Special Review

Translating New Imaging Technologies to Clinical Practice

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Radiology continues to benefit from constant innovation and technological advances. However, for promising new imaging technologies to reach widespread clinical practice, several milestones must be met. These include regulatory approval, early clinical evaluation, payer reimbursement, and broader marketplace adoption. Successful implementation of new imaging tests into clinical practice requires active stakeholder engagement and a focus on demonstrating clinical value during each phase of translation.

Key Words: Imaging technologies; technology adoption; clinical translation; medical devices; regulatory approval.

INTRODUCTION

Medical imaging plays a central role in screening, diagnosis, and treatment management. Imaging technology has advanced at a tremendous pace, and new imaging techniques are being employed in an increasing number of clinical scenarios (1). Physicians rely on the power of medical imaging to guide diagnoses and treatment plans. Surgeons and interventional radiologists are increasingly using novel imaging techniques to guide percutaneous and intraoperative procedures. However, even after years of corporate development, many novel imaging applications face multiple additional hurdles before widespread clinical adoption. These include regulatory approval, robust clinical evaluation, and third-party reimbursement.

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As technological innovation is the cornerstone of medical imaging, radiology investigators should possess a basic understanding of how novel imaging technologies are translated into clinical practice. Individual radiologists can play a critical role in each step of technology development and clinical adoption. To provide an overview of this important topic to the general radiology audience, the Radiology Research Alliance Task Force on Translating New Imaging Technologies into Clinical Practice was convened to produce this white paper. The objectives of this effort were to provide a synopsis of the technology adoption pathway after manufacturer development, and to encourage radiologists to more effectively engage in bringing new advanced imaging techniques to clinical use, further advancing the field of imaging.

This white paper discusses the following four major phases that new imaging technologies must pass through before incorporation into routine clinical practice: (1) federal regulatory approval, (2) early adoption, (3) payment coverage, and (4) broad adoption (Fig 1). For each of these phases, we introduce standard terminology and major milestones, and stress the important roles that radiologists can play in facilitating the translation of new imaging technologies from bench to bedside. We use digital breast tomosynthesis (DBT), a recently adopted advanced imaging technique, as an example across these different phases. Finally, we conclude with a brief discussion of policy-related and political barriers to imaging technology adoption, highlighting the need for active radiologist engagement at the earliest phases of translational research.

FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL PHASE

Imaging technologies are considered medical devices under the Federal Food, Drug, and Cosmetic Act of 1938 and as

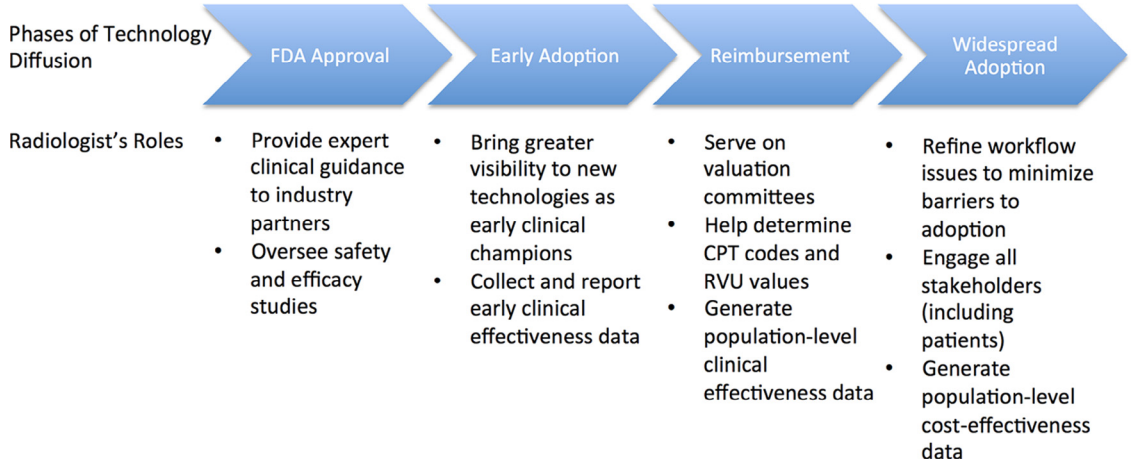

Figure 1. Four phases of translating a new imaging technology into clinical practice. CPT, Common Procedural Terminology; FDA, Food and Drug Administration; RVU, relative value unit.

amended by the Medical Device Regulation Act of 1976. Under federal regulation, the U.S. FDA, through its Center for Devices and Radiological Health, is tasked with overseeing the domestic production, the distribution, and sales of medical imaging devices. FDA approval is necessary before a manufacturer can distribute and market a new imaging device. Medicare reimbursement also requires FDA approval. Even though the FDA permits off-label use of a device at an individual physician's discretion, a manufacturer cannot market off-label indications. Additionally, federal reimbursement is often more challenging without approval for specific clinical indications (2).

Medical Device Classes

Medical devices fall into one of three classes (I, II, and III), with progressively increasing stringency of FDA standards concordant with the level of safety requirements (3). Most medical imaging technologies are either Class I (eg, radiographic markers and contrast syringes) or Class II devices (eg, computed tomography scanners and magnetic resonance imaging machines). Class I and II devices representing an evolution of existing imaging technologies (eg, multislice computed tomography scanners) constitute the majority of new imaging technologies entering the market. These devices are eligible to go through the 510(k) pathway to obtain premarket approval. Under this FDA approval pathway, new medical imaging devices must be shown to be at least as safe and effective or "substantially equivalent" to a pre-existing legally marketed device (4). A device is deemed substantially equivalent when it has the same intended use and the same technological characteristics, or different technological characteristics without additional safety or efficacy concerns (4).

Major alterations to either the intended clinical use or alterations to technology compared to the predicate device could result in a next-generation imaging technology being classified as a Class III device. This involves a lengthier premarket approval process, which includes the need for clinical trials. Such was the case with digital mammography, which was designated a Class III device due to a change in both the indication for use (ie, detection of cancer) and the application of new technology (ie, digital radiography) compared to its predicate, screen-film mammography. In contrast, the first DBT system approved was the Hologic Selenia Dimensions 3D system in 2011 through the 510(k) pathway. Eligibility was based on its equivalence to the Hologic 2-D full-field digital mammography unit, supported by initial and follow-up reader studies comparing the device sensitivity and specificity to full-field digital mammography. Unlike the transition from screen-film to digital mammography, the transition from digital mammography to DBT did not involve a change to either the intended clinical use (detection of cancer) or the technology applied (digital radiography).

Safety and Effectiveness

For Class III devices (ie, medical imaging technologies without a substantially equivalent predicate), a higher level of clinical effectiveness and safety data is needed beyond radiologist reader studies. Radiologists can and should nonetheless serve as active participants in clinical trials that demonstrate that a device is safe and effective for its intended clinical use (eg, improved sensitivity and specificity without patient harms). Additional evidence is required demonstrating that the information provided from a novel imaging technique is clinically useful from the providing physicians' perspective. Moreover, after a novel device obtains premarket approval and distribution, radiologists should adhere to strict guidelines for reporting device malfunction or related serious injury or death as required by the FDA's medical device regulation guidelines (3). The medical device regulation requires users to identify and to monitor for adverse events, and ensures the detection and resolution of problems in a timely manner.