ASTRO) determined that defining a minimum set of data elements for radiation therapy is high priority for the future of clinical trials, registries, access to patient data, and quality reporting. In recent years, ASTRO has received requests for a standard list of data elements from other societies, database architects, Electronic Health Record (EHR) vendors, and most recently the pharmaceutical industry. These requests point to a growing interest in capturing radiation oncology data within registries and for quality measurement, interoperability initiatives, and research. In addition to these priorities, this effort may improve clinical care for patients with cancer by expanding the visibility of radiation therapy treatment details in other electronic systems. This advancement will lead to improved care coordination, a reduction in data entry by practice staff, and a more complete view of the holistic approach required for cancer treatment.

Scope

A review of radiation therapy data elements in use within national databases, ASTRO programs, and resources from other cancer-related organizations was conducted to identify areas of overlap and priority. This analysis generated a short list of minimum data elements (MDEs) relevant to radiation therapy that should be included in all scenarios, represented in Table 1. This document seeks to define the most crucial radiation therapy data elements that must be entered in the oncology information system and seamlessly exchanged between electronic systems. Promoting this list also provides an opportunity to educate those outside of the field about what data are necessary to capture and transfer. Table 2 aims to define the modality and technique data elements that are commonly used with high variability. This paper also provides further detail on specific, complex data elements such as dose and treatment site.

Indications and Considerations

Standardization

The Healthcare Information and Management Systems Society (HIMSS) defines interoperability as "the ability of different information systems, devices or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data among stakeholders, with the goal of optimizing the health of individuals and populations."[2] The Healthcare Information and Management Systems Society, like many other informatic organizations, breaks down levels of interoperability based on functionality: foundational, structural, and semantic (Fig 1). Most radiation therapy data currently reside at the foundational level. For example, some treatment summary data can transfer to a hospital information system, or even a registry, within discrete data fields, but most cannot be interpreted by that secondary system. Within the radiation oncology field, different members of the radiation oncology team interpret data accurately; however, when relevant and necessary treatment data are viewed by those outside the field, it can be meaningless, or worse, misinterpreted. Although there are codified health care languages already in use to standardize communications, like the Systematized Nomenclature of Medicine, there remains a lack of standardization in radiation therapy treatment planning and delivery. The existing languages are often too general to capture the unique elements of radiation oncology. Without standards, clinicians must rely on lower levels of interoperability and seek conformity among users. For information to be used meaningfully, data must use common concepts with agreed-upon meaning and intent.[3] Further, information must be entered in consistent locations, using consistent wording to facilitate communication across departments and health systems. This lack of interoperability often leads to the question of why the technological efficiencies found in other industries have not yet been realized in health care. One reason is the lack of consistency in workflows across

Table 1 Minimum data elements

Data element	Definition	Detail
Treatment course data elements		
Diagnosis	Identify disease(s) relevant to treatment	ICD-10
Modality	Radiation type - Records the list of all modalities used during treatment course (Check all that apply)	Reference Table 2 for detail
Technique	Treatment delivery method - Records the list of all techniques used during treatment course (Check all that apply)	Reference Table 2 for detail
Number of fractions planned	Records the total number of treatments prescribed in a treatment	
Number of fractions delivered	Records the total number of treatments delivered in a treatment course	
Start date of treatment	Indicates the date on which the patient commences course of delivered radiation treatment	MMDDYYYY
End date of treatment	Indicates the date on which the patient ends or completes a course of delivered radiation treatment	MMDDYYYY
Prescribed dose-level data elements (Note: Multiple dose levels are possible for a given treatment. The following elements are completed for each dose level.)		
Anatomic site of each prescribed dose level	Indicates the primary anatomic site(s) targets for each dose level	Reference the Standards for Oncology Registry Entry (supplementary material, available online at https://doi.org/10.1016/j.prro.2019.07.017)
Total dose planned for each prescribed dose level	Dose prescribed to each dose level	cGy
Total dose delivered for each prescribed dose level	Dose delivered to each dose level	cGy

clinical care and the fact that often workflows must be altered to match different system requirements (Fig 1).

In addition to the potential for streamlined workflows, standardized data can also facilitate innovation in the development of personalized medicine and the use of decision support tools. For example, decision support tools have been used to identify high-risk cases and to affect outcomes.[4] Abstraction of structured data from an institutional EHR and the application of machine learning have been used to model and accurately predict acute encounters such as emergency visits or hospitalizations for patients with cancer.[5-8] Harnessing these tools can further personalized medicine and improve quality.

Patient safety

To minimize risks associated with standardization, interoperability, and access to patient data across specialties, it is critical that MDEs be simple, reproducible, and understandable. Despite significant investment in EHRs and other systems, digital health information remains vertical and does not horizontally track patients across the care continuum. Achieving patient care and safety objectives in health care requires collaboration and coordination between multiple specialties and health professionals. Although there are regulatory standards for care coordination, such as the Meaningful Use Criteria,[9] that are designed to improve safety and promote standardization, homogeneity in data definitions will promote horizontally complete data. MDEs can play a role in improving patient safety by providing unambiguous data to the clinician when it is needed.

Quality improvement

Quality improvement relies heavily upon the collection of standardized data that facilitate measurement and improvement. Clinical registries provide an outlet for data collection and aggregation. Examples abound within both oncology (eg, Quality Oncology Practice Initiative Reporting Registry, National Cancer Database) and other disciplines (eg, National Cardiovascular Data Registry, American College of Surgeons National Surgical Quality Improvement Program). Some radiation-specific data elements are complex and currently require a large amount of human curation by trained registrars, with potential for human misinterpretation and errors from manual data entry. Defining these MDEs will position radiation oncology practices to integrate their data consistently and create an environment where continuous learning and quality improvement can occur.

Research

Research has also increased the volume of data from multimodality treatments in clinical trials. In recent years,

Table 2 Modality and technique: check all that apply

Modality		Technique
External beam radiation therapy (EBRT)	Protons	Passive scattering
		Scanning beam intensity modulated proton therapy
		Scanning beam multi-field optimization
		Scanning beam single-field optimization
	Electrons	2D
		3D planned
		IORT
	Photons (LINAC)	2D
		3D
		IMRT/VMAT
	Photons (isotope source)	2D
		3D
		Intracranial stereotactic
	Neutrons	2D
		3D
		IMRT/VMAT
	Carbon	2D
		3D
		IMRT/VMAT
Brachytherapy	Low dose rate	Interstitial permanent
		Interstitial temporary
		Intracavitary permanent
		Intracavitary temporary
	High dose rate	Interstitial temporary
		Intracavitary temporary
		IORT
	Pulse dose rate	Interstitial temporary
		Intracavitary temporary
	Radiopharmaceuticals	Sealed
		Unsealed
	Electronic brachytherapy	Intracavitary
kV x-rays	IORT	
	Superficial	
	Orthovoltage	

Abbreviations: 2D = 2-dimensional; 3D = 3-dimensional; IMRT = intensity modulated radiation therapy; IORT = intraoperative radiation therapy; LINAC = linear accelerator; VMAT = volumetric modulated arc therapy.

efforts to personalize treatment based on unique biological characteristics of patients' individual tumors have begun to emerge. Although the proportion of this research is increasing, only a fraction incorporates radiation therapy as part of the treatment protocol, even though radiation therapy is given to more than 50% of all patients with cancer at some point in their course of treatment.

There is also an increase in the number of clinical trials that test promising new immunotherapy and molecular targeting drugs in combination with radiation earlier in the drug development cycle. With this evolution, there are opportunities available within research to increase cancer cure rates for a greater proportion of patients before the development of metastatic disease, but most clinical trials include only a binary radiation data element. This lack of detail does not provide researchers with the tools to evaluate comparative effectiveness or the efficacy of treatment pairings. For these major reasons, a core set of radiation therapy data elements is needed to set the foundation for this work and future development.

Specific Data Elements

The task group's recommendations for minimum data elements are shown in Table 1. Some data elements were simple to define; however, others required significant discussion and debate. The task group identified 3 main areas in urgent need of standardization: radiation dose and fractionation, technique and modality, and treatment site. What follows is the rationale on these specific data elements that demanded more detail.

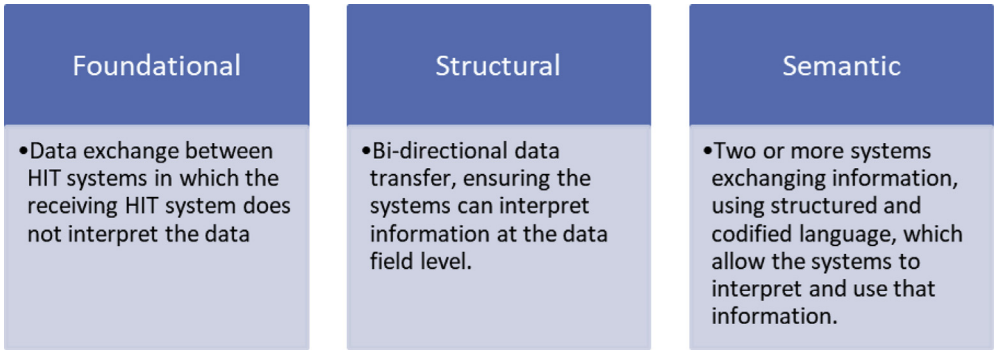

Figure 1 Levels of interoperability.

Dose and fractionation

Understanding radiation dose delivered to a site is recognized as crucial in both clinical care and research and more broadly in population health work. Given the potential for a course of radiation therapy to contain multiple targets and doses, the group recommended defining the delivered dose to each prescribed target as the minimum data element, with the additional documentation of number of fractions and treatment start and end dates. The recommendation is to specifically identify the primary anatomic site(s) within each targeted dose level with dose reported in cGy as recommended in "Standardizing Dose Prescriptions: An ASTRO White Paper."[10] ASTRO is aware that there is ongoing discussion of a standard unit for proton therapy and is interested in joining this work. Until a standard is set, we will use cGy. Cumulative dose should only be reported for a course of treatment where the characteristics of radiation therapy delivery is the same, eg, a single course of prostate treatment that includes a simultaneous integrated boost would be reported as one, but a course of breast treatment that has an initial phase of planned photons followed by an enface electron boost to the tumor bed would be reported separately (see supplemental material, available online at https://doi.org/10.1016/j.prro.2019.07.017, for examples).

Technique and modality

A course of radiation treatment may involve a combination of radiation modalities and techniques. These terms are commonly misunderstood by the nonradiation oncology community, and as a result, the impact of modern innovations and progress may be unrecognized by researchers and policy makers unfamiliar with the relevant terms. Generally, the term "modality" means the type of radiation used to deliver treatment (eg, photons, protons, brachytherapy). "Technique" means the method by which the modality is applied (eg, intensity modulated radiation therapy, intraoperative radiation therapy). Radiation therapy dose is difficult to interpret without understanding these vital elements.

To record the minimum data elements for radiation modality and technique, preset options are needed for standard data capture. The options need to be reasonably granular but succinct. Several difficult choices were made by the task group regarding treatment modality. First, stereotactic treatment was not included. Rather, it was left up to dose, fraction size, fraction number, and other indicators of technique to imply the various forms of stereotactic radiation therapy (eg, stereotactic body radiation therapy, stereotactic ablative radiation therapy, stereotactic radiosurgery). Second, it was decided not to include radiation treatment energy, despite this being a commonly recorded data element in commercial radiation oncology EHR systems, because it was felt that beam energy did not contribute enough information to be considered necessary.

As the field continues to learn more about the radiobiology of different radiation modalities such as heavy ion particles versus photon beam and brachytherapy versus external beam, it is also important to consider the modifying effect of technique—3-dimensional conformal therapy versus modulated techniques, etc. The type of photon indicative of source (gamma ray vs x-ray) was considered a minimum data element given the regulatory implications and the connotations regarding treatment type and technique.

Additionally, there are several techniques that are not widely disseminated but that may experience increased use in the future, such as flash treatment and biology-guided radiation therapy. To avoid frequent iterations of this list, the categories must be broad enough to account for future innovation (eg, the broad category of "radiopharmaceuticals"). Finally, given the many potential combinations of multiple modalities and techniques for a patient's overall radiation treatment, the task group recommends the capture of multiple phases of treatment so that combinations of treatment can be recorded in discrete data fields.

Treatment site ontology

An ontology represents the current knowledge in a domain (eg, radiation oncology or human anatomy) in a formal manner. It defines a set of concepts and categories in a subject area that shows their properties and the relationships

between them. It further structures these concepts in a narrower-broader hierarchy (eg, radiation pneumonitis is a radiation-induced toxicity). Ontologies can create semantic interoperable data—data in which not only the syntax but also the meaning of a data element is clear. An example is a Fast Healthcare Interoperability Resource message (a syntax) in which an ontology (eg, the Systematized Nomenclature of Medicine) and code (eg, 84004001 for radiation pneumonitis) are used so that it is unambiguously clear what is meant. There are several efforts underway in the radiation oncology field to make an ontology.[11-14]

There was immediate consensus in the MDE task group that an ontology of anatomic site(s) targeted during the treatment course (eg, primary or metastatic gross tumor volume or clinical target volume) was needed. However, it was not within the scope of the project to create and maintain ASTRO's own unique ontology, so instead an existing list needed to be identified. However, as the task group explored this issue further, it became evident that there would be some challenges.

One such challenge was the appropriate level of anatomic specificity. At one extreme, the recommendation could have included every anatomic structure being targeted during a course of treatment. For example, when describing a course of definitive treatment for stage IIIB non-small cell lung cancer, the recommendation could require specifying the following: right lower lobe, right level 10 lymph nodes, level 7 lymph nodes, right level 4 lymph nodes, and left level 4 lymph nodes. At the other extreme, a high-level generic description such as "chest" could be used. Not surprisingly, neither of these approaches seemed appropriate. A related issue was whether it would be best to use a list of generic anatomic descriptors such as the Foundational Model of Anatomy,[15] which is a detailed ontology of anatomic structures, or to use descriptors that are more commonly used in radiation oncology. The American Association of Physicists in Medicine has formed a radiation therapy ontology workgroup as part of their Big Data Subcommittee[16] to create a radiation oncology–specific ontology.

It was also important to identify a list that is used widely and in a variety of settings with tested reliability and feasibility and that is likely to be maintained and updated as problems with its use are uncovered. Lastly, the task group wanted a list that was not proprietary so that its existing coding could be used to facilitate its implementation into radiation oncology–specific EHRs.

Perhaps unsurprisingly, an available ontology that meets all the current needs of radiation oncology could not be identified. The task group explored a variety of existing options, including the Foundational Model of Anatomy, and ultimately endorsed the use of the names listed in the "phase I Radiation Primary Treatment Volume" table of the Commission on Cancer American College of Surgeons 2018 Standards for Oncology Registry Entry.[17] This list includes most relevant anatomic sites in enough detail, has been used widely in all different settings, and is updated regularly.

Implementation and Next Steps

It is important to not only identify a working data set but to plan for integration and use in current systems. As mentioned previously, many national databases are interested in adding radiation therapy data elements into their current data capture. The MDE proposal is expected to be vetted in a pilot study with the NCI Surveillance, Epidemiology, and End Results Program. The pilot is directly testing the feasibility of capturing ASTRO's recommended MDE from current systems and is collaborating with vendors to make needed technical changes to software. They will also be able to benchmark initial data reliability and troubleshoot areas where manual abstraction and quality assurance are still needed.

Researchers focused on immunotherapy are interested in aggregating data to learn more about radiation sequencing within cancer care, and the National Cancer Institute is seeking more dosimetric information in their radiopharmaceutical trials. Based on this increased interest, we expect to see the MDE incorporated into clinical trials soon.

Integrating the Healthcare Enterprise domains were created to maintain harmonization between different groups as digital health care information became more ubiquitous. To date, 12 such domains exist, including radiation oncology. The Integrating the Healthcare Enterprise radiation oncology task force will integrate the minimum data elements into upcoming use cases so that specific interoperability profiles can be developed and used to guide vendor improvement and ultimately tested to successfully exchange information in a routinely scheduled Connect-a-thon.[18] This partnership is key to successful integration of MDEs in commercial electronic systems. Thus far, although vendors have understood the need for seamless information exchange, they have been waiting for an agreed-upon critical data list of elements on which to focus their efforts. With these recommendations, vendors can begin work.

International efforts are working toward the same goal of identifying and defining a minimum set of data elements. For many years, the National Clinical Analysis and Specialised Applications Team has defined the National Radiotherapy Dataset to be used by all National Health System facilities providing radiation therapy.[19] Newer efforts include the European Society for Radiation Oncology and the European Organisation for Research and Treatment of Cancer E2-RADIatE platform, a pan-European standardized radiation oncology data infrastructure that is being deployed for patients with oligometastatic disease and those undergoing proton therapy.[20] Although implementation of MDEs is not currently planned in any of these international efforts, ASTRO welcomes the opportunity.

There are additional cross-specialty data elements like disease status, staging, and treatment intent that are integral to oncology and that need specification. ASTRO is aware of current initiatives such as Minimal Common Oncology Data Elements and is interested in collaborating on these shared elements with oncology leaders as well as integrating MDEs to create unified definitions for all oncology specialties (see supplemental materials for examples, available online at https://doi.org/10.1016/j.prro.2019.07.017).

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Supplementary Data

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