

January 2016

Response submitted by:

Philippa Brice
philippa.brice@phgfoundation.org

Leila Luheshi
leila.luheshi@phgfoundation.org

Accelerated Access Review: interim report

The NHS faces a massive practical and financial burden in the form of rapidly increasing health needs and demands, as a result of factors including the ageing population, rising patient expectations, and new technological opportunities. The PHG Foundation believes that more personalised healthcare can deliver solutions to these issues via:

- An increased focus on disease prevention, including more personalised prevention
- More personalised care and treatment, including greater patient involvement in care
- Harnessing new technologies that can make care more personalised and effective

We set out these proposed solutions in more detail in our current [Innovation Manifesto](#).

Scope and aims of the Accelerated Access Review

The broad aim of the Accelerated Access Review, to speed up access to innovative drugs, devices and diagnostics for NHS patients, is therefore in line with our own belief in the potential value of the life sciences and digital health technologies to deliver improvements in healthcare, although it is important to note that there is currently a paucity of evidence to demonstrate robustly that accelerating health system access to innovations will indeed address health service needs.

There is currently a paucity of evidence to demonstrate robustly that accelerating health system access to innovations will indeed address health service needs.

Innovations that impact across clinical boundaries are also poorly supported by current systems of funding that create siloes within distinct clinical specialties.

Whilst we believe that this will indeed be the case, in order to demonstrate both this point in general and the success of the Accelerated Access Review in particular, we suggest that it will be important to set out defined measures of success alongside aims in the final report.

Recommendation: The Review should include requirements to generate evidence that measures the results of accelerating access to innovations in both faster patient pathways and improved health outcomes.

Innovations and their operating environment

Issue: There is more to health innovation than product invention and development

In his introductory letter, John Bell describes innovations as including therapeutics, devices, diagnostic and digital 'products'. The problem with this categorisation is that it is an oversimplification that fails to recognise that most innovative products are used within much more complex care pathways (diagnosis, treatment and care) – all of which may span primary, secondary and tertiary care and impact on different clinical specialties. For example, primary care physicians must decide which patients presenting with colorectal bleeding to refer for specialist investigation; new diagnostics may change (and improve) the way in which they triage patients for referral, with potential knock-on effects for the specialist clinic as well as their own practice.

It is rare that even direct substitution of one product for another within these care pathways does not also have significant impacts across other aspects of the service as a whole. Innovations that impact across clinical boundaries are also poorly supported by current systems of funding that create siloes within distinct clinical specialties.

Example: Non-invasive prenatal testing using genomic technology

The typically wide-ranging impact of newer, cutting edge technologies, such as genetic and genomic tests, is notable. For example, non-invasive prenatal testing (NIPT) of fetuses, arguably one of the most ground-breaking and potentially transformative health innovations of recent years, will have impacts across the antenatal care pathway, which is a complex multispecialty service spanning primary, secondary and potentially tertiary care services. These include:

- A new group of patients being offered testing and consequent changes in the flow of patients through the pathway
- Changes in the demand for amniocentesis provided by the fetal medicine service
- Major change to the national fetal anomaly screening programme procedures for Down's Syndrome

Translational / implementation research is a vital activity, but we suggest that it should not be the main focus of this Review, since extensive infrastructure and funding to support NHS R&D activity already exists (notably in the form of the NIHR).

- A demand for training of health professionals to offer appropriate information, counselling and consent, and a need to update written information to pregnant women about this new test and its implications for their pregnancy

So the innovation becomes part of a new clinical pathway. It follows that offering innovative 21st century medicine is rarely a question of ‘diffusion’ - an individual clinician hearing about a product and substituting it within their current practice – but more a question of whole system change with introduction across a care pathway, agreed by a multidisciplinary team and compatible with funding and provision of services across a trust or even a wider network.

Who should be the ‘innovators’ and for what innovations?

Issue: Not all health professionals can or should be developing and evaluating health innovations, but all health professionals must be empowered to adopt those innovations that research shows to be cost-effective

Health service innovators – by which we mean implementers of innovative practice and adopters of innovative products, as opposed to the inventors of those innovations – are vital, but arguably not all individuals, teams and services can or should be innovating at the same level.

There are some 230,000 medical practitioners either registered in specialist practice or in general practice, not to mention doctors in training, nurses, laboratory scientists, dieticians and other allied health professionals. Whilst we would hope and expect that they would all be open to new products or ways of working, we surely expect that for their choice of diagnostics or treatments for a given group of patients, the vast majority would largely be following evidence based guidelines, albeit adapting these on the basis of their own professional experience and their understanding of individual patients. It is arguably only at the operational level that most should be introducing innovations themselves – for example, deciding on the best way of introducing an agreed new test or treatment locally, or on different ways of progressing patients through existing care pathways.

In general, it is likely to be mainly more specialised clinicians (for example, in teaching hospitals or the Biomedical Research Centres where clinical care and research are more closely intertwined) who are true innovators, in the sense of trying to introduce new ‘products into practice’ – what is sometimes known as translational research, which we term ‘implementation’ clinical research.

Translational / implementation research is a vital activity, but we suggest that it should not be the main focus of this Review, since extensive infrastructure and funding to support NHS R&D activity already exists (notably in the form of the NIHR). Rather, the Review should concern itself

primarily with ensuring swift movement from innovation arising from any origin, including but not limited to specialist centres, to equitable implementation throughout the NHS.

Recommendation: The Review should distinguish between two crucial but distinct activities, the development and testing of innovative products and service pathways by specialist clinicians, and the implementation of innovative products and services across the health service by all front-line health professionals.

Issue: In our view, Academic Health Science Networks, whilst being important centres for the development of cutting-edge innovations with the potential to improve healthcare, are not fundamentally well suited to lead on NHS-wide adoption and diffusion of these innovations.

Individual clinician researchers are genuinely keen to make improvements to the care of their own patients and demonstrate health benefits, but they typically lack both opportunity and incentives to support wider efforts, such as developing national guidance.

Example: Supporting uptake of new diagnostics for intellectual disability

A Cambridge group developed new regional clinical guidance on the investigation of intellectual disability / developmental delay, based on extensive research into new genomic diagnostic methods and evidence. Supported by the PHG Foundation, they were also able to develop tools to support uptake in the form of a supplementary diagnostic flowchart for clinicians and a new tailored guide for the parents of patients.

The real issue: from innovation to implementation

Issue: The main barrier to achieving the goal of accelerated access to improved patient care through healthcare innovation is the ongoing failure to achieve the pathway-specific and system-wide changes necessary to embed those innovations proven to work effectively and affordably in research or pilot programmes into the health service in ways that achieve equitable and efficient access by patients to the benefits they offer.

This is not just a question of making healthcare practitioners 'innovation ready' and encouraging 'diffusion', but rather of undertaking the painstaking and often problematic processes including:

- Assembling evidence of clinical effectiveness and utility that empowers and motivates clinicians to change their practice
- Undertaking system redesign that facilitates delivery of the innovative services their patients want in ways their local health economy can afford
- Developing guidelines that provide the practical peer-developed support frontline clinicians need to change their practice

- Educating of staff in new skills and practices
- Persuading commissioners and trusts to invest and take a long term view, particularly where 'spend to save' arguments have to be made in the face of short term budget pressures
- Coordinating the cooperation of different centres and services in national strategic development

Putting really transformative innovations in place in the NHS must involve major redesign and development of NHS processes and pathways. This is typified by current planning for the ongoing revolution in NHS genomic services, which is being achieved through a number of interlinked initiatives including:

- The reconfiguration of genetic laboratories to offer streamlined, national, high quality genomic diagnostic services across multiple clinical specialities
- The development of specialist centres for rare diseases
- Development of infrastructure and agreed common practice for clinical genomic data sharing including initiatives developed by the National Information Board
- Procurement of sequencing, analytical and data storage capacity through the 100,000 Genomes Project
- Development of rare disease registration services within PHE

Recommendation: The Review needs to ensure that proposals prioritise achieving safe, effective and equitable implementation of useful innovations across the NHS, as the essential, rate-limiting step, rather than ensuring swift access to the NHS market for innovative commercial products.

Obviously, different stakeholders have varied needs that ideally will all be addressed by the review, and so encouraging a supportive environment for innovation is also desirable, but delivering equitable access to health services and interventions that improve the health outcomes for patients and the wider population should remain the priority.

Using innovations ahead of formal evaluation and regulation

Issue: Current regulatory frameworks exist at least in part to ensure both patient safety and efficacy of the intervention, and curtailing or circumventing these regulations creates both risks and benefits for patients.

Achieving a suitable balance between risk and benefit is vital, and this sort of decision-making is not something that every health professional can or should undertake, only those who are suitably specialised and operating at the cutting edge of their own area of practice.

Recommendation: Only the most specialised health professionals in a position to make an effective risk-benefit calculation and articulate this to their patients, should be considering using innovative technologies (diagnostics, medicines or other treatments) that have not been subject to rigorous formal processes of evaluation. This should continue to be the subject of special arrangements similar to those for clinical pilots and implementation research and the existing processes allowing the compassionate use of unlicensed medicinal products.

Appropriate obligations for post-marketing surveillance should also be maintained for all innovations that are approved for accelerated access.

Issue: The aims of the last NHS reorganisation of commissioning organisations has led to the current focus of NHS commissioning on contracting, rather than being engines that drive innovation and its adoption.

Health service commissioners will need support to access and properly interpret good evidence about effectiveness and cost effectiveness of innovations as relevant to their health systems and implement in the light of local circumstances and configurations.

Recommendation: Additional NHS commissioning capacity is urgently needed to undertake the clinical engagement, strategy development, service specifications and delivery of innovative technologies.

Efforts to accelerate access to innovations cannot bypass decisions regarding implementation, affordability and prioritisation by individual hospital trusts and commissioning bodies.

The Review should also examine the extent to which existing evaluation processes are fit for purpose for accelerated access to innovations, *i.e.* are they sufficiently flexible, quick, easily understood and adaptable to more personalised medicine, where subpopulations are smaller but more closely characterised?

A patient pathway and health systems approach

Innovations should never be considered as isolated products, but always in relation to particular patient care pathways and inter-twined networks of clinical service provision. The roles of both NHS England and Public Health England in supporting NHS system change in response to emerging scientific opportunities merit urgent consideration. The 100,000 Genomes Project is an ideal opportunity to pilot this sort of process for transformational change within the NHS arising from new technological opportunities, but to achieve this, a significantly increased emphasis on system change to underpin the most effective implementation will be needed.

There is also a need to identify which potentially transformative innovations are likely to require large scale health system changes and to agree a clear plan for how stakeholders (commercial, research, healthcare providers, patient and public groups, regulators, commissioners) will work together to ensure that health services are ready.

Dedicated resources are needed to undertake this sort of collaborative policy development work, exemplified by our recent national strategic review and policy recommendations to allow rapid and optimal utilisation of the potential for improvements in prevention, monitoring, detection and control of infectious diseases through recent progress in pathogen genomics, set out in the 2015 report *Pathogen Genomics Into Practice*.

Failure to undertake this sort of work results in significant opportunity costs as initial government investment in great science is wasted through a lack of concerted effort to plan the best approach to NHS deployment.

Stronger emphasis on clinical engagement and leadership

The Review's current emphasis on increasing patient focus and involvement is highly laudable, but in practical terms achieving better patient access to the best innovations depends on engagement with the people who will deliver these, which are often (although not always) clinicians and allied healthcare professionals. Frontline clinicians are generally highly focused on improving patient care and outcomes and are therefore already motivated to seek out opportunities to adopt innovations.

However, the PHG Foundation's experience in developing policy to support the introduction of scientific innovations within health services over the last nineteen years is that the structure and function of the health service does not empower clinicians to act on this motivation, and instead stifles this impulse through failure to provide the resources, training and, most importantly, time needed for any medical professional to deliver changes in their practice safely and effectively.

Involvement from patients, researchers and commissioners in developing new pathways and systems for the implementation of innovations is also essential, as set out above, but a clinically-led approach is the most generally effective. In order to undertake this role, health professionals will require dedicated resources, incentives and support, including:

- Appropriate understanding of the underlying science and implications
- Evidence of clinical utility / patient benefit
- Consideration of how existing care pathways could be adapted or redesigned
- Support and funding for collaborative work to develop or adapt care pathways, professional standards and other policy work needed to support optimal implementation of innovations

- Funded and protected time out from clinical duties for such work
- Professional recognition of such work

Inclusion of such activities in professional training and continuing professional development would be desirable.

It is also essential to recognise that what works in a centre of excellence may not necessarily work in the same way everywhere; inclusion of the views of non-specialist health professionals is a highly valuable element in collaborative efforts to underpin the introduction of innovations.

Responses to individual consultation questions (PHG Foundation responses shown in bold)

Proposition 1: Putting the patient centre stage

Patients should be given a stronger voice at every stage of the innovation pathway. An increasingly empowered population of patients is already taking advantage of innovation, particularly in the digital sphere, to manage their own care across a range of conditions. But helping all patients to become active participants in decision-making will require better-developed system architecture at every stage of the innovation pathway.

How could patient-led outcome measures inform the evaluation of new products and the decisions made by regulators and other key bodies in the system?

Establishing appropriate frameworks and methodologies for patient-led outcomes to inform evaluations will be important. It is essential that evidence of the value of measures to accelerate access in terms of faster patient pathways and improved patient health outcomes should be generated and reviewed.

What are the key concerns for patients across the whole pathway of an innovation product?

Individual patients are likely to be concerned with access to a particular diagnostic or therapeutic, and their interests in this area are likely to be best represented by patient groups. However, equity of access to innovations is an important national issue and one that requires urgent consideration from a patient perspective. At present, patients who are able to access individual areas of clinical excellence and expertise have much more opportunity to benefit from innovations than patients in the rest of the country.

Prioritising widespread access to innovations via national adoption should therefore be a priority for the Review, and it is important to recognise that existing systems and incentives for implementation research and development do not address these.

How can we make sure our proposed system architecture includes sufficient opportunity for patient interaction?

Both patient and public groups should be involved in the development of trials and policy development related to the use of scientific and technological innovations to improve health. This includes anticipating the potential impact of innovations on current clinical practice and developing proposals for necessary changes.

Condition-related patient groups are best placed to advise on patient concerns and priorities for that condition and its management, working alongside specialist clinicians. However, the implementation of any innovation will impact in some way on the healthcare provided to other patients not involved in the pathway.

It is therefore vital that the public voice is also involved in the decision making of the implementation and adoption of new innovations as part of the overall healthcare prioritisation decision making process.

The inclusion of wider public groups will ensure appropriate representation of ‘potential patients’ – especially if there is to be greater emphasis on harnessing innovations to enhance disease prevention.

Proposition 2: Getting ahead of the curve

We need a radical new approach to accelerate and manage the entry of significant, promising, potentially transformative new products into our health system. We have to position ourselves for the future if we are to keep as far as possible ahead of the curve: getting the best value for innovation that promises the most benefit to patients.

How could each component of the accelerated pathway for medicines, devices, diagnostics and digital health products work?

The important issue is that they should not work in isolation, but in the context of the relevant clinical pathways in which they may operate. Consideration of the impact (including potential benefits) for all likely applications is needed to gain suitable insight into the transformative potential of a technology, although the area closest to initial clinical utilisation may be much narrower.

The impact of the accelerated pathway for any innovation should be evaluated in terms of measurable improvement in patient outcomes.

What could be the role of key national bodies in delivering the accelerated pathway and how can these bodies ensure patients are embedded in all decision-making processes?

All trials of innovations within the NHS should certainly adhere to common policy on data sharing within the NHS, as currently too much NHS funded research generates data that is not shared appropriately across the NHS. Effective genomic data sharing policies could become an important exemplar of this.

Proposition 3: Supporting all innovators

As well as accelerating access to a select number of the most promising new products, our end-to-end pathway should be more responsive to all innovation that contributes to better outcomes for patients and more efficient ways of delivering care.

How useful do you find our proposals for a new system of guidance and support?

The concept of interlinked systems for the trial, evaluation and implementation of innovations at local and national levels are constructive, provided the various bodies concerned can work together effectively. One of the limitations is a current lack of incentives for local hospitals to work together to share best practice and learning on useful innovations; indeed, competition for commissioned service delivery is a major barrier to such activity, especially where innovations are too costly to be supported at multiple sites. However, collaboration is badly needed and so the proposed national Innovation Partnership would need to address this issue.

Are there any quick wins or significant barriers to innovation that our proposals for a new system support do not address?

One important limitation is the focus on products. Not all innovations are as well defined products as a specific new therapeutic or diagnostic, and more importantly they do not operate independently but in the context of clinical care pathways. Greater recognition of the relevant care pathway environment for any given innovative product will be invaluable in effective evaluation.

The obvious quick win would be to provide dedicated resources and develop the necessary infrastructure (similar to that currently devoted to supporting clinical research) to support national implementation. This would need to work with all stakeholders to assess the potential wider impact of an innovation on existing care pathways, clinical guidance and budgets, and to develop constructive recommendations for steps to appropriately equip local and national healthcare commissioners and providers to adopt cost-effective innovations to improve patient care.

The obvious quick win would be to provide dedicated resources and develop the necessary infrastructure (similar to that currently devoted to supporting clinical research) to support national implementation.

The equitable implementation of innovative technologies that offer improved patient care relies on the associated development of amended care pathways and health systems.

Proposition 4: Galvanising the NHS

The NHS must be an active partner in promoting innovation, and must be incentivised to adopt new products and systems quickly and effectively. We need to harness the influence of clinical and system leaders, as well as patients themselves, to act as champions of change. The benefits of innovation in terms of patient care, outcomes and system productivity need to be properly articulated. System improvement expertise needs to be hardwired into the system, through education and training from the bottom up.

How can the NHS be incentivised and supported to introduce innovative technologies?

Firstly, it is necessary to note that patient access to innovations will remain dependent on national and local considerations of affordability and prioritisation.

Secondly, the equitable implementation of innovative technologies that offer improved patient care relies on the associated development of amended care pathways and health systems.

To incentivise the process of developing system-wide changes to care pathways and procedures, clinical engagement is crucial. The best way to achieve this is to find a means of giving individual clinicians the time and incentives not only to participate in developing and evaluating innovations that could improve patient care, but also in sharing their learning with local and national colleagues, and in national consensus building and policy development for appropriate amendments to care pathways, clinical guidance and commissioning to support widespread adoption of beneficial innovations.

Incentivising teaching hospitals to champion innovation is a good idea, mirroring as it does the normal tendency for centres of excellence to develop around individual clinical experts and teams, but it will be important also to incentivise their participation in wider implementation efforts – perhaps by requiring a certain amount of clinical expert time be allocated to this. If we are to rely on AHSCs to champion change outside their own area, appropriate scrutiny and incentivisation will be essential.

Requirements for appropriate surveillance and review of the safety and clinical impact of innovations will need to be maintained, irrespective of whether they have been accelerated into clinical practice.

How could a fund to support system re-design operate and how could it be funded?

Provision of dedicated resources for collaborative policy development work of this kind (typified by our 2015 national strategic review and policy recommendations to make the most of pathogen genomics

for the care and control of infectious diseases, Pathogen Genomics Into Practice) is essential. Failure to do so results in opportunity costs; national investment in system redesign should actually save money in the mid- to long-term, by accelerating the introduction of innovations that benefit patients – provided that consideration of the cost-effectiveness of an innovation as an element of benefit is retained.

It would therefore be advisable to fund this directly via the Department of Health, to avoid any concerns over inappropriate influence of commercial concerns. The respective roles of NHS England and Public Health England in the process should be reviewed.

Of note, the 100,000 Genomes Project is an invaluable opportunity to pilot the process for transformational NHS system change based on technological innovation.

How could this proposed new system architecture be developed in a way that galvanises the NHS to promote innovation?

An insistence on the inclusion of health economic measures and due consideration of their implications would be of paramount value. At the moment it is much easier to demonstrate clinical than cost benefits, and to reveal upfront costs over longer-term savings, especially where expenditure in one budget yields reductions in costs in another. Some method of joining these elements nationally, and in supporting local CCGs and hospitals to do so similarly, is needed.

Whilst inclusion of in-depth health economic analyses may be impractical for many trials, an increased requirement for the provision of basic information on comparative costs and expected financial benefits is needed, especially if supported by expert advice and guidance.

What are the costs and benefits of this new approach, which positions the NHS as an active partner in promoting innovation?

Nurturing a receptive NHS environment for innovations that deliver better patient care is a laudable aim in general, and developing the NHS as the premier national testbed for healthcare innovations is a good idea for national health and wealth. It will however be important to retain a focus not on innovation for innovation's sake, but rather on recognising and adopting innovations that have proven or significant potential to improve patient care and outcomes.

NHS staff should therefore be encouraged to be active partners in developing, evaluating and implementing useful innovations where appropriate, but not to prioritise innovation ahead of patient care.

An insistence on the inclusion of health economic measures and due consideration of their implications would be of paramount value. At the moment it is much easier to demonstrate clinical than cost benefits...

We have real concerns about the reliance on the AHSN as a means to support the entirely laudable aims of coordinating innovation and alignment with models of care and national partners

Accelerated implementation of innovations will necessarily involve some degree of risk, which will vary considerably between different innovations but may not become fully apparent until widespread adoption is achieved. This risk should be explicitly acknowledged in each case, whilst also emphasising steps that are being taken to safeguard patients.

Finally, given the pressing need to provide more and better healthcare with limited resources, healthcare innovations need to provide solutions to financial limitations rather than exacerbating them.

Proposition 5: Delivering change

A new system architecture is required at local and national level to accelerate development of, and access to, the best new products. This must build on existing structures, rather than duplicating them, to streamline the work of key health bodies around their collective goals. This new infrastructure could incorporate a network of innovation exchanges, with a complementary Innovation Partnership at national level. A central part of this partnership will be collective agreement of all those involved to the ambitions set out in this review.

How should we define the remit and priorities of the Innovation Exchange function and the Innovation Partnership?

We have real concerns about the reliance on the AHSN as a means to support the entirely laudable aims of coordinating innovation and alignment with models of care and national partners. In our experience, AHSNs typically prioritise translational research, and there is a lack of incentives for members (however highly skilled and productive) to participate in efforts to support widespread NHS adoption of innovations – their professional priorities are naturally funding for their own research among patients and publication of the results. However, it is desirable that they should also participate in the development of professional consensus, national clinical guidance and supporting resources for health professionals and patients – all of which require a substantial time commitment.

Since significant barriers to national implementation efforts for innovations already exist, it will be essential to have a really robust mechanism to incentivise and scrutinise constructive AHSC participation in supporting change, innovation, and sharing of learning and good practice via the Innovation Exchanges and Innovation Partnership. Similarly, the Innovation Partnership should have the power to impose priorities and SMART objectives for the Innovation Exchanges linked to funding.

Efforts should be made to ensure that the patient / public voice in Innovation Exchanges and the Innovation Partnership is consistently supported, not as a token presence serving to fill a tick-box on applications for research funding, but a powerful influence from the earliest stages of the process of supporting implementation through to national uptake. Patient priorities and feedback should be an important element in trials and commissioning guidance.

Should the proposed Innovation Partnership and Concordat be held to account by a supporting co-ordinating committee?

Definitely, with appropriate transparency. Very clear accountability and requirements for the Innovation Exchanges is also desirable.

What are the costs and benefits of the proposed new system architecture to accelerate the development of, and access to, the best new products?

The hub and spokes model could work very effectively provided that there is a genuine commitment to ensuring it will deliver results and serve patients and the public as much as commercial and clinical interests.

It is worth paying attention to how far the system will support innovations that originate in the NHS as well as those of academic and commercial origin, given that commercial developers will potentially have greater scope to fund trials and indirectly influence implementation planning (for example, by funding patient representation). This is not to say that the commercial voice should not be appropriately represented, as they are important stakeholders in innovative healthcare, but 'home-grown' innovations should also be encouraged wherever possible.

The PHG Foundation is an independent genomics and health policy think tank based in Cambridge, UK. Our mission is making science work for health.

For more information about the PHG Foundation visit
www.phgfoundation.org