MANAGEMENT OF TRANSLATIONAL MEDICINE: THE NEXT REVOLUTION IN CLINICAL LABORATORY?

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Abstract: Translational medicine is a biomedical discipline. Translational medicine integrates diverse medical and non-medical disciplines to improve health. Translational research is a major component of translational medicine, is generally interdisciplinary and often involves a collaboration of researches and physicians from different specialties. Translational research transforms scientific discoveries found in the laboratory into ways to prevent diagnosis or treat disease.

Keywords: translational medicine, translational research, clinical laboratory.

Basic biomedical research
Access to the best, up-to-date knowledge and information is being increasingly recognised as crucial to bridging the gap between what is known and what is actually being done in health. To improve health, findings from these basic research studies must be translated into practical applications. For many years, extensive resources have been devoted to basic biomedical (bench) and clinical (human subject) research; however, significant barriers continue to exist in moving knowledge bi-directionally between basic research, clinical research, and applications to improve health outcomes in individuals and the community. Basic biomedical research is booming its impact, in terms of new therapies and diagnostics, is growing far more modestly Translational medical research concentrates on the interface between experimental basic science and clinical medicine (1).

Translational and clinical science
Translational and clinical research is core components of a full-spectrum biomedical research enterprise. Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. It is used to translate research findings more quickly into medical practice for the purposes of diagnosing, preventing and treating medical conditions. Translational science is a way of conducting scientific research to make the results of research applicable to the population being studied. There has been little investment in methodological research to improve the tools used by clinical and translational scientists. Clinical and translational researchers require more dedicated and structured learning time and a clear path for both promotion and tenure, combined with opportunities for true scientific inquiry in an intellectual environment conducive to such (1).

Clinical and translational research
Translational research is seen as a solution to this disparity, ensuring that the bounty of discoveries is effectively translated into benefits in the everyday world of medicine.

The term translational research has emerged recently as a potentially integrative description for the various terms that have been used over several decades to capture the need for greater attention to transforming research and other information into action. The term appears to be bringing together most, if not all, of the other terms, including research utilization, knowledge utilization, research transfer, knowledge transfer, implementation science, and knowledge translation (2).

There is not yet an agreed definition of translational research. Translational research is the translation of scientific discoveries into practical applications (3).

The term translational research describes efforts directed toward converting basic and clinical research discoveries into new clinical and research tools, medications, and therapies. Translational research is a set of processes aiming to bridge the gap between laboratory discoveries and clinical medicine by harnessing and integrating advances in basic and medical sciences, and converting them into novel approaches for disease prevention, diagnosis and treatment, and also to provide feedback from clinical observations to experimental basic biology research (4).

Translational research transforms scientific discoveries found in the laboratory into ways to prevent, diagnosis or treat disease. Translational research reflects the desire to test novel ideas generated by basic investigation with the aim of turning them into useful clinical applications. Translational research also responds to the need to identify novel scientific hypotheses relevant to human disease. Translational medicine seeks to coordinate the use of new knowledge in clinical practice and to incorporate clinical observations and questions into scientific hypotheses in the laboratory (5, 6).

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. The first area of translation, from laboratory findings to clinical practice (and visa versa - from clinical observations back to the laboratory for further testing) is often called “bench to bedside and back” or T1 translation. The second area of translation, to the community and back, is called T2 translation. T2 translation has long been the purview of public health scientists, who study and facilitate the application of research findings to the community. (7).

The main goal of translational research is to identify scientific, financial, ethical, regulatory, and legislative and provide creative solutions to facilitate this process. A further goal is to accelerate the rational transfer of new insights and knowledge onto clinical practice for improving patient’s outcomes and public health. Increased complexity in biomedical research has distanced the laboratory from clinical scientists, and thus there is a need for clinical scientists who can serve as facilitators of the translational process (8).

Translational research helps turn early-stage innovations into new health products, advancing the innovation to the point where it becomes attractive for further development by the medical industry or healthcare agencies. Translation research helps to overcome such obstacles, bridging the gap between basic research and a deliverable product (9).
Clinical and translational research using multidimensional data from both molecular biology and medicine thus accelerates and shortens the process to translate preclinical knowledge into clinical applications. Translational research also describes the process of moving knowledge obtained from clinical research into a wider community or practice setting (10).

**Translational medicine**

Translational medicine (also referred to as translational science) is a relatively young area of biomedicine. Translational medicine is the broad term for a relatively new, paradigm-shifting approach to research and practice. The term translational medicine was introduced in the 1990s but only gained wide usage in the early 2000s. Translational medicine, also called translational medical science, preclinical research, evidence-based research, or disease-targeted research, area of research that aims to improve human health and longevity by determining the relevance to human disease of novel discoveries in the biological sciences. Translational medicine is a rapidly growing discipline in biomedical research.

Translational research, a major component of translational medicine, fundamentally differs from traditional, highly specialized medical research. Its pan-disciplinary “bench to bedside” approach may include medicine, pharmacology, finance, ethics, regulatory, legislative and other investigative areas and issues, from research concepts to decisions at every subsequent stage. Patients, physicians, and other practitioners tend to use the term to refer to the need to accelerate the incorporation of benefits of research into clinical medicine and to close the gap between “what we know” and “what we practice” (3).

Translational medicine is focused on ensuring that proven strategies for disease treatment and prevention are actually implemented within the community (11, 12).

Translational medicine involves the transformation of laboratory findings into new ways to diagnose and treat patients. Translational medicine, the process in which basic research moves from discoveries in the laboratory to actual clinical applications, is an important new field in science that requires collaboration across multiple disciplines. Translational medicine, has the great potential to develop and deliver new information that may assist prevention, diagnosis, and treatment of disease (13,14).

**Clinical and translational medicine**

Clinical and translational medicine plays a unique and critical role in fostering the flow of bidirectional information between basic and clinical scientists, optimizing new biotechnologies, improving clinical application of new therapeutic concepts, and ultimately improving the quality of life for patients. Clinical and translational medicine integrates clinical research with modern methodologies in systems and computational biology, genomics, proteomics, metabolomics, pharmacomics, transcriptomics, and high-throughput image analysis. Clinical and translational medicine is a limiting factor and accelerator in the process of moving from preclinical discovery and development to clinical application, validating the application of new technologies in patients, and developing new strategies to improve the quality of life for patients (3).

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biotechnologies, improving clinical application of new therapeutic concepts, and ultimately improving the quality of life for patients. Clinical and translational medicine can be used to understand the mechanisms of clinical variation between diseases, pathogenesis, biomarkers, and therapies (4).

Clinical laboratory
A clinical laboratory is a laboratory where tests are done on clinical specimens in order to get information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease. Translational research is often defined at two levels: 1) Applying and advancing research-generated discoveries in the laboratory to research trials in human subjects; and 2) Research that promotes the adoption of best practices in clinical practice settings and the community and policy development. Clinical laboratory is characterized by its focus on translating research practice into clinical practice. Translation is the process of turning observations in the laboratory and clinic into interventions that improve the health of individuals and the public - from diagnostics and therapeutics to medical procedures and behavioral changes. For clinical laboratory professionals, translational research responds to the need to accelerate the capture of benefits from research in daily medical practice. Laboratory diagnostics has undergone relevant changes providing new opportunities. In the field of laboratory medicine, the transfer may involve many sequential processes: development and validation of clinical assays, reliable implementation into clinical practice through training laboratory professionals, refining interpretation and utilization of the new information by all medical personnel. There is a lack of effective communication between clinicians, researchers and manufacturers (15).

A growing body of evidence indicates that pre-analytical variables affect test results. Specimen handling (collection, pipeting, diluting) strongly contributes to pre-analytical error. Another sources of variation is biological (both between-subject and within-subject variation), and the effects of variables (including age, gender, common drug ingestion, dietary habits, and exercise) on results obtained with laboratory techniques. The analytical evaluation comprises several measures including trueness, accuracy, repeatability, and reproducibility, as well as the determination of linearity and limits of detection and quantification (16, 17).

Conclusions
Translational medicine is the emerging field which focuses on using what is learned in pre-clinical studies to do smarter things in the clinic. Translational medicine helps in the course of predicting, preventing, diagnosing, and treating diseases. Translational medicine also uses what can be gleaned in clinical studies to sharpen and improve what is done in pre-clinical efforts to discover new medicines. Translational medicine represents a paradigm shift in the biomedical research enterprise. Pre-analytical variables can dramatically affect the results of any laboratory test.

References