

Oncology Roundtable

Innovations in Radiation Oncology

Oncology Innovations Series

- Practice 1: Advance Evidence-Based Care
- Practice 2: Facilitate Shared Decision Making
- Practice 3: Identify Opportunities to Improve Safety
- Practice 4: Adopt a Value-Based Investment Strategy



Oncology Roundtable

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The Clinical Innovations in Oncology Series

With increasing financial pressures, growing responsibility for costs and outcomes, and increasingly strict reimbursement requirements, cancer programs must revamp their investment strategy. It is essential that program leaders carefully weigh the benefits and risks, evaluate the evidence base, and consider the value of each investment from the perspective of their organization, payers, and community.

This four-part series will help cancer program leaders and administrators evaluate current and upcoming technology and treatment innovations in radiation, medical, surgical, and interventional oncology. Additionally, each provides guidance for creating a best-in-class program and maximizing the return on investment.

For the full series, please visit advisory.com/or/clinicalinnovations

Innovations in Radiation Oncology

Due to large capital costs and a shifting payer mindset, cancer program leaders need to dramatically rethink their investment strategy for radiation oncology. While radiation continues to be the most profitable component of the oncology service line for most organizations, payers are demanding evidence of the benefits of technology before paying for it, and many are exploring the potential for bundling radiation therapy services.

In response, program leaders need to revamp their investment strategy, stay on top of emerging evidence, find opportunities to reduce costs, and ensure that patient safety and preferences are top of mind. To accomplish this, this research brief includes four technology overviews and four best practices.

Technology in Brief: Proton Beam Therapy	. <u>7</u>
Technology in Brief: Image Guided Radiation Therapy	<u>8</u>
Technology in Brief: MRI-Guided Radiation Therapy	<u>10</u>
Technology in Brief: Radiosensitivity Testing	<u>12</u>
Practice 1: Advance Evidence-Based Care	<u>17</u>
Practice 2: Facilitate Shared Decision Making	<u>21</u>
Practice 3: Identify Opportunities to Improve Safety	<u>23</u>
Practice 4: Adopt a Value-Based Investment Strategy	<u>26</u>

The Basics of Radiation Oncology

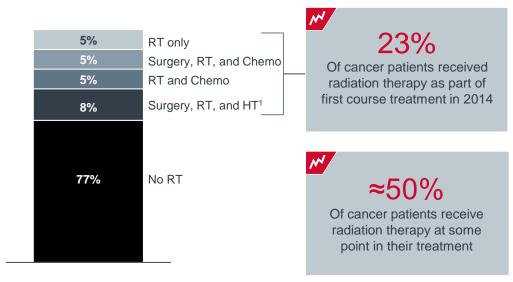
Radiation therapy is one of the cornerstones of cancer treatment. In 2014, 23% of newly diagnosed cancer patients received radiation as part of their first course of treatment, and approximately half of all cancer patients undergo radiation at some point in their care.

Radiation therapy volumes are expected to grow due to increasing cancer incidence and expanded indications. Rising cancer incidence is by far the biggest driver of volume growth. However, new indications will also drive volumes for specific patient populations. For example, stereotactic body radiosurgery (SBRT) is increasingly used to treat earlystage lung cancers.

Although Advisory Board forecasts indicate overall radiation therapy volumes will increase for the foreseeable future, some factors are having a dampening effect on demand. For example, the HPV vaccine is expected to reduce the incidence of HPV-related cancers, which are sometimes treated with radiation. More significantly, changes in prostate cancer screening and treatment guidelines have significantly reduced the number of new diagnoses and increased active surveillance at the expense of radiation volumes. Another factor that could reduce volumes is hypofractionation, which delivers the same total dose of radiation to patients over fewer treatments.

A Critical Component of Cancer Care

Patients Receiving Radiation Therapy as First Course Treatment in 2014 n=884,768



Growth in Most Modalities Likely

	EBRT ²	Brachytherapy
Growth Drivers	 Aging population leading to higher cancer incidence Expanded use of SBRT for lung cancer Shift in stage of lung cancer diagnosis 	 Aging population leading to higher cancer incidence Increased use in gynecologic cancer patients
Growth Barriers	 Hypofractionation Changes in screening and care guidelines for prostate cancer 	 HPV vaccine reduces incidence of HPV-related cancers Changes in screening, care guidelines for prostate cancer

1) Hormone therapy.

A Major Contributor to Service Line Profitability

Radiation therapy is a significant revenue generator and the most profitable oncology sub-service line. Reimbursement for the most common treatment modalities (3D-CRT and IMRT) has been relatively stable and favorable in the hospital outpatient department (HOPD) setting.

Prior to 2013, Medicare paid higher rates to freestanding centers than to HOPDs for certain treatment modalities. However, in 2013 Medicare cut freestanding reimbursement. Since then, rates for hospitalbased outpatient centers have remained higher for every modality.

Although radiation therapy requires a large upfront capital investment, variable costs, such as equipment maintenance and staffing, are relatively low. Consequently, LINACs are often very profitable in their later years of operation. The bar chart on the right models the cash flow generated by a multifunctional LINAC at a typical cancer program. Most cancer programs are able to breakeven on their investment in the third year of operation.

Given the standardized nature of radiation treatments, most cancer programs generate substantial returns from radiation therapy, which are often used to subsidize other services for cancer patients. To maximize profits, centers must focus on efficiency and throughput.

1) Intensity-modulated radiation therapy 2) Three-dimensional conformal radiation therapy

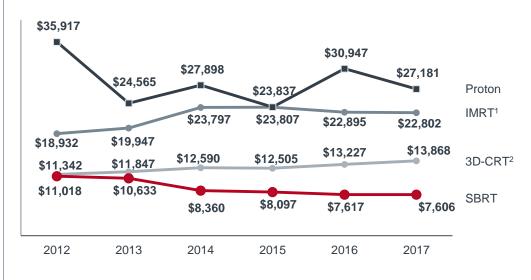
3) Linear accelerator.

- Costs include: \$3.6 million for multifunctional LINAC; \$0.75 million for installation; \$0.25 million for yearly maintenance; \$1.1 million for salaries; \$0.1 million for incidental costs.

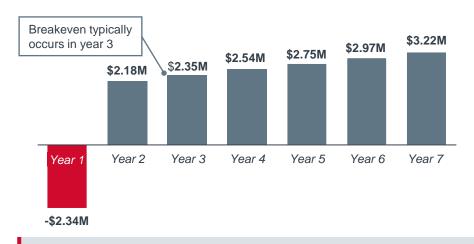
5) Stereotactic radiosurgery

Reimbursement a Mixed Bag

Reimbursement Trends by Modality



Annual Cash Flow Generated by Multifunctional LINAC³



Model Assumptions

- Assumes fixed and variable costs⁴ including annual changes to volumes • and reimbursement
- Initial patient mix: 100 3D-CRT patients, 1 SRS⁵ patient, and 82 IMRT patients

The Technology Landscape

Many Innovations Still in Research Phase

To help cancer program leaders develop a radiation therapy investment strategy, the chart below provides a list of treatment technologies organized by prevalence. The most common technologies, such as 3D-CRT and IMRT, are listed on the left. Most cancer programs have these technologies, and they are the most common forms of radiation therapy treatments. On the right side of the chart are newer technologies that are comparatively rare, still in development, or most often used for research studies. These include real-time adaptive guidance technologies and carbon-ion technology. The technologies in the middle are most often found at high-volume cancer programs.

The next several pages provide more details about the technologies listed in bold below and describe key trends affecting their use.

3D-CRT	Multifunctional LINAC	Dedicated SRS/SBRT Platform	Carbon Ion Technology
IMRT		Beacon Technology (e.g., Calypso)	Proton Therapy Technology
CBCT ¹ Volu Imaging	umetric		MRI-Guided Technology
KV/MV Plar Imaging	nar		Real-Time Adaptive Technology

Overview of Radiation Therapy Technology Adoption

Widespread

Limited to Research

advisory.com

Less Expensive Proton Therapy Options Continue Growth

Although proton therapy is not new, it continues to receive a great deal of attention due to its high cost and the hope that it will reduce side effects. In recent years, the advent of single-vault systems have reduced the upfront investment cost to approximately \$30 million. Nevertheless, few proton centers are able to generate a profit given the technology's limited indications and declining reimbursement. As a result, proton beam therapy is most often found at research centers.

Medicare reimbursement for proton therapy has fluctuated dramatically for several reasons. Typically when new technologies are introduced, Medicare sets reimbursement rates high, and then it reduces reimbursement over time as more operating cost data becomes available. Reimbursement for proton therapy has generally followed that pattern, but because there are so few proton centers in operation, Medicare's cost calculations are highly sensitive to changes at individual facilities. For example, equipment depreciation, the opening of new centers, and even errors in coding have led to significant fluctuations in Medicare rates year-to-year.

At the same time, commercial payers are increasingly resistant to reimbursing for proton therapy given the absence of evidence that it yields superior outcomes. Most pay the same rates for proton as for IMRT.

Proton Beam Therapy Centers in Operation and Planned in the United States



- In Operation
- Under Construction or Development
- Single Vault in Operation
- Single Vault Under Construction or Development

10

Estimated number of three-vault proton centers needed in the US¹

Reasons to Invest

- Improves clinical outcomes for certain patient populations (e.g., pediatric patients, chordomas)
- May differentiate cancer program from competitors
- · Creates research opportunities
- May help attract physicians and patients

Reasons Not to Invest

- Requires large up-front investment
- No evidence of improved outcomes for majority of patient populations
- Requires substantial staff time to operate and maintain
- Does not provide predictable reimbursement

Need for more research into comparative effectiveness

Source: "National Proton Beam Therapy Service Development Programme Value for Money Addendum to Strategic Outline Case," UK Department of Health; Oncology Roundtable interviews and analysis.

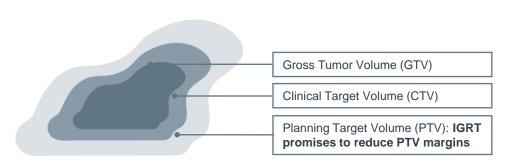
Estimate based on the 2012 UK model, which identified two three-vault centers as sufficient to treat <1.500 patients annually who have cancers for which there is evidence indicating the superiority of proton treatment.

IGRT Still Promises to Improve Accuracy

Like proton therapy, the goal of image guided radiation therapy (IGRT) is to increase the precision of radiation treatment to target the tumor, reduce irradiation of healthy tissue, and ultimately improve patient outcomes.

Conventional IGRT includes planar imaging and volumetric imaging. Planar imaging produces a two-dimensional image. Volumetric imaging is a form of three-dimensional imaging that captures multiple planar images at different angles to produce a representation that includes height, depth, and width.

Illustration of RT Margins



Conventional and Emerging IGRT Technologies

Conventional IGRT Includes portal imaging, planar imaging, volumetric imaging (CBCT), ultrasound

MRI-Guided RT

Uses MR¹ to produce images that can guide radiation delivery

Real-Time Adaptive RT

Uses intra-fraction adaptive dose delivery and beam generation

There is a strong and growing body of evidence that conventional IGRT, such as volumetric and planar imaging, can reduce treatment margins. More recently, evidence has started to emerge that links margin reduction with better outcomes. For example, one study found that IGRT reduced late toxicity for head and neck cancer patients by more than half. Several other studies have measured reductions in PTV margins and toxicity for other patient populations.

Studies Indicate Improved Accuracy and Precision

REDUCED MARGINS ·

≈50%

Reduction in PTV margins (from 5mm-3mm) for head and neck cancer patients receiving IMRT with daily IGRT Reduction in PTV margin for NSCLC patients receiving

IMPROVED OUTCOMES -

daily IGRT

5mm

Allowable PTV margin for prostate patients receiving hypofractionated RT with daily IGRT (CBCT or KV-KV imaging)

48%

40%

Reduction in Grade 2 or higher late urinary toxicity for IGRT versus non-IGRT prostate patients

>50%

Reduction in late toxicity for head and neck patients receiving IMRT with daily IGRT

Source: Chen AM, et al., "Long-term Experience With Reduced Planning Target Volume Margins and Intensity-Modulated Radiotherapy with Daily Image-guidance for Head and Neck Cancer," Head & Neck 36. no.12 (2014; Zelefsky MJ, et al., "Improved clinical outcomes with high-dose image guided radiotherapy compared with non-IGRT for the Treatment of Clinically Localized Prostate Cancer," International Journal of Radiation Oncology" Physics, 84, no.1 (2012); Oehler C, et al., "<u>PTV</u> Margin Definition in Hypofractionated IGRT of Localized Prostate Cancer," International Journal of Radiation Oncology, 9, no.1 (2014); Otosson W, et al., "Evaluation of Setup Accuracy for NSCLC Patients; Studying the Impact of Different Types of Cone-beam CT Matches Based on Whole Thorax, Columna Vertebralis, and GTV," Acta Oncologica, 49, no.7 (2010); Oncology Roundtable interviews and analysis.

1) Magnetic resonance.

Importantly, using IGRT does not guarantee margin reduction. The technology must be combined with consistent highquality treatment planning and delivery procedures in order to achieve superior results.

A recent study surveyed radiation oncologists about IGRT modality/frequency, PTV expansions, method of image verification, and perceived utility/value of IGRT. Analysis of the 601 responses found no association between the frequency with which radiation oncologists use image guidance and PTV margins. However, the study's authors do not attribute this finding to deficiencies in the technology; rather, they point to variation in how the technology is used.

To realize the benefits of image guidance, the authors recommend the development of consensus-based guidelines and increased standardization of treatment planning and delivery. On the right is a list of the best practices recommended.

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2016 Survey of Radiation Oncologists' Utilization of IGRT

"Our survey has identified...**no statistically significant association** between IGRT frequency and CBCT utilization and PTV margins...

"Our findings demonstrate that a more detailed, treatment sitespecific, and imaging modality-specific consensus guideline by a major body (ASTRO, ACR, AAPM) for standardization of US IGRT procedures is needed."

Nabavizadeh et al., 2016

Sample Suggestions from ASTRO to Ensure Safe and Effective IGRT Use

- Develop institution "IGRT team" of medical physicists, planners/dosimetrists, therapists, and radiation oncologists
- · Conduct regular QA on IGRT systems
- Identify site-specific planning procedures, especially for defining PTV margins, and link these to IGRT procedures
- Use peer review to verify identified PTV margins for IGRT procedures
- · Develop checklist for IGRT procedures
- Train staff on IGRT procedures
- Capture data on accuracy to inform revisions to IGRT procedures

MRI Has Potential to Improve Accuracy, Reduce Radiation

MRI-guidance is a newer form of IGRT. It offers two potential advantages. First, it creates images of anatomical structures without exposing patients to additional radiation. As a result, patients can be imaged more frequently. Second, MRI produces images with greater detail than conventional imaging.

ViewRay first introduced this technology several years ago with its cobalt-60 system. Since then, both ViewRay and Elekta have developed MRI-guided LINACs. ViewRay received 510(K) clearance for the MRidian Linac in early 2017, and Elekta expects to receive 510(k) clearance for their MRI Linac in late 2017 or early 2018.¹

To date, few cancer programs have invested in MRI-guidance due to the additional cost and lack of evidence that it yields superior outcomes. Those that have invested or plan to acquire the technology are motivated by the opportunity to use it for research and to differentiate themselves from competitors.

ViewRay MRidian System



Benefits of MRI Guidance

- Produces images of actual anatomy, not surrogates, with no additional radiation dose
- Captures high-resolution images quickly that can serve as input to support real-time adaptive RT
- Better visualization has potential to reduce margins and number of fractions
- Functional MR imaging may allow for better targeting and treatment of cancer

Technology in Brief: Elekta MR LINAC

- System developed by Elekta, a human care company headquartered in Stockholm, Sweden, and Phillips, a technology company headquartered in Amsterdam, Netherlands
- Multifunctional LINAC with integrated 1.5 Tesla MR imaging system; will use software to improve motion management and online adaptive planning
- Seven locations participating in the International Elekta MR-LINAC consortium to research and develop the technology
- Currently unavailable for sale or distribution in the United States

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Technology in Brief: ViewRay MRidian LINAC

- System developed by ViewRay, a radiation therapy technology firm headquartered in Cleveland, Ohio
- Previous system integrates 0.35 Tesla MR imaging system into Cobalt 60 radiation therapy machine; in clinical use since 2014; first clinical use of on-table adaptive treatments and real-time MR direct tumor tracking
- New system has same functionality but swaps out Cobalt 60 with LINAC and a high-definition double-focused MLC; uses software to improve motion management and online adaptive planning; system is currently being installed for clinical use at two centers in the United States

Real-Time Adaptive RT Adjusts with Patient Movement

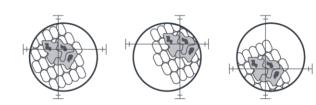
Real-time adaptive radiation therapy is another emerging form of IGRT. Its goal is to adjust the radiation beam in response to small movements in the patient created by breathing or digestion.

The system's software uses information produced by beacons implanted near the tumor to re-shape the beam. Essentially, the software translates tumor motion into beam motion. The result is a beam that changes shape with the tumor.

To date, effectiveness studies have been small, but early findings are promising. Unlike other new treatment technologies, real-time adaptive RT would likely only require software upgrades; hence, it is expected to be relatively affordable. Consequently, many experts are excited about its potential to improve patient outcomes at a relatively small marginal cost.

Real-time adaptive radiation therapy is still in early development, but experts expect it will be available in the US in next three to five years.

Real-Time Adaptive RT Systems Aim to **Further Reduce Margins**



MLC-Tracking¹ for Lung Cancer Patient Receiving SBRT



41% Reduction in PTV margins

30%

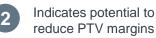
Reduction in mean dose of radiation delivered to healthy lung tissue

Study in Brief: MLC-**Tracking for Lung Cancer Patient Receiving SBRT**

- Study conducted by researchers at University of Sydney; involved 80-year-old man with single left-lobe metastasis treated with SBRT (48GY/4Fr)
- Used in-house software integrated with standard linear accelerator to adapt the treatment beam shape and position based on electromagnetic transponders implanted in the lung
- Technology allowed clinicians to reduce PTV margin by 41% and mean lung dose by 30%

MLC-Tracking for Prostate Cancer Patients Receiving VMAT²

Doses delivered with MLC tracking more consistent with planned dose than would have been without MLC tracking



Study in Brief: Real-Time **Image Guidance for Prostate Cancer Patients**

- Study conducted by researchers at University of Sydney; involved 15 prostate cancer patients receiving 513 fractions in total
- Used in-house software to allow MLC tracking, a process that uses information on MLC location and prostate location to reconstruct the dose delivered by the VMAT machine during treatment delivery
- Doses delivered with MLC tracking were more consistent with planned dose than they would have been without MLC tracking; indicates potential to reduce PTV margins

1) Multi-leaf collimator tracking 2) Volumetric modulated arc therapy

Source: Booth JT, et al., "The First Patient Treatment of Electromagnetic-guided Real Time Adaptive Radiotherapy Using MLC Tracking for Lung SABR," Radiotherapy and Oncology, 121, no.1 (2016); Keall PJ, et al., "Real-Time 3D Image Guidance Using a Standard LINAC: Measured Motion, Accuracy, and Precision of the First Prospective Clinical Trial of Kilovoltage Interfaceion Monitoring Church Reader Motion, Accuracy, and Precision of the First Prospective Clinical Trial of Kilovoltage Intrafraction Monitoring-Guided Gating for Prostate Cancer Radiation Therapy," International Journal of Radiation Oncology Biology" Physics, 94, no. 5 (2016); Keall PJ, et al., "The First Clinical Treatment with Kilovoltage Intrafraction Monitoring (KIM); A Real-time Image Guidance Method," Medical Physics, 42, no.1 (2015); Oncology Roundtable Interviews and analysis.

Precision Medicine Comes to Radiation Therapy

In addition to advances in imaging and treatment technologies, radiosensitivity testing is a new approach to improving the effectiveness of radiation therapy while reducing toxicity.

Radiosensitivity testing is a type of molecular test. It identifies genetic markers that provide information about how tumors are likely to respond to radiation. That information can then be used to determine whether a particular patient is likely to benefit from radiation therapy, and, if so, refine the treatment plan accordingly.

Overview of Testing for Radiosensitivity





Multi-gene expression assay sequences genes known to play a role in tumor radiosensitivity





System uses test results and regression algorithm to calculate radiosensitivity index (RSI) score

Low RSI score indicates tumor cell is radiosensitive (i.e., unlikely to survive radiation therapy)





RSI score is used to identify the optimal RT dose for patient's specific tumor



Number of tumor sites for which RSI has been validated

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Technology in Brief: Cvergenix

- Genomics informatics company founded by clinicians and researchers at Moffitt Cancer Center in Tampa, Florida
- Researchers identified multiple genes found across tumor sites that play a role in a tumor's susceptibility to radiation—i.e., the tumor's radiosensitivity; used these genes to develop a test that predicts tumor radiosensitivity
- Technology helps radiation oncologists determine optimal dose and number of fractions for each patient based on tumor's radiosensitivity score

A Changing Reimbursement Landscape

Public and Private Payers Looking to Rein In Spending on Radiation Therapy

As noted previously, reimbursement for the most common radiation therapy modalities (i.e., 3D-CRT and IMRT) has been relatively stable in recent years. However, as payers look for new opportunities to reduce spending, radiation therapy is increasingly a target. In fact, both public and private payers have begun to experiment with new payment policies designed to reduce spending on radiation therapy. For example, Medicare introduced a comprehensive APC (ambulatory payment classification), or C-APC, for SRS, which effectively bundles payments for treatment planning and delivery services. Private payers have increased prior authorization requirements, both by expanding the number of services that require prior authorization and by increasing the documentation that providers need to obtain prior authorization. While risk-based payments for radiation therapy treatment are still rare, several payers have piloted bundled payments.



1 Public

- Payment for proton continues to fluctuate with downward trend
- Payment for SBRT has declined steadily for the past five years
- Reimbursement rates for certain RT services provided in freestanding setting frozen at 2016 rates for 2017 and 2018
- Image guidance technical component packaged into treatment delivery service APC¹
- SRS C-APC² packages payments for numerous related services

2 Private

- Many payers require prior authorization for all RT treatments
- Private payers are implementing alternative payment models for radiation therapy including bundled payment

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1) Ambulatory payment classification.
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More Changes on the Horizon

Radiation therapy has several features that make it a target for bundled payments. To start, unlike most drug therapies, radiation therapy has clear beginning and end points, making it easier to define a treatment episode. In addition, because radiation treatments are relatively standardized, it is much easier for providers and payers to determine the cost of providing the service and to calculate a reasonable reimbursement rate. Most importantly, bundled payments have the potential to change providers' economic incentive to promote more efficient and effective care.

Under fee-for-service payment, providers are economically incentivized to recommend the highest-cost treatment modality and the highest number of treatments. Bundled payments can remove these incentives and may encourage the use of hypofractioned treatment plans.

To date, there have been only a few radiation therapy bundled payment programs implemented. However, the Patient Access and Medicare Protection Act of 2015 requires CMMI to develop an alternative payment model for radiation therapy delivered in the freestanding setting. Although they have not yet released any specifics, it is likely to take the form of a bundled payment.

Radiation Therapy Bundles Likely to Proliferate

Factors Making Radiation Therapy an Attractive Target for APMs¹



Clear treatment end-points make it easier to determine episode length and attribute patients



Relatively standardized with fewer unexpected costs makes it easier to determine payment rate



Potential to reduce costs by changing clinical practice (e.g., type of technology, hypofractionation)

Prototypical RT Bundle Emerging

Three Common Features of Radiation Therapy Bundles



Tumor-Site Specific

Payment amount specific to tumor site being treated



Modality Agnostic

Payment does not depend on modality used for treatment



Risk Agnostic

Patient acuity, stage not factored into payment

Benefits of Bundles to Providers



Maintain autonomy in deciding treatment



Receive predictable payments



Reduced or eliminated prior authorization requirements



Improved patient satisfaction with billing process

Source: Highmark BlueCross BlueShield, Pittsburg, PA; 21st Century Oncology, Fort Myers, FL; Mantz C, "<u>Procedural Payment Bundles: Case Study in Radiation Oncology</u>," http://www.ehcca.com/presentations/BPSummit6/mantz_cs2.pdf; Loy BA, et al., <u>"Do Case Rates Affect Physicians" Clinical Practice in Radiation Oncology</u>," *ASCO Annual Meeting Proceedings*, 32, no. 30 (2014); Oncology Roundtable interviews and analysis.

1) Alternative payment models.

Lessons Learned from an Early Adopter

The longest running example of a radiation therapy bundled payment comes from 21st Century Oncology. In 2012, they worked with a national commercial payer to develop standardized lump sum payments for patients in 13 diagnosis groups. The diagnosis groups cover the most common tumor sites, such as lung, breast, and prostate cancers.

The bundled payment includes payment for all radiation therapy services. 21st Century Oncology and the payer renegotiate the rates each year to reflect the most recent data on costs and utilization. Radiation oncologists maintain clinical decision making authority and are free to use any radiation therapy modality and treatment plan as long as it meets minimum treatment standards.

The primary benefit for 2^{1st} Century Oncology is that providers no longer have to obtain prior authorizations, which cuts down on administrative expenses for both the payer and the cancer center. It also helps to prevent treatment delays and simplifies the insurance process for patients. In fact, patient satisfaction scores related to the insurance process have increased almost 50% since the program's start.

The program also appears to support hypofractionation, which is less costly for payers, and more convenient and less costly for patients. Since the program began, the number of fractions per course of treatment for breast cancer patients and palliative patients has dropped by approximately 8%. However, it is important to note that because the bundled payments are re-calculated each year to reflect the most recent utilization patterns, increasing use of hypofractionation puts downward pressure on reimbursement rates over time.

21st Century Oncology has not published the clinical or financial results of the program so it is difficult to evaluate its success. In May 2017, the cancer program for Chapter 11 bankruptcy protection, but it is unclear whether their bundled payment program played any role in that outcome.

21st Century Oncology Radiation Therapy Bundle



Structure of the Program

Provides bundled payments for 13 different diagnosis groups, such as lung cancer and breast cancer, that cover more than 98% of all episodes



Uses weighted average of various RT care pathways for each diagnosis group to identify a single, nonadjustable payment amount for all RT services



Payer and provider conduct annual review to evaluate for service underuse, ensure bundled prices reflect actual utilization, and consider inclusion of new technologies

Results to Date



Patient satisfaction with insurance experience has increased from 66% to 92%



Increase in use of hypofractionation for breast and palliative patients (5-10%) fewer fractions for these cases)



Increased payer interest in pursuing similar programs

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Case in Brief: 21st Century Oncology

- 21st Century Oncology is a medical practice headquartered in Fort Myers, Florida; operates 145 centers in the United States and 36 in Latin America; partnered with a large, national commercial payer
- Bundled payment contract started August 2012; contract covers patients treated at any of 21st Century's facilities
- 21st Century Oncology provides radiation therapy for 13 cancer diagnoses in exchange for bundled payment; diagnoses include breast, lung, prostate, gastrointestinal, and gynecological cancers; payment includes consultation, imaging, dosimetry, treatment delivery, and follow-up for 90 days

Prepare for Value-Based Reimbursement

While much remains uncertain about the future of risk-based payments, cancer providers will inevitably be charged with decreasing costs and improving quality moving forward, underscoring the need to reexamine their business strategy. The Oncology Roundtable recommends cancer program leaders take four steps to ensure that their radiation therapy programs can thrive in the value-based market.

The first practice is to encourage the development of more clinical evidence and to rapidly incorporate new information on cost and patient outcomes into treatment protocols. The second is to engage patients in treatment decisions that factor in costs to the patient, outcomes, and their goals for care. Third, cancer programs should constantly seek new opportunities to improve quality and safety. Fourth and finally, cancer programs need to re-think their approach to radiation therapy technology investment. In the past, cancer programs often purchased new technologies to gain prestige and differentiate themselves from competitors. However, in the future, it will be imperative for cancer programs to invest in technologies that promote higher-value care.

Four Practices to Succeed in the New Normal



Advance Evidence-Based Care



Identify Opportunities to Improve Safety



Facilitate Shared Decision Making



Adopt a Value-Based Investment Strategy

Source: Barbieri M, et al., "<u>What is the Quality of Economic Evaluations</u> of Non-Drug Therapies? A Systematic Review and Critical Appraisal of <u>Economic Evaluations of Radiotherapy for Cancer</u>," Applied Health Economics and Health Policy, 12, no. 5 (2014); Oncology Roundtable interviews and analysis.

Limited Evidence Is a Challenge

To deliver higher-value care, providers need clinical outcomes and cost data to inform the choice of treatment modality, image-guidance technology, and treatment plan.

Today, there is limited evidence to draw upon, in part because there has been little incentive to do research in these areas. In the past, payers were willing to pay for more expensive treatment and imaging technologies, even without evidence that they produced superior outcomes. Providers were often willing to invest in new technologies that promised better outcomes, even if they were not yet proven.

With the transition to valuebased payment, the need for evidence is growing. Payers want to develop informed payment policies, and providers will need the data to determine how to lower costs while continuing to provide highquality care.

Despite the limited evidencebase, there are steps that cancer programs can take immediately to incorporate available evidence into practice and encourage further research.

But There Are Still Steps We Can Take

Three Steps to Become Evidence-Centered

2

Pay Attention to Available Evidence

Hardwire Evidence-Based Practice

Help Build the Evidence Base

3

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1

"[T]here is a dearth of up-to-date, robust evidence on the effectiveness and cost effectiveness of radiotherapy in cancer."

Barbieri, et al., 2014

Recent Research Reveals Opportunities to Cut Costs

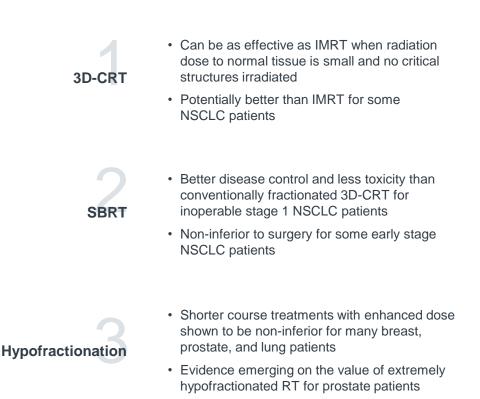
The first step is to track new evidence about costs and outcomes as it becomes available. On the right is a list of key findings from recent studies that pinpoint opportunities to reduce the total costs of care without compromising quality. For example, 3D-CRT, which is less costly than IMRT, has been shown to be as effective and safe as IMRT when the radiation dose to healthy tissue is small and avoids critical structures. By incorporating this information into their clinical decision making, radiation oncologists can increase the value of care they provide.

Admittedly, providers in a feefor-service environment may lose revenues if they act upon these opportunities, making them hesitant to change their practice. However, there are many benefits that can help offset any lost income. First, reducing the costs of care reduces patients' out-of-pocket expenses, improves patient access, and increases patient satisfaction. Second, proactively taking steps to increase value helps build goodwill with payers. Finally, research shows that clinical practice change takes time. Thus, in anticipation of the shift to value-based payments, cancer program leaders should take steps now to ensure that they are positioned for success under new payment models.

Unfortunately, research shows that providers do not always act on new clinical evidence, even when they are aware of it.

Providers Need to Pay Attention to Available Evidence

Evidence-Based Opportunities to Cut Costs



Source: Steingisser L, et al., "Bending the Cost Curve: A Unique Collaboration Between Radiation Oncologists and Blue Cross Blue Shield of Massachusetts to Optimize the Use of Advanced Technology," *Journal of Oncology Practice*, 10, no. 5 (2014); Yu JB, et al., "Comparative Effectiveness of Surgery and Radiosurgery for Stage I Non-small Cell Lung Cancer," *Cancer*, 121, no.14 (2015); Hu V, et al., "Is IMRT Superior or Inferior to 3DCRT in Radiotherapy for NSCLC? A Meta-Analysis," *PloS one*, 11, no.4 (2016); Navaria P, et al., "P19. 03 Randomized Double Arm Phase III Study to Evaluate Feasibility and Safety of Gamma Knife Radiosurgery Versus LINAC Based (Edge) Radiosurgery in Brain Metastatic Patients," *Neuro*-*Oncology*, 18 suppl 4 (2016); Lub Jy, et al., "In Regard to Nabavizade H et al.," *Int J Radiat Oncol Biol Phys*, 96, no.2 (2014); Buyyounowski MK, et al., "Stereotactic Body Radiotherapy for Early-stage Non-small-cell Lung Cancer, Report of the ASTRO Emerging Technology Committee," *International Journal of Radiation Oncology* Biology* Physics*, 78, no.1 (2016); ASTRO, "Extremely Hypofractionated Radiation Therapy Shows Promising Toxicity Results for Intermediate Risk Prostate Cancer Patients," 2016, Oncology Roundtable interviews and analysis.

A Missed Opportunity

For example, hypofractionation presents a clear opportunity to increase value. There is now a strong body of evidence (as documented on the following page) showing that hypofractionated treatment plans yield as good, if not better, outcomes than conventionallyfractionated treatments for certain breast and prostate cancer patients—at a lower cost to payers and patients. Also, because it requires fewer treatment visits, it is more convenient for patients. Despite these benefits, most providers do not routinely use hypofractionation. This is not surprising in a fee-for-service environment in which providers' revenues correlate with the number of treatment visits.

However, there are some specific cases in which the benefits outweigh the revenue lost to the cancer program. For example, patients who have to travel long distances to a cancer center or are unable to take time away from work or family obligations may chose to delay or forgo radiation therapy when presented with a conventional treatment plan.

Hypofractionation can be a strategy for retaining these patients and revenues. Similarly, centers operating at full capacity have the potential to increase patient access and revenues by adopting hypfractionation.

Some cancer programs are taking steps to capture these benefits by hardwiring evidencebased practice.

1) Whole breast irradiation.

Percentage of Breast Cancer Patients Receiving Hypofractionation Data from 14 Commercial Health Plans, 2013



Hypofractionation-Endorsed Cohort

n=8,924

- · Over 50 years of age
- Stage T1,2 w/ no lymph node involvement
- No prior chemotherapy and achievable homogenous radiation dose distribution



Hypofractionation-Permitted Cohort

n=6,719

- Patient does not meet one of the criteria for endorsement
- Guidelines neither endorsed nor prohibited hypofractionated WBI¹ for this patient

Changing Practice Step by Step

One cancer program has been able to substantially increase the use of hypofractionation for breast cancer patients by making incremental changes to their internally-developed breast cancer pathway. Each amendment to the pathway incorporates the most recent evidence on hypofractionation and makes it more difficult for radiation oncologists to unnecessarily use conventional treatment plans.

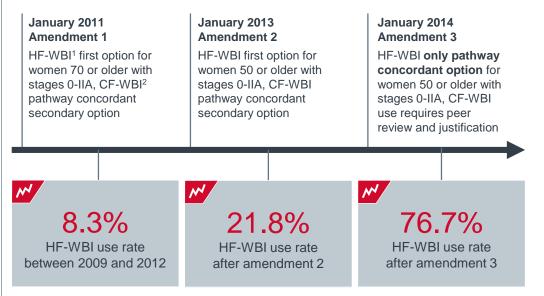
By taking an incremental approach, the cancer program allowed the radiation oncologists time to adapt to each change before adding the next.

Other cancer programs are turning to clinical pathways to hardwire evidence-based care. Over the past decade, clinical pathways have become an increasingly common tool to help medical oncologists identify the best and lowest cost drug regimens for their patients. Now, cancer programs are beginning to implement clinical pathways for radiation therapy.

To date, radiation therapy pathway adoption has been limited. One reason is that cancer programs are limited to the treatment modalities they offer and so may not always be able to treat patients "on pathway." Another reason is that because the clinical evidence in radiation oncology is more limited, the value of clinical decision support is lower.

Incremental Changes Encourage Hypofractionation

Major Milestones in Breast Clinical Pathway Development



The Pros and Cons of Radiation Therapy Clinical Pathways

Pros

- Leverage available evidence to identify appropriate modality, number of fractions, and image guidance technology
- Factor cost of technology into appropriate use determinations
- Standardize RT treatment across the organization

Cons

- Second-best pathway often required because some programs lack first option technology
- Evidence base for RT pathways significantly smaller than evidence base for chemotherapy pathways
- Less room for improvement given smaller variability in RT treatments

Source: Chapman BV, et al., "<u>Clinical Pathways: A Catalyst for the</u> Adoption of Hypofractionation for Early-Stage Breast Cancer," International Journal of Radiation Oncology" Biology" Physics, 93, no.4 (2015); Oncology Roundtable interviews and analysis.

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¹⁾ Hypofractionated whole breast irradiation.

²⁾ Conventionally-fractionated whole breast irradiation

Help Patients Be Their Own Advocate

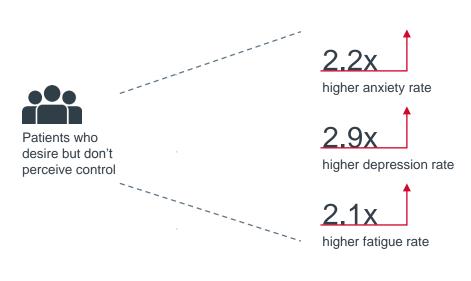
In the absence of a strong evidence base, physicians and patients are often faced with choosing between two or more treatment options, each with pros and cons. Similar to other types of cancer patients, radiation therapy patients want to feel some degree of control over the care they receive. They want to both understand their options and feel that they play a role in choosing their treatment. When they feel as if they have no control, they suffer from increased rates of anxiety, depression, and fatigue. Fortunately there are multiple ways to engage radiation therapy patients in shared decision making.

Perceived Empowerment Impacts Well-Being, Outcomes

Impact of Shared Decision Making on Patient-Reported Outcomes

Radiation Therapy Patients in Last Week of Treatment

n=80 patients who desired and perceived control n=17 patients who desired but did not perceive control



7

Related Resources

Learn more about patient engaged in the following Oncology Roundtable resources, available on advisory.com:

- Shared Decision Making Resources Compendium for Cancer Programs
- <u>Strategies to Engage Cancer Patients and Caregivers</u>

Helping Patients Understand Their Options

Several years ago, Jefferson Health developed a systematic shared decision making process to help low-risk prostate cancer patients choose a treatment modality that best suits their needs and goals. As a result, they saw a significant increase in the percentage of men choosing active surveillance.

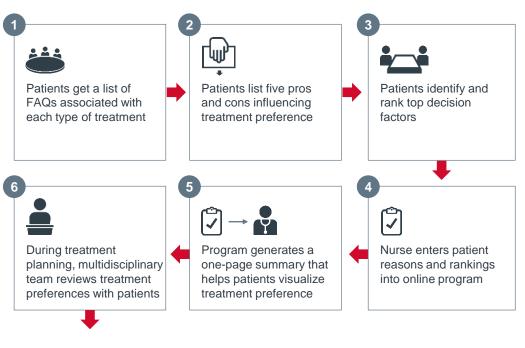
The process begins with patient education. Upon diagnosis, patients are given a list of frequently asked questions about their treatment options. Patients are then prompted to list the pros and cons of each treatment for them personally. For example, for active surveillance, a pro might be "My doctor recommends this treatment," while a con could be "I'm afraid my cancer will turn into the aggressive type."

After patients rank order what is most important to them, a nurse enters their responses into an online program that generates a one-page summary to help patients visualize which treatment options meet their treatment goals. Providers and patients use the one-page summary to help guide their decision making.

In a pilot, Jefferson found that 83% of low-risk prostate cancer patients in the Decision Counseling Program chose active surveillance rather than active therapy.

Decision Support Impacts Course of Care

Jefferson Health Decision Counseling Program



Of Decision Counseling Program participants with lowrisk prostate cancer who chose active surveillance

7

83%

Case in Brief: Jefferson Health

- 905-bed academic medical center located in Philadelphia, Pennsylvania
- Created Decision Counseling Program (DCP), an online interactive program to engage patients, clarify their treatment preference, and help them discuss their options with clinical team
- Patients are educated about options and asked to identify and rank the factors and preferences involved in their decision; nurse enters results into online program which generates a one-page summary for patients and providers to use in treatment planning
- Program leaders involved radiation oncologists, urologists, and patients in development of education and decision assistance materials
- 83% of the patients using DCP elected active surveillance rather than aggressive treatment
- DCP led to increased patient knowledge, increased satisfaction with decisions, and decreased decisional conflict

Source: Thomas Jefferson University, Philadelphia, PA; Hoffman-Censits JH, et al., "Impact of a Novel Decision Counseling Program on Treatment Knowledge. Decisional Conflict, and Choice in Men with Early-Stage. Low-Risk Prostate Cancer," Journal of Clinical Oncology, 31, no. 9 (2013); "New Program Makes Prostate Cancer Treatment Decisions Easier," Thomas Jefferson University, October 21, 2013; Oncology Roundtable interviews and analysis.

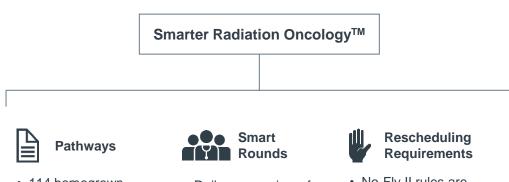
A Disciplined Approach to Patient Safety

Another critical issue in radiation therapy is patient safety. While radiation is a very effective cancer treatment, any amount of radiation exposure increases patients' chances of developing secondary cancers and, in extreme cases, dosing errors can cause permanent harm or death. As a result, clinicians must take steps to protect patients' healthy tissue and minimize the radiation dose to the smallest effective amount.

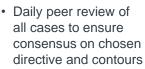
Northwell Health has made a long term commitment to safe radiation therapy practices. The program started by creating a multidisciplinary quality management team that mapped the radiation treatment process from first consult to treatment completion and then divided it into seven discrete phases. For each phase, the team created safety and quality checklists. The checklists assigned accountability and provided deadlines for each process step. Finally, they implemented what they call a "No Fly" policy. The policy mandates if key steps have not been completed by a specified time, then staff must delay patients' treatment start.

Northwell has since revised and expanded the program, and named it the Smarter Radiation Oncology (SRO) program. It has three components: evidencebased pathways, daily peer review to ensure consensus on directives and contours, and rescheduling requirements designed to ensure every step occurs sequentially.

Northwell Uses Evidence and Consensus to Increase Patient Safety



- 114 homegrown, evidence-based, consensus-approved directives
- Includes dose, simulation instructions, treatment planning constraints, clinical care details



- Cases must receive consensus before start of treatment planning
- No-Fly II rules are forcing functions to ensure no process is rushed or skipped
- Uses an electronic whiteboard to track each patient's progress in care pathway, alert staff of next steps, and identify overdue work

E7

Case in Brief: Northwell Health

- 21 hospital health system based in Lake Success, New York; formerly known as North Shore-LIJ Health System
- Radiation department began top-to-bottom review of patient care to develop system of accountability and quality assurance; developed culture for department operations called Smarter Radiation Oncology[™] (SRO)
- SRO encompasses clinical care, operational efficiencies, safety management, and quality control
- Uses 114 homegrown, evidence-based, consensus-approved treatment directives; includes dose, simulation instructions, treatment planning constraints, clinical care details
- Daily peer-review of all cases to ensure consensus on chosen directive and contours
- Unlike the original No-FLY rules which set deadlines and delayed care when deadlines were not met, No-Fly II delays treatment start only when there is a delay in upload or IMRT quality assurance
- Uses electronic whiteboard to plan and track the planning process, track clinician performance, and identify improvement opportunities

Source: Cox B, et al., "Prospective contouring rounds: A Novel, High-impact Tool for Optimizing Quality Assurance," Practical Radiation Oncology, 5, no.5 (2015); Northwell Health, Lake Success, NY; Potters L, et al., "Implementation of a "No Fly" Safety Culture in a Multicenter Radiation Medicine Department," Practical Radiation Oncology, 2011; Oncology Roundtable interviews and analysis.

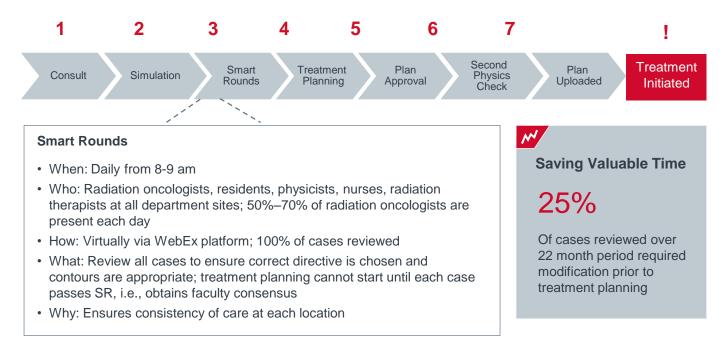
Start on the Right Foot

Daily Peer Review Identifies Problems Before Treatment Initiation

Every day during the daily peer review, radiation oncologists, nurses, and therapists gather to review cases and make sure the correct pathway and contours are chosen. If the group decides something is incorrect, the case is sent back for modification. Treatment planning does not begin until the team reaches consensus about the optimal pathway and contours.

Although the peer review process is time consuming, leaders at Northwell report that it actually saves time over the long run because it reduces the number of treatment plans that require modification later on, which can create inconvenient delays for patients.

Over a 22-month period, the team at Nothwell identified problems in 25% of cases. Once identified, most problems are easily fixed and do not usually create delays in patients' treatment. Not only does this approach help to improve patient safety, but it also promotes a standardized approach to care across Northwell's facilities.



Seven Phases to Radiation Therapy Treatment Initiation

Learn from Your (and Others') Mistakes

One of the primary ways that radiation therapy programs will be able to distinguish themselves in the value-based market is through their safety record, and one of the best ways to improve safety is to seize opportunities to learn from mistakes.

The Radiation Oncology Incident Learning System (RO-ILS) facilitates this process. There are currently more than 200 practices enrolled in the system. Participation is free. To enroll, cancer programs sign a contract with Clarity PSO, the vendor that provides patient safety services to participants. Participants that submit data on incidents through the system are protected by the secure, nonpunitive, privileged environment. In exchange, they receive regular aggregate as well as facility-level reports.

These reports contain information that can help programs identify and prevent errors related to the radiation therapy process. Additionally, participating practices will receive MIPS (Merit-Based Incentive Payment System) clinical improvement activity points that can positively impact their Medicare reimbursement.

Radiation Oncology-Incident Learning System[®] (RO-ILS) Event Form

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Benefits of Participation

- Participating organizations receive quarterly aggregate-level and twice-yearly facility-level data reports
- Participating organizations receive credit for one MIPS clinical improvement activity
- Data reports include case studies and best practices as well as trend reports for topic areas, such as:
 - Type of events reported (e.g., patient incident, near miss, unsafe condition)
 - Workflow step where events occurred
 - Treatment technique involved
 - Current and future impact of event on patients

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Technology in Brief: RO-ILS: Radiation Oncology-Incident Learning System®

- System developed by ASTRO and AAPM to enhance shared learning across radiation oncology practices
- Uses Clarity Group, Inc.'s Healthcare SafetyZone® Portal; Clarity PSO provides patient safety services to participating programs
- · Program launched in 2014; over 200 organizations currently participating

Changing Our Investment Strategy

In the past, cancer programs' decisions about whether to invest in a new treatment technology were often driven by the theoretical promise of the new technology. However, a number of market pressures, including reductions in reimbursement, changing payer policies, and the shift to valuebased reimbursement, are forcing cancer programs to change their investment strategy.

The defining feature of this new strategy is a focus on the proven—not theoretical—value of a new technology. As a result, many cancer programs may find that they need to delay new investments until clinical and cost data become available.

In the past, capital equipment's ROI was primarily determined by its impact on cash flow and capacity. These are still important, but program leaders also need to consider nontraditional returns, such as cost avoidance resulting from reduced toxicities.

Importantly, this value-driven approach applies to all types of investments, not just radiation therapy equipment. But given the cost and lifespan of these technologies, the ramifications of investment decisions are greater and longer lasting.

Old Investment	Factors Driving	New Investment
Strategy	Change	Strategy
 Focus on theoretical value of technology Emphasis on being an early adopter Focus on new technology as market differentiator Driven by lack of comparative effectiveness data, payers' willingness to reimburse despite lack of evidence, hospital capitulation to specialist's demands 	Payers demand evidence of benefits Budget tightening for cancer programs Cancer programs increasingly responsible for total cost of care	 Focus on proven value of technology Evidence of clinical effectiveness Evidence of cost effectiveness Focus on outcomes and costs as market differentiator Investments aligned with research priorities Includes physician champion on technology acquisition team

Theoretical Value Isn't Enough Anymore

New Investment Strategy Evaluates ROI Differently

Need to Look Beyond Generated Cash Flow and Impact on Capacity

New Return	Payment Model Change	Suggested Investment Model Change	Example
Cost Savings	Some investments do not directly generate revenue but still may benefit a provider by reducing the cost of care	Inclusion of per-unit cost reduction and the cost of future investments avoided as positive cash flows	Beacon gating technology can reduce late-stage toxicity by shrinking PTV margins
Quality-Based Incentive Revenue and Avoided Penalties	Public and private payers are leveraging incentives and penalties to tie reimbursement to quality of care	Addition of estimated impact on quality-based incentives (e.g., quality scores) and readmissions reduction, which results in positive cash flow, tied to investment	Hypofractionation can improve patient satisfaction with care experience, which will be reflected in new patient- satisfaction quality metrics

Source: Service Line Strategy Advisor, <u>Primer: Assess New</u> <u>Investments with the Value-Based Pro Forma</u>; Oncology Roundtable interviews and analysis.

Taking a System Approach to New Investments

Aurora Health Care was an early adopter of value-driven technology investment. The health system has a systemwide multidisciplinary radiation oncology planning committee that is responsible for all technology investment decisions. In addition to deciding whether to purchase a given technology, the committee also determines where to place new technologies across the system.

The committee relies on clinical and cost-effectiveness data to guide their decision making. Committee members write evidence reviews for specific technologies, which are then presented to the larger group. They also continually review utilization data to ensure that the system is maximizing the return on its purchases.

Aurora's Planning Committee Focuses on Proven Value

Responsibilities of Aurora's Radiation Oncology Planning Committee

Radiation Oncology Planning Committee

- Who: VP cancer service line, senior director cancer service line, two radiation oncologists, capital acquisition specialist, radiation oncology managers, hospital president representative, IT specialist, physicist representative, radiology leadership
- When: Meet monthly
- Why: Ensure appropriate RT technology at each site and evaluate and prioritize requests for new technology

Identify Appropriate Technology

- Review evidence on clinical and cost effectiveness of technologies
- Analyze impact of technologies on existing service offerings

Allocate Technology

- Conduct market
 assessments to
 understand current and
 projected need
- Review technology utilization at each facility to identify underutilized equipment

Support Facilities

- Provide training to ensure appropriate utilization of technologies
- Manage the capital acquisition process to ensure all systems have access to necessary technologies

Case in Brief: Aurora Health Care

- · 15-hospital health system based in Milwaukee, Wisconsin
- System-wide radiation oncology planning committee meets monthly to discuss radiation therapy technology utilization, placement, and acquisition
- Committee responsibilities include:
 - Reviewing evidence on clinical and cost effectiveness of technologies
 - Analyzing impact of technologies on existing service offerings
 - Identifying minimum standard of technology to be located at each site
 - Ensuring each site has the necessary technology
 - Conducting market assessments to understand current and projected need
 - Reviewing technology utilization at each facility to identify underutilized equipment
 - Providing training to ensure appropriate utilization of technologies

Radiation Oncology Innovations

Potential Impact in the Next Three to Five Years

In summary, the table below provides an assessment of the radiation therapy technologies discussed in this brief and key considerations for investment. Notably, based on the Oncology Roundtable's research, these technologies are not expected to drive significant revenue growth. The primary reason is that payers are increasingly reluctant to reimburse for new treatments and services in the absence of a significant body of clinical and cost-effectiveness data. Given that the current evidence base for these technologies is limited, it will likely take several more years for that data to emerge. That said, even in the absence of a clear business case, cancer programs that wish to establish themselves as research centers or further advance their research capabilities may determine that there is value in investing in these technologies.

Innovation	Impact on Outcomes	Impact on Cost Savings	Impact on Patient Volumes	Impact on Research
	How much will this improve patient outcomes?	How much can this decrease costs?	What is the potential number of patients impacted?	How much will this differentiate us as a research program?
Proton Therapy		\bigcirc		
MRI-Guidance		\bigcirc		
Real-Time Adaptive Technology				
Radiosensitivity Testing				
\bigcirc	No Minimal Impact	Moderate Impact	Significant Max Impact Imp	kimum act

Key Takeaways

1. Use cost- and clinical-effectiveness evidence when making investment decisions.

Due to tightening budgets, payer demands for clinical evidence, and shifting reimbursement models, programs need to pursue an investment strategy that focuses on the proven—not theoretical—value of investments. Non-traditional returns on investment, such as cost savings, should be factored into investment decisions as well.

2. Prepare for radiation therapy bundles in the value-based market.

Characteristics of radiation therapy, such as clear end points and the opportunity to achieve savings by changing clinical practice, make it an attractive target for payment reform.

3. Aim to become an evidence-centered program.

Despite the current deficiency of comparative effectiveness data for radiation therapy technologies, there are concrete steps programs can take to ensure they are providing—and can continue to provide—evidence-based care. These include hardwiring evidence-based practice and helping to build the evidence base through the use of registries.

4. Treat mistakes as an opportunity to learn.

Programs can facilitate the learning process by participating in a PSO¹, such as the Radiation Oncology-Incident Learning System. Other programs may develop internal processes to ensure the delivery of safe, high-quality care.



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