Bringing MRI Scanners to the Brachytherapy Suite

A Study of Innovation in the Field of Radiation Oncology

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Table of Contents

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INTRODUCTION AND BACKGROUND

Radiation therapy has been used to treat human disease for more than 100 years.[1] Currently, radiation therapy is a mainstay of cancer therapy, used to treat approximately 1 million patients per year in the United States.[2] Radiation works by causing damage to cellular DNA. It is particularly useful in treating cancer because neoplastic cells, which lack many normal DNA repair capabilities, making them more susceptible to radiation-induced DNA damage than healthy cells.[3]

Radiation therapy can be delivered in one of two ways: (1) through external beam radiation therapy (EBRT), in which a beam of photons or particles is aimed directly at the tumor site, or (2) via brachytherapy, in which a radioactive source is placed either inside or directly adjacent to the tumor.[4] Brachytherapy is further divided into high-dose-rate (HDR) and low-dose-rate (LDR). In HDR brachytherapy, a potent radioactive source is used to treat the tumor for a very short period of time. In LDR brachytherapy, weaker sources are used which may remain in the tumor indefinitely.[3] Regardless of the form of radiation used, the goal of therapy is the same: to provide the highest possible dose to the tumor while sparring nearby, healthy tissues.[5] However, radiation toxicity to healthy tissues is common, which leads to numerous side effects and may limit the total dose that can be safely delivered to the tumor, decreasing the chance of cure.[6]

Many of the advancements in radiation therapy that occurred during the previous century have resulted in an improved ability to deliver high doses of radiation to tumors, avoid healthy tissues, or both[7]. One low-tech example is fractionation—used with both EBRT and brachytherapy—through which the course of therapy is broken up into multiple sessions, provided over the course of days or weeks. Fractionation allows healthy tissues to recover between treatments, limiting toxicity, while still allowing a large cumulative dose to be delivered to the tumor.[8] Fractionation has many practical implications for the planning and delivery of radiation therapy, which will be discussed in more detail below.

The advent of advanced diagnostic imagining—primarily CT and MRI—has driven much of the innovation in radiation treatment planning and delivery.[9] Prior to the introduction of CT and

MRI, physicians were not able to directly visualize the size and shape of tumors or the precise position of nearby "organs at risk" (OAR). As a result, radiation therapy treatment planning was crude, using standardized bony landmarks and general anatomic principles to guide delivery. Due to uncertainty regarding tumor location and size, wide treatment margins were used, often resulting in substantial damage to nearby tissues and a high rate of severe side effects.

Although the field of radiation oncology has experienced an explosion of innovation, the advancements have been disproportionately applied to EBRT. Since the 1980s, there have been two major revolutions in EBRT, (1) 3D-conformal radiation therapy (3D-CRT) and (2) intensity modulated radiation therapy (IMRT). Both of these technologies combined advancements in delivery methods with 3D-imaging to provide more conformal tumor targeting, improving patient outcomes and decreasing the severity of side effects:[8,9]

1. 3D-CRT: The principle behind 3D-CRT was that by treating patients with a combination of intersecting 2D-beams, a 3D dose distribution could be produced that approximated the shape of the tumor (as determined by CT imaging). 3D-CRT provided better coverage to the tumor and decreased dosages to OAR than previous methods. However, the process had a steep learning curve and was tedious and inefficient, slowed primarily by the era's limited software and computing capabilities.[5] Physicists had to do much of the treatment planning and calculations by hand, searching through trial and error for beam combinations that resulted in acceptable dose distributions.
2. IMRT: IMRT was introduced in the 1990s and revolutionized EBRT, replacing 3D-CRT for the treatment of many forms of cancer (the adoption of IMRT is discussed in detail below). IMRT was made possible by the coalescence of 3 distinct technologies: (1) multileaf collimators—collections of motorized "leaves" of tungsten—that could be programmed to move in and out of the path of a radiation beam, creating a series of "beamlets" whose intensity could be varied according to the dimensions of the tumor,[10] (2) 3D-imaging, used to determine the precise size and shape of tumors and location of OAR, and (3) "inverse-planning" software, which uses advanced algorithms to determine the optimal way of combining hundreds to thousands of beamlets to optimally deliver

radiation dosages according to plans drawn on digital CT-images by physicians.[11] With IMRT, highly complex tumor shapes can be treated with precision, resulting in excellent dose delivery to the tumor yet sparing nearby tissues.[10] Multiple clinical trials have demonstrated improved tumor control and decreased incidences of severe side effects for patients treated with IMRT relative to 3D-CRT.[12] Thus, IMRT has replaced 3D-CRT as the standard of care for many forms of cancer.

In contrast to EBRT, brachytherapy treatment has changed little during the last several decades. Cervical cancer, for example, is still predominately treated using the Manchester system, developed in the 1930s.[13] Patients are imaged using standard plain films (2D x-rays) and radiation dosage is prescribed to a fixed point that approximates the location of the cervix. This system still uses stand bony landmarks for planning and does not account for the size and topography of the tumor or the location of OAR. Similarly, for prostate cancer, radiation seeds are placed throughout the whole prostate, irradiating the entire organ, rather than the individual tumor.[14]

Although crude planning methods are still used to provide brachytherapy for many forms of cancer, improved methods incorporating 3D-imaging (referred to as 3D-image guided brachytherapy, or "3D-IGBT") have been developed for cervical cancer, are currently being investigated for prostate cancer, and have been proposed for several other forms of cancer.[15] In the case of cervical cancer, there is convincing evidence that MRI-guided 3D-IGBT leads to improved outcomes relative to conventional brachytherapy, more than doubling survival for patients with tumors >5 cm.[16] As a result, in 2005 the American Brachytherapy Society (ABS) adopted recommendations for implementing 3D-IGBT for cervical cancer;[17,18] updated guidelines were published by the ABS in January of 2012.[19,20,21] However, very few radiation therapy centers have adopted the recommended treatment techniques.[22] The goal of this paper is to explore why. First, I will provide a review of the evidence supporting 3D-IGBT for cervical cancer as well as a description of research into 3D-IGBT for prostate cancer. Second, I will compare the adoption of IMRT to that of MRI-guided 3D-IGBT (referred to as "MR-IGBT"), drawing inferences for the future of MR-IGBT where possible. Finally, I will perform a scenario

analysis, evaluating the impact of various uncertainties in the healthcare environment on the future of MR-IGBT for both cervical and prostate cancer.

BRACHYTHERAPY – CONVENTIONAL METHODS AND MR-IGBT

It is important to understand both the methods used for conventional brachytherapy as well as the advantages and limitations of MR-IGBT. This section describes conventional brachytherapy treatment for cervical and prostate cancer, potential benefits of MR-IGBT, and barriers to adoption of MR-IGBT.

A. Cervical Cancer

Conventional Treatment: The conventional 2D-brachytherapy system for cervical cancer uses orthogonal plain films to plan and prescribe radiation to a set of defined points. This system does not take into account the unique size and shape of a tumor or the location of OAR.[23] This may lead to tumor under-dosage and OAR over-dosage, increasing the probability of cancer recurrence and the incidence of severe side-effects.

Patients are typically treated with HDR brachytherapy, delivered in 5 daily fractions. Prior to each treatment, an applicator—the conduit through which the radiation source is passed—is placed in the patient's vagina. X-rays or ultrasound images are used to verify correct positioning of the applicator. Applicator placement can cause uterine perforation, which may not be detected by plain film or ultrasound imaging, and can subsequently lead to an unacceptably high dose to the uterus and surrounding tissues,[24] causing severe healthy tissue damage.

This system does not account for changes in the position of the tumor or OAR, which can change between fractions as a result of patient positioning and physiologic processes such as bladder filling and emptying. As a result, the actual radiation delivered to the patient may vary greatly from day to day, resulting in major deviations from the intended treatment.

3D-IGBT: 3D-IGBT can technically be performed using either CT or MRI. However, MRI is the recommended imaging modality, as it provides superior soft tissue resolution and allows for far better visualization of tumors and critical structures. Additionally, a recent study demonstrated that CT images cause overestimation of tumor width;[25] as a result, planning based on these images leads either to reduction in dose to the tumor (due to efforts to spare OAR), or increased dose to OAR (if tumor dose is optimized).[26] Thus, all guidelines published to date

strongly recommend adoption of MRI for IGBT panning as quickly as possible. For centers without access to MRI, IGBT with CT imaging is recommended until MRI scanners are available.

Current guidelines recommend MR-imaging prior to delivery of each daily fraction, immediately after applicator insertion.[19,27] Daily scanning allows for (1) verification of correct applicator placement and (2) daily modifications to the treatment plan based on the location of OAR and changes in size or configuration of the tumor. The position of OAR, particularly the bladder and sigmoid colon, can change dramatically from day to day as a result of physiologic processes such as bladder filling or movement of gas and stool through the colon. Failure to account for these movements can cause healthy tissue toxicity, leading to side effects such as rectal bleeding. Moreover, the dimensions of the tumor can change as a result of small changes in patient positioning, radiation-induced tumor necrosis, or treatment-related edema.[23] 3D-planning has been shown to reduce the incidence of severe rectal bleeding,[28] while also improving local tumor control and more than doubling survival (28% for conventional brachytherapy vs. 58% for MR-IGBT, p=0.003) for patients with large tumors.[16] Due to the need to scan patients immediately after insertion of the applicator but prior to treatment, the MR scanner should be located either within the brachytherapy treatment suite or in very close proximity to it (i.e., within the radiation therapy department).[15]

B. Prostate Cancer

Conventional Treatment: Prostate cancer patients are typically treated with LDR brachytherapy, consisting of permanently implanted radioactive seeds. Patients with advanced or aggressive disease may receive an HDR “boost” in addition to or in place of standard LDR brachytherapy. Planning often is conducted in the days or weeks prior to seed implantation, but can be done immediately prior to implantation or even during implantation. The prostate is located and measured via trans-rectal ultrasound (TRUS). The images are used to create a seed placement plan; the entire prostate is treated, either with uniform dose distribution or with increased density at the periphery in order to decrease dose to the urethra (which passes through the center of the prostate). The seeds are then implanted using trocars that are inserted through the skin of the perineum. After the seeds are placed, images are taken of the prostate using

either plain films, CT, or (rarely) MRI. This allows the physician to visualize seed location and determine how closely the dose distribution matches the initial plan. If seed placement is suboptimal, additional seeds can be inserted for improved coverage. Though any of these imaging methods can be used, all have limitations: plain films do not identify soft tissue structures and therefore cannot be used to determine the spatial distribution of the radiation dose. CT provides additional geometric information, but provides poor soft-tissue contrast making identification of the prostate borders difficult. As a result, the prostate volume is often overestimated (by as much as 30%), resulting in overdose to nearby healthy tissues. Finally, MRI provides excellent resolution of soft tissues, but poor visualization of the actual seeds, which can be confused with blood vessels or calcifications within the prostate.[14]

The limitations of conventional brachytherapy for prostate cancer are similar to those for cervical cancer. The entire organ is treated, rather than the individual tumor(s). As a result, a significant amount of healthy tissue may be irradiated, leading to side effects such as urethral bleeding. Efforts to avoid side effects reduce the total dose that is prescribed, which may reduce the likelihood of cure. Finally, the imaging methods used to plan and subsequently verify seed placement are inexact, resulting in overestimation of the target volume and subsequent unnecessary irradiation to tissues surrounding the prostate.

MR-IGBT: Researchers at Harvard Medical School have explored methods of using real time MR-guidance for brachytherapy seed placement in prostate cancer treatment.[15] MRI provides better resolution of the prostate than conventional methods (CT and TRUS), allowing physicians to pinpoint the location of focal tumors within the prostate, accurately determine the prostatic borders, and visualize surrounding soft tissues.[29] Using this information, a plan can be created that targets the tumor specifically, rather than the whole prostate as with conventional treatment. Real time MR-imaging is then used to guide seed insertion, allowing for precise positioning and placement of each seed. Early clinical data suggest that 5-year control for patients using this technique is similar to that of radical prostatectomy, the gold standard of prostate cancer treatment.[30] However, the procedure is still experimental and limited to research settings.

C. Implementation Challenges

The main impediment to MR-IGBT adoption is access to MRI scanners. Very few radiation oncology departments currently house MRI scanners. This is largely because CT has been the imaging method of choice in the past. CT was available before MRI, leading to widespread adoption in the 1980s. As a result, nearly all commercially available treatment planning software was programmed to work with digital CT images.[31] This became the standard and has persisted for nearly 30 years. CT has other advantages over MRI, including lower cost, faster imaging times, and fewer shielding requirements (MR scanners must be housed in a large, metal Faraday cage).

Although nearly all U.S. hospitals now have access to MRI scanners, nearly all are housed in the radiology department and used for diagnostic imaging procedures. Typically, the radiology and radiation oncology departments are not located in close proximity to each other, as radiation oncology is usually performed in an outpatient setting and radiology is primarily used for imaging inpatients. Due to the physical distances that often separate these departments, use of MRI scanners for treatment planning purposes by radiation oncology personnel is not practical. As discussed earlier, the scanners must be in very close proximity to brachytherapy treatment rooms in order to minimize patient movement and prevent discomfort.

Purchase, installation, and operation of new MRI scanners by radiation oncology departments may be problematic for several reasons. First, MRI scanners are very expensive, costing $1-1.5 million for a high quality machine. Second, scanners must be housed in a shielded room, which can cost up to $1 million to build. Third, operating scanners and interpreting the images requires additional personnel and expertise. Thus, radiation therapy departments would have to either hire additional employees or provide training to existing employees, adding to the overall expense.[32]

Finally, adoption of MR-IGBT may place additional strains on radiation therapy departments. Not surprisingly, it takes much more time to plan and deliver MR-IGBT than conventional therapy; acquisition of detailed, 3D images takes significantly longer (up to 45 minutes) than plain films (seconds to minutes). Individualized treatment planning based on 3D images then

takes several more minutes and requires the input of both physicians and medical physicists.[33] Since patients are scanned every day prior to treatment, the overall increases in treatment planning time are substantial. As a result, radiation centers must either treat fewer patients per day or add additional capacity (including more rooms, equipment, physicians, physicists, and technicians) in order to maintain stable patient volumes.

THE ADOPTION AND DIFFUSION OF RADIATION THERAPY TECHNOLOGY—A COMPARATIVE ANALYSIS OF IMRT AND MR-IGBT

The introduction of new medical technologies has wide-ranging implications for nearly all groups in the U.S. healthcare system, including patients, physicians, administrators, insurers, policy makers, and producers of commercial technology. The introduction and adoption of new technologies is a principle driver of the rapid growth of medical spending,[34] which strains the budgets of governments, employers, and individual households. However, technological advances in medical technology are also responsible for much of the increases in life expectancy enjoyed by Americans since 1900.[35]

In this section of the paper, I first describe general patterns of technology diffusion and adoption. I then examine and compare the early diffusion pattern of two radiation oncology technologies with similar capabilities: IMRT and MR-IGBT, both of which allow for more targeted radiation treatment. Differences in their diffusion rates are examined in relation to their unique attributes as well as the characteristics of the environments that surrounded their emergence.

A. Diffusion and Adoption of New Technologies

The adoption of new technologies frequently follows a predictable S-shaped pattern.[36] Adoption is generally rather slow shortly after an innovation is introduced to market–it takes time for news of the innovation to spread, potential purchasers may be reluctant to invest in an unproven technology, and initial users may be subject to a steep learning curve. However, after approximately 20% of the population of potential users has adopted the innovation, the "tipping point" is reached, after which adoption becomes much more rapid.[37]

Prospective adopters of an innovation self-select into five segments (innovators, early adopters, early majority, late majority, laggards), based primarily on their aversion to risk and the intensity of their needs. These characteristics lead to predictable differences in their time of adoption, which can be represented as a bell-shaped curve when plotted over time.[36]

These models describe general patterns of adoption, but do little to predict how quickly an innovation will be accepted. They do not predict, for example, if it will take 20 weeks or 20 years for the laggards to adopt the innovation in question. Four key characteristics of a product have been shown to impact the speed of its adoption: (1) perceived advantages of the new product over its alternatives; (2) perceived risks of adopting new technology due to uncertainty regarding its benefits and financial potential; (3) barriers to adoption, such as investment in prior technologies or a steep learning curve; and (4) opportunities to try and learn, providing buyers with the ability to gain first-hand exposure to the product prior to investing in it.[36]

In the healthcare market, researchers have further refined and characterized factors that influence the adoption of new technologies. Chief among these are: (1) scientific and clinical potential, (2) government regulation, (3) insurer reimbursement, (4) competitive pressure to provide clinical services, and (5) cost relative to purchasing power.[38,39]

It is unclear how quickly and to what extent MRI-IGBT will be adopted into clinical practice. Despite the publication of guidelines and recommendations by numerous physician specialty societies several years ago, MR-IGBT is currently rarely used in clinical practice.[22]

In this section, the early adoption of MR-IGBT will be compared to that of IMRT, a radiation treatment innovation that also allowed for improved targeting of tumors. The effect of each of the five key drivers of technology adoption in healthcare settings will be examined and compared for both technologies. Finally, the impact of these drivers on the future adoption and spread of MR-IGBT will be explored.

B. Diffusion and Adoption of IMRT and MRI-based 3D-IGBT

Methods

Data regarding the adoption of IMRT and 3D-IGBT were obtained by searching PubMed for case studies and surveys of practice patterns of radiation oncologists in the United States. In order to understand and characterize the environment surrounding the early adoption of IMRT, specialty journals were searched for review articles, opinion pieces, and editorials discussing both the scientific promise and limitations of IMRT, as well as any systemic factors that could

potentially have influenced its adoption (e.g., the reimbursement and regulatory environment, competitive pressures between providers, etc.). These sources were also searched for information regarding the environment currently surrounding MR-IGBT. When information was not available in the published literature, interviews with experts (radiation oncologists and medical physicists) were conducted. ClinicalTrials.gov, an online registry of clinical trials conducted throughout the world, was also searched for studies of MR-guided brachytherapy in order to identify study sites with MR-IGBT capabilities. By examining the dates of patient enrollment of each study, the timing of adoption at each center was estimated.

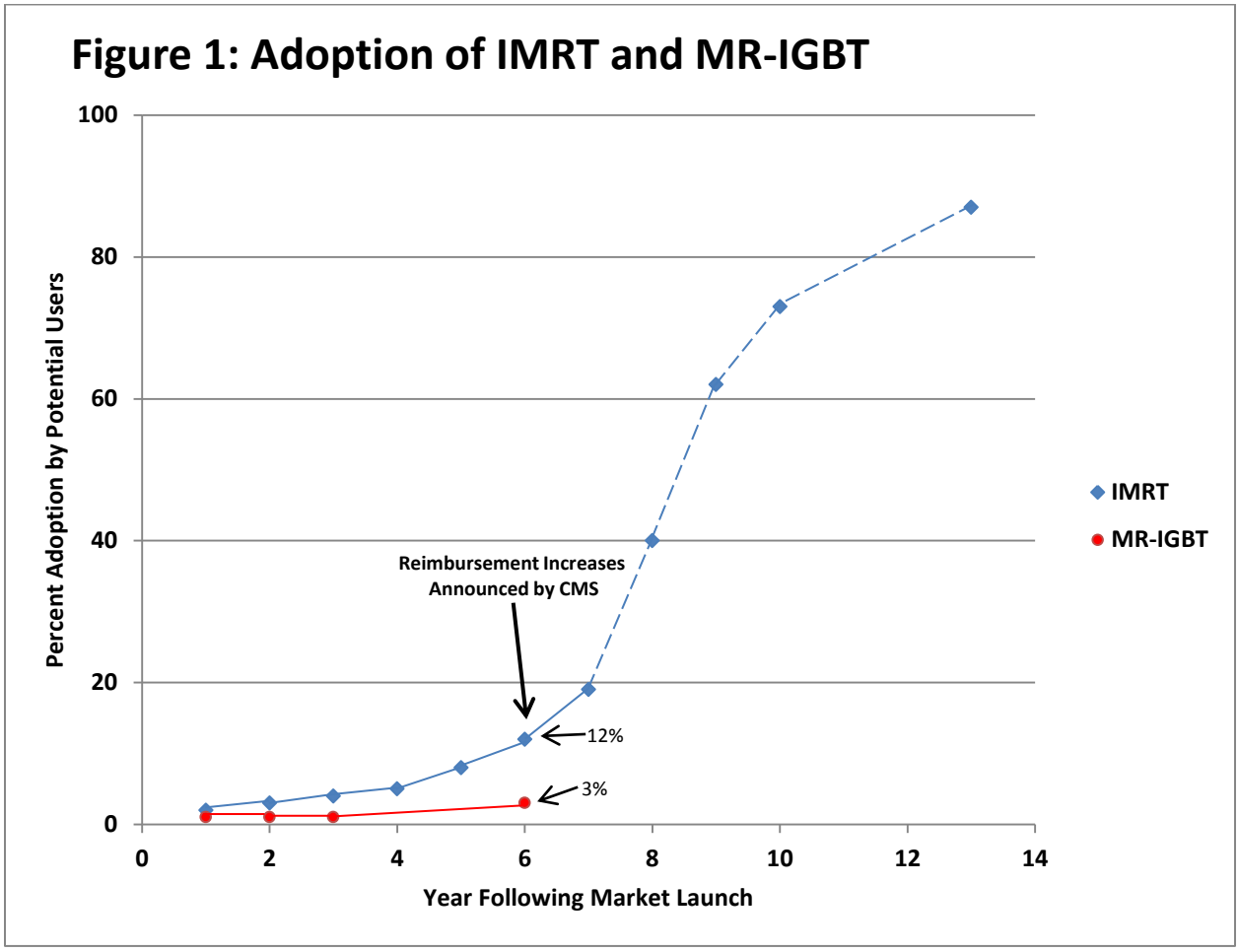
The "introduction" of IMRT was defined as 1994 (year 0), the time at which the first commercial IMRT equipment was made available for purchase. Since MR-IGBT can be performed using existing equipment, the "introduction" of 3D-IGBT was defined as 2005 (year 0), corresponding to the ABS adoption of guidelines advocating the adoption of MR-IGBT for cervical cancer in the U.S.

Published adoption rates for IMRT were reported in percentages. In contrast, the absolute number of centers using MR-IGBT was determined. To convert this number to a percentage, the total number of centers treating cervical cancer patients was estimated indirectly using previously published data as follows: In a survey previously mailed to the 256 physician members of the American Brachytherapy Society, 94% of respondents (133/141) treated at least one cervical cancer patient per year.[22] Thus, it was estimated that 241 physicians (94% x 256) treat cervical cancer patients annually.

Results

Figure 1 depicts cumulative adoption of IMRT and MRI-guided IGBT in the years following market introduction. Surveys of practice patterns of IMRT documented steady increases during years 1-6, from 2% in 1995 (year 1) to 12% by year 2000 (year 6). By 2004, approximately one decade after introduction, 73% of potential users had adopted IMRT.[40,41] Three years later, the last year for which data are available, 87% of potential users had adopted IMRT.[42] Information regarding the adoption of MR-IGBT was primarily obtained from the 2007 survey of ABS members[22] and interviews with experts. As of 2011, only seven centers were identified that

offered MR-IGBT for cervical cancer and only one that provided MR-IGBT for prostate cancer[32] (~3% of potential users). Of note, all of these centers were large academic medical centers with strong research interests.



As depicted in figure 1, there were striking differences in the early adoption rates of IMRT and MR-IGBT. Six years after introduction, approximately 12% of potential users had adopted IMRT, while only an estimated 3% had adopted MR-IGBT by 2011. Moreover, at year 6 there was tremendous demand for IMRT machines–96.5% of non-adopters surveyed during the early 2000s (expressed plans to adopt IMRT in the near future.[40] In years 7-12 (2001-2007), IMRT adoption accelerated dramatically (Figure 1, dotted line), which coincided with the announcement of new billing codes and significant reimbursement increases for IMRT by the Center for Medicare and Medicaid Services (CMS) in the early 2000s.[43]

In contrast, there currently appears to be very little interest in adopting MR-IGBT by the radiation therapy community, particularly among non-academic centers. The vast majority of published literature is from specialty societies advocating the adoption of MR-guided IGBT. With IMRT the situation was reversed–many experts advocated restraint regarding IMRT adoption until additional evidence of clinical benefit and safety could be accumulated.

Discussion

New technologies are often quickly adopted by the medical community and incorporated into clinical practice. Examples of technologies that enjoyed explosive growth include CT imaging, MRI, cardiac stents, minimally invasive surgery, and IMRT. Other seemingly beneficial technologies are adopted far more slowly. Undoubtedly, the most highly-publicized example of today is electronic medical records.

At this point, it is uncertain what the future holds for MR-IGBT. However, by examining both attributes of technology and environmental factors that have been shown to influence the adoption of new technologies for both IMRT and MR-based IGBT, we can gain insights that may explain the differences between the paces of adoption and also help predict the future of MR-IGBT. The impact of each of the five critical drivers of medical technology is examined for both MR-IGBT and IMRT in Table 1.

Table 1: Drivers of Med-Tech Adoption: IMRT and MR-IGBT 6-years After Market Introduction

DRIVER	IMRT (circa 2001)	MR-IGBT (2011)	Advantage
1. Scientific and Clinical Potential	IMRT provided the ability to deliver more conformal treatment to tumors with better avoidance of OAR. In the early 2000s, IMRT was promoted by key opinion leaders as a beneficial treatment primarily for cancers of the prostate (diagnosed in 240,000 patients per year), head and neck (40,000 per year), and central nervous system (22,000 per year).[9] However, practitioners quickly began using IMRT for	MR-IGBT also provides the ability to provide more conformal treatment with better avoidance of OAR. However, it is currently only advocated for use in cervical cancer (diagnosed in 12,000 patients per year,[44] of which only a fraction receive brachytherapy). There are theoretical benefits for prostate cancer. Experts (including those who have already adopted MR-IGBT for	IMRT >> MR-IGBT From a strictly scientific standpoint, the two technologies offer similar benefits. However, the addressable patient population for IMRT is much, much larger than that for MR-IGBT. Acceptance of MR-IGBT for prostate cancer will

	other cancers as well, including lung (240,000/year) and breast (230,000/year).	cervical cancer) are pessimistic regarding the utility of MR-IGBT for other cancer sites.[32,31]	substantially increase the potential patient population, but the clinical indications will still remain far more limited than those of IMRT, because brachytherapy has fewer uses than EBRT due to the technical limitations of source placement.
2. Government regulation	As of 2001, multiple device manufacturers had been approved to sell IMRT equipment. IMRT was a well-recognized and accepted cancer therapy, so regulation likely had little impact on adoption at this time.	All of the equipment required for MR-based IGBT has gained FDA approval. Several manufacturers manufacture and market MRI-capable IGBT treatment systems.	IMRT = MR-IGBT Several years after market entry, regulatory issues likely have little role on the adoption of medical technologies.
3. Insurer reimbursement	From 1995-2000, IMRT was reimbursed at the same level as its predecessor, 3D-CRT. Following intense lobbying by radiation therapy societies, CMS approved new codes granting increased reimbursement for hospitals in 2001. The following year, new codes and reimbursement levels were also announced granting a >400% increase in payment for both the planning and daily administration of IMRT. These reimbursement increases were intended to help treatment centers finance the purchase of IMRT equipment and software and also compensate physicians for the increased time required to plan and deliver therapy.[9,43]	MR-IGBT is currently reimbursed at the same rate as conventional brachytherapy. Moreover, cervical cancer patients overwhelmingly come from disadvantaged backgrounds[45] and are either uninsured or covered by Medicaid. Thus, treating cervical cancer is rarely financially rewarding, even if inexpensive conventional methods are used. Experts are currently very pessimistic regarding future reimbursement increases for IGBT, due to system-wide reimbursement pressure by CMS.	IMRT >> MR-IGBT Reimbursement for IMRT was increased substantially, greatly accelerating adoption.[46] In contrast, MR-IGBT is reimbursed at the same rate as conventional brachytherapy. Due to the current reimbursement environment and socioeconomic characteristics of cervical cancer patients, the reimbursement outlook for MR- IGBT is very poor. The poor reimbursement outlook will slow MR-IGBT adoption.
4. Competitive pressure to provide clinical services	Competition to provide clinical services was one of the primary drivers of IMRT adoption.[40,41] IMRT offered a new, improved	Competition over cervical cancer patients is very low, due to poor reimbursement and low patient volume. However,	IMRT > MR-IGBT Competition to provide services was far greater

	way of treating common cancers, including prostate cancer, the "bread and butter" of many radiation therapy centers. After CMS approved reimbursement increases, which helped treatment centers finance the purchase of IMRT machinery, centers throughout the country rushed to adopt IMRT.	among physicians at academic medical centers, there is pressure not to "fall behind" peer institutions. Thus, competition to remain at the cutting edge is currently driving limited demand among academic medical centers; however, there appears to be essentially no demand for MR-IGBT among non-academic centers.	for IMRT than MR-IGBT, largely because the addressable patient population for IMRT constituted a majority of patients treated by most centers. In contrast, MR-IGBT is only recommended for cervical cancer, a relatively uncommon cancer in the U.S.
5. Cost and Purchasing Power	The cost of purchasing new IMRT equipment and compatible software was approximately $1.5-2 million (existing equipment, if available, could be upgraded at a lower cost) in the early 2000s.[43] Adoption of IMRT also required centers to hire additional medical physicists and technicians, thereby increasing annual operating costs.[47] As of 2003, only 15% of radiation oncology sites capital budgets were above $1.5 million.[42] Thus, the decision to adopt IMRT likely required innovative financing measures by most centers; however, IMRT adoption also nearly guaranteed substantial increases in cash flow, making the purchase of IMRT machinery an intelligent investment decision.	The cost of purchasing an MRI scanner and upgrading a brachytherapy suite (MRI scanners must be shielded with a Faraday cage) is approximately $2 million.[32] Adoption of MR-IGBT also requires additional personnel, including technicians trained to operate MRI scanners. Delivery of MR-IGBT also takes longer than conventional therapy, so more physicians and physicists are needed to treat any given number of patients. By 2008, the number of sites with capital budgets above $1.5 million reached 32%.[42] Presumably, the percentage had increased further by 2011. However, due to the low volume of cervical cancer patients and poor reimbursement for MR-IGBT treatment, purchase of necessary equipment is unlikely to have a positive net present value (NPV).	IMRT = MR-IGBT The costs of adopting IMRT and MR-IGBT are similar. Both require a substantial initial capital expenditure (up to $2 million) and increased manpower to plan and deliver treatment. Capital budgets have grown significantly in recent years; however, due to the low volume and poor reimbursement associated with cervical cancer, investment in MR-IGBT is likely a far worse financial decision than investment in IMRT was in the early 2000s.

Conclusion

At the surface, IMRT and MR-IGBT appear to share many similar characteristics. Both allow for similar scientific improvements in tumor targeting, both are used by specialists in the same field of medicine, and both required purchase of expensive equipment. However, the financial potential of IMRT and MR-IGBT are far different, which likely accounts for much of the difference in their adoption rates.

In the early 2000s, IMRT offered a new, exciting treatment modality for prostate cancer patients – the "bread and butter" of many radiation treatment centers. It was also very easy to see how IMRT could be applied to almost any cancer in the body. Critically, CMS approved very generous reimbursement for IMRT planning and delivery. Thus, radiation centers rushed to adopt IMRT, driven both by excitement over new the technology and profit potential. Centers that were slow to adopt IMRT lost market share to their competitors, leading them to adopt as quickly as possible in order to remain competitive.

MR-IGBT is promising technology that is currently used to treat an uncommon form of cancer that is unfortunately a disease of disadvantaged women. From a financial standpoint, cervical cancer brachytherapy is of marginal importance. Increased focus on "bending the cost curve" by policy makers, in part by decreasing reimbursement for physician services and diagnostic imaging, make reimbursement increases for MR-IGBT highly unlikely.

Without dramatic increases in the uses of MR-IGBT (i.e., large scale adoption for use in prostate cancer brachytherapy), the rate of adoption will likely continue to increase very slowly. However, there are several areas of uncertainty regarding the future that could dramatically impact the spread of MR-IGBT. These key uncertainties are discussed in the next section.

PLANNING FOR FUTURE FOR MR-IGBT – SCENARIO ANALYSIS

The American healthcare system is currently facing unprecedented levels of uncertainty, fueled largely by the ongoing legal and political battles over healthcare reform and the Patient Protection and Affordable Care Act (PPACA).[48,49] Uncertainty creates problems for all stakeholders in the healthcare system, including patients, physicians, hospital administrators, insurers, and drug and device makers. Without a reasonable forecast of what the future will hold, it is difficult (and may seem impossible) for any of these stakeholders to make strategic plans now that will best position them going forward.

In the case of brachytherapy, key decision makers such as physicians, hospital purchasers, and device developers may, without a full grasp of the range of possible futures, make ill-informed and ultimately costly decisions. For example, taking an overly optimistic view regarding the adoption of MR-IGBT could cause hospitals to purchase costly equipment that will go largely unused. Conversely, adopting an overly pessimistic view could cause a device maker to cancel plans to build new technologies around MR-IGBT, resulting in a loss of future profits and erosion of market share to competitors.

Fortunately, there are methods that can be used to help make uncertainty manageable and guide decision making. One such method, pioneered by Royal Dutch/Shell in the 1960s and 1970s, is scenario planning.[50] Scenario planners use a disciplined approach to systematically identify major trends and key uncertainties surrounding a particular technology, industry, or market. By carefully choosing the set of uncertainties to include, and then constructing scenarios around contrasting outcomes, scenario planners illustrate a limited set of "potential futures" that effectively constitute the boundaries of the full range of possibilities.[51] Through careful analysis of the implications of these scenarios, the two main sources of error in decision making–tunnel vision and overconfidence–can be avoided.[50]

Scenario planning was most famously used by Royal Dutch/Shell in the 1970s, allowing them to prepare for the 1973 oil crisis. However, scenario planning has also been used successfully in other industries, including mining, healthcare, agriculture, publishing, and insurance.[51] Scenario planning is now used here to gain insight into the future of MR-IGBT.

Scenario Planning for MR-IGBT

Scenario analysis is a systematic, multi-step process, described in detail by Professor Paul J.H. Schoemaker in the *Sloan Management Review*.[50] For this paper, the following actions were taken at each step in the process:

Step 1: Define the Scope

The chief elements of scope include time frame, markets, geographic areas, and technologies.[50] Many elements of the PPACA are not set to take effect until the end of this decade. Moreover, alternatives to these regulations would likely take as long or longer to enact and implement. Thus, 10 years was chosen as the time frame.

The structure of healthcare systems differs dramatically between countries and can have a dramatic impact on adoption and use of health technologies. Since the United States constitutes the world's largest healthcare market and generally is at the forefront of technology creation and adoption, the geographic scope of the scenarios was limited to the United States.

The technology was limited to MR-IGBT, the topic of this report. Additionally, since the importance of expanding the addressable MR-IGBT patient population was established in the previous section, in this exercise it will be assumed that clinical trials demonstrate MR-IGBT to be safe and effective for prostate cancer treatment.

Step 2: Identify the Major Stakeholders.

Stakeholders include anyone who could potentially have an interest in these issues, be affected by them, or influence them.[50] For this exercise, the stakeholders include: cancer patients, radiation oncologists, hospital/treatment center administrators, health insurance providers (including CMS and private insurers), medical regulators (the FDA), and medical device and equipment manufacturers. The implications of each scenario are discussed from the view of a hospital or radiation treatment center. The impact of strategic moves by hospitals and radiation treatment centers on device and equipment makers is discussed briefly.

Step 3-4: Identify Basic Trends and Key Uncertainties

In order to identify the issues likely to impact the healthcare sector and affect the adoption of 3D-IGBT, an extensive literature search was undertaken. 14 issues were identified, which were then categorized into trends and uncertainties (see Tables 2-3). Trends are issues whose outcomes are relatively certain; uncertainties are issues whose outcomes cannot be reasonably predicted.[50]

The list of uncertainties was presented to various experts in the field of MR-IGBT (including a medical physicist, a radiation oncologist, and a radiation-oncology software entrepreneur). These experts were then asked to choose the uncertainties that they believed would be most important in dictating the future of MR-IGBT. The experts selected reimbursement (U7) and extent of coverage (U6) as the two most important uncertainties. These two uncertainties were crossed, creating the framework for four possible scenarios (Table 4).

Table 2: Trends in U.S. Healthcare through 2022	
T1	Efforts to reduce the overall burden of healthcare spending will result in continued downward reimbursement pressure, both from CMS and private payers.
T2	Increasing administrative costs and high student loan burdens will result in long-term continuation of the exodus of physicians from private practice to hospital-based employment contracts.
T3	The aging of the population will increase the number of patients with chronic diseases and age-related diseases, such as cancer and dementia.
T4	Physician extenders (physician assistants and advanced practice nurses) will provide an increasing percentage of primary care in the U.S.
T5	Quality improvement and patient safety initiatives will become a focus of hospital administrators and physicians.
T6	Efforts to drive "value" in healthcare will result in increased public reporting of outcomes and costs of care by healthcare providers and hospitals.
T7	Patients will increasingly leverage the abundance of health information available on the internet to become involved in medical decision-making and demand access to cutting-edge treatments.

Table 3: Uncertainties in U.S. Healthcare Through 2022	
U1	How will the regulatory system for medical devices be reformed?
U2	To what extent will evidence based medicine and comparative effectiveness research impact clinical practice?

U3	How will hospital consolidation affect competition, healthcare spending, and the quality of care?
U4	How will healthcare reform impact the market and pricing of health insurance? How will these changes impact both patient and physician medical decision making?
U5	How will personalized medicine impact the healthcare system?
U6	Will MR-IGBT gain coverage for prostate cancer treatment?
U7	In an era of decreasing reimbursement, how will promising new technologies (such as MR-IGBT) be financed?

Background information on each of the uncertainties is provided below:

U1. Regulatory Reform: In 2011, the Institute of Medicine (IOM) published the results of a comprehensive review of the 510(k) clearance process used by the FDA to review most medical devices. In the report, the IOM found that the 510(k) process is fundamentally "flawed" and could not be improved through modifications alone. Rather than fixing the current processes, the authors of the report recommended the FDA develop an "integrated premarket and postmarket framework that provides a reasonable assurance of safety and effectiveness through the device life cycle". [52] No changes have yet been made to the review process and it is unclear what, if any, changes will be made in the future.

U2. Evidence Based Medicine/Comparative Effectiveness: "Evidence based medicine" (EBM) refers to a movement within the medical community to use rigorous scientific evidence to guide clinical decision-making. The push for EBM has been strengthened by research from Dartmouth Medical Center showing tremendous regional variation in treatment patterns throughout the US, indicating that norms and customs within communities may guide clinical practice more strongly than scientific data and treatment guidelines. Many proponents of EBM advocate incorporating measures of EBM adherence into physician payment reform (in other words, providing financial incentives for adoption of EBM). Many physicians strongly oppose this movement, fearing a loss of autonomy to guideline-driven "cookie cutter" medicine.

The PPACA established the Patient-Centered Outcomes Research Institute (PCORI), created to fund comparative effectiveness research of medical treatments. Essentially, the goal of PCORI is to fund rigorous, head-to-head trials comparing alternative treatments for a given condition. The data generated from this research is supposed to be useful both to physicians looking for high quality data and patients considering the different treatments available to them.[53]

At this point, it is unclear how physicians will respond to increased pressure to adopt EBM-based practice, how best to incentivize physicians to do so, or how successful PCORI will be at generating useful information for physicians and their patients.

U3. Hospital Consolidation: Consolidation within U.S. the hospital industry accelerated beginning in the late 2000s. The two central tenets of healthcare reform are cited as key drivers of consolidation—cost control and improved coordination and quality.[54] The PPACA encourages consolidation through the creation of Accountable Care Organizations (ACOs). ACOs may be most successfully if local health systems become vertically integrated, with a single entity coordinating and managing a patient's care from start to finish. However, policymakers fear that consolidation could have the adverse effect of increasing healthcare spending, if large systems leverage their size to monopolize markets and demand higher reimbursement from private insurers. At this point, it is unclear at what pace consolidation will continue and how it will impact competition, prices, and quality.

U4. Health Insurance Reforms: Health insurance and, more generally, the financing of healthcare, was a major focus of the PPACA, both directly and indirectly. The most significant provisions in the bill were (1) the "individual mandate" and (2) the establishment of health insurance exchanges (HIEs).

The individual mandate is currently the most controversial element of the PPACA. The PPACA proposes to fine any citizen who does not purchase health insurance. The fine is supposed to incentivize everyone to purchase health insurance. Theoretically, if nearly everyone purchased health insurance, insurance markets would become more efficient

by minimizing adverse selection. As a result, insurance premiums would decrease, even if total health expenditures remained unchanged. However, the constitutionality of the individual mandate has been challenged and will be reviewed by the Supreme Court during the summer of 2012.

HIEs are a key element of the PPACA. Under the law, states are required to establish and manage HIEs by January 1, 2014. HIEs are intended to serve as a market place for health insurance, offering individuals a variety of pre-screened insurance plans. The federal government will subsidize premiums on a sliding scale for all individuals earning below 400% of the federal poverty line.

U5. Personalized medicine: The goal of personalized medicine is to provide customized treatment plans to patients based on their individual genetic makeup. By sequencing a patient's genome (or the mutated genome of their tumor), one could theoretically understand the precise biochemical processes responsible for a particular illness. This information could then be used to design custom therapies tailored to each patient's disease, optimizing the probability of cure.

Two key obstacles currently stand in the way of personalized medicine. The first is purely scientific. Although any person's genome can now be sequenced, scientists lack the knowledge required to understand the significance of most of this information. The second obstacle is largely financial. Although the cost of gene sequencing is rapidly dropping, it is still prohibitively expensive to sequence genomes on a large scale. Additionally, providing all patients with truly personalized treatments would likely require far more time and manpower than is now available. However, insurance companies have started paying for limited genetic testing of some cancer patients prior to initiating expensive biologic therapies. Thus, there are forces both pushing for and impeding the rise of personalized medicine. At this point, it is unclear to what extent personalized medicine will affect the healthcare sector during the next decade.

U6. Insurance coverage: In order to be paid for by private insurance companies or CMS (Medicare/Medicaid), a treatment or service must first be included the plan's list of

covered therapies. This process is distinct from the FDA regulatory process. A treatment can be approved by the FDA but not covered by any insurance plans (though FDA approval is a prerequisite for coverage). For example, many cosmetic surgery treatments have been FDA approved, but are not covered by any insurance plans. Patients who elect to receive them must pay out of pocket. CMS is the main government body that makes coverage decisions. CMS is required to cover any treatments or services that are "reasonable and necessary", a term that has never been defined by Congress. Thus, CMS has some leeway in making coverage decisions. Generally, private insurance companies follow CMS when making coverage decisions, approving or rejecting treatments and services shortly after CMS delivers its coverage decisions.

U7. Reimbursement: After a treatment or service gains coverage by CMS and private insurers, reimbursement levels must be established. Various methodologies are used by CMS to set payment schedules for services, which differ based on the setting (outpatient or inpatient) in which care is delivered. The fees set by CMS are intended to reflect the underlying cost or effort required to provide a particular treatment or service. However, payment distortions are common, leading some treatments to be very profitable for providers and many others to be money-losing propositions. Insurance companies determine reimbursements rates independently, typically after negotiating directly with hospitals and physicians. Private insurers nearly always set reimbursement rates above those of Medicare/Medicaid. Although reimbursement levels are general decreasing for many services, for new treatments there is always uncertainty regarding the precise fees that will be established.

Step 5-6: Construct Initial Scenario Themes, Check for Internal Consistency and Plausibility

Crossing the two key uncertainties (U6 and U7) creates a total of four possible scenarios, as depicted in Table 4. One of the possible scenarios, however, was rejected as the combination of outcomes seemed implausible (high reimbursement despite limited coverage). The process of obtaining reimbursement increases from CMS requires intense lobbying from industry and

physician groups. It is unlikely that these groups would spend the time and effort required to achieve this for a small patient load; thus, this scenario was rejected.

Table 4: Scenario Overview

		Coverage of MR-IGBT	
		Immediate	Delayed
Reimbursement	High	A. Reform Interrupted	X
	Low	B. New Age of Medicine	C. Radical Redesign

Table 5: Scenario Blueprint

SCENARIO	A. Reform Interrupted	B. New Age of Medicine	C. Radical Redesign
U1. Device Regulation	No change	Minor change	Major change
U2. EBM	Minimal impact	Major impact	Major impact
U3. Consolidation and Competition	Major impact (more competition)	Minor impact (less competition)	Major impact (much less competition)
U4. Insurance	Minor change	Major change	Radical change
U5. Personalized medicine	Minor change	No change	No change

Step 7-8: Develop Learning Scenarios and Identify Research Needs

Narratives were constructed around the three sets of outcomes. When it was unclear how various stakeholders would act in a given scenario, additional research was performed to help predict their behaviors.

Scenario A in 2022: Reform Interrupted

The Supreme Court ruling in the summer of 2012 reversed the momentum behind healthcare reform while also hobbling President Obama's reelection efforts. After the ruling declared that the individual mandate was indeed unconstitutional, republicans regained the political strength required to retake the White House and majorities in both branches of Congress. As promised,

the Republican led government wasted no time in systematically repealing or replacing the reforms put forth by the PPACA. As a result, major stakeholders in the healthcare industry enjoyed far less regulation than had been anticipated. Although reimbursement for most services and treatments decreased slightly each year, overall healthcare spending growth has continued to grow rapidly, accounting for more than 20% of GDP by 2020.

The cost of medical care continues to dominate political discourse. Although nearly everyone agrees that healthcare spending is a leading problem facing the nation, the political parties and their constituents cannot agree on solutions. Republicans favor market-based approaches, continued deregulation, and increased competition between providers. Democrats advocate for a top-down approach, with federally determined nationwide fee schedules, government sponsored health insurance, and greater controls on the adoption of expensive new technologies. With each side refusing to compromise, no meaningful reforms have been passed since the PPACA was overturned nearly a decade ago.

The continued increase in per capita medical spending has translated into rapidly escalating health insurance premiums. As a result, a record number of citizens now lack insurance. The majority of self-employed and small business employees are now uninsured. These individuals largely forgo care, pay out of pocket when necessary, and travel abroad for cheaper care when possible. Employees of medium and large business continue to enjoy employer-subsidized insurance, but “consumer driven” plans, with very high deductibles, health savings accounts (HSAs), and co-insurance dominate the marketplace. Skilled workers of medium to large firms (lawyers, accountants, bankers, etc.) continue to carry traditional PPO health insurance, with excellent benefits and minimal out of pocket expenses. Medicare and Medicaid budgets are now under record strain. CMS has held reimbursement increases well below the rate medical inflation. As a result, Medicare and Medicaid patients face extreme difficulty finding providers and must often wait for extended periods of time to undergo elective procedures or diagnostic testing.

Although the IOM called for a redesign of the FDA approval process of medical devices in 2011, no meaningful changes have yet been implemented. The FDA continues to rely on the 510(k) pathway for review of the vast majority of medical devices.

Shortly after the death of the PPACA, the pace of provider consolidation ground to a halt. Without the financial incentives for consolidation to create Accountable Care Organizations (ACOs), hospital executives saw little upside in purchasing physician practices or rival hospitals. As a result, competition over profitable patient segments has intensified throughout the decade, leading to fierce marketing and technology wars between rival health systems.

Without the appropriate financial or organizational measures in place to enforce and incentivize adoption, large-scale implementation of evidence based medicine has largely failed. Best practices continue to take years before gaining widespread adoption by physicians and dramatic regional variation in care practices continues to be the norm.

MR-IGBT in Scenario A: Shortly after favorable clinical trial data were released regarding the use of MR-IGBT for prostate cancer, CMS predictably issued a ruling granting coverage for the new treatment for Medicare beneficiaries. Powerful lobbying groups led by radiation oncology societies immediately begin lobbying CMS for substantial reimbursement increases for MR-IGBT relatively to conventional brachytherapy. Although CMS initially failed to act, the requested increases were approved after several prominent Congressmen (all survivors of prostate cancer) and patient advocacy organizations publically lobbied for approval. As usual, private payers quickly follow CMS, approving generous coverage and reimbursement for MR-IGBT as well.

Recommended Business Strategies in Scenario A

Understanding the importance of three key elements of this scenario will guide successful strategy for hospitals and physicians. First, MR-IGBT has become a rare winner within a sea of treatments experiencing reimbursement cuts. Second, hospital consolidation has stopped, leading to increased competition between rival hospitals. Third, the patient population has bifurcated into two extremes–those with adequate-to-excellent coverage and those with either

no insurance or poorly paying Medicare and Medicaid. Hospitals that successfully attract the former group will succeed financially, while those left treating the remainder will suffer.

Winning hospitals will invest heavily in new technologies that can attract profitable patient groups. Prostate cancer patients, predominantly working middle-aged men, will be a key demographic. Hospitals will rush to offer MR-IGBT and will market the technology aggressively, making it the newest weapon in the technological "arms race" between cancer centers, much like that of IMRT in the early 2000s.

Medical device and equipment manufacturers will succeed by creating all-in-one MR-IGBT treatment machines that streamline and simplify the treatment process, allowing patients to be treated more quickly and efficiently. Physicians and hospital purchasers will tolerate premium prices for machinery that allows them to treat a large volume of patients. The equipment will evolve rapidly, as manufacturers will receive minimal delay from the FDA or other regulators.

Scenario B in 2022: The New Age of Medicine

After the Supreme Court upheld the individual mandate in the summer of 2012, Barack Obama continued his inevitable path to victory in the fall elections, crushing the unpopular Mitt Romney with a substantial majority of the popular vote. During his second term, President Obama aggressively pushed for the adoption of the remaining elements of PPACA.

The greatest changes involved insurance coverage and financing. In early 2013, states finally began investing time and money required to establish health insurance exchanges (HIEs). Though many states missed the January 1, 2014 deadline, by 2016 all 50 states had launched fully operational exchanges in compliance with PPACA rules and regulations.

The impact of HIEs on individual citizens was largely dictated by their employment status. Most large employers continued to self-insure, favoring the flexibility of being able to design plans to meet the needs of their employee populations. In contrast, small- to medium-sized companies, lacking the financial resources to self-insure, found HIEs to be a more economical means of insuring their workers. By essentially out-sourcing the task of selecting and managing health benefits to state governments, these companies were able to reduce human resource

expenditures without adversely impacting employees. The combination of the individual mandate and HIEs nearly eliminated the problem of adverse selection that had previously plagued the individual insurance market, resulting in reduced premiums for individual purchasers. As a result, the vast majority of self-employed individuals also purchased coverage through HIEs. The net effect was a reduction of the number of uninsured from 50 million in 2012 to fewer than 20 million in 2022, almost precisely as predicted by the authors of the PPACA.

Large ACOs now dominate the hospital industry. As hospital systems consolidated to form ACOs, competition over patients decreased steadily over the course of the decade. Although ACOs continue to invest in new technologies to gain prestige and remain current, they do so with far less vigor than in the pre-reform era. Rather, many ACOs have focused on leveraging health information technology to reduce waste, increase efficiency, and improve quality, resulting in several years of zero and even negative growth in nation-wide health expenditures.

ACOs, now employing nearly all practicing physicians, wield considerable power over their behavior. Physicians are evaluated and reimbursed largely based on their adherence to evidence-based guidelines. As a result, best practices diffuse far more quickly than at the start of the decade and nearly all patients receive recommended preventive and screening services. While rates of preventable diseases, such as cervical cancer, are expected to decrease over time, it is still too early to detect any significant changes at this time.

MR-IGBT in Scenario B: After clinical trials demonstrated that MR-IGBT was superior to standard therapy for prostate therapy, physicians, hospital executives, and device makers salivated over the potentially lucrative new technology. With the compelling study data, CMS quickly concluded that MR-IGBT was “reasonable and necessary” and granted coverage for the huge population of prostate cancer patients.

As expected, physician groups, patient advocacy organizations, and device manufacturers lobbied CMS for favorable reimbursement. CMS, however, viewed the issue as an early and crucially important test of its mandate to control medical spending. Emboldened by calls for more data by PCORI, CMS refused to reimburse more for MR-IGBT than standard 2D

brachytherapy. CMS promised to revisit the issue when a full technology assessment is finished, knowing it could take up to a decade for the research to be funded, conducted, and analyzed by policymakers.

Recommended Business Strategies in Scenario B

Unlike Scenario A, Scenario B does not have a clearly dominant business strategy. Without the reimbursement policy in place to compensate hospitals for the cost of acquiring MRI scanners and the additional time required to plan MR-IGBT, it is not clear if offering MR-IGBT treatment would be a winning strategy in this situation.

Hospital and physician executives must consider several factors before making the decision to purchase MRI scanners and adopt MR-IGBT. First, due to the decrease in system-wide competition, there is no urgency to make quick decisions. Second, they must consider how the adoption of expensive, cutting-edge technology fits into their strategic goals. For large, tertiary care academic centers, adoption of financially risky technologies may be acceptable for two reasons: (1) their reputation as world-class medical centers may require early adoption of these technologies in order to differentiate themselves from other medical centers and (2) they may be uniquely positioned to generate additional revenue from the equipment through externally funded research activities to offset the costs of purchase. In contrast, smaller hospital systems have less to gain from early adoption of MR-IGBT and would be wise to delay purchasing new machinery until the acquisition costs decrease. Finally, potential purchasers must consider potential patient volumes. In order to break even or generate a profit, utilization of the equipment will likely need to at or near capacity, allowing the high fixed costs of equipment purchase to be spread over as many patients as possible. Again, for smaller centers with low or unreliable patient volumes, adoption of MR-IGBT may be a losing proposition until the costs of purchasing scanners decrease.

In this scenario, device and equipment manufacturers would find success by providing scaled-down, less expensive versions of MR-IGBT machines. Understanding that the majority of healthcare providers will not rush to adopt MR-IGBT, manufacturers can focus on learning the

critical functions valued by purchasers and then design equipment that fulfills these needs as inexpensively as possible.

Scenario C in 2022: The Radical Redesign

In an unexpected turn of events, shortly after President Obama won a second term and helped Democrats regain control of Congress in 2014, many business leaders threw their support and money behind far more radical reforms of the health system than were originally proposed in the PPACA. Arguing that U.S. industry could only remain competitive with peer nations if health spending decreased dramatically, these business leaders lobbied hard for strict price controls and limits on the adoption of new, expensive technologies.

The most dramatic change was the adoption of a single-payer system with universal coverage, managed by the federal government and financed by general tax revenue. In order to reduce the administrative complexity of transitioning to this new system, a uniform fee schedule for all health services was adopted. Fees are now set annually by a federally appointed pricing committee and can be manipulated to control both the rate of spending growth and total national health expenditure. Hospital payments are bundled by “episodes of care”, through which a single payment is provided to reimburse for all aspects of care for a given diagnosis. Bonus payments are provided to hospitals and physicians that meet certain quality and performance benchmarks, but total reimbursement remains far lower than in the pre-reform system.

The FDA review process for medical devices and pharmaceuticals underwent a significant overhaul. The burden of evidence required to gain and subsequently maintain approval was increased dramatically. The 510(k) pathway was abolished. All manufacturers of new technologies are now required to complete multiple trials demonstrating safety and efficacy of their products. Additionally, manufacturers must submit cost effectiveness data to the federal pricing committee in order to gain insurance coverage. The prohibitively high cost of gaining regulatory approval and coverage has doomed many technologies to failure before launch. However, in the wake of the new reforms, there has been an unprecedented drop in medical spending attributable to new technologies.

Reform accelerated the consolidation of hospitals and physician practices. No longer able to compete on price, efficiency and cost cutting became the primary means of survival. With their large size and resulting purchasing power, hospital systems were able to achieve economies of scale and also slash administrative expenses by eliminating redundant middle managers. Physicians are now predominantly employed by hospitals, resulting in low morale and constant complaints over their loss of autonomy. However, adherence to EBM guidelines is at an all-time high, driven largely by the pay for performance incentives built into the federal reimbursement scheme.

The medical community has slowly accepted that many of the high-tech but expensive dream therapies of the previous decade, such as gene therapy and personalized medicine, have no place in this new medical system. Rather, "reverse innovation" has become the new mantra of the market place, as major industry players compete to offer the low cost technologies and equipment demanded by hospital purchasers.

MR-IGBT in Scenario C: Trial results for MR-IGBT were published in prominent medical journals, gaining attention of the medical community and lay media. However, the trials were designed prior to the reforms that unexpectedly transformed the healthcare system. It quickly became clear to researchers leading the trials that far more evidence would be required by regulatory agencies in order for MR-IGBT to gain coverage by the federal pricing committee. Given the dismal reimbursement prospects for MR-IGBT under the new universal fee schedule, the researchers could not justify funding the additional trials required to gain approval. Thus, no new studies of MR-IGBT were conducted, making it one of the first casualties of the reformed health system.

Recommended Business Strategies in Scenario C

The business strategies that succeeded in the pre-reform world have no place in this scenario. All stakeholders in the healthcare system must dramatically alter their business plans in order to survive and succeed.

For hospital systems, competition with other hospitals now plays a minimal role in financial success. With universal insurance, hospitals are no longer required to compete over privately insured patients. Moreover, due to a wave of consolidation, the hospital industry is far less fragmented than before, resulting in minimal competition within regional markets. Therefore, the drive to purchase new technologies in order to differentiate from rivals is minimized.

Instead, hospitals will succeed by eliminating unnecessary services and providing the minimal amount of services required to qualify for reimbursement and maintain quality standards for each episode of care. Hospital purchasers will favor low cost equipment and technologies that increase efficiency, rather than technologies like MR-IGBT that provide incremental improvements over predecessor technologies but sacrifice efficiency.

Device companies will need to adapt to the new regulatory environment and customer demands for low cost equipment. Instead of developing new technologies and undergoing the costly review process, successful companies will invest in simplifying and improving technologies that have already gained FDA approval.

Implications

These three scenarios illustrate the importance of two key uncertainties—coverage and reimbursement–on the future of MR-IGBT. Although these two issues may seem to be closely interrelated, the information and policies used to make coverage and reimbursement decisions are in fact quite different. Coverage decisions are based on the scientifically demonstrated benefits of one technology over its alternatives. CMS is explicitly prohibited from factoring cost into coverage decisions. Reimbursement, on the other hand, is far more complex. Issues such as cost of providing a treatment, technical complexity, and risk may be factored into setting reimbursement levels.[55] In practice, lobbying by key stakeholders often plays a considerable role in obtaining favorable reimbursement for new technologies. Many other issues and interests may affect reimbursement, though currently concerns among policymakers over rapid increases in medical spending have resulted in downward pressure on reimbursement.

Scenarios A and B demonstrate the importance of reimbursement to the speed of adoption of MR-IGBT. In both scenarios, favorable clinical data drive coverage of MR-IGBT for prostate cancer. However, in scenario A, the technology is adopted very quickly because radiation treatment centers can justify acquiring new technology based on both clinical and financial criteria. This scenario closely resembles the environment that drove the explosive adoption of IMRT in the early 2000s. In scenario B, though the clinical merits of MR-IGBT have been demonstrated, investment in MRI scanners is risky for early adopters. In this scenario, it may be prudent for radiation therapy centers to wait several years until the early adopters and other innovators drive the technology to greater efficiency and lower cost. This scenario closely mirrors today's environment with regard to proton therapy – some centers have invested over $100 million in proton therapy equipment despite an unfavorable reimbursement environment (proton therapy is reimbursed higher than IMRT but the level is quite low relative to the cost of providing proton treatment).[56] The vast majority of radiation treatment centers, however, have been far more cautious, choosing instead to learn from the experiences of early adopters and/or wait for the price of technology to decrease.

Scenario C illustrates the inevitable failure of technologies that do not succeed in gaining coverage by insurers. It further demonstrates the difficulties that a single payer system and greater regulatory requirements could pose to developers of new technologies. Ultimately, no matter how effective a treatment proves to be clinically, it will not be widely embraced unless offering the treatment is financially rational for hospitals and physicians.

Although a diverse group of stakeholders was identified at the outset of this exercise, the timing of decision making is quite different for each group. For example, CMS—despite playing a critical role in the outcome of each scenario—would gain little from further analyzing these scenarios. In contrast, it is far more important for radiation oncology centers to attempt to anticipate the future when making major technology purchases or facility renovations. A center currently planning a new facility, for example, may want to maintain flexibility, designing brachytherapy suites that can house MRI scanners in the future. This way, they can enable

rapid incorporation of MRI scanning for brachytherapy treatment but avoid the purchase of expensive equipment until the future is more certain.

Radiation centers currently struggling to plan for future purchases should attempt to quantitatively model the probabilities of the outcomes discussed in these scenarios. Managers at these centers should closely watch the actions of CMS to determine how reimbursement decisions are made in the future–many new technologies will likely be presented to CMS for review before (if ever) MR-IGBT undergoes coverage and reimbursement review.

CONCLUSION

MR-IGBT is a promising technology that improves outcomes and reduces side effects for cervical cancer treatment. MR-IGBT holds promise for the treatment of prostate cancer and may potentially prove beneficial for other cancers as well. However, the adoption of MR-IGBT in the U.S. has been slow and will continue to be limited unless compelling clinical evidence supports its use for common forms of cancer, such as prostate cancer. The rate of adoption will be dictated largely by coverage and reimbursement levels established by CMS and private insurers. Interested stakeholders such as radiation therapy centers, device makers, and physicians should closely monitor the results of clinical trials studying MR-IGBT for prostate cancer, the political climate and attitudes guiding healthcare reform, and the actions of CMS and other third party payers in order to determine when, if ever, to embrace MR-IGBT.

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