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Breast IMRT Payment Policies: Effort to Increase Access to Quality Care

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Effort to Increase Access to Quality Care

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Abstract

This investigation explores whether private insurance policies decreases access to Intensity Modulated Radiation Therapy (IMRT) as compared to Medicare for intact breast treatments at XYZ Cancer Center (XYZ). An examination of treatment charts was carried out on new intact breast patients at XYZ over a one month period to compare the number of IMRT prescriptions as a function of Medicare or private insurance policies. A survey of physicians who treat breast cancer patients at XYZ was made to discover how physician use of IMRT is affected by insurance policies. The review of breast cancer patient charts in the sample period showed private insurers permitted slightly fewer IMRT prescriptions than Medicare (3/18 vs. 4/14). This result was consistent with another finding that 3 IMRT prescriptions results when both IMRT and private insurance policies were independently applied to the 18 privately insured patients. The physician survey showed both Medicare and private insurer policies hinder their use of IMRT. New internal policies for IMRT use are recommended to replace insurer policies, which are anticipated to be lost with changes in healthcare payment models.

Chapter 1 - Introduction

Cancer is daunting. The National Institute of Health (NIH), National Cancer Institute (NCI) estimated 246,660 new cases of female breast cancer in 2016, 14.6% of all new cancer cases (NIH, 2016). In the same year, deaths from breast cancer were estimated at 40,450, or 6.8% of all cancer deaths. Although breast cancer is the leading type of new cancer diagnoses, it is the third leading cause of death. Survivors hope and strive for recovery with the aid of current treatment technologies and supported by loved ones.

Much progress has been made in treatment of cancer which offers more hope for survival and quality of life; however, cancer therapy can take weeks or months of strenuous tests, treatments, and hopefully recovery. Imagine embarking on a course of treatment and discovering your insurance policy presents a hurdle if the insurance provider does not authorize treatment. Physicians and healthcare provider billing staff face a daily challenge in aligning physician prescriptions and orders with patients' insurance company policies to deliver the best quality cancer care.

Research Problem

The concern in this research is the discovery of potential difficulty in accomplishing this delivery as experienced in Radiation Oncology at XYZ Cancer Center (XYZ). This research examines variation of insurance policies of female, intact breast cancer patients to measure when policies may challenge access. A patient rightfully expects quality care from a provider and quality service from an insurance company. In the ideal situation, the physician prescribes the best treatment and the insurance company approves the treatment. Patients are dependent on the good faith of providers and insurers to deliver the highest quality services.

Public insurance in the form of Medicare provides coverage based on regimens evidenced by published scientific studies and clinical trials. Local coverage determinations (LCDs) inform physicians and billing staff as to the type of treatment that Medicare pays. Private insurance companies offer plans that may follow Medicare policy or justify their own provisions. The design of insurance policies are to meet both the fiduciary interest of the insurer and medical need of the patients.

Healthcare insurance coverage is much more challenging for consumers to choose in regards to accepting paying a premium for a defined level of risk. This is particularly true with cancer, since when and how cancer may strike is unpredictable. For those receiving health benefits as part of job compensation, the choice of carrier belongs to the company owner. The quality of the carrier in this case is pre-determined if only one option exists. Unless there is advanced knowledge of a specific medical need, it is not possible to discriminate the best level of coverage. The specifics of policies regarding breast cancer treatment will most likely be unknown to those electing coverage, leaving the insured uninformed about policies until a need presents. Furthermore, one would not know the policies of interest to compare with other carriers even if the possibility of choice exists.

Lack of awareness regarding specific policy criteria is not itself a problem for a prospective patient for breast cancer, but only if the policy of interest introduces either a delay in treatment or denial of the prescribed therapy. Because carriers define their own policies, the physician and billing staff must assess how the desired treatment conforms to those limitations. An appeal process is offered to providers to advocate overturn of a denial of claim. Policies that exclude radiation therapy exist but presents a different issue than this study. Instead the focus here is on those carriers that do provide coverage but place constraints on how the treatment is

delivered. Variable private insurance policies may create inefficiencies for providers to facilitate patient treatment. Delays in start of treatment can have an impact on the success of treatment outcomes. Medicare policies will be used to define a benchmark for comparison of how quickly authorization for breast treatments are obtained between Medicare and private insurers. If there is evidence that authorization for treatments are impacted by private insurance policies, the data may support a regulatory need to standardize breast treatment policies.

Research Hypothesis

The working hypothesis for this research is that variation in private payer insurance policies regarding breast cancer treatment reduces access to quality care as compared to Medicare for patients at XYZ. Support of the hypothesis requires the qualitative data analysis to demonstrate that the access to quality of care is superior for Medicare patients as compared to private insurance patients. The hypothesis will be refuted if there is no measurable difference in access for these patients. This main hypothesis contains a series of sub-hypotheses that may also be tested in this investigation:

- Interpretation of clinical results varied between insurers, producing different payment policies.
- The absence of a clear cut definition for appropriate billing of breast plans has led to a conflict between delivery of the preferred care and what insurers will allow.
- Adopting Medicare policies regarding breast cancer treatment will reduce policy ambiguity and enhance access to quality of care for all patients at XYZ.

Background and History

Basic breast treatment delivery

Radiation therapy utilizes beams of x-rays produced by high energy linear accelerators. In breast irradiation, typically two opposed fields are directed tangentially to the chest wall to focus the radiation on the breast and avoid minimize exposure to uninvolved tissue and organs, like lung and heart. Decades of planning delivery for breast treatment utilizes static fields using blocks to conform the fields and beam modifiers to alter the intensity of the radiation to maximize uniformity of target dose and minimize dose to healthy tissue. This mode of treatment is known as three dimensional conformal radiation therapy (3DCRT). The 3DCRT modality is reimbursed at the lowest rate compared to the more advanced modality.

Advanced breast treatment delivery

Intensity Modulated Radiation Therapy (IMRT) was developed in the late 1990's and became a prevalent option in the early 2000's. An inverse calculation is used to generate a plan that invokes pre-determined dose objectives to derive a solution. This allowed IMRT to escalate dose to the tumor while concurrently reducing the dose to critical organs. In addition to inverse planned IMRT there is a variation of IMRT known as "forward" planned IMRT. Instead of introducing dose objectives as in inverse planning, the planner manually shapes fields in a stepwise fashion to reduce inhomogeneity in the dose delivery. Reimbursement for inverse planned IMRT is more than forward planned IMRT and 3DCRT.

Breast treatment plans at XYZ

Breast treatment can be delivered entirely using 3DCRT, with limitations on quality in terms of delivering a homogenous dose. To improve uniformity, 3DCRT can be delivered in

combination with inverse or forward planned IMRT. At XYZ, the 3DCRT component of a breast treatment typically constitutes the majority of the prescribed dose when applied in combination with any IMRT. Forward planned IMRT is not typically utilized for intact breast treatments at XYZ.

IMRT authorization process

There are three major insurance companies that represent the majority of the privately insured patients; Blue Cross, Blue Shield, and United Healthcare. Publicly insured patients carry Medicare or MediCal. Prior to consultation of the patient by the physician, Billing staff researches and documents the specifics of the patient's insurance policy to inform the treating physician what potential limitations might exist. Included in the billing note will be respective insurer's policies on IMRT delivery. Based on results from the consultation and test results, the physician completes a diagnosis. If the physician prescription includes a request for IMRT treatment, the billing office will submit an authorization request to the insurance company. It is possible, particularly with Medicare, that submission of an application for IMRT authorization is not necessary and the intent to treat with IMRT is considered automatic. But when required, receipt of approval for IMRT should be within a couple days so the treatment planning process can proceed.

Insurance policy review

Following are policy summaries of Medicare (Noridian), Blue Cross, Blue Shield, and United Healthcare policies. A table is included in Appendix A (Table I) to provide a summary view of the policies for easier comparison.

Noridian Healthcare Solutions, LLC, Intensity Modulated Radiation Therapy (IMRT) Policy # L34217, effective date 10/01/2015.

The Medicare claims processed in Northern California are performed by Noridian Healthcare Solutions, LLC. A list of nine criteria is provided for which one or more conditions must be documented in the medical record to prove coverage need. Examples of these criteria include

- The target volume is irregularly shaped and in close proximity to critical structures that must be protected.
- The volume of interest is in such location that its parameters can only be defined by MRI or CT.
- Important structures adjacent to, but outside the volume of interest are sufficiently close to the margin such that IMRT is required for additional safety and morbidity reduction related to radiation.

The majority of the LCD is a list of ICD-10 (International Classification of Diseases, version 10) codes that Medicare considers IMRT approved for medical necessity. Amongst approximately 13 full length pages of codes are 12 that are specific to breast IMRT (9 left and 3 right breast). Thus a Medicare patient with any of the 12 listed ICD-10 codes will not require pre-authorization to receive IMRT treatment.

Anthem Blue Cross, Intensity Modulated Radiation Therapy (IMRT) Policy # THER-RAD.00007, effective 5/12/2016.

Description of medical necessity for breast cancer includes 3 general categories that are qualified by specific conditions. The general categories are;

a. Individuals with left-sided breast lesions

b. Individuals with large breasts

c. Individuals who are to receive internal mammary node irradiation

Except for the criteria mentioned above, the policy states that IMRT for breast cancer is considered investigational and not medically necessary.

Blue Shield of California Intensity-Modulated Radiotherapy of the Breast and Lung Policy #8.01.46, section 8.0 Therapy, effective date October 1, 2016.

The policy statement lists left breast with two conditions (high cardiac exposure with non-IMRT techniques and proven lower exposure with IMRT) and large breasts with one condition (dose inhomogeneity greater than 10% with 3D conformal technique) as deserving IMRT for medical necessity. The guidelines include a statement that IMRT may be covered for a diagnosis designated as investigational, not medically necessary, or not identified. One of two conditions must be met, either;

- The target area is in close proximity to critical structures that must be protected (with 2 conditions) or
- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision

Case by case evaluation would be made under this circumstance.

United Healthcare Community Plan Policy CS064.E, effective February 1, 2016.

This policy is applicable to patients 19 years or older. IMRT is covered without further review for 18 years and younger. The chief criterion described for IMRT breast treatment is a breast size of 25.5 cm or greater, measured tangentially through the chest and delineated by the

treatment field edges. IMRT might be covered if the above criterion is not met, if one of two conditions are satisfied;

- A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity
- The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance of nearby normal tissue.

  Exceptions as above would be evaluated on a case-by-case basis.

Research Need

Quality care is the timely delivery of the preferred treatment as prescribed by the radiation oncologist. The successful delivery of this care depends on insurance providers authorizing billing claims on behalf of patients. Past experience in the billing process has made an impression there are more difficulties with private insurance companies authorizing payment as compared to Medicare. This research purpose is to document the nature of issues related to gaining authorization from insurers, and propose recommendation(s) for changes in practice or policy. In assessing the frequency and type of issues associated with IMRT treatment authorization, the main question to answer is whether insurance policies for breast cancer treatment support the highest quality care at XYZ. If the answer is yes, then the current policies and practices are adequate. If the answer is no, the data will better inform possible changes to improve quality.

This is the ideal condition, but data collection will provide quantitative and qualitative results to demonstrate a better understanding.

Scope and Limitations

The area of study includes female intact breast patients referred to XYZ Medical Group (XMG) radiation oncologists practicing at XYZ Cancer Center (XYZ). XYZ includes treatment centers located in 5 cities distributed in the vicinity. The patients in the study will be residents of the XYZ region, including the XYZ foothills. Retrospective data will be gathered from patients scheduled for CT simulation in the month of May 2016. The insurance companies underwriting these patients will constitute the policies that will be examined and compared with physician practice. This includes public and private insurers. Patients with Medical or private insurers not previously listed will not be included. This study is constrained to treatment of the intact breast following breast conservation surgery (BCS).

Chapter 2 - Literature Review

The review of literature produced no previous research relating access to quality care and differences in breast radiation treatment policies. However, the search produced two studies that investigated the relationship between health insurance and breast cancer treatment outcomes. Ali et al. (2014) examined the impact of health insurance type on early-stage breast cancer using breast conserving surgery (BCS) with radiation treatment. Objectives of the study included: (1) examination of the impact of health insurance type and other socioeconomic and demographic factors on the use of BCS with radiation therapy for early stage breast cancer; (2) examine race/ethnicity as an independent variable in regard to recommended treatment among women with the same type of insurance, and (3) look for trends in Florida's statewide cancer registry system. Three take away points included; (1) type of health insurance was significantly associated with the likelihood of receiving BCS with radiation; (2) significant differences in receiving treatment were correlated with race, marital status, age, and education in those patients with the same insurance and (3) a need to identify means to bridge the gap in treatment disparities. Ali et al. identified insurance policies of these patients, specifying Medicare and Medicaid, but grouping all private payers as one category. Although different forms of surgery were documented, the modality of external beam used after BCS was not specified.

A second study of breast cancer outcomes for older women looked at the differences related to insurance type (Lee-Feldstein et al., 2001). The retrospective study sampled patients in a highly managed market in Northern California. The insurance types included Medicare alone, Medicare/Medicaid, Medicare with group model HMO, non-group model HMO, or private fee-for-service (FFS) supplement. The authors found little difference in stage and survival for

patients with Medicare in HMOs and those with private FFS supplemental insurance. But poorer outcomes were identified for Medicare/Medicaid or Medicare alone.

Neither of these two examples identified treatment modality as an independent variable. Ali et al. was published in 2014, a period of time in which breast irradiation utilized two modes of radiation delivery (3DCRT and IMRT). Lee-Feldstein was published in 2001, and sampled patients diagnosed in 1987-1993. Generally only 3DCRT of delivery would have been available at that time, and therefore no anticipation of today's use of IMRT.

Several studies have compared IMRT, 3DCRT, and other modalities for breast cancer treatment. Fiorentino et al. (2016) did a comparison study comparing 3DCRT with sliding window IMRT to treat 22 patients. This study found IMRT to be superior in target dose coverage and critical organ sparing. A Canadian study showed 10 year results in comparing IMRT and 3DCRT delivery using wedges (Pignol et al., 2016). The authors concluded IMRT did not reduce long term side effects compared to 3DCRT, but there was significant correlation between late toxicities and acute side effects. This suggested that IMRT can be recommended for selected patients because of improved dose uniformity over 3DCRT. A third study compared IMRT and 3DCRT treatments for patients with median follow up of 8.2 years (Yang et al., 2016). Equivalence in local control, disease free survival, and overall survival were found between the two. The conclusion was that IMRT can be considered a standard technique for breast cancer treatment.

A 2015 study looked at the growth rate of IMRT use for early stage breast cancer following BCS (Wang et al., 2015). In 2004, 5.3% of patients received IMRT, growing to 11.6% in 2009. Some decline was seen in 2010 and 2011 but staying at 10.7%. Patients in non-

academic centers were more likely to receive IMRT, and privately insured patients were more likely to receive IMRT than the uninsured and those on Medicaid.

A dissertation in 2011 investigated a relationship between IMRT utilization rates and physician incentives (Dosoretz, 2011). A physician induced demand model showed an 85% decrease in probability to treat with IMRT when reimbursement is cut by 30%. A study in the New England Journal of Medicine showed an increase of 146% in IMRT due to self-referrals of urologists to their own radiation therapy centers (ASTRO, 2013). A study in the Journal of the National Cancer Institute reported findings that suggest reimbursement policy and practice setting strongly influenced the adoption of IMRT billing for breast cancer. A study to assess variation in service use between physicians included IMRT after breast-conserving surgery as one of five analyzed (Lipitz-Snyderman et al., 2016). The conclusion showed use of IMRT for breast cancer treatment exhibits a pattern of consistent use more than personalized patient care decisions.

Further literature search produced studies on the denial of insurance claims. A study in California showed that among 1400 cases of denials, the most common was cancer care (Chuang, 2004). A benefits trade journal article explains the importance of specifying criteria to evaluate coverage in carrier's decision-making to protect against court ruling to overturn denial of coverage (Mamorsky, 1991). A health care finance management article reports medical necessity and notification denials are difficult to prevent and have the lowest recovery rate (Olaniyan, et. al., 2009).

Insurance Policy Rationale

In this review of literature concerning what scholars and practitioners have published on breast radiation treatment, four themes surfaced and are described and examined separately below. Those themes are: (1) IMRT does not improve survival compared to 3DCRT; (2) IMRT

reduces heart toxicity for left breast treatment compared to 3DCRT; (3) IMRT reduces acute skin toxicity compared to 3DCRT and (4) larger breasts increase inhomogeneity. These themes are apparent in the citations for the private insurers, but not explicit in the Noridian/Medicare LCD.

Noridian Healthcare Solutions, LLC Intensity Modulated Radiation Therapy (IMRT) Policy # L34217, effective date 10/01/2015.

The "Sources of Information and Basis for Decision" section of the LCD shows a very brief and dated list of references. The range of years of publication is between 1994 (Moss & Cox) and 2000 (Nutting et al.). No rationale is offered beyond the criteria and references. The absence of rationale prevented explicit themes to emerge.

Anthem Blue Cross, Intensity Modulated Radiation Therapy (IMRT) Policy # THER-RAD.00007, effective 5/12/2016.

Extensive review of policy rationale regarding IMRT breast treatment is presented. The first paper cited is a literature review of supporting evidence of the use of radiotherapy as part of breast conservation therapy (BCT) (Poortmans, 2007). The review includes discussion of different modalities and techniques of breast irradiation, including IMRT. The latter was mentioned as a newer technique that required longer follow up to determine whether long term toxicity is improved using more conformal coverage of the target volumes and better shielding of organs at risk. A central conclusion was that BCT with radiation therapy provides the same outcome as mastectomy for stage I & II cancers. No recommendation is made in favor or opposed to IMRT as a preferred modality. The NCCN (National Comprehensive Cancer Network) Guidelines mentions IMRT amongst a couple alternative methods to improve homogeneity of target dose and sparing of normal tissues (NCCN, 2016). Options listed include tissue wedges and forward planning using segments. The billing guide from ASTRO (American

Society of Therapeutic Radiation Oncology) was referenced to indicate IMRT as a common clinical indication for "selected cases (i.e. not routine) of breast cancer with close proximity to critical structures".

A planning comparison was made between "inverse planned sliding window" and 3DCRT (wedge tangents) (Selvaraj, 2007). This study showed improvement in dose homogeneity with sliding window as compared to 3DCRT, concluding that IMRT may improve cosmetic results and reduce late toxicity. Next a randomized trial was cited that directly tested outcomes between 2D radiotherapy (RT) and IMRT for breast patients (Donovan et al., 2007). A statistically greater incidence of change was shown for patients receiving standard 2D RT as compared with the IMRT arm. This test did not show a difference in quality of life between the two modalities. Another randomized trial was cited that reported outcomes for acute side effects (Pignol et al., 2008). The rate of moist desquamation was reduced from 47.8% with standard therapy using wedge RT to 31.2% with breast IMRT ($p=0.002$). Smaller breasts ($p\leq0.001$) and IMRT ($p=0.003$) both were associated with decreased risk of moist desquamation at 6 weeks. The presence of moist desquamation was significantly correlated with pain and decreased quality of life.

Blue Shield of California, Intensity-Modulated Radiotherapy of the Breast and Lung Policy #8.01.46, section 8.0 Therapy, effective date October 1, 2016.

The literature review for breast cancer policy rationale is categorized by systematic reviews, randomized controlled trials, and nonrandomized comparative studies.

Dayes et al. (2012) reviewed 6 previously published studies for evidence showing IMRT use in whole breast irradiation to quantify benefits and make recommendations. Results did recommend IMRT over conventional RT after breast conservation surgery to avoid acute adverse

effects. The results did not demonstrate a benefit of IMRT to improve treatment outcomes or late toxicity. As was the case with Anthem Blue Cross, Pignol et al. (2008) and Donovan et al. (2007) were cited in this policy. The former showed improved acute side effect with IMRT, and the latter showed improved breast appearance change with IMRT. The Cambridge Breast IMRT trial's aim was to investigate late toxicity for all breast sizes, comparing wedge tangents to forward planned IMRT. Breast shrinkage and induration were associated with surgery results, not RT. However 2 year follow up showed reduction in telangiectasia with IMRT. A non-randomized comparative study was performed on prone patients (Hardee, 2012). IMRT was compared to 3D conformal RT and showed modest reduction in acute skin toxicity and no difference in late toxicity. A recommendation provided was to use IMRT as a first choice when insurance carriers paid for it.

United Healthcare Community Plan Policy CS064.E, effective February 1, 2016.

The first study cited was a study that looked at 3D conformal RT vs. IMRT for 63 partial-breast patient treatments (Rusthoven et al., 2008). This reference is unique as compared to the previously mentioned references due to analysis of treatments where the whole breast was not treated. Nevertheless, the result was that IMRT reduced dose to normal tissue without compromise to the target volume. Inverse planned IMRT was compared with wedge tangent fields. As was the case with Anthem Blue Cross and Blue Shield of California, United Healthcare also cited Pignol et al. (2008) and Donovan et al. (2007). A retrospective study cited (McDonald et al., 2008) by United Healthcare compared IMRT and conventional RT. The result was reduced acute skin toxicity with IMRT and excellent but similar local control as compared to conventional RT. The fifth citation investigated the scatter dose to the ipsilateral lung, heart, or contralateral breast using IMRT for breast treatment (Bhatnagar et al., 2006). This non-randomized study

found breast size to affect the scatter dose to the contralateral breast, but no effect to the ipsilateral lung or heart.

Chapter 3 - Research Methods

This embedded research design is a mixed methods case study of how breast IMRT insurance policies relate to patient access to radiotherapy treatments. Secondary data was gathered from historic patient records. Charts were reviewed for notes made by billing staff that document evidence indicative of the quality of access for each patient. Medicare and the three major payers included in this research (Blue Cross, Blue Shield, and United Healthcare) were represented. Of interest in this study is the difference between Medicare patient access and private payer access. Comparative studies was made to assess possible differences between the payers in terms of patient access to IMRT treatments. Medicare vs. private payer comparisons will be made at two levels: individual and population. Individual comparisons will be made by experimentally applying Medicare policies to private payer patient diagnoses and documenting outcome of IMRT authorization. A measured difference is detected if the outcome differs between Medicare and the private insurance carrier. Population comparisons will require grouping patient access by respective carriers and analyzing differences amongst the groups. This comparison will provide statistical analysis attributed to each insurer.

The existence of differences between the policies is a phenomenon that is also of interest. Together with an assessment of the results of this study, a possible theory may be generated to explain the origin of these differences. The results regarding access to IMRT afforded by insurance providers may also produce data to discuss if the delivery of IMRT breast treatment is influenced by the way IMRT is defined. Should the data be demonstrative of Medicare patients having better access to IMRT treatments as compared to privately insured patients, a possible outcome of this study is a policy recommendation for uniform adoption of Medicare breast treatment policies to enhance overall quality of care.

A decrease in access is measured using differences in need or time for IMRT pre-authorization between Medicare and private insurance carriers. The time measurement of interest is the interval period between submission of the request for pre-authorization and receipt of response. If pre-authorization is not required for Medicare or a private payer in a given case, then there is no difference in access. If Medicare alone does not require pre-authorization, then the time required to receive authorization from a private insurer is considered a reduction in access. Only differences between Medicare and private insurers are considered relevant to the hypothesis. Qualitative examination will be used to probe results, first by review of notes in the patient charts regarding the billing process. Interviews of billing staff and/or prescribing physicians in those particular cases will be applied as needed. Cases when denial of IMRT authorization and/or appeal of denial are likely examples for qualitative investigation.

Primary data was composed of survey results from a structured interview to investigate physician perspectives on the effect of insurance policies on prescribing IMRT. The survey was presented using electronic mail with a link to an on-line questionnaire. Survey Monkey was used to form the questionnaire, and the questions are listed in Appendix II. The key informants were XYZ radiation oncologists, who share a well-established and busy practice. The short, six question assessment is focused on the physician experience in the context of prescribing radiotherapy for breast patients. To contrast the difference of impact between private and public insurance policies on prescribing IMRT, a question is devoted to each probe each type. The questions ask whether respective policies permit prescription of IMRT when the physician desires to provide it. The third question ascertains their professional opinion on whether alternatives to IMRT are acceptable when either policies do not favor IMRT or level of confidence in not prescribing IMRT. The fourth and fifth questions asks the respondent to reveal his or her

perspective on the body of clinical research as it informs insurance policy design, both early research when IMRT was new and more recent data, after IMRT has grown as a standard modality, The sixth and final question seeks physician perspective on how IMRT prescription may be affected by anticipated changes in payment models.

Research Hypothesis

This research design will evaluate evidence from patient charts on the hypothesized decrease in access resulting from disparate policies regarding IMRT for breast treatments. Because the billing staff has primary responsibility for assuring that any requisite prior authorization for IMRT is duly obtained, they represent the chief informants as to an assessment of policy application in patient care. The billing staff documents the insurance policy provisions in the patient charts on behalf of the treating physicians. Based on the prescriptions made by the physicians, the billing staff is core to the process of submitting applications for pre-authorization, if the patient prescriptions call for IMRT. The dates of submission and response are documented in the patient charts by the billing staff. Depending on the findings, follow-up interviews of the billing staff may be needed to discern facts not evident strictly from the billing notes. The treating physicians in these cases may also provide information in other documentation such as justification for IMRT directed to the insurance companies. An analysis of the success or difficulty as evidenced in the billing notes and other pertinent documentation will demonstrate whether patients are negatively affected as consequences of their insurance carrier policies. The stakeholders in these findings include patients whose treatments are slowed or altered from the physician's preferred intent. Such findings also serve the needs of XYZ in using objective data to enhance access for all patients by advocating or promoting policy changes amongst the private

insurers for the benefit of affected breast patients as well as process improvement for the billing staff.

A proposed change may be to standardize policies to achieve process improvement and patient access to IMRT treatments. The model envisioned as a sub-hypothesis is the application of Medicare breast IMRT policies for privately insured patients. This simulation can be executed concurrent with the review of patient billing notes. The diagnoses codes located in the patient charts will be compared to the approved IMRT codes in the Medicare policy. If there is a collective result that demonstrates Medicare could have improved access for some patients, then the hypothesis would be supported and such a change in policy would be validated.

Data Collection

The data sampled includes all patients referred for intact breast treatments in May 2016. The electronic medical record used by XYZ is Mosaiq from Elekta Instrument AB (Stockholm, Sweden), which is the means to retrieve records. The simulation schedules for the centers (5 metropolitan cities) are reviewed for intact breast patients. The individual insurance policies held by these patients constitute the independent variable of this study. The recorded data includes the ICD code, insurance provider, presence of IMRT authorization, date of request, and whether IMRT was approved or denied. Physicians and billing personnel compose the key informants. They contribute to the billing notes that chronicle events such as appeals after denial of claims. The attending physician in an appealed case can provide richer detail on treatment objectives than might be evident from the documentation needed for the appeal. A staff of four in the billing department processes the claims and produces the notes to document status of authorization. Personal interview and/or e-mail are used to provide specifics on patients who may not receive IMRT treatment as constrained by insurance policies.

Operational Terms and Definitions

Hypothesis:

Private insurance policies decreases access to quality care for patients prescribed for IMRT intact breast treatments at XYZ.

Independent variable:

breast insurance policies

Dependent variable:

Decreased access to quality care for patients prescribed for IMRT intact breast treatments at XYZ.

Public insurance:

Medicare

Private insurance:

Anthem Blue Cross, Blue Shield of California, and United Healthcare

Decreased access:

The number of patients covered by private insurance policies that slow or prevent access to prescribed IMRT treatment, as compared to patients covered by Medicare

Quality care:

The most preferred, timely treatment prescribed by a physician

Patients:

persons diagnosed with cancer, under the supervised care of a radiation oncologist

IMRT:

intensity modulated radiation therapy using an inversely calculated treatment plan

Internal Validity

This study will document the administration of respective policies in comparison to Medicare policies, as related to breast IMRT radiotherapy. The provision of authorization for IMRT treatment depends on the diagnosis conforming to the provisions. This study regarding access to IMRT is focused on the instances where authorization is denied because the insurer's assessment is in disagreement with the provisions. However there may be cases where a denial of claim for IMRT results because the application is incomplete or in error. To protect against counting such cases in error, documentation in the billing notes should provide indication that such cases be excluded. Another potential threat to validity might present if an insurer did not follow the policy as stated. This possibility of a mismatch between policy and practice can be verified as part of the data collection. It is also possible for a physician to unintentionally not follow insurance guidelines and unwittingly prescribe treatment without a proper understanding of the patient's insurance plan. In this retrospective study, the billing office would have identified a conflict between the prescription and insurance policy when completing a claim form and resolved the theoretical discrepancy.

External Validity

Generalization of this study to breast patients at other institutions is dependent on having the same or similar policies at play. External validity is maintained when the same or similar public and private insurance policies are applied at other institutions. Medicare policies can vary by geographic region due to different Medicare contractors processing claims. This difference is a threat to external validity should differing Medicare policies and/or private insurance companies alter the outcome compared to the accessible population. Another variable that would clarify the applicability of this study is department policy regarding the interpretation and action based on

insurance policy criteria. If an institution adopts the same interpretation and action as XYZ, then the study has external validity. However the likelihood of this is unknown. This study cannot be generalized to other treatment sites, as the treatment techniques and geometry are unique to breast treatments.

Reliability

The notes regarding treatment authorization are recorded by billing office staff for each patient and serves as the primary instrument used to collect data. These notes are permanently recorded as part of the patient treatment record. The principle data recorded are dates of authorization request, receipt, and necessity of pre-authorization for IMRT as dictated by the insurance provider. A potential source of error may be the recording of the wrong date for submitting a request or receipt of authorization. A date/time stamp is also provided by Mosaiq when a note is entered.

Chapter 4 – Results and Findings

Objectives

The use of IMRT for breast treatment at XYZ Cancer Center (XYZ) began around 2002. This new modality provided new ability to deliver highly tailored treatment plans with the help of computerized algorithms. The goal of tailored treatment plans is to deliver the maximum dose to the cancer and minimize the dose to healthy organs. Prior to the use of IMRT, conventional 3DCRT was the standard of mode for delivering the most optimal dose for breast treatments. However, 3DCRT had limited capability of producing homogeneous dose distributions and ability to limit the dose to heart, lung, and other tissue outside the field. Research studies investigating the efficacy of IMRT were published to aid practitioners in the appropriate utilization. These studies showed equivalence in terms of survival, but reduced toxicity and improved cosmesis using IMRT in selected patients. The mixed result in recommended use for IMRT resulted in a practice of limiting the use of the higher cost modality. Public and private insurance policies did not universally pay for IMRT to treat breast patients. Medicare created a simple process for providers to bill IMRT by creating a list of pre-authorized diagnosis codes that met Medicare payment policy. Private insurers published provisions that defined their respective IMRT payment policies. The concern of this investigation is whether insurance policies supports access to IMRT treatments as prescribed by XYZ physicians.

To probe to the bottom and center of this study, primary data was derived from a survey of 14 key informants, experts in the field of Breast IMRT treatment. Nine respondents provided data through the customized Survey Monkey electronic questionnaire. Secondary data was derived from the literature produced by scholars and practitioners in the field of breast treatment. In addition, a retrospective review of billing notes in 32 breast patient charts were examined to

derive a history of physician experience in prescribing IMRT for the sample population. The notes contained identification of the patient's insurance plan, a list of applicable IMRT provisions, assessment of need for authorization, and any information provided by the physician, patient, or provider related to treatment billing.

Research Question

The research question in this study is whether private insurance policies reduces access to IMRT breast treatments in comparison to Medicare. Three sub-questions were examined:

1. Interpretation of clinical results varied between insurers, producing different payment policies.
2. The absence of a clear cut definition for appropriate billing of breast plans has led to a conflict between delivery of the preferred care and what insurers will allow.
3. Adopting Medicare policies regarding breast cancer treatment will reduce policy ambiguity and enhance access to quality of care for all patients at XYZ.

This chapter presents the collection of primary and secondary data examined and synthesized to address these research questions.

Overview of Results

Review of the survey is presented first. The survey was sent to all 14 XYZ radiation oncologists, distributed at 5 centers that collectively treated 2,348 patients in 2015 (all anatomical sites). The physicians have an estimated average of 20 years in the field and are all certified by the American Board of Radiology in the field of radiation therapy. Nine respondents (64%) completed the survey, which was presented in the form of six statements. Level of agreement or disagreement was sought in response to the statements. The survey results were designed to

collect physician perspective on the impact of insurance policies on their clinical practice concerning breast IMRT prescriptions.

Following the survey results, the analysis of the secondary data is presented. The result of the chart reviews that documented the number of IMRT prescriptions, type of insurance, and frequency of authorizations and denials. A test was performed to count the number of IMRT prescriptions that could result if the Medicare policies were applied to the privately insured patient diagnoses. The results of that test is presented.

List of Survey Responses

Statement #1: Medicare breast IMRT policies allow prescription of IMRT when I wish to prescribe it.

Only TWO OF NINE respondents agreed, while SIX OF NINE disagreed TO THIS STATEMENT. This indicates the dominant opinion is the list of pre-authorized diagnoses codes do not cover all cases believed deserving of IMRT.

Statement #2: Private insurance (Blue Cross, Blue Shield, United Healthcare) breast IMRT policies allow prescription of IMRT when I wish to prescribe it.

None of the NINE respondents agreed with this statement. TWO respondents were unsure, FIVE disagreed and TWO strongly disagreed. Compared to the results of Statement #1, privately insured patients access to IMRT is perceived to be more restricted than Medicare. However the difference is only a small degree.

Statement #3: Alternatives to IMRT such as forward planning and 3DCRT are sufficient techniques when IMRT is not an option.

The distribution of responses were almost uniform between agreement and disagreement, showing a polar view for physicians when IMRT is not authorized by payers. FOUR of NINE respondents have relinquished confidence in using techniques that were formerly the best available. For almost half of the respondents, the gatekeeping function of limiting IMRT use forces use of undesired techniques. This is a profound professional conflict for caregivers who are committed to providing the highest quality care.

Statement #4: In general, public and private insurance policies regarding prescription of breast IMRT accurately reflect published data when IMRT was new (>10 years ago).

One respondent strongly agreed, and FOUR OF NINE agreed. This results highlights a belief that policies were grounded in research over 10 years ago. However the responses from Statements #1 and #2 indicate that that policies today do not support the use of IMRT as desired. A gap between practice and policies has developed since IMRT was new.

Statement #5: In general, public and private insurance policies regarding prescription of breast IMRT do not incorporate newer data/clinical expertise.

FOUR of NINE agreed. Adding TWO respondents who strongly agreed, the dominant view is that insurance policies have not kept current with research. In light of the responses to all the previous statement responses, the practice-policy gap can be explained by the belief that the policies do not reflect today's experience and desired use.

Statement #6: Public and private insurance policies regarding prescription of breast IMRT become obsolete as we transition to MIPS/APMs and bundled payments for oncology care.

The respondents agreed that insurance policies regarding breast IMRT become obsolete when there is a transition to merit-based incentive payment systems (MIPS)/alternative payment models (APMs) and bundled care. MIPS and APMs are considered to be alternative payment models to the current model, fee-for-service (FFS). The alternative payment models are components of a bill to create a framework to incentive providers to provide care with greater efficiency. The bill was passed in December 2015, and entitled "Medicare and CHIPS Re-Authorization Act" (MACRA). Six of nine respondents agreed with the statement, and one strongly agreed. Though a gap may exist in policy support of IMRT for breast treatments today, the change in healthcare payments will erase the need to take any action because the provider will be accepting the financial risk instead of the insurer.

Summary of Survey Results

The survey of physicians does not indicate a strong difference in access to IMRT between private insurance policies and Medicare. The more impactful finding is that both insurance types are perceived to reduce access to IMRT, at least to the desired level of use. This issue is

compounded by belief in almost half of the physicians that the alternatives to IMRT are no longer believed to be satisfactory options to treat patients.

These alternatives were formerly the standard of care over 10 years ago, when IMRT was a new modality and the object of research and developing use in breast treatments. Most physicians agreed that the evidence at that time was incorporated in the policies that permitted selected approval of IMRT but defaulting to the traditional methods otherwise. Since then, IMRT use has grown to be the standard and the policies are believed to not have been updated with current research and expertise. The literature review in this work did produce studies from 2015 and 2016 that were not cited in the rationales documented in the respective policies. One of these studies (Yang et al., 2016) did conclude that IMRT can be considered a standard technique for breast cancer.

Due to the anticipated change in healthcare reimbursement from FFS to value-based payments, most of the respondents concluded that the practice-policy gap regarding IMRT will not be an issue in the future. Over the next few years as the provisions of MACRA are promulgated, providers will transition to a system where insurers will provide a bundled payment for cancer care. In a bundled care payment system, XYZ will be paid a lump sum to cover expenses for all aspects of cancer care. Therefore the XYZ physicians can prescribe IMRT based on exclusively on their own medical practice and judgment.

Secondary Data Presentation

Table II presents an overview of the billing notes found in the chart:

Insurance Type (n)	%	3DCRT Rx	IMRT Rx	IMRT Auth Required	Denied IMRT
Private (18)	56%	15 (83%)	3 (17%)	1	0
Public (14)	44%	10 (71%)	4 (29%)	0	0
Total (32)	100%	25 (78%)	7 (22%)	1	0

Table II.

With regard to patient access for IMRT, a greater percentage of Medicare patients were prescribed IMRT treatments as compared to private payers (4/14 vs. 3/18). This comparison supports the main hypothesis that the private insurance policies reduces access to IMRT as compared to Medicare. Given the low sampling, the significance of the difference weak.

The first sub-hypothesis asserted that differences in interpretation of research data regarding IMRT contributed to variation in policies. Review of the literature cited by each private insurer showed more similarity with each other than differences. This was not evident from the text of the policies alone, which contained differences in provisions. The similarities in references the insurance policies, and no significant difference between policies in producing IMRT prescriptions, did not produce a basis for a finding regarding how the impact of research on individual policies.

There was no finding with regard to the second sub-hypothesis, of a conflict between providers and insurers with respect to billing of breast plans. The study period produced no denial of claims or evidence in billing notes that showed conflict of billing. The absence of denials may also be the result of the finding that the majority of IMRT prescribed patients did not require requests for authorization (6 or 7 patients). This may be further evidence that there is a practice of avoiding the authorization process.

In regard to the third sub-hypothesis, a second analysis was based on experimentally testing access to IMRT by applying Medicare policies amongst the 18 patients carrying private insurance policies. When the Medicare policies were applied to the 18 privately insured patients, both insurance types produced 3 patients each that received IMRT. None of the patients were common to both types of insurance. Finding the same number of patients prescribed with IMRT, independent of private or public insurance, it appears the apparent variation does not have an effect. This result refutes the sub-hypothesis.

Chapter 5 – Conclusions and Recommendations

The intent of this study was to investigate insurance policy impact on the provision of IMRT treatment for breast cancer. The main hypothesis was that private insurance policies were constraining the provision, compared to Medicare. The findings supported the hypothesis, however there is only a slight difference between public and private policies. Differences in interpretation of data and the lack of definition of IMRT were hypothesized as factors in the differences. However, the findings were insufficient to produce evidence to support or refute these two sub-hypotheses. In fact the literature search found the rationales for the policies were similar, which in theory should produce similar outcomes in terms of IMRT use. This conclusion was further supported in the finding of the last sub-hypothesis. Medicare and private insurance policies produced the same number of IMRT prescriptions, which refutes the proposition that Medicare improves access to IMRT.

The survey results underscored the most important conclusion produced in this investigation is that insurance policies, public or private, do not support the use of IMRT for breast treatment. This issue is more important than the hypothesized differences between private and public insurance policies. A proposed change in policy to close the gap between practice and policy is needed to improve access to IMRT. However, the pending changes in healthcare payments, and difficulty in achieving changes in payment policy, render the significant effort wasted. The most fruitful effort is for XYZ Cancer Center to work on internal policies so physicians agree when IMRT is justified.

To improve access to IMRT in the future, the following recommendations are made:

1. Investigate and monitor proposed changes in payment policies through professional organizations such as the American Society of Therapeutic Radiation Oncology (ASTRO), the American College of Radiation Oncology (ACRO), and the American College of Radiology (ACR). Through work performed in committees, these organizations can influence decisions made by the Centers for Medicare and Medicaid (CMS), which governs healthcare payment policy.
2. Investigate and document the most current evidence and practice regarding use of IMRT for breast treatment. Attempt to reach consensus and establish policy for IMRT use that is based on current evidence and group experience.

MACRA maps a road to transitioning U.S. healthcare from FFS to value-based reimbursements. This change alters what is currently a volume-based business model, where treatment decisions can be influenced by the desire to treat more patients and increase profit. To incentivize care providers, MACRA introduces bonus payments to those providers who demonstrate quality improvement in their organizations. Quality metrics become necessary for organizations to demonstrate improvement and qualify for bonus payments. Although a timeline for transition is mapped to begin in 2017, it will be necessary for the professional societies to provide feedback to CMS and members on the actual timeline for execution.

This drive for improved quality is in conjunction with trying to reduce operational costs. Value has derived from the increase in quality and reduction of cost. Rather than insurance companies forcing change, providers are tasked with finding value and giving the best care at the lowest cost. New payment models give caregivers the responsibility for the quality and cost of care. XYZ Cancer Center will then have freedom to deliver IMRT to all patients that are deemed

qualified. Insurance companies will not have a role in this determination, therefore, XYZ Cancer Center physicians will need to set policy.

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Appendix A

Table I. Summary of Breast IMRT Policies

Provider	IMRT is provided…
Medicare	for the following ICD-10 codes: 1-6 left breast-C50.012 (nipple and areola), C50.112 (central), C50.212 (upper-inner quadrant, C50.312 (lower-inner quadrant), C50.612 (axillary tale), and C50.812 (overlapping sites); 7-8 lobular ca in situ-D05.01 (right breast) and D05.02 (left breast); 9-10 intraductal ca - D05.11 (right breast) and D05.12 (left breast); and 11-12 other specified type in situ- D05.81 (right breast) and D05.82 (left breast)
Blue Cross	In individuals with left-sided breast lesions when cardiac dose is high with 3DCRT or in individuals with large breasts or in individuals who are to receive internal mammary node irradiation.
Blue Shield	for left-sided breast cancer after breast-conserving surgery when all the following conditions have been met. Significant cardiac radiation exposure cannot be avoided using alternative radiation techniques IMRT dosimetry demonstrates significantly reduced cardiac target volume radiation . IMRT may be considered medically necessary in individuals with large breasts when treatment planning with 3-dimensional (3D) conformal results in hot spots
United Healthcare	when the patient has a separation of 25.5 cm or more in the intra-thoracic distance. IMRT may be covered for a diagnosis when: A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity. The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue. Requests for these exceptions will be evaluated on a case-by-case basis.

Appendix B

I am currently completing my Master's degree in public administration at Golden Gate University. I am inviting you to participate in a brief survey to obtain your personal perspectives on breast IMRT insurance policies.

This survey should take you approximately 5 minutes to complete and is being conducted via www.surveymonkey.com). Your response will be considered finished only when you press the "Done" button. Your name is not required to complete this survey. Your answers will be kept confidential and anonymous. The survey will only be used by me for the purpose of completing my project. I will not publicly release your responses or other information about you. If you have questions or difficulty completing the survey please contact me. My hope is that you complete the survey by Monday February 13. Thank you in advance for participating and for helping complete my research study. Your participation and input is important.

1. Medicare breast IMRT policies allow prescription of IMRT when I wish to prescribe it.

    a. Strongly Agree
    b. Agree
    c. Unsure
    d. Disagree
    e. Strongly Disagree

2. Private insurance (Blue Cross, Blue Shield, United Healthcare) breast IMRT policies allow prescription of IMRT when I wish to prescribe it.

    a. Strongly Agree
    b. Agree
    c. Disagree
    d. Unsure
    e. Strongly Disagree

3. Alternatives to IMRT such as forward planning and 3DCRT are sufficient techniques when IMRT is not an option.

    a. Strongly Agree
    b. Agree
    c. Disagree
    d. Unsure
    e. Strongly Disagree

4. In general, public and private insurance policies regarding prescription of breast IMRT accurately reflect published data when IMRT was new (>10 years ago)

    a. Strongly Agree

b. Agree
c. Unsure
d. Disagree
e. Strongly Disagree

5. In general, public and private insurance policies regarding prescription of breast IMRT do not incorporate newer data/clinical expertise.
   a. Strongly Agree
   b. Agree
   c. Unsure
   d. Disagree
   e. Strongly Disagree

6. Public and private insurance policies regarding prescription of breast IMRT become obsolete as we transition to MIPS/APMs and bundled payments for oncology care.

   a. Strongly Agree
   b. Agree
   c. Unsure
   d. Disagree
   e. Strongly Disagree