Radiation Oncology Alternative Payment Model (RO-APM)

April 27, 2017

Value Statement

The American Society for Radiation Oncology (ASTRO) embraces the spirit and goals of the Medicare Access and CHIP Reauthorization Act (MACRA) and is committed to ensuring that radiation oncology can fully participate in an Advanced Alternative Payment Model that drives greater value in cancer care.

ASTRO members are medical professionals, practicing at community hospitals, academic medical centers, and freestanding cancer treatment centers in the United States and around the globe, and who make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy.

The Radiation Oncology Alternative Payment Model (RO-APM) provides the field of radiation oncology with a meaningful and viable opportunity to participate in the evolving world of health care payment reform as initiated by MACRA. The model achieves the three primary goals as set forth by the ASTRO Payment Reform Workgroup:

1. RO-APM rewards radiation oncologists for participation and performance in quality initiatives that improve the value of health care for patients.
2. RO-APM ensures fair, predictable payment for the radiation oncologist in both hospital and community cancer clinics to protect cancer patients' access to care in all settings.
3. RO-APM incentivizes the appropriate use of cancer treatments that result in the highest quality of care and best patient outcomes.

ASTRO has worked to develop the model in close consultation with leading members of the radiation oncology community, including those practicing in hospital and freestanding centers. In addition, ASTRO has closely monitored and participated in the activities of the Physicians Technical Advisory Committee (PTAC), and we have met with the Centers for Medicare and Medicaid Innovation (CMMI) on several occasions to solicit advice and guidance from Agency experts regarding the development of Advanced APMs. The RO-APM seeks to satisfy the requirements of both entities. It is ASTRO's goal to provide radiation oncologists with an Advanced APM in which to participate beginning January 1, 2018.

Background

Radiation therapy, or radiotherapy, is the use of various forms of radiation to safely and effectively treat cancer. Radiation therapy works by damaging the genetic material within cancer cells. Once this happens, the cancer cells are not able to grow and spread. When these damaged cancer cells die, the body naturally removes them. Normal cells are also affected by radiation, but they are able to repair themselves in a way that cancer cells cannot. Through a multi-step

process, radiation oncologists develop a plan to deliver the radiation to the tumor area, shielding as much surrounding normal tissue as possible.

Radiation therapy can be delivered in a number of different ways: externally, internally and through surface application. During external beam radiation therapy, the radiation oncology team uses a machine to direct high-energy rays or particle beams at the cancer. Internal or surface radiation therapy, also called "brachytherapy," involves placing radioactive material (i.e., radioactive seeds) inside the patient or on the surface of their body.

In all treatment delivery modalities, the total radiation dose that the patient receives is prescribed and may be given in one session or over several sessions. If the radiation is delivered over several sessions, the total dose is divided into fractions, an approach that is referred to as fractionated delivery. Hyperfractionated delivery is a type of fractionated delivery administered in smaller than usual doses, typically, two or three times a day instead of once a day. Occasionally, moderate to large doses of radiation are given twice a day. This is called accelerated fractionation. Hypofractionated delivery involves larger doses of treatment delivered over a shorter period of time.

Executive Summary

The American Cancer Society estimates there were 1.7 million new cancer cases in 2016[1]. Of those cancer patients, 250,000 were diagnosed with breast cancer; 225,000 were diagnosed with lung cancer; 181,000 were diagnosed with prostate cancer; 95,000 were diagnosed with colorectal cancer; and 72,100 were diagnosed with head and neck cancer. Medicare SEER data analysis indicates that, of the Medicare patients receiving radiation therapy, 83 percent had one of the five primary disease sites, which accounts for 93 percent of the total Medicare spend on radiation therapy services between 2007 and 2011[2].

The RO-APM features a common payment framework that applies to the five primary disease sites, including: breast, lung, prostate, colorectal and head and neck. The model also applies to two secondary disease sites: bone metastases and brain metastases. The distinction between the primary and secondary disease sites is that the treatment involved with the primary disease sites is curative in nature, while the treatment associated with the secondary disease sites is palliative.

Once a patient has made the decision with their family and caregivers to pursue radiation therapy, the model episode is triggered by one of three distinct radiation therapy treatment planning codes (CPT Code 77261, 77262, and 77263) combined with an ICD-10 code that corresponds with one of the seven disease sites included in the model. The episode of care begins at clinical treatment planning and concludes 90 days after the last radiation therapy treatment. Throughout the episode participating physicians must adhere to ASTRO guidelines, as

[1] Cancer Facts & Figures 2016, American Cancer Society, https://old.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf

[2] Chen MD MPP, Aileen, et al., Medicare Spending in Cancer: A SEER-Medicare Analysis, Dana-Farber Cancer Institute, Boston, MA, 2016.

well as National Comprehensive Cancer Network (NCCN) guidelines, to ensure that patient care is appropriate and of the highest quality.

Medicare claims data from a specific reference period will be used to determine payments per episode within a disease site. A participating provider's target rate will be based on their historical reimbursement rate, which will be weighed against the regional and national benchmark rates for the same episode of care. The provider will be paid a portion of the target rate once an episode is triggered, as well as a monthly Patient Engagement and Care Coordination (PECC) fee. The remaining portion of the target rate will be paid at the completion of the episode of care. The model features a two-sided risk corridor, in which a provider may share in savings if they spend below the target. However, if the provider exceeds the target, they will be responsible for any overpayment up to a specific amount.

The quality component of the RO-APM model is multi-pronged. It begins with a patient engagement component that involves shared decision making, nurse care management, care plan development, specialty care communication, and survivorship planning. ASTRO's Accreditation Program for Excellence (APEx) or equivalent standards serve as a standard practice requirement. APEx consists of a series of standards and measures relating to the performance of a radiation oncology practice. APEx evaluates the clinical programs provided by radiation oncology practices focusing on quality and safety of radiation oncology processes. Additional quality measures based on guidelines that are disease site specific will be layered on top of accreditation. The purpose of these quality measures is to track how frequently participating practices are adhering to the disease site specific guidelines identified as part of the model. Adherence to clinical guidelines can improve the quality, outcomes and cost effectiveness of health care. Finally, the inclusion of the MIPS Radiation Oncology Measures Set meets the requirement that Advanced APMS include MIPS comparable measures.

After a pay for reporting period to allow for the establishment of benchmark quality data, a pay for performance mechanism will be implemented that will modify payment in future years based on quality measures' performance. Similar to the Bundled Payments for Care Improvement (BPCI) model, the base rate discount will be modified in future years based on quality measures' performance in a prior year.

We believe this model is highly consistent with Quality Payment Program's (QPP) recommended characteristics for an Advanced APM. It includes requirements that physicians assume accountability for controlling the total cost of Medicare spending related to the condition, in this case the treatment of cancer, as well as the total cost of Medicare spending on all services the patient receives during the episode of care.

RO-APM Payment Framework

The RO-APM framework is applicable to five primary disease sites: breast, lung, prostate, colorectal, and head and neck, as well as two secondary disease groups, bone metastases and brain metastases. Cases are allocated to high-order disease groups that are comprised of multiple and anatomically similar ICD-10s. Individual disease groups are not divided further for the purposes of payment (e.g., all breast cancer cases have the same modeled payment). The chart below details the various disease groups and the associated ICD-10 codes.

Primary Disease Site	ICD-10 Code	ICD-10 Comments
Breast	C50, D05	All invasive and in situ disease
Respiratory	C33-C34	All NSCLC and SCLC
Prostate	C61	-
Lower GI	C18-C21	Colon, rectum and anus
Head & Neck	C01-C14, C30-32, C69 & C76	-
Secondary Disease Site		
Bone Metastases	C79.5	-
Brain Metastases	C79.3	-

Episode Definition

Clinical Treatment Planning, CPT Codes 77261-77263, trigger the initiation of an episode of care. Each clinical treatment planning code may be reported only once per episode, and therefore represent the anchor code for the episode of care. The co-reporting of one of these CPT codes and a qualifying ICD-10, as described in the chart above, on the same claim serves as the identification mechanism for an APM-eligible episode.

All radiation therapy services reported with 3-month run-in to and 8-month run-out from the anchor code are included within the episode, provided that no other anchor code is reported during the same period. The run-in period allows for billing procedures where Clinical Treatment Planning is reported at the completion of treatment. The run-out period allows for cases where the radiation oncologist consults with the patient prior to the completion of other therapies (e.g., surgery and chemotherapy) and where the radiation oncologist develops the clinical treatment plan, resulting in the reporting of a Clinical Treatment Planning Code.

CPT codes 77499 *Unlisted Procedure, Therapeutic Radiation Treatment Management* or 99499 *Unlisted Evaluation and Management Service* will designate the end of treatment. CPT code 99024 *Post Operative Follow Up Visit* will initiate the 90-day post treatment follow-up period. End of treatment is designated through the issuance of a claim denoting the last treatment delivery code reported and an end of treatment note.

In order to prevent episode overlap and the potential for gaming, the model contains a 30-day clean period that is initiated at the end of the 90-day post treatment period. This prevents physicians from initiating another episode of care at the end of a treatment period, that could have been combined with the original treatment. If services are delivered during the clean period they would be billed FFS and not included in a new bundle.

An eligible episode consists of all modalities of radiation therapy, including brachytherapy, conventional radiation therapy, Intensity Modulated Radiation Therapy (IMRT), Stereotactic Radiosurgery (SRS), Stereotactic Body Radiotherapy (SBRT) and Proton Therapy. Included

services within an eligible episode are all MPFS services pertinent to the delivery of radiation therapy and/or brachytherapy: treatment delivery, dosimetry, treatment devices, image guidance, weekly physician's management as well as special services.

Weekly treatment management includes the treatment of radiation therapy related symptoms, such as esophagitis and mucositis Appendix A includes a list of disease site specific symptoms and complications that would be included in an episode of care. The intent of the model is to initially account for those symptoms and complications that are attributable to radiation therapy. To eliminate the inclusion of outliers in the development of a base rate and to prevent physicians from taking on unwarranted risk, ASTRO recommends that CMMI institute an inclusion threshold of 2 percent to account for the majority of care related symptoms during the 90-day post treatment period. ASTRO recognizes that there are often multi-modality treatment symptoms and complications that frequently result in hospitalizations and ED visits. We believe that those types of symptoms and complications deserve additional study to determine appropriate attribution in a model. In addition to multi-modality complications, also excluded in the model are all other part B services (e.g., chemotherapy drugs and administration, surgery, diagnostic studies).

In order to account for the additional resource intensity associated with caring for more complex patients, ASTRO recommends a risk adjustment based on multiple factors, including age, performance scores and existing patient co-morbidities, along with using CPT code 77470 Special Treatment Procedures. The 77470 code is already included in reference claims data as it is frequently used for those cases that require additional physician effort and work, as well as technical resources.

Clinical Trials and New Technology

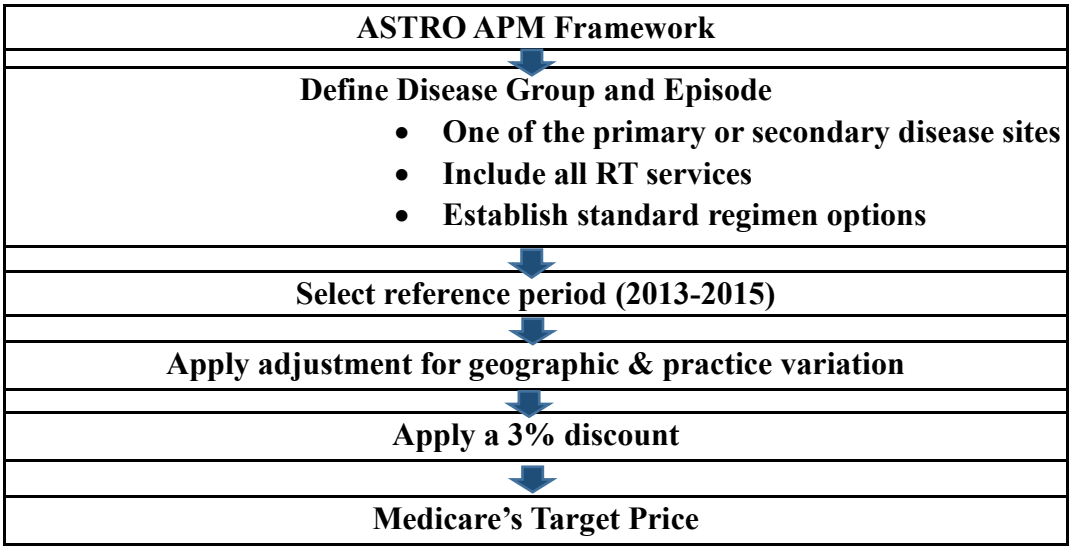
Clinical trials and new technology would be paid for outside the model. This allows for the continued exploration of new techniques and treatments in cancer care, and alleviates concerns that a model might hamper innovation. ASTRO is committed to developing a model based on technologies that are evidence based and that utilize existing best practices, thus creating a space for clinical trials and new technologies to flourish and grow. Once new services become common standards of care, they can be folded into future versions of the model.

Episode Target Price Calculation

All payments made within the time and service constraints during a specific reference period, as described above, are summed and adjusted to account for geographic variation. Separate, site specific (hospital or freestanding), episode payment calculations are made for (1) the eligible participant during the reference period, (2) all regional providers during the reference period and (3) all national providers during the reference period. Aggregated episode payments are averaged into a single value according to a 70:20:10 weighting of participant, regional and national payment averages. The weight-averaged payment is then discounted by 3 percent to yield the episode's Medicare Target Price.

The model will be initiated in 2018 and it will be effective for a period of five years. Annual rate adjustments would be applied to the fixed target price to account for inflation. Additionally,

adjustments to the discount rate would occur annually based on quality measures performance. To account for the significant fixed costs associated with operating radiation oncology practices, there will be no consideration given to changes in utilization during the demonstration period. The graphic below provides a depiction of the process used to determine the target price for each episode of care.



Patient Engagement and Care Coordination Fee (PECC)

The Patient Engagement and Care Coordination Fee (PECC) accounts for services that would be provided in the model that are currently not billable. ASTRO is recommending a PECC fee of $160 per month during an episode of care. The following are services that are required as part of RO-APM participation and would be funded through the PEC:

- 24/7 access to triage patient needs;
- Provide patient care navigation, including patient education and symptom management;
- Coordination of care and communication of information following evaluation and treatment with other care providers engaged in the patient's treatment;
- Documented care plan that contains 13 components of the Institute of Medicine Care Management Plan;
- Documented peer review for professional feedback and learning; and
- Documented survivorship plan (Appendix B).

PECC will ensure that practices can establish 24/7 availability, so that patients can reach providers at any time during their course of treatment. Additionally, the establishment of care navigation programs will provide patients with educational tools and symptom management resources, including nursing care. Symptom management clinics or triage units established in oncology settings have proven to be successful at reducing costs and ensuring that patients have access to resources that improve their quality of life during their episode of care. These units are typically run by nurse care managers who meet with patients during regular clinic visits to assess symptoms associated with radiation therapy and provide guidance regarding self-management, as

well as treatment follow up. A recent UNC Chapel Hill study demonstrated significant savings associated with the implementation of a symptom management program leading to reduced unnecessary ED visits and inpatient admissions[3]. Programs such as this are currently not reimbursable, yet have a significant impact on the patient's quality of life and the cost of care.

PECC will also pay for activities that are currently not billable, such as care coordination, a documented care plan, and survivorship planning. The addition of Peer Review allows for the important exchange of clinical information and the application of best practices that can only be achieved when physicians are given the opportunity to discuss cases and share patient experiences and outcomes. Additionally, the use of a Qualified Clinical Data Registry (QCDR) will allow for the collection and dissemination of quality measures across participating practices, that will further enhance the development of best practices as the model evolves.

Prospective Payment

Once an episode is triggered, the participating physician would receive a portion of the episode payment. Monthly PECC payments would begin as well. Claims would continue to be submitted to CMS throughout the duration of the episode. A final payment would be made to the physician once the final claim is submitted to CMS indicating the completion of the episode.

While ASTRO's goal is to establish an RO-APM that can be implemented in freestanding, as well as hospital based settings, we are keenly aware of the challenges associated with operationalizing this model in every environment. Due to the variation in the different types of contractual relationships that radiation oncologists have with the facilities they operate, ASTRO is proposing that the model apply to three specific groups of radiation oncologists: 1) physicians practicing in freestanding settings; 2) physicians who are directly employed by hospitals; and 3) physicians who contract solely with hospitals. To address concerns that a physician may shift complex patients between settings, ASTRO is proposing to omit physicians who operate in freestanding facilities but also contract with hospital based practices from participating in the model.

The base rate developed for participating practices will involve a historical reference period that will be averaged against similar settings (freestanding or hospital based) at a regional and national level; i.e. a freestanding setting will be compared to other freestanding settings and hospital settings will be compared to other hospital settings. In a freestanding setting, the APM includes all global payments. In hospital based settings, the APM will apply to both professional fee and technical fee components. The model is designed in such a way that the framework for the episode of care can be applied to participating practices in any setting.

Risk Corridor: Shared Savings & Stop Loss

The model contains a risk corridor that establishes shared savings and a stop loss policy. The risk corridor establishes the opportunity for physicians to participate in shared savings up to 15 percent of the target price. This policy prevents potential stinting or withholding of care while

[3] Chera, Bhishamjit S., Reducing Emergency Room Visits and Unplanned Admissions in Patients with Head and Neck Cancer, University of North Carolina Cancer Hospital Lineberger Comprehensive Cancer Center, Clinical Journal of Oncology Nursing – June 2017 anticipated publication

still encouraging the use of higher value therapy options. It also establishes a stop loss policy at 10 percent of the target prices, which is applied to any overages. This policy holds radiation oncologists responsible for overages in payment but does not penalize them for caring for patients that may be more expensive due to advanced disease, complications due to multiple co-morbidities or other factors that increase the cost of care.

RO-APM Quality Component

Patient Engagement

The RO-APM Patient Engagement component is four pronged. It begins with shared decision making; the development of a care plan, which includes communication with other care providers; and is completed with a survivorship care plan at the end of treatment.

Shared decision making enhances the patient's experience and recognizes that no two cancer patients are alike. A cancer diagnosis is a significant healthcare event that warrants consideration of all treatment possibilities, which often can be confusing and have varying levels of cost and side effects. The establishment of a shared decision making component supports patient engagement and the use of a multidisciplinary care team in working with the patient and their caregivers to identify goals associated with treatment and post treatment quality of life. ASTRO would like to explore through this model potential quality measures associated with setting and achieving patient goals, such as returning to work and participation in daily activities.

Additionally, the development of a care plan, issuance of a specialist report, and a survivorship care plan ensures continued patient and provider engagement throughout the process of care allowing for opportunities to discuss progress, address concerns and track progress toward meeting patient goals.[4][5] The specialist report requires the radiation oncologist to follow up with the referring provider regarding the patient's care, further bolstering the importance of communication among specialists. Similarly, the survivorship care plan allows for additional dialogue between the patient and the radiation oncologist once treatment is completed, ensuring that the patient knows what to expect as they move into survivorship.

APEx Accreditation

The ASTRO Accreditation Program for Excellence (APEx) program is a critical component of the model. APEx builds upon and integrates ASTRO's quality improvement initiatives. Those initiatives include meeting required standards in five key areas: 1) Patient Evaluation, Care Coordination and Follow Up, 2) Treatment Planning, 3) Patient Specific Safety Interventions and Safe Practices in Treatment Preparation and Delivery, 4) Staff Roles and Accountabilities, and 5) Qualifications and Ongoing Training of Staff[6].

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[4] *Development of a Standard Survivorship Care Plan for Radiation Oncologists*. Chen, Ronald C. et al, Practical Radiation Oncology, Volume 6, Issue 1, 57-65.

[5] *U.S. Radiation Oncology Practice Patterns for Post-Treatment Survivor Care*. Koontz, Bridget F. et al, Practical Radiation Oncology, Volume 6, Issue 1, 50-56

[6] *APEx Program Standards*, www.astro.org/uploadedfiles/_MAIN_SITE/Daily_Practice/Accreditation/Content_Pieces/ProgramStandards.pdf

The APEx standards (Appendix C) were derived through an interdisciplinary, inclusive and transparent process using *Safety is No Accident: A Framework for Quality Radiation Oncology and Care* (Appendix D), white papers and consensus practice guidance for radiation oncology. The APEx standards identify systematic quality and safety approaches that build on and reinforce regulatory requirements to add value for practitioners and health care consumers. The ASTRO standards translate the goals outlined in the *Safety is No Accident* framework into objective, verifiable expectations for performance in radiation oncology practice.

Facilities that obtain APEx practice accreditation will have the systems, personnel, policies and procedures that are needed to meet the APEx standards for high-quality patient care. It offers transparent, measurable, evidence- and consensus-based standards that emphasize a professional commitment to safety and quality. Additionally, evidence indicators required for APEx accreditation map to 17 MIPS improvement activities (Appendix E), further enhancing the RO-APM model's commitment to including MIPS comparable measures as required by MACRA.

ASTRO recognizes that not all participating practices are currently APEx accredited, and consideration should be given to accreditation programs with comparable quality measures and patient safety standards. The accreditation requirement serves as an anchor to the key safety issues required for high quality radiation oncology care.

Clinical Guidelines Adherence Measures

ASTRO's Clinical Guidelines and Choosing Wisely Statements (Appendix F) provide radiation oncologists with evidence based guidance that allows them to make appropriate health care decisions in a variety of clinical circumstances in a consistent manner. Adherence to guidelines can lead to less variation in treatment, greater efficiency, and improved clinical outcomes. The following ASTRO clinical practice guidelines will be included in the RO-APM model:

- **Breast**
  - Accelerated partial breast irradiation consensus statement
  - Fractionation for whole breast irradiation guideline (Update complete by end of 2017)
  - DCIS margin width guideline
  - Post-mastectomy radiation guideline
  - Margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer consensus guideline
- **Lung**
  - Role of radiotherapy in locally advanced NSCLC guideline
  - SBRT for Early Stage Non-small Cell Lung Cancer guideline
- **Bone metastases guideline update**
- **Prostate**
  - Adjuvant and salvage radiotherapy after prostatectomy guideline
  - Adjuvant and Salvage Radiation Therapy After Prostatectomy: American Society for Radiation Oncology/American Urological Association Guideline
- **Brain**
  - Radiotherapeutic and surgical management for newly diagnosed brain metastasis/es guideline
  - Radiation Therapy for Glioblastoma
- **Colorectal**

- Appropriate customization of radiation therapy for stage II and III rectal cancer: An ASTRO clinical practice statement using the RAND/UCLA appropriateness method

Additionally, NCCN guidelines will be used to underscore the importance of a radiation oncology referral in situations in which the model is applied in multi-disciplinary settings.

Guideline-specific measures will be developed to ensure that adherence is occurring and that patients are receiving high value care. Below is a grid that provides examples of guideline-specific measures.

Condition	Relevant guideline and data	Quality metrics
Early breast cancer, node negative, tangents only	ASTRO breast fractionation guideline; numerous RCTs showing equivalent tumor outcome and lower toxicity with shorter schedules	Compliance with guideline-endorsed schedule of treatment
Uncomplicated bone met	ASTRO guideline and choosing wisely, multiple RCTs showing same pain control and lower toxicity with shorter schedules	Compliance with guideline-endorsed schedule of treatment
Prostate cancer, NCCN low risk or very low risk	ASTRO Choosing Wisely NCCN ProTECT study results	Discussion of active surveillance documented If treated, compliant with NCCN
Lung Cancer, stage III	NCCN Lots of data showing combined RT+chemo better RTOG 0617 showing too much RT is bad	Use of concurrent chemo unless medical contraindication Total dose <70 Gy

The model will also require reporting on the MIPS Radiation Oncology Measures Set to meet the QPP Advanced APM MIPS comparable measures requirement.

MIPS Radiation Oncology Measures Set		
1.	MIPS – Quality Measure - Person and Caregiver Centered Experience and Outcomes - Process - NQF 0384/PQRS 143, OCM Measure, APEx Standard 1.2.4	Oncology: Medical and Radiation – Pain Intensity Quantified: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
2.	MIPS – Quality Measure - Person and Caregiver Centered Experience and Outcomes - Process NQF 0383/PQRS 144, OCM Measure, APEx Standards 1.2.4 and 1.3.7	Oncology: Medical and Radiation – Plan of Care for Pain: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
3.	MIPS Process Measure – Patient Safety NQF 0382	Oncology: Radiation Dose Limits to Normal Tissues – Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.
4.	MIPS Process Measure – Efficiency and Cost Reduction NQF 0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients – Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.

Similar to other alternative payment models, the guidelines adherence and MIPS measures would be implemented over a period of time to give participants an opportunity to determine the best way to collect and report the necessary data. ASTRO is working collaboratively with the American Society for Clinical Oncology (ASCO) on the development of a Qualified Clinical data Registry (QCDR) that would be launched to coincide with the APM. This collaborative effort recognizes the importance of multi-disciplinary coordination in cancer care, which results

in better patient care and improved outcomes. The first year of the APM will be used as a data collection period for setting benchmarks. In the first year, participants will be paid for reporting, but must report on every applicable measure. Once benchmarks are identified for each participant group they will be announced and applied to quality measures performance in year two. After year two, thresholds will be identified for participant groups and they will be rewarded based on achievement of the threshold and additionally for any improvement beyond the threshold.

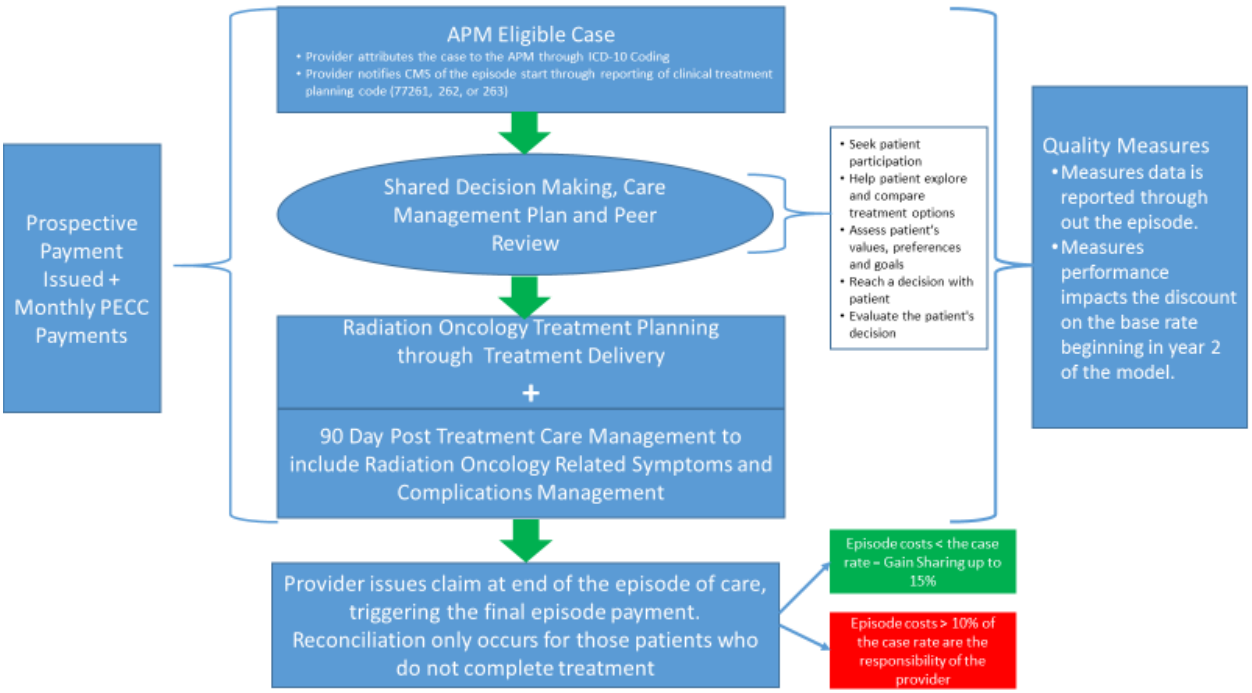
Quality Based Payment

Quality measures performance will impact the target rate discount beginning in year two. Once the model is ready to transition to a full pay for performance model, it will operate similarly to the BPCI program in which a discount rate is applied to the target discount based on quality measures performance. Below is an example of how this would work:

> Consider Qualified APM Participants (QPs) participating in a region where Medicare historically spent an average of $50,000 for each Breast Cancer episode of care, taking into account the costs of radiation therapy as well as all related care provided in the 90 days after treatment. Target prices would reflect the average historical pricing minus the discount rate based on quality performance and improvement.
>
> QP A is performing at the highest overall level on quality measures and its discount rate is 1.5 percent for the episode. As a result, its quality-adjusted target price for the breast cancer episode is $49,250 (or $50,000 minus the discount of $750). By taking measures to avoid complications and other unnecessary costs, QP A is able to reduce costs to $48,000. QP A would be paid average savings of $1,250 per patient.
>
> QP B in the same region also reduces its average costs to $48,000 per patient. However, it achieves only acceptable overall performance on quality measures. Its discount rate is 3 percent and its quality-adjusted target price is $48,500 (or $50,000 minus the discount of $1,500). QP B would be paid average savings of $500 per patient.
>
> QP C also only achieves acceptable performance on quality measures (discount rate of 3 percent) and has a quality-adjusted target price of $48,500. However, QP C has average costs of $50,000 per patient. If Hospital C is unable to improve its cost and/or quality performance, it would be responsible for the overage of $1,500 per patient.

Below is a graphic demonstrating the model framework and how it would be operationalized.

Radiation Oncology APM Framework



RO-APM - Value over Volume

The RO-APM meets the value over volume quotient by eliminating the reimbursement differential that currently exists in the Fee-For-Service system and replacing it with an episode-based payment that remains the same regardless of the course of treatment. This incentivizes physicians to consider treatments that are less expensive and equally as effective. There have been numerous studies regarding the effectiveness of shorter courses of radiation therapy in the treatment of breast and prostate cancer[7][8]. The RO-APM eliminates the reimbursement differential by establishing an episode based payment rate that is the same regardless of the modality of treatment or length of treatment. This incentivizes radiation oncologists to identify those patients who would benefit most from shorter course of treatment, which results in improved patient quality of life and potential cost savings.

Additionally, through the combination of widely-accepted quality measures -- initially focused on structure and process, but later to involve outcomes derived from registry reporting -- and a modality agnostic framework, the RO-APM is consistent with a value-based approach to

[7] Lee, Robert W., et al, *RTOG 0415 A Phase III Randomized Study of Hypofractionated 3DCRT/IMRT versus Conventionally Fractionated 3DCRT/IMRT Patients Treated for Favorable-Risk Prostate Cancer*, December 18, 2014
[8] Whelan, Timothy J., et al, *Long-Term Results of Hypofractionated Radiation Therapy for Breast Cancer*, The New England Journal of Medicine, 362;6, February 11, 2010.

radiation oncology care[9]. The model risk corridor allows for shared savings while protecting against stinting on care. The value based approach is further supported through the application of quality based performance that has a direct impact on the discount rate applied to payment in future years. By incentivizing higher quality of care at lower total costs of care during the episode, the model will achieve greater value in the delivery of radiation therapy and the effective management of patients with cancer.

RO-APM – Patient Centric and Physician Focused

As mentioned previously, the RO-APM is patient centric in that it requires patient engagement throughout the episode of care. This is supported through the establishment of the PECC fee, which provides physicians, nurse care navigators and other members of the care management team with the opportunity to engage with the patient more frequently to ensure proper care is delivered and appropriate follow up is taking place.

The model is physician focused in that it allows the physician to continue to deliver care based on what they believe is most appropriate for the patient, and which aligns with the patient's goals. The model incentivizes the use of evidence based clinical practice guidelines that result in care that is efficiently delivered but also of higher quality when compared to current practices.

The model creates a framework that is applied to any one of seven major disease sites and allows physicians the opportunity to provide patients with options for treatment, which aligns with the importance of shared decision making. This is a significant improvement over current circumstances in which physicians are constrained by payer coverage policies, as well as reimbursement differences that can influence clinical judgement. The common payment framework reduces administrative burden for providers as well as for CMS and private payers. It also eliminates the need for prior authorization of services, and perhaps, ultimately the need to process claims throughout the episode.

Those physicians who are currently in compliance with best practices will find the model reasonable and flexible. Those who are not in compliance with best practices will find that they need to change their practice behavior to come into compliance. The model seeks to reward those physicians who have been operating efficiently, in terms of cost and quality, while incentivizing others to do the same.

RO-APM – Application and Scalability

The ability of radiation oncologists to participate in alternative payment models is currently limited to the Oncology Care Model (OCM), which is initiated at the infusion of chemotherapy and encompasses all Medicare Parts A and B costs. This includes any radiation therapy delivered to the patient during the six-month episode. The involvement of radiation oncologists in the OCM is passive, as the medical oncologist determines the patient's course of care in this model. The OCM model creates a potential disincentive for the use of appropriate radiation therapy and contrasts with the multidisciplinary nature of modern cancer care. The goal of the RO-APM is to

[9] Teckie, McCloskey and Steinberg, *Value: A Framework for Radiation Oncology* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4152714/

provide radiation oncologists with the opportunity to participate in an Advanced APM in an active and engaged manner. The model aligns incentives that allows the physician to maximize efficiencies, while ensuring patients are receiving high quality care through clinical guideline adherence, as well as improved nurse care management and care coordination.

The RO-APM is designed to operate independently, as well as dove tail with the alternative payment models for other modalities of cancer care, including the OCM. In those cases, in which a patient requires only radiation therapy treatment, the model stands alone as it encompasses an episode of care that begins with treatment planning and ends 90 days after the last radiation treatment is delivered. Additionally, the model is designed to work simultaneously with other modalities of treatment, such as when a patient may be receiving radiation therapy along with medical oncology or surgical oncology care.

The RO-APM can be scaled up over time to include all 4,500 radiation oncologists currently practicing in the United States. Every year, 1.6 million Americans are diagnosed with cancer[10]. Of that number, two-thirds or just over 1 million patients will be treated with radiation therapy. Additionally, Medicare beneficiaries over age 65 account for 54 percent of all new cancer cases and breast, lung, prostate, colorectal, and head and neck cancers account for more than half of new cancer cases among the elderly. These disease sites also account for the largest spend in combined modality (medical, surgical and radiation oncology), as well as radiation oncology treatment alone.

Conclusion

ASTRO believes this model is highly consistent with MACRA recommended characteristics for an Advanced APM. It includes the requirements that physicians assume accountability for controlling the total cost of Medicare spending related to the condition, in this case the treatment of cancer, as well as the total cost of Medicare spending on all services the patient receives during the episode of care. It also institutes MIPS comparable measures and measures that are disease site specific further enhancing the emphasis on delivering high quality care.

We look forward to continued opportunities to work with CMMI on the development and implementation of this model.

[10] *Lifeline: Why Cancer Patients Depend on Medicare for Critical Coverage*, American Cancer Society, www.acscan.org/content/wp-content/uploads/2013/06/2013/-Medicare-Chartbook-Online-Version.pdf

APPENDICES:

A - Radiation Oncology Disease Site Symptoms and Complications

B - Development of Standard Survivorship Care Plan for Radiation Oncologists & US Radiation Oncology Practice Patterns for Posttreatment Survivor Care

C - APEx Standards

D - Safety is No Accident

E - APEx MIPS Improvement Activities

F - ASTRO Guidelines & Choosing Wisely Recommendations

Appendix A
Radiation Oncology Specific Symptoms and Complications

Breast Cancer:

- Skin reactions, including management of moist desquamation—which can rarely be severe and require wound care, and about 20% of which involves moist desquamation that requires a prescription burn treatment like silvadene
- Fatigue (which can require counseling, exercise, nutrition evaluation)
- Pneumonitis (uncommon, 1% incidence, but if it does occur, requires testing to r/o infection, steroids, etc)
- Pain (as a result of RT soft tissue inflammation/skin reaction)

Prostate Cancer:

- Urinary frequency, urgency or weaker stream
- Changes in bowel habits. Urgency or loose bowel movements and sometimes rectal bleeding
- Mild tiredness
- Mild skin irritation
- Impotence
- Infertility

Lung:

- Esophagitis
- Fatigue
- Lung inflammation/scarring (i.e., pneumonitis causing shortness of breath)

Colorectal:

- General: Decreased energy, weight loss, fatigue evaluation
- Skin reactions: Erythema, tanning, wet or dry desquamation
- Gastrointestinal symptoms: Diarrhea, Tenesmus, rectal bleeding, hemorroidal irritation, change in number of bowel movements per day (compared to baseline)
- Genitourinary: AUA symptom score (baseline versus followup), dysuria, incontinence
- Sexual function: Compare SHIM (Sexual Health Inventory For Men) score from followup to baseline. This may be more applicable is a long-term measure.

Head and Neck Cancer:

- Xerostomia
- Osteoradionecrosis
- Dysphagia
- Odynophagia
- Dysgeusia (taste disturbances)
- Skin reactions
- Fatigue
- Pain (apart from odynophagia)

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Original Report

Development of a standard survivorship care plan template for radiation oncologists

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Abstract

Purpose: In response to a need expressed by members of the American Society for Radiation Oncology (ASTRO), the ASTRO Board of Directors approved an initiative to create a radiation oncology-specific survivorship care plan (SCP) template.

Methods and Materials: Members of the ASTRO Health Services Research Committee (which was subsequently renamed the Clinical, Translational, and Basic Science Advisory Committee) were charged with this task. Creation of the ASTRO SCP template was informed by existing SCP templates published by other organizations and modified to add radiation treatment details felt to be important by committee members. An emphasis was placed on describing diagnostic and treatment details in ways that patients and referring physicians can understand. The resulting template subsequently underwent ASTRO committee review, public comment, and was ultimately approved by the ASTRO Board of Directors.

Results: The standardized template includes 2 components: the first 2 pages represent an SCP that is to be given to the patient and referring physicians, whereas page 3 includes additional technical

Conflicts of interest: None.

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radiation therapy details which are usually included in a traditional radiation treatment summary. That is, the template serves two purposes—obviating the need for radiation oncologists to create an SCP for patients and a separate treatment completion note.

Conclusions: The standardized ASTRO SCP template serves an immediate need of practicing radiation oncologists to have a template that is radiation-specific and meets current requirements for SCP and radiation treatment summary. Potential future work may include development of disease-specific templates that will include more granular details regarding expected toxicities and follow-up care recommendations and working with electronic medical record system vendors to facilitate autocreation of SCP documents to reduce the burden on physicians and other staff. These future developments can make this intervention more helpful to patients, and further reduce the burden of creating SCPs.

Introduction

A survivorship care plan (SCP) is a personalized document that gives cancer patients and health care providers a summary of the patient's diagnosis and treatment and guidance regarding follow-up care and available resources for cancer survivors.[1] The Institute of Medicine (IOM) published a 2005 report on cancer survivorship care in the United States, "From Cancer Patient to Cancer Survivor: Lost in Transition," which recommended SCPs be provided for all patients at the end of their treatment.[1] Core components of the SCPs include a summary of treatments completed as well as a written follow-up care plan with key elements such as: anticipated course of recovery from treatment-related toxicities, need for additional health maintenance or cancer care, plan for surveillance testing, anticipated late toxicities of treatments, expected functional or social impairments, recommended healthy behaviors, preventive measures, cancer information resources, and referrals to supportive care providers.[1,2] SCPs are intended to address unmet needs to educate cancer survivors, to improve communication between oncologists and primary care providers, and to facilitate coordinated posttreatment health care.[1]

In many ways, radiation oncology has been ahead of the curve with a long tradition of creating radiation completion notes that summarize the treatment received for every patient. This document incorporates key data regarding the patient's cancer diagnosis, radiation site, volume and timing, and basic information regarding follow-up. Although the radiation treatment completion note contains many of the elements recommended by the IOM, survivorship care plans differ in several fundamental ways. The completion notes were primarily written for other radiation oncologists, with emphasis on the technical details of the radiation treatment. The target audiences for the SCP, on the other hand, are the patients and their primary care physicians. Thus, there is a need for less technical detail and more focus on future care needs. The SCP also addresses key issues regarding survivorship, health promotion, and recommendations for care coordination, highlighting the value of the patient perspective. Transforming this process from a radiation completion note to the SCP essentially shifts the central focus from the radiation oncologist to the patient.

Although the IOM initially recommended SCPs in 2005 and the American College of Surgeons Commission on Cancer is requiring accredited programs to provide an SCP for at least a portion of their patients in 2015 (with SCPs for all curative patients by 2019), there has been limited implementation of SCPs in radiation oncology. In a recent American Society for Radiation Oncology membership survey, only 40% of US radiation oncologists indicated they currently use SCPs.[3] However, the vast majority of radiation oncologists indicated SCPs add value for patients, and 84% indicated the need for the development of a radiation oncology-specific standardized SCP.

To address this need, the ASTRO Board of Directors requested that members of the Clinical, Translational, and Basic Science Advisory Committee develop an SCP template for radiation oncology with input from the radiation oncology community. This manuscript outlines the components of the ASTRO SCP template, the rationale for including these elements, and the ways this radiation oncology–specific SCP is different from existing available SCPs.

Methods

In 2011, members of the ASTRO Health Services Research Committee (which was subsequently renamed the Clinical, Translational, and Basic Science Advisory Committee) began a project to standardize radiation completion notes. There was a recognized need for this because, although radiation oncology had a long-standing tradition of creating completion notes, there lacked a society standard on which data elements should be included in these notes. Further, the committee, in creating this standardized template, focused on summarizing information in a way that patients and

primary care physicians could understand. The committee held monthly conference calls, and through a consensus process created a standardized treatment summary template that subsequently underwent review by multiple ASTRO committees.

With increasing emphasis on SCPs throughout oncology, a mandate to incorporate them into our practice starting in 2015, and a recognized need for a radiation oncology–specific template, in 2014 the ASTRO Board of Directors requested that this completion note template be modified to become a standardized SCP template. The committee reconvened and added to the template components related to healthy behaviors and preventive care. The resulting template subsequently underwent public comment and is described in the following section.

Results

The 2-page SCP template (Appendix) was designed to help radiation oncology patients and referring/primary care physicians understand the diagnosed cancer and treatments, while also addressing the patient's physical and psychological needs. This template design is in compliance with American College of Surgeons Commission on Cancer Standard 3.3 of *Cancer Program Standards*, 2012: *Ensuring Patient Centered Care*, v. 1.2.1, requiring radiation oncologists to provide SCPs for curative intent patients.

The SCP starts with names of the treating radiation oncologist, primary care physician, surgeon, and medical oncologist. Other providers such as the gastroenterologist in a rectal cancer patient and a pulmonologist in a lung cancer patient may also be included as appropriate.

Next, there is a section summarizing the cancer diagnosis, including disease site as well as histology. Other important site-specific details such as ER/PR/HER2 for breast cancer patients and Gleason score and prostate-specific antigen for prostate cancer patients can also be indicated. Although not specifically stated on the template, this can include other biomarkers as they are adopted into clinical practice. Overall stage is included in this section while a more detailed TNM staging is included in page 3 (Appendix; the completion note portion of the template). Goal of treatment is indicated as either curative/definitive, or not curative/to relieve or prevent symptoms. The committee members agreed to not use the term "palliative" because this term may be emotionally distressing to the patient.

A concise treatment summary follows that includes surgery, systemic therapy, and radiation therapy; free text boxes allow details to be provided at the discretion of the physician. For example, it may be useful to have details on extent of surgery and perhaps date of surgery, which would allow calculation of interval between surgery and radiation when relevant. Extent of surgery may be useful in discussing toxicity when combined with radiation. Systemic treatment details including drug names, frequency of delivery, and doses can be similarly useful when discussing with patients potential expected toxicity.

The minimalistic radiation details included in the SCP are: start and end date of treatment, body area treated, total dose, and number of fractions. The SCP also includes an indication of whether the patient participated in a clinical trial. More technical details of radiation including simulation, treatment planning, and delivery details are included on page 3 (completion note portion of the template).

The next portion of the SCP concisely describes the patient's treatment course, such as whether the planned treatment was completed and acute toxicities. Possible side effects that may occur after treatment completion are also described; instructions for patients to seek care when experiencing certain symptoms should be included in this section. Many clinics may have prepared treatment-completion instructions for patients that can supplement the SCP.

Delivery of an SCP to patients provides an opportunity for patients to indicate additional areas of concern beyond treatment and toxicity, and patients can indicate these areas of need to trigger appropriate referrals for additional ancillary services such as psychosocial services, physical therapy, nutritional services, financial counselors, or other medical specialties. Lifestyle and behavioral modification counseling, especially when done by the treating physician or nurse, may have a greater impact on the patient. The end of treatment is an opportunity to shift focus to survivorship and ways to emphasize healthy living, including smoking cessation and changes in diet and physical activity. Finally, follow-up information is provided with free text boxes allowing for additional details as needed, such as tests (mammograms, blood tests) and appointments with other providers.

Page 3 of the template includes the technical details usually included in a radiation completion note. This information is too technically detailed for most patients and may or may not be of any interest to their other physicians, but are critical to another radiation oncologist should the patient move and require further treatment. Together, the 3-page template comprises a traditional radiation completion note that can be kept in the department's records; the first 2 pages are printed out as the SCP and given to the patient and referring physicians.

Discussion

The radiation oncology–specific SCP template described in this article was created to help meet the

Table 1 Summary of existing survivorship care plan templates

Features/recommended components	Journey Forward	Livestrong	American Society of Clinical Oncology	Memorial Sloan Kettering	Prescription for Living	Minnesota Cancer Alliance
Covers all disease sites	No	No	No	No	No	No
Covers specific disease sites	Yes	Yes	No	No	No	No
Customizable for specific disease	Yes	Yes	Yes	Yes	Yes	Yes
Treatment Summary						
Contact information for providers	Yes	No	Yes	Yes	Yes	Yes
Documents diagnosis/dates of treatment	Yes	Yes [a]	Yes	Yes	Yes	Yes
Treatment received (surgery, chemotherapy, radiation)	Yes	Yes	Yes	Yes	Yes	Yes
Acute side effects experienced	Yes	Yes	Yes	No	Yes	No
Genetic testing	Yes	No	Yes	No	No	Yes
Follow-up Care Plan						
Late and/or long-term side effects	Yes	Yes	Yes [b]	No	Yes	Yes
Recommends cancer surveillance tests	Yes	Yes	Yes	Yes	Yes	Yes
Recommends cancer screening tests	Yes	Yes	No	Yes	Yes	Yes [b]
Addresses emotional/psychosocial/ financial concerns	Yes	Yes	Yes	No	No	Yes
Recurrence symptoms	Yes	Yes	Yes	No	Yes	No
Follow-up visit schedule	Yes	Yes	Yes	Yes	No	Yes
Healthy behavior recommendations	Yes	Yes	Yes	Yes	Yes	Yes
Additional resources provided	Yes	Yes	Yes [b]	No	No	Yes

[a] Only diagnosis documented.
[b] Must be written in.

need of radiation oncologists to fulfill the current and future requirements to create SCPs for their patients. Although survivorship care plan templates are being recognized as important throughout oncology, and several SCP templates currently exist (summarized in Table 1), having a SCP specific for radiation oncology allows for the capture of critical radiation details that are often not included in other existing templates. For example, the current American Society of Clinical Oncology SCP only has radiation as a "yes/no" checkbox, plus body area treated and year of treatment. The ASTRO SCP template allows inclusion of radiation details that makes the document serve a dual purpose—SCP and completion note. This is an important consideration because 1 template that fulfills both needs (SCP and completion note) is more likely to be used by radiation oncologists, in contrast to having to use 2 templates to create 2 notes for every patient. Indeed, the time needed to create SCPs and lack of resources (including staff) to devote to their creation has been described as a main obstacle limiting widespread adoption of SCPs. Prior studies have estimated that SCPs require at least an hour to complete, but can take up to 4 hours for more complex patients.[4–6] The ASTRO SCP template helps reduce this obstacle for radiation oncologists.

Although SCP creation is now required by the American College of Surgeons Commission on Cancer as part of the accreditation standards, the efficacy of SCPs in improving patient outcomes has not been clearly demonstrated. To date, 4 reported randomized trials have examined the efficacy of SCPs (Table 2). In the first randomized study ever published on SCP, Grunfeld and colleagues randomized 408 long-term, early-breast cancer survivors in Canada to the receipt and discussion of a SCP before care-transfer to the primary care physician (PCP) or care-transfer (and usual care without SCP) alone; the primary endpoint of the study was cancer-specific distress, with secondary endpoints including quality-of-life, satisfaction, and coordination of care.[7] Patients who received the SCP did not experience improvements in any of these outcomes, although they were statistically more likely to identify the PCP as the physician primarily responsible for follow-up care. In another randomized study in New York City, 141 patients with stage 0-III breast cancer were randomized between usual care and a survivorship intervention at the completion of primary treatment, which involved a 1-hour discussion of the treatment, future risks of the delivered therapy, and surveillance and lifestyle recommendations, in accordance with American Society of Clinical Oncology guidelines; both groups were given a

Table 2 Summary of 4 randomized trials on survivorship care plans

Study	Patient population	Study design	Intervention	Primary endpoint	Result	Comments
Grunfeld[6]	Women with early-stage breast cancer, at varying stages in follow-up; N = 408	Randomized trial	SCP and discussion, information also sent to PCP	Cancer-specific distress in patients	No significant differences in primary endpoint, although PCP more likely identified as physician in charge of follow-up	Patients were already in various phases of follow-up after primary treatment (many after 2 years)
Hershman[7]	Women with nonmetastatic breast cancer, finishing primary treatment; N = 141	Randomized trial	In-person survivorship discussion	Cancer-worry subscale in the Assessment of Survivor Concerns questionnaire	No significant differences in primary endpoint, but less health worry seen at 3 months only	Survivorship intervention was in-person; personalized document not created
Brothers[5]	Women with gynecologic cancer seen in follow-up over first year; N = 121	Randomized trial, 6 physicians were randomized	SCP given to patient and discussion	Patient satisfaction	No significant differences	Significant heterogeneity in treatments; patients were already in various phases of follow-up
Ezendam (ROGY)[8]	Women treated for gynecologic cancer; N = 266	Randomized trial, 12 hospitals were randomized	SCP given to patient and PCP	Questionnaire to PCPs on their satisfaction with information, contact with specialists, desire to receive SCP in future	No significant differences	Compliance was limited; 67% of PCPs in SCP hospitals reported never receiving a SCP.

PCP, primary care physician; ROGY, Registration system Oncological Gynecology; SCP, survivorship care plan.

copy of the National Cancer Institute publication "Facing Forward: Life after Cancer Treatment."[8] The primary endpoint of the study was the difference in the cancer worry subscale of the Assessment of Survivor Concerns questionnaire at 3 months. In findings that echoed the Grunfeld study, the authors found nearly no differences in patient-reported outcomes between the groups, although there was less health worry—but not cancer worry—at 3 months in the intervention arm, an improvement that disappeared by 6 months.

Two studies have been performed in the gynecologic cancer population. In 1 study, 6 gynecologic oncologists were randomized to provide and discuss an SCP to their patients seen in follow-up within 1 year of the end of therapy.[6] All patients were then given a survey developed by the investigators, and only those patients who sent in the survey (n = 121, 55% of total) were included in the analysis. This instrument tested patient satisfaction with administrative, clinical, and educational services as well as the helpfulness of written materials, their overall experience, and the likelihood to recommend the clinic. Consistent with the other 2 trials previously described, this study found no significant difference in any of these domains between patients given the SCP and those who were not. However, because the randomization of this trial was between physicians and not patients, many unknown confounders were not necessarily balanced between the 2 groups. Finally, Ezendam et al recently reported the results from a pragmatic cluster randomized trial in which 12 Dutch hospitals providing gynecologic oncology care were randomized to either provide usual care or "SCP-care," in which the latter hospitals provided survivorship care plans to the patients and their PCPs.[9] The primary endpoint of this study was a questionnaire completed by the internists, in which the investigators assessed their satisfaction with the information, personal contact with specialists, and desire to receive a SCP in the future. There was no difference in any domain between PCPs in the 2 arms of the trial, although the results were limited by compliance and crossover, as 67% of the PCPs in the SCP arm reported never having received a SCP and 16% of the PCPs in the usual care arm did.

These negative trials highlight the key issues that must be addressed as the oncology community moves

forward in further prospective evaluations of survivorship care plans. First, who is meant to benefit the most from the SCP? Does its main utility lie in providing important information to the patient, or is it meant to facilitate communication between the health care team (ie, PCP-specialist coordination)? Second, the intervention must be carefully designed. Is the document by itself sufficient, or must there be a conversation between practitioner and patient to review its content? In addition, what is the proper outcome measure for the introduction of a SCP? Patient satisfaction is welcome, if improved, but it is almost certainly more important to measure improvements in health behaviors, such as smoking cessation or participation in rehabilitation programs. Finally, it is important to generalize the study population, certainly beyond women but also into different disease sites. Patients with head and neck cancer, for example, have tremendous survivorship needs, and the marginal importance of a SCP in that cohort may be quite large over an otherwise healthier group of patients. The motivation to improve survivorship care was generated from the recognized gap in posttreatment care in the vulnerable population of cancer survivors. Yet, as these randomized data show, we have not yet proven that the resource-intensive solution for this chasm—the survivorship care plan—is the proper response to this problem, and more work must be done to optimize its content and delivery to the patient and his or her other caregivers. Ultimately, for an intervention that requires effort (and therefore cost to the health care system) to deliver, cost-effectiveness must be studied. Although many policymakers, physicians, and patients agree that SCPs are a "good idea," studies that can demonstrate measurable improvements in patient outcomes are needed.

The most effective method of implementing SCPs in the clinical setting has not been established, and prior studies have described a variety of factors that should be considered in developing effective models for completing survivorship care plans. Though prior models have created SCPs at time points ranging from the start of treatment until several years following completion, the optimal timing for completion of a survivorship care plan is soon after treatment, with patients preferring to receive plans at the time of treatment completion or shortly afterwards.[5] However, completion of the care plan can depend on the availability of complete medical records, especially if a patient has received multiple modalities of treatment (surgery, chemotherapy, radiation), and health care providers have suggested that a window of 3-6 months following treatment may be more feasible.[10] Nurses, physicians, and other trained medical or nonclinical personnel can all play important roles in creating SCPs and ensuring that appropriate issues are addressed.[5,11,12] Previous models have delivered SCPs during a normal oncology follow-up visit, during a specialized education session with a nurse, by regular mail, or by web-based communications.[13] Although most studies have evaluated models consisting of paper-based care plans,[14] the use of electronic medical records[11] and the internet[10,15] have the potential to simplify the process of plan development, reduce time burden, and allow more timely delivery of SCPs.[12] Furthermore, inclusion of other resources, including educational booklets, videos, and web-based materials, can augment the survivorship care plan.[14]

The standardized ASTRO SCP template published in this article will, necessarily, evolve over time as data elements are added and subtracted based on the usefulness to inform and impact care. The current version serves an immediate need of practicing radiation oncologists to have a template that is radiation-specific and meets current requirements for SCP. Future work will include development of disease-specific templates that will include more granular details regarding expected toxicities and follow-up care recommendations; and working with electronic medical record system vendors to facilitate autocreation of SCP documents to reduce the burden on physicians and other staff. These future developments can make this intervention more helpful to patients and further reduce the burden of creating SCPs. A current effort by the ASTRO Integrating the Healthcare Enterprise – Radiation Oncology committee to facilitate accurate radiation treatment data transfer across vendors will contribute toward this goal.

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Appendix. Sample Survivorship Care Plan

Page 1-2 of the attached represent a survivorship care plan, which contain information regarding the patient's diagnosis and treatment, and outlines follow-up plans. This document is meant to be given to the patient, primary care and referring physicians.

Page 3 of the attached includes *additional* technical information usually contained in a radiation treatment summary note. Thus, pages 1-3 together can be used as a treatment summary.

The attached is meant to show representative content, and not necessarily to dictate the exact format of how this information is to be presented at each institution for its patients.

Patient History

Patient name: _____ **Date of birth:** __/__/____ **MRN:** _____
Treating radiation oncologist: _____ **Phone:** _____
Primary care provider: _____ **Phone:** _____
Surgeon: _____ **Phone:** _____
Medical oncologist: _____ **Phone:** _____
Other providers: _____ **Phone:** _____

Diagnosis

Primary site: _____ **Histology:** _____
Is this a new cancer or a recurrence? □New □Recurrence

Overall Stage (if new diagnosis): □0 □I □II □III □IV
(if applicable): □A □B □C

□Alternate staging system_____

Site specific information (if applicable): *E.g. for breast cancer, ER/PR/HER2 status; for prostate, Gleason score, and PSA*

Treatment Summary

***Goal of treatment*:** □Curative (definitive) □Not curative; to relieve/prevent symptoms

Surgery: □Prior to RT □Planned to follow RT □Not planned

Optional free text box for details

Systemic treatment (e.g. Chemotherapy): □Yes □No

□Before radiation	*Optional free text box for details*
□During radiation	*Optional free text box for details*
□After radiation	*Optional free text box for details*

Radiation Treatment: Start Date: __/__/____ End Date: __/__/____

Body Area Treated	

Total Dose: _____ (Gy) Total Number of Treatments: _____

On clinical trial: □Yes □No

Optional free text box for details

Treatment Course and Side Effects

Did the patient complete treatment as planned?

□Yes □No, due to toxicity □No, due to cancer progression □Other

Optional free text box for details

Treatment interruptions: □Yes □No

Optional free text box for details

Side effects during and at the end of treatment:

Free text box for details on side effects and management (interventions, medications)

Possible side effects which may occur later:

Free text box for details on side effects and when to seek medical care

Survivorship

If you have any concerns about these areas, please discuss with your doctors or nurses to seek help and advice:

□Emotional and mental health □Fatigue □Weight changes
□Physical functioning □Insurance □Work/school □Parenting
□Financial assistance □Fertility □Sexual functioning □Memory loss
□Other _____

Please discuss these lifestyle/behavior changes with your doctor or nurse to improve your overall health:

□Smoking/tobacco cessation □Healthy diet □Physical activity
□Weight management (gain/loss) □Alcohol use □Sunscreen use □Other

Next appointment:

□With Radiation Oncologist, in____weeks/months

□None or only as needed with Radiation Oncologist

□With other provider(s) *Free text*

□Follow-up testing *Free text*

Instructions given to patient (optional):

Optional free text box for details

Additional Details for a Radiation Completion Note

Prior radiation therapy (any site): □Yes □No

Optional free text box for details

External beam and stereotactic radiotherapy treatments:

Treatment site	Treatment technique / Modality	Dose per fraction	Total number of fractions	Total dose	Start Date	End Date	Fractions per day	Fractions per week
e.g. Site 1								
e.g. Site 2								
Total								

Special technical considerations: details to be included here can include (as relevant) 4D techniques, image guidance/gating, simulation technique, image fusion during planning, prescription point, etc.

Brachytherapy treatments:

Treatment site	Treatment technique (LDR/ HDR/other)	Isotope	Dose per fraction	Total number of fractions	Total dose	Start Date	End Date	Fractions per week

Applicator used (for HDR only)**:** _____

Special technical considerations: details to be included here can include (as relevant) simulation technique, image fusion during planning, prescription point, etc.

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Original Report

US radiation oncology practice patterns for posttreatment survivor care

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Abstract

Purpose: Increasing numbers of cancer survivors have driven a greater focus on care of cancer patients after treatment. Radiation oncologists have long considered follow-up of patients an integral part of practice. We sought to document current survivor-focused care patterns and identify barriers to meeting new regulatory commission guidelines for survivorship care plans (SCPs) and provide guidance for survivorship care.

Methods and Materials: A 23-question electronic survey was e-mailed to all practicing US physician American Society of Radiation Oncology members. Responses were collected for 25 days in March 2014. Survey data were descriptively analyzed.

Results: A total of 574 eligible providers responded, for a response percentage of 14.7%. Almost all providers follow their patients after treatment (97%). Length of follow-up was frequently extensive: 17% followed up to 2 years, 40% for 3-5 years, 12% for 6-10 years, and 31% indefinitely. Ancillary services, particularly social work and nutrition services, are commonly available onsite to patients in follow-up. Fewer than half of respondents (40%) indicated that they currently use SCPs for curative intent patients and those who do generally use internally developed templates. SCPs typically go to patients (91%), but infrequently to primary care providers (22%). The top 3 barriers to

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Conflicts of interest: None.

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implementation of SCPs were cost (57%), duplicative survivorship care plans provided by other physicians (43%), and lack of consensus or professional guidelines (40%). Eighty-seven percent indicated that SCPs built into an electronic medical record system would be useful.

Conclusions: A significant part of radiation oncology practice includes the care of those in the surveillance of follow-up phase of care. SCPs may be beneficial in improving communication with the patient and other care but are not widely used within our field. This survey identified key barriers to use of SCPs and provides specialty guidance for important information to be included in a radiation oncology oriented SCP.

Introduction

With projections estimating more than 18.9 million cancer survivors in the United States by 2024,[1] the care of patients after cancer treatment (cancer survivorship) is an issue of increasing importance. Longer patient lifespans following cancer therapy have raised discussions surrounding the need for continued care of these patients from the time of treatment until the end of life. This effort, driven heavily by patient advocates, highlights a perspective that the care of cancer survivors should be a comprehensive process that not only encompasses surveillance but additionally covers management of medical and psychosocial late treatment effects, future cancer prevention, and coordination of care among all care providers. In response to an Institute of Medicine report "From Cancer Patient to Cancer Survivor: Lost in Transition" calling for increasing efforts for cancer survivorship care,[2] multiple organizations including the American Society of Clinical Oncology[3] and the American College of Surgeons[4] have responded with evidence-based guidelines for survivorship care and recommendations on the use of survivorship care plans (SCPs)—documents that summarize a patient's diagnosis, treatments received, and follow-up plans.

At least half of all cancer patients undergo radiation therapy at some point in their course of treatment[5]; and radiation is a curative treatment modality for the majority of common cancers in the United States. After the active treatment phase is complete, patients may need to undergo adjuvant therapies, surveillance testing, and monitoring for treatment-related sequelae. These components of ongoing oncologic care integrate into ongoing medical care by other providers for noncancer health conditions. In addition to the practical and clinical need for radiation oncology–specific survivorship care, the American College of Surgeons Commission on Cancer requires survivorship programs to be in place by January 1, 2015, for accreditation (although 100% penetration to all curative patients is not required until 2019).[6] Therefore, survivorship care is a relevant clinical issue in radiation oncology. However, the current practice of survivorship care by radiation oncologists has not been well-documented. It is also unknown if radiation oncologists are prepared to meet the American College of Surgeons Commission on Cancer requirements for SCPs. As a needs assessment, the American Society for Radiation Oncology (ASTRO) commissioned a membership survey to assess current attitudes, practice, and barriers to providing cancer survivorship care. Results of this survey are described in this article.

Methods

This survey was designed by the authors as members of the ASTRO Clinical, Translational, and Basic Science Advisory Committee and approved by ASTRO's Science Council and Board of Directors. The purpose of the survey was to determine the knowledge base of US radiation oncology providers regarding SCPs, the current use of SCPs in clinical practice, and the perceived benefits and barriers to implementing SCPs in the radiation oncology clinic. The survey contained 23 questions and is available in Appendix 1.

An e-mail describing the purpose of and link to the electronic survey were sent to 3987 US radiation oncology

Table 1 Respondent characteristics

Gender (n = 570)	
Male	386 (68%)
Years posttraining (n = 572)	
0-5	99 (17%)
6-10	82 (14%)
11-20	168 (29%)
21+	223 (39%)
Primary practice/work setting (n = 570)	
Academic/university system	215 (38%)
Hospital not affiliated with academic institution	137 (24%)
Government/public sector	12 (2%)
Industry	2 (0.3%)
Independent contractor/Locum Tenens	14 (2%)
Physician group practice	172 (30%)
Location of practice (n = 570)	
Northeast	126 (22%)
Midwest	148 (26%)
South	183 (32%)
West	113 (20%)

The percentages are calculated based on total number of respondents per question. Regions defined by the US Census.

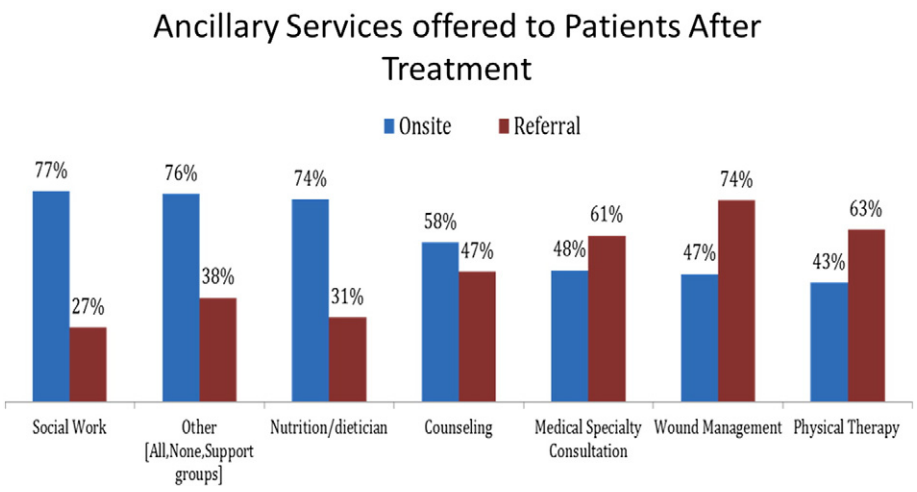

Figure 1 Ancillary services offered to patients after treatment.

physician members of ASTRO. Two e-mail reminders to complete the survey were sent subsequently; overall, the survey was open for 25 days and closed on March 31, 2014. Responses were anonymous and respondents were not compensated for completing the survey. There were 588 respondents (14.7%), 574 were in active practice in the United States and included in the analysis. Descriptive statistics were used to summarize the survey results. Because answers were not required to proceed along the survey, the number of respondents for each question is described in the results. The Pearson chi-square test was used to compare categorical variables. A P value < .05 was considered statistically significant.

Results

Respondent characteristics

Table 1 summarizes respondent characteristics. Respondents included those who ranged from new residency graduates to those who have been in practice for >20 years. There was also diversity in practice setting with 39% in a university system, 24% in nonacademic hospitals, and 32% in group practice. Sixty-eight percent of respondents were male.

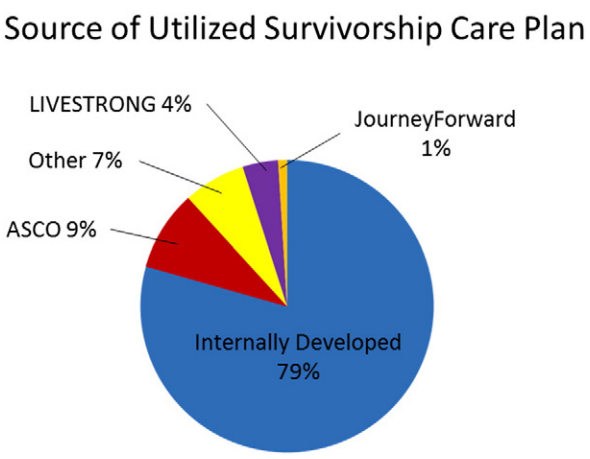

Figure 2 Source of used survivorship care plan. ASCO, American Society of Clinical Oncology.

Current patterns of practice

Almost all (97%) respondents indicated that they provided follow-up for curative-intent patients for more than 6 months after treatment; 66% indicated that they followed all curative patients, and 31% indicated they followed at least some curative patients (N = 569). When responses were stratified based on region of practice, there were significant differences between regions in the likelihood of providing longitudinal care to curative patients (Northeast, 76%; South, 65%; Midwest, 63%; West, 59%; P = .01).

For physicians following curative intent patients, 17% indicated they follow patients for 2 years or less after treatment completion, 40% follow patients for 3-5 years, 12% for 6-10 years, and 31% follow their patients indefinitely (N = 547). Again, there was regional variation in preferred duration of follow-up (preference for follow-up of 6 or more years: Northeast, 54%; South, 38%; Midwest, 44%; West, 40%; P = .03). The vast majority (87%) of respondents indicated that they personally saw their patients in follow-up, whereas 7% indicated another physician in their practice followed their patients and 6% stated a nonphysician provider followed their patients.

Figure 1 illustrates ancillary services offered to patients after treatment (N = 574). Social work (77%) and nutrition referral to dietitian (74%) were the most common services offered onsite; more than half offered onsite counseling services. Physical therapy and wound management were more often referred outside of the respondents' practice.

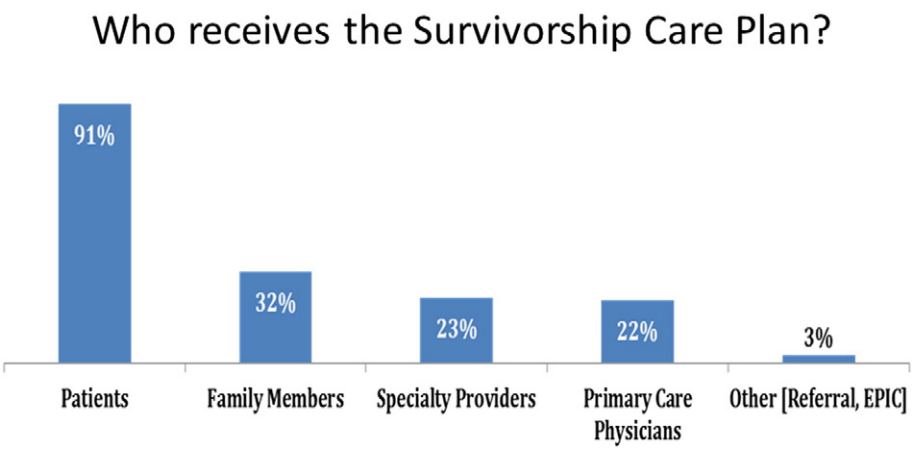

Figure 3 Who received the survivorship care plan?

Modes of communication with primary care physicians and oncology specialists (N = 574)

Twenty-two percent of respondents do contact the primary care provider (PCP). Almost all (98%) of the practitioners communicate with the primary care physicians via copies of notes/letters. Other modes of communication include telephone (57%), face-to-face meetings (36%), and e-mail (48%). Communication with other oncology specialists also occurs predominantly via copies of notes/letters (97%), but there is a much higher use of complementary modes of communication: 97% also communicate via telephone, 98% in face-to-face meetings, and 98% via e-mails.

Use of SCPs

Only 53% of respondents were aware of the Commission on Cancer's accreditation requirement of providing SCPs in 2015 (N = 564). Fewer than half of respondents (40%) indicated that they currently use SCPs for curative intent patients (N = 560); only 19% use SCPs for palliative intent patients (N = 558). When evaluated by years in practice, those in practice for 21+ years were more likely to already be using an SCP for curative and palliative patients than other subgroups. For curative patients, use of SCP was 44% for those in practice for 21+ years versus 36% for 11-20 years and 38% for 0-10 years ($P = .033$). For palliative patients, the corresponding frequencies of SCP use were 24% versus 21% versus 11% ($P = .064$). Of the 102 respondents who indicated using SCPs, 79% used an institutional template; others used commonly available templates from American Society of Clinical Oncology (9%), LIVESTRONG (4%), JourneyForward (1%), and 7% others (Fig 2).

Of the 174 respondents who answered the question regarding who receives radiation oncology–produced SCPs, 91% sent to patients, whereas only 22% and 23%

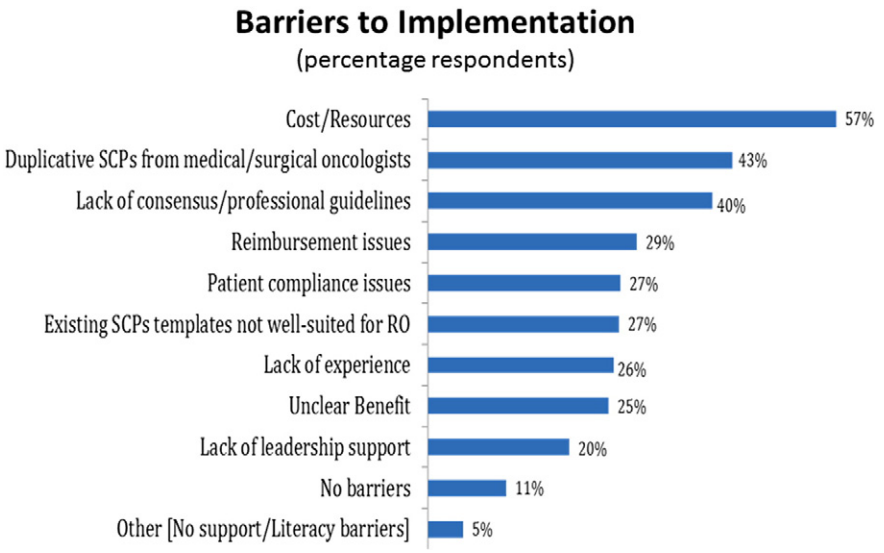

Figure 4 Barriers to implementation (percentage of respondents). RO, radiation oncology; SCP, survivorship care plan.

Table 2 The relative importance of each SCP as identified by ASTRO survey respondents and compared to the current modified CoC essential components of an SCP[6]

ASTRO Survey Identified Component	Percentage of survey respondents who felt this item was important component of an SCP	Relative importance of component by survey results	Defined by CoC as an essential component of an SCP[6]
Summary of cancer diagnosis (reference)	87%	1.00	Yes
Summary of radiation treatment	85%	0.98	Yes
Summary of systemic therapy (ie, hormonal therapy, chemotherapy, immunotherapy)	74%	0.85	Yes
Summary of key surgery events	66%	0.76	Yes
Summary of key radiology findings	40%	0.46	No
Summary of potential side effects	73%	0.84	Yes
Summary of future tests/appointments	78%	0.90	Yes
Summary of recommended surveillance	85%	0.98	Yes
Recommendations for healthy behaviors	69%	0.79	Optional
Contact information for providers	73%	0.84	Yes
Contact information for local support groups	52%	0.60	Tailored
Contact information for national cancer organizations	38%	0.44	Tailored
Options for ancillary services (ie, physical therapy, counseling, dietary consultation)	58%	0.67	Tailored

ASTRO, American Society for Radiation Oncology; CoC, Commission on Cancer; SCP, survivorship care plan.
The most frequently chosen item was used as reference to rank the remaining items. Essential items that were not included in the survey include "For selected cancers, genetic/hereditary risk factor(s) or predisposing conditions and genetic testing results if performed" and description of recommended adjuvant therapy. Wording of CoC recommendations allowed optional and tailored items to be specific to the individual patient's needs.

of respondents send these SCPs to either a primary care provider or other specialty provider, respectively (Fig 3).

Resources offered in lieu of SCPs

Of the 60% of the respondents who did not offer a standardized SCP (N = 285), the following documents were provided in lieu of SCPs: summary of radiation treatment (57%), contact information for providers (56%), ancillary services (55%), and a summary of further tests, appointments, and potential side effects (48%). Other documents provided include summary of cancer diagnosis (47%), recommendations for healthy behaviors (44%), contact information for local support groups (42%), summary of recommended surveillance (37%), contact information for national cancer organization (25%), summary of key radiology findings (19%), summary of systemic therapy (16%), and summary of key surgery events (13%).

Among variables identified as barriers to implementing SCPs (Fig 4), the top 3 were cost (57%), duplicative SCPs provided by other physicians (43%), and lack of consensus or professional guidelines (40%). Other barriers identified include reimbursement issues (29%), existing SCP templates not well-suited to radiation oncology needs (27%), patient compliance (27%), lack of experience (26%), unclear benefit (25%), and lack of leadership support (20%).

Developing a radiation oncology–specific SCP

A significant number of respondents (84%) felt that developing a radiation oncology–specific standardized SCP will offer additional benefit to patients beyond traditional management, and 87% indicated that SCPs built into an electronic medical record system would be useful (N = 527). Important benefits identified include: providing documentation of follow-up recommendations (73%); educating and informing patients regarding their treatment (71%); increasing patient understanding of treatment received (66%); establishing a communication tool among providers (54%); helping cope with after effects of treatment (50%); and providing a measure of performance quality (28%).

The respondents identified the top 3 necessary components of an SCP to be: summary of cancer diagnosis (87%), summary of recommended surveillance (85%), and summary of radiation treatment (85%) (Table 2). Other important components of an SCP identified by the respondents include: summary of future tests and appointments (78%); summary of systemic therapy (74%); summary of potential side effects (73%); contact information for providers (73%); recommendation for healthy behaviors (69%); summary of key surgery events (66%); and options for ancillary services (58%).

Discussion

Improvements in both treatment and early detection of cancer have led to significant increases in cancer patient survival with the number of patients surviving 5 or more years anticipated to increase by 37% in the next decade.[7] Coupled with an aging population and rising cancer

incidence, the number of survivors in the United States is projected to increase from 14.5 million (January 2014) to 18.9 million by January of 2024.[1] Cancer survivors face a myriad of challenges/changes after they complete cancer treatment, including financial, psychosocial, and emotional issues. In recognition of these challenges, multiple organizations have called for increasing focus on survivorship care issues. Because radiation oncologists are centrally involved in treating patients who will become long-term survivors, these issues are critically important for ASTRO members. This is especially true because, as this survey showed, most radiation oncologists provide long-term follow-up care to their patients after treatment completion.

There are several important findings of this survey. First, the majority of radiation oncology providers provide follow-up care after treatment completion as well as a broad range of cross-disciplinary supportive services to patients in need. This practice pattern may become more challenging because time and cost constraints are currently driving specialists to consider future management approaches that maintain patient care in a system of diminishing resources. Addressing this conflict may be of increasing value as the number of cancer survivors burgeon. An integrated "shared care" approach alternating follow-up between all oncology providers and PCPs is 1 way to balance time and cost constraints while maintaining the specialized input from radiation oncologists to ensure radiation-induced effects are appropriately navigated. Adoption of electronic health record systems, with the possibility of interhealth system and practice electronic communication, may reduce the burden of integrating a shared-care model into current practices.

Second, our survey highlights how we as a community communicate with other care providers. Although we used multiple and complementary methods to ensure seamless treatment management with other oncologic specialties, survey results noted that communication pathways with PCPs are not as robust. Because cancer patients transition back to the PCP for general medical care, the oncologic team must expand for practical purposes to include the PCP. As part of the multidisciplinary team, radiation oncologists are uniquely positioned to recognize radiation late effects and help patients manage these symptoms effectively. Because radiation effects may not be recognized as such by the patient, SCPs can be a resource reference for PCPs on what signs or symptoms could be common or high-risk radiation effects, hopefully shortening time to diagnosis of a late effect. In addition, PCPs can support and encourage patient compliance with adjuvant therapy and surveillance testing, particularly when they are recognized as part of the survivor care team.

Third, the survey results point to important needs currently unmet in the radiation oncology community. Only 53% of respondents were aware of the Commission on Cancer's accreditation requirement of providing SCPs in 2015, and only 40% indicated that they currently provide SCPs for their curative patients. Penetration of SCPs into medical oncology practices has also struggled; a recent survey found that only 64% of medical oncologists discussed survivorship care with survivors and <5% provided a written survivorship plan to patients.[8] The top 3 barriers to implementation of SCPs reported in our results were cost (57%), duplicate SCPs (43%), and lack of consensus/professional guidelines (40%). Autopopulation from existing data fields has the potential to reduce both cost and time by reducing duplicative work, addressing 2 of the identified barriers. The noted barrier of "duplicate SCPs" may be best addressed among each practicing multidisciplinary team. In each practice setting, we recommend that broad-based discussions with medical and surgical oncologists should be conducted to determine what responsibility the radiation oncologist has in developing and reviewing the individualized SCP for each patient. Increasing opportunities for research and discussion of evidence-based survivorship care at regional and national meetings can improve overall awareness of these issues.

In its referendum for improved survivor-focused care "From Cancer Patient to Cancer Survivor: Lost in Transition,"[2] the Institute of Medicine defines essential components of caring for cancer survivors: (1) prevention of additional cancers and late effects, (2) surveillance for recurrence and late effects, (3) intervention for consequences of cancer and its treatment, and (4) coordination between care providers to adequately address all survivor's health needs. The report also calls for utilization of an SCP, which is meant to provide a framework to summarize cancer diagnosis and treatment and make recommendations for follow-up care, addressing the key focus areas described previously. After first being recommended by the 2004 President's Cancer Panel, SCPs have been championed by patient advocacy groups, national foundations, and professional societies to improve coordination between oncologists, primary care providers, and patients. Multiple free-access online SCP templates exist (Appendix 2). However, many of these templates are oriented toward a medical oncology patient population, and do not include pertinent information reflecting radiation treatment or effects. This deficit is suggested in our survey results where 79% of those using SCPs used internally developed templates and has led to the development of a radiation oncology–specific SCP template[9].

This report has limitations related to the low response rate; therefore, results may not be representative of all practicing radiation oncologists in the United States. In addition, advanced care practitioners, who in some settings perform a large portion of survivor-based care,[3] were not included in the survey. Strengths include the balanced representation of experience, gender, and practice types/location that match the characteristics of the field. Despite these limitations, this survey provides important and novel insights about how cancer survivors are currently being managed by radiation oncologists.

Conclusion

Earlier cancer detection, improving therapeutics, and an aging population are creating an increasing number of cancer survivors with unique medical and psychosocial issues readily recognized by the specialists who treat them. These burgeoning numbers coupled with curtailed resources place further challenges on the oncology team, and a multidisciplinary shared care team approach that includes primary care, to facilitate this care may be one solution. Radiation oncologists have an opportunity to provide our perspective in developing modern survivor-based care guidelines. Given the significant role and unique toxicities of radiation therapy, a need exists for input by radiation oncologists into the development of SCP templates. Although SCPs can be a useful communication tool between oncologists, primary care physicians, and the patient, they are not widely used within our field. This survey identified key barriers to use of SCPs and provides specialty guidance for important information to be included in a radiation oncology oriented SCP.

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ASTRO Accreditation Program for Excellence

Safety and quality for radiation oncology practice ™

APEx® Program Standards

The following standards are the basis of the APEx program.
Level 1 standards are indicated in **bold**.

Standard 1: Patient Evaluation, Care Coordination and Follow-up

The radiation oncologist is accountable for patient evaluation, ongoing assessment and follow-up, as well as for coordinating and communicating with other providers involved in the patient's care.

1.1 A comprehensive patient evaluation by the radiation oncologist prior to initiation of treatment that includes documentation of:

1.1.1 Patient history including, as applicable: current medications, implantable cardiac device, pregnancy status, allergies, and previous radiation therapy history.

1.1.2 Review of systems.

1.1.3 Physical examination findings.

1.1.4 Pathology review.

1.1.5 Staging or documentation of metastatic disease.

1.1.6 Laboratory findings.

1.1.7 Imaging studies.

1.1.8 Pain assessment including, as applicable: pain intensity assessment and pain management plan.

1.1.9 Recommendation for care (initial plan).

1.1.10 Physician's signature and date.

1.2 During treatment the physician conducts and documents direct patient evaluation at least once every five patient treatments, which includes:

1.2.1 Review of cumulative interim dose delivered.

1.2.2 Patient examination.

1.2.3 Assessment of tolerance to treatment and, as appropriate, patient reported subjective and physician reported objective assessments of disease response to treatment.

1.2.4 Pain assessment including, as applicable: pain intensity assessment and pain management plan.

1.2.5 Physician's signature and date.

1.3 A documented post-treatment summary by the radiation oncologist that includes the following information:

1.3.1 Site of treatment.

1.3.2 Dose per fraction.

1.3.3 Cumulative dose delivered.

1.3.4 Treatment date range (start and end dates).
1.3.5 Concurrent systemic therapy.
1.3.6 Assessment of tolerance to treatment and, as appropriate, patient reported subjective and physician reported objective assessments of disease response to treatment.
1.3.7 Pain management plan for patients with unresolved pain.
1.3.8 Follow-up plan.
1.3.9 Physician's signature and date within two weeks of the patient's completion of care.

1.4 Coordination of care and communication of information

1.4.1 Following the initial patient evaluation, ROP transmits a copy of the comprehensive patient evaluation (Evidence Indicator 1.1) to other involved providers (including the referring provider and primary care provider) within four weeks.

1.4.2 Following treatment completion, the ROP transmits a copy of the post-treatment summary (Evidence Indicator 1.3) to other involved providers (including the referring provider and primary care provider) within four weeks.

1.4.3 The ROP participates periodically in multidisciplinary review programs (such as a Tumor Board), with other members of the patient's care team (medical oncologist, surgeon and other specialists), either remotely or on-site.

1.5 Patient follow-up:
1.5.1 Occurs within four months of treatment completion.

Standard 2: Treatment Planning

The radiation oncology practice uses a written treatment planning directive resulting in a patient-specific treatment plan.

The planning process:

2.1 Is based on data from a simulation procedure that:

2.1.1 Is conducted according to the written simulation direction of a radiation oncologist.

2.1.2 Includes documentation of factors that impact reproducibility including: patient positioning, patient immobilization devices and verification of accurate information transfer from simulation machines to treatment planning systems.

2.2 Is based on a documented, patient-specific planning directive that:
2.2.1 Guides treatment planning staff and defines target and normal tissue volume goals.

2.3 Culminates in a formal treatment prescription and plan that includes the physician's order for the following elements of radiation therapy:
2.3.1 Anatomic treatment site.
2.3.2 Type and method of radiation treatment delivery.
2.3.3 Energy.

2.3.4 Total dose.

2.3.5 Dose per fraction.

2.3.6 Number of fractions.

2.3.7 Frequency of treatment.

2.3.8 Imaging guidance.

2.3.9 Physician signature and date prior to initiation of treatment.

Standard 3: Patient-specific Safety Interventions and Safe Practices in Treatment Preparation and Delivery

The radiation oncology team follows standard operating procedures to ensure patient safety and consistent high-quality care prior to and during radiation therapy.

3.1 The ROP verifies patient identity:

3.1.1 For each patient, at each point in which patient-specific information is transferred from one information system to another, using two patient-specific identifiers.

3.2 For each patient, a time out is performed prior to all procedures, including all treatments, to conduct patient-specific quality and safety checks evidenced by documentation of:

3.2.1 Verification of patient identity using at least two patient-specific identifiers.

3.2.2 Verification of patient treatment site.

3.2.3 Verification of correct patient positioning for external beam radiation therapy (EBRT).

3.2.4 Verification of treatment delivery parameters against the approved prescription and plan.

3.3 For each patient:

3.3.1 A medical physicist performs an end-of-treatment review of the medical record within one week of the completion of therapy.

3.4 The ROP follows written standard operating procedures for each treatment modality that address the number of each professional discipline required, roles, responsibilities and QA activities, imaging and motion management(as applicable) in the use of:

3.4.1 External Beam Radiation Therapy (EBRT), including 2-D, 3-D and 4D.

3.4.2 Intensity Modulated Radiation Therapy (IMRT).

3.4.3 Stereotactic Radiosurgery (SRS).

3.4.4 Stereotactic Body Radiation Therapy (SBRT).

3.4.5 Particle beam therapy; including protons, neutrons and carbons.

3.4.6 Intraoperative Radiation Therapy (IORT).

3.4.7 Brachytherapy; including HDR, LDR and electronic.

3.4.8 Unsealed radioactive sources.

3.4.9 All other radiation therapy procedures not already identified in 3.4.1-3.4.8

3.5 For non-emergency cases, a qualified medical physicist verifies the following elements before treatment implementation and when changes are made to the plan:

3.5.1 Treatment plan compared to treatment prescription.

3.5.2 Dosimetric results.

3.5.3 IMRT quality assurance.

3.6 A qualified medical physicist performs periodic checks of:

3.6.1 The accuracy of treatment delivery in relation to both the formal treatment prescription and plan at least every five treatment fractions.

3.6.2 The accuracy of treatment set up parameters in relation to both the formal treatment prescription and plan at least once every five treatment fractions.

Standard 4: Staff Roles and Accountabilities

The radiation oncology practice defines the roles and responsibilities of each member of the team and consistently implements procedures according to these definitions.

The ROP has:

4.1 Job descriptions that define scope of practice.

4.1.1 For each professional discipline involved in patient care, job descriptions that are consistent with professional standards applicable to the individual.

4.2 A designated Medical Director for the radiation oncology practice who is board certified or board eligible in radiation oncology and:

4.2.1 Has oversight of standard operating procedures for the practice.

4.2.2 Is accountable for quality of patient care.

Standard 5: Qualifications and Ongoing Training of Staff

The radiation oncology practice establishes and monitors qualifications and training requirements for all personnel to ensure initial and continuous competency in job requirements.

For each professional discipline the ROP defines:

5.1 Requirements for certification, that are consistent with ASTRO's "Safety is No Accident" for the following:

5.1.1 All radiation oncologists possess state licensure and possess or are eligible for American Board of Radiology (ABR) certification in radiation oncology, therapeutic radiology, or equivalent certification.

5.1.2 All medical physicists possess state licensure, where applicable, and possess or are eligible for certification in Therapeutic Medical Physics by The American Board of Radiology, The American Board of Medical Physics, or The Canadian College of Physicists in Medicine.

5.1.3 All radiation therapists possess or are eligible for certification as American Registry of Radiologic Technologists (ARRT) in radiation therapy and, where applicable, state licensure.

5.1.4 All medical dosimetrists possess or are eligible for certification as a Qualified Medical Dosimetrist through the Medical Dosimetrist Certification Board (MDCB).

5.1.5 Nurses have licensure, certificates, additional experience and/or educational preparation in radiation oncology.

5.1.6 Nurse practitioners, clinical nurse specialists, advanced practice nurses, physician assistants and other non-physician providers have licensure, certificates, additional experience and/or educational preparation in radiation oncology.

5.2 A process and timeline:

5.2.1 For individuals who are eligible but not currently certified to achieve certification that is consistent with the requirements of Evidence Indicator 5.1.

5.3 Requirements for obtaining and maintaining appropriate credentials.

5.3.1 Maintaining licensure, obtaining new certifications and maintaining certification on an ongoing basis for each professional discipline.

5.4 A process for initial credentialing:

5.4.1 Of licensed or certified personnel that includes primary source verification for each professional discipline.

5.5 A process for license and certification monitoring of:

5.5.1 Annual compliance of licensed and/or certified personnel.

5.6 A process for onboarding staff that includes:

5.6.1 Initial training, orientation and job-specific competency testing process for each team member.

5.7 Implements an on-going staff training and competency testing program that includes:

5.7.1 Annual staff training and successful completion of competency testing for organizational procedures, including standard operating procedures, infection control, radiation safety and Health Insurance Portability and Accountability Act (HIPAA).

5.7.2 Training and successful completion of competency testing for new equipment and/or procedures before either are put into clinical use.

5.7.3 Training of staff with direct responsibilities on the use of treatment machines and completion of successful competency testing before staff are permitted to use the treatment machine(s) without direct supervision.

5.7.4 Address specific training, precautions and/or other requirements for patients with special needs including pediatrics, patients undergoing conscious sedation, use of intravenous contrast and/or other special procedures.

<u>Standard 6: Safe Staffing Plan</u>

The radiation oncology practice establishes, measures and maintains staffing requirements for safe operations in clinical radiation therapy.

The ROP identifies:

6.1 Staffing requirements for each professional discipline that:

6.1.1 Are derived from measurable criteria.

6.1.2 Specify the number of each professional discipline required to be on-site, directly involved in patient treatment (including at least two radiation therapists per patient when external beam radiation therapy is being delivered) or available remotely during operating and non-operating hours.

6.1.3 Describe how the practice will provide coverage during planned and unplanned absences of professional staff.

6.2 Requirements for supervision of:

6.2.1 Non-certified or non-licensed personnel and assistants participating in treatment processes.

6.3 Requirements of availability of:

6.3.1 A qualified radiation oncologist on-call 24 hours a day, seven days a week to address patient needs and/or emergency treatments.

6.4 The process for referring patients to emergency care:

6.4.1 During both operating and non-operating hours.

6.5 The process for the use of temporary personnel (locum tenens) that includes:

6.5.1 Credentialing, background checks, orientation and training on the ROP's standard operating procedures and successful completion of competency testing before the temporary personnel is allowed to function without direct supervision within the ROP.

Standard 7: Culture of Safety

The radiation oncology practice fosters a culture of safety in which all team members participate in assuring safety, the practice capitalizes on opportunities to improve safety and no reprisals are taken for staff that report safety concerns.

The ROP:

7.1 Has a policy on patient safety that:

7.1.1 Articulates the practice's approach to patient safety.

7.1.2 Specifies that patient safety events, including patient safety incidents and near misses, are to be reported and tracked within the practice.

7.1.3 Identifies methods for staff to report patient safety events and unsafe conditions, including a method for staff to report anonymously.

7.1.4 Encourages timely reporting of patient safety events and unsafe conditions by all staff.

7.1.5 Specifies periodic reporting back to staff on activities and findings of the culture of safety program.

7.1.6 Specifies that procedures are not started until all questions and/or concerns are resolved.

7.1.7 Provides assurances that there will be no reprisals based on reporting of patient safety events and unsafe conditions.

7.1.8 Identifies a role for patients in the culture of safety program.

7.1.9 Designates an accountable individual from the practice leadership who is:

7.1.9a Responsible for implementing the requirements of Standard 7, which states that the ROP fosters a culture of safety in which all team members participate in assuring safety, the practice capitalizes on opportunities to improve safety and no reprisals are taken for staff that report safety concerns.

7.1.9b Responsible for collection of information and investigation of patient safety events and unsafe conditions.

7.1.9c The lead on convening Interdisciplinary Safety Rounds.

7.1.9d Evaluated in part for providing leadership to the practice's culture of safety program.

7.2 Conducts Interdisciplinary Safety Rounds at least quarterly to:

7.2.1 Promote a team-based approach to safety.

7.2.2 Review all patient safety event and unsafe condition data from patients, staff and equipment.

7.2.3 Proactively assess the ROP's structure and processes that promote safety.

7.2.4 Develop, implement and assess progress of action plans to improve safety.

7.3 If a patient safety incident occurs, the ROP:

7.4.1 Undertakes an immediate review, with the goal of understanding underlying factors and taking action to prevent future occurrence.

7.4.2 Complies with institutional, state, local and national requirements for reportable patient safety incidents.

7.4 Reports to and participates in:

7.4.1 A Patient Safety Organization (PSO).

Standard 8: Radiation Safety

The radiation oncology practice establishes safe radiation practices for all patients and staff.

8.1 The ROP complies with requirements of:

8.1.1 The Nuclear Regulatory Commission (NRC), Agreement State and/or locality.

8.2 The ROP utilizes:

8.2.1 A radiation exposure monitoring system for staff consistent with NRC, Agreement State or local requirements.

8.3 The ROP provides:

8.3.1 Annual radiation safety training to all staff.

8.4 The ROP conducts:

8.4.1 Radiation surveys pre- and post-treatment for brachytherapy and radiopharmaceutical procedures.

8.5 The ROP utilizes:

8.5.1 Imaging protocols for simulation and treatment to reduce unnecessary radiation

dose to patients.

Standard 9: Emergency Preparation and Planning

The radiation oncology practice has procedures and training for emergency contingencies that address short- and long-term patient and staff safety.

9.1 The ROP has a written plan for emergencies that pose an immediate threat to patient safety, that addresses:

9.1.1 Patient clinical emergencies such as falls, cardiac events, threats of violence, anesthesia events, allergic events or other emergencies.

9.1.2 Radiation equipment failure while a patient is undergoing treatment.

9.1.3 Clinical continuity.

9.1.4 Evidence of annual training for staff in emergency procedures.

9.2 The ROP identifies and plans for other emergencies or disasters based on a formal disaster analysis or other assessment and prepares for applicable potential events:

9.2.1 Power failure.

9.2.2 Information system failure, with preparation and a back-up plan that addresses business continuity, including data redundancy and recovery plan.

9.2.3 Radioactive material release.

9.2.4 External threats including natural disasters.

Standard 10: Facility and Equipment

The radiation oncology practice has a facility and equipment to support the delivery of safe, high quality care.

The ROP:

10.1 Provides radiation shielding for each radiation area that is:

10.1.1 Consistent with workload.

10.1.2 Based on shielding calculations performed by a qualified medical physicist.

10.1.3 Validated with radiation surveys performed by a qualified medical physicist.

10.1.4 Monitored by a qualified medical physicist with updates to ensure ongoing compliance when there are changes in workload, utilization and/or equipment.

10.2 Provides monitoring though:

10.2.1 **Functional video and audio patient monitoring systems in all treatment rooms.**

10.3 Performs radiation therapy simulations including, at a minimum, CT simulation and ensures that:

10.3.1 Simulations enable reproducibility of patient positioning during treatment.

10.3.2 Trained radiation therapists conduct the simulations.

10.3.3 Patient-specific considerations are taken into account before simulation begins.

10.4 Has an infection control program that:

10.4.1 Includes procedures for equipment, devices and individuals.

10.4.2 Contains procedures that address infection control risk, communicable disease, sterilization of devices and equipment, hand washing, and disinfection of immobilization devices.

10.4.3 Includes staff training on infection control.

Standard 11: Information Management and Integration of Systems

The radiation oncology practice maintains information management systems to support patient care, planning and documentation, and assures safety and interoperability of the systems.

The ROP:

11.1 Defines and maps:

11.1.1 Components of the information management system that impact patient care.

11.2 Designates authorized users for each type of system that:

11.2.1 Limits access to information based on the user's job function and need for that information.

11.2.2 Uses individualized passwords or other methods to prevent unauthorized access.

11.2.3 Have the ability to track changes made to electronic patient records or system specifications.

11.3 Conducts a quality assurance program for each information management system and combination of systems, including:

11.3.1 System acceptance testing prior to clinical use.

11.3.2 Commissioning prior to clinical use and re-commissioning as necessary.

11.3.3 Ongoing quality assurance of information system performance.

11.3.4 Verifying the fidelity of information transferred between systems.

11.4 Ensures, prior to clinical use, that:

11.4.1 Staff receive training on system functionality and safety features of each information management system and combination of systems.

11.5 Ensures information management system support.

11.5.1 Staff have ongoing access to support for each information management system, including retraining as necessary.

11.6 Enables information management support improvement.

11.6.1 Optional software features that improve quality and/or safety.

Standard 12: Quality Management of Treatment Procedures and Modalities

The radiation oncology practice operates a comprehensive quality management program and safe practices for each treatment procedure and modality.

The ROP's comprehensive quality management program for each treatment procedure and modality:

12.1 Is consistent with American Association of Physicists in Medicine (AAPM) or equivalent body standards of practice for:

12.1.1 External beam radiation therapy dosimetry, mechanical, safety and respiratory management checks.

12.1.2 Brachytherapy dosimetry, mechanical and safety checks.

12.1.3 Quality assurance of measurement equipment.

12.1.4 Acceptance testing, clinical commissioning and clinical release.

12.1.5 End to end dosimetric system testing.

12.1.6 Simulation dosimetry, mechanical, safety and respiratory management checks.

12.2 Includes processes for maintaining systems.

12.2.1 Routine Preventive Maintenance Inspection (PMI) of mechanical, electronic and software systems.

12.2.2 Reinstating clinical use status of mechanical, electronic and software systems following repair, upgrade or maintenance.

12.2.3 Taking action on data that deviates from expected findings.

12.3 Maintains and reviews records and trend analysis on machine calibrations, quality assurance results, down time and service reports.

12.4 Includes external validation of machine output accuracy:

12.4.1 Prior to clinical use.

12.4.2 At least annually thereafter for photons and protons, and every two years for electrons.

Standard 13: Peer Review of Clinical Processes

The radiation oncology practice implements a robust program to provide peer to peer learning that promotes continuous quality improvement in treatment practices.

The ROP:

13.1 Defines and implements a process for prospective, concurrent or retrospective peer review for each professional discipline providing patient care that specifies:

13.1.1 Objectives for peer to peer review.

13.1.2 Frequency of peer review activities.

13.1.3 The number, type and frequency of cases for peer review.

13.1.4 How the information obtained from peer review will be used for professional feedback and future learning.

Standard 14: Patient Consent

The radiation oncology practice implements a written procedure regarding education of patients on the risks and benefits of radiation therapy treatment and documentation of consent for treatment.

The ROP:

14.1 Secures informed patient consent by:

14.1.1 Providing information regarding risks and benefits of radiation therapy.

14.1.2 Obtaining consent before the simulation phase of treatment begins.

14.1.3 Verifying consent is current (within 60 days prior to treatment).

14.1.4 Requiring a date and signature of the radiation oncologist.

14.2 Addresses a process for communication with patients:

14.2.1 Who do not speak English fluently or who have other communications barriers.

Standard 15: Patient Education and Patient Health Management

The radiation oncology practice educates the patient and assists the patient in managing side effects.

The ROP:

15.1 Assesses patient education needs for:

15.1.1 Self-management of treatment-related side effects before treatment begins and at least one time during the course of treatment.

15.2 Educates patients on:

15.2.1 Options for treatment and the rationale for each option (for example, surgical, chemotherapy or choices of radiation modality).

15.2.2 Intent of treatment (curative / palliative) and what to expect in the treatment process.

15.2.3 Management of treatment-related side effects involving pain, skin care, weight loss (need for nutrition support) and other side effects suitable for self-care, as necessary.

15.2.4 The cost of treatment, on request.

15.3 Uses:

15.3.1 Written or online materials in addition to verbal communication to educate patients.

15.4 Provides:

15.4.1 Therapeutic interventions to manage treatment-related side effects.

15.5 Has a patient referral process for:

15.5.1 Specialized radiation therapy and/or other services not provided by the ROP.

Standard 16: Performance Measurement and Outcomes Reporting

The radiation oncology practice measures and evaluates the patient experience and takes actions to improve performance.

The ROP:

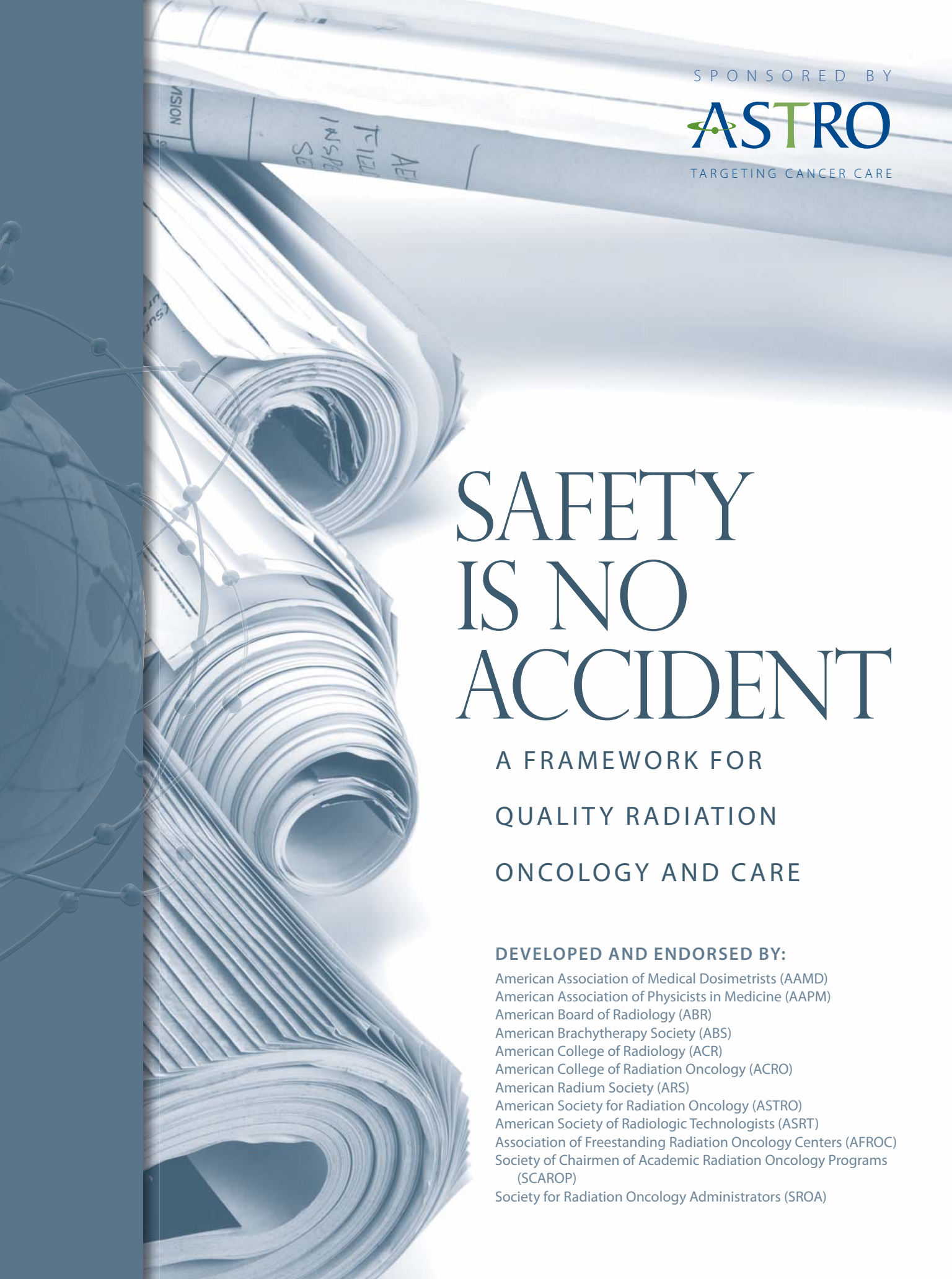
16.1 Measures and evaluates, at least annually:

16.1.1 The patient experience using a survey and/or other tools.

16.2 Response to patient complaints.

16.2.1 Accepts patient complaints.

16.2.2 Evaluates and responds to patient complaints.



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A FRAMEWORK FOR QUALITY RADIATION ONCOLOGY AND CARE

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SAFETY IS NO ACCIDENT: A Framework for Quality Radiation Oncology and Care

Technologic advances and systemic changes in health care delivery mean that the field of radiation oncology and its processes of care are in continuous evolution. These changes must be reflected in this book and so a mechanism for timely review and revision is necessary. The radiation oncology intersociety meeting is held biennially, bringing together the participating societies to discuss issues of importance to the field. As planning begins for each intersociety meeting, this safety document will be reviewed to assess whether a significant update is needed. If so, the update will become the subject of the next intersociety meeting.

ASTRO

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Introduction

During the later part of the twentieth century, the "Blue Book" had a unique importance in defining the shape of a modern radiation oncology department. It set standards regarding personnel, equipment and quality assurance and has been an invaluable guide for department chairs and practice leaders. Twenty years have elapsed since the last edition was published and during that time the world of radiation oncology has changed beyond measure. These two decades have seen an unprecedented expansion in the technological tools at our disposal with clear benefits to our patients. At the same time, however, the "Great Expansion" has added the challenge of deep complexity to our planning and treatment delivery. These decades have also been associated with a vigorous awareness of safety in medicine generally and radiation oncology in particular. This movement is pushing the practice of medicine toward integrated teamwork and effective, simple, quality assurance procedures.

The safe delivery of radiation therapy was never a simple matter and is now exceedingly complex. This new document is designed to address the specific requirements of a contemporary radiation oncology facility in terms of structure, personnel and technical process in order to ensure a safe environment for the delivery of radiation therapy. It was developed through collaboration between all of the major societies in the field representing physicians, medical physicists, radiation therapists, medical dosimetrists, nurses and administrators. It explicitly sets a high bar below which no radiation oncology facility should operate, and it foresees that the bar will be raised further in the years ahead. This book is unapologetic in its strong stance because, as the title states, safety is no accident. It comes from well-run facilities with good processes operating harmoniously within their capabilities. We recognize that some with smaller facilities may find the standards set here hard to achieve but we do not believe that they are impossible. We recognize that, in a declining economy, these high bars may prove a challenge but we believe this interdisciplinary document will help facility leaders advocate on behalf of patients from a position of strength. The authors wish this book to be a living manifesto of the specialty's dedication to patient safety and, after initial publication, will place it on the web with regular updating to follow.

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2011-2012 "Safety Is No Accident" Writing Chairmen

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CHAPTER 1

The Process of Care In Radiation Oncology

Leader: **James Galvin**
Albert L. Blumberg
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The "process of care" in radiation oncology refers to a conceptual framework for guaranteeing the appropriateness, quality and safety of all patients treated with radiation for therapy. Each of the aspects of the process of care in radiation oncology requires knowledge and training in the natural history of cancer, certain benign disease processes, radiobiology, medical physics and radiation safety that can only be achieved by Board certification in radiation oncology (or equivalent training), to synthesize and integrate the necessary knowledge base to safely and completely render care. This high level of training and Board certification applies as a recommendation for all of the specialists on the radiation oncology team. The medical therapeutic application of ionizing radiation is irreversible, may cause significant morbidity and is potentially lethal. Use of ionizing radiation in medical treatment, therefore, requires direct or personal physician management, as the leader of the radiation oncology team, as well as input from various other essential coworkers.

The radiation oncology process of care can be separated into the following five operational categories.

- Patient Evaluation
- Preparing for Treatment
  - o Clinical Treatment Planning
  - o Therapeutic Simulation
  - o Dosimetric Treatment Planning
  - o Pretreatment Quality Assurance and Plan Verification
- Radiation Treatment Delivery
- Radiation Treatment Management
- Follow-up Evaluation and Care

A course of radiation therapy is a function of the individual patient situation, composed of a series of distinct activities of varying complexity. All components of care involve intense cognitive medical evaluation, interpretation, management and decision-making by the radiation oncologist and other members of the clinical team. Each time a component of care is completed and reported, it should be appropriately documented in the patient record.

The clinical team, led by the radiation oncologist, provides the medical services associated with the process of care. Other team members involved in the patient's planning and treatment regimen include the medical physicist, medical dosimetrist, radiation therapist and nursing staff. Many of the procedures within each phase of care will be carried to completion before the patient's care is taken to the next phase. Others will occur and recur during the course of treatment, and they are by necessity repeated during treatment due to patient tolerance, changes in tumor size, need for boost fields or port size changes, protection of normal tissue or as required by other clinical circumstances (that is, certain procedures may need to occur multiple times during the treatment course).

1.1.0 PATIENT EVALUATION

Patient evaluation is a service provided by a physician at the request of another physician, the patient, or an appropriate source, and is intended to recommend care for a specific condition or problem, including further work-up, or to recommend treatment. The radiation oncologist, as part of this process, will review the pertinent history, patient complaints, physical findings, imaging studies, pathology and lab findings. If treatment is recommended and accepted, this patient visit, or a return visit, should

also be used for patient counseling, informed consent, coordinating care and making recommendations about other aspects of oncologic management or staging.

The evaluation with the radiation oncologist will often be followed by discussions with other members of the multidisciplinary care team, as indicated. This will include a review of details regarding pathology, disease extent based on radiographic imaging and other procedures, and potential sequencing of treatment modalities either used or planned, including surgery, chemotherapy, hormonal therapy or molecular targeted therapy. Full details of the patient evaluation are beyond the scope of this safety document.

1.2.0 PREPARING FOR TREATMENT

1.2.1 Clinical Treatment Planning

Clinical treatment planning is a comprehensive, cognitive effort performed by the radiation oncologist for each patient undergoing radiation treatment. The radiation oncologist is responsible for understanding the natural history of the patient's disease process, conceptualization of the extent of the disease relative to the adjacent normal anatomical structure, integration of the patient's overall medical condition and associated comorbidities. Knowledge of the integration of chemotherapeutic and surgical treatment modalities with radiation therapy is essential. An understanding of the integration of the various radiation treatment modalities is an essential part of this phase in the process of care.

Clinical treatment planning for either external beam radiation therapy (EBRT) or brachytherapy is an important step in preparing for radiation oncology treatment. This planning includes several components: determining the disease-bearing areas based on the imaging studies described above and pathology information; identifying the type (brachytherapy, photon beam, particle beam, etc.) and method of radiation treatment delivery (intensity modulated radiation therapy [IMRT], intensity modulated proton therapy [IMPT], three-dimensional conformal radiation therapy [3-D CRT], two-dimensional conformal radiation therapy [2-D CRT], low-dose-rate [LDR] or high-dose-rate [HDR] brachytherapy, etc.); specifying areas to be treated; and specifying dose and dose fractionation. In developing the clinical treatment plan, the radiation oncologist may use information obtained from the patient's initial clinical evaluation, as well as the additional tests, studies and procedures described above that are necessary to complete treatment planning. Studies ordered as part of clinical treatment planning may or may not be associated with studies necessary for staging the cancer, and may be needed to obtain specific information to accomplish the clinical treatment plan. In this regard, the radiation oncologist must consider toxicities and tolerances associated with definitive radiation therapy or combined-modality therapy. Review is needed of imaging studies and lab tests to determine treatment volume and critical structures, commonly referred to as organs at risk (OARs), in close proximity to the treatment area or more distant and receiving a dose of radiation that needs monitoring.

For either EBRT or brachytherapy, clinical treatment planning results in a complete, formally documented and approved directive. Details including total desired dose to all targets and OARs, fractionation, treatment modality, energy, time constraints and all other aspects of the radiation prescription are recorded in a written or electronic format and must be provided by the radiation oncologist prior to the start of treatment planning. In some cases, this prescription can require modification based on the results of the treatment planning process.

1.2.2 Therapeutic Simulation, Fabrication of Treatment Devices and Preplanning Imaging

Simulation is the process by which the geometry of the treatment device in juxtaposition to the patient is simulated for the purpose of developing an accurate and reproducible treatment delivery plan. For this purpose, it is necessary initially to acquire radiographic images of the patient in the preferred treatment position. Selecting a comfortable and appropriate patient position for treatment is an important part of the simulation process. The selected position should consider the location of the target and anticipated orientation of the treatment beams. Appropriate immobilization devices provide comfort, support and reproducibility.

In some cases the exact treatment position cannot be duplicated for some imaging procedures that are not under direct control of the radiation oncology team; clinical considerations should be made to compensate for such differences.

Some computed tomography (CT)-Simulator devices include the ability to register imaging datasets. However, most image registration is still performed manually with rigid datasets. Treatment planning systems can also provide the software for this capability. Using the software included with the treatment planning system shifts this part of the process to the treatment planning phase of the overall care process.

1.2.2.1 Team Interaction

The radiation oncology team, under the leadership of the radiation oncologist, works to deliver irradiation safely and reproducibly. Most radiation treatments use standard

operating procedures (SOPs) describing the treatment approach. These SOPs are considered to be an essential component of any radiation oncology department. In those situations where the patient presents with target and critical sensitive structure geometric relationships that are not easily handled using available SOPs, the involvement of the radiation therapy team is necessary. Team interactions that include the radiation therapists, medical dosimetrists, medical physicists and representation from the departmental nursing staff can prove helpful in specific situations. The purpose of these meetings is to carefully consider how treatments might be tailored to a particular patient's situation.

1.2.2.2 Fabrication of Immobilization Treatment Devices

Immobilization of the patient in a comfortable position for treatment might involve the construction or selection of certain treatment devices, facilitating accurate treatment delivery. This step must take into account the potential treatment planning considerations so that the immobilization aids do not restrict the treatment techniques. A personalized approach is required here, taking into consideration each patient's unique anatomy, at times requiring special accommodations appropriate for the individual case-specific concerns.

1.2.2.3 Therapeutic Simulation for EBRT

Simulation is the process of determining critical information about the patient's geometry, to permit safe and reproducible treatments on a megavoltage machine. Simulation for external beam radiation treatment is imaging based. Most simulation procedures have now shifted away from the direct use of the treatment beam to using X-rays in the diagnostic range of energies. In general, this part of the overall process of care reveals the relationship between the position of the target, or targets, and the surrounding critical structures. It is helpful here to think of the simulation step as the imaging needed for input to the treatment planning process. These images can be obtained in a large number of ways. Modern conventional simulators, like the CT-Simulator, can include the ability to produce volumetric data in addition to 2-D images. Intravenous contrast should be used during simulation, as indicated, to improve enhancement within both target and normal tissues/structures.

Preparing for EBRT treatment can also depend on other imaging modalities that are directly or indirectly introduced in the simulation process. In some cases, extra time and effort are required to directly incorporate the information available from other imaging modalities. For example, magnetic resonance (MR) and/or positron emission tomography (PET) are now available, and treatment planning systems that include image registration capabilities allow combining of information from other imaging modalities with the standard CT dataset obtained during simulation in appropriate situations. It is now possible to produce image datasets that quantify the motion of structures and targets due to respiration, cardiac motion and physiologic changes in the body. These four-dimensional (4-D) datasets include time as the fourth dimension and are used for motion management techniques like respiratory tracking or gating. Ultrasound imaging has a role in both EBRT and brachytherapy. Ultrasound comes into play as a preplanning imaging technique and can also be used as an image guided radiation therapy (IGRT) technique during the treatment delivery and verification steps of the care process.

1.2.2.4 Therapeutic Simulation for Brachytherapy

For certain brachytherapy procedures, preparing for treatment is similar to the procedure described above for EBRT. The simulation portion for this treatment modality is also imaging based, and can involve either planar X-rays or CT scans. Other imaging modalities may be important for some brachytherapy procedures and these studies can be obtained as part of the preplanning imaging process.

1.2.2.5 Treatment Planning for Radiation Therapy Using Unsealed Sources

For clinical situations where therapy using unencapsulated radionuclides is indicated, a distinct treatment planning process is necessary due to its multidisciplinary execution. The process can involve calculations of the anticipated dose distribution to the target organ or tumor(s) based on knowledge of the patient's vascular anatomy or biological imaging, such as nuclear medicine scans. This process should include multidisciplinary evaluation of the patient and consideration of clinical indications and radiation safety precautions. The American College of Radiology (ACR)/American Society for Radiation Oncology (ASTRO) Practice Guidelines regarding the Performance of Therapy with Unsealed Radiopharmaceutical Sources and NRC Guidelines discuss these issues in greater detail[1].

1.2.3 Dosimetric Treatment Planning

The computer-aided integration of the patient's unique anatomy, the desired radiation dose distribution to the tumor and normal tissues inside the patient, and the technical specifications of the treatment delivery device yield a work product referred to as the dosimetric treatment plan. The plan is a programmed set of instructions for the linear accelerator or brachytherapy device whereby a combination of external beams or internal source position-

ing will administer the intended dose of radiation to the target volume while minimizing the exposure of normal tissues. Accordingly, before the medical dosimetrist begins the treatment planning process, the radiation oncologist needs to define the target volumes and dose limiting organs and structures on the diagnostic images obtained during simulation.

The skills of the appropriately trained and credentialed medical dosimetrist and medical physicist relate to the efficient and effective use of the complex treatment planning system hardware and software. These individuals must also understand the clinical aspects of radiation oncology in order to interact with the radiation oncologist during the planning process. The role of the medical physicist is to guarantee proper functioning of the hardware and software used for the planning process, consult with the radiation oncologist and medical dosimetrist, check the accuracy of the selected treatment plan and perform measurements and other checks aimed at assuring accurate information exchange between radiation therapy devices and delivery of the treatment plan.

At various steps in the treatment planning process, the radiation oncologist is presented with one or more treatment plans for evaluation. The plans are evaluable by a combination of graphic visual representations of the radiation dose distribution inside the patient and quantitative statistics describing the dose to the tumor and normal tissue of interest. The radiation oncologist must then decide whether to accept or reject a given plan. Typically, this process is iterative and requires multiple revisions and adjustments to the initial plan in order to achieve a dose distribution that is both clinically acceptable and technically feasible. The radiation oncologist is responsible for selecting and formally approving the plan ultimately selected for treatment.

1.2.4 Pretreatment Quality Assurance (QA) and Plan Verification

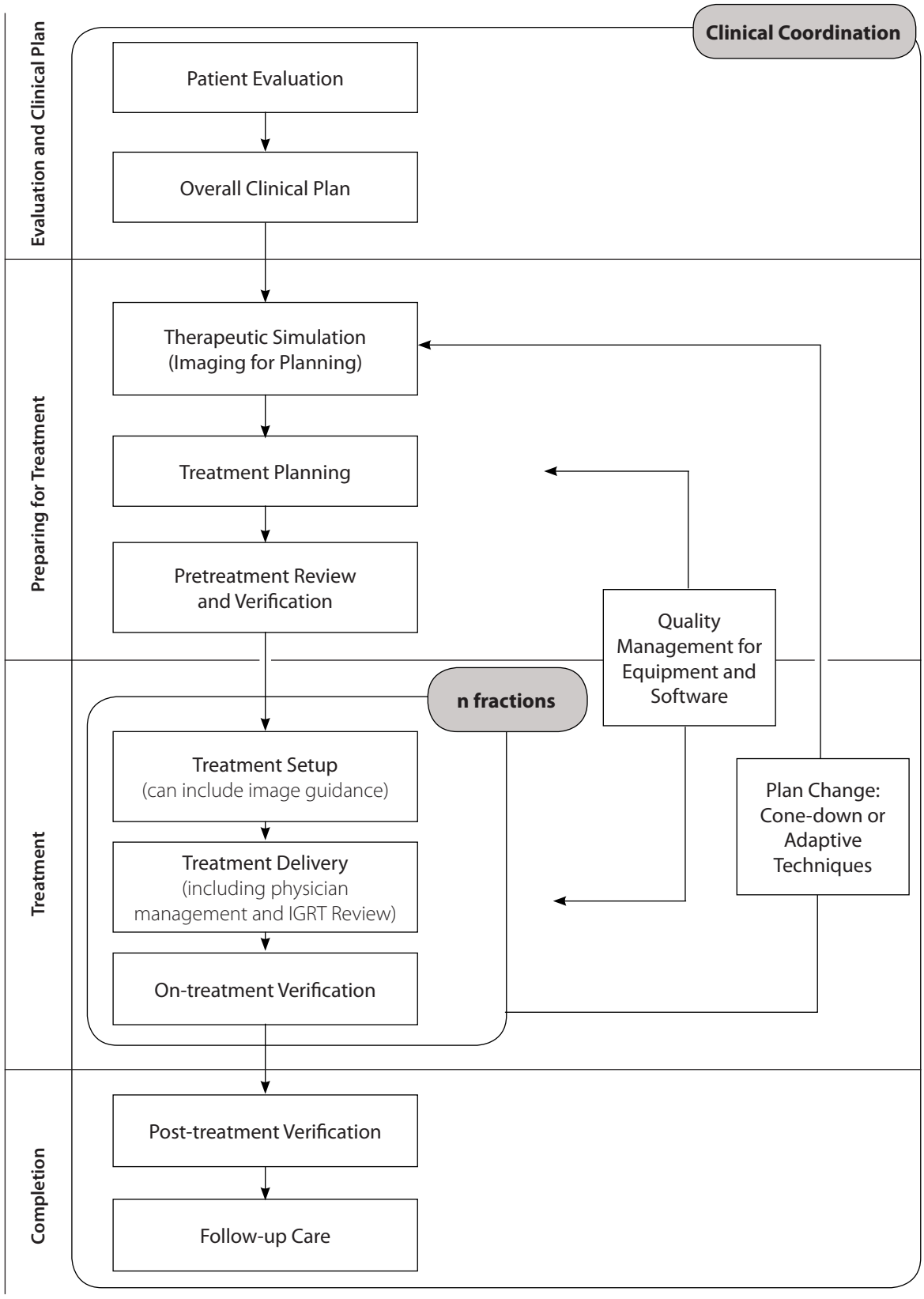
The QA steps taken after treatment planning is completed and before the start of treatment are critical for guaranteeing patient safety. An important initial step is an independent calculation of the machine output setting (monitor units) for external beam radiation therapy or radioactive source dwell times for brachytherapy. This recalculation may be accomplished as a manual point dose verification in the center of the treatment volume based on printed tables relating the effective field size to the administered dose at given depths from the surface. Alternatively, this can be performed in a computer-assisted manner, whereby data from the patient's planning images are entered into a separate software program along with parameters describing the prescription dose to the tumor and beam or source arrangements. In either case, the key result is confirmation of linear accelerator output settings or brachytherapy dwell times that reduce the risk of error related to an input mistake in the initial treatment planning software operation. If an independent calculation method is not available, then an appropriate measurement technique should be used. The radiation onologist ensures that a pretreatment quality assurance program is in place and followed for every patient.

In the past, treatment verification consisted of field aperture imaging using radiographic film. These images are referred to as portal images or port films. These images are now frequently obtained using electronic portal imaging devices (EPIDs). With the introduction of IMRT, imaging of individual apertures is no longer practical. However, the traditional method of verifying the plan isocenter position using orthogonal imaging is often used for both 3-D CRT and IMRT. For IMRT, this important QA technique is not considered to be completely sufficient to guarantee patient safety. In addition to this isocenter check procedure, patient-specific QA measurements are also required for IMRT and other complex delivery techniques that use inverse treatment planning. In terms of clearly organizing the different steps in the process of care for radiation oncology, a blurring of the separation between the verification step described in this subsection and the treatment delivery step described in section 1.3.0 occurs on the first day of treatment and whenever the treatment plan is changed. While patient-specific QA measurements are obtained prior to the start of treatment, dosimeters are sometimes also placed on the patient as a verification of correct dose delivery. The information gathered on the first day of treatment, if within acceptable limits, allows the treatment to continue for all fractions using the same treatment plan.

IGRT equipment is now available for checking the patient setup on the treatment table immediately prior to treatment delivery and then adjusting the patient position as needed to localize the target volume precisely within the volume that receives the prescription dose. This equipment can be used to verify the patient setup daily and can supplement port film information. IGRT has the advantage that it sometimes provides volumetric imaging capabilities. The extra setup accuracy provided by IGRT can allow for the use of treatment plans that reduce the volume of normal tissue around the tumor receiving a high dose of radiation, since there is less uncertainty in the target volume location. This process goes well beyond the simple plan verification process discussed further in the treatment delivery section.

For either portal imaging or isocenter verification imaging (using volumetric or planar images), it is necessary to have a reference image for comparison. This information

Figure 1.1. Process of Care for External Beam Radiation Therapy



is obtained from the imaging that is performed during the therapeutic simulation step in the process.

The QA process must include other steps that are aimed at checking the accuracy of both the dose calculations and the data used for treatment through the complete chain of systems (e.g., CT-Simulator to treatment planning to record and verify to accelerator control computer).

Another important step in the QA part of the process is the performance of secondary monitor unit calculations to check the primary calculation used to treat the patient.

1.3.0 RADIATION TREATMENT DELIVERY

1.3.1 External Beam Radiation Therapy

With treatment plan and treatment portal verification complete, the patient is ready for treatment. The initial step in this part of the process is patient setup on the treatment table using several different techniques, such as simple skin marks or a room laser system that localizes the treatment unit isocenter in space. Alternatively, the IGRT system may be used on each day of treatment.

Radiation treatment delivery includes various methods, modalities and complexities of radiation therapy. The physician is responsible for verification and documentation of the accuracy of treatment delivery as related to the initial treatment planning and setup procedure.

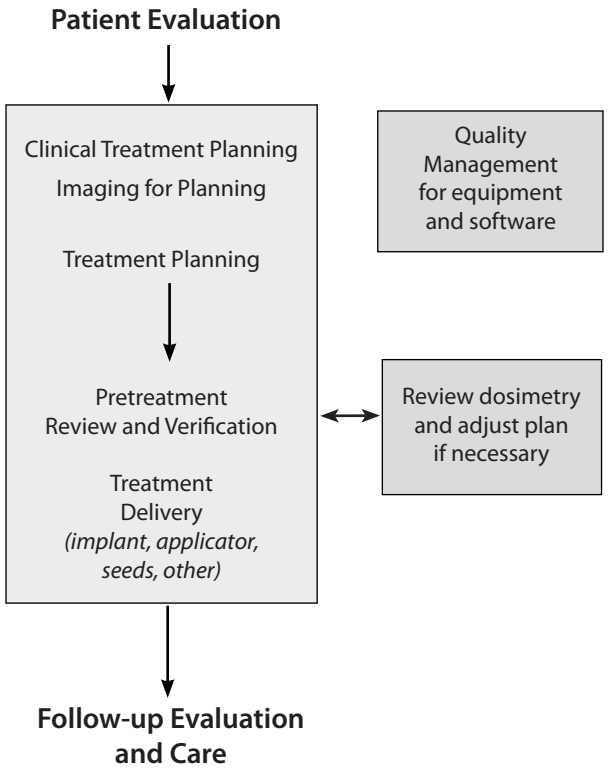
IGRT may be performed to ensure accurate targeting of precise radiation beams where certain needs of dose and organs at risk (OARs) tolerance exist. IGRT corrects for the positioning errors encountered when an internal target can move from day to day and can be reliably identified. The physician is responsible for the supervision and review of these images and shifts in order to ensure the therapy delivered conforms to the original clinical and dosimetric plans. Similarly, management of organ motion during treatment delivery, when indicated, is the responsibility of the treating physician ***(Figure 1.1, see page 7)***.

The overall clinical plan can involve selection of chemotherapy, surgery, EBRT, brachytherapy or a combination of modalities. Adaptive techniques can involve a modification to the initial treatment plan to adjust for an observed change.

1.3.2 Brachytherapy

Brachytherapy involves the temporary or permanent placement of radioactive material inside or immediately adjacent to a tumor-bearing region. One example is permanent seed implants for prostate cancer, either as definitive therapy for early stage disease or as a boost treatment following external beam treatment for intermediate- or high-risk disease ***(Figure 1.2)***.

Figure 1.2.
Process of Care for Brachytherapy



1.3.3 Calibration Procedures, Ongoing Equipment QA and Preventive Maintenance

The initial commissioning, ongoing performance evaluation and periodic calibration of radiation treatment delivery devices are important tasks that are vital to the safe administration of radiation therapy. In general, it is the medical physicist who is primarily responsible for the device evaluations necessary for compliance with applicable state and federal regulations concerning radiation treatment delivery technology. The American Association of Physicists in Medicine (AAPM) has published extensive guidelines on the conduct of these duties and regularly updates its educational materials when new technologies enter into standard clinical practice. The radiation oncologist, medical physicist and other members of the radiation therapy team should maintain a clear channel of communication on this issue of treatment device performance so that any possible sign of impending machine malfunction is quickly recognized and diagnosed, and any necessary corrective or reparative action is taken prior to use of the machine to deliver a clinical treatment to a patient.

1.4.0 RADIATION TREATMENT MANAGEMENT

Radiation treatment management encompasses the radiation oncologist's overall management of the course of treatment and care for the patient as well as checks and approvals provided by other members of the radiation therapy team that are necessary at various points in the process. For the radiation oncologist, radiation treatment management requires and includes a minimum of one examination of the patient by the physician for medical evaluation and management. The professional services furnished during treatment management may include:

- Review of portal images
- Review of dosimetry, dose delivery and treatment parameters
- Review of patient treatment setup
- Patient evaluation visit (described in section 1.1.0)

Not all of these parameters of treatment management are required for all patients for each week of management (except for the patient evaluation visit) because the clinical course of care may differ due to variation in treatment modality and individual patient requirements. For example, use of port films may vary based on certain technical characteristics (i.e., electron beams) and modification of dose delivery can vary based on individual patient needs, depending on the patient's tolerance of therapy or variation in tumor response. Examinations and evaluations may be required more often than weekly.

It should be emphasized that weekly treatment management requires the integration of multiple medical and technical factors, which may be required on any day through the treatment course. While nurses and nonphysician providers can effectively participate in the management of patients receiving radiation therapy, typically by helping to manage side effects associated with the treatment ***(Table 2.1, see page 12)***, their efforts do not represent the comprehensive effort of management for which the radiation oncologist is solely responsible. Additionally, regardless of whether a nurse or nonphysician provider evaluates the patient, the proper quality care for a patient receiving radiation therapy involves a personal evaluation by the radiation oncologist at least once for every five treatments given, and this evaluation should be documented in the patient's record.

1.5.0 FOLLOW-UP EVALUATION AND CARE

Continued follow-up evaluation and care of patients who have completed irradiation is necessary to manage acute and chronic morbidity resulting from treatment, as well as to monitor the patient for tumor relapse. Such follow-up is preferably provided through in-person examinations by the radiation oncologist and/or nonphysician provider, or when this is not feasible, by electronic communications and/or patient reports. The radiation oncologist should consult with the other members of the radiation therapy team when unexpected morbidity is observed or reported for the purpose of trying to identify measures that might reduce the risk of toxicity for future patients.

The ultimate goal for radiation treatment is to achieve the best possible outcome for the patient. This result depends on a number of factors. The training of the various members on the radiation therapy team is a major consideration. Board certification is one useful measure of competency of the team members. After receiving this important credential, the members of the team should actively pursue continuing education as required by the certifying Board.

Creating an error-free environment is an essential part of any radiation oncology department. This can be accomplished by understanding and properly implementing all steps in the process of care as described here.

CHAPTER REFERENCES

[1] Henkin RE, Del Rowe JD, Grigsby PW, et al. ACR-ASTRO practice guideline for the performance of therapy with unsealed radiopharmaceutical sources. *Clin Nucl Med 2011*;36(8):e72-80.

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CHAPTER 2

The Radiation Oncology Team

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2.1.0 ROLES AND RESPONSIBILITIES

The radiation oncology team ensures every patient undergoing radiation treatment receives the appropriate level of medical, emotional and psychological care before, during and after treatment, through a collaborative multidisciplinary approach.

The primary radiation oncology team consists of, but is not limited to, radiation oncologists, medical physicists, medical dosimetrists, oncology nurses and radiation therapists. On-site or by consultation, services provided by nonphysician providers can include, but are not limited to, nurse practitioners, clinical nurse specialists, advanced practice nurses and physician assistants, dentists, clinical social workers, psychologists/psychiatrists, nutritionists, speech/swallowing therapists, physical therapists, occupational therapists, genetic counselors, integrative medicine specialists and pastoral care providers. These services are available to the interdisciplinary team to meet the complex needs of patients.

The process of care in radiation oncology involves close collaboration between a team of qualified individuals. The attending radiation oncologist has ultimate and final responsibility, as well as accountability for all aspects of patient care.

While **Table 2.1** *(see page 12)* does not specifically define individual roles within the radiation oncology team, it is an attempt to clarify those roles and relative responsibilities. The scope of practice of each team member should be based on the criteria established by their professional organization and local jurisdiction. Each facility must have policies and procedures defining the roles of these team members.

2.2.0 QUALIFICATIONS AND TRAINING

Board certification is the primary consideration for establishing proper qualifications and training for a professional working in radiation oncology. The relevant professional societies establish the eligibility requirements to sit for a board exam, including education, training and clinical residency requirements. In addition, where applicable, professionals must meet requirements for obtaining a state license, as shown in **Table 2.2** *(see page 13)*.

Each facility should have a policy regarding orientation, competency, credentialing and periodic evaluations of all team members.

2.2.1 Medical Director

The medical director is a radiation oncologist who is responsible for oversight of the facility, in addition to establishing policies and procedures.

2.2.2 Radiation Oncologist

The radiation oncologist has American Board of Radiology (ABR) certification in Radiation Oncology, Therapeutic Radiology or equivalent certification. Additional processes of certification as defined by ABR are published at: www.theabr.org.

2.2.3 Nonphysician Providers (Physician Extenders)

Nonphysician providers include, but are not limited to, nurse practitioners, clinical nurse specialists, advanced practice nurses and physician assistants. The roles, qualifications, licensure requirements and maintenance of credentials for these individuals should be determined by their professional organizations, scope of practice, rules and

Table 2.1. Roles and Responsibilities of the Radiation Oncology Team

	RADIATION ONCOLOGIST	MEDICAL PHYSICIST	MEDICAL DOSIMETRIST	RADIATION THERAPIST	NONPHYSICIAN PROVIDERS (NP/PA)	ONCOLOGY NURSE
Clinical evaluation	x				x	x
Ongoing psycho/social evaluation	x				x	x
Decision to deliver external radiation therapy (XRT)	x					
Patient +/- family education	x			x	x	x
Interdisciplinary coordination of care	x			x	x	x
Patient positioning and image acquisition	x	x	x	x		
Fusion and registration	x	x	x			
Contouring/segmentation	x	x	x			
Dose-volume constraints	x	x	x			
Dose calculation	x	x	x			
Review of final treatment plan	x	x	x	x		
Patient-specific QA	x	x	x	x		
Treatment delivery	x	x	x	x		
Special procedures (SRS, SBRT, HDR, etc.)	x	x	x	x		
Monitor accuracy of delivery (ports, dose, etc.)	x	x	x	x		
Weekly evaluation	x	x	x	x	x	x
Follow-up	x				x	x
Survivorship	x				x	x
Equipment, software and systems acceptance testing, maintenance and commissioning	x	x	x	x		

regulations of individual institutions and licensure regulations within individual jurisdictions (American Academy of Nurse Practitioners [AANP], www.aanp.org; American Nurses Credentialing Center [ANCC], www.nursecredentialing.org; National Commission on Certification of Physician Assistants [NCCPA], www.nccpa.net; American Academy of Physician Assistants [AAPA], www.aapa.org).

2.2.4 Medical Physicist

Medical physicists should be certified in accordance with the appropriate qualification for the designation of Qualified Medical Physicist (as published at www.aapm.org), Therapeutic Medical Physicist (as published at www.theabr.org) or equivalent certification.

Table 2.2. Certification and Licensure Requirements

Profession	Relevant Certifying Body	State Licensure Required?	Information Resources
Radiation Oncologist	ABR	Yes	www.theabr.org
Medical Physicist	ABR ABMP CCPM	In 3 states as of 2011(FL, NY, TX)	www.theabr.org www.abmpexam.com www.ccpm.ca
Medical Dosimetrist	MDCB	No	www.mdcb.org
Radiation Therapist	ARRT ASRT	Yes (Currently in 35 states)	www.arrt.org www.asrt.org
Nurse Practitioner	AANP ANCC	Yes Yes	www.aanp.org www.ancc.org
Oncology Nurse	ANCC ONCC	Yes	www.www.nursecredentialing.org www.oncc.org
Clinical Nurse Specialists	ANCC	Yes	www.ancc.org
Physician Assistant	NCCPA	Yes	www.nccpa.net

2.2.5 Medical Dosimetrist

A medical dosimetrist is competent to practice under the supervision of a qualified physician and qualified medical physicist. An individual is considered competent to practice in medical dosimetry if that individual is eligible or certified in accordance with the appropriate qualification for the designation of Qualified Medical Dosimetrist through the Medical Dosimetrist Certification Board (MDCB) at www.mdcb.org.

2.2.6 Radiation Therapist

A qualified radiation therapist is considered competent to practice in radiation therapy if he or she is eligible or certified in accordance with the appropriate qualification for the designation of Radiation Therapist, published by the American Registry of Radiologic Technologists (ARRT) at www.arrt.org and the American Society of Radiologic Technologists (ASRT) at www.asrt.org.

2.2.7 Radiation Oncology Nurse

A qualified oncology or radiation oncology nurse has oncology certification, in addition to basic educational preparation to function as a registered professional nurse, as determined by the individual jurisdiction. Oncology certification can be obtained through the Oncology Nursing Certification Corporation (ONCC, www.oncc.org), American Nurses Credentialing Center (ANCC, www.nursecredentialing.org), or National Association of Clinical Nurse Specialists (NACNS, www.nacns.org).

2.3.0 CONTINUING EDUCATION AND MAINTENANCE OF CERTIFICATION

The applications, technologies and methodologies of radiation oncology continue to expand and develop. Lifelong learning is vital to ensure incorporation of new knowledge into clinical practice, therefore, each member of the interdisciplinary team should participate in available Continuing Medical Education (CME) and, where applicable, Maintenance of Certification (MOC) programs.

2.4.0 STAFFING REQUIREMENTS

The staffing needs of each facility are unique and vary based greatly upon the patient mix, as well as on the type and complexity of the services offered. Patient load, number of machines and satellites/affiliated centers also influence the need to allocate management manpower and full-time employees (FTEs) ***(Table 2.3)***, as well as teaching responsibilities and vacation time. As such, it is impossible, in the current era, to prescribe hard staffing levels.

The radiation oncology facility should have a qualified radiation oncologist on-call 24 hours a day, seven days a week, to address patient needs and/or emergency treatments. An adequate number of other members of the radiation oncology team should be available to deliver urgent treatments in off-hours. Otherwise, the facility must have arrangements for referral of emergency patients for timely treatments.

CHAPTER APPENDIX: ILLUSTRATIVE SAFETY STAFFING MODEL

In the current environment, radiation oncology as a profession is providing more complex special procedures. The above guidelines reflect the combined input from the surveys performed by several professional organizations (ACR, ASTRO, AAMD, AAPM and the ABR studies) during the last decade. Additional personnel will be required for research, education and administration. For a progressive clinic, the above recommendations may be insufficient to accurately estimate the medical physics and dosimetry FTE effort required to provide all special patient procedures and services.

Table 2.3 Minimum Personnel Requirements for Clinical Radiation Therapy

CATEGORY	**STAFFING** (See important comments below.)
Chief Radiation Oncologist	One per facility
Chief Medical Physicist	One per facility
Department Manager	One per facility (in some departments this function may be filled by a member of the team)
Medical Dosimetrist*	As needed, approximately one per 250 patients treated annually
Radiation Therapist*	As needed, approximately one per 90 patients treated annually
Brachytherapy Technologist*	As needed, approximately one per 100 brachytherapy patients treated annually
Mold Room Technologist	As needed to provide service
Social Worker/Dietician	As needed to provide service

* This number may be higher or lower depending upon the complexity of patients treated by an individual physician or by the complexity of technology.

**It is recommended that a minimum of two qualified individuals be present for any routine external beam patient treatment.

A sample worksheet for calculating medical physics and dosimetry staffing in radiation oncology:

			Relative FTE Factor		Required FTE		Required Total FTE	
	Services -– # of Units or Licenses*	No. of systems*	Physicist	Dosimetrist	Physicist	Dosimetrist	Physicist	Dosimetrist
Equipment, Sources and Systems	Multi energy accelerators		0.25	0.05				
	Single energy accelerators		0.08	0.01				
	Tomotherapy, CyberKnife, GammaKnife		0.3	0.03				
	Cobalt Units, IMRT, PACS, EMR & Contouring		0.08	0.03				
	Orthovoltage and superficial units		0.02	0.01				
	Manual brachytherapy; LDR Seed Implants		0.2	0.03				
	HDR brachytherapy		0.2	0.02				
	Simulator, CT-Simulator, PET, MRI Fusion		0.05	0.02				
	Computer planning system (per 10 workstations)		0.05	0.02				
	HDR planning system		0.2	0.01				
						Subtotal		
No. Patient Procedures	**Annual # of Patients undergoing Procedures****	**No. of patients****						
	External Beam RT with 3D planning		0.0003	0.003				
	External Beam RT with conventional planning		0.0002	0.002				
	Sealed source Brachytherapy (LDR & HDR)		0.008	0.003				
	Unsealed source therapy		0.008	0.005				
	IMRT, IGRT, SRS, TBI, SBRT		0.008	0.005				
						Subtotal		
Nonclinical - Estimated Total FTE Effort	**Estimated Total (Phys & Dosim) FTE Effort*****	**FTE Effort*****						
	Education & Training (FTE)		0.667	0.333				
	Generation of Internal Reports (FTE)		0.667	0.333				
	Committees & Meetings; Inc. Rad. Safety (FTE)		0.667	0.333				
	Administration and Management (FTE)		0.667	0.333				
						Subtotal		
						Total		

** Enter the sum of the number of therapy units, imaging systems, workstations, support systems and technologies in each category (column 3).*

*** Enter the annual number of new patients that undergo each of the following planning and treatment deliver procedures; count each new patient one time (column 3).*

****Enter the summed total medical physicist and medical dosimetrist estimated FTE effort in each of the following categories. See Component FTE table for typical FTE (column 3)*

Multiply the entries in column 3 by the Physicist FTE factor (column 4) and the Dosimetrist FTE factor (column 5); report these in columns 6 and 7. Sum and total in columns 8 and 9. Example below:

			Relative FTE Factor		Required FTE		Required Total FTE	
	Services -– # of Units or Licenses*	**No. of systems***	**Physicist**	**Dosimetrist**	**Physicist**	**Dosimetrist**	**Physicist**	**Dosimetrist**
Equipment, Sources and Systems	Multi energy accelerators	4	0.25	0.05	1	0.2		
	Single energy accelerators	0	0.08	0.01	0	0		
	Tomotherapy, CyberKnife, GammaKnife	1	0.3	0.03	0.3	0.03		
	Cobalt Units, IMRT, PACS, EMR & Contouring	0	0.08	0.03	0	0		
	Orthovoltage and superficial units	0	0.02	0.01	0	0		
	Manual brachytherapy; LDR Seed Implants	1	0.2	0.03	0.2	0.03		
	HDR brachytherapy	1	0.2	0.02	0.2	0.02		
	Simulator, CT-Simulator, PET, MRI Fusion	1	0.05	0.02	0.05	0.02		
	Computer planning system (per 10 workstations)	1	0.05	0.02	0.05	0.02		
	HDR planning system	1	0.2	0.01	0.2	0.01		
						Subtotal	2.00	.033
No. Patient Procedures	**Annual # of Patients undergoing Procedures****	**No. of patients****						
	External Beam RT with 3D planning	500	0.0003	0.003	0.15	1.5		
	External Beam RT with conventional planning	200	0.0002	0.002	0.04	0.4		
	Sealed source Brachytherapy (LDR & HDR)	100	0.008	0.003	0.8	0.3		
	Unsealed source therapy	25	0.008	0.005	0.2	0.125		
	IMRT, IGRT, SRS, TBI, SBRT	400	0.008	0.005	3.2	2		
						Subtotal	4.39	4.33
Nonclinical - Estimated Total FTE Effort	**Estimated Total (Phys & Dosim) FTE Effort*****	**FTE Effort*****						
	Education & Training (FTE)	0.1	0.667	0.333	0.0667	0.00333		
	Generation of Internal Reports (FTE)	0.1	0.667	0.333	0.0667	0.00333		
	Committees & Meetings; Inc. Rad. Safety (FTE)	0.1	0.667	0.333	0.0667	0.00333		
	Administration and Management (FTE)	0.5	0.667	0.333	0.0667	0.00333		
						Subtotal	0.53	0.27
						Total	6.92	4.92

Another resource for calculating radiation oncology staffing is: Battista JJ et al. Medical physics staffing for radiation oncology: a decade of experience in Ontario, Canada. *J Appl Clin Med Phys*. 2012;13(1):3704.

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CHAPTER 3

Safety

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3.1.0 THE NEED FOR A CULTURE OF SAFETY

Modern radiation therapy is complex and rapidly evolving. The safe delivery of radiation therapy requires the concerted and coordinated efforts of many individuals with varied responsibilities. Further, safety and efficiency go hand in hand. Inefficient systems lead to staff frustration, rushing and sometimes cutting corners, thus, all team members need to work together to create a safe and efficient clinical environment and workflow.

The need for efficiency is heightened by the increasing demands being placed on all members of the radiation oncology team. Changes in the levels of reimbursement for some clinical activities, global changes in the national healthcare system (e.g., structural, financial) and increasing levels of administrative burden (e.g., documentation requirements) require physicians to search for improved levels of efficiency. This is essential in order to provide staff with necessary time to perform critical safety-related activities.

The rapidly-evolving nature of radiation oncology requires that processes and workflows be continually reassessed. Each member of the team needs to accept that optimal approaches are not static, but will necessarily change to accommodate the evolving practice. Long-held traditional approaches will need to be challenged and possibly modified.

People may be hesitant to change, often for good reasons. Good clinical practices usually evolve over years if not decades, so change should be carefully implemented. It is critical that a culture that appropriately manages change exists, ensuring change facilitates safety and quality. Furthermore, all team members must be open to having any member of the team (whether in leadership positions or not) raise concerns about safety as well as suggesting and considering change. Indeed, it is often the frontline staff that are more likely to understand the limitations of current procedures and suggest improvements. Thus, an ideal open environment with a safety-minded culture only exists where staff are permitted and encouraged to suggest and lead change to improve safety, quality and efficiency.

3.2.0 LEADERSHIP AND EMPOWERING OTHERS

Physicians and medical physicists comprise the primary leadership roles within a radiation oncology clinical site. They must empower all members of their team to be active participants in improving clinical processes. This is true from a practical perspective, as one person cannot possibly understand all aspects of the complex field. Further, such empowerment is a meaningful way to provide team members with a feeling of responsibility, thereby increasing job satisfaction, raising expectations and enhancing performance. Staff should know that they have a meaningful and beneficial impact in the work environment.

In the radiation oncology clinic, these professionals are ultimately responsible for creating a culture of safety. Society has entrusted physicians and medical physicists as the guardians of both the individual and societal health care structure. With this trust, they are empowered to operate as advocates for safety-related initiatives. Leadership needs to make all staff feel comfortable to raise concerns about safety without fear of reprimand or reprisal.

3.3.0 EVOLVING ROLES AND RESPONSIBILITIES OF EACH TEAM MEMBER

The field of radiation oncology is ever-evolving, and as such, there are rapid changes in the roles and responsibilities of each team member. **Table 3.1** *(see page 21)* summarizes some of these changes and associated challenges. Entries are meant as examples, as this is not an exhaustive list.

3.4.0 EXAMPLES OF TOOLS/INITIATIVES TO FACILITATE SAFETY, AND THE SAFETY CULTURE

3.4.1 Staffing/Schedules

Staffing levels need to be adjusted to reflect the workload, particularly in physics, dosimetry and treatment, where the demands have markedly increased (e.g., patient-specific QA for IMRT). Schedules should be realistic to avoid/minimize hurrying through a given task and risking error. An excessive workload can lead to errors. Conversely, light workloads can also be a problem since a certain level is needed to maintain "situational awareness" [1, 2].

3.4.2 Communication/Facilities

Systems that facilitate clear, unambiguous and efficient communication between all team members are critical. This is particularly true between physicians, medical dosimetrists, medical physicists and radiation therapists, given the large number of hand-offs and interdependent tasks that routinely occur during the planning and treatment-implementation processes. Well-defined charting procedures, either paper or preferably electronic, are critical. In planning the layout of a department, one might centrally locate dosimetry, and/or establish dedicated time for physicians and medical dosimetrists to work together, thereby facilitating the iterative "directive-segment-computation-review-repeat" cycle. This is a particular challenge when physicians and planners rotate between facilities. Enhanced tools are needed to enable efficient and accurate communication/transfer of complex 3-D data between centers. A well-defined communication pathway between workers will reduce the need for ad hoc/variable solutions and provide for messages being sent, received and verified.

3.4.3 Workflow/Efficiency

Clinical practice is complex, often mired in administrative and historically-derived procedures. Efficiency impacts quality and safety. Harried workers are more prone to error, therefore eliminating nonessential tasks increases time available for critical tasks. Lean approaches (adapted from the Toyota Production System)[3] have been adopted by many to streamline clinical workflow and alter the work environment. Some have implemented rapid improvement events (Kaizens [4]) where participating representative members of involved groups create process maps for particular tasks. Value-added steps are identified, with wasteful steps and unnecessary stressors being eliminated, and a more streamlined, unambiguous, standardized process emerges. Having stakeholders meet to discuss and define their work builds teamwork and mutual respect, while fostering an environment in which staff know that they can positively impact their work.

3.4.4 Standardization

Standardization is widely recognized as a means to reduce errors and confusion. This might be particularly useful in group practices where radiation therapists, medical dosimetrists and medical physicists interact with numerous physicians, each having their own preferred methods. Having too many diverse approaches can lead to confusion. It is helpful if providers can agree on standard approaches to common diseases using reference or guide sheets to avoid confusion among planning staff. Standard treatment practices and QA mechanisms, as well as associated policies and procedures, should be vetted through a review committee and required for every technique or site, with regular updates, as needed. These should be posted with easy access for all who may need to refer to them.

3.4.5 Hierarchy of Effectiveness

Different methods used to affect behaviors have variable expectations for success [5]. Reliance on policies and training is the usual but least effective approach. In a large database of errors from the State of New York, "failure to follow policies/procedures" was implicated as a contributing factor in 84 percent of events, versus "inadequate policies/procedures" in 16 percent of events. Whenever possible, it is best to "hardwire" the systems for success using simplification, standardization, automation and forced functions to create workflows and systems that support human work. Checklists and time-outs are effective [6, 7] especially if:

- They are focused on the task at hand;
- The user believes in their utility; and
- The user is forced to use them (e.g., "hard stop").

Table 3.1. Examples of Safety-Related Roles and Challenges – Radiation Oncology Staff

Team Member	Traditional Role	Evolving Role	Challenges
Physician	• Patient care • Supervises RT (e.g., sets dose/ volume criteria, approves plan and treatment images, manages toxicity)	• Team leader for patient safety • Coordination with multidisciplinary team • Continuous education (e.g., image evaluation/segmentation, new software/technology)	• Relinquish some autonomy to other personnel • Engaging others in safety mission
Medical Physicist	• Assure the safe and effective delivery of radiation as prescribed	• Incorporating technological innovations to improve patient/ staff safety • Assess safety of treatment processes, (e.g., with statistic processes, failure mode analysis, fault trees, etc.)	• Role shift to increase emphasis on safety-related work • Education in advanced process analysis tools for patient safety
Medical Dosimetrist	• Treatment planning • Plan and TPS QA	• Image cataloging/manipulation (e.g., fusion/registration/ segmentation) • Assist in IMRT/IGRT/equipment QA	• Adequate instruction in anatomy • Proper utilization of emerging imaging/segmentation tools
Radiation Therapist	• Provide safe and effective delivery of radiation as prescribed • Daily equipment and new patient treatment QA	• Assessment of 2-D/3-D images to make decisions concerning patient treatment/ motion/ alignment	• Safe and proper use of additional imaging and treatment delivery systems
Nurse	• Assist with patient care/ education • Manage toxicity	• Patient pain • Assist in multidisciplinary coordination	• Adequate instruction in evolving technologies • Knowledge of evolving chemotherapy agents
Nonphysician Providers	• Assist physician with patient care	• Coordination with multidisciplinary team	• Legal or regulatory restrictions
Administrator	• Oversight of regulatory compliance	• Support patient safety program	• Resource allocation
IT Specialist	• Desktop support	• Connectivity • Failure mode analysis • Data archiving/recovery	• Resources • Space • Vendor interoperability
All Clinical Staff	• Proper patient identification • Peer review	• QA/Quality Improvement (QI) • Increased documentation in EMR • Evolving peer review • Compliance with evolving regulatory requirements	• Identification/discussion of near-misses • Continuous education • Increased reliance on EMR • Adequate instruction with software/technological advances • Dedicating time for safety initiatives • Minimizing distractions

"Knowledge in the field" (automatic computer/machine functions and checklists) is more likely to improve human performance than is "knowledge in the head" (memory).

3.4.6 Human Factors Engineering [5, 8]

Human-machine interactions are ubiquitous. Human factors engineering aims to define processes, interfaces and machinery that facilitate correct usage. For example, the forcing function of an automated teller machine can require withdrawal of the bankcard before money is dispensed. Similarly, placing console control buttons that perform particular functions in a consistent location enables users to more reliably operate equipment in a predictable and correct manner. Safety is improved with workspaces that are designed to reduce noise, interruptions and visual clutter. Improving lighting, temperature and desk height are additional factors proven to affect performance.

In the radiation oncology field, complicated computer screen layouts, keyboard functions and treatment consoles are a few examples of the hundreds of human-machine interfaces that are navigated daily. These require increasing mental effort as they become more complicated or lack standardization. Many are well designed, but there is ample room for improvement. For example, within individual products, shortcut keyboard commands should be consistent whenever possible. Standardization of nomenclature, monitor layouts and shortcuts across different vendors are examples of enhancements that might also be helpful.

3.4.7 Incorporating QA Tools/Functionality Into Software

Often, QA is not incorporated into the planning or record and verify delivery systems. For example, user-configurable checklists and time-outs are not an option. Although potentially valuable, such embedded checklists still require the user to verify that checklist items are appropriately addressed rather than being automatic. Some embedded automatic QA functions would be useful, such as:

- For a new plan, the system searches its directory archive for patients with the same name to identify inadvertent retreatment.
- For common diagnoses, the planning system compares the proposed target volumes and associated dose parameters to a library of user-specified "expected" parameters and issues predefined alerts.
- Normal tissue dose-volume parameters are compared to user-specified constraints.
- Automatic highlighting of under-dosed target, or normal tissue hot-spots.
- Beams and plans are named automatically to reflect the treatment planner, date, etc.
- Common nomenclature of target volumes, organs at risk and plans to facilitate review of plans and identification of outliers.

Some of these functions may already exist. At least one manufacturer is "training" their planning system to identify discrepancies between pending plans and their library of "similar plans" [9].

3.4.8 Peer and Interdisciplinary Review

Peer review is an essential part of the safe delivery of radiation. Prospective peer review is critical, especially for new technologies such as IMRT and IGRT [10, 11]. Once treatment has been initiated, the threshold for making a meaningful change in image segmentation or motion-management strategy is relatively high because it may result in time-consuming replanning and QA. Physician-to-physician peer review is useful, and review of target delineation and image segmentation prior to planning deserves more standardization. Peer review is also conducted as part of the chart rounds process. See Chapter 4, sections 4.1.5 and 4.1.6, in this document for the specifics regarding the components of this process.

Peer review is clearly important for other team members as well. As an example, medical dosimetrists can check each other's work (e.g., choice of beam selection/weighting). A distinction is often made between quality assurance and peer review ***(Table 3.2, see page 23)***. Quality assurance is often taken to relate to objective/quantitative "right versus wrong" actions (e.g., was the correct plan sent from the planning system to the treatment machine? Is the machine beam output correct?), that can readily lead to major clinical events that affect one or many patients. Peer review is often used to refer to somewhat more subjective items (e.g., target definition or dose selection) that are perhaps less likely to lead to major clinical events, and not affect a large number of patients. These interactions traditionally occur roughly as physics-, planning- or therapy-based versus physician-based. However, this distinction can be readily blurred. For example, should there be a double check for things such as machine QA? (e.g., there may be two people to confirm the machine output). Similarly, a physician can make gross right or wrong type errors in target delineation (e.g., mislabeling the left atrium as a sub-carinal lymph node) or misinterpreting published data leading to systematic errors in treatment recommendation that could affect many patients.

Table 3.2. Examples of Peer Review and Quality Assurance Items *

	Peer Review	Quality Assurance
Physician	• Target definition	• Verify appropriate nomenclature and documentation • Verify dose constraints are within policy • Review portal films
Medical Physicist	• Verify machine output	• Verify the correct transfer of data from the planning system to the treatment machine
Medical Dosimetrist	• Assess selection of beam orientation and weighting • Evaluate plan for target coverage and normal tissue exposure	• Verify that prescription matches the treatment plan
Radiation Therapist**	• Double check patient setup accuracy	• Ensure patient-specific procedure time-out

* Examples shown are items that might be (somewhat arbitrarily) divided into the peer review and quality assurance.

** In addition, two radiation therapists should always be available in the event of emergencies and as a "second set of eyes" to verify information during time-outs for procedures.[12]

There is additional utility to prospective multidisciplinary interactions (e.g., between physician, medical physicist, medical dosimetrist, nurse and radiation therapist). A dosimetrist might note inconsistencies in the segmentations and directives, and anticipate dosimetric challenges (e.g., "I cannot meet both the cord and the planning target volume [PTV] doses due to their proximity") prior to initiating planning. Such a preplanning/treatment meeting facilitates a healthy interdisciplinary dialogue that can make the subsequent planning/treatment processes smoother, but may also require more time between simulation and treatment.

3.4.9 Daily Morning Meetings

Having all members of the team meet daily to review the upcoming clinical activities can be a useful exercise to preempt potential problems. For example, the CT-Simulation therapists can review the day's schedule, noting patients whose records lack clear directives. Patients presenting unique challenges or learning opportunities can also be identified and discussed. The availability or lack of openings for add-ons can be noted. Medical dosimetrists can alert the group regarding treatment plans that are proceeding more slowly than expected and seek direction. The chief radiation therapist can note to the group patients who will need pre-RT films/imaging reviewed that day, the daily patient treatment census and potential challenges (e.g., anesthesiology cases). All members of the group are invited to raise concerns, make announcements, and so forth. The morning meeting serves the practical function of trying to anticipate the upcoming challenges and avoid chaos in the clinic. It also serves a social and cultural function to bring the department together daily, fostering an environment of easy communication among all team members.

3.4.10 Safety Rounds

Safety rounds may be characterized by personal 15- to 20-minute interviews by the chairman (or members of the safety or quality committees) and members of the leadership team with staff members in groups of one to three people at their worksite, asking about near-misses or unsafe conditions causing potential or real harm to patients or employees.

3.4.11 Routine Public Announcements/Updates

Issues relating to safety/quality/efficiency should be routinely included in all departmental activities. For example, the morning meeting is a good opportunity for leadership to make announcements about ongoing initiatives.

Similarly, regular reports summarizing the outcomes of safety rounds can be provided to all department members and posted in prominent locations throughout the department. This demonstrates the responsiveness of leadership and reinforces leadership's commitment to process improvement. Achievements of staff working in these areas should be publicly acknowledged and celebrated. This helps to create an environment where people may be more willing to speak openly about safety concerns.

3.4.12 Address Errors and Near-Misses

Employees should be encouraged to report both errors and near-misses (errors that almost happen). Experienced employees typically know how to rapidly work around challenges, and may not always recognize the potential problems that could arise, since they are so skilled at adapting to situations. The study of near-misses is powerful in identifying problems with work processes that can lead to an error. The reporting of near-misses should be met positively, and not with fear of punitive action. Near-misses should be addressed with a similar vigor as that applied to errors, and reported through the Quality Assurance Committee.

3.4.13 Quality Assurance Committee

A dedicated formal QA committee should consist of a multidisciplinary team (e.g., physicians, medical physicists, medical dosimetrists, nurses, radiation therapists and IT support) that meets regularly and serves as liaison with leadership and hospital-wide safety committees. This committee should develop initiatives related to patient safety (e.g., sections 4.1-4.12), which are feasible and work best for the individual institution. This committee should ensure that a mechanism for reporting and monitoring errors and near-misses is in place, that leadership is aware of trends, and that a process exists for implementing change when needed. Monitoring appropriate compliance with local, national and international safety, licensure and credentialing standards falls under this committee, as does developing mechanisms to investigate serious or potentially serious incidents in near real-time (e.g., less than 24 hours). Such mechanisms may include having a dedicated team on-call to meet with staff involved in an error or near-miss, to help in determining root causes of the incident, to provide input on the potential impact of the error or near-miss and on proposed solutions or recommended changes (if any). This committee also disseminates safety information through peer review meetings, the morning meeting and safety rounds, in addition to more formal safety, QA or possibly morbidity/mortality rounds.

Peer review meetings, QA Committee, morning meetings and safety rounds are examples of initiatives that promote staff involvement in seeking positive change in their workspace. These activities help foster a sense of openness, mutual respect, group participation and responsibility. Staff should be encouraged to raise concerns and be reassured that reporting and raising safety concerns will not be punitive.

3.4.14 Credentialing and Training

Institutional policies must exist for appropriate training and credentialing of personnel. This could be challenging with new technologies where there are few training programs or the technology is rarely available. Nevertheless, centers must ensure that providers are qualified to deliver any care for which they are privileged.

3.5.0 INGRAINING SAFETY INTO EVERYDAY PRACTICE

Safety and quality initiatives are often viewed as separate from routine practice. For example, QA meetings are something that The Joint Commission (TJC) requires, where the leadership reacts to events in the clinic by generating rules/policies in a hierarchical manner that are (often) ignored. This is an unfortunate historical paradigm. A preferred approach is to ingrain safety considerations into the fabric of our clinical operations, such that it is seen as a natural component of evolving clinical practice ***(Figures 3.1A and B, see page 25)***. This requires a persistent acknowledgement of safety concerns by the leadership to enable an increased mindfulness among the staff.

Figure 3.1A. Hierarchical Model

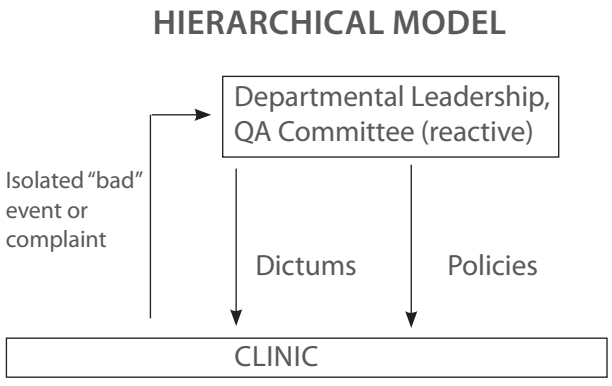


Figure 3.1B. Collaborative Model

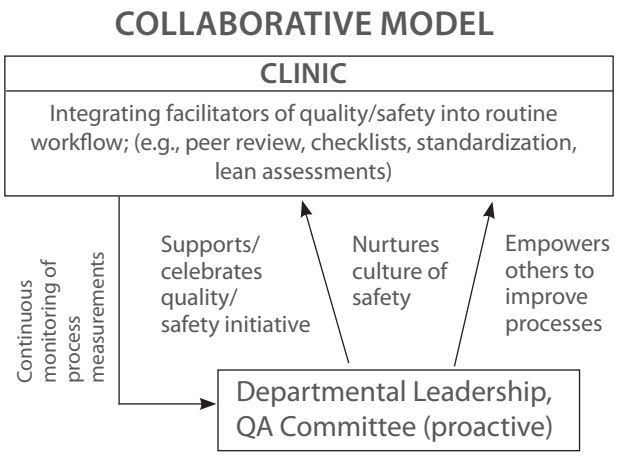
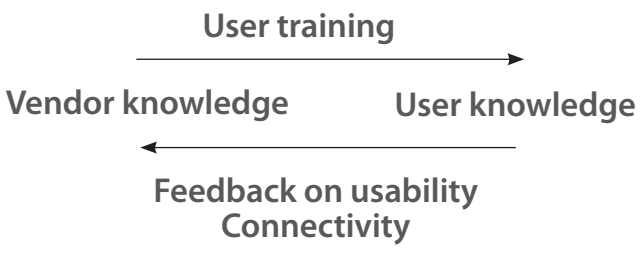


Figure 3.1. Panel A: Hierarchical model where departmental leadership and QA committee operate in a largely reactive mode where policies and dictums are "handed down" to the clinic, often in response to isolated events. Panel B: Collaborative Model where departmental leadership and QA committee proactively support and nurture a culture of safety. All staff are encouraged to become engaged in improving operations. Measures from the clinic are continually monitored to assess for opportunities for improvement.

3.6.0 COLLABORATION BETWEEN USERS AND VENDORS

The practice of modern radiation oncology requires the use of multiple commercial products. As safety becomes an increasing concern, our partnership with the vendors of these products must mature. An open exchange is needed where users and manufacturers work synergistically to maximize the likelihood of optimal outcomes ***(Figure 3.2)***. The responsibilities and opportunities are complementary.

Figure 3.2. User/Vendor Relationship



Users and vendors have a synergistic relationship that is critical for the healthy evolution of safe and useful products. The vendor needs to educate the user as to the capabilities and limitations of their products. Users need to share their concerns with the vendors and work with them to improve products.

Vendors need to create user-friendly products to maximize the probability that they are used as intended *(see section 3.4.6, Human Factors Engineering)*. Products should typically not be marketed until they are relatively free of known flaws, especially those with serious clinical implications. Vendors should be forthcoming with information about all known shortcomings of their products. This should include challenges related to the integration of their products with other vendor's products (i.e., even when the "problem" is not inherent to their product alone, but rather arises from the interaction with other products). Since these issues often only become known to the vendors as their products become more widely used, vendors need to share this information, as it evolves, rapidly with their wider user-base.

Similarly, users need to operate products in the settings and modes in which they were intended, and use care when utilization is extended to uncharted territory. Problems, both real and potential, should be reported to the vendor (and regulatory agencies as required) in a timely fashion, and with enough information (e.g., the context) to enable the vendor to make a full assessment. Users should take the time to familiarize themselves with the functionality of new/evolving products prior to their clinical implementation and communicate with the vendors so that they can work together to seek needed improvements to products.

It is important that the team tasked with managing the needs of the radiation therapy department's information technology reviews and approves any and all software or hardware that is involved in treatment planning and delivery. Vendor specifications and network connectivity requirements must be approved prior to the purchase of any new system *(see Chapter 4, section 1.6, Equipment and Devices)*. There could be logistic challenges that limit the ability for vendors to rapidly alter products (e.g., Food and Drug Administration [FDA] regulatory review, and user acceptance of "short cycle" upgrades).

3.7.0 INVOLVING THOSE BEYOND RADIATION ONCOLOGY

Cancer care is multidisciplinary and often involves surgeons, medical oncologists, diagnostic radiologists, pathologists, internists (gastroenterology, pulmonary, neurology, other), social workers and others. Communication between disciplines is challenging but exceedingly important as our treatment approaches involve multiple disciplines. Many of the initiatives and concepts described herein can, and should, be applied on a broader scale ***(Table 3.3).***

Table 3.3. Multidisciplinary Approaches to Quality in Cancer Care Delivery

Radiation Oncology Initiative	Analogous Multidisciplinary Initiative
Pretreatment team discussion	Tumor board
Daily meeting	Regular multidisciplinary meetings to review patients under treatment
Determining unambiguous methods of communication between team members in the radiation oncology EMR	Determining unambiguous methods of communication between multidisciplinary care providers in an oncology-specific or hospital-wide EMR
Safety rounds within radiation oncology	Safety rounds within cancer center
Departmental safety culture	Cancer center or hospital-wide safety culture
Discipline-specific training	Team training

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4

CHAPTER 4

Management and Assurance of Quality in Radiation Oncology

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4.1.0 QUALITY REQUIREMENTS FOR RADIATION ONCOLOGY PROGRAMS

The overall goal of the guidelines summarized in this chapter is the delivery of high quality radiation oncology treatment to all patients. Note that quality assurance is a shorthand term which is often used to describe some or all of the different aspects involved in quality management (QM) and a culture of safety.

4.1.1 Facilities

A radiation oncology facility must satisfy numerous requirements:

- General space requirements include providing adequate clinic space, exam rooms and equipment, patient waiting and changing space, convenient patient parking, treatment rooms, simulation/imaging room(s), brachytherapy source preparation and storage space (if service is offered), dosimetry and treatment planning rooms, office space for professional staff (physicians, medical physicists, nursing, etc.) and medical physics laboratory/equipment storage space. The extent of facilities should be appropriate for the volume of patients seen and treated, as well as the modalities offered.
- Treatment rooms for linear accelerators or other treatment machines (e.g., tomotherapy, cobalt, robotic accelerator systems, etc.) must be carefully designed for radiation shielding, environmental conditions, adequate storage space for spare parts, testing and dosimetry equipment, patient access and safety, while also allowing installation, testing and repair of the treatment system. Design must include video and audio patient monitoring systems, dosimetry monitors (when required), electronic cables for dosimetry, computers and other systems.
- Each department must have access to CT imaging for treatment planning. Radiation oncology CT-Simulator room designs must carefully protect staff from accidental radiation exposures, while allowing patient positioning, immobilization device implementation or fabrication. The same requirements apply to MR-Simulation rooms (when the modality is offered) with the additional requirements for the establishment of an MR safety zone.
- Rooms used for brachytherapy procedures require special attention to the specific radiation protection requirements associated with the particular brachytherapy modalities used. If the brachytherapy procedure load warrants it, a brachytherapy suite should be available, including patient waiting space, procedure rooms, recovery rooms (if necessary) and brachytherapy source preparation and storage areas, so that the entire brachytherapy process can be performed within a well-designed and controlled space, to ensure radiation protection and source control.
- Each department must have electronic access to the hospital, clinic or outside information system(s) and picture archiving and communication system (PACS), interaction with other medical specialties to insure

coordination of care as well as access to laboratory services, and other ancillary services such as social service, dentistry and nutrition for the benefit of patients during therapy.

4.1.2 Program Requirements

Each radiation oncology program must satisfy a number of general requirements.

4.1.2.1 Program Accreditation

Each radiation oncology program should become accredited by an established radiation oncology-specific accreditation program. This process will verify that crucial basic capabilities and procedures necessary for quality radiation therapy are performed, and will raise the general level of radiation oncology practice in the country.

4.1.2.2 Required Capabilities

The following specific capabilities and methods for various aspects of the radiation therapy process are essential:

- Calibration of treatment machines, CT and MR scanners, treatment planning systems and brachytherapy sources shall be carefully accomplished according to the appropriate protocols described by scientific/professional organizations.
- A safety program designed to improve patient safety, avoid radiation incidents and prevent errors in the treatment process shall be in place and periodically reviewed and enhanced.
- The system for documenting radiation therapy treatment, and other aspects of the patient's medical care ("charting") must be rigorous, periodically reviewed and enhanced, and available to all members of the radiation oncology team when needed.
- High quality and comprehensive treatment planning, using 3-D computerized treatment planning for dose calculations, imaging and other aspects of the planning process, is essential.
- A comprehensive quality management program, including quality assurance, quality control (QC) and other quality improvement tools shall be in place.
- Radiation monitoring of machinery, sources and patients (where necessary) and staff exposures are crucial.
- All radioactive sources shall be carefully controlled and monitored, as required by regulatory agencies
- A careful and pre-emptive program for maintenance and repair of equipment is essential.
- Staff training shall be comprehensive, ongoing and well documented.
- Each department shall have a well-developed strategy for peer review, for the entire department and its procedures, as well as for individual clinical care, physician and qualitative decisions made throughout the process (e.g., treatment plan quality, patient setup technique acceptability).
- Each department must have access to medical oncology, surgical oncology and other physicians involved in the multidisciplinary care of the patient, as well as access to dentistry, nutrition, laboratory testing and other supportive services necessary for patient care or handling of patient toxicity that arise during (or after) therapy.

4.1.2.3 Policies and Procedures

Each department shall develop and implement careful and well-described policies and procedures for each aspect of the process used for patient care, for QA of the patient care process, and for staff behavior, as well as those issues impacting safety for patients and/or staff. Each specific treatment (e.g., IMRT, IGRT and SBRT) should have detailed documentation of its treatment planning and delivery process, roles and responsibilities of each team member in that procedure, QA checklists and test procedures, and a plan for continuous quality improvement and safety.

4.1.3 Radiation Safety

Radiation safety, for patients and staff, is a crucial responsibility for all members of the radiation oncology department. This section documents, in brief, the technical requirements for facilities and machines that will facilitate safety.

4.1.3.1 Radioactive Source Procedures

AAPM Task Group Reports 56[50], 59[33], 138[15] and 144[72] outline safety and quality standards for the handling of radioactive sources such as those used in brachytherapy clinical procedures and QA. Safety considerations should be consistent with state and federal regulations. The radiation oncologist, medical physicist and radiation safety officer should define local radiation safety guidelines that are consistent with the ASTRO, ACR/ASTRO, American Brachytherapy Society (ABS) and regulatory brachytherapy guidelines.

4.1.3.2 Accelerator Safety

Once the treatment room is correctly designed, staff procedures for accelerator use, patient treatment and other work performed in the accelerator room must be designed to ensure patients and staff members do not receive any

unwarranted radiation exposure. A monitoring program that updates and enhances the safety of this program must be a part of the departmental procedures.

4.1.3.3 Safety for Imaging Devices

Unlike the general situation with diagnostic imaging and image guided surgery, imaging in radiation therapy adds the imaging dose to an already high level of radiation therapy. There is a strong correlation between increased imaging and improved quality of delivery of the therapeutic dose; therefore, the emphasis in radiation therapy should be on optimizing rather than simply minimizing the imaging dose. AAPM Task Group 75[38] provides guidance on optimal use of imaging and strategies for reducing imaging dose without sacrificing its clinical effectiveness.

4.1.4 Monitoring Safety, Errors and Medical Quality

One of the most crucial activities in a quality radiation oncology department is the organized review and monitoring of all aspects of safety, errors and quality. Creating a "culture of safety" depends on guidance, direction and financial means from the leadership of the institution and of the radiation therapy department; on individual effort by every member of the department; and on organized support for quality and safety at every level in the institution. This section briefly describes a few of the organization- and department-level activities that can help to create the necessary culture and awareness.

4.1.4.1 Quality and Error Monitoring

Each department should have a department-wide review committee which monitors quality problems, near-misses and errors in treatment, diagnosis, patient care or other procedural problems that might lead to errors. This committee should organize the collection and analysis of such events, work to identify potential problems in devices or processes, and then try to mitigate these problems by modifying processes or adding new checks or actions to minimize the likelihood of further problems. It is important that these kinds of safety-related efforts, data and notes be identified as peer review protected and not subject to legal discovery. Further detail can be found in Chapter 3, Safety.

4.1.4.2 Safety, Morbidity and Mortality Rounds

Radiation oncology departments must at a minimum hold rounds quarterly, or more typically monthly, to review patient morbidity and mortality, dose discrepancies and any incident reports involving an accident, injury or untoward effect to a patient. Morbidity and mortality to be reviewed should include unusual or severe acute complications of treatment, unexpected deaths or unplanned treatment interruptions. At a minimum, participants included should represent all the team members, including radiation oncologists, nurses, medical physicists, medical dosimetrists, radiation therapists and administrators. Minutes of this review should be recorded.

4.1.4.3 Minimizing Time Pressures

In order to avoid safety problems or quality lapses caused by rushing to meet unrealistic scheduling expectations, each institution should determine the appropriate process time allocated for each step in the process. ***Table 4.1*** *(see page 32)* is an example of such a record, listing basic steps in the process. It is the responsibility of each institution to develop its own guidelines for the amount of time allocated to each step in order to avoid inappropriate time pressures. The goal of this effort is to avoid safety issues caused by time pressures, while satisfying the responsibility of the radiation oncology team to set a course of action that will assure a timely, yet safe and accurate transition from patient clinical evaluation to treatment.

4.1.5 Monitoring Professional Performance

Over the past several years, there has been increasing interest on the part of public and government agencies in requirements for greater oversight for physicians and other healthcare providers. In response to the public's concerns, the American Board of Medical Specialties (ABMS) decided that all medical specialties should develop MOC programs to replace current recertification initiatives. The ABMS has defined four components of MOC: professional standing, lifelong learning and self-assessment, cognitive expertise and practice quality improvement (PQI).

Many specialty societies offer opportunities for radiation oncologists and medical physicists to satisfy the requirements of MOC. For example, ASTRO has developed online courses with self-assessment modules (SAMs) to fulfill the lifelong learning requirements and a special program called the Performance Assessment for the Advancement of Radiation Oncology Treatment (PAAROT)[76] to meet the PQI requirements. ACR has the R-O PEER program and the AAPM offers similar initiatives for medical physicists. Radiation oncologists and medical physicists should take advantage of these opportunities.

One important aspect of those programs is the use of peer review methods to help individuals learn from other practitioners in the field. Peer review is relevant in a number of different aspects of clinical practice: overall review

Table 4.1. Scheduling and Minimum Process Time (Required for Safety)

Individual institutions should create a table like this for their process(es) and circumstances, assigning appropriate values to the minimum process times ("x"). Cases identified as emergencies and other specialized techniques will require special consideration.

Process Step	Minimum Process Time Required for Safety
After imaging: Completion of target volumes, definition of plan intent, normal structure volumes; anatomy approved	x days
After anatomy approval: Planning: 3-D CRT Planning: 3-D IMRT, Volumetric Modulated Arc Therapy (VMAT) Planning: 3-D SBRT Planning: SRS	 x days x days x days x hours
Plan evaluation and physician approval	x minutes (though xx hours must be allocated to schedule this time)
IMRT QA and analysis	To be completed x hours before treatment
Treatment preparation (transfer from treatment planning system to treatment management system before treatment start)	Allow x hours
Final checks before treatment	x minutes or hours
Treatment setup and delivery (based on complexity)	x minutes

of the behavior of the practice, review of individual skills and methods, as well as the common practice of reviews of physician clinical decisions which occur at a weekly "chart rounds" type review of ongoing patient treatments. Note that peer review is a quality improvement tool that has application throughout the process of radiation therapy (see, for example, the Safety White Paper on Peer Review [77]).

4.1.5.1 Ongoing Monitoring/Evaluation of Staff Qualifications

It is equally important that the other members of the radiation oncology team have proper credentials and training in the simulation, treatment planning, treatment delivery and QA processes of each specialized treatment technique. The staff should also be appropriately trained to use each specific device.

Radiation oncology is a technologically demanding field which is dependent on well-trained and highly-skilled members of the radiation oncology team, as described earlier in this report. It is crucial that all members of the team maintain the proper credentials, skills and training levels, satisfying clinical competencies annually. In some cases (for example, radiation therapists moving between different kinds of treatment machines), additional training or review sessions in the use of specific devices may be necessary more often than annually. Each facility should follow the ASTRO recommendations and ensure that the staff have opportunity to maintain continued competence in their job responsibilities. See, for example, the roles, responsibilities and training requirements for each staff member described in the recent Safety White Paper on IMRT[37].

4.1.6 Equipment and Devices

Radiation oncology is a highly technical field which relies on computer-controlled treatment machines, interconnected imaging, delivery and planning systems and important ancillary equipment. This section describes general requirements for radiation oncology equipment and systems, including guidance on system-specific quality assurance. Further patient- and process-oriented quality measures and QA are described later.

4.1.6.1 General Guidance

For any device, system or process to be integrated into the radiation oncology care process, many of the same general methods and issues must be addressed, as described here.

System Specification, Acceptance Testing, Clinical Commissioning and Clinical Release: Any new radiation therapy system should go through the following process as it is prepared for clinical use:

- ***System Specification:*** To prevent later safety or effectiveness problems, each system should be carefully specified before acquisition, purchase or development, including design, expectations, capabilities, tolerances, hazards, necessary training, usability and technical specifications.
- ***System Connectivity:*** To prevent data communication errors and clinical efficiency issues, each system must be interoperable and interconnectable with other systems in the clinic. Integrating Healthcare Enterprise-Radiation Oncology (IHE-RO) compliance can help ensure interoperability and interconnectivity of devices in the clinic.
- ***Acceptance Testing:*** To document that the new system satisfies the specifications, acceptance testing must be performed. Often, the acceptance criteria and/or testing methods should be documented as part of the specification for the system.
- ***Clinical Commissioning:*** All the activities that must be performed to understand, document, characterize and prove that a given system is ready to be used clinically are included in clinical commissioning. Determination of the limitations under which the system can be used safely is one of the important parts of the commissioning process. Such commissioning should be dependent on the clinical use(s) of the system, and typically is not a static thing that can be done only once, since clinical system use usually evolves and changes with time and clinical needs. Standard operating procedures, training and hazard analysis should be part of the commissioning process.
- ***Clinical Release:*** Each new system, device, capability and process must be formally released for clinical use after clinical commissioning has been completed.

Device, System or Process QA: Clinical use of a device, system or process must be included in the creation and application of a safety- and quality-oriented program which helps assure that the system is working appropriately and as desired. This kind of program has many aspects:

- ***Quality Management:*** QM, the overall program that aims to organize all the quality efforts appropriately to assure the quality and safety of the use of the system, must be established for each new system or process. The QM program should include hazard analysis, quality control, quality assurance, training and documentation, and ongoing quality improvement efforts.
- ***Hazard analysis:*** Hazard analysis, the active evaluation of the potential for failures that will cause incorrect results or harm to the patient, should be performed in some fashion for any new system, as it will help delineate issues which can benefit from QC, QA, training or other mitigation strategies. The methodologies, such as failure mode and effect analysis (FMEA), that are prevalent in the industrial world are being adapted for process and quality improvement in healthcare. The Joint Commission now requires every hospital to use FMEA as one means to improve its processes.
- ***Quality Control:*** QC includes activities that force specific quality on a process. It entails the evaluation of actual operating performance characteristics of a device or a system, comparing it to desired goals and acting on the difference.
- ***Quality Assurance:*** QA includes all activities that demonstrate the level of quality achieved by the output of a process. QA checks, along with QC, are essential parts of the QM for most devices and systems, as they can check the output of potentially complicated decisions or actions performed by the system. The choice of QC, QA or other methods depends on how to prevent errors most efficiently. Note that QA is the typical shorthand term used throughout the field to describe the entire QM program, not just the quality assurance aspect.
- ***Training and Documentation:*** Training of staff in goals, methods, results, operation and evaluation of the quality of output can be very important in proper use of any system. Documentation of appropriate operating procedures is also critical, so new staff can be trained. Both training and documentation should be updated often. In particular, it is often necessary to perform retraining of staff after time away from a system, or to refresh current knowledge.

The QM program for each system, device or process should be individualized to attain the most effective safety and quality as efficiently as possible. Adequate time and resources should be allocated for the QA/QC/QM program. Maintenance programs (below) are another important part of any QM program.

Maintenance: All systems, devices and processes require routine maintenance. While most people are familiar with the maintenance needs of mechanical devices, electronics and software, processes also need routine maintenance, though the specifics of the maintenance required are different:

- ***Mechanical systems:*** Routine mechanical and preventative maintenance programs are crucial to prevent major component failures, and are safety critical, as failures can lead to major potential safety problems.
- ***Electronic systems:*** Preventative maintenance in electronic systems can involve monitoring parameter values and behavior to look for components of the device that are beginning to fail or show undesirable behavior.
- ***Software systems:*** Since software is never completely bug-free, and the use of the system can evolve as experience is gained, maintenance in the software context often involves the installation of new versions of the software. This new version can be a simple "bug-fix" version with no planned new functionality, or it can be a major version upgrade with major new functionality and/or internal structure. Any new version (minor or major) can contain significant new problems that can be unrecognized before the commercial release of the software, so these upgrades can involve new testing, commissioning, QA and training as part of the release of that software. It is crucial to investigate the scope of any new software upgrade, and to design appropriate commissioning, QA and training to assure the safety of the clinical use of that new system.
- ***Processes:*** All processes evolve as they are used clinically. This evolution therefore changes the potential failures that the process may be sensitive to, so the QM program associated with that progress must be modified (maintained) just as other systems require maintenance.

Adequate time, materials and resources must be allocated for the maintenance program of all systems and devices.

Interconnectivity and Interoperability of Devices and Systems: Nearly all major pieces of radiation oncology equipment are computer-controlled or software-based devices, and they are virtually all interconnected. The safety and quality of any therapy planned or performed with this system of interconnected devices is crucially dependent on the accuracy and completeness with which the various devices communicate data, commands and the overall process which is being performed. Any flaws in the communication protocols, interfaces or underlying system designs can allow errors, most of which will be systematic errors that will always occur given a specific set of circumstances. These errors can be nearly impossible to find without specific formal hazard analysis and directed testing.

A concerted program directed toward rigorous testing and documentation of the accuracy and correctness of computer system interconnections, interfaces and interoperability must be used for all systems involved in radiation therapy. The IHE-RO program is one effort to address this need, but each institution should evaluate and implement QM/QA/QC testing programs to confirm that interconnected systems used in their center are correct and safe. IHE-RO compliance should be part of this testing.

External Review: Single points of failure, or extremely unlikely combinations of errors, can happen to anyone or any institution. Independent review of crucial aspects of any quality program is an extremely effective way to avoid those highly unlikely or single point failures, and should be used wherever practical.

The intersociety group recommends the creation of mechanisms to support the following independent/external reviews:

- Basic treatment machine calibration should be confirmed before clinical use and annually thereafter by a nationally-available program (similar to the radiological physics center [RPC] remote monitoring program).
- Special treatment techniques (including IMRT, SBRT, SRS, IGRT, intraoperative radiation therapy [IORT] and others) should undergo external peer review initially and at regular intervals to maintain "competency" in that technology.
- Review of treatment planning system implementation and use should happen initially and at regular intervals. Comparisons can be detailed, as performed by the RPC, or more limited comparisons performed with the appropriately designed plan comparison strategies, including use of similar machine data and calculation methods.
- Treatment protocols and standard operating procedures should be peer reviewed by an external radiation oncologist every five years (as part of accreditation).
- Many more aspects of a radiation oncology program will benefit from similar review, including the device calibration and QA program, clinical protocols and nursing support.

Equipment Replacement, Upgrades and Additions: Radiation therapy devices require replacement or upgrades when they become technologically obsolete or worn out. For example, the average life of a linear accelerator is typically 8-10 years if: the equipment is properly maintained; replacement parts are readily and economically available; and the operational characteristics and mechanical integrity meet performance and safety standards. On the other hand, treatment planning systems require replacement or upgrade when the hardware becomes obsolete or the software functionality limits its ability to satisfy the current standard of care.

Beyond its useful working life, a treatment planning and/or delivery system needs to be withdrawn from clinical service if it cannot be upgraded to warranty status, even if it is not technologically obsolete. This periodic replacement and renovation of equipment is necessary not only for quality care, but for patient and personnel safety and efficient economical operation. Equipment replacement must be justified based on departmental and institutional, not geographical or political, needs.

Furthermore, the need for additional equipment in a specific facility should be based upon an increasing number of patients requiring treatment, changing complexity of treatment or addition of a new specialized service. An increased commitment to clinical research and teaching is another reasonable justification for equipment addition.

4.1.6.2 External Beam Treatment Machines

Minimum Device Requirements: State-of-the-art radiation oncology facilities require a standard treatment delivery platform to deliver 2-D and 3-D conformal external beam radiation therapy and IMRT. Standard features include one or more photon energies, multiple electron energies, multileaf collimator (MLC), electronic portal imager and a computerized treatment delivery and management system. The equipment capabilities should be sufficient to provide a continuum of care for patients. As an example, it is unrealistic to assume that all patients needing electron beam therapy will be specifically referred to an "outside" facility for that purpose. However, there is also justification for the establishment of specialized care facilities for complex circumstances, like treatment of pediatric cases, radiosurgery and proton therapy. These types of centers can provide focused expertise in certain complex treatment delivery techniques that may require special considerations in terms of staffing and training. Professional and scientific organizations in the United States (AAPM, ACR, American College of Radiation Oncologists [ACRO] and ASTRO) have established practice guidelines/standards that outline accepted processes related to these complex techniques. Referral of patients to such facilities for specialty care should be supported and encouraged.

Minimum QA Requirements: The bulk of radiation therapy treatment is performed with external beam machines (linear accelerators, tomotherapy, robot accelerator systems, etc.). A complete quality management program is essential for each device, and should include routine quality assurance and quality control procedures, monthly and annual testing, as well as a hazard analysis of the treatment process used for that machine to identify procedural problems in addition to the technical or mechanical issues that the QA/QC checks address. Current quality expectations are described in detail by well-known guidance documents ***(Table 4.2)***. Modern techniques such as IMRT and IGRT have become the standard of care for the treatment of a wide variety of disease sites. The basic QA/QC and clinical practice guidelines for these procedures are also well documented ***(Table 4.2)***. Newer IMRT delivery techniques such as VMAT and Flattening Filter-Free (FFF) treatment delivery do not have published guidelines. Therefore, it is the responsibility of medical physicists (along with other members of the radiation oncology team) to evolve and modify existing QA programs to make them as effective as possible for the clinical treatments

Table 4.2. Basic External Beam QA Requirements

Name	Issue	Recent Summary	References
Linac + MLC	Linear Accelerator Use	TG 40 + TG 142. TG 148 (tomotherapy), TG 135 (robot accelerator)	[32], [31], [34], [16]
3-D CRT	3-D Conformal Therapy and Treatment Planning	ACR 3-D, TG 53	[1], [20]
IMRT	Intensity Modulated Radiation Therapy	IMRT Safety White Paper	[37] and references therein
IGRT	Image Guided Radiation Therapy	IGRT Safety White Paper	[30] and references therein

performed in that institution, as well as to deal with evolution of the technology and capabilities of the equipment.

4.1.6.3 Brachytherapy Devices

Minimum Device Requirements: Due to its century-long record of clinical implementation, the field of brachytherapy has grown into a subspecialty, having devices developed specifically for each disease site. Still, there are frequent advances that move the field forward and permit improved local control rates and/or minimized healthy tissue toxicities. It is not feasible to outline the minimum standards for devices used for every current disease site. However, the expected minimum standard is to provide at least the same current level of safety and capability as existing devices. New capabilities that supersede existing capabilities are required for new brachytherapy devices.

Minimum QA Requirements: The AAPM and other radiation therapy professional societies have prepared reports issuing quality standards for the sources and devices used for brachytherapy. ***Table 4.3*** indicates the associated reports providing guidance for these sources and devices.

4.1.6.4 Imaging Devices

Minimum QA Requirements: Numerous imaging devices are crucial to the radiation therapy process, including diagnostic systems used for development of the treatment approach and plan (e.g., CT, MR, PET), as well as systems used during treatment for patient setup, positioning, alignment, motion assessment and IGRT (e.g., megavoltage portal imaging, kilovoltage imaging, cone beam CT [CBCT] and numerous alternate technologies). Finally, the advent of adaptive and individualized approaches to the treatment course, based on serial CT and/or MR imaging, as well as functional MR, PET and Single Photon Emission Computed Tomography (SPECT) images, has led to new QA requirements for the use of these systems within the radiation therapy treatment course.

- Diagnostic systems used in radiation therapy (CT, MR, PET) must satisfy the usual diagnostic QA requirement[85, 84], but must also satisfy the more stringent geometric requirements forced by the use of the images for patient and beam geometry. Additional testing for this issue is recommended.
- QA for the kV and MV imaging systems which are used for patient localization, setup and motion assessment is well described by recent reports[86-91], as well as the recent ASTRO IGRT Safety White Paper[30] and the ACR/ASTRO IGRT Standard of Practice[2]. It is essential that the recommendations of these reports be used, but they should be modified to appropriately handle the specific requirements of the IGRT or other positioning techniques used in each institution, paying close attention to the tolerances which the entire process allows.

Table 4.3. Brachytherapy Devices

Brachytherapy sources or devices	References
Radiation sources	
General	[48], [32], [49]
HDR and pulsed-dose-rate remote (PDR) afterloaders	[50], [70], [15], [23]
LDR sources	[33], [51]
^{90}Y unsealed sources	[72]
Electronic brachytherapy sources	[74], [53]
Liquid radioactive sources (Iotrex)	[73]
Intravascular brachytherapy (IVBT) sources	[52], [13]
Applicators	[50], [73]
Hardware	[50]
Imaging devices	[50]
Treatment planning systems and dose calculation processes	[48], [32], [49], [20], [50]
Survey instruments, badges, radiation safety	[48], [32], [50]

- The use of functional and metabolic imaging as part of the adaptive treatment process is a technique which is just developing now, so many changes are expected. For each specific metric, biomarker and/or decision process used for adaptive treatment strategy changes, the sensitivity, repeatability and tolerances of the metrics with respect to their clinical use must be considered as specific QA methods are developed.

4.1.6.5 Treatment Planning Systems

Minimum Device Requirements: 3-D computerized treatment planning based on CT data is the minimum state-of-the-art for modern radiation therapy. Safe and effective use of planning requires direct input of CT, MR and other imaging information; the capability to define (by contouring and other segmentation) 3-D anatomical objects (targets and normal tissues); beams and/or radioactive sources defined in 3-D; well-characterized and accurate dose calculations; dose-volume histograms (DVHs) and other plan evaluation metrics; and electronic downloading of treatment plan information to the treatment management system. Many special treatment techniques require specific and sophisticated use of additional planning capabilities, as described in **Table 4.4** *(see page 38)*.

Minimum QA Requirements: Computerized treatment planning is an essential requirement of virtually every radiation therapy treatment, so the quality assurance of the planning system and of the process in which it is used is crucial. AAPM TG 53 [20] provides a general guidance to all the issues which must be addressed in order to use modern treatment planning in a safe and appropriate way, including discussion of acceptance testing, clinical commissioning, routine QA, training, dosimetric and nondosimetric testing, and more, while more specialized technique issues are described in **Table 4.4**. Specific discussion of dose calculation algorithm issues is described by a number of reports, including the recent TG 105 on Monte Carlo treatment planning issues [92].

4.1.6.6 Treatment Management Systems (TMS)

Minimum Device Requirements: State of the art radiation therapy involves the use of a computerized treatment management system (TMS) which manages treatment delivery and/or all the treatment preparation and planning steps involved before treatment. These systems, evolved from record and verify systems which were used to check manually set treatment parameters on "analog" treatment machines, now involve 1) an information system piece (sometimes called an "RT-EMR") which includes database(s) storing patient demographics, planning and treatment delivery data, applications used to create/modify/edit and manage the data, as well as some procedural and workflow tools, and 2) a treatment delivery system that directly manages the flow of activities during treatment delivery, as well as patient setup, imaging and IGRT, treatment verification and other activities that happen during each fraction of a patient's treatment. The TMS communicates with the departmental network, hospital EMR, other ancillary treatment setup, verification, dosimetry and scheduling systems.

Minimum QA Requirements: The TMS is one of the newest and most quickly evolving systems involved in radiation therapy. As such, the quality management program, which should be associated with safe use of the system, is less well-described and understood than almost any other system. A few of the crucial QA issues for TMS that have been published are listed in **Table 4.5** *(see page 39)*, however, new efforts to develop improved guidance in this area are needed.

4.1.6.7 Particle Therapy

Minimum Device Requirements: Particle therapy is another contemporary form of radiation therapy that has its own unique challenges. The precision and accuracy of both the treatment planning and delivery of proton therapy are greatly influenced by uncertainties associated with the delineation of volumes of interest in 3-D imaging, imaging artifacts, tissue heterogeneities, patient immobilization and setup, inter- and intrafractional patient and organ motion, physiological changes and treatment delivery. Furthermore, the locations, shapes and sizes of diseased tissue can change significantly because of daily positioning uncertainties and anatomical changes during the course of radiation treatments. To ensure safe and accurate treatment planning and delivery of particle therapy, minimum device requirements include on-line image guidance, a robotic couch capable of six degrees of motion (three translations plus pitch, roll and rotation), a robust immobilization system, a computerized TMS to manage treatment preparation and delivery, and adequate QA equipment.

Minimum QA Requirements: Particle therapy does not currently have QA guidelines published by our national scientific organizations, though there are AAPM task groups at work on aspects of proton therapy QA. Therefore, it is the responsibility of medical physicists (along with other members of the RT team) to evolve and modify existing QA programs to make them as effective as possible for the clinical treatments performed with a particle therapy system, as well as to deal with evolution of the technology and capabilities of the equipment.

Table 4.4. Additional Treatment Planning Requirements

Technique	Requirement	References
IMRT	Automated optimization, cost function creation, MLC sequencing (or equivalent delivery script creation)	[19], [37], [25]
SBRT	Preparation of IGRT reference data (annotated digitally restored radiographics [DRRs], or reference data for CBCT comparisons)	[64], [10], [6], [58]
SRS	Integrated use of stereotactic frame coordinate systems, integrated use of specialized radiosurgery applicators and arc delivery	[5]
VMAT	Field and MLC optimization capabilities for specialized IMRT arc therapy delivery, including delivery constraints	[69]
Use of MRI, PET, etc.	Requires image dataset registration and fusion of imaging information	[20], [71]
NTCP and Biological Modeling Features	Clinical use of normal tissue complication probability or other biological modeling information requires appropriate algorithms and especially the relevant clinical data. Specifically note the recent Quantitative Analysis of Normal Tissue Effects in Clinic (QUANTEC) project publications [80].	[80], [36]

4.1.6.8 Specialized Techniques and Devices

Advances in imaging, computer science and information technologies, coupled with the development of sophisticated radiation delivery systems, have resulted in a plethora of specialized radiation therapy techniques and devices. Robotic radiation delivery systems, SRS, SBRT, IORT, electronic brachytherapy, motion and setup management devices and unsealed radiopharmaceutical sources are some of the examples of such specialized techniques and devices. Each of these techniques and devices have unique performance and QA requirements that should be critically evaluated before they are introduced in the clinic. Issues that should be considered include: reason(s) for device/technique introduction and use; minimum requirements to use device safely (including an adequate team both for the planning and delivery process, *see section 4.2.2.2*); description of how device is to be introduced; necessary training; and need to compare results with current clinical standard with respect to clinical objectives for use and outcomes.

Often, but not always, the introduction of specialized techniques and devices prompts professional organizations such as ASTRO, AAPM and ACR to develop clinical/QA guidelines. For example, ACR and ASTRO already have practice guidelines for the performance of IMRT, IGRT, SRS, SBRT, total body irradiation (TBI), electronic brachytherapy and therapy with unsealed radiopharmaceutical sources. AAPM also has QA task group reports on most of these specialized techniques and some devices. However, the development of these guidelines and recommendation usually lag behind their clinical implementation. Therefore, it is incumbent upon the early adopters of emerging technologies and techniques (radiation oncologists and medical physicists) to develop clinical procedures and QA programs that can ensure safe and efficient use of specialized techniques and devices in the absence of published guidance documents.

4.2.0 PATIENT-RELATED QUALITY MANAGEMENT

Concentration of QA efforts and scrutiny of the devices and processes involved in radiation therapy address only one aspect of the overall problem. Within the complex and many-step process with which radiation therapy patients are treated, patient-specific issues must be carefully and comprehensively analyzed, documented and verified.

Table 4.5. Treatment Management and Delivery System Issues

Safety/Quality Issue	Recommendations	Reference
Computer-controlled delivery	Acceptance test procedures for new software and/or control features should be designed to test software and control aspects of the system. Safety interlocks and new functionality should be tested in accordance with vendor documentation and testing information	[59]
Software upgrade testing	Routine updates of software for a computer-controlled machine should be treated as if it includes the possibility of major changes in system operation. All vendor information supplied with the update should be studied carefully, and a detailed software/control system test plan created. All safety interlocks and dosimetry features should be carefully tested, regardless of the scope of the changes implied by the update documentation.	[59]
System interconnectivity	IHE-RO protocols	[81]

4.2.1 General Guidelines

4.2.1.1 General Medical Issues

Each radiation oncology facility, regardless of its location, size or complexity, must appropriately manage and adhere to high quality standards of practice for general medical issues, including:

- Drug allergies
- Do-not-resuscitate codes
- Cleanliness and efforts to reduce infection
- Patient confidentiality and security of protected health information

4.2.1.2 Multidisciplinary Physician Conferences and Multidisciplinary Clinics

Modern oncology patient care very often involves multiple modalities and requires the review and discussion of experts in various oncology-related disciplines. It is critical that many types of cancer, and most complex cases, are addressed by the appropriate mix of disciplines. Regular presentation of these cases to multidisciplinary physician conferences (conventional tumor boards or prospective disease-site treatment planning conferences) is one standard of care, and should be performed for most cancer cases to determine the appropriate combination (and coordination) of therapies for each individual case. An alternate approach is to have patients seen in traditional or virtual multidisciplinary clinics by various specialists (surgeon, radiation oncologist, medical oncologist) in concurrent or sequential fashion (see The Advisory Board Oncology Roundtable, 2008 on Multidisciplinary Cancer Clinics).

4.2.1.3 Quality and Safety in Patient Care Process

The process of patient care in radiation oncology departments varies between institutions, and depends on the specific organization and details of each department. However, maintenance of the safety and quality of the radiation therapy process for most patients requires that a number of procedures must be performed adequately. Guidelines regarding many common radiation oncology procedures are addressed in the ACR Practice Guideline for Radiation Oncology[94]. These SOPs include:

- ***History and Physical (H/P):*** It is essential for the radiation oncologist to obtain a clear, accurate and detailed description of the patient's history, current status and medical issues so that appropriate radiation therapy decisions are made. The H/P information must be available to others who interact with the patient so they can make informed and appropriate decisions.

- ***New patient conference:*** In most departments, a brief presentation of the details of each patient's H/P, disease status and plan for therapy to the other physicians and staff involved in patient care is used as early peer review for the basic treatment decisions and plan.
- ***Multidisciplinary physician conferences (tumor board/prospective disease-site treatment planning conferences) or multidisciplinary disease-site clinics:*** As previously mentioned, discussion in a multidisciplinary physician conference or evaluation in concurrent or sequential multidisciplinary clinics is essential for many patients' cases.
- ***CT-Simulation:*** Virtually all patients who receive non-superficial radiation therapy should receive a CT-based simulation.
- ***Contouring/contour review:*** After the physician defines target volumes and normal organs/tissues, this anatomical description of the patient should be reviewed and confirmed (by physician, with peer review if possible) before treatment planning begins.
- ***Plan evaluation and approval:*** After treatment planning, the physician and members of the planning team must review the plan, verify that it satisfies the clinical requirements and prescription(s) from the physician, and that it can be carried out accurately.
- ***On-treatment visits:*** For most patient care, on-treatment visits of the patient to the physician are essential for continuity of care and monitoring of patient response and toxicity. Typically, this happens approximately every five fractions at a minimum, but clinical circumstance may require more frequent visits.
- ***Patient chart rounds:*** Traditionally, chart rounds is an important peer review procedure used throughout radiation oncology, involving weekly review of patients under treatment by the radiation therapy team, including multiple physicians, radiation therapists, nurses, medical dosimetrists and medical physicists. The ongoing review of patients under treatment is crucial, and many institutions are attempting to develop improved methods for both peer review and technical quality assurance techniques. See, for example, the ASTRO Safety White Paper on Peer Review[77]. Note that for small or remote centers, electronic peer review or other collaborative method from other locations may be necessary.
- ***Follow-up visits:*** Patient follow-up visits are crucial to clinical patient management and to gather treatment outcome information. Newer processes, including patient-reported outcome reporting, are in development. The frequency and method of follow-up are specific to each type of cancer, stage and clinical status of the patient. Patients would preferably have a component of their follow-up performed in the office(s) of the treating radiation oncologist by either the radiation oncologist or a nonphysician provider so that the most accurate information is obtained with regard to both treatment tolerance and disease status (free of disease; local, regional or distant relapse).

4.2.1.4 Charting and Documentation

In a highly technical field like radiation oncology, documentation of all the relevant details of the overall plan for patient care, including the technical details of all procedures as well as the clinical trade-off decisions and compromises that led to decisions about the treatment course, are crucial. Maintenance and improvement of the quality and accessibility of the documentation of patient's treatment strategy and delivery is a high priority.

Radiation oncology is currently involved in the transition from paper charts to EMRs and a paperless environment, so many of the old standards of care are being revised or completely changed to handle the new EMR environment. Radiation oncology departments, practices, vendors and everyone else in the field must continue to improve the design, implementation and effectiveness of electronic documentation for radiation oncology care, changing processes and quality management strategies to address the fundamental change and the kinds of errors or misunderstandings that may commonly occur with electronic systems.

Currently, there is significant emphasis on behalf of governmental bodies and regulations attempting to push the health enterprise toward improved use of EMR technology. The radiation oncology team should make use of EMR technology to enhance patient care coordination, as required by the recent HITECH ACT[78].

4.2.1.5 Outcome Assessment

Performance status and organ function prior to treatment should be assessed in many clinical circumstances to determine baseline status. Thereafter, routine and consistent assessment of patient outcomes and toxicity should occur both during and after treatment. This is a crucial aspect of quality radiation therapy treatment, and must be performed in a systematic way, preferably in the treating physician's office, as noted in section 4.2.1.3. Changes in patient response to treatment may identify large or even subtle changes in technique, equipment performance or clinical decision strategies, and are a valuable independent check on the success of the overall quality management system for the institution. Standard toxicity scoring schemes (e.g., RTOG, European Organisation for Research and

Treatment Center [EORTC] or similar) should always be employed when applicable. Departments should consider the collection of "Patient Reported Outcomes" as another aspect of outcomes assessment since these valid instruments have come into common use. These results can also be linked with physician quality reporting systems (PQRS) as they become available.

4.2.1.6 Outcomes Registry

In addition to the assessment of outcomes by each individual institution for their local QA, reporting clinical patient outcomes, such as treatment-related toxicity and control rates, to a shared registry serves an important role in the development of the "Rapid Learning Health System"[93]. Registries also serve to identify variations in technique, physician methods, process of care, patient selection and various other confounding variables that will allow for improvement in radiation oncology treatment. Outcomes data will be most accurate if obtained in the treating physician's office (radiation oncologist, NP or PA), as noted in section 4.2.1.3.

4.2.2 External Beam Quality Assurance (QA)

4.2.2.1 General Guidelines

QA for the Standard External Beam Process: Nearly all external beam treatment processes involve the following steps, each of which must be carefully confirmed as part of the patient-specific QA process: determination of patient setup position and immobilization; cross-sectional imaging (CT-Simulation); creation of the anatomical model (contouring); specification of the treatment intent; creation of the planning directive and treatment prescription by the physician; computerized treatment planning and dose calculation; monitor unity (MU) calculation and/or IMRT leaf sequencing; plan and electronic chart preparation; plan evaluation; download to TMS; patient-specific QA typically performed for IMRT, SRS and SBRT; patient setup and delivery; plan verification checks; plan adaptation and modifications; chart checks; and more. See for example[1, 3, 25, 37] and many other references. **Table 4.6** *(see page 42)* describes a standard set of quality assurance process steps commonly used to help prevent errors or loss of quality in most standard external beam treatment processes. The sequence of these steps may vary depending on clinical presentation and circumstance.

Commissioning and QA of the Treatment Planning and Delivery Process: Commissioning and quality assurance of the process used for planning and delivery of treatment to each patient is just as crucial as the commissioning and QA for the systems used as part of that process. After testing each component of the clinical system, it is essential that the full process be considered, tested and finally released after commissioning has been completed. Commissioning of a clinical process typically should include the following:

- Commissioning and testing of each individual component of the process
- Evaluation of the potential failure modes of the process using a hazard analysis or similar technique to look for potential weak points in the process
- Directed testing of the interfaces between systems (for example, testing the download connection from treatment planning to the treatment management and delivery system)
- End-to-end testing for representative treatments, performing the entire process, with dosimetric or other quantitative tests that can be evaluated at the end of the test to confirm accurate delivery of the planned treatment
- Review and identification of QA tests or other process changes which can prevent or mitigate the most likely failure modes of the process
- Identification of quality metrics which can be monitored to ensure that the process is performing as designed and which can help identify problems in the process

4.2.2.2 Technique-Specific Issues

There are a variety of specialized techniques in radiation oncology that are used in appropriate clinical situations (3-D CRT, IGRT, IMRT, SRS, SBRT, TBI, partial breast irradiation [PBI], IORT). Details regarding recommended clinical practices and quality assurance parameters, developed by expert panels, are covered in documents from ASTRO, ACR and other professional organizations. The reader may consult these documents for more comprehensive information ***(Table 4.7, see page 43)***.

3-D Conformal Radiation Therapy: Clinical requirements for appropriate use of 3-D CRT include:

- Experience with dual photon energy linear accelerators with electron beams, radiographic imaging and megavoltage imaging devices
- Clinical experience with use of CT scanner equipped with CT-Simulation software and laser alignment devices
- Knowledge and experience with 3-D treatment planning software, including the ability to contour target(s) and adjacent critical structures and ability to perform volumetric dosimetric analysis with DVHs
- Experience with design and use of beam shaping devices (including cerrobend blocks or MLCs)
- A radiation oncology team (physician, medical dosime-

Table 4.6. General Clinical QA Guidelines

This table describes optimal quality assurance process checks which are commonly used during routine radiation therapy. There are a wide variety of times when these checks are performed. This table describes the timing that is likely the most efficient.

Subject	Checks Performed By	Tasks	Most Efficient Timing
Overall treatment strategy	Radiation Oncologist Peer Review, Multidisciplinary Physician Conference/ Clinic	Review of patient case, clinical issues, possible treatment strategies, overall patient treatment strategy to be pursued; peer review of general treatment strategy	Before planning process
Planning directive	Radiation Oncologist, Medical Dosimetrist, Medical Physicist	Describe plan intent, target volumes, dose expectations, normal tissue limits, other treatment constraints or goals; peer review of goals and limits is important.	Before planning process
Approval of volumes	Radiation Oncologist, Medical Dosimetrist, Medical Physicist	Verify accuracy and appropriateness of target volumes (including GTVs, CTVs, PTVs, ITVs (per ICRU-50 [52], ICRU-62 [53], and ICRU-70 [54]) and critical normal tissues; peer review of target volumes and decisions is important.	Initial step of planning process
Treatment prescription accuracy	Radiation Oncologist, Medical Dosimetrist, Medical Physicist	Define dose fractionation techniques and dosimetric constraints	Before final plan checks
Treatment plan quality	Medical Dosimetrist, Medical Physicist	Verify beam designs, dose calculation parameters and reasonability of dosimetric results; check evaluation metrics for correctness and compare to plan directive; peer review of plan adequacy, quality and complexity is important.	Before final physics and physician review, before plan preparation for treatment
Treatment plan approval	Radiation Oncologist	Approval of treatment plan	Before final checks and clinical use
MU calculation	Medical Physicist	Verify accuracy and appropriateness of MU calculation.	After plan approval; before plan download to TMS
Patient-specific QA checks	Medical Physicist	Dosimetric (for example, IMRT) or geometric patient-specific checks of plan data, delivery accuracy, etc.	Typically, day before treatment starts
Preparation and download of electronic plan	Medical Physicist	Verify plan information has been prepared correctly and downloaded accurately from treatment planning into TMS.	Recommended at least 1 hour before treatment, as last minute difficulties are a potentially serious problem
Day 1 Treatment verification	Radiation Oncologist, Medical Physicist, Radiation Therapist	Specific Day 1 verification methods, including portal imaging, patient SSD measurements, etc.	For each changed plan
Daily treatment verification	Radiation Therapist	Standard daily treatment protocol (includes patient identification, setup, prescription check, etc.)	Daily as part of each fraction
"Weekly" chart checks	Medical Physicist	Formal procedure for chart check, including dose tracking, prescription, plan parameters, etc.	At least every 5 fractions (standard fractionation), as often as daily for few fraction SBRT
Final check	Radiation Oncologist, Medical Physicist, Medical Dosimetrist	Verify accuracy and completeness of the record of the patient's treatment course, including the physician's summary	For each patient

trist, medical physicist) with anatomic knowledge and the ability to contour structures correctly, as well as to interpret DVHs and other plan evaluation metrics
- Appropriate use of patient positioning and immobilization devices (mask, alpha cradle, etc.) to allow reproducible patient positioning
- Planning system dose calculations accurately reproduce beam characteristics and include sophisticated heterogeneity corrections
- Physician must have appropriate knowledge of normal tissue tolerances in order to make good plan optimization choices
- If MR, PET or other imaging is used for planning, software and clinical knowledge, combined with experience with image dataset registration and information fusion, is essential.

Intensity Modulated Radiation Therapy: IMRT is a highly technological method that can be used to deliver highly conformal therapy. In addition to the requirements (above) for 3-D conformal therapy, IMRT also requires the following:

- The machine must be equipped with IMRT capability, including segmental MLC or dynamic MLC delivery of modulated beam intensity (compensators are also possible).
- The IMRT planning and delivery system must be carefully characterized and clinically commissioned, and techniques for routine patient-specific IMRT QA must be implemented, tested and characterized so that accuracy of individual patient IMRT plans is confirmed.
- The treatment delivery system must be used with computer-controlled delivery and verification of the IMRT plan for each treatment fraction.
- The radiation oncologist and planning team must have extensive knowledge of anatomy for structure delineation and normal tissue tolerance, as well as detailed experience creating optimized IMRT treatment plans.
- IMRT QA and QC program and devices are crucial, as well as direct oversight of the QA processes by the physics staff.

Image Guided Radiation Therapy: IGRT has become an important part of modern radiation oncology, and its utilization is growing each year. The ACR guideline on IGRT[57] and the recent IGRT Safety White Paper[30] summarizes all the recent safety and quality guidance on the use of IGRT processes in the clinic.

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy: SRS and SBRT are techniques that deliver high radiation doses in a small number of treatment fractions (typically 1-5). While single fraction SRS is typically confined to the brain and spine, clinical data on the use of few fraction SBRT to sites in the body has been growing. Both SRS and SBRT use multiple photon beams, carefully shaped to the target and delivered with high precision, often with high precision IGRT guidance (SBRT). Practice guidelines from the ACR and ASTRO [5, 6, 58] have been published, and guidance on technical aspects of the treatment process have been described in AAPM reports including TG 101[10]. The recent Safety White Paper on

Table 4.7. General Procedure Guidelines

Specialized Technique/Modality	Organization	Reference #
3-D External Beam and Conformal Radiation Therapy (EBRT, CRT)	ACR/ASTRO	[1]
Image Guided Radiation Therapy (IGRT)	ACR/ASTRO ASTRO	[2], [57] [30]
Intensity Modulated Radiation Therapy (IMRT)	ACR/ASTRO ASTRO	[3], [25] [37]
Stereotactic Radiosurgery (SRS)	ACR/ASTRO ASTRO	[5] [63]
Stereotactic Body Radiation Therapy (SBRT)	ACR/ASTRO ASTRO	[6], [58] [78]
Total Body Irradiation (TBI)	ACR/ASTRO	[7]
Partial Breast Irradiation (PBI)	ASTRO	[63]

SBRT summarizes much of the recent guidance on quality and safety for these techniques[64]. For patients treated with curative intent SRS or SBRT, a qualified radiation oncologist and medical physicist should be present for the treatment.

Photon Total Body Irradiation: TBI is a treatment modality mainly to support stem cell graft-host success in the practice of bone marrow transplantation. The ACR and ASTRO have issued practice guidelines on this modality[7] and the AAPM has issued quality assurance standards for oversight of safe treatment delivery[75].

Intraoperative Radiation Therapy: IORT is most commonly given as a single boost dose of 10-20 Gy with electrons or HDR brachytherapy, combined with 45-54 Gy of fractionated EBRT in standard 1.8-2 Gy fractions, for patients treated with curative intent. Occasionally IORT is given as the only component of irradiation (primarily early breast cancer). In view of the large single fraction size, a qualified radiation oncologist and physicist should be present for the treatment.

4.2.3 Brachytherapy QA

The QA process for brachytherapy, similar to that of external beam, involves several components that must be carefully confirmed as part of the patient-specific QA management: treatment planning; treatment delivery systems; applicator commissioning; applicator periodic checks; imaging (i.e., CT-Simulation or plain film) checks; specification of the treatment intent; planning directive; treatment prescription by the physician; plan and chart preparation; plan evaluation; download toTMS; plan verification checks; plan modifications; and chart checks. Some aspects of quality assurance directed at preventing errors in treatment planning and delivery specific to brachytherapy are summarized in the following references:

- ACR: Technical Standard for the Performance of Brachytherapy Physics: Remotely Loaded HDR Source Res. 18[4]. This document is a general description of HDR brachytherapy physics.
- ESTRO Booklet 8[18] is a full-length book detailing quality procedures for brachytherapy, including HDR brachytherapy. While some of the procedures, such as calibration of an HDR brachytherapy unit in air, are considered outdated because of the uncertainties involved, most of the material remains current.
- IAEA TECDOC – 1257[29] is simply an overview for hospital administrators in developing countries.

4.2.3.1 Qualification of Brachytherapy Personnel

To administer brachytherapy, a qualified physician and medical physicist must be present for the initiation of treatment. Board certification or eligibility is required by the radiation oncologist and the medical physicist with other staff requiring registration for all cases. A specific "Focused Practice" certification in brachytherapy through the ABR is now available for brachytherapy practice, signaling the specialty's recognition of the increased complexity of many procedures and the need for enhanced expertise for all but the most routine brachytherapy cases.

4.2.3.2 Brachytherapy Treatment Recommendations

The use of brachytherapy, particularly HDR brachytherapy, has increased significantly and adherence to recommended standards is important in the process of patient care. Trained personnel must be appropriately informed and work together to ensure accurate and safe treatment of a variety of well-defined procedures. Several organizations have generated guidelines and recommendations that review details of the processes required for proper patient care, including the American Brachytherapy Society (ABS), ASTRO, the Groupe Européen de Curiethérapie-European Society for Therapeutic Radiology and Oncology (GEC-ESTRO), the ACR and the AAPM. For patients treated with HDR brachytherapy, a qualified radiation oncologist and medical physicist must be present in the control room. **Table 4.8** *(see page 45)* outlines the various topics covered by these organizations with respect to specific clinical sites.

Table 4.8. General Brachytherapy Guidance for Specific Clinical Sites

Site	Issue	Organization	Online	Reference #
General Principles	General guidelines	ACR/ASTRO	*http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Radiation_Oncology.pdf*	
	HDR	ACR/ASTRO	*http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/High_Dose_Rate_Brachy.pdf*	[17]
		ASTRO	White Paper	[65]
	LDR	ACR/ASTRO	*http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Low_Dose_Rate_Brachytherapy.pdf*	
Gynecology Cervical Cancer	General principles	ABS	*http://www.americanbrachytherapy.org/guidelines/index.cfm*	[66]
	Equivalent dose worksheets	ABS		
	HDR			
	LDR/PDR	ABS		[67], [41]
	MR-based contouring	ABS		[35], [43]
	Dose-volume parameter reporting	GEC-ESTRO		[24] [55]
	Postoperative cylinder	ABS		[39], [61]
	Vaginal cancer interstitial	ABS		[11]
Prostate	LDR	ACR/ASTRO	*http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Brachy_Prostate_Cancer.pdf*	[60], [21]
	LDR	ABS		[42], [12], [40], [14]
	HDR	ABS		[68]
Breast		ASTRO		[62]
		GEC-ESTRO		[54]
		ABS		[8], [9]
Esophageal	Endoluminal	ABS		[22]
Microspheres		ACR	*http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/RMBD.pdf*	[82], [83]
Vascular		ABS		[44]
		GEC-ESTRO		[56]
		ACR	*http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Coronary_Vascular_Brachy.pdf*	
Sarcoma		ABS		[45]
Head and Neck		ABS		[46]
Uveal Melanoma		ABS		[47]

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APPENDIX I:

Acronym Glossary

A

AAMD = American Association of Medical Dosimetrists
AANP = American Academy of Nurse Practitioners
AAPA = American Association of Physician Assistants
AAPM = American Association of Physicists in Medicine
ABMP = American Board of Medical Physics
ABMS = American Board of Medical Specialties
ABR = American Board of Radiology
ABS = American Brachytherapy Society
ACR = American College of Radiology
ACRO = American College of Radiation Oncology
AFROC = Association of Freestanding Radiation Oncology Centers
ANCC = American Nurses Credentialing Center
ARRT = American Registry of Radiologic Technologists
ASRT = American Society of Radiologic Technologists
ASTRO = American Society for Radiation Oncology

B

C

CBCT = cone beam computed tomography
CCPM = Canadian College of Physicists in Medicine
CME = continuing medical education
CT = computed tomography

D

DRR = digitally restored radiographs
DVH = dose-volume histogram

E

EBRT = external beam radiation therapy
EMR = electronic medical record
EORTC = European Organisation for Research and Treatment Center
EPID = electronic portal imaging device

F

FDA = Food and Drug Administration
FFF = flattening filter-free
FMEA = failure mode and effect analysis
FTE = full-time employee

G

GEC-ESTRO = Groupe Européen de Curiethérapie-European Society for Therapeutic Radiology and Oncology

H

H/P = history/physical
HDR = high-dose-rate

I

IGRT = image guided radiation therapy
IHE-RO = Integrating the Healthcare Enterprise-Radiation Oncology
IMPT = intensity modulated proton therapy
IMRT = intensity modulated radiation therapy
IORT = intraoperative radiation therapy
IVBT = intravascular brachytherapy

J

K

L

LDR = low-dose-rate

M

MDCB = Medical Dosimetrist Certification Board
MLC = multileaf collimator
MOC = maintenance of certification
MR = magnetic resonance (imaging)
MU = monitor unity

N

NACNS = National Association of Clinical Nursing Specialists
NCCPA = National Commission for the Certification of Physician Asssistants
NP = nurse practitioner
NTCP = normal tissue complication probability

O

OAR = organs at risk

P

PA = physician assistant
PAAROT = Performance Assessment for the Advancement of Radiation Oncology Treatment
PACS = picture archiving and communication system
PBI = partial breast irradiation
PDR = pulsed-dose-rate
PET = positron emission tomography
PQI = practice quality improvement
PQRS = physician quality reporting systems
PTV = planning target volume

Q

QA = quality assurance
QC = quality control
QI = quality improvement
QM = quality management
QUANTEC = Quantitative Analysis of Normal Tissue Effects in Clinic

R

RPC = radiological physics center
RT = radiation therapy
RTOG = Radiation Therapy Oncology Group

S

SAM = self-assessment module
SBRT = stereotactic body radiation therapy
SCAROP = Society of Chairmen of Academic Radiation Oncology Programs
SOP = standard operating procedure
SPECT = Single Photon Emission Computed Tomography
SROA = Society for Radiation Oncology Administrators
SRS = stereotactic radiosurgery

T

TBI = total body irradiation
TG = task group
TJC = The Joint Commission
TMS = treatment management system
TPS = treatment planning system

U

V

VMAT = volumetric modulated arc therapy

W

X

Y

Z

0-9

2-D CRT = two-dimensional conformal radiation therapy
3-D CRT = three-dimensional conformal radiation therapy
4-D = four-dimensional

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APEx MIPS Improvement Activities

ASTRO's Accreditation Program for Excellence (APEx) focuses on a culture of quality and safety, as well as patient-centered care. Evidence indicators required for APEx accreditation map to the following 16 MIPS improvement activities.

Activity Name	Activity Description	Activity Weight	Activity ID
Provide 24/7 access to eligible clinicians or groups who have real-time access to patient's medical record	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management	High	IA_EPA_1
Collection and use of patient experience and satisfaction data on access	Collection of patient experience and satisfaction data on access to care and development of an improvement plan, such as outlining steps for improving communications with patients to help understanding of urgent access needs.	Medium	IA_EPA_3
Implementation of episodic care management practice improvements	Provide episodic care management, including management across transitions and referrals that could include one or more of the following: Routine and timely follow-up to hospitalizations, ED visits and stays in other institutional settings, including symptom and disease management, and medication reconciliation and management; and/or Managing care intensively through new diagnoses, injuries and exacerbations of illness.	Medium	IA_PM_15
Implementation of use of specialist reports back to referring clinician or group to close referral loop	Performance of regular practices that include providing specialist reports back to the referring MIPS eligible clinician or group to close the referral loop or where the referring MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the certified EHR technology.	Medium	IA_CC_1
Regular training in care coordination	Implementation of regular care coordination training.	Medium	IA_CC_7
Implementation of documentation improvements for	Implementation of practices/processes that document care coordination activities (e.g., a documented care coordination encounter that tracks all clinical staff involved	Medium	IA_CC_8

practice/process improvements	and communications from date patient is scheduled for outpatient procedure through day of procedure).		
Collection and follow-up on patient experience and satisfaction data on beneficiary engagement	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.	High	IA_BE_6
Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms.	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms.	Medium	IA_BE_13
Evidenced-based techniques to promote self-management into usual care	Incorporate evidence-based techniques to promote self-management into usual care, using techniques such as goal setting with structured follow-up, Teach Back, action planning or motivational interviewing.	Medium	IA_BE_16
Participation in an AHRQ-listed patient safety organization.	Participation in an AHRQ-listed patient safety organization.	Medium	IA_PSPA_1
Participation in MOC Part IV	Participation in Maintenance of Certification (MOC) Part IV for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.	Medium	IA_PSPA_2
Use of decision support and standardized treatment protocols	Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs.	Medium	IA_PSPA_16
Measurement and improvement at the practice and panel level	Measure and improve quality at the practice and panel level that could include one or more of the following: Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group(panel); and/or Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.	Medium	IA_PSPA_18
Implementation of formal quality improvement methods, practice changes or other practice improvement processes	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following: Train all staff in quality improvement methods; Integrate practice change/quality improvement into staff duties; Engage all staff in identifying and testing practices changes; Designate regular team meetings to review data and plan improvement cycles; Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or Promote transparency and engage patients and	Medium	IA_PSPA_19

	families by sharing practice level quality of care, patient experience and utilization data with patients and families.		
Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes	Ensure full engagement of clinical and administrative leadership in practice improvement that could include one or more of the following: Make responsibility for guidance of practice change a component of clinical and administrative leadership roles; Allocate time for clinical and administrative leadership for practice improvement efforts, including participation in regular team meetings; and/or Incorporate population health, quality and patient experience metrics in regular reviews of practice performance.	Medium	IA_PSPA_20
Implementation of fall screening and assessment programs	Implementation of fall screening and assessment programs to identify patients at risk for falls and address modifiable risk factors (e.g., Clinical decision support/prompts in the electronic health record that help manage the use of medications, such as benzodiazepines, that increase fall risk).	Medium	IA_PSPA_21

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Five Things Physicians and Patients Should Question

1 Don't initiate whole breast radiotherapy as a part of breast conservation therapy in women age ≥50 with early stage invasive breast cancer without considering shorter treatment schedules.

- Whole breast radiotherapy decreases local recurrence and improves survival of women with invasive breast cancer treated with breast conservation therapy. Most studies have utilized "conventionally fractionated" schedules that deliver therapy over 5–6 weeks, often followed by 1–2 weeks of boost therapy.
- Recent studies, however, have demonstrated equivalent tumor control and cosmetic outcome in specific patient populations with shorter courses of therapy (approximately 4 weeks). Patients and their physicians should review these options to determine the most appropriate course of therapy.

2 Don't initiate management of low-risk prostate cancer without discussing active surveillance.

- Patients with prostate cancer have a number of reasonable management options. These include surgery and radiation, as well as conservative monitoring without therapy in appropriate patients.
- Shared decision-making between the patient and the physician can lead to better alignment of patient goals with treatment and more efficient care delivery.
- ASTRO has published patient-directed written decision aids concerning prostate cancer and numerous other types of cancer. These types of instruments can give patients confidence about their choices, improving compliance with therapy.

3 Don't routinely use extended fractionation schemes (>10 fractions) for palliation of bone metastases.

- Studies suggest equivalent pain relief following 30 Gy in 10 fractions, 20 Gy in 5 fractions, or a single 8 Gy fraction.
- A single treatment is more convenient but may be associated with a slightly higher rate of retreatment to the same site.
- Strong consideration should be given to a single 8 Gy fraction for patients with a limited prognosis or with transportation difficulties.

4 Don't routinely recommend proton beam therapy for prostate cancer outside of a prospective clinical trial or registry.

- There is no clear evidence that proton beam therapy for prostate cancer offers any clinical advantage over other forms of definitive radiation therapy. Clinical trials are necessary to establish a possible advantage of this expensive therapy.

5 Don't routinely use intensity modulated radiotherapy (IMRT) to deliver whole breast radiotherapy as part of breast conservation therapy.

- Clinical trials have suggested lower rates of skin toxicity after using modern 3-D conformal techniques relative to older methods of 2-D planning.
- In these trials, the term "IMRT" has generally been applied to describe methods that are more accurately defined as field-in-field 3-D conformal radiotherapy.
- While IMRT may be of benefit in select cases where the anatomy is unusual, its routine use has not been demonstrated to provide significant clinical advantage.

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Five More Things Physicians and Patients Should Question

6 Don't recommend radiation following hysterectomy for endometrial cancer patients with low-risk disease.

- Patients with low-risk endometrial cancer including no residual disease in hysterectomy despite positive biopsy, grade 1 or 2 with <50% myometrial invasion and no additional high risk features such as age >60, lymphovascular space invasion or cervical involvement have a very low risk of recurrence following surgery.
- Meta-analysis studies of radiation therapy for low-risk endometrial cancer demonstrate increased side effects with no benefit in overall survival compared with surgery alone.

7 Don't routinely offer radiation therapy for patients who have resected non-small-cell lung cancer (NSCLC) negative margins N0-1 disease.

- Patients with early stage NSCLC have several management options following surgery. These options include: observation, chemotherapy and radiotherapy.
- Two meta-analysis studies of post-operative radiotherapy in early NSCLC with node negative or N1 disease suggest increased side effects with no benefit for disease-free survival or overall survival compared to observation.
- Patients with positive margins following surgery may benefit from post-operative radiotherapy to improve local control regardless of status of their nodal disease.

8 Don't initiate non-curative radiation therapy without defining the goals of treatment with the patient and considering palliative care referral.

- Well-defined goals of therapy are associated with improved quality of life and better understanding on the part of patients and their caregivers.
- Palliative care can be delivered concurrently with anti-cancer therapies.
- Early palliative care intervention may improve patient outcomes, including survival.

9 Don't routinely recommend follow-up mammograms more often than annually for women who have had radiotherapy following breast conserving surgery.

- Studies indicate that annual mammograms are the appropriate frequency for surveillance of breast cancer patients who have had breast conserving surgery and radiation therapy with no clear advantage to shorter interval imaging.
- Patients should wait 6–12 months after the completion of radiation therapy to begin their annual mammogram surveillance.
- Suspicious findings on physical examination or surveillance imaging might warrant a shorter interval between mammograms.

10 Don't routinely add adjuvant whole brain radiation therapy to stereotactic radiosurgery for limited brain metastases.

- Primary analyses of randomized studies have demonstrated no overall survival benefit from the addition of adjuvant whole brain radiation therapy (WBRT) to stereotactic radiosurgery (SRS) in the management of selected patients with good performance status and brain metastases from solid tumors.
- The addition of WBRT to SRS is associated with diminished cognitive function and worse patient-reported fatigue and quality of life. These results are consistent with the worsened self-reported cognitive function and diminished verbal skills observed in randomized studies of prophylactic cranial irradiation for small cell or non-small-cell lung cancer.
- Patients treated with radiosurgery for brain metastases can develop metastases elsewhere in the brain. Careful surveillance and the judicious use of salvage therapy at the time of brain relapse allow appropriate patients to enjoy the highest quality of life without a detriment in overall survival. Patients should discuss these options with their radiation oncologist.

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How This List Was Created (1–5)

Following approval of the participation of the American Society for Radiation Oncology (ASTRO) in the *Choosing Wisely* campaign, a survey was sent to ASTRO committees and panels related to health policy, government relations, and clinical affairs and quality in order to identify potential items for inclusion in the list. A work group, comprised of seven physicians drawn from these three areas, was also selected and convened. The work group members were asked to pick their top eight items from the total of 34 topics that had been suggested in the initial survey. The results were tabulated and a list of the highest scoring items generated, creating a short list of 13 draft items.

Three conference calls were subsequently held to further refine the list and finalize the wording of the items based on input from ASTRO's Board of Directors. A literature review was conducted for each topic by ASTRO staff and each work group member took the lead on writing text and selecting references for one or more draft items. The final items for submission were selected by ASTRO's Board of Directors. ASTRO's disclosure and conflict of interest policy can be found at: www.astro.org.

How This List Was Created (6–10)

In January 2014, the American Society for Radiation Oncology (ASTRO) formed a group to develop its second *Choosing Wisely* list, which included representatives from health policy, government relations, and clinical affairs and quality. The work group began by narrowing a list of 28 draft concepts to nine potential *Choosing Wisely* items. Next, an electronic anonymous survey was sent to the ASTRO membership to rate the value and relevancy of each of the items. The survey also included an open text box for members to comment on the suggested items and to provide additional ideas for *Choosing Wisely* items. Based on the survey results, the work group submitted a short list of eight items to the ASTRO Board of Directors, from which the Board chose five items to move forward.

Literature reviews were conducted for the five *Choosing Wisely* items selected by the Board and the group drafted verbiage, bullet points and references for each item. Following a second review by the Board of Directors, one of the items was replaced with an alternate item from the short list. The final list received approval from the Board and was then submitted to the ABIM Foundation. ASTRO's disclosure and conflict of interest policy can be found at: www.astro.org.

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About the ABIM Foundation

The mission of the ABIM Foundation is to advance medical professionalism to improve the health care system. We achieve this by collaborating with physicians and physician leaders, medical trainees, health care delivery systems, payers, policymakers, consumer organizations and patients to foster a shared understanding of professionalism and how they can adopt the tenets of professionalism in practice.

To learn more about the ABIM Foundation, visit www.abimfoundation.org.

About the American Society for Radiation Oncology

ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. To learn more about ASTRO, visit www.astro.org.

For more information or to see other lists of Five Things Physicians and Patients Should Question, visit www.choosingwisely.org.

Appendix F – ASTRO Guidelines

Breast

- **Accelerated Partial Breast Irradiation Consensus Statement** (*Published. Practical Radiation Oncology, Vol. 7, Issue 2, March-April 2017, Pages 73-79. Originally published in 2009.*)
- **Evidence-based Guideline on Whole Breast Irradiation** (*in progress-anticipated publication in 2017/2018*)
- **Margins for Breast-Conserving Surgery with Whole-Breast Irradiation in Ductal Carcinoma In Situ** – with Society of Surgical Oncology and American Society of Clinical Oncology (*Published. Practical Radiation Oncology, Vol. 6, Issue 5, September-October 2016, Pages 287-295. Also published in Journal of Clinical Oncology and Annals of Surgical Oncology.*)
- **Postmastectomy radiotherapy: An American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology focused guideline update** – with Society of Surgical Oncology and American Society of Clinical Oncology (*Published. Practical Radiation Oncology, Vol. 6, Issue 6, November-December 2016, Pages e219 – e234.*)
- **Consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive beast cancer** – with Society of Surgical Oncology (*Published. Int J Radiation Oncol Biol Phys, Vol. 88, No 3, March 2014, Pages 553 – 564.)*

Lung

- **Definitive and Adjuvant Radiotherapy in Locally Advanced Non-Small Cell Lung Cancer** (*Published. Practical Radiation Oncology, Vol. 5, Issue 3, May-June 2015, Pages 141-148 [definitive RT] and 149-155 [adjuvant RT]*.)
- **Stereotactic Body Radiotherapy for Early-Stage Non-Small Cell Lung Cancer** (*Accepted to Practical Radiation Oncology for publication.*)

Bone Metastases

- **Palliative Radiotherapy for Bone Metastases Guideline** (*Published. Practical Radiation Oncology, Vol. 7, Issue 1, January-February 2017, Pages 4-12. Originally published 2011.*)

Prostate

- **Hypofractionated Radiation for Localized Prostate Cancer** – with American Society of Clinical Oncology and American Urological Association (*In progress. In writing phase.*)
- **Adjuvant and Salvage Radiation Therapy After Prostatectomy: American Society for Radiation Oncology/American Urological Association Guideline** – with American Urological Association (*Published. Int J Radiation Oncol Biol Phys, Vol. 86, No. 5, August 2013, pp. 822 – 828.)*

Brain

- **Radiotherapeutic and surgical management for newly diagnosed brain metastasis/es** (Published. Practical Radiation Oncology, Vol. 2, Issue 3, July-September 2012, Pages 210-225.)
- **Radiation Therapy for Glioblastoma** (*Published. Practical Radiation Oncology, Vol. 6, Issue 4, July-August 2016, Pages 217-225.*)

Colorectal

- **Appropriate Customization of Radiation Therapy for Stage II and II Rectal Cancer** (*Published. Practical Radiation Oncology. Vol. 6, Issue 3, May-June 2016, Pages 166-175.*)