Examining the Use of Comparative and Cost-Effectiveness Analyses in Radiology

Alexander Goehler[1,2,3,4]
G. Scott Gazelle[2,3,5]

OBJECTIVE. This article explores key principles of comparative effectiveness analysis—in particular, how radiologic comparative and cost-effectiveness studies differ from other clinical trials. Exemplary studies are reviewed to show how comparative effectiveness has been implemented in radiology and how future studies might be conducted. Finally, the article closes with a discussion of several additional key themes relevant to quality and value in clinical radiology going forward.

CONCLUSION. Comparative effectiveness is likely to require a paradigm shift in thinking within the discipline. For new radiologic applications to be accepted, we will need to show at least a significant change in treatment planning and at best a meaningful change in patient outcomes. This shift will require a forward-thinking approach to robust evidence generation for new imaging modalities or indications and the inclusion of other modes of value demonstration such as clinical decision support and intelligent data mining.

[1]Department of Radiology, Yale University School of Medicine, 333 Cedar St, PO Box 208042, New Haven, CT 06520-8042. Address correspondence to A. Goehler (agoehler@post.harvard.edu).

[2]Institute for Technology Assessment, Massachusetts General Hospital, Boston, MA.

[3]Harvard Medical School, Boston, MA.

[4]Alfried Krupp von Bohlen und Halbach Foundation, Institute for Health Systems Management, University of Duisburg-Essen, Essen, Germany.

[5]Department of Health Management and Policy, Harvard School of Public Health, Boston, MA.

The Patient Protection and Affordable Care Act (PPACA) has helped to usher in a new era of value-based health care delivery for the U.S. health care system in which there is an increasing focus on achieving the best patient outcomes at the lowest cost [1]. The changes associated with this new focus on value are coming fast and are likely to affect both delivery and payment structures across medical disciplines.

Within this changing environment, diagnostic radiology as a discipline faces multiple challenges, and numerous approaches to improving the quality of radiology services as a means of value demonstration have been discussed in the recent literature [2–4]. Among others, these approaches include standardized reporting, 24/7 availability of advanced imaging modalities, and improved imaging access. Although all of these concerns are important to both clinical teams and patients, value demonstration has an effect on outcomes beyond the matrix of the service beneficiaries' satisfaction and the ultimate impact of radiologic studies on medical decision making is what should justify imaging requests.

With an understanding that the decision to order imaging studies is often complex and multifactorial, this article will focus on core concepts in comparative and cost-effectiveness analyses and value demonstration for radiology in this evolving health care context. In particular, we argue that for new radiologic applications to be accepted, it will be necessary to show at least a significant change in treatment planning and at best a meaningful change in patient outcomes; further, we contend that these expectations are likely to require a substantial paradigm shift in thinking within the discipline as a whole. In building this argument, we first explain the principles of comparative effectiveness analysis—in particular, how radiologic comparative and cost-effectiveness studies differ from other clinical trials. We then review two key examples that show how comparative effectiveness has been implemented in radiology and how future studies might be conducted. Finally, we close by discussing several additional themes relevant to the quality and value of clinical radiology in the future.

Comparative Effectiveness Research: Concept, History, and Application to Radiology

Although comparative effectiveness research (CER) is a concept whose definition

has been debated in the literature, the Institute of Medicine (IOM) [5] recently defined CER as follows:

> …the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition, or to improve delivery of care.

The focus of CER is on comparing alternative approaches to patient care.

For most clinical scenarios, there already exists at least one standard-of-care practice, and new technologies (which may include a test, single treatment, or more comprehensive approach) are compared with that standard. This effort to compare approaches is relevant because a new technology should, at a minimum, be comparable to the current standard of care and should ideally be superior to be considered a valid alternative. However, these comparisons can become complex when more than one outcome is being considered; for example, a new medical therapy may be slightly less effective but may have substantially fewer or less severe side effects and better tolerability compared with the current standard of care. In these situations, a decision-analytic approach can help to weigh the various properties of the alternative methods by incorporating aspects associated with both clinical efficacy and side effects—for example, mortality and quality of life—to determine the difference between the two alternative treatment options as quantified by a common metric, such as the difference in quality-adjusted life-years [6, 7].

Although comparative cost data are currently not a routine component of CER in the United States, there is debate about whether they should be [8–10] and it is important to briefly introduce cost-effectiveness analysis (CEA) in the context of the broader CER framework. Simply put, CEA quantifies the difference in health outcomes for two or more strategies in relation to the differences in their costs. First described in 1977, the incremental cost-effectiveness ratio (ICER), which is defined as [outcome1 – outcome2] / [cost1 – cost2], was thought to aid in the decision-making process about the allocation of limited health care resources [11]. Today, cost-effectiveness is one of multiple considerations that inform reimbursement decisions by institutions such as the National Institute for Health and Care Excellence in the United

Kingdom and the Institute for Quality and Efficiency in Health Care in Germany [12, 13].

Historical efforts to include CER in the U.S. health care context date back to the 1970s with the creation and dissolution of the short-lived National Center for Health Care Technology [14]. The most recent sustained effort to design and implement CER studies began with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This law provided $15 million to support the establishment of an "effective health care program" within the Agency for Healthcare Research & Quality (AHRQ) [15] whose goal was to review, synthesize, and publish evidence "geared to the differing needs of clinicians, patients, and policy-makers." This initial investment was then followed by a larger appropriation of $1.1 billion for CER under the American Reinvestment and Recovery Act (ARRA) of 2009.

Alongside this support from the ARRA, the IOM offered an agenda of priorities for CER, and nine of their top 100 priorities were relevant to radiology. These priorities included the use of modern imaging modalities for cancer radiology; imaging strategies for screening for breast and colorectal cancer and strategies for obstetric ultrasound; cardiac CT for risk stratification of patients; and various treatment options, including ablation, for liver metastases [16]. Two non–disease-specific topics were also included: the role of specialists versus generalists in ordering studies and the performance of diagnostic studies by radiologists versus nonradiologists [16]. Then, with the passage of the PPACA, the Patient-Centered Outcomes Research Institute (PCORI) was created as a public-private partnership with a goal to support CER. Under the PPACA, Medicare and private insurers pay a small fee for each insured life and the resulting revenue is designated to support PCORI. Under the PPACA, PCORI is expected to receive approximately $3.5 billion to support patient-centered outcomes research through 2019 [17]. It is in this context of an increasing emphasis on patient-centered outcomes that the expectations for value demonstration of new imaging techniques are becoming increasingly essential.

Comparative Effectiveness in Diagnostic Imaging

Unique challenges have been faced in efforts to expand CER in diagnostic imaging. It is widely recognized that diagnostic imaging is most often an intermediate step in the pathway from patient presentation to patient out-

comes. Traditional outcomes such as patient morbidity and mortality may be affected by a range of additional factors such as the underlying natural history of the disease, treatment approaches chosen, and health system performance. In addition, diagnostic imaging modalities often have multiple applications, and the effectiveness of these modalities is some weighted average of their use.

In 2011, the Radiological Society of North America (RSNA) sponsored a Working Group on Comparative Effectiveness Research for Imaging whose goal was to develop a framework that [18]:

> …recognizes the unique properties of diagnostic imaging technologies and acknowledges that to move imaging technologies from discovery to delivery requires a different level of outcomes depending on various characteristics of the technology and its application.

The Working Group expanded a hierarchic list of evidence levels relevant to the evaluation of diagnostic test initially described by Fineberg [19] and later modified by Fryback and Thornbury [20] by taking into account the population at risk, the anticipated clinical impact, and the economic impact associated with the technology (Fig. 1).

The result of this framework was a so-called "hierarchical model of efficacy" [18] that can be structured to both evaluate and interpret studies of imaging techniques. To inform our analysis, we adapt the definitions of each level from the Gazelle et al. [18] as follows: Technical efficacy (level 1) relates to the quality of the images, and diagnostic accuracy efficacy (level 2) relates to the sensitivity and specificity associated with the interpretation of the images. In addition, diagnostic thinking efficacy (level 3) addresses whether the information provided by the diagnostic imaging technique affects the referring physician's diagnostic thinking, whereas therapeutic efficacy (level 4) concerns the effect this information has on the clinical management plan. Finally, patient outcomes efficacy (level 5) offers a quantitative measurement of the effect of the information on patient outcomes, and societal efficacy (level 6) measures the costs and benefits of a diagnostic imaging technology to society. In this framework, it is important to note that efficacy at a lower level of the hierarchy is necessary but is not sufficient for efficacy to be shown at a higher level.

In the next section, we summarize both the challenges and trial design strategies used to evaluate two key diagnostic imaging techniques and assess these cases using the framework [18].

Case 1: Use of CT for Lung Cancer Screening

The first example involves the use of CT as compared with chest radiography for lung cancer screening. Given the relatively small incidence of pulmonary malignancies uncovered in relation to the large number of benign pulmonary nodules, early screening studies such as the Mayo Lung Project [21] and the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO) [22] were unable to provide conclusive outcomes. The primary challenges facing the Mayo Lung Project and the PCLO studies were inefficient screening intervention (both evaluated chest radiography vs no screening, not CT), limited sample size (Mayo Lung Project included only men [$n = 9211$]), and improper risk profiling of patient participants (focusing on patient populations that were too low risk). For example, of the PLCO study participants, 36% of the men had never smoked and 55% of the women had never smoked [22]. Ultimately, the National Lung Screening Trial (NLST) [23] overcame these challenges by randomizing 53,454 patients at high risk of lung cancer to three annual screenings with low-dose CT or single-view posteroanterior chest radiography. Thus, the study was able to examine a practical screening approach in a sufficiently large and high-risk sample to estimate the impact of lung cancer screening on mortality. The trial was terminated early because it showed a statistically significant reduction in both lung cancer mortality and all-cause mortality in the CT group [23], providing level 5 evidence (i.e., patient outcomes efficacy per the framework by Gazelle et al. [18]) for a diagnostic intervention.

Largely based on the findings of the NLST [23] and in combination with modeling work done through the National Cancer Institute's (NCI) Cancer Intervention and Surveillance Modeling Network (CISNET) consortium [24], the U.S. Preventive Services Task Force (USPSTF) [25] recently issued a grade B recommendation to screen current and former smokers who are 55–80 years old and have a smoking history of at least 30 pack-years, thus closely matching the population enrolled in the NLST. This USPSTF recommendation has been viewed as a key step to-

Fig. 1—Diagram shows efficacy framework. (Modified with permission from [18]: Gazelle GS, Kessler L, Lee DW, et al.; Working Group on Comparative Effectiveness Research for Imaging. *Radiology* 2011; 261:692–698 © Radiological Society of North America)
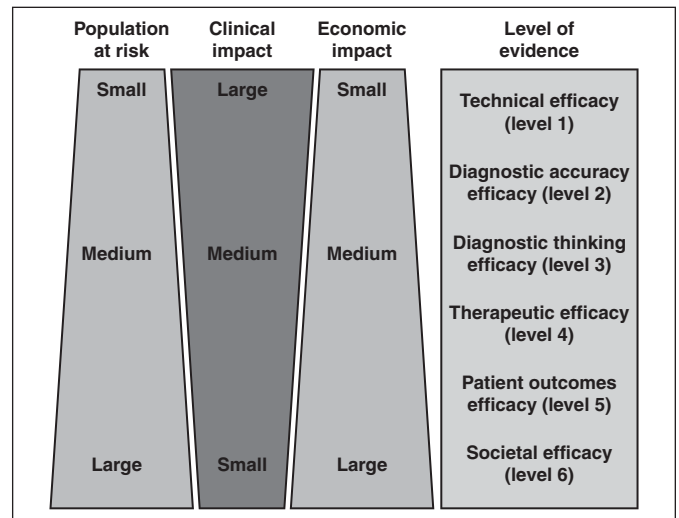
ward broadening insurance coverage for lung cancer screening because the PPACA mandates that USPSTF grade A or B recommendations be reimbursed by insurers [26].

Despite this success, questions remain about the practical implications of these findings beyond the NLST. The USPSTF also noted a need for studying what happens to patients when low-dose CT lung cancer screening is used more often in diverse community settings where there is likely to be greater variability in follow-up protocols. Poor follow-up care could, according to the USPSTF, result "in a different balance of benefits and harms" than those observed in the studies on which the USPSTF recommendation is based [25]. Other concerns arise from the fact that the NLST included screening of patients who fit the NLST criteria for enrollment and excluded other groups who may be at equal or higher risk (e.g., higher risk based on a diagnosis of chronic obstructive respiratory disease and family history). Thus, greater precision is needed to clarify the indications for screening.

These types of questions about the practical applications of lung cancer screening are consistent with societal efficacy (level 6) under the framework proposed by Gazelle and colleagues [18] because they largely concern the societal impact of this screening technique once applied to a larger population. Although we can expect additional results from European trials with regard to varying patient risk profiles and follow-up algorithms [27], such as the Dutch-Belgian Randomised Lung Cancer Screening Trial (NELSON), the German Lung Cancer Screening Intervention Study (LUSI), and the U.K. Lung

Cancer Screening Trial (UKLS), time, budget constraints, and the realities of a real world setting simply make it impossible to study all possible scenarios sufficiently through clinical trials.

In these situations, simulation models provide valuable information in addition to and based on clinical trial evidence. One example of such an endeavor is the NCI's CISNET [24]. This collaboration, established in 2000, uses modeling to provide additional insights into screening, prevention, and treatment of five major types of cancer, including lung cancer [24]. Six different interdisciplinary research groups with broad experience in decision-analytic modeling have developed independent lung cancer simulation models that meet current methodologic standards and are able to provide a comparative modeling analysis for important questions that cannot be addressed directly in trials [28]. Most recently, a research group was able to provide certainty ranges for multiple screening scenarios with varying eligibility criteria (age, pack-years smoked, years since quitting smoking) and screening intervals [29]. Furthermore, on the basis of the work by CISNET, the USPSTF decided to extend the recommended age for lung cancer screening from 74 to 80 years, beyond the age cutoff for NLST study eligibility. These analyses can ultimately provide reassuring evidence at the societal level to inform future reimbursement decisions for lung cancer screening [30]. Thus, the use of CT for lung cancer screening offers an excellent example of how the demand for robust evidence showing the impact of an imaging modality on patient outcomes has required a paradigm shift in

approaches to evidence generation, including the careful design of clinical trials and supplemental modeling studies.

Case 2: Use of Coronary CT Angiography for Chest Pain Evaluation

Coronary CT angiography (CCTA) is a relatively new modality that has been shown to be a viable alternative to established enzymatic and functional tests for patients with acute and chronic chest pain [31, 32]. Whether to use CCTA for chest pain evaluation is relevant given the potential societal impact because more than 5 million patients present to emergency departments in the United States with chest pain each year; of those patients, approximately 35% are admitted to the hospital and 17% are ultimately diagnosed with acute coronary syndrome (ACS) [33]. In addition, approximately 3–4 million Americans are newly diagnosed with stable angina and about 4–5 million undergo functional tests annually [34].

CCTA serves as a useful example of how an evolving methodology requires different levels of evidence as it matures. In 2002, Wicky and coauthors [35] described cardiac MDCT protocols that optimize image quality to the CT dose indexes, thus showing technical efficacy (level 1). Then, in 2005, the Rule Out Myocardial Infarction Using Computed Assisted Tomography (ROMICAT) I Trial [36] used an observational design in which caregivers and patients were blinded to the CCTA results. The results of that study showed that CCTA has good diagnostic accuracy on several endpoints (diagnostic accuracy efficacy, level 2) and also offered insights about how CCTA results might change patient management [36–38]. At present, blinding providers to the results of CCTA falls outside accepted clinical practice because multiple studies of a total of more than 16,000 patients have shown that CCTA findings predict cardiac morbidity, revascularization, and mortality [39, 40] (diagnostic thinking efficacy, level 3).

Recently, studies by Hoffmann et al. [31] and Litt et al. [32]—both of which were multicenter randomized studies comparing a standard evaluation versus a CCTA-guided triage strategy in patients with chest pain and suspicion for ACS—have shown equal safety for the CCTA-guided triage strategy compared with the standard evaluation (no cases missed) and reduced hospital admissions and decreased length of stay (therapeutic efficacy, level 4). Unfortunately, no data beyond

30-day outcomes are available for these trials, but a simulation study based on the ROMICAT II data predicted improved survival in the CCTA arm due to the higher coronary artery disease (CAD) detection rate in the CCTA strategy [41]. Ultimately, the Prospective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE), a multicenter randomized study of 10,000 patients that compares initial CCTA versus functional testing on the composite primary outcome of major cardiovascular disease events in the past year, will provide evidence regarding if and to what extent this difference in testing approaches should change clinical management [42] (patient outcomes efficacy, level 5). This study completed enrollment in September 2013 and the first results are expected at the end of 2014.

How have funding agencies considered the clinical use of CCTA? In March 2008, the Centers for Medicare & Medicaid Services (CMS) [43] issued a decision memo stating the following:

> We have decided that no national coverage determination on the use of cardiac computed tomography angiography for coronary artery disease is appropriate at this time and that coverage should be determined by local contractors through the local coverage determination process or case-by-case adjudication.

However, in May 2009, the Washington State Health Care Authority [43], a body that makes coverage decisions for state employees and Medicare beneficiaries in Washington state, was one of the first state agencies to approve "coverage of CCTA use for the investigation of acute chest pain in a hospital emergency department using at least a 64-slice scanner but not outside the emergency department setting" on the basis of a comprehensive health technology assessment [44, 45]. Given the variations in local coverage decision making for Medicare and private payers, it is difficult to provide a granular overview; however, in general, nonemergency CCTA examinations always require prior individual authorization and the option to use CCTA in the emergency department for the triage of acute chest pain varies. Recent studies have helped to bolster the evidence base in favor of the use of CCTA [31, 32], and the PROMISE Study is likely to provide further evidence that, together, may result in a reevaluation of the prior CMS de-

cision. Until then, more research is needed for evidence generation. Finally, it may be important to establish a foundation for a CAD health policy simulation platform similar to CISNET [24]—one that is, perhaps, endorsed by the National Heart, Lung, and Blood Institute, RSNA, and ARRS—that can help to extend the results of trials to address questions relevant to the societal efficacy of this technology.

Complementary Aspects of Value Demonstration in Diagnostic Imaging

In addition to providing adequate evidence about new technologies, there are other aspects of value demonstration in diagnostic imaging that are germane to the future of radiology. Although it is not possible to address them in detail in this article, we briefly discuss several of these important considerations because they are complementary to CER.

First, it is critical to ensure the appropriate use of imaging studies. The American College of Radiology's Appropriateness Criteria [46] can serve as a starting point for radiologists and clinicians and can be adapted to fit institutional, local, or regional needs and consensus. In addition, the use of clinical decision support to provide appropriate feedback to physicians ordering imaging studies has been shown to yield significant gains in efforts to reduce the overuse of outpatient CT, MRI, and ultrasound studies [47] and has been shown to impact which studies are ordered in the emergency department [48, 49].

Furthermore, the use of standardized reporting and additional BI-RADS [50] and Bosniak-equivalent [51] classification systems for specific diseases that then directly link imaging findings to management recommendations will help to improve the clarity and consistency of communication with ordering physicians. A recent study by Lu and colleagues [52] showed how a decision support tool linked to a dictation system improved consistency in follow-up recommendations for incidental lung nodules. The tool integrated standardized text into the voice-recognition dictation system based on the patient's risk profile and relevant Fleischner Society criteria [52].

Finally, the broad availability of electronic medical records provides many opportunities to create new knowledge for radiology through intelligent data mining [53], including automated feedback on certain findings, such as a newly diagnosed mass. Today, most radiologists still manually follow-up on find-

ings by returning to the patient's chart at certain intervals. However, tools exist that could enable the radiologist to flag cases for follow-up and to then receive relevant updates, such as newly released surgical notes or pathology reports about that patient [54].

In conclusion, in this article we show how comparative effectiveness is likely to require a paradigm shift in thinking within the discipline. For new radiologic applications to be accepted, we will need to show at least a significant change in treatment planning and at best a meaningful change in patient outcomes. This shift will require a forward-thinking approach to robust evidence generation for new imaging modalities or indications and the inclusion of other modes of value demonstration such as clinical decision support and intelligent data mining.

Acknowledgments

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