Translational research and experimental medicine in 2012

Science is changing. Fast. Internationally, basic research is generating more exciting ideas and possibilities than ever before. The advances in understanding molecular targets, genetics, stem cells, drug delivery systems, devices, biomarkers, and other technologies reported week by week in peer-reviewed journals often need to be validated in clinical studies if they are to answer today’s clinical questions and strengthen tomorrow’s therapeutic pipeline. Yet budgetary restrictions and, sadly, conservative and bureaucratic regulatory attitudes mean that only a limited number of promising interventions are tested for patient benefit. To take better advantage of the possibilities available to improve health, researchers, clinicians, funders, and editors need to adopt more responsive approaches to encourage the safe and efficient translation of laboratory findings into early proof-of-concept studies in man.

The new era of translational research is being led on two fronts. One is by investigators whose ideas and skills have democratised research by enabling academic health science systems and science-led consortia to compete more widely for investment. The other is by funders, who recognise that the migration of clinical trials from developed to developing countries (where they can be undertaken to similar, if not better, standards of quality, time, and cost) releases mature infrastructures and skilled personnel for translational research. Examples of how this increased capacity can be developed are the National Institutes of Health’s Center for Advancing Translational Sciences in the USA and, in the UK, the appointment of the Medical Research Council (MRC) as lead public sector organisation for experimental medicine by the Office for Strategic Co-ordination of Health Research.

By experimental medicine we mean investigations undertaken in human beings to identify mechanisms of pathophysiology or disease, or to demonstrate proof-of-concept evidence of the validity and importance of new treatments (this definition is adapted from the MRC). Although the number of candidates for translational research is large and the likelihood of success is small, several fora exist for investors and innovators to collaborate. Yet not all innovations with potential health benefits will have obvious commercial appeal. Therefore other types of support are needed. One example to start this year is the Creative Research Awards for Transformative Interdisciplinary Ventures from the National Science Foundation in the USA. These grants of up to US$1 million have a streamlined review process and require investigators to integrate, rather than just incorporate, other disciplines. Their goal is research that changes not only practice, but also thinking.

Between researchers and funders are those with the most immediate potential to gain from more effective translation of early research: patients and practitioners. Their participation is essential to promote a culture of open-minded support for translational research and wider appreciation of both the risks and potential of new developments. Clinicians in particular should be encouraged to resist the stagnating dichotomy between clinical practice and research, and to consider instead how they can strengthen research. Although research undoubtedly informs care, the process is far more fertile when practice informs research questions, particularly when individuals with expertise at both bench and bedside become engaged.

Journal editors also have a responsibility to foster innovation by ensuring that perceived difficulty in publication does not discourage the entire culture of translational research. The Lancet recognises a continuum between discovery science and population health, and has consistently promoted the value of research to inform clinical care. In 1882, the Arris and Gale lectures defended the contribution of experimental physiology to “practical medicine”; in 1997, we made a commitment to peer-review the results from promising protocols (such as the CaVenT trial in today’s issue); and in 2006, we published an invitation for submissions of phase 1 studies. To these the editors send a strong signal that submissions of high-quality translational research and experimental medicine, which have the potential to transform clinical care, are welcome at The Lancet. Examples of this commitment can be found in early clinical applications that we have published on regenerative medicine, to which we seek to add as new frontiers open and are translated into practice. Readers should not interpret this invitation as a shift away from the journal’s existing research content, but rather recognition that as the possibilities of medicine expand, so will The Lancet to accommodate them. ■ The Lancet

For the Arris and Gale lectures see Lancet 1882; 119:939–42, 977–79, 1021–23
For more on protocol reviews see www.thelancet.com/protocol-reviews
For more on phase 1 studies see Comment Lancet 2006, 368:827–28