

Effecting Translational Research Practices

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The issue of transferring medical research findings into practice is currently a topic of concern in most scientific circles. Our society has never experienced such an explosion of new scientific findings as we have seen in recent years. Yet practitioners/clinicians do not adopt many of these new findings into their practice. Scientists and research funding organizations such as the National Institutes of Health (NIH) remain frustrated over this issue termed 'translational research'. For example, the budget of the NIH last year was \$24 billion for medical research. That is a large portion of the Federal Government's budget and represents the hard earned tax dollars of U.S. citizens. This investment in medical research yielded many new discoveries yet they remain largely in scientific journals. They have yet to be incorporated into practice and do not benefit the society that paid for them. The reasons for this are varied. Some studies on the problem cite the large masses of new information practitioners have to continually absorb. Others cite human nature and its resistance to change.

The clinical laboratory is not immune from this issue. New procedures are constantly being developed. The question begs which procedures are to be added to the formulary of laboratory procedures. If all new procedures were added to every laboratory, our laboratories would be very large, expensive, and inefficient. The model that the laboratory profession has chosen to follow over many years is having reference laboratories provide the newer, more esoteric tests and the local laboratories provide the more routine and frequently ordered tests. As the esoteric tests transition to a routine nature, the local laboratories incorporate them into their formulary. Other factors come into play in this process such as the specialty type of physician using a particular laboratory and what laboratory tests they require to augment their

clinical decisions. So in one sense the process is better developed than in other professions.

One must also examine who conducts the research, which is what advances any scientific discipline or field. This question is particularly pertinent to clinical laboratory science (CLS). Who advances the field of CLS? Who advances the field in any discipline? If we look at the basic sciences, we see biologists conducting research in biology, chemists conducting research in chemistry, and physicists conducting research in physics. In the social sciences we see psychologists conducting research in psychology, sociologists conducting research in sociology, and anthropologists conducting research in anthropology. However in healthcare there is more of an interdisciplinary approach. A team of physicians, nurses, CLSs, pharmacists, and other healthcare professionals often conducts research regarding prevention or treatment of a disease. Yet within each of these domains there is a certain amount of research that is specific to that domain and conducted by that profession.

Historically the field of CLS has been advanced by other disciplines and not CLS. For example, clinical chemists research promising methods for detection of specific substances using chemical reactions. Microbiologists also investigate new methods of identifying specific bacteria, viruses, and parasites. Oncologists have done most of the work in researching hematology advances. Companies that manufacture laboratory equipment then capitalize on these research findings. They take the science and couple it with their engineers to commercialize the process. The commercialization may result in a simplified prepackaged manual process or in an automated piece of equipment. The CLS then learns how to use the equipment and possibly conducts some in-service on the new test to other healthcare professionals. So what is the involvement of the CLS in advancing the field? Very little, if any. Is this situation a barrier or a protective factor in promoting the profession and serving patients? One perspective is that it is a positive situation as the PhD prepared chemist or microbiologist is better prepared to conduct research and advance the field while the CLS is best at simply running the tests without thought or creativity. Another perspective is that CLSs know the day to day needs of their

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patients and clinicians and they should be the ones working in concert with other researchers to advance the field of CLS.

If the model used by other disciplines is followed, then the CLS profession should be actively involved in developing new scientific discoveries and advancing these findings to the clinical laboratory. One may argue that CLSs are involved with the companies that sell laboratory equipment. This is true; however, their involvement is typically in the preparation of instructional material, marketing, and technical service, not in the research/developmental aspect. These services are needed and important but they do not per se advance the field in the manner that occurs in other disciplines. So what is needed? Perhaps it is time to rethink the field of CLS. Is it simply one of running tests in the laboratory and spitting out results or is it one that is a true practitioner that is involved in developing its own field and applying the knowledge it has gained to improve the healthcare of the people it serves?

I would argue that laboratory medicine has become very sophisticated and complex. Not necessarily in the performance of tests but inclusive of the continuum from new scientific discoveries, specimen processing and testing, to the management of laboratory data that optimizes laboratory services. We find ourselves in the same situation as nursing and pharmacy. Those professions have also experienced an explosion of new knowledge and the practice of their profession has become quite sophisticated out of necessity. Nursing has addressed the problem by establishing numerous doctorate programs in nursing and convincing Congress to establish the National Institute of Nursing Research (NINR). NINR is part of the National Institutes of Health. Its sole purpose is to conduct research in nursing so as to advance the field of nursing. Pharmacy has gone a step further and now requires the doctorate degree as the entry-level degree to the profession. The doctorate in pharmacy (Pharm D) is a professional degree designed to prepare an individual to practice the new pharmacy model which includes patient assessment, counseling, and medication management as well as filling of prescriptions. Both nursing and pharmacy offer professional degrees as well as the PhD that prepares an individual to conduct research. Both of these models have strengths and limitations.

Will these models work for the clinical laboratory? The professional doctorate degree may serve the CLS profession well; however, a generic PhD in CLS may not be able to compete with the PhD in chemistry or microbiology for the simple reason that the PhD in CLS would have to master chemistry, microbiology, virology, hematology, immunology, and the other laboratory specialties. This is not realistic, requiring the need for a new model. Perhaps the model used in pharmacy offers some potential. Pharmacy offers a joint degree program consisting of the Pharm D and PhD. The PhD in CLS could specialize in one of the subspecialties of the laboratory, e.g., chemistry, microbiology, or immunology. Progression in any profession occurs in step wise fashion. The development of programs such as these are the logical extension of the field as we engage in quality patient care on the floors and in the research laboratory by providing a professional who has both the clinical skills and research skills necessary to work as a researcher.

Few would argue that automation in the laboratory has made testing straightforward and the need for highly educated and trained personnel is not necessary to simply do testing. What many have failed to recognize is the big picture that encompasses all aspects of laboratory medicine not just the testing phase. This lack of perspective limits the benefits of the laboratory to both patients and clinicians. Another reality is that someone from outside the profession is not going to make this happen. Not administrators, third parties, or the government. Whatever the models used to accommodate the complexity and sophistication of contemporary laboratory medicine must stem from the professionals themselves. It won't be easy to agree amongst the profession but a realistic compromise that advances the field to the benefit of the patient and the profession has to be reached. This model must then be marketed to other healthcare professionals, third party payers, and above all the public. It will not be easy but it hasn't been easy for any other profession. It is part of the price to pay when advancing the field.

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