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Defining Translational Research: Implications for Training

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Abstract

Because translational research is not clearly defined, developers of translational research programs are struggling to articulate specific program objectives, delineate the knowledge and skills (competencies) that trainees are expected to develop, create an appropriate curriculum, and track

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outcomes to assess whether program objectives and competency requirements are being met. Members of the Evaluation Committee of the Association for Clinical Research Training (ACRT) reviewed current definitions of translational research and proposed an operational definition to use in the educational framework. In this article, the authors posit that translational research fosters the multidirectional and multidisciplinary integration of basic research, patient-oriented research, and population-based research, with the long-term aim of improving the health of the public. The authors argue that the approach to designing and evaluating the success of translational training programs must therefore be flexible enough to accommodate the needs of individual institutions and individual trainees within the institutions but that it must also be rigorous enough to document that the program is meeting its short-, intermediate-, and long-term objectives and that its trainees are meeting preestablished competency requirements. A logic model is proposed for the evaluation of translational research programs.

The National Institutes of Health (NIH) has traditionally supported the training of basic and clinical scientists in a variety of disciplines. More recently, it has supported the training of scientists in translational research through the K30 and Clinical and Translational Science Award (CTSA) programs.¹ Because both basic research and clinical research are clearly defined, developers of programs to train individuals in these types of research have been able to articulate program objectives, delineate the knowledge and skills (i.e., competencies) that trainees are expected to develop, create an appropriate curriculum, and track outcomes to assess whether program objectives and competency requirements are being met. In contrast, because translational research is not clearly defined, developers of translational research programs are struggling with some of these processes.

As members of the Evaluation Committee of the Association for Clinical Research Training (ACRT), we began to address this problem by reviewing the definitions of different types of research. We then developed working definitions of translational research and associated terms. Here, we present our working definitions, discuss their implications for educational training programs, and offer a framework to guide institutions in developing processes of program evaluation.

Definitions of Basic Research and Basic Science

According to the American Cancer Society, basic science involves laboratory studies that provide the foundation for clinical research.² As one cancer center indicates, basic science entails gathering knowledge that is essential for applying discoveries to patient care.³ However, in 1945, when the director of the US Office of Scientific Development and Research proposed the establishment of the National Science Foundation (NSF), he made the following distinction between basic research and applied research:

Basic research is performed without thought of practical ends. It results in general knowledge and an understanding of nature and its laws. This general knowledge provides the means of answering a large number of important practical problems, though it may not give a complete specific answer to any one of them. The function of applied research is to provide such complete answers.⁴

The NSF definition thus identifies the main objective of basic research as the acquisition of knowledge without the obligation to apply it to practical ends.

Basic research training is pervasive in medical schools. With PhD programs offered in disciplines such as the biomedical sciences, computational biology, and neuroscience, the basic science field has been well established. Competencies within the basic sciences have been clearly defined, allowing for effective development and evaluation of educational programs.

About 60% of the NIH budget is allocated for basic research, and most of the basic research funds go to PhD scientists.⁵

Definitions of Clinical Research

In 1997, the NIH Director's Panel on Clinical Research issued the following 3-part definition of clinical research:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiologic and behavioral studies.
3. Outcomes research and health services research.⁶

In 1998, the NIH introduced the Clinical Research Curriculum Award to "improve the quality of training in clinical research."⁷ Over 50 training programs were funded through this award, and many of these programs grant degrees in clinical research.

The NIH's definition of clinical research has been widely accepted by institutions and programs and provides a common basis for the NIH-funded clinical research training programs. The definition has facilitated cross-program efforts to identify core competencies, best practices, and meaningful outcomes that are relevant across the broad spectrum of training in clinical research. This in turn has allowed program evaluators to develop useful assessment metrics to document the success of training programs.

Today, about 30% of the NIH budget is spent on clinical research.⁵ However, some believe that this figure includes studies of animal models, in which case the actual support for clinical research would be much less.⁵

Definitions of Translational Research

The definition of translational research is less clear than the definitions of basic and clinical research.

Although a Medline search indicates that the term *translational research* appeared as early as 1993, there were relatively few references to this term in the medical literature during the 1990s, and most references were to research about cancer. At the time, the literature on cancer tended to use the term *translational research* to refer to work spanning different types of research (e.g., immunology studies spanning basic and clinical research) or work spanning disciplines within a particular type of research (e.g., bench research involving molecular genetics and immunology). Today, the literature includes a plethora of attempts in various fields to define the term.⁸

In a recent announcement about applying for a CTSA, the NIH offered the following definition:

Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.⁹

According to this definition, translational research is part of a unidirectional continuum in which research findings are moved from the researcher's bench to the patient's bedside and community. In the continuum, the first stage of translational research (T1) transfers knowledge from basic research to clinical research, while the second stage (T2) transfers findings from clinical studies or clinical trials to practice settings and communities, where the findings improve health.

In a commentary published in 2008, Steven Woolf pointed out that “translational research means different things to different people”¹⁰(p211) and argued that the different types of translational research are too narrowly defined. In particular, he argued that if T2 research is going to result in the knowledge needed to improve health and the quality of life, then T1 research must include sciences related to populations (e.g., epidemiology, psychology, economics, and behavioral sciences).¹⁰

When the Institute of Medicine (IOM) convened the Clinical Research Roundtable, the roundtable group developed a model for translational research that was highly aligned with the NIH definition.¹¹

Like the NIH and the IOM, the Translational Research Working Group of the National Cancer Institute (NCI) included both basic and clinical research in the T1 segment of the continuum: “Translational research transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce cancer incidence, morbidity, and mortality.”¹² But given that basic research and clinical research involve inherently different knowledge sets and methodologies, including both of them in the same segment of the continuum (i.e., in T1) obscures the fact that multidisciplinary translational research can also occur at the interface of basic and clinical science.

A Framework to Design and Evaluate Translational Research Programs

As members of the ACRT Evaluation Committee, our goal was to develop a framework to assess translational research programs. We quickly realized, however, that disagreements over what is and is not included in the definition of translational research would make it difficult for us to define competency requirements and determine whether these requirements were being met. We therefore began discussing the definitions outlined above. We also consulted articles published on the topic of translational research^{8,10,11,13,14} and data provided on the Web sites of the first 12 CTSA recipients.¹⁵

Working definitions

We developed the following working definition of translational research:

Translational research fosters the multidirectional integration of basic research, patient-oriented research, and population-based research, with the long-term aim of improving the health of the public. T1 research expedites the movement between basic research and patient-oriented research that leads to new or improved scientific understanding or standards of care. T2 research facilitates the movement between patient-oriented research and population-based research that leads to better patient outcomes, the implementation of best practices, and improved health status in communities. T3 research promotes interaction between laboratory-based research and population-based research to stimulate a robust scientific understanding of human health and disease.

We believe that when T1 is conceptualized as the process of moving from bench to bedside, it represents a movement toward the goal of improved health. It may evoke the image of a patient receiving medical care or the image of a healthy individual benefiting from

improvements in health care or public health. Alternatively, it may suggest that patient-oriented research (research at the bedside) is a key step toward improvement in the treatment or prevention of disease.

The model that we propose (see Figure 1) captures the dynamic interplay inherent in the concept of translational research. The model's circular structure suggests that research is a continuing cycle, and its bidirectional arrows emphasize that new knowledge and hypotheses are generated at each step. Some basic research and population-based research is translational, but neither type of research is by definition translational. In contrast, patient-oriented research fundamentally addresses issues that have the potential to translate to clinical practice and therefore affect health. For these reasons, the model includes only part of basic research and population-based research within the circular structure but includes all of patient-oriented research within this structure.

The concept of basic research, as defined earlier, is generally well understood. The concepts of patient-oriented research and population-based research fall within the broader rubric of clinical research as defined by the NIH. We use the term *patient-oriented research* to refer to studies that include groups of patients or healthy individuals and are designed to understand the mechanisms of disease and health, to determine the effects of a treatment, or to provide a decision analysis of the care trajectories of patients.¹⁶ Clinical trials are an example of patient-oriented research that has the potential to directly affect clinical practice. We use the term *population-based research* to refer to studies involving epidemiology, social and behavioral sciences, public health, quality evaluation, and cost-effectiveness.

In our model, the T1, T2, and T3 arrows represent bridges from one type of research to another. Examples of T1 research are drug development, pharmacogenomics, and some studies of disease mechanisms and research into new areas such as genetics, genomics, and proteomics. Examples of T2 are clinical epidemiology, health services (outcomes) research, and the newly developing methodology of community-based participatory research. Examples of T3 are emerging disciplines such as molecular and genetic epidemiology. T3 research highlights, for instance, how research in populations informs hypotheses that can be tested in basic science laboratories and how biomarkers in animal models can translate into population-based screening tools.

Implications for the design of training programs

The interaction of several disciplines is required to translate knowledge from one type of research to another (e.g., to move a basic science discovery to the bedside). Collaboration among disciplines through multidisciplinary teams facilitates the emergence of novel concepts and approaches to addressing important health issues. The emergence and development of new ideas are goals of translational research, and there are many possible models of training that can provide the academic path to these goals.

Training in translational research will vary depending on the background of trainees and the areas of research they plan to pursue. Given the diversity of educational backgrounds and research interests, it will be necessary to design a customized curriculum for almost every trainee. To ensure an understanding of complementary disciplines and to enhance communication and collaboration, trainees who have focused on basic laboratory research will need to become immersed in clinical sciences and clinical practice, while trainees with a clinical focus will need to gain exposure to basic science research. Both types of individuals will also benefit from training in population-based sciences, as is encouraged, for example, by the Burroughs Wellcome Fund, which sponsors the Institutional Program Unifying Population and Laboratory Based Sciences.¹⁷

The details of a clinical immersion experience will depend on the area of research interest. For example, trainees interested in neuroscience may wish to accompany clinicians in a psychiatry or neurology clinic, and trainees working on bone tissue regeneration may participate in the activities of a clinical orthopedic surgery program. Trainees seeking laboratory immersion could take courses in techniques of molecular biology or genetics and work at the bench for a concentrated period of 3–4 months. Trainees who have a background in the social sciences or economics and are interested in health services research may need to join a team of investigators working in their area of interest.

All trainees could benefit from fundamental instruction concerning study design, data collection, statistical analysis, ethics and research integrity, protection of human subjects, the search for funding sources, the writing of institutional review board protocols and grant applications, the pursuit of patents and technology transfer, and government requirements for new drugs and devices. Because of the nature of translational research, it is also imperative for training programs to ensure that trainees develop the competencies needed to thrive in a multidisciplinary collaborative team. These competencies include communication and negotiation skills as well as ethical and humanitarian attitudes.

The most effective approach would be to design an individualized curriculum for each trainee, guided by a customized, learner-centered advisory committee that includes mentors with various and complementary backgrounds in clinical practice and basic and clinical research. One of the mentors would assume the role of primary mentor to ensure coordination of efforts and the success of the mentoring process.

Mentoring is a demanding but highly rewarding enterprise whose success depends on the widely varying skills, needs, and attitudes of different individuals.¹⁸ Mentors who are able to monitor the incorporation and understanding of translational research essentials will be crucial to the positive outcomes of training programs. However, trainees will also need to have critical thinking skills and practical knowledge about how to work collaboratively and manage teams. Although most medical schools now realize the importance of teaching their students how to think critically,¹⁹ the truth is, as Jerome Groopman points out, that the older generation of students were not taught to think as clinicians.²⁰ Although recent emphasis has shifted to training medical students and residents how to follow preset algorithms and decision trees, these approaches are challenging when clinicians need to think outside their domains.²⁰ Since clinical and translational research in this century necessitates out-of-the-box thinking, training programs must teach young researchers how to excel as critical thinkers.

Historically, medicine has taken a hands-off approach to teaching management and leadership, the notion being that learning how to manage and lead is simply intuitive. “Something about management looks so easy that we...never doubt that we could succeed where others repeatedly fail,” says Thomas Teal, former senior editor of the *Harvard Business Review*.²¹(pp3–4) Because managing is less a series of technical tasks and more a set of human interactions, managers and team leaders require what Daniel Goleman and his colleagues call “emotional intelligence”²² and other skills that are not usually taught in research training programs. When we think of innovation and creative problem solving, we often look to engineers and designers to learn about these processes.²³ Similarly, when we think of management, we often look to the corporate sector. A useful approach to creating a supportive environment that fosters critical thinking and leadership and management skills must include the explicit training of fellows and junior faculty in these areas.

An effective training program in translational research must use traditional curricular elements in new ways to ensure understanding across disciplines. In addition, it must create and use new curricular elements and approaches to ensure that its trainees are able to do the following:

critically examine the research process; think “out of the box” to develop ways to impact health care by transferring knowledge from and to the bench, bedside, and community; engage in multidisciplinary collaboration; understand successful approaches to community engagement; and develop appropriate techniques to manage multidisciplinary research teams in the future. Using multidisciplinary skills, the translational researcher will be able to think and perform in an integrated interdisciplinary manner and become a new type of investigator.

Meeting these goals is a challenge because research training programs are not traditionally content-based. We need to consider the creation of a community of learners and leaders by fostering the use of problem-based learning^{24,25} as a gateway to collaborative leadership. Adopting these techniques will require a change in culture in medical schools, but the time is right to begin the process of this cultural shift if we wish to take a leap forward in enhancing the practice of moving from bench to bedside to community and back in translational research.

An approach to evaluation

With the necessity of customizing training in translational research, the approach to evaluation must be flexible. One of the most flexible approaches is to design a logic model that offers a graphic display of the relationships between program elements, objectives, and desired outcomes in the short term, intermediate term, and long term. The accompanying logic model (List 1) provides an example of a framework for a training program in translational research. The logic model approach has the advantage of being adaptable as definitions of research and research goals evolve. Specific elements in the model can change, along with indicators and data sources, without completely disrupting the overall logical flow of objectives.

In the logic model for a translational research program, the domains to be evaluated could include (1) whether the tools employed to achieve preestablished objectives, including general and scientific area specific competencies in translational sciences, are adequate; (2) whether the trainees acquire the cognitive and practical skills they need to effectively conduct translational research; (3) whether the trainees are successful in developing and pursuing a translational research career; and (4) whether the program as a whole promotes and enhances translational research. The outcomes of each of these domains could include (1) evidence that courses, seminars, workshops, and laboratory experiences offered in the program lead to fulfillment of preestablished competency requirements; (2) evidence of improvement over time in the trainees’ knowledge and skills regarding translational research topics and endeavors, as assessed via testing and via evaluations provided by scientific advisory committees; (3) evidence of successful career development, as measured by the ability to publish articles in peer-reviewed journals, to obtain research grants and academic appointments, and to gain leadership positions in multidisciplinary teams; and (4) evidence of the increased impact of the program at the institutional level and the national level, as judged by whether more translational research is funded and conducted at these levels.

Conclusion

We believe that translational research moves in a bidirectional manner from one type of research to another—from basic research to patient-oriented research, to population-based research, and back—and involves collaboration among scientists from multiple disciplines. The design of an effective training program in translational research is a challenge because the program must offer each of its trainees the opportunity to master a combination of skills that are not taught together in traditional training programs. The approach to evaluating the success of translational training programs must be flexible enough to accommodate the needs of individual institutions and individual trainees within the institutions, but it must also be rigorous enough to document that the program is meeting its short-, intermediate-, and long-term

objectives and that its trainees are meeting preestablished competency requirements. A logic model framework with appropriate domains may be well suited to these evaluation efforts.

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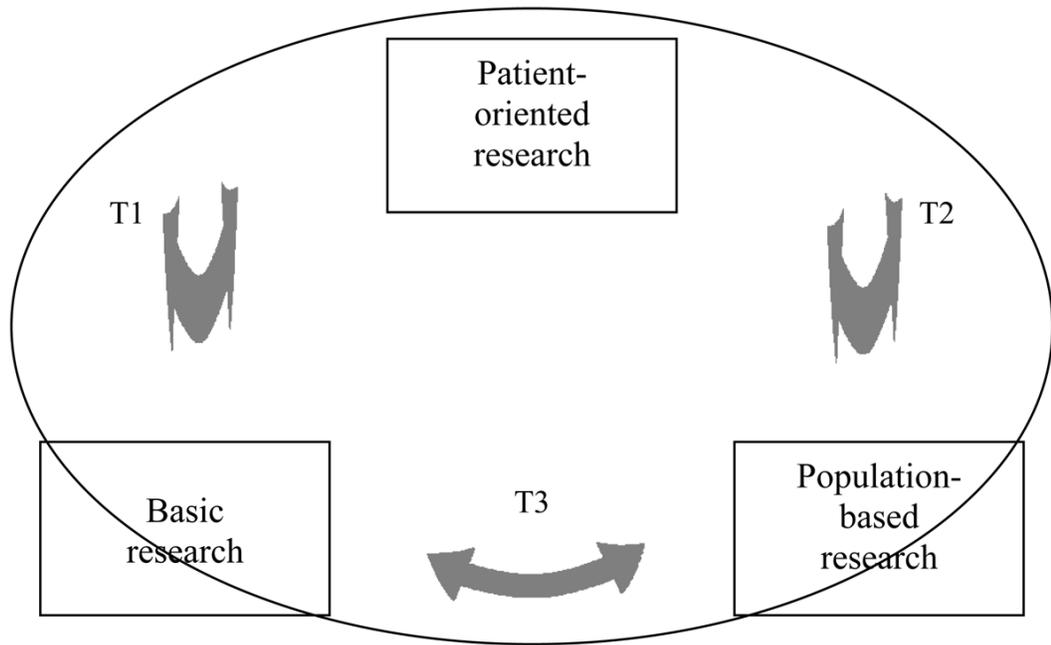


Figure 1. Model for translational research, as proposed by the Evaluation Committee of the Association for Clinical Research Training.

List 1

Logic Model for Training in Translational Research

Inputs	Activities	Outputs	Short-Term Outcomes (Training Changes)	Intermediate-Term Outcomes (Practice Changes)	Long-Term Outcomes (Impact)
Financial inputs; institutional investments; tuition; National Institutes of Health funding of trainees (T32, Clinical and Translational Science Award, etc.); and other federal and private funding of trainees. Human resources: trainees (clinicians and bench scientists); program faculty and administrators; mentors (clinical researchers, bench scientists, geneticists, biomedical engineers, social scientists, and behavioral researchers).	Didactic coursework about research methods, epidemiology, biostatistics, research management, ethics, basic science, scientific communication, and community engagement. Mentored clinical research, including scholarly writing, presentation, and publication of results. Cross-disciplinary research collaborations. Practicums in community academic partnerships.	Well-trained and well-mentored translational researchers working in a collaborative, participatory, multidisciplinary environment and linking bench, bedside, and community-based resources in a cyclical process. Innovative thinking and problem solving.	Increased satisfaction of trainees, program administrators, and mentors. Effective translational research studies designed in collaboration with multidisciplinary colleagues. Relevant ethical and legal issues considered during the design and implementation of clinical research. Competitive grant proposals prepared for translational research funding.	Effective translational research studies conducted in a multidisciplinary environment. Effective use of human subjects in clinical translational research trials. Cross-disciplinary research teams managed in a collaborative and participatory manner. Research manuscripts submitted for publication in peer-reviewed research journals.	Increased national capacity for translational research. Improved human health status indicators.