Accelerated Access

Review of innovative medicines and medical technologies supported by Wellcome Trust

Accelerated Access Review: Interim report

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Accelerated Access Review: Interim report

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Re: Accelerated Access Review

I was delighted and honoured to be asked to act as the independent Chairman of this review.

I was privileged to be one of the team that developed the first NHS Constitution. It contains this ringing declaration about the value of the NHS to the people of this country:

“It works at the limits of science – bringing the highest levels of human knowledge and skill to save lives and improve health”.

The question at the heart of the review is this: can we continue to honour that great claim in what is simultaneously the most exciting era for innovation in all health technologies in recent times and a time when all international health economies, including ours, are facing unprecedented cost pressures and constraints?

This dilemma is brilliantly captured in a paper prepared by Prof. Sir John Bell, the Chairman of our External Advisory Group, to set out some of the context for the review from the national perspective. I have appended this paper at Annex A.

As Chairman of the Board of a leading NHS Trust, I also have my own perspective. I am reminded on a daily basis of the restless drive of our clinicians and researchers to work at “the limits of science” and the “highest levels of human knowledge” in order to find new and improved ways of treating and caring for our patients – in their own homes and in our hospitals. I see our partners in primary and social care, and in mental health services, working to the same end.

But I also see the threats we are facing.

We have a strong science base in this country. We do outstanding basic and translational research. Our research infrastructure has been enhanced and is working very effectively. We have the potential to build upon our thriving life sciences industry, through which our economy as well as our patients will benefit. But we will lose ground if research budgets are threatened, if our leading academic hospitals cannot afford to support research or use the latest drugs and technologies to pioneer developments in the treatment of the most complex conditions, or if the wider system is paralysed by the

cost pressures it is facing and fails to invest in the change and innovation it requires to deliver better care to patients more efficiently and productively.

Patients can and should be at the centre of this stage. They and their representatives have been fully engaged in this review. For them, and in the best interests of the economy and our health system, we have to meet two challenges.

First, we have to find a way of getting ahead of the curve in anticipation of the potentially transformative technologies that are on the horizon, and in some cases already with us, so that these can be brought to our health system in a sustainable way which benefits our patients, which taxpayers can afford, and which works for innovators themselves.

Second, we have to energise our health system so that it is receptive to innovation and sees and uses new technologies as the best lever for delivering improved care with greater efficiency.

Underpinning these challenges is the recognition that the NHS currently faces significant financial constraints. In an environment where the system is being asked to make significant efficiencies, we need innovation more than ever both to improve productivity and to generate wider benefits for UK growth. The review's recommendations will support this, exploring how accelerated access to the most transformative products can be positioned as part of the affordability solution, rather than the problem.

My engagement on this review has given me real confidence that there is a collective will in our system to face and resolve those challenges. We have had a tremendous response – a rich source of engagement and evidence on which we can draw. I am particularly grateful for the input of my External Advisory Group and its Chair, Prof. Sir John Bell, the five Champions – Prof. Richard Barker, Dr Stuart Dollow, Richard Murray, Hilary Newiss and Rob Webster – as well as the Accelerated Access Review team.

The interim report attached to this letter is deliberately high level. We have boiled down the evidence we have heard and the work we have done to five key propositions and some key areas for action which, provisionally, we think could deliver a real step forward. We have some outstanding material on which to draw for our final report, including examples of successes – and some failures – in our current system. Our aim here is simply to set out where we have got to in order to test that preliminary analysis and, with stakeholders and colleagues in all the key national organisations, to use the next phase of our review to plug gaps and work up the proposals that really will make a difference to a level of detail that will support their implementation.

There is still much to do. But we are on course to let you and your Ministerial colleagues have a full report and recommendations in Spring 2016.

Sir Hugh Taylor
Chairman

Approach

1. The review has explored the question of accelerated access through four workstreams spanning the development pathway and a fifth focussing on patient engagement in all parts of the pathway. Each workstream has looked across issues concerning drugs, devices, diagnostics and digital health products.

2. Two pieces of background work were completed early in the review process – one to map the existing development pathways for drugs and medical technologies, the other to explore learning from international comparators. These pieces informed much of our early stakeholder engagement, with many of their findings reflected in the propositions surfaced in this interim report.

3. We welcome the huge interest we have had in the review so far. We have reached over 600 stakeholders, including patients and carers, the NHS frontline, researchers and industry (spanning the pharmaceutical, device, diagnostic and digital sectors). This engagement has included mail-outs, 121 meetings and a series of roundtables hosted by umbrella bodies including National Voices, the Association of Medical Research Charities and a number of trade associations. Underpinning this process has been an open and transparent web engagement exercise which attracted 392 comments, 54 submissions and 97 survey responses. The first stage drew to a close on 11 September, with a pause in engagement to collate and analyse the feedback submitted.

4. Our first stage of engagement has identified a number of factors driving the rapid uptake of innovative products (Figure 1), which the review will look to build on as a new accelerated access landscape is developed.

Figure 1 – Common drivers of rapid access

5. We have also been able to build a rich picture of the barriers or systemic tensions perceived to be slowing access in the existing landscape. While Figure 2 may not reflect every barrier in the system, it does highlight those which stakeholders have identified as particularly key to accelerating patient access, as well as a number of overarching themes. We will use this analysis to test our conclusions and proposals throughout the review's next stage of engagement.

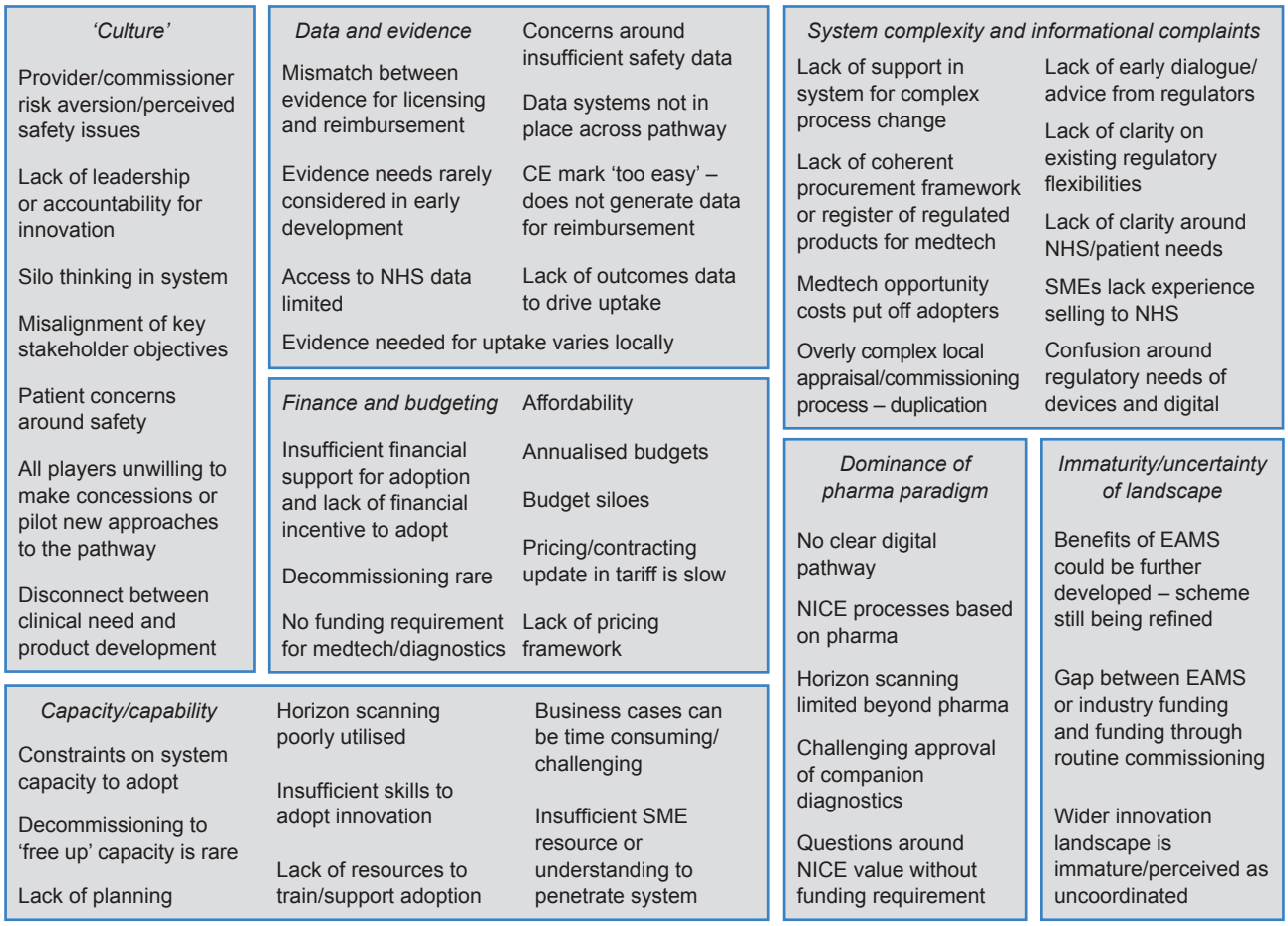

Figure 2 – Perceived barriers/tensions to rapid access

6. We asked stakeholders a number of questions (Figure 3) to stimulate debate and inform discussion across workstreams 1 to 4, with questions about patient engagement embedded in each workstream.

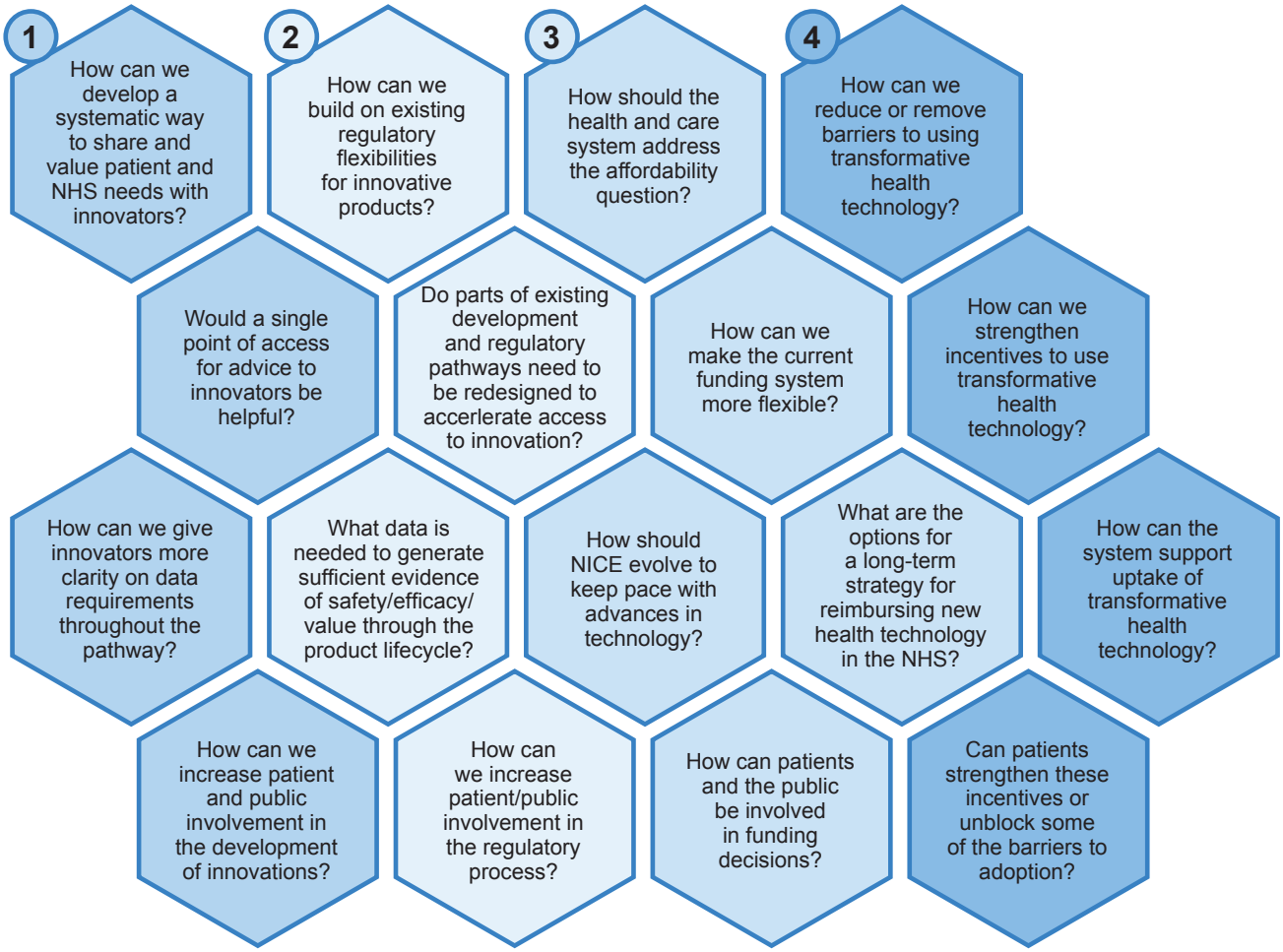

Figure 3 – Key questions

7. From the responses received to these questions, we have distilled five key propositions and a number of provisional, high-level conclusions associated with each proposition. We propose to use these as a framework for more detailed analysis and evaluation, and for further engagement with stakeholders in the next phase of the review. The propositions are outlined below, with further detail presented over the following pages of the report:

    - **Putting the patient centre stage:** Patients should be given a stronger voice at every stage of the innovation pathway.
    - **Getting ahead of the curve:** A radically new approach is required to accelerate and manage entry into our health system for the emerging products that promise the most significant, potentially transformative impact in terms of patient benefit and overall value.
    - **Supporting all innovators:** In addition to accelerating access to a select number of the most promising new products, our end-to-end innovation pathway can, and should, also be more responsive to the wider, irrepressible surge of innovation presented at all levels of the system,

particularly where its introduction will contribute to better outcomes for patients and more productive and efficient ways of delivering care.

- **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.
- **Delivering change:** Building on existing health system structures, a new system architecture is required at local and national level to accelerate access to the best new products and related models of care on a sustainable basis, within a framework of collective agreement to ambitions and goals.

8. We would welcome early feedback on these propositions and provisional conclusions, in particular on potential gaps. We will be inviting further engagement with stakeholders as we iterate and develop this framework before setting out our final recommendations in Spring 2016.

PROPOSITION ONE: PUTTING THE PATIENT CENTRE STAGE

Patients should be given a stronger voice at every stage of the innovation pathway.

9. Giving real life to this proposition will provide the health and care system with an insistent stimulus to search for new ways of diagnosing, treating and caring for patients by:

    - directing innovation towards the outcomes that matter most to patients;
    - giving further impetus to earlier trials and pilots of new products, as affected patients are more accurately stratified and patient appetite for risk (higher, we are told, than is often allowed for) is more explicitly taken into account; and,
    - increasing pressure on the system to pull through promising new technologies and models of care, while decommissioning superseded or ineffective products and ways of working.

10. There is much activity in this space already, with an increasingly empowered population of patients taking advantage of innovation, particularly in the digital sphere, to manage their own care across a range of conditions. But to ensure that all patients have the opportunity to become active participants in decision making will require better developed system architecture at every stage of the innovation pathway, making provision for:

    - innovators and other key players in the pathway to be given better, earlier and more systematic opportunities to hear at first hand from patients, meaning that, from the outset, product development is routed in and guided by the views of patients on the outcomes that matter most to them;
    - patients to be better informed about the pipeline of possible new products and treatments, and given earlier access to trials and pilots;
    - patients to influence the processes of prioritisation, evaluation and implementation more directly and effectively throughout the innovation pathway, both from the ground up and at national level;
    - patients to be better informed about, and given more opportunity to understand, the decisions made by national and local agencies on the availability of new products and treatments; and,
    - patients to be given a platform to seek assurances on, and where appropriate press for, the uptake of new products and models of care.

11. This proposition, alongside the insights that support it and the requirements for its delivery, have been a key driver for proposals set out in more detail under Proposition Five. This highlights the need for a coordinated network of local Innovation Exchanges and a complementary Innovation Partnership at national level, both of which should ensure that patients are given a stronger voice at every stage of the innovation pathway.

Next Steps

We will use the next phase of the review to work with patients, carers, patient charities and other key stakeholders to:

- test this proposition and its related insights further;
- explore the scope for identifying and codifying patient-led outcome measures, designed to inform the evaluation of new products and the decisions made by regulators and other key bodies in the system;
- develop 'I' statements that represent principles reflecting the patient voice across the pathway, including concerns relating to inequalities, safety, efficacy and transparency; and,
- work up the proposed system architecture in more detail, ensuring that it captures the need for patient interaction with sufficient granularity and weight at all stages of the innovation pathway (see Proposition Five).

PROPOSITION TWO: GETTING AHEAD OF THE CURVE

A radically new approach is required to accelerate and manage entry into our health system for emerging products which promise the most significant, potentially transformative impact in terms of patient benefit and overall value.

12. Nothing is more important than this proposition if we are to keep our health system on the leading edge of innovation and a 'go to' place for pharmaceutical and technology companies to trial and develop their most promising new products. It is a priority for our patients. It is vital to our life sciences industry.

13. We have a strong platform on which to build: an excellent science base; research infrastructure provided through the National Institute for Health Research (NIHR) which is better placed than ever to deliver rapid access to patient trials; ground-breaking initiatives such as the 100,000 Genomes Project, the Catapult network and the Francis Crick Institute; and internationally-renowned bodies for regulation and Health Technology Assessment. Moreover, we have, in the NHS, a potentially unique environment in which to evaluate innovations early in their development on a national scale.

14. But a fundamental shift to a much more proactive approach is now required if we are to build on these assets and meet the challenge of delivering earlier patient access, at a cost the system can afford, to the relatively small number of new products which promise to be truly transformative. We are simultaneously in the most exciting era in recent times for health innovation, and in a time when all international health economies, including ours, are facing unprecedented cost pressures and constraints. This is a challenge our health system cannot ignore.

15. 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 impact. We can do this by managing access to our system for the most promising products in a way that gives these products the best chance of succeeding and bringing earlier benefit to patients. This will require:

    - stronger mechanisms and a more transparent decision making process for identifying and prioritising this relatively small group of products – using a wider, more systematic approach to horizon scanning. This should be combined with a commitment to working with the companies concerned at a much earlier stage of development on bespoke packages for licensing, evaluation and reimbursement, and then at every stage of the innovation pathway, supporting them to deliver these products to our health system at the earliest possible opportunity;

- as a vital component of such an approach, enhanced provision in the system for commercial access agreements, linking assessment and budgetary control – with the aim of managing the entry of a product to the system as early as possible in the product cycle, when the evidence to determine its longer-term value has not been fully established. This form of managed access can be described as a 'conditional yes' decision, leading to agreements between companies and the health system that both specify requirements for access, and control financial risk. It would have, as a key feature, some form of conditionality – financially or performance based, or a combination of the two – and it would be supported by new, more flexible approaches to reimbursement over the period of the managed access agreement. These could include simple discounts, but also more complex schemes such as price-volume agreements, multi-year agreements conditional on the achievement of certain outcomes, patient cost caps or free/discounted treatment initiation. Such a system, carefully managed, offers the best prospect for our NHS of achieving timely patient access to the most promising new products, while ensuring that growth in healthcare budgets is sustainable;
- optimal use, on a product by product basis, of current and future flexibilities in the regulatory processes for the licensing and conditional approval of new products. For medicines, this should build on existing initiatives such as the Early Access to Medicines Scheme (EAMS), European Medicines Agency (EMA)'s Conditional Approval and the Adaptive Pathways Pilot. It must recognise that the UK sits in a global ecosystem of regulation and evidence generation, considering how our country can lead thinking to shape the requirements of other regulatory regions. As such, our accelerated access approach should be combined with a continued drive to accelerate pathways at a European level and to plan for the effects of European Union regulatory changes (for example in relation to devices and in vitro diagnostics);
- supporting and operationalising the prioritisation of potentially transformative medtech (devices, diagnostics and digital health products) through the possible development of a new designation showing promise. This could encourage external investment in a product that shows significant potential for national implementation, attract research support, and be submitted to NICE for rapid appraisal on a new accelerated pathway;
- further improvements in timescales for access to patient trials and a greater emphasis on evaluation through commissioning. These should be taken forward alongside exploration of the scope of new trial methodologies which could accelerate evidence generation and take cost out of the process. This is particularly key where traditional – sometimes lengthy – fully powered randomised controlled trials may not be feasible, ethical or necessary, for example for the new generation of precision medicines or for certain medtech and digital products;

- better use of existing data assets, building on initiatives such as the National Information Board, to ensure that data systems are secure, interoperable and future-proofed and are supported by a binding commitment from all providers in our health system to make anonymised real-time patient data available for this purpose.

Next Steps

Working with key stakeholders, including patients and their representatives, we will use the next stage of the review to:

- test this proposition and our core proposals for delivering it. This will include some worked examples of how it might apply to different therapies or disease areas, including dementia, cancer and ultra-orphan products, which we will 'litmus' test with stakeholders including patients and clinicians in the field;
- work up, in more detail, each component of the accelerated pathway we have set out for medicines, devices, diagnostics and digital health products. This will include:
  - exploring the principles and processes which could be used to identify 'the most promising, financially transformative products' across the system;
  - looking at the impact of a new managed access pathway for current schemes such as EAMS, the Adaptive Pathways Pilot and the Cancer Drugs Fund (which might be developed in a way consistent with this approach), and for NICE; and,
  - exploring implications for current, and potentially future, models of pricing and reimbursement (including modelling affordability implications);
- further assess more flexible approaches to reimbursement – including, but not limited to, price-volume agreements, multi-year agreements conditional on the achievement of certain outcomes, patient cost caps or free/discounted treatment initiation – alongside mechanisms for how these could be funded;
- assess the roles of key national bodies in delivering this pathway, including developing proposals on how to ensure that patient engagement is embedded in all decision making processes; and,
- assess how the proposed Innovation Partnership (see Proposition 5) should operate to ensure effective coordination and cooperation between those bodies to deliver a transparent and integrated accelerated pathway.

PROPOSITION THREE: SUPPORTING ALL INNOVATORS

In addition to accelerating access to a select number of the most promising new products, our end-to-end innovation pathway can, and should, also be more responsive to the wider irrepressible surge of innovation presented at all levels of the system, particularly where its introduction will contribute to better outcomes for patients, and more productive and efficient ways of delivering care.

16. Innovation presses on the system from all sides. It is not something that can or should be 'nationalised'. Clinicians, researchers, entrepreneurs and companies both big and small come forward all the time, and on an increasing scale, with new ideas for improving health and care – from digital apps to the latest cutting-edge developments in remote monitoring, imaging, diagnostics or robotics. Some innovations in this category may never run. Others may be tried and fail quickly. Some will support new models of care where the gain is in the system change. Others may be game changers in their own right. For innovations such as these, the health system can appear – and in practice can be – an opaque, complex and discouraging environment in which to explore new ideas, launch a product or market it to scale.

17. Moreover, there will continue to be a wider category of 'mainstream' products – particularly, but not exclusively, medicines – that need licensing and evaluation at national level but either do not require, or do not justify, the kind of managed access pathway described under Proposition Two. That does not mean that these innovators should not be given better support in navigating our regulatory system, or benefit from wider improvements in the way the innovation pathway is managed. The NHS needs innovation – and therefore innovators – at all levels, not least to help it become a more efficient, productive provider of high quality care to patients. The principle that unites both 'mainstream' products and locally-borne innovations in Proposition Three, and that we return to in Proposition Four, is that all our innovators should be supported, particularly at their point of entry to the system, in a way that gives their product the best chance of succeeding – or, if it is not a runner or fails to fly, to discover that quickly.

18. A wide range of excellent information and support services are already available, for example in the Catapults, NIHR's Office for Clinical Research Infrastructure, MHRA and NICE's advice services, NICE's recently launched Office for Market Access, NHS England's Innovation Connect and the AHSNs. But innovators – particularly start-ups and smaller device, diagnostic and digital health companies – have emphasised the potential value of more accessible and integrated advice, as well as clearer, simpler

guidance around how to accelerate the development of new products. In our view, this will require the new system architecture we describe in Proposition Five – an Innovation Partnership at national level linked to Innovation Exchanges at local level – to deliver:

- a new pathway for digital products which clarifies the steps involved in getting a product to market and the evidence required for evaluation and uptake;
- simple 'how to' guides for navigating the innovation pathway – from regulatory flexibilities at national level, through the data required for cost effectiveness evaluation or adoption, to where to go at both regional and local level with an innovation and the information to be armed with when doing so;
- better signposting at both national and local levels to dedicated facilities for particular categories of innovation, such as the Catapults, in order to give more bespoke support for particular products; and,
- a system that genuinely operates as a real exchange; a more vibrant, accessible market place. Innovations that come into the system at national level but are not identified as nationally 'promising products' should be referred quickly to a well-coordinated network of AHSN-based Innovation Exchanges, where locally-borne innovations should also be given support. An innovator's approach to one Innovation Exchange should be advertised more widely across the network for exploration and potential take-up. Locally-borne ideas that are picked up, tested and show promise in one area should be better shared with others, and innovations which could have national application should be referred to the national Innovation Partnership, with the potential to rapidly scale those which are successful. The facility for this already exists embryonically in some AHSNs. But it needs stronger systematisation and coordination, as well as better connection between local and national levels, if it is to properly support diffusion of innovation across the country.

19. Alongside better information and support, we are considering how NICE could evolve its existing health technology evaluation programme to develop a stronger, more flexible and more streamlined system for evaluating pharmaceuticals and medtech products – and how this might be combined with a more streamlined process for evaluating "non NICE" products at regional level in the NHS. We are exploring whether, for devices, diagnostics and digital products, this approach could support a wider set of innovations, many of which are designed to deliver care more efficiently, to enter the NHS more rapidly. This could include increasing the number of these products evaluated by NICE. We are also exploring how the current tariff system can best respond to the new wave of devices, diagnostics and digital health products, and be linked systematically to the range of activities that support adoption, such as advice on coding and implementation.

Next Steps

Working with key stakeholders, including national agencies and the AHSNs, we will use the next stage of the review to:

- take these proposals to the next level of detail, ensuring that any new systems of guidance or support complement or streamline, and do not duplicate, current systems;
- test the usefulness of these proposals with patients, the NHS and innovators; and,
- identify 'quick wins' we may have missed, or significant barriers to innovation that these proposals, along with our other propositions, do not address.

PROPOSITION FOUR: 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.

20. While there are good examples of where transformative innovations have spread rapidly across the country, our analysis has demonstrated that the NHS is currently perceived as a health system that is slow to adopt new products and, in some cases, resistant to change. It is possible to debate the reasons for this perception and to identify a number of genuine barriers the system faces – particularly when seeking to invest in innovations that may have uncertain or longer-term benefits, or which benefit the wider system but not their institution or speciality directly. But perhaps the biggest risk the NHS faces is that the current resource constraints under which it is operating will paralyse the system, inhibiting it from investing in the change it needs to undergo – supported by innovative technologies – to improve the quality of the care it offers to patients and the productivity and efficiency of the system.

21. Both the new models of care proposed in NHS England's Five Year Forward View, and the work of the new NHS Improvement Agency, are direct responses to that risk. Proposition Four is intended to align with these strategies, embedding the work of this review into the future NHS architecture. It is an article of faith for those of us involved in the review that better care for patients, delivering improved outcomes, should increase efficiency and productivity. Demand pressures in the system may overtake what would otherwise be cash savings. But the gain should be there in terms of improved productivity and, above all, better patient outcomes. That is the overriding case for the NHS to embrace innovation in the face of its current challenges.

22. But simply telling people they should innovate is unlikely to work. In a survey run by the review team, almost 90% of respondents in the health and care system identified the capability and capacity of providers to undergo system redesign as a significant barrier to the rapid adoption of innovation. Our conviction based on the evidence we have heard is that the system needs to better incentivise adoption and implementation. We are considering a range of ways in which this could be done, including, but not limited to:

    - incentivising those health economies committed to innovation, such as the accredited 'vanguards' of new models of care and the Test Bed sites, to take on a clear leadership role in actively supporting the accelerated uptake of innovative products and systems to drive improvement. This is particularly pertinent to those vanguards focussed on system integration

at local level – bringing together services across social, primary and acute care boundaries in both physical and mental health to both support better care for patients and improve the management of chronic disease. They – and potentially other health economies – could be incentivised to do this through a new fund earmarked for the purpose of building a stronger, more coherent, offer of practical support for system redesign. We are exploring potential models for such a fund, including social investment, match-funding and re-purposing of existing funds. Funding could be channelled through the AHSNs, with the emphasis on using the fund as a source of true investment, with clear demands and expectations in relation to return on investment. The AHSNs are already beginning to use their resources in this way, but in our view this needs greater scale, a more systematic approach to prioritising and assessing the case for investment, and even stronger alignment with the new models of care, with the ambitions of the newly formed NHS Improvement Agency, and with the wider NHS productivity agenda;

- building on the new emphasis on accountable care organisations and systems to incentivise the leading teaching hospitals with supporting research infrastructure to act as champions of innovation. These hospitals could be accountable for their existing, and potentially a wider range of, specialist services provision, aligning their research pathway with the delivery of new products, and leading and supporting innovation in their local health care systems, including in primary care. This could require them to commit, for example, to: early adoption of 'promising products'; keeping at the leading edge of innovation in the most complex care for which they are responsible which is often then adopted more widely; working with their network of referring hospitals, particularly in relation to specialist services, but also more widely in primary care and other settings, to ensure they are implementing and using the latest, most efficient and effective products; and agreed metrics for speeding up access to patient trials and supporting schemes such as Commissioning through Evaluation. This approach could be incentivised through an earmarked fund or, perhaps more appropriately, through a new, more refined, highly selective and conditional system of specialised supplementary funding linked to the specialist services tariff;
- ensuring that commissioners play an active role in innovation, stimulating new approaches to service development and ensuring service delivery to improve health and care outcomes. Too often commissioning is reduced to the art of "contracting", and, while this is important, commissioners must also be supported to embrace engagement, strategy development, innovative service specification and delivery. We will need to ensure that commissioners work together on the appropriate geography to support innovation, which has the potential to generate a shift towards commissioning for value as well as for improved outcomes; and,

- re-focussing local Drugs and Therapeutics Committees to focus on supporting cost reduction and better care by optimising the use of medicines and wider health technologies, ensuring that products with a positive NICE Technology Appraisal are taken up comprehensively (rather than, as some stakeholders suggest, second-guessing NICE's decisions at local level) and using patient data to support the decommissioning of superseded or ineffective products.

23. In addition we need to:

- harness the influence of clinical and system leaders, as well as patients themselves, to act as champions of change, articulating the benefits of innovation in terms of patient care, outcomes and system productivity; and,
- hardwire system improvement expertise through education and training from the bottom up.

Next Steps

Working with stakeholders, including those in the NHS, we will use the next phase of the review to:

- test these proposals, including scoping new ways of incentivising and supporting the NHS to improve efficiency and patient care through the introduction, on a sustainable basis, of innovative technologies. This will involve giving clarity on the purpose and conditions of funding, and how this would be resourced from within available NHS resources and, potentially, other external sources of funding;
- test these proposals to ensure that these are the right vehicles to accelerate the adoption and diffusion of innovative products, financially or otherwise incentivised, and identify additional vehicles if appropriate;
- assess the potential costs and benefits of such an approach; and,
- develop our proposed system architecture in a way that supports this proposition.

PROPOSITION FIVE: DELIVERING CHANGE

Building on existing health system structures, a new system architecture is required at local and national level to accelerate development of, and access to, the best new products and related models of care on a sustainable basis, within a framework of collective agreement to ambitions and goals.

24. This is the thread which, in a sense, underpins all our other propositions. The last thing the health system needs is a new body, or a further re-organisation, to deliver the aims of this review. We recognise that there are already organisations working both locally and nationally to exchange innovation and support innovators, patients and the system across the pathway. But there is scope for harnessing and enhancing these collaborative structures both to improve their reach and align commitments across the pathway. We think this will require:

    - further development of the network of AHSNs. Many already make a strong offer to patients, innovators and the system, although we recognise that these offers vary in maturity and scope across the network, reflecting the AHSNs' relatively recent genesis. We will continue to consider questions around AHSN remit – while retaining their local focus, there could be more systemisation of the facilities they provide and stronger mechanisms for coordinating information and innovation across the network for aligning with the new models of care and for interacting with national partners. All AHSNs should facilitate:
        - what we have described as a network of Innovation Exchanges: a real and virtual forum in each AHSN area to ensure that the voice of patients is heard by innovators, regulators, commissioners and providers;
        - support for innovators to promote, test and launch products both within an AHSN area and across the wider national AHSN network, allowing for testing at scale; and,
        - prioritised funding as proposed under Proposition Four to support change and innovation and to share learning and good practice across the network.
    - a complementary Innovation Partnership at national level with links to the network of local Innovation Exchanges. This partnership of the key bodies in the innovation pathway, including (but not necessarily limited to) NIHR, MHRA, NICE, NHS England and NHS Improvement, would be collectively responsible for managing the innovation pathway seamlessly at national level, supporting the rapid and sustainable introduction of innovative

products in the best of interests of patients, the public and the UK's life science industry. Its role could include ensuring that:

- priorities are identified collaboratively, with patients seen as active participants in decision making;
- objectives are shared across the pathway, with clear and agreed metrics of success;
- horizon scanning is comprehensive and acted upon;
- coordinated, cross-pathway planning is undertaken for the uptake and implementation of 'promising products', and,
- patients are properly listened to and involved across the innovation pathway.

25. A central part of this Partnership will be collective agreement on the part of all its key players to a Concordat committing them to the ambitions set out in this review and to the development of an agreed action plan to implement its final recommendations. This Concordat will accompany the review's final report.

Next Steps:

Working with key stakeholders, including those who would be involved in the Innovation Exchanges and Innovation Partnership, we will use the next phase of the review to:

- further define the remit and priorities of the Innovation Exchange function and the Innovation Partnership;
- test whether there is appetite for the proposed Innovation Partnership and Concordat to be supported by a light touch coordinating committee, perhaps independently chaired, to ensure that the key participants hold themselves individually and collectively to account for their leadership and management of the innovation pathway; and,
- test and cost this proposition, recognising the resource constraints under which the system is operating.

ANNEX A: THE ACCELERATED ACCESS REVIEW, MY REFLECTIONS AND THE CASE FOR CHANGE

Prof. Sir John Bell, Chair, Review's External Advisory Group

The introduction of innovative therapeutics, devices, diagnostic, and more recently, digital products has, over the past 35 years, transformed healthcare and contributed greatly to the quality of life of most individuals in the UK. We are now entering an era of 21st century innovation where the pace of discovery of such novel and effective interventions is likely to increase and, if introduced effectively for patient benefit, health gains are likely to be even more substantial. In order to prepare for this new generation of innovations, the system whereby the NHS evaluates, regulates, adopts and diffuses innovations needs to be effectively tuned to ensure society obtains the best health outcomes from these new technologies quickly and systematically. At the same time, this adoption needs to be achieved in the context of financial constraints where decisions about the most appropriate use of resources will be critical.

There have been a multitude of important advances in the way we categorise disease, develop and target new therapies and are able to flex regulatory structures in order to ensure that patients get the early benefits of radical, new and increasingly more effective interventions. These are apparent in most therapeutic areas. Drugs, which have underpinned the 70% reduction we have seen in cardiovascular mortality and the dramatic improvements in breast cancer mortality seen over the past 30 years, will continue to be a mainstay of modern medicine. The pharmaceutical industry is now regaining its ability to deliver important new drugs for major diseases. In cancer, the new immune/oncology drugs clearly have the ability to produce durable responses in many cancer types and will likely transform its treatment. In Hepatitis C, new drugs are again transformational, curing the disease in the vast majority of patients. Drugs that target the genetically validated targets PCSK9 and BCL2 are dramatic in their impact, and new classes of drugs for diabetes (SGTL2 inhibitors) that reduce mortality by almost 40%, as well as the first new effective drug for heart failure in a generation, will allow these chronic diseases to be treated more effectively. Medical devices are being developed which will provide implantable nano capabilities to monitor disease and stimulate organ function, while new diagnostics such as genome sequencing will underpin precision medicine, and new digital tools will allow patients to be monitored continuously and managed more effectively in the community. These are revolutionary advances but they will not be available to any health care system for free. A key challenge will be to determine how both regulators and the NHS take advantage of this new environment to improve patient outcomes, ensure rapid and maximum coverage of patient populations and to do so in the context of a new regulatory environment and a constrained financial environment. A failure to anticipate the

challenge and manage it with new pathways for rapid adoption and diffusion of innovation could, in the longer-term, be damaging both to the NHS and to its patients.

Several rapidly evolving trends emerging in medicine will require a significant shift in the way we evaluate and introduce new medicines, diagnostics and devices. After 25 years of intense molecular characterisation of disease, it is increasingly possible to define precisely the mechanisms responsible for mediating disease and consequently, how it can be best managed or treated. Our ability to categorise disease in patients much more precisely is likely to have a profound effect on clinical medicine as we identify subpopulations of patients likely to obtain maximum benefit from therapies. Resources can thereby be concentrated on those who will benefit the most rather than the population at large. This focus on patient subpopulations, which is the basis of "precision medicine", has already begun to affect the quality of new therapeutic products. Hence, our understanding of the mechanisms that mediate disease have generated targets for therapy that have proved to be more tractable than has previously been the case. In addition, the availability of other tools emerging from the digital revolution are likely to provide powerful mechanisms to identify at risk patients and populations, keeping individuals out of hospital and concentrating resources on those who are likely to benefit. Together, new targeted therapies, alongside a host of digital tools, will change medicine and healthcare faster even than what we have previously witnessed. Some of these new innovations should reduce costs and create opportunities for improved productivity and efficiency. Others will yield substantial benefits in patient outcomes, albeit at an increased cost. This will produce significant challenges for the NHS. However, if the UK population and the NHS are to benefit from this major inflection point in the introduction of healthcare innovations, these are challenges that will have to be addressed.

While the NHS has ultimately succeeded in delivering many of the benefits of innovation to patient populations over the past few decades, the process under which this occurs is far from optimal. On one hand, the system benefits from one of the most rigorous health technology assessment organisations in the world that provides clear and robust evidence of the clinical and health economic benefits of new interventions. On the other hand, the introduction of innovation into the NHS has been extraordinarily complex and difficult; and the adoption and diffusion of new innovations is widely perceived to be slow. Together, these issues mean that UK patients are often amongst the last to see the benefits of new innovations in their disease areas. This also creates an environment that the life sciences industry can find challenging because of the lack of clear routes to the market.

The need for a more dynamic and responsive system to deal with the host of innovations now emerging has been recognised by many countries. Regulators in particular are moving quickly to attempt to respond to their responsibility to ensure that highly effective new therapies get to patients more quickly than has historically been the case. New approaches to conditional and more rapid approval by drug regulators is having a profound impact in countries such as the USA where the 'break-through' designation, now applied to more than 40 exciting new therapeutic agents, has considerably improved the speed by which the market can be accessed for high impact new medicines. Systems of conditional

or adaptive licensing are also being progressed by the EMA, which is also considering its own form of 'break-through' designation, and already several countries in the EU, such as France and Denmark, have rapid routes to market for new, innovative products. Japan and Canada also have clear routes for rapid market access. Similarly, the regulation and evaluation of new digital products is evolving in both the USA and Europe and attempts are being made to ensure that these products can be approved quickly for rapid adoption. In diagnostics, regulators have begun to grapple with the availability of the dramatic technical advances in areas such as genome sequencing to enable patients to obtain these benefits quickly and effectively. Thus, the UK is operating in a context where many countries have recognised the need for significant changes in the ability to regulate and adopt new, highly effective products in all areas of healthcare, drugs, medical devices/diagnostics and digital, and are working hard to ensure these benefits get to patients as quickly as possible.

In order to handle this new wave of innovation in the context of a dramatic shift in the way we define disease and target interventions, the NHS will need a new approach to the whole pathway of regulation, evaluation and adoption. Without a new approach, it is likely that the NHS will find it increasingly challenging to deliver innovation in a timely way to the population and that it will struggle to maintain the balance between the cost of innovation and the need to provide patients with novel approaches to deliver improved care.