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Impact of Report Recommendation on Follow-Up Ultrasound Studies in the Work-Up of Incidental Thyroid Nodules

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IMPACT OF REPORT RECOMMENDATION ON FOLLOW-UP ULTRASOUND STUDIES IN THE WORK-UP OF INCIDENTAL THYROID NODULES

BY

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A doctoral project submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree

Doctor of Health Administration

in the College of Health Professions

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ABSTRACT

Abstract of Doctoral Project Presented to the Doctoral Program in Health Administration & Leadership Medical University of South Carolina In Partial Fulfillment of the Requirements for the Degree of Doctor of Health Administration

Impact of Report Recommendation on Follow-Up Ultrasound Studies in the Work-Up of Incidental Thyroid Nodules

Chairperson: **Kit N. Simpson, DrPH**

Committee: **Jay Bronner, MD and Thomas Jay Crawford, DHA**

The primary objective of this study was to determine the impact of report recommendation on follow-up ultrasound studies in the work-up of incidental thyroid nodules. Secondary objective was to determine the rate of cost savings, number of missed thyroid cancers avoided, and number of negative fine needle aspirations/biopsies avoided. This study utilized de-identified data of RadPartners (RP) from 102 hospitals and 180 outpatient centers, 1936 CT scans pre-intervention and 2121 CT scans post-intervention were analyzed. Secondary analysis was performed utilizing Medicare cost data from a 5 percent sample data set from the Comparative Effectiveness and Data Analysis Resource (CEDAR). Results demonstrate a cost savings of $23,057,207 in the Medicare population with 7,592 negative fine needle aspirations/biopsies and 750 additional thyroid cancers detected. Using a clinical decision tree model and economic modeling, best practice development for the reporting of incidental thyroid nodules will lead to improvement in value of care. This model can be applied in future studies of other common incidentaloma management and associated Medicare cost analysis.

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INTRODUCTION

1.1. Introduction

Healthcare in the United States is fraught with complexity, fragmentation, inefficiency, tremendous variation, and an inordinate amount of waste. Less than fifty percent of care delivered is derived from evidence-based guidelines (McGlynn, 2003). There are multiple contributors to healthcare waste as recognized by the Institute of Medicine (IOM, 2012). Overuse, underuse, and misuse of care continue to plague the specialty areas. Two of these contributors will be a focus of this thesis: unnecessary radiology services, and inefficiently delivered radiology services. In today's health care market, all health care systems need to focus their initiatives and goals on improving the value of health care while improving quality of care and reducing total medical costs. Health care reform in the United States has resulted in a paradigm shift in the practice of radiology aimed at creating patient value by improving quality through improving patient-centered care (Itri, 2015). In 2007, the Institute for Healthcare Improvement (IHI) proposed a framework for optimizing health system performance known as the "Triple Aim". Improving the patient-centered care is a component of the "Triple Aim" ("Better Health, Better Care, Lower Cost") of healthcare in the United States (Berwick, 2008).

As the healthcare industry transitions from focusing on volume-based to value-based outcomes, radiology practices will be faced with the task of demonstrating value to their patients, referring physicians, health care executives, and more importantly, Medicare and 3rd party payers. Creating value through development of best practices will be a critically important component of the shift to value-based outcomes. Despite these measures, health care expenditures in the United States are growing at an unsustainable rate representing close to 18% of the gross domestic product (GDP) (Fuchs,2013).

Medical imaging is one of the most important contributors to these rising health care costs surpassing more than 14% of Medicare Part B expenditures (Bernardy, 2009). Overutilization of diagnostic imaging in the Emergency Department (ED) and in the outpatient departments is becoming a critical problem that hospitals of all sizes will need to deal with due to the implementation of the Protecting Access to Medicare Act of 2014 (PAMA) on January 1, 2018.

Government reimbursements represent a significant portion of all payments to physicians and hospitals. Government sponsored programs account for the largest proportion of funding here in the United States, making them an attractive target for improving mechanisms. Add to that the aging of the population into Medicare, and state Medicaid expansion programs covering a greater proportion of the underserved, making value based care an even more attractive goal. With Medicare accounting for 22 percent of all healthcare spending, and Medicaid funding 20 percent of all United States healthcare, we are approaching almost half of all reimbursements coming from government programs (CMS, 2017). This leads to the intense focus on optimizing value-based care in radiology and the prelude to metrics for radiologists in the era of value-based healthcare delivery (Sarwar, 2015). Medicaid costs taxpayers $475 billion per year and covers more than fifty million Americans. The growth in Medicaid and Medicare has been dramatic. To put the Medicaid federal and state program in context, Medicaid spending on an annual basis exceeds Wal-Mart's worldwide annual revenue (U.S. House of Representatives, 2013).

In the last decade, various policies have been enacted to help reduce the cost of healthcare in the United States. In March 2014, Congress passed **H.R. 4302**, known colloquially as the Protecting Access to Medicare Act (PAMA). PAMA requires that caregivers who order advanced imaging exams must provide evidence of consultation of a Clinical Decision Support Mechanism (CDSM). The CDSM must leverage Appropriate Use Criteria (AUC) from a qualified Provider Led Entity (qPLE) (Protecting Access to Medicare Act of 2014).

In April 2015, Congress passed **H.R.2**, known colloquially as the Medicare Access and CHIP Reauthorization Act (MACRA). As part of MACRA, the Quality Payment Program established the Merit-Based Incentive Payment System (MIPS) to drive evidence-based and practice-specific quality improvement through a performance-based payment system (Medicare Access and CHIP Reauthorization Act of 2015).

In the current Medicare fee-for-service (FFS) payment system, volume carries more weight than quality, rewarding physicians for treatment of disease in volume rather than promotion of quality health outcomes. Placing volume ahead of quality has led to an unsustainable payment model. Driven by the Affordable Care Act (ACA) of 2010, the Centers for Medicare and Medicaid Services (CMS) have recently taken significant steps toward future higher quality of care through several quality improvement and payment programs including: MIPS, Alternative Payment Models (APMs), Accountable

Care Organizations (ACOs), Patient Centered Medical Homes, and bundled payment models.

CMS' objective is to increase the value of care delivered to the patient by improving quality while reducing costs. The transition from fee-for-service to newer payment models is based on shared savings arrangements. MACRA was designed to quicken the adoption of a purely value-based health system and to make comprehensive changes to how Medicare pays for physician services. Under MACRA there are two differing pathways, MIPS and APMs. MIPS remains a modified fee-for-service model that resembles the old/current model in which physicians are reimbursed for each service they provide, but under MACRA they will be financially incentivized to report on required quality measures designated by CMS. On the other hand, APMs are a completely new payment model. Under a bundled payment APM, a physician, group practice, or other entity contracts with a payer to receive one bundled payment for services provided for a patient or groups of patients based on specific clinical conditions. That payment is then divided among the parties who provide that care. Under an ACO, or shared-savings APM, eligible professionals (EPs) who improve quality while reducing costs share in the cost savings realized. CMS is clearly directing physicians toward APMs by offering a simpler reporting system and higher annual financial incentives.

In November 2, 2017, CMS published the CY 2018 **Medicare Physician Fee Schedule** (MPFS) and **Quality Payment Program** (QPP) Final Rules to revise PAMA and MACRA. These rules align the qCDSM consultation requirements of the

PAMA with the quality initiatives of MACRA, and thus, help to clarify the requirements for the creation of Clinical Decision Support (CDS) programs for compliant imaging AUC consultations.

Radiology Practice

Radiology is the art and science of providing medical imaging to diagnose and treat diseases within the body. Various imaging techniques are applied to the practice, such as plain film radiography, interventional radiography, ultrasound, mammography, computed tomography (CT), nuclear medicine imaging including positron emission tomography (PET), and magnetic resonance imaging (MRI). During the past decade, imaging services and their associated costs have grown at about twice the rate of other technologies in healthcare (Smith-Bindman, 2008). By far, the greatest proportion of imaging services is used for older patients, a population segment that will expand dramatically over the next several years as the baby-boomer generation age into retirement and Medicare. The growth rate of imaging reflects advances in imaging technologies and expanded applications that have occurred over the past decade including those in high-tech imaging services CT, MRI, and PET. A substantial fraction of the growth, however, results from the overutilization of imaging services for both diagnosis and image-guided therapy (Hendee, 2010).

With an estimated 1.7 million Americans diagnosed with cancer, resulting in 600,000 deaths annually, access to imaging services is essential for diagnosing critical disease states when they are most treatable and providing clinicians the ability to determine if a treatment is working as intended (NIH, 2017). Medical imaging plays an integral role in therapeutic and diagnostic treatments offering highly personalized, non-invasive and cost-effective care for 50-60 percent of all diagnosed cancer patients today (Hricak, 2011).

Both medical imaging and radiation therapy are integral to established evidence-based medicine and radiology medical guidelines. These guidelines reflect clinical recommendations developed by radiology specialty physician groups on how best to diagnose, assess, and treat specific critical medical conditions. They are based upon proven guidelines, best practices, widely accepted standards, and scientific evidence. They also mitigate the risks and costs of over-utilization.

Clinicians' more recent willingness to concede that overuse is a problem comes as good news for regulators who have long worked to increase awareness of this aspect of medicine in the United States. Overuse is costly, pervasive, and causes harm to patients. Yet it has been challenging to get the medical profession, payers, health care advisors, and the general public to take note of it, let alone reduce it. Today, however, there are efforts underway to change that. The radiology profession has taken an initial step, by acknowledging the scope and scale of the problem (Brownlee, 2014).

Overutilization can be defined as the application of imaging procedures where circumstances indicate that they are unlikely to improve patient outcomes. One such example is the focus of this thesis research, overutilization of incidental thyroid nodule follow-up exams. Numerous studies have suggested that as many as 20-50 percent of advanced imaging procedures fail to provide additional information that improves patient outcomes (Iglehart, 2009). These percentages should be interpreted with caution, however, because they fail to acknowledge the value of true negative imaging results and the influence such information has on patient management and treatment.

Moreover, for this thesis, overutilization of imaging exams in the emergency room and out-patient imaging has resulted in a high number of incidental findings that include but not limited to the detection of incidental thyroid nodules (ITN). An ITN is defined as a nodule identified on an imaging exam that was not present on earlier exams or is suspected based on a clinical exam (Hoang, 2014). It has been reported that ITNs are seen in 16-18% of CT and MRI scans in which the neck is imaged (Hoang, 2014). Given this relatively high number of ITNs noted, there is currently a paucity of reported guidelines on the management of ITNs and a high variability in reporting of by radiologists. There is agreement on how to manage the ITN of 1 cm or greater in size; however, standard reporting of nodules less than 1 cm is lacking (Johnson, 2011). There is a high variability in radiologists' reporting practices of ITNs, especially for nodules less than 10 mm (Hoang, 2014). The lack of report standardization regarding ITNs has resulted in a new initiative in best practices for managing and reporting of ITNs. In a future value-based health care market, health care providers must be able to demonstrate their ability to effectively manage an entire population of patients, and providers will be evaluated on cost and outcomes rather than volumes. The basis of this value-based care will depend significantly on the effective communication of imaging recommendations and subsequent adherence to follow-up recommendations.

The ultimate goal of any best practice initiative is to elevate patient care and reduce costs, thus improving patient value and creating relevance for value-based medicine. In the United States, we currently lack a clinical, management information system that objectively measures the patient overall benefit, integrating all benefits and adverse events associated with health care interventions. Furthermore, to improve quality of care and reduce costs, objective patient value will need to be determined. The gain in patient value associated with any health care invention will be defined by the improvement it confers in the quality-adjusted life years (QALY). While QALY was not measured for this baseline study, future studies could readily utilize one of the many quality-of-life instruments such as the highly accepted Short-Form-36 (SF 36) (Whitehead, 2010).

The term Value-Based Medicine originated at the Center for Value-Based Medicine (Brown, 2005). As such, the practice of Value-Based Medicine is based primarily upon the values attached to patient and financial aspects associated to any health care intervention and, thus, involves a standardized cost-utility analysis. In this study, a cost utility model was performed on the basis of a parallel decision analysis model. In health care, there are three types of costs: direct medical costs, direct non-medical costs, and indirect costs (Brown, 2005). In performing a health care economic analysis, all costs need to be considered. The performance of just a direct medical costs analysis is known as the third-party insurer cost perspective. The most standardized health care costs in the

United States are the average national costs paid by Medicare. Commercial insurers are those who insure patients under the age of 65, whereas Medicare insures those 65 years and older, in addition to disabled populations. Value-Based Medicine integrates cost-utility analysis on the following principles (Brown, 2005):

(1) The practice of medicine should be based upon the value (improvement in patient QALY) conferred by health care interventions.

(2) The highest level of interventional, evidence-based, medical data available should be utilized for conversion to Value-Based Medicine data.

(3) Patients should receive the health care interventions that confer the greatest value.

(4) When interventions confer similar value, the intervention that is least expensive should be considered the preferred treatment.

(5) Utilities are obtained from patients who live or have lived with the health condition under study.

(6) Until another form of utility value analysis is demonstrated to be preferable, time trade-off utilities are used.

(7) The input costs (average Medicare) and cost perspectives (third party insurer and societal) are standardized to allow a comparison of all analysis.

(8) Any cost-effectiveness outcomes used in public policy should be reviewed by a consensus group (e.g. physicians, hospitals, members of the general public, vendors, program officials, and so forth).

Value-Based Medicine comparative effectiveness and cost effectiveness offer the following advantages to all stakeholders in health care (Brown, 2012):

(1) Maximize quality of care by integrating patient preferences for QALY and demonstrating which interventions provide the greatest patient value.

(2) Maximize scarce resources by identifying interventions which confer the same or greater patient value for less cost.

(3) Identify interventions that actually return money to patients and society.

This area of viewing health care interventions as 'profit centers' for the betterment of the overall wealth of the country is in a development stage, yet is critically important in an environment of concern over the direct costs of healthcare.

Despite the need and recent uptick in the number of physicians making the transition to value-based care, a majority of clinicians, 53%, remain skeptical and reluctant to switch from traditional fee-for-service, based on a recent survey conducted jointly by the American Academy of Family Physicians and Humana (Mullins, 2017). Yet many payers, providers, and other health care organizations are moving away from fee-for-service and toward value-based payments (VBP). There has been a paucity of research on whether these alternative reimbursement models have resulted in lower overall health care costs. Developing best practices may be a first step into a universal VBP, e.g., by standardizing ITN reporting and recommendations by radiologists, a major theme of this study.

1.2 Background and Need

The United States spends more on health care than other high-income countries over the past three decades (Exhibit 1). As one of the most developed economies globally, the United States strives to ensure that all citizens have access to the best possible health care (Dieleman, 2016; World Health Organization, 2015). Despite these efforts to ensure access to affordable health care, health care costs continue to rise out of proportion and the United States ranks last overall in health care outcomes (Exhibit 2). According to official estimates, US spending on healthcare rose to $2.9 trillion in the year 2014 (Dieleman, 2016). Between 2013 and 2014 spending on health care increased by 5.3 percent (Dieleman, 2016). Despite the significant amount of resources the US spends on health care, much remains unknown about the exact costs of treating many health conditions. A better understanding of how health care expenses varies across health care ecosystems is essential for health science researchers and healthcare policy makers in order to improve the delivery and value of health care. As noted and demonstrated above, the United States has the highest total spending per person per year on health care of any world country. The cost and utilization of advanced imaging studies is rising in parallel. The overutilization of advanced imaging has been well documented (Smith-Bindman, 2012). The federal Health Information Technology and Economic Health (HITECH) Act of 2009 aims to improve quality of healthcare and reduce waste through meaningful use of health information technology (IT), including a major focus on clinical decision support (CDS) (Raja, 2015).

Thyroid Nodule Reporting

Most thyroid nodules are benign, and most small thyroid cancers are indolent. The workup of ITNs is costly for both the patient and the associated health care system. The incidence of thyroid cancer has increased worldwide 3- to 15-fold over the last two decades, but with no significant increase in mortality (Pellegritti, 2013). Papillary thyroid cancer accounts for 95% of differentiated thyroid cancers and has been reported to be increasing at an estimated rate of 4% to 5% per year (Yip, 2018). This may result from the increased number of ITNs found on clinical imaging exams. It has been proposed that an ultrasound-based risk stratification system be used to identify and classify thyroid nodules that need further work-up or biopsy, similar to the breast imaging, reporting and data system (BI-RADS) classification widely used for breast imaging. The acronym TI-RADS (Thyroid Imaging, Reporting and Data System) for thyroid imaging was developed and reported on (Tessler, 2017). Best practice models are needed to support the decision of no further work-up needed for the majority of ITNs to reduce morbidity associated with unnecessary diagnostic surgery. There is a paucity of studies demonstrating the best practice model for the evaluation of ITNs. No studies could be found that describe an economic model to best demonstrate the value of building a best practice model to evaluate ITNs and produce results that could be generalized to other clinical best practice models, e.g., ovarian cysts or other CT incidentalomas.

1.3. Problem Statement

There is a high prevalence of thyroid nodules in the general population found at autopsy, 30-60% and the majority of these nodules (>95%) are benign (Lehnert, 2014). The ultrasound prevalence is estimated to be 13-67% and 16-18% on CT and MRI exams as stated above. In order to create a best practice approach to the work-up of ITNs radiologists need to give referring physicians better guidance of what the work-up should include if anything at all. Currently, the United States has no screening program for thyroid cancer. Despite the lack of such a program, thyroid cancer incidence has increased by 185% in 35 years, and at a rate much greater than cancers that currently have screening programs, prostate and breast (Esserman, 2013). Despite the increase in incidence the mortality rate has not changed (Davies, 2014). The overutilization of follow-up thyroid imaging and potential thyroid ablation techniques has resulted in adding to the rise of healthcare spending and reducing the QALY in patients with ITNs.

We know that radiologists are cautious and fearful of missing critical findings. However, there is an ingrained mentality on the part of radiologists to recommend more and more imaging. From this there is also the risk that such utilization of imaging might lead to further potentially unnecessary, risky, and costly procedures, perpetuating the overuse dynamic.

1.4. Study Objectives

The purpose of the study is to evaluate the impact of adding the following statement to a CT report that has discovered an ITN: "No further follow up is indicated for the ITN." It is important to determine if this statement will have a significant effect on the reduction of follow up thyroid ultrasound, thyroid fine needle biopsy, thyroid surgery, and health care dollars saved in forming this best practice of managing ITNs. Creating value through an economic model should lead to a significant reduction in overall health care dollars spent, an improvement in overall health care system performance ranking, and an improvement in overall patient health status.

1.5. Study Hypothesis

The research question is as follows:

-RQ: Does the best practice model of indicating that no further testing is needed for the ITN have a significant effect on the reduction of advanced medical imaging utilization, thyroid biopsy, thyroid surgical ablation techniques, and an increase in health care dollars saved on advanced medical imaging of patients with an ITN.

The hypotheses are as follows:

H0. Best practice models indicating no further work-up are needed of ITNs does not have a significant effect on the reduction of advanced medical imaging utilization, thyroid biopsy, thyroid ablations, or an increase in health care dollars saved on advanced medical imaging of patients diagnosed with an ITN.

H1. Best practice models indicating no further work-up are needed of ITNs does have a significant effect on the reduction of advanced medical imaging utilization, thyroid biopsy, thyroid ablations, and an increase in health care dollars saved on advanced medical imaging of patients diagnosed with an ITN.

1.6. Study Design

It has been suggested that the overutilization of further work up of ITNs with ultrasound is not cost effective and potentially harmful to the patient (Hoang, 2017). This study analyzes how effective a simple reporting practice is on the further workup of ITNs. By showing the effectiveness of this clinical best practice an economic model will be proposed that will be generalizable across other best practice clinical models. A retrospective study of CT scan reports will be performed. The study will use a quantitative, non-experimental predictive design. A predictive research design is most appropriate for examining the impact of the independent variable on the dependent variable (Vaishnavi, 2015). A predictive design should be chosen, since the purpose of this study is to examine the impact of the independent variable (i.e., wording of the recommendation) on the dependent variable (i.e., medical imaging follow-up study or procedure) (Vaishnavi, 2015). Exclusion criteria will consist of a known thyroid nodule, prior thyroid surgery, known thyroid pathology, and previous neck irradiation. Data will be collected from 102 hospitals and 180 outpatient centers.

The other potential research designs are not appropriate for examining the impact of the independent variable on the dependent variable (Creswell, 2013; Cooper, 2014). Thus, a predictive design has been selected over the other research design methods. A correlational design is appropriate for measuring the relationship of variables instead of the impact of the independent variable on the dependent variable. A causal-comparative quantitative research design is suitable for measuring the difference between variables

(Bernard, 2012; Vaishnavi, 2015). Experimental design is most appropriate for describing the variation of information under different conditions (Dillman, 2002; Leedy, 2016; Remler, 2010).

BACKGROUND/LITERATURE REVIEW

The concept of value-based care is critical to the management of a wide range of health conditions that affect individuals and society as a whole. Value-based care refers to a healthcare delivery ecosystem where clinicians focus on patient health outcomes. In other words, the focus of the care provision process is to reduce the adverse effects of a disease, improve the health of patients, and help patients improve their QALY (Gentry, 2017). The one main advantage of value-based care is that it ensures a savings of health care dollars while providing increase in quality of care. When clinicians embrace value-based care, they help to ensure that patients face fewer medical tests, follow up physician visits, and a reduction of unneeded procedures (Chazel, 2016). Value-based care can also serve to improve the efficiency of health care processes and ultimately achieve greater patient satisfaction. Patient engagement measures and quality of care will ultimately increase when clinicians focus on value and not volume. Thus, value-based care will be critical to the management of ITNs.

Thyroid Nodule

The thyroid gland is an endocrine organ that consists of a left and right lobe connected by an isthmus at the midline. It is imperative to state that the thyroid gland is encapsulated by a layer of cervical fascia and has lymphatic drainage that drains to the mediastinum, paratracheal region, and retropharyngeal space. It has a rich blood supply and shows avid concentration of iodine contrast during computed tomography (CT) exams. Available research evidence shows that a significant number of people suffer from disorders and diseases of the thyroid gland that are demonstrated on CT exams (Bin Saeedan, 2016). In the United States for instance, about 37,000 thyroid cancers are reported annually and the incidence has doubled in the last 30 years (Hoang, 2013). In 2013, the incidence rate of thyroid cancer in the United States was 15.3 cases per 100,000 persons (USPSTF, 2017). The primary thyroid cancers reported include papillary, follicular, medullary, and anaplastic. These cancers are usually detected as a thyroid nodule from either physical exam or a diagnostic imaging study and most cases have a good prognosis; the 5-year survival rate overall for all types is 98.1 percent (USPSTF, 2017). Thyroid cancer is the ninth most common cancer in the United States, fifth most common among women. Thyroid cancer incidence rate has increased at a much quicker pace than cancers monitored with screening programs like prostate and breast cancers (Hoang, 2015). There are currently no screening programs for thyroid cancer.

An early report of the incidence of thyroid nodule at autopsy is reported to be 50% in patients with no past medical history of thyroid disease (Mortensen, 1955). Since then there have been several studies utilizing ultrasound exams to report the frequency of ITNs. Steele (2005) reported on the frequency of ITNs during carotid duplex examination. He retrospectively reviewed 2,004 bilateral carotid duplex ultrasounds and found 9% ITNs. In another study using carotid ultrasounds Carroll (1982) a 13% incidence of ITNs was reported. Woestyn (1985) found a 19% incidence of ITNs on carotid ultrasound studies. The highest reported incidence occurred in a study by Ezzat (1994), which showed ITNs in 67% of patients. This study may be flawed due to the large sample of women 84% (Ezzat, 1994). It has been demonstrated in all studies that women have a higher incidence of ITNs, as high as 60% (Bartolotta, 2006).

Other studies looking at the incidence of ITNs, the imaging modalities of CT and MRI were looked at. In a study utilizing contrast enhanced CT scan of the neck, 16% incidence of ITN's was reported (Yoon, 2008). In another study utilizing both CT and MRI contrast enhanced studies of the neck; an incidence of ITNs was 16% (Yousem, 1997). Neither of these studies was controlled for a history of prior neck radiation, a known etiology for the development of thyroid carcinoma.

It has been shown that in the advanced imaging modality of FDG-PET scans thyroid ITNs are detected with a much lower frequency. One such study looking at 4525 subjects found a reported incidence of ITN's of 2% (Cohen, 2001). In another study utilizing FDG-PET in 1,330 subjects, there was an ITN detection rate of also 2% (Kang, 2003). The low incidence rate of ITN detection utilization may be explained by the fact that small nodules present may be below the threshold for accurate detection and/or the detection of ITNs utilizing FDG PET may be limited to those thyroid lesions that are metabolically active and therefore may be more likely malignant. In summary, the presence of ITNs are frequently seen on advanced imaging exams which include, US, CT, MRI and FDG-PET studies. For purposes of this study the modality of CT will be emphasized.

Choosing Wisely

In 2014, the ABIM funded a research study to conduct a national survey of physicians in order to gauge physicians' attitudes regarding the issues of performing unnecessary tests and procedures in our healthcare system. The views on the causes and perspectives on various solutions were also analyzed. The survey also measured exposure to the Choosing Wisely campaign. A sample size of 600 practicing physicians selected randomly from the American Medical Association's (AMA) Physician Masterfile participated in the survey (ABIM, 2014). Results were summarized based on views about the problem, the cause, and the solution. The majority of the physicians surveyed (73%) agreed that unnecessary tests and procedures in our healthcare system are a serious problem. More than half of the physicians believed that the unnecessary tests and procedures are about the physicians' own reassurances and mostly regarding malpractice concerns.

The majority of the physicians felt the responsibility to make sure their patients avoid unnecessary testing and they are in the best position to address the problem. While the majority of physicians surveyed do not recall hearing about the Choosing Wisely Initiative; those who report exposure to the campaign are more likely to have reduced the number of unnecessary tests. They also believe an effective way to address the problem is to have specific evidence-based recommendations around unnecessary tests and exams that can be discussed directly with the patients.

Despite these key efforts, there is a persistent disconnect between publicizing the tremendous examples of waste, overutilization of imaging services, and achieving true value-based care in today's health care practice. One of the key issues with this thesis is do reduce the variability in radiologists reporting practices in order to create a best practice model in order to reduce the number of unnecessary workups of ITNs and hopefully advance the concepts of Choosing Wisely and value-based care. Inappropriate use of medical imaging tests can cause physical harm by exposing patients to excess radiation, worsen patient outcomes and increase health care spending. Yet ordering the right tests can be difficult for physicians facing time constraints, pressure from patients and lack of access to evidence of tests' effectiveness and knowledge of best practices.

Clinical Decision Support

Clinical decision support (CDS) is a key functionality of health information technology and a centerpiece of Medicare and Medicaid EHR Incentive Programs. CDS focuses on probabilities in disqualifying unreliable diagnoses (Musen, 2014). Therefore, any system that only provides warnings is excluded from the definition of CDS. In order to qualify as a CDS, a system must provide outputs on the basis of a calculation using the physicians' data regarding patients' symptoms.

CDS is an important functionality of health information technology (HIT) (Pluye, 2004). It provides patients and physicians with person-specific information and helps clinicians improve their decision-making since it includes various tools such as computerized alerts and reminders (Ash, 2012). The primary goal is to improve appropriateness of imaging care thus, reducing overutilization.

CDS has numerous advantages, it is likely to enhance quality of care, health outcomes, efficiency, and patient satisfaction (Adler-Milstein, 2015). It is a competitive advantage in a value-based care market. It will help hospitals avoid adverse events and mistakes. In addition, it is an elegant health IT component requiring biomedical knowledge, person-specific data, and a reasoning mechanism (Musen, 2014). CDS presents important information that is organized to physicians, it has proved to be a powerful tool for influencing clinician behavior (Ash, 2012). This information helps physicians take action and assist physicians to integrate knowledge into care delivery (Adler-Milstein, 2015).

While many electronic health record (EHR) users might associate CDS with alerts and notifications, it has much more robust capability and includes a variety of helpful practice tools, from clinical guidelines to focused patient data reports. Within diagnostic imaging, CDS promotes sound decision making by providing immediate access to details of radiation doses and other risks, as well as costs. In addition, it provides physicians with tools they need in the exam room to help patients understand the rationales for ordering, delaying or not performing specific tests. It also enables clinicians to demonstrate to payers that they are ordering appropriate imaging tests. While CDS was not a focus of this study, it can certainly be integrated into future studies evaluating the cost effectiveness of implementing Choosing Wisely with development of best practice models as in this study looking at the need of further work up for ITNs.

Low-Value Care

While many health care services have been designated as a low-value service the follow up of ITNs has not been well studied in the cohort of the commercially insured adults. Low-value spending has been well studied in order to reduce waste in health care. Low-value services have added to the more than $750 billion of US health care wasted spending annually, including approximately $200 billion in overtreatment (Olson, 2010). In a recent study looking at 28 Choosing Wisely low-value services, in over a million commercially insured adults, 3 services including triiodothyronine measurement in hypothyroid patients, imaging of non-specific low back pain, and imaging of uncomplicated headaches were determined to cost $32.8 million in unwarranted spending (Reid, 2016). These are just a few examples of just a small segment of the low-value care spending, which also include follow-up imaging of ITNs.

As Choosing Wisely has become a more widespread initiative the American College of Radiology (ACR) has introduced its Radiology Support Communication and Alignment Network (R-SCAN) in 2016. This is a platform for clinicians and radiologists to collaborate on projects that improve imaging appropriateness based on Choosing Wisely recommendations. While most of the Choosing Wisely recommendations have focused on changing the practice patterns of ordering clinicians, the radiologists recommended follow-up exams have also become a major source of the high rates of imaging utilization. While the ITN has not been well studied in the context of R-SCAN resources, numerous efforts have utilized R-SCAN's resources to improve imaging appropriateness. Radiologists' recommendations for follow-up imaging have been studied in the case of incidental adnexal cysts (Broder, 2017).

The cost and frequency of use of advanced imaging studies including ultrasounds (US), magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine studies, continues to rise. The annual budget for advanced imaging studies for Medicare alone as of 2007 was $14 billion, and the per-beneficiary spending doubled between 2000-2006 (Iglehart, 2009). The general concept of overutilization of advanced medical imaging has been well documented (Smith-Bindman, 2012). The prevalence and cost of unnecessary follow-up of ITNs has not been well studied previously from a radiologic recommendation perspective.

TI-RADS/Thyroid Cancer

In 2012, the American College of Radiology (ACR) established committees to provide recommendations for reporting ITNs, develop a standard lexicon for US reporting of thyroid nodules, and propose a Thyroid Imaging, Reporting and Data System (TI-RADS) (Tessler, 2017). The 2015 ACR white paper on ITNs provides a set of evidence-based recommendations on the further workup of such thyroid nodules. The basis of TI-RADS was to establish a reliable, noninvasive method to identify which thyroid nodules warranted a fine needle aspiration (FNA) based on a significant likelihood of having a malignant potential. The purpose of the white paper was to present the system of risk stratification, designed to identify the most clinically significant malignancies while reducing the overall number of biopsies performed on definite benign nodules (Tessler, 2017). The basis of TI-RADS is to use the ultrasound features of the ITN and to categorize them as benign, minimally suspicious, moderately suspicious, or highly suspicious for malignancy. The ultrasound features of the nodule are categorized into five descriptors—composition, echogenicity, shape, margin, and echogenic foci. Points are given to each category and are added up to establish the TI-RADS number. The lower the number the more likely benign and higher the number the more likely malignant.

The over-diagnosis of thyroid cancer problem was first raised in a study by Davies (2006) who reported incidence and mortality data for thyroid cancer from the Surveillance, Epidemiology, and End Results (SEER) program. Davies and colleagues saw a mismatch between trends in incidence and mortality. As the incidence trend was rising for thyroid cancer, the mortality trend for the same period was unchanged and extremely low. (Davies, 2006). The problem of over diagnosis of thyroid cancer raised the question of over screening. Given this epidemic of newly diagnosed thyroid cancer cases due to over diagnosis, it becomes critical for radiologists to recognize the role that imaging has had in this issue.

Three main reasons for the growth in thyroid cancer diagnoses (Hoang, 2015):

(1) Imaging of ITNs—ITNs are very commonly reported as noted above. It is noted the malignancy rate of ITNs on CT and ultrasound is less than 12 percent.

(2) ITNs biopsies—ITNs are easy to image and biopsy. The threshold to biopsy is low; therefore, a decision to biopsy may not necessarily correspond to the recommendation to do nothing.

(3) Pathology specimens with incidental findings—Routine processing of surgical specimens for thyroid conditions such as goiter and thyrotoxicosis reveal incidental cancers in 6-18 percent of patients. Growth in number of these surgical procedures could be contributing to an increase in subclinical cases of thyroid cancers detected.

The US Preventive Services Task Force (USPSTF) has recently published their updated recommendations on screening for thyroid cancer. In asymptomatic adults, the USPSTF recommends not to screen for thyroid cancer (Lin, 2017). Currently no studies are directly evaluating the benefits of screening patients for a thyroid cancer and then treating those patients without symptoms. The potential benefit of a screening thyroid program is earlier treatment. However, it is unclear whether treating early-stage thyroid cancers with surgery is more beneficial than just monitoring the cancer. The potential harms of screening for thyroid cancer are related to the risks of performing a thyroid biopsy as well as the potential serious side effects of neck surgery. These major adverse effects include: permanent hypoparathyroidism, permanent recurrent laryngeal nerve palsy, secondary malignancies, and salivary gland dysfunction.

Unnecessary and or low value care as determined by the Choosing Wisely initiatives is one of the bigger drivers of our unsustainable increasing health care cost trends. In a recent study by Becker's hospital review, more than 600,000 Washington state patients received $282M in unnecessary medical care in one year (Washington Health Alliance, 2018). This report is likely substantially underestimating the current problem. Clinical value programs should focus on implementing best practices regarding what not to do, and that is the main thesis of our study. Development of these best practices will improve quality and eliminate wasting of valuable health care resources. Radiology can and should be a leader in the transformation of health care to a value-based care system, one that will create a sustainable health care system for generations.

CONCLUSIONS

As the U.S. healthcare system inevitably shifts from being volume-based to being value-based, radiologists and other specialists will find themselves under increasing pressure to prove their value to the care delivery chain, particularly as more and more patient care organizations take on financial risk and develop accountable care organizations (ACOs), participate in population health management, and use analytics to improve their efficiency, cost-effectiveness, and patient outcomes. It is becoming increasingly important for radiology practices to demonstrate their value and exactly how to provide the most cost-efficient care. R-SCAN has tools that will assist radiologists in developing best practices. Although the overall goal of decreasing the number of follow up studies for ITNs might be relevant and significant for all radiologic practices to consider, efforts to influence radiologists' practices still need to be tailored at a local level.

Potential benefits of this study include

1. reducing the risks from additional unnecessary imaging exams, including the risks of additional radiation exposure and risks associated with any surgical or interventional procedure;
2. limiting the costs of managing ITNs to patients and associated health care systems;
3. achieving greater consistency in recognizing, reporting, and managing ITNs, as a component of formal quality improvement initiatives;
4. helping to focus future research efforts for an evidence-based best practices approach to ITNs and other non-important incidental findings on advanced imaging exams.

As we become more cognizant of detecting and reporting of ITNs all treating physicians and third-party payers must question the need for a policy of universal evaluation. The cost of pursuing a workup of these lesions and their high prevalence in the general population raises questions regarding the appropriate management strategy.

Thus, best practice imaging initiatives such as the change in recommendations regarding the follow-up care of ITNs should confirm that clinicians have used results and recommendation information properly. Physicians should understand the results and adhere to act on the recommendations provided by the radiologist. To survive in a value-based care health care environment, radiology must be able to demonstrate how it contributes to long-term patient outcomes. The specific definition for health care value can differ widely based on the perspective of the patient, provider, or payer. There is however, general agreement that value should include cost, health outcomes (or quality of care), and foremost patient satisfaction. For all clinicians, payments will ultimately be tied to the creation of value. This study aims to improve appropriateness of management of ITNs and to reduce the variability of radiologists' recommendations, while at the same time demonstrate both clinical and economic value of this best practice.

Physicians, and radiologists specifically, do not like the future of potentially changing practice patterns, especially those that threaten their revenue base. Value-based radiology reimbursements threaten the core of their business. Advanced imaging will be greatly affected by any future plan of a new reimbursement model. Efforts to move away from our current fee-for-service (FFS) reimbursement are driven by the sense that FFS results in a higher cost of healthcare; it is now clear that the current and traditional radiology reimbursement models are not sustainable. Individual patient demand, defensive practices of medicine, and an aging population compound the issue. Clinicians rely heavily on imaging exams to make diagnostic treatment decisions and that model probably won't change no matter what reimbursement model the government and 3rd party payers initiate. The challenge is ensuring that value is defined and the payments result on the basis of quality and not surely based on volume (Knaub, 2014).

METHODOLOGY

3.1 Study Design

The focus of this study is to demonstrate that adding a direct recommendation that "no further workup is needed for the ITN detected" will directly result in the development of a best practice regarding ITNs and influence downstream utilization of follow up ultrasounds, thyroid biopsies, and thyroid surgical ablations. Development of a best practice will be shown with analysis of a second data set following implementation of the recommendation.

The retrospective cohort evaluation is designed to assess the effect of adding the phrase to a radiology report recommendation, "No further work-up needed for the ITN" on (a) the number of follow-up ultrasound examinations recommended for insignificant thyroid lesions and (b) subsequent provider adherence with best practice guidelines. No IRB approval will be needed based on the use of de-identified patient data.

The study will use a quantitative, non-experimental predictive design. A predictive research design is most appropriate for examining the impact of the independent variable on the dependent variable (Vaishnavi, 2015). A predictive design model should be chosen, since the purpose of this study is to examine the impact of including a statement regarding the need for further workup in the report where the ITN was detected (i.e., the independent variable) on the reduction of additional advanced imaging and the increase in physician compliance on developing this best practice (i.e., the dependent variable) (Vaishnavi, 2015).

Data from an evidence table will be used to construct a decision tree, which will be "rolled back" to estimate study outcomes. This decision analysis study will be used to address research question #1: "Does the inclusion of a report recommendation specifically addressing the need for additional workup of an ITN have a significant effect on the reduction of follow-up advanced medical imaging utilization and a significant effect on the development of a best practice in a follow-up dataset. A probabilistic sensitivity analysis will be performed to test the effect of assumptions and variation rates of events and estimated costs used in the decision tree. Medicare costs data will be obtained from a five percent sample data set from the Comparative Effectiveness and Data Analysis Resource (CEDAR).

3.2 Methods

3.2.1 Study Objectives

To evaluate the impact of report recommendations on follow-up behavior of implementing a best practice of follow up of ITNs.

Research Question. Does the addition of a report recommendation increase the rate of adherence to best practices?

3.2.2. Study Hypothesis

H1. A statement of "no further work-up is needed" reduces use of advanced medical imaging, thyroid biopsy, thyroid surgical ablations, and medical expenditure for further work-up for patients diagnosed with an ITN.

3.3 Data Sources

De-identified data of RadPartners (RP) was utilized for this study. Data from 102 hospitals of varying size and 180 outpatient centers was collected. Patients were excluded if there was a history of a previous known thyroid nodule, history of thyroidectomy, or known thyroid dysfunction.

Scoring of adherence to best practice was performed by a group of nine highly trained board certified radiologists who were blinded to the data collection. A randomized list of cases was provided to each radiologist. A SmartSheet entry form was utilized for data entry by each reviewer.

3.4 Data Analysis

Data for all CT scans were blinded and exported as an Excel file. This file included information on the eight specific radiology practices involved and data on the relevant results of the CT scan and follow-up recommendations. Descriptive statistics on presence of nodule, nodule size, recommendation for ultrasound (US) were calculated for the pre- and post- intervention period. Analysis was performed using SAS version 94.4.

Primary analysis comparing the rate of imaging in the baseline population preceding the report recommendation implementation and following the intervention categorized by hospital sizes using clinical decision and probabilistic sensitivity analysis (PSA). A multi-way PSA using a Monte Carlo simulation with 10000 iterations was performed.

3.5 Limitations

This study had several limitations. First, the patients were not randomly assigned to our study groups, and thus the potential for selection bias. Second, the 5% Medicare Data did not include a full representative sample of the potential payers and thus the generalizability of the study may be in question. There were private payers and Medicare patients utilized for this study. A cross-section of the payers was not included in the data acquisition. Finally, some patients were excluded from the study because the initial data collection failed to include certain data variables that were being analyzed. Physician training and skill in performing thyroid nodule analysis could also possibly influence the study outcome. The sensitivity and specificity of thyroid ultrasound, as well as the performance of thyroid ultrasound, were also considered to be limitations to the study. As in all comparative effectiveness research, the strength of the study lies in its ability to generalize the results.

Impact of Report Recommendation on Follow-Up Ultrasound Studies in the Work-Up of Incidental Thyroid Nodules

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Key Points

Question: What benefit can be obtained from the best practice recommendation of no further work-up needed for the incidental thyroid nodule?

Findings: In this clinical decision analysis study that included 4057 adults, the post-intervention adherence to best practice was 84.35% increased from 30.81% pre-intervention, a significant difference. There is a projected significant cost-savings in Medicare population and a significant health benefit of reduction in number of negative FNAs.

Meaning: Development of best practice policies may benefit the work-up of most incidentalomas found on advanced imaging modalities.

Abstract

The workup of incidental thyroid nodules (ITNs) is costly for both patient and associated health care system. No studies have described an economic model to best demonstrate the value of building a best practice model to evaluate ITNs. The purpose of the study is to evaluate the impact of adding the following statement to a CT report where an ITN has been discovered: "No

further follow up is indicated for the ITN." It is important to determine if this statement will have a significant effect on the reduction of follow-up imaging and health care dollars saved in forming the best practice of managing ITNs. Tertiary care multicenter clinical decision analysis study to address the research question: Does the inclusion of a report recommendation that "no further work-up is needed on an ITN" have a significant effect on the reduction of follow-up advanced medical imaging utilization and a significant effect on the development of a best practice of following ITNs. The primary outcome measured was the adherence to the best practice of not ordering a follow-up ultrasound (US) given the appropriate clinical presentation of the ITN. Data was collected from eight radiology practices for pre-intervention six-month period February-July 2015, 1936 CT scans, and post-intervention period July-December 2015, 2121 CT scans. The incidence of an ITN was 18.8 percent. During the pre- period a total of 65 (30.81%) of 211 nodules were reported according to best practice, post- period was 194 (84.35%) of 230 nodules. Pre- and Post- intervention data was utilized in a clinical decisions analysis tree. Medicare cost data was obtained from a 5 percent sample data set from the Comparative Effectiveness and Data Analysis Resource (CEDAR). An annual cost savings of $23,057,207 is projected in the Medicare population based on the implemented intervention of reporting "no follow-up needed for the ITN." At the same time, 7,592 negative fine needle aspirations and 750 additional thyroid cancers will be detected. Development of best practices is indicated for detection and work-up of ITNs. Significant cost control and universal health benefit can be achieved if referring physicians adhere to the best practice of not following-up ITNs that meet criteria.

Introduction

An incidental thyroid nodule (ITN) is defined as a nodule identified on an imaging exam that was not present on earlier exams or is suspected based on a clinical exam (Hoang, 2014). ITNs are a relatively common finding on advanced medical imaging exams. It has been reported that ITNs are seen in 16-18% of CT and MRI scans in which the neck is imaged (Hoang, 2014). In order to create a best practice approach to the work-up of ITNs radiologists need to give referring physicians better guidance of what the work-up should include if anything at all. The overutilization of follow-up thyroid imaging and potential thyroid ablation techniques has resulted in adding to the rise of healthcare spending and reducing the quality adjusted life years (QALY) in patients with ITNs. We know that radiologists are cautious and fearful of missing critical findings. However, there is an ingrained mentality on the part of radiologists to recommend more and more imaging. From this there is also the risk that such utilization of imaging might lead to further potentially unnecessary, risky, and costly procedures, perpetuating the overuse dynamic.

Value in health care is defined as the quality of care delivered per dollar spent (Porter, 2010). Given the current economic environment and the need to develop innovative health care best practices that increase the value of care, the purpose of our study was to evaluate the impact of adding the following statement to a CT report that has discovered an ITN: "No further follow up is indicated for the ITN." It is important to determine if this statement will have a significant effect on the reduction of follow up thyroid ultrasound, thyroid fine needle biopsy, thyroid surgery, and health care dollars saved in forming this best practice of managing ITNs. Creating value through an economic model should lead to a significant reduction in overall health care dollars spent, an improvement in overall health care system performance ranking, and an improvement in overall patient health status.

Methods

This study involved eight tertiary referral hospitals. Computed tomography (CT) imaging was reviewed in a pre-intervention six-month period February-July 2015. CT imaging was then reviewed for a post-intervention six-month period July-December 2015. Patients were excluded from the study if there was a history of a known thyroid nodule, history of thyroidectomy, or known thyroid dysfunction. Scoring of adherence to best practice was performed by a group of nine highly trained board certified radiologists who were blinded to the data collection. A randomized list of cases was provided to each radiologist. A "Smart Sheet" entry form was utilized for data entry by each reviewer. Descriptive statistics on presence of nodule, nodule size, recommendation for ultrasound (US) follow-up were calculated for the pre- and post- intervention period.

Analysis was performed using SAS version 94.4. Pre- and Post- intervention data was utilized in a clinical decisions analysis tree. The percentages utilized in the analysis tree were obtained from the study dataset and from the literature reviewed. The results from the decision tree analysis were used to identify expected differences in long term outcomes for the study. Cost data was obtained for follow-up US, fine needle aspiration(FNA)/biopsy, and thyroidectomy. Medicare cost data was obtained from a 5 percent sample data set from the Comparative Effectiveness and Data Analysis Resource (CEDAR).

Results

Table 1 and Fig. 1 summarize the frequency distribution of facilities for the pre-intervention period.

Table 2 and Fig. 2 summarize the frequency distribution of facilities for the post-intervention period.

Fig. 3 depicts the decision tree structure.

Table 3 summarize the data used for the decision analysis estimates.

Table 4 summarizes the sensitivity analysis for cost savings.

Table 5 summarizes the sensitivity analysis for missed number of cancer cases avoided.

Table 6 summarizes the sensitivity analysis for the number of negative FNA avoided.

Pre- and Post-Intervention Dataset

Data for the pre-intervention period includes a continuous series of 1936 CT scans of the chest, neck, and cervical spine performed during a six-month period February-July 2015. Data from the post-intervention dataset period includes a series of 2121 CT scans of the chest, neck, and cervical spine performed during a six-month period July-December 2015. A total of 4057 CT scans were examined. Of these, 766 (18.88%) had an observed nodule and 295 (38.51%) of these nodules were noted in the CT report. Each facility contributed a mean of 254 CT scans in the pre- and post- period with a range of 358 to 816 exams towards the study. During the pre-period a total of 65 (30.81%) of 211 nodules were reported according to best practices. This best practice reporting range varied from a high of 53.94% to a low of 7.14% (p=.0005) between practices. The adherence to best practices during the post period was 194 out of 230 observed nodules for a best practice adherence of 84.35%. The variation in adherence to best practice between practices ranged from 56.25% to 91.18%. This difference was not statistically significant (p=0.0751). The variation in adherence to best practice between the pre- and post-intervention increased from 27.0% in the baseline period to 73.0% in the post-intervention period. This difference was statistically significant (p<.0001).

Using the decision analysis tree estimates and data from the 5% Medicare sample data set estimates were made of three variables: the estimated cost savings, the number of additional thyroid cancer cases detected, and the number of negative FNA avoided. The base value savings was $23,096,970, 750 additional thyroid cancers detected, and 7,592 negative FNA avoided.

Discussion

Incidentalomas such as ITNs, are a relatively frequent finding of medical imaging exams. Our study results are consistent with previous studies, in terms of the frequency of ITNs 18.88% (Hoang, 2014). During the pre- period 30.81% of the 211 nodules identified were reported on and in the post- period 84.35% of 230 nodules were reported on. This is a significant response to adhering to a best practice. If applied to a cohort of Medicare patients, this best practice would generate a cost savings $23,096,970 and would result in approximately 750 additional thyroid cancers detected, and 7,592 negative FNA being avoided.

Thyroid nodule evaluation and management has always been very cumbersome for radiologists and referring clinicians. With the recent ACR adoption of the TI-RADS risk stratification system for classifying thyroid lesions, thyroid reporting has become more streamlined. While the workup of a thyroid nodule with ultrasound and a FNA/biopsy seems rather benign, there are several issues regarding the further workup that may prove to be harmful and disadvantageous for the patient. The plan is simple for nodules that are benign or malignant. When findings suggest a benign cytological diagnosis, there is a good prognosis in terms of patient-important outcomes this should ultimately encourage all clinicians to encourage appropriate follow-up or as in our study, “No further follow-up needed for this ITN.” This will hopefully avoid overwhelming the healthcare system with useless overutilization of unneeded thyroid imaging and FNA/biopsies. If a thyroid nodule is malignant, the need for follow-up management utilizing thyroidectomy is indicated. An issue arises when a patient is categorized as non-diagnostic or indeterminate. These patients then require a second FNA/biopsy adding to the cost of the thyroid nodule workup. In the categories of suspicious for malignancy, or suspicious for follicular neoplasm, diagnostic thyroid lobectomy is recommended. Of patients who undergo FNA biopsy for thyroid nodules 22% to 41% proceed to a diagnostic surgical thyroid lobectomy (Shrestha, 2012). Of further interest, in a retrospective review of this patient cohort (those patients proceeding to surgery following FNA biopsy) 76% percent of those patients had surgically proven benign results (Bahl, 2014). The harm with this scenario, the patient should be relieved that there is no diagnosis of cancer, but the unneeded thyroid surgery exposes the patient to the potential risks of surgery and anesthesia, in addition, to the added healthcare costs incurred by the patient and healthcare system.

Over-diagnosis of thyroid cancer is another potential problem if best practices are not implemented in the follow-up of ITNs. Over-diagnosis is the detection of disease that will not result in death or cause symptoms related to a particular disease process. Thyroid cancer happens to be one such condition. There is a mismatch in rates between the incidence of thyroid cancer and the mortality (Welch, 2010). The incidence of thyroid cancer in 2009 was 14.3 per 100,000 persons, which represented a quadrupling in incidence in 36 years, however there was no change in the mortality rate, which in 2009, was 29 times lower than the incidence (Davies, 2014). The mismatch between incidence and mortality suggests that additional cancers were treated without survival benefit.

For the cases of thyroid cancer that proceed to treatment, of either thyroidectomy or radioactive iodine therapy, there are multiple possible significant complications. In addition to the general risks of surgery, potential risks of recurrent laryngeal nerve injury, hypoparathyroidism, hypocalcemia, and vocal cord paresis exist (Vashishta, 2012). Patients requiring total thyroidectomy also require lifelong thyroid hormone replacement with regular monitoring of thyroid hormone blood levels. Radioactive iodine treatment also has potential serious adverse side effects with associated risks of future secondary cancers.

The costs of thyroid cancer to the US health care system are substantial. Most of the costs are incurred during the initial diagnosis and follow up phases of treatment. With such a burden on the US health care system, there is a need for more cost analysis studies to better understand the real impact on society. Using a model developed in 2014 and current incidence trends, thyroid cancer costs are estimated to exceed $3.5 billion dollars. While our study did not specifically look at the costs of thyroid cancer treatment there is considerable overlap with previous cost analysis studies, in particular a study performed in 2013 estimating the overall societal cost for the treatment of differentiated thyroid cancer. Using this model, the predicted costs by year 2030 based on current incident trends are projected to exceed $3.5 billion (Lubitz, 2014). Our study projects a significant cost-savings that would offset the billion-dollar cost of managing and treating ITNs.

In order to control costs, recommendations for the work-up of ITNs need to be embraced. A 2015 ACR white paper on ITNs provides a set of evidence-based guidelines for radiologists to follow. This white paper aimed to improve appropriateness of the management of ITNs and also to reduce variability in radiology recommendations regarding the further work-up of ITNs (Hoang, 2015). Our study verifies the need for a best practice regarding recommendations for further work-up of ITNs detected at computed tomography (CT). From the ACR 2015 white paper, dedicated thyroid ultrasonography (US) is only recommended for nodules at least 1.5 cm in patients 35 years or older and for nodules at least 1.0 cm in patients younger than 35 years. As demonstrated in our study, when best practice models are adhered to, the use of the radiology report is a powerful platform in order to convince clinicians that no further work-up is required. The goal of any best practice model should be to diagnose clinically significant diseases, while reducing unnecessary workup and provide guidance for clinical practice.

Future studies to consider would be to utilize this model to evaluate the impact of recommendations regarding other common incidentalomas, examples being ovarian cysts or adrenal nodules, and potential follow-up management. Associated economic modeling utilizing Medicare cost data and probability sensitivity analysis could be used to generate a cost-savings to Medicare as was done in this study. The cost-saving to Medicare could be projected to be in the billions of dollars without much effort, financial investment, or change in practice pattern for clinicians.

Table 1.
Frequency distribution of facilities at pre-intervention (baseline)

Facility	Frequency	Percent
Facility 1	408	21.1
Facility 2	214	11.1
Facility 3	179	9.2
Facility 4	158	8.2
Facility 5	182	9.4
Facility 6	348	18.0
Facility 7	181	9.3
Facility 8	266	13.7
Total	1936	100.0

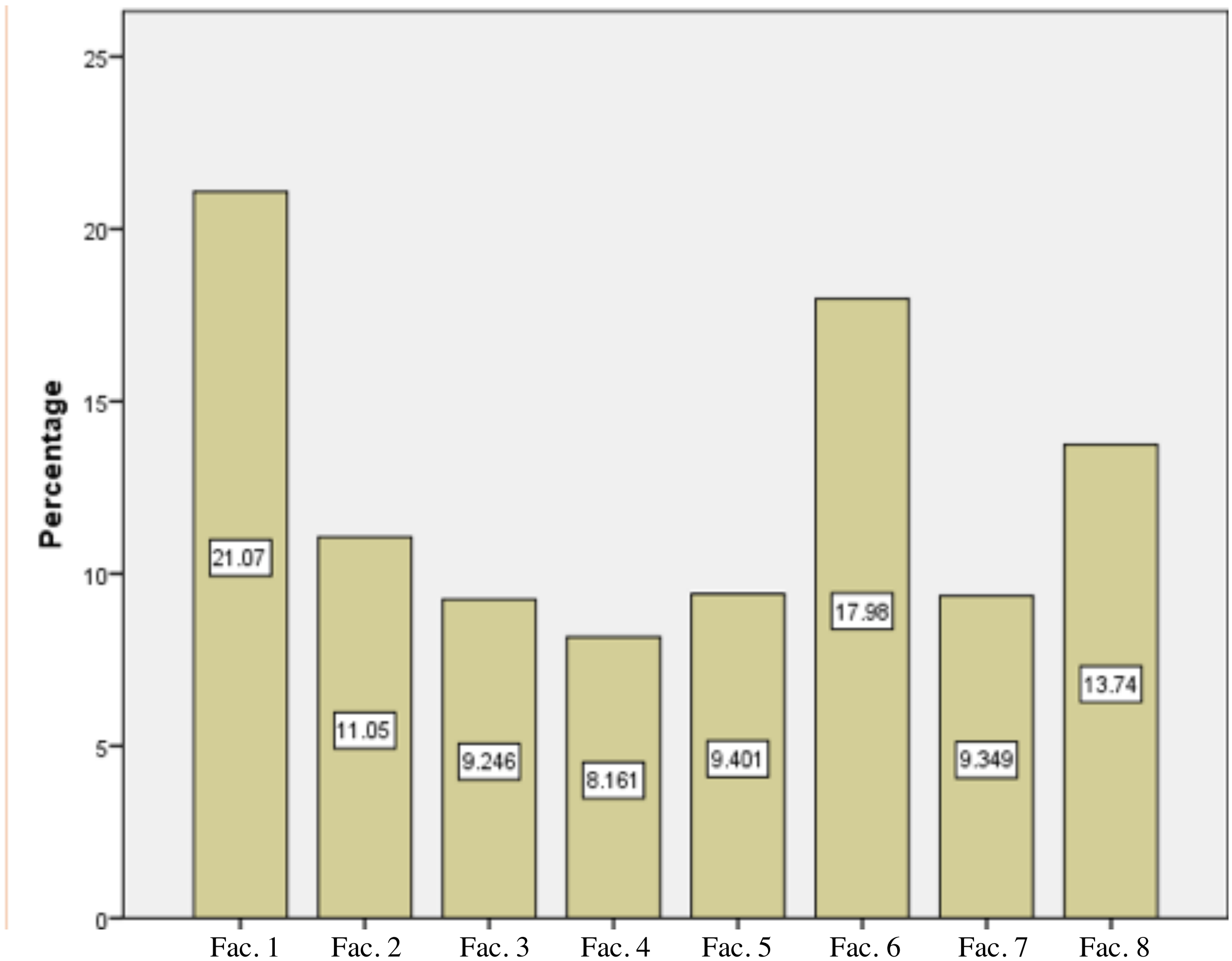

Figure 1. Bar chart of facilities distribution of pre-intervention period

Table 2.
Frequency distribution of facilities at post-intervention

Facility	Frequency	Percent
Facility 1	408	19.2
Facility 2	418	19.7
Facility 3	181	8.5
Facility 4	200	9.4
Facility 5	180	8.5
Facility 6	369	17.4
Facility 7	182	8.6
Facility 8	183	8.6
Total	2121	100.0

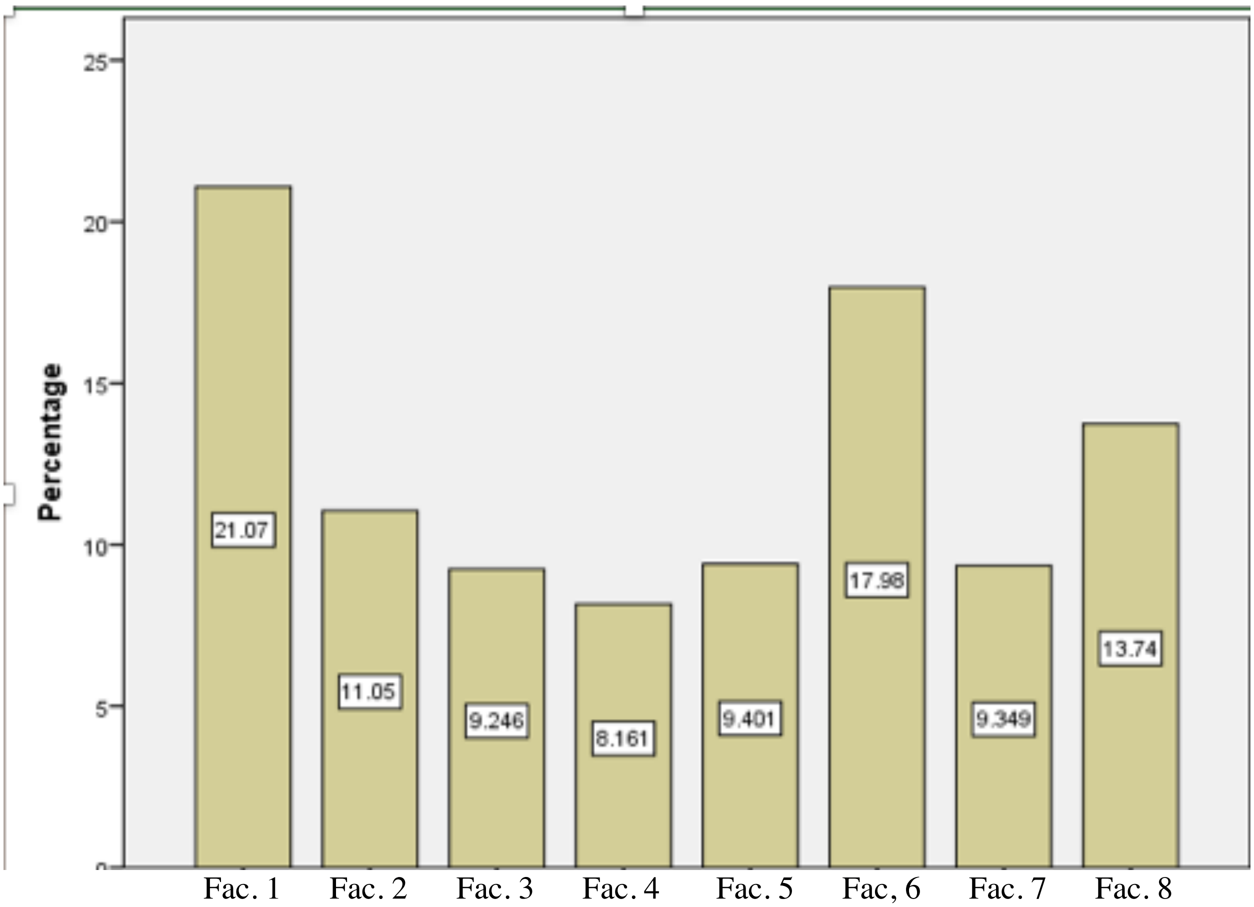

Figure 2. ***Bar chart of facilities distribution at post-intervention period***

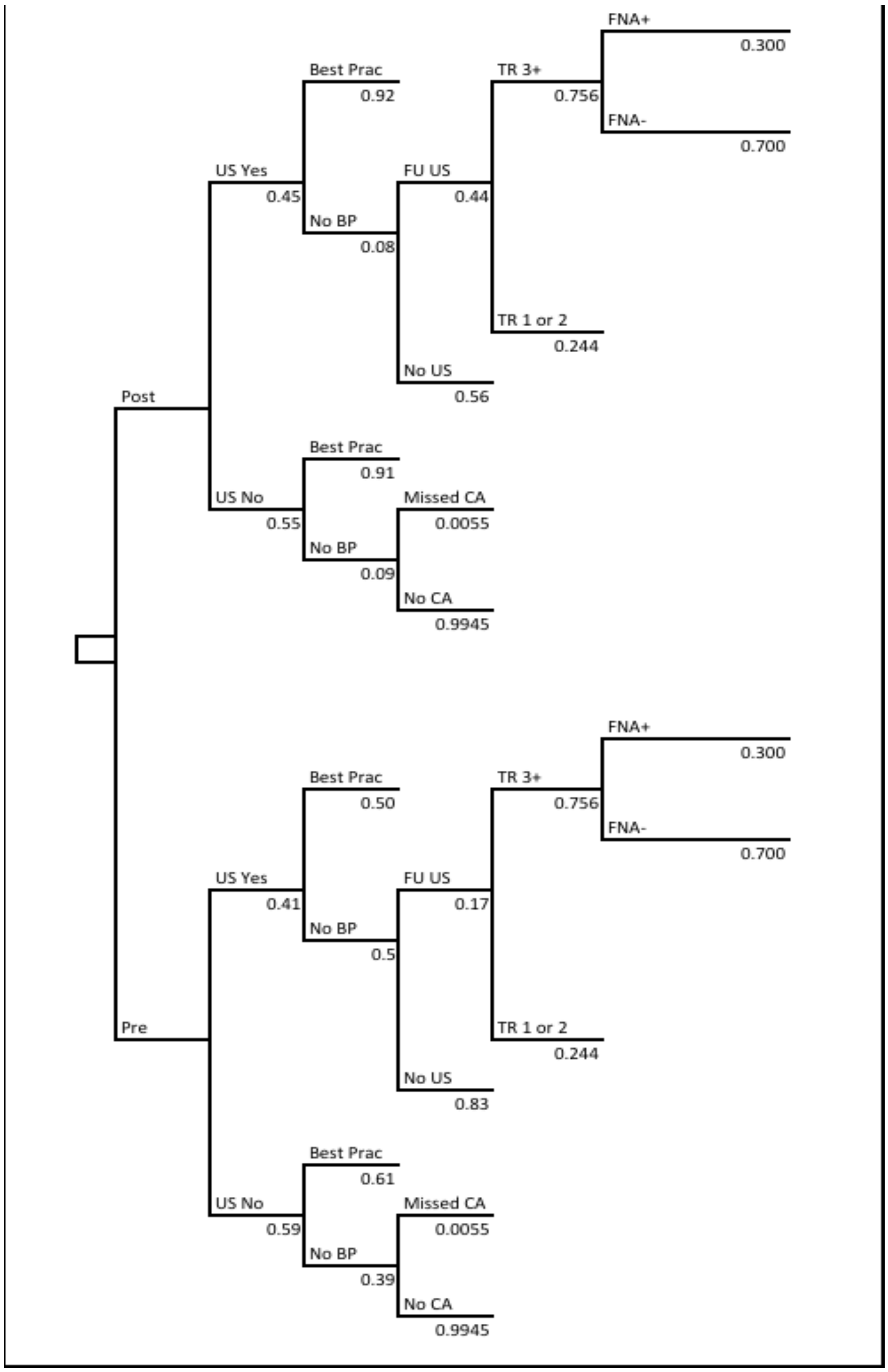

Fig. 3 Decision tree model

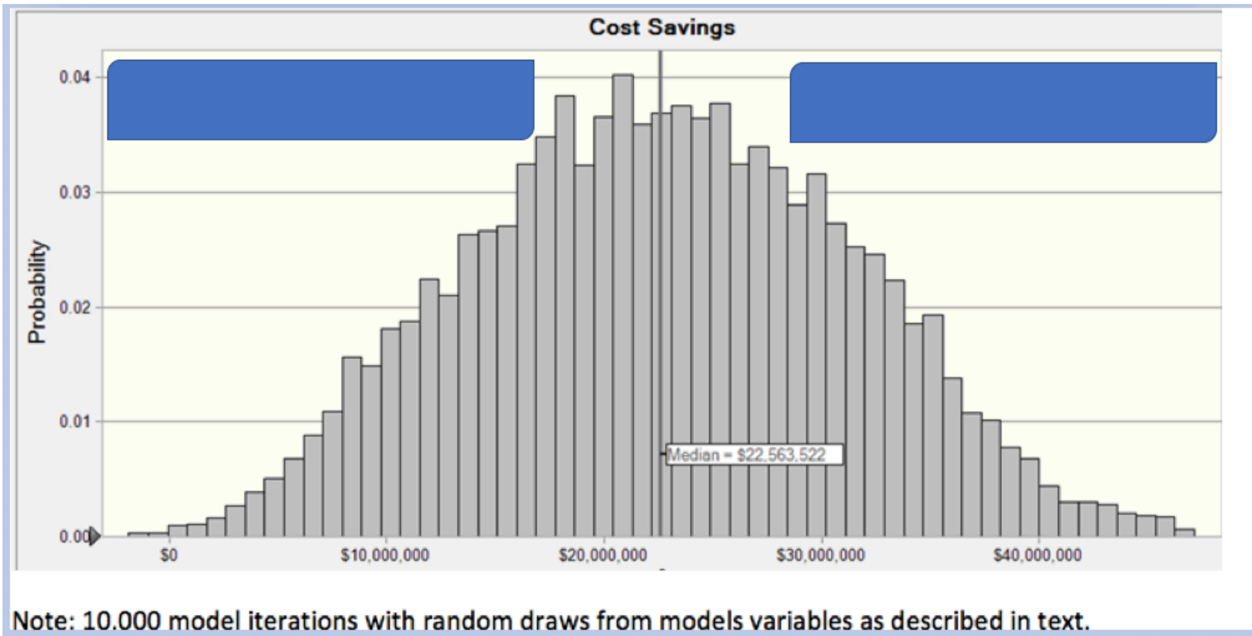

Fig. 4 ***Cost Savings/Monte Carlo Simulation Output***

Variable Name	Base Value	Range	Data Source
Population Nodule Rate	.1888	.1707-.2087	CT Study Data
Pre Percent Received US	0.41		CT Study Data
Post Percent Received US	0.45		CT Study Data
Pre Percent US BP	0.50		CT Study Data
Post percent US BP	0.92		CT Study Data
No BP FU US (PRE)	0.17		CT Study Data
No BP FU US (POST)	0.44		CT Study Data
Pre Percent TR3+	0.756		Pantano Study 2018
Post Percent TR3+	0.756		Pantano Study 2018
Pre Percent FNA+	0.300		Pantano Study 2018
Post Percent FNA+	0.300		Pantano Study 2018
Pre Percent Missed CA	0.0055		Ospina Study 2016
Post Percent Missed CA	0.0055		Ospina Study 2016

Table 3. Summary of data used for the decision analysis estimates

Notes:	Medicare 2016		Study Rates	
CT Scans		185976		
Expected Nodules		38813		
US Num		5162		
US rate		13.30%	9.39%	
FNA Num		5642		
FNA rate		3.08%	2.63%	
Surg Numbers		693	SD	Median
Surg Rate/FNA		12.3%	22.6%	
OP Surge Cost N=467	$	3,921	1024	3830
IP Surg Cost N=226	$	13,970	12568	11641
Surg Cost W mean	$	6,741		
FNA Cost	$	36	$ 11	
US Cost	$	54	$ 36	

Table 4- ***Base Estimates***

	Pre-Intervention	Post-Intervention
Chest CT Scans	3,615,800	3,615,800
Rate of Nodules	0.2087	0.2087
CT Nodule Population	754617	754617
Study US Received %	0.41	0.45
Study US Best Practice %	0.50	0.92
Study No US BP %	0.61	0.91
Study No BP FU US %	0.17	0.44
Lit. TR3+	0.756	0.756
Lit. FNA +	0.300	0.300
Lit. Missed CA	0.0055	0.0055
Estimated Cost Medicare 2016		
US cost	$54	$54
FNA Cost	$36	$36
Surgery Cost	$6741	$6741
Total Cost	$42,302,658	$19,245,450
Missed Cancers	955	205
Neg. FNA’s	13917	6326
Cost Savings	$23,057,707	
Additional Thyroid CA Detected	750	
Neg. FNA Avoided	7592	

Table 5. Pre- Post- Base Estimate Cost Savings

Sensitivity Analysis +/- 10%	Post Intervention Model Value	Changed Value	Cost Savings Output
US received	0.45 (+10%)	0.495	$21,172,262
US received	0.45 (-10%)	0.405	$25,021,322
US Best Practice	0.92 (+10%)	0.99	$39,936,431
US Best Practice	0.92 (-10%)	0.83	$1,445,828
No US Best Practice	0.91 (+10%)	0.99	$23,096,792
No US Best Practice	0.91 (-10%)	0.82	$23,096,792
No BP FU US	0.44 (+10%)	0.48	$21,347,219
No BP FU US	0.44 (-10%)	0.40	$24,846,365
Change to Med. OP SC	Base $6741	$1,024	$4,496,659
Change to Med. OP SC	Base $6741	$12,568	$42,055,168
US $ change	Base $54	$36	$22,838,577
FNA $ change	Base $36	$11	$22,825,666

Table 6- ***Sensitivity Analysis/Cost Savings***

Sensitivity Analysis +/- 10%	Post Intervention Model Value	Changed Value	Additional Thyroid Cancers Detected
US received	0.45 (+10%)	0.495	766
US received	0.45 (-10%)	0.405	733
US Best Practice	0.92 (+10%)	0.99	750
US Best Practice	0.92 (-10%)	0.83	750
No US Best Practice	0.91 (+10%)	0.99	932
No US Best Practice	0.91 (-10%)	0.82	544
No BP FU US	0.44 (+10%)	0.48	750
No BP FU US	0.44 (-10%)	0.40	750
Change to Med. OP SC	Base $6741	$1,024	750
Change to Med. OP SC	Base $6741	$12,568	750
US $ change	Base $54	$36	750
FNA $ change	Base $36	$11	750

Table 7- ***Sensitivity Analysis/Additional Thyroid Cancers Detected***

Sensitivity Analysis +/- 10%	Post Intervention Model Value	Changed Value	# Neg. FNA Avoided
US received	0.45 (+10%)	0.495	6,959
US received	0.45 (-10%)	0.405	8,224
US Best Practice	0.92 (+10%)	0.99	13,126
US Best Practice	0.92 (-10%)	0.83	475
No US Best Practice	0.91 (+10%)	0.99	7,592
No US Best Practice	0.91 (-10%)	0.82	7,592
No BP FU US	0.44 (+10%)	0.48	7,016
No BP FU US	0.44 (-10%)	0.40	8,167
Change to Med. OP SC	Base $6741	$1,024	7,592
Change to Med. OP SC	Base $6741	$12,568	7,592
US $ change	Base $54	$36	7,592
FNA $ change	Base $36	$11	7,592

Table 8- ***Sensitivity Analysis/Neg. FNA Avoided***

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Appendix A

U.S. Health Care Costs 1950-2014

Year	Dollars	% GDP
1950	$12.7 billion	4.5%
1965	$ 40 billion	6%
1980	$230 billion	9%
2000	$1.2 trillion	14%
2014	$3.18 trillion	17.6%

Source CMS 2015