Published in final edited form as:

Acad Radiol. 2009 May ; 16(5): 593–596. doi:10.1016/j.acra.2009.01.017.

Translational Research in Radiology: Challenges and Role in a Patient-based Practice

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Translational research has, in recent years, become a popular agenda item at the National Institutes of Health (NIH) and within the biomedical community at large. The NIH's interest in the topic, which arose from the apparent disconnection between basic science discoveries and their implementation in the clinic, is reflected in the Roadmap for Medical Research, announced in 2003 [1]. The Roadmap proposes three trends for the advancement of medical science: (1) "New pathways to discovery," dedicated to the development of new methods to understand complex biological systems; (2) "Research teams of the future," aimed at facilitating interdisciplinary research; and (3) "Re-engineering the clinical research enterprise," emphasizing clinical and translational or "patient-oriented" research. This has spawned several new initiatives; the most important, with respect to translational research in radiology, are the Institutional Clinical and Translational Science Awards (CTSA) [2], the NIH Rapid Access to Interventional Development Pilot Program [3] and the National Center for Biomedical Computing [4].

Lean et al. [5] define translational research as the process that leads from evidence based medicine to sustainable solutions for public health problems. This process clearly cuts a wide swath through clinical science, and these authors conceive three crucial phases for its successful pursuit:

1. Exploration of needs for and development of potential treatments in basic laboratory research and testing of safety and efficacy.
2. Assessment of how findings from phase 1 function when applied to routine clinical practice.
3. Collection of information to convert effective tools found as part of phase 2 research into sustainable solutions and evidence based policies.

With respect to imaging research, these steps can be viewed as exploration of the need for and development of more sensitive and specific imaging techniques and/or markers of disease processes; assessment of their performance in routine clinical practice; and further investigation of these techniques and their implementation at an epidemiological level to formulate and change the standard of care in imaging.

This is a big challenge, but radiologists can learn from their past success. Indeed, the development of imaging technology and its integration into routine clinical care is one of the prime examples of a successful translational pathway over the last three decades. During this

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Disclosure: The authors report no conflicts of interest.

period, three of the top five medical innovations, as ranked by physicians, are related to imaging advances: Magnetic resonance (MR) and computed tomography imaging, balloon angioplasty and mammography [6]. It is astonishing that these relatively new techniques are now firmly integrated into clinical practice, and radiology as a discipline deserves tremendous credit for the successful integration of physics and computer technology with clinical applications.

More recently, the development of integrated positron emission/computed tomography (PET-CT) imaging devices has had a tremendous impact on the diagnosis and management of cancer patients [7]. The development of the first dual-modality imaging devices for clinical applications occurred in the 1990s. A combined PET-CT prototype underwent clinical evaluation from mid-1998 onward. The results from the initial three-year evaluation program stimulated the demand for commercial designs, and in 2001 the first commercial PET-CT scanner was installed in the clinic. Today there are over 2500 PET-CT scanners in operation worldwide. PET-CT is widely used in the diagnosis, staging and follow up of patients with a large range of malignancies, in many instances changing clinical management.

Given these success stories, can we conclude that the translational research pathway in the world of radiology is a well established niche that is ready to meet the emerging challenges of molecular based diagnostic and treatment techniques? Is translational research within radiology capable of coping with rising healthcare costs and shrinking research budgets?

The answer to these questions is “Not quite.” Though the trail has been blazed, crucial challenges to successful promotion of translational research remain – particularly, and not surprisingly, the high up-front financial and opportunity costs. Innovative and comprehensive research projects take significant amounts of time to initiate and maintain, and the radiologist’s time is an expensive commodity. Time away from the clinical schedule, even for radiologists with external funding, can result in short-term losses in clinical revenue for the department or hospital. (In the context of technical development with potential clinical application, however, these losses should more properly be considered investments.) This situation may be exacerbated as the economy slows down and hospital revenues decrease. Since academic medical centers take care of a large portion of the uninsured and underinsured populations, they are especially vulnerable to economic downturns.

At an individual faculty level, financial considerations lead to a reluctance by some department chairpersons to support junior researchers who wish to apply for external funding through mechanisms such as NIH career development grants (so-called “K awards”) as well as grants from professional and disease-focused societies or companies. Such grants often stipulate that the awardee spend a majority of their time – commonly 50% to 75% – on research-related activities.

The objections to granting academic time, while rooted in the bottom line, are often couched in clinical terms – specifically, the argument that a junior faculty member will be an inadequate radiologist if at least 50% of his or her time, and perhaps more, is not spent doing clinical work. The experiences of our colleagues in medical fields, many of whom are outstanding clinicians who receive referrals from around the world, adequately combat these arguments. In addition, as imaging tools become ever more disease-specific rather than driven by hardware, radiology may need to adopt a similar approach to the one that has served our clinical colleagues so well. As such, we may need to promote even greater subspecialization, particularly within academic departments, so that radiologist-scientists can maximize the value of their clinical work and provide the highest possible level of clinical care.

The need for protected research time is especially acute for junior faculty members. These faculty members, despite their relative inexperience, often bear the brunt of the clinical workload and call schedule. Additionally, inefficient time management and lack of experience

in balancing clinical and scientific duties are both common problems for early-career investigators. At the same time, these investigators, who are just out of training and may therefore be most up to date on clinical practice in radiology's sister specialties, the work of which will benefit greatly from developments in imaging-related techniques, may be ideally suited to make transformational discoveries.

Scanner time is another costly commodity and needs to be made less expensive for translational research to progress. The typical cost of an hour of research time on a clinical MR scanner is on the order of \$600–\$700. This adversely affects translational research efforts by limiting the number of study participants who can be imaged within the constraints of a research project budget, resulting in underpowered studies that cannot adequately test the study hypothesis. In addition, the high cost of scanning time – and the fact that clinical reimbursement is by procedure rather than by exam length – means that there is little time on the clinical schedule to try new imaging sequences, a crucial step in incorporating new technology into routine clinical care that commonly occurs outside the standard hypothesis-driven scientific structure.

Furthermore, there is significant resistance on the part of payors to reimburse studies performed with newer, more expensive, imaging techniques, even if those techniques have been shown to be useful in research studies. Brain MR spectroscopy, for example, which can provide very useful information in distinguishing recurrent tumor from radiation necrosis in brain tumor patients, is not currently reimbursed by Medicare and Medicaid and is only sporadically reimbursed by private insurance companies. This is a huge barrier to widespread use of newer tools that can significantly improve patient care.

To preserve its future as an independent, innovative branch of medicine, radiology must take a leadership role in performing and promoting translational research efforts. The use of imaging equipment in the research realm is not our birthright: If we don't do it, others will. Indeed, a substantial proportion of neuroimaging research, for example, is currently performed by neurologists and psychiatrists. Since practitioners of these disciplines generally receive much lower reimbursement for their clinical work, there is less resistance and greater incentive to give productive and promising researchers protected research time.

Translational research in imaging would definitely benefit from a more concerted effort on the part of academic radiology departments to foster this type of research. Such efforts are necessary to preserve the central role of our discipline in a new era of patient care. Incentives for researchers can range from academic (rewarding successful, important translational research central through academic promotion) to financial (for example, assistance with the process of commercial development of translational research discoveries).

Development of the necessary infrastructure for translational research within each department – toward the goal of creating a translational research pipeline – is another crucial step. Important examples are provision of low-cost or free scanning time for pilot projects and reduction in scanning costs for researchers; establishment of effective professional assistance with lab management and grant writing; and creation of effective mentorship programs.

Radiologists need to assume a key role in establishing multidisciplinary research communities that can serve as “centers of excellence” in promoting advances in imaging of different disease entities. There needs to be a paradigm shift where radiologists begin to use their expertise in imaging to lead these research efforts rather than assuming a secondary, “technical support” role in these groups. Such collaborative research could be promoted at the institutional level by establishing additional forums – such as retreats, speaker series, and journal clubs – to promote fruitful interaction between imaging scientists or disease biologists and clinical radiologists.

For example, two of the authors (MP and DSR) are part of a successful and growing translational research team within our institution. The team is called Magnetic Resonance Imaging in Multiple Sclerosis (MRI in MS); it is comprised of approximately 25 individuals interested in the development of innovative MR technology for the diagnosis and follow up of MS patients. The group consists of radiologists, neurologists, psychologists, physiologists, MR physicists, biomedical engineers and molecular biologists and meets on a regular basis to discuss ongoing research projects. It brings together basic and clinical researchers and has been particularly effective in translating knowledge regarding the pathogenesis of the disease acquired from animal models to clinical studies as well as directing animal research studies to optimize extraction of clinically relevant information. Close collaboration within the group has also optimized use of available funding to acquire the maximum possible amount of research data. Our experience with this group and the productivity we have seen in this setting strengthen our belief that investing in the establishment and maintenance of similar entities for different diseases will be central in supporting translational research in imaging.

On the national level, there are significant “cultural” barriers within the world of radiology that impede translational research efforts. Radiology has traditionally been a primarily clinical specialty and as such has had difficulty attracting research-oriented individuals. (For example, there has traditionally been a disproportionately lower number of candidates with MD PhD degrees applying for radiology residencies). Moreover, the research studies that have traditionally been performed under the radiology rubric have been descriptive rather than hypothesis-based. However, there is now a concerted effort to recruit more academically inclined medical students to radiology residencies. Research pathway options are offered at many institutions, offering protected research time during the residency training period. The Radiological Society of North America (RSNA) has been particularly supportive of such programs through its resident and fellow research grants.

The current structure of the residency and fellowship training system in radiology is not optimally structured for the development of translational researchers. The training period for general radiology is relatively long (five years including the clinical internship year), whereas subspecialty fellowship programs within radiology usually do not exceed one year. This imbalance does not enhance the development of solid, mutually beneficial, collaborative relationships between clinicians and radiologists within a subspecialty. The situation makes it difficult for radiology trainees to meet the mandates of the NIH CTSA program, which asks academic institutions to “captivate, advance and nurture a cadre of well-trained multi- and interdisciplinary investigators and research teams.” Reforming our current training scheme system with more emphasis on subspecialty training would help to remedy the situation, allowing the development of collaborative research initiatives and enabling trainees graduate to faculty positions with more solid research plans in place [8].

Research-oriented trainees without master’s degrees or doctorates will require formal and experiential training in laboratory-based scientific methods. Not only is such training a crucial part of building translational research programs and effective collaborations with basic researchers, but it has become especially important with the emergence of molecular imaging methods. Existing schemes that provide young researchers with practical training in research methods and, for example, biostatistics are often based on the internal medicine residency/fellowship training schedule. This schedule typically involves three years of general internal medicine residency training and three or more years of subspecialty training. The first fellowship year is a “core clinical year,” whereas the last two years are focused on research activities and can accommodate formal training programs. These programs do not fit well into the current structure of radiology fellowship training, limiting the use of such training schemes already by radiology trainees.

Active research programs leading to development of new technologies, including novel therapies and innovative monitoring and diagnostic techniques, are crucial to sustaining and expanding the presence of a medical specialty. Successful translation of technology into clinical practice is an integral part of radiology. To maintain and enhance our role in the imaging sciences, we need to build research programs that address changing healthcare needs and questions in a timely and focused manner [9]. Achieving this will require a paradigm shift in the structure and goals of our residency and fellowship training systems, together with development of and investment in the careers of promising young faculty members. It will also involve a long term commitment on the part of academic radiology departments to the creation and maintenance of an effective basic and clinical research infrastructure and multidisciplinary research efforts.

The task may seem daunting. However, as Elias Zerhouni – radiologist-turned NIH director – admonished in his 2007 Eugene P. Pendergrass New Horizons Lecture, “the greatest risk in science is to stop taking risks” [10]. As this article has made clear, investment in translational research infrastructure is not even risky; it’s necessary and urgent. “Today’s research is tomorrow’s practice” – the mantra of clinical science – has never been more appropriate [11]. If we do not make this commitment, we will seriously undermine our specialty’s future.

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