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## PERSPECTIVES

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# What's in a Name? A Paradigm Shift for Clinical Research

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A myriad of terms are used to describe the types of research activities required to translate basic science and technological advances into health benefits. Examples include clinical, patient-oriented, translational, health services, and effectiveness research. The various terms have profound implications for funding, interdisciplinary interactions, promotion and tenure metrics, and the workforce, as well as the way such researchers are perceived by their peers. In describing and analyzing the problem, the nomenclature itself stands out as a significant inhibiting factor to translating basic life science discoveries into health benefits. This is consistent with the central theme of semantics that language underlies human thought. The lack of uniformity in terminology limits effective practice and collaboration, confuses the public, and raises barriers to integrated research.

We propose that the term *translational research* be used to give a name that encompasses what most medically related research is about. Using the name *basic research* does not itself describe every basic science discipline. However, it conveys the message that whether it be chemistry, biochemistry, or cell biology, basic research under such names involves applying scientific and technological methods to advance science. To add specifics, one may say “cell biology research” to specify research studies to understand basic cellular processes. Likewise, the term *translational research* may not describe every medically related research activity. However, it does convey the message

that, whether it be patient-oriented, clinical, or effectiveness research, research activities under such names involve applying basic and nonbasic scientific and clinical methods to advance medicine. The term *translational research* will thus serve as the brand name of medically related research. It will serve to identify and describe the distinctive merits and value of non-basic research.

Using such a brand name will not detract from those individuals who by tradition or by objectives already do translational research. For example, many PhD-trained individuals are involved in translational research activities. Being a PhD-trained researcher should not alone segregate one into being a “basic researcher.” Likewise, individuals who strongly identify themselves with being an outcomes or effectiveness researcher and not necessarily a translational researcher should not be excluded or their activities in any way devalued by now being considered translational researchers. Indeed, all such individuals have much to gain from uniformly being recognized by their research activities, which aim to advance medicine and, ultimately, patient care.

As the landscape of research and development competition changes worldwide, it is imperative that researchers in the United States sharpen their focus and refine their efforts. A brand name for medically related research will not only address an identity crisis, it will also address the multifaceted challenges that the new landscape in research is bringing about. At a time when multidisciplinary science is being encouraged and incentives are being given to facilitate synergism and undo the silo mentality in the life sciences, harmonizing our terminology of the various non-basic research disciplines is essential. This will allow us to frame our core values for medically related research based on the primacy of the patient's needs.

Well-defined occupational purposes and goals can help clarify basic and translational research, thereby attracting and retaining more translational researchers to enter and remain in the field.<sup>1–9</sup> Basic research is concerned with discovering and uncovering basic facts

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of nature. Translational research is concerned with discovering and uncovering the functional utility and applications of basic science discoveries, as well as their systems interplay. Between basic and translational research is a robust, dynamic, two-way flow of ideas that further fuels new discoveries and applications in either research domain. Everything in medical research is interrelated. There is no actual starting point on this circle when information is being synthesized, discovered, or translated or when it becomes routine clinical practice. Thus, bench to bedside and clinic to community or back from bedside to bench are only components of a circular process leading back to fundamental questions about the life sciences.

There is currently an ongoing change in emphasis in the clinical research enterprise toward the concept of translational research. Support for this change is being spearheaded by the National Institutes of Health (NIH) owing in part to proposals by clinical research stakeholders.<sup>1-3,10,11</sup> There is no doubt that basic research in the life and physical sciences continues to be of fundamental importance. Arthur Kornberg, who shared the 1959 Nobel Prize in physiology or medicine with Severo Ochoa, stated that “the pursuit of curiosity about the basic facts of nature has proven, with few exceptions throughout the history of medical science, to be the route by which the successful drugs and devices of modern medicine were discovered.” Indeed, study of the fundamental biology of human diseases has yielded answers and clues to the development of successful therapies. However, the multitude of terms for nonbasic research has contributed to a lack of understanding and collaboration among the research communities and to a persistent notion that nonbasic research is somehow of lesser scientific rigor or quality.

Two areas in which the consequences are particularly problematic are the promotion and tenure metrics used at research institutions and the securing of research funding. The challenges may be subtle, but the consequences, which include implied scholarly status or outright greater number of publications, can all lead to career advancement or failure. The number and quality of publications in peer-reviewed journals are strong factors considered in most promotion and tenure deliberations.

Some individuals have pointed to the greater appeal and chances of publishing in higher-impact journals when reporting for the first time on an unknown factor or novel observation.<sup>12</sup> However, it becomes more difficult to do the studies needed to understand the functions and even more difficult to develop the health application of the new factor or novel observation. Likewise, publishing these subse-

quent studies in journals with high-impact factors is more difficult.<sup>1,12,13</sup> Basic science investigators are more likely to garner more publications and in more prestigious journals owing to the increased concreteness of basic science research.<sup>12</sup> On the other hand, clinician-scientist researchers are less likely to have sufficient publications, especially first or senior author papers, when their evaluation comes up. Not only does translational research, as we define it here, tend to require more time to complete, but the authorship is more likely to be distributed among many coauthors, thus diminishing the relative credit each individual receives for promotion consideration.

Given that it is less concrete, translational research is more likely to be a large team effort, and typically several groups may be necessary to conduct a study, further diluting the credit for a given individual. Thus, neither the numbers nor the time constraints favor the clinician-scientist investigator to receive promotion or tenure.<sup>1,2,12</sup> Indeed, these factors alone can be sufficient to discourage the pursuit of a translational research career. Add patient-care duties and you have a more demanding, and possibly less appealing, career path.<sup>1-9,12</sup> Moreover, the perception of an individual's scientific ability to quantitate the quality of life of patients owing to an intervention may not appear as convincing as the ability to dissect a cellular pathway and how it may relate to a disease.<sup>1-9</sup>

Securing funding is equally challenging for the clinical, translational researcher.<sup>1-7</sup> The absence of sufficient publications weakens established record credibility. Those at an early career stage, who are already a diminishing breed, have been well documented to have a lesser chance of getting funded or even of resubmitting their grant applications.<sup>2,13,14</sup> Studies have shown that such researchers move away from research pursuits because of the unfavorable conditions for success, appreciation, and rewards.<sup>1,2,11,13-15</sup> Collectively, the above two problem areas have stymied recruitment and retention of clinical, translational researchers and led to their workforce decline.

Translational research should be today's term for moving advances in biomedical research through the pipeline and turning discoveries into applications. Use of the translational research term should become an equivalent descriptor of clinical research disciplines as much as basic research conveys for its various disciplines. Additional reasons to abandon less descriptive and less encompassing terms for the various medical science disciplines include the desire to place clinical research on par with basic research and the desire to create a true appreciation of the value of translational research.

There is a need to embrace the term that best describes the goals and expectations of the clinical research sciences. The change in terminology will serve as a catalyst for workforce growth and innovation same as the financial resources that NIH's new initiatives will contribute.<sup>11</sup> Developing such a workforce will increase the number of stakeholders, invite a broader dialogue across many areas of research, and create a balanced research portfolio that will improve the overall performance of the research enterprise.<sup>1–7,10,11</sup> This restructuring, renaming, and redefining of translational research will promote a sweeping array of dynamic changes in organization, ownership, and regulations as we know them today.

As the competition fields level off around the world, it is becoming more evident that global competitiveness will become the norm in research and development, as it has in manufacturing and services.<sup>16</sup> Like other science and technology fields, basic science and translational research are being affected by this surge of global competition. Leaders in academic medicine must see the coming globalization in translational research and adapt their vision accordingly. They must reposition translational research as a whole and ensure refocusing of terminology, resources, and efforts to foster the translation of life sciences research into public health benefits.

The United States, with all of its talent resources, must continue its leadership in science and medicine. Already a paradigm shift is occurring and is steering basic biomedical and translational research into personalized medicine that aims to be prospective and preventive.<sup>11,17</sup> This visionary direction for the medical care of the future will capitalize on our current resources and is the product of our built momentum and talent pool.<sup>17</sup> The academic medical and research communities must seize leadership in this refocusing of research efforts. Failure to do so will contribute to placing the United States in a declining trend of scientific and medical leadership.

The time has come to introduce the umbrella term *translational research* with respect to non-basic science research to unify and clarify clinical research-related disciplines. Current terms may be used occasionally as adjectives if and when they provide additional identity or specificity, much as in the basic science disciplines. With use of the term *translational research*, people will begin to hear, recognize, and understand all that it encompasses. Such terminology will more precisely define what happens or is expected to occur after basic discoveries are made and will raise the expectations for this type of research. Sharpening

our focus on translational research will directly enhance our intellectual vitality and world competitiveness and accelerate translation of scientific discoveries into health benefits for all.

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