

Innovation Review

Response from the PHG Foundation

Introduction

The PHG Foundation (Foundation for Genomics and Population Health) is the successor body to the UK Public Health Genetics Unit and an independent non-profit policy research organisation. Its overarching purpose is to foster and enable the application of biomedical science, particularly genome-based technologies, for the benefit of human health. The Foundation has a particular interest in the way that new technologies emerging from genetic and genomic research are translated within health services, and their impact upon clinical and public health services.

Relevance to innovation

The PHG Foundation is a public health orientated organisation. Active for the past 15 years, it has significant experience in the practical translation of biomedical innovations into routine practice, bringing together techniques derived from public health practice and change management. It does this by utilising a multidisciplinary team with skills in the biological sciences, the population sciences, and the humanities and social sciences, all of whom develop a working understanding of disciplines other than their own, in our case as it relates to genetics and genomics. Our detailed understanding of the translation of genomic innovations into health services support completely the findings of the Innovation Review, that uptake is extremely patchy and represents a significant failure in the efficient and effective use of research findings. Potential benefits to population health and wellbeing are not realised.

Processes of translation

There has been much discussion in the literature in recent years about translation and translational blocks. Translation has largely been conceptualised in two distinct categories: the first, at the interface of basic science and clinical medicine was described as turning scientific understanding into a product or intervention ('bench to bedside'); the second as the translation of these products into practice for patient benefit 'research into practice'. A similar set of phases are described in the Cooksey Report (www.hm-treasury.gov.uk/d/pbr06_cooksey_final_report_636.pdf), which outlines a pathway from basic research through preclinical development, clinical trials, health technology assessment and health services research into healthcare delivery. The various gaps in translation noted would be filled through activities such as the HTA programme, NICE and the NHS SDO programme and finally through Knowledge Management programmes in the NHS. Cooksey, however, did not make the distinction between translation and translational research; nor did he consider the roles played by the population sciences, or the humanities and the social sciences, as necessary for effective translation in the real world.

We have argued over many years that the processes of translational **research**, though essential, are not enough. They will not enable the systematic adoption at the pace and scale that the current Innovation Strategy seeks to ensure. They need to be accompanied and followed by explicit change management processes, which, in themselves must also be adequately resourced. We conceptualise this change management process as the **process**

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of translation (or implementation), which is distinct from either basic research or translational research.

Essentially these processes bring together a number of elements that include ‘knowledge brokering’ and specific activities of strategic development and intervention, which can be encapsulated as requiring analysis, synthesis, dissemination and action.

Knowledge brokering, thus, would include:

- a thorough understanding of the technology or innovation itself, which may be quite complex, for example in the case of new genomic technologies
- the conditions or clinical areas that the technology or innovation would address and the expected clinical impact on an individual and population basis
- the epidemiology of relevant conditions or risk factors
- an evaluation of the technology or innovation in clinical or public health practice including health economic evaluation
- the current health services and pathways into which this technology will be placed and the wider impact of introduction within these services
- the skills required for health providers to introduce the technology, and how these will be developed
- the express needs and desires of relevant patient groups and the likely acceptability of the innovation to them
- the wider ethical, legal and social impact of their introduction (for example, issues of data confidentiality, ‘fairness’, and the wider effects on society)

These stages must include input from all relevant experts and organisations. In our experience the required input must be multi-disciplinary and fine-tuned to the innovation in question. In genomics, for example it will include laboratory scientists, geneticists, specialist and generalist clinicians and GPs, patients and patient organisations, genetic and other epidemiologists, lawyers, social scientists, ethicists, and health service professionals including commissioners and health economists.

A process of agreeing relevant recommendations for implementation and pursuing these with the appropriate organisations must follow the knowledge brokering stage. Such actions might include, for example, developing a framework for commissioners that describes the new technology, appropriate applications, the care pathways in which it should be placed, quality aspects of such pathways and estimated volume of provision; the development of a professional network to continue taking the innovation forward; the development of supporting resources (such as educational resources for professionals or information for patients); and a programme of further questions that need to be answered (for example, in the case of implementation of new technologies for genetic tests, how incidental findings will be dealt with).

It can be seen that both the knowledge brokering and implementation phases are highly skilled, resource intensive and time-consuming. Further, even if they possessed the necessary skills, those at the forefront of the innovation, who are likely to be basic researchers or busy clinicians, would not usually take the lead in initiating these activities, nor would they prioritise this work. Our experience is, however, that if others undertake their organisation and leadership senior scientists and clinicians are keen to participate and to engage.

PHG Foundation experience

Our experience is that the translation process requires a detailed understanding of the science involved, the clinical, epidemiological and public health implications, and the ethical, legal and social context of its introduction, as well as skills in change management. These elements must all be present for the efficient and effective introduction of innovation into the NHS. We are not aware of anyone but ourselves using the model that we describe. There are two main reasons for this:

- 1 **Skills and capacity:** There are very few individuals and organisation that have the necessary multi-disciplinary skills to undertake this work at a level that commands the authority of the relevant established researchers (innovators), clinicians and policy makers. The profession of public health provides the essential basis including a population perspective, health service evaluation and change management. However, in the UK, particularly in the area of modern biomedical technological innovation, there are very few public health specialists who understand the essentials and have the necessary experience.
- 2 **Resources:** These processes are not explicitly resourced. They do not count as research and so cannot command research grants. Financially constrained commissioners do not see it as their responsibility to fund such cross-cutting activities as described above; commercial organisations have in the past often failed to see the immediate value. Yet, in essence, the resources that are spent on harnessing the benefits of scientific research will be wasted if this third stage (following basic research and translational research) is not explicitly considered in the translational pathway, established as an essential process and explicitly funded.

The PHG Foundation has had now almost fifteen years experience in the translation of genomic and genetic science into practice. Examples of practical translational work in the context of genomic medicine are shown below:

1. Consideration of the introduction of array CGH as a first line diagnostic technology in the investigation of developmental delay: www.phgfoundation.org/reports/4969
2. The use of cell-free fetal DNA in prenatal testing (including prenatal screening): www.phgfoundation.org/reports/4985/
3. Introduction of specialised services for inherited cardiac conditions that will utilise new genetic testing technologies. Work included the development of a commissioning framework and promotion through the NHS Heart Programme: <http://www.phgfoundation.org/reports/4986/>

Many other examples are available on our website:
www.phgfoundation.org/pages/work.htm.

One current programme is focussed on the expected impact of whole genome sequencing technologies on health and health services, and will include a range of recommendations to optimise their use within UK NHS: www.phgfoundation.org/pages/wholegenome.htm

Such work takes place over a period of around 12-18 months, led by our multi-disciplinary public health team, and includes significant background research, an expert Steering Group, collection and analysis of wider 'stakeholder' input, an explicit process of policy development, and considerable follow-up with relevant parties to support implementation. The efficiency of these processes is crucially dependent on having basic in-house knowledge of the science and its implications, in our case genetics and genomics, and not learned *de novo* each time. However, demand for our services outstrips capacity, since our team is relatively small and our funding is predominantly from a small, independent source.

We believe that this is a model that is generalisable to other aspects of innovation and the health service, for example the neurosciences, imaging, or other clinical areas such as obesity and diabetes. Experienced public health physicians should be well placed to lead such multidisciplinary activities, but academic colleagues aside, there are few within the service that have the necessary scientific background, or interest, to take on such work. Moreover, the present plans for the public health service appear not to place high priority on health service links. Clinicians could take on such a role, but if they do, will need training in change management and to gain an understanding of epidemiological and public health principles. It is entirely possible that the current generation of clinical leaders might find such work exciting and challenging.

We are aware that the NHS and DH are familiar with using management consultants for a variety of activities that pertain mainly to finance, organisational change and transformation. We do not believe, however, that conventional general management consultants are able to effect the translational changes necessary to introduce major innovation into health services because of their lack of specialised knowledge; and suggest that the establishment of multidisciplinary units such as we describe will be much less costly and more effective in its objectives. We would be happy to share any further information with the Innovation Review if requested.

Recommendation

We recommend to the Innovation Review that more attention should be paid to the implementation phase of innovation, a process that includes knowledge brokering, and which we characterise as involving analysis, synthesis, dissemination and action. The translation or implementation of innovation should be regarded as an explicit activity requiring dedicated resources and the development of specific skills and capacity. It is to be distinguished from translational research. The PHG Foundation (Foundation for Genomics and Population Health) is a public health organisation with experience in this work in the context of genomics. Its experience could be a model for use in other fields and could provide the necessary core of expertise for such further expansion.

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