Introduction

1. The Academy of Medical Sciences welcomes the opportunity to contribute to the NHS Next Stage Review. In this short response we have focused on issues of innovation, responding to Mark Britnell’s letter of November 2007.

2. The opportunities and challenges for innovation in health were recently set out by the Prime Minister, including the need for reforms to embrace technical change, meet rising expectations of healthcare and adapt to shifts in disease priorities. This submission draws on views developed in previous Academy reports and consultation responses. We have focused on innovation in products and services, structuring the submission to address the three questions posed by Mark Britnell. These issues continue to be of great importance to the work of the Academy and its FORUM with industry and we would be happy to expand on any of the points made in this submission.

3. Tackling the barriers so as to realise the potential of innovation in the NHS requires a concerted strategy across a broad front. We make specific recommendations in the following paragraphs; in summary we emphasise the following points:
   • Patients in the NHS suffer because of the lack of innovation; barriers to innovation negatively impact on patient care.
   • The NHS must learn how to measure the value of innovation, as well as to appreciate this value. An innovative medicine or device may be expensive but it can still be cost-effective; innovators must be appropriately rewarded.
   • An innovation culture can provide opportunities not only to adopt better practices, but also to discontinue less effective practices. A major current problem is that the NHS does not decommission past practices as new ones are introduced.

What are the existing barriers to innovation in the NHS?

4. Historical underperformance
   Overall, the UK has a good track record in biomedical innovation in industry and academia, based on sustained commitment to R&D investment. However, this has not always been the case in the NHS. In the past, it was recognised that R&D in the NHS suffered through the diversion of money intended for research into other areas. Furthermore, the NHS has not encouraged academic development (e.g. contracts for consultants do not include research) and there has been a lack of incentives for R&D in NHS performance targets. Until recently, the NHS was therefore perceived by the academic and commercial research community to be a difficult and unreliable place in which to conduct research.

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1 7 January 2008 "Prime Minister outlines NHS reforms". www.number10.gov.uk/output/Page14172.asp
2 Previous Academy documents of relevance to this response include (i) Reports: on “Safer Medicines”; “Personal data for public good: using health information in medical research”; “Stratified Medicine”; “MB PhD Position paper”; “Careers for biomedical scientists and clinicians in industry”; “The freedom to succeed”, “Medical research: assessing the benefits to society”; (ii) Responses to: MHRA consultation; OSI consultation on Department of Health; House of Commons Health Committee Inquiry on NICE; House of Commons Science and Technology Committee Inquiry on Cooksey Review. See www.acmedsci.ac.uk.
5. **Lack of NHS culture of research and knowledge transfer**

In the Academy’s view, the prime objective of health R&D is to ensure the effective translation of scientific advances into patient benefit. This requires innovative products and services, but also better policy development. Improving the research culture within the NHS - and the Department of Health more generally – must be augmented by efficient mechanisms to translate research into improved healthcare, as well as by close interaction with industry to capitalise on commercial R&D advances.

6. Historically, the NHS has experienced difficulties in identifying and protecting its Intellectual Property and its 'innovation hubs' have enjoyed only limited success. There are lessons to be learnt from other research funders, including MRC Technology, Cancer Research Technology and certain universities, who have considerable experience in supporting knowledge transfer; this will be facilitated by the closer partnerships that are possible within the Office for the Strategic Coordination of Health Research (OSCHR).

7. **Public procurement as a current barrier to innovation**

A good case can be made for the NHS to do much more to encourage innovation through its procurement of products and services. Promoting a culture of innovation within public procurement provides incentives to reward commercial company investment in R&D and, thereby, expand business innovation. In the immediate future, it will be important to ensure that the Government’s desire to achieve greater efficiency in NHS expenditure, through re-opening negotiation on the Pharmaceutical Price Regulation Scheme, does not inadvertently impede pharmaceutical sector investment in R&D by weakening the reward for innovation.

8. **First steps in tackling the obstacles**

We greatly welcome recent efforts by the NHS to inculcate a more effective research culture and to seek to capitalise on major new opportunities for innovation in experimental medicine, clinical trial design and public health science, among other areas. We acknowledge that significant progress has been made in tackling the barriers to innovation in the NHS. The Department for Health’s 'Best Research for Best Health’ strategy is a timely and valuable initiative, although it is still too early to judge its impact on the key criteria of research quality, relevance and utility to deliver innovation. The recent establishment of OSCHR is also very welcome in building partnership between the public and private research sectors, as well as between NIHR, MRC and other public sector funders. The creation of new mechanisms to coordinate the translation of medical research into better healthcare promises to be fundamental to the progress of NHS innovation. Of course, much remains to be done, as noted in our responses to questions 2 and 3.

**What are the most important policy measures we could take in order to realise the full potential of innovation across the NHS?**

9. **Continue to build the NHS research culture**

Research reforms in the NHS must be consolidated and further developed. This requires a series of integrated measures, including:

- Ensuring transparency of research funding and allocations, high quality peer review, governance and decision-making.
- Developing a culture of enquiry and innovation in the NHS and a sense of ownership of the research and innovation agenda by NHS staff, health professionals and Trust managers.
• Maintaining the engagement of other major research funders from both the charitable and commercial sectors.
• Avoiding barriers to interdisciplinary work between different types of health researcher and between different scientific disciplines.
• Coordinating the NHS in England and the Devolved Administrations to harness existing science for innovation and to identify gaps and opportunities (see also paragraph 18).
• Identifying new areas of science that may lead to innovation for ‘pump prime’ funding, while avoiding the temptation to be prescriptive in selecting priorities and targets. Identifying areas for strategic support will be influenced by patient need and determined by scientific opportunity – creative ideas, the availability of talented researchers, and advances in technology. We stress the need for continued basic research to fuel the pipeline for translational exploitation.

10. Improving regulatory, governance and IT structures
The NHS itself is a major asset for the UK science base. But funding alone will not be sufficient to fulfill its potential for research and innovation: this will also require improvements in the regulatory, governance and IT structures. The NHS is both a research resource and test-bed in which to develop, monitor and optimise the utility of new products. However, we are concerned that a number of factors, including confusing legislation and professional guidance, and bureaucracy of process, are having a detrimental effect. In particular, the development of the National Programme for IT (NPfIT) and the Electronic Patient Record offer unparalleled opportunities that could have a real and significant impact on future health in the UK. We expect the NHS to take a leadership position both in engaging with the public to explain the value of research using healthcare records and in ensuring that NPfIT and associated activities underpin the research mission of the NHS.

11. Building partnership
The need for the NHS to work with research partners in pursuit of innovation has been outlined in previous paragraphs. Increasing the inward research investment into the NHS can help promote the innovation culture, develop infrastructure and improve research quality, relevance and efficiency. One key area for NHS partnership with academia and industry is safety assessment – combining the objectives of safeguarding public health and promoting innovation. This was addressed in the Academy’s report ‘Safer Medicines.’ New partnership activities are needed to expedite the application of novel technologies in safety assessment, create networks to investigate emergent clinical safety issues, address the decline in capacity in safety assessment, and to engage with prescribers and the public to reduce the risk of adverse drug reactions.

12. Improving NICE evaluation
NICE is a key part of the NHS procurement process and is central to developing the culture of innovation. As the Academy has observed previously, there is a need to improve NICE procedures for: gathering evidence; engaging the public; external scrutiny; approval and policy decisions; ensuring comparison with systems elsewhere; and providing consistent implementation of NICE advice across the UK. We welcome the recent scrutiny of NICE by the House of Commons Health Committee and its recommendation to encourage innovation by changing ineffective patterns of care. We concur with the Committee’s recommendations to provide help to PCTs to implement NICE guidance and to include the wider benefits and costs of treatment to society in the evaluation of cost-effectiveness. We support the desire to introduce

earlier assessment of all new medicines prior to launch, but we are more cautious about the introduction of a lower QALY threshold during early assessment. Ultimately, we emphasise that developing the role of NICE requires additional resources. It should also be emphasised that the NHS innovation culture needs to provide the opportunities to discontinue less effective practices. A major current problem is that the NHS does not decommission past practices when new ones are introduced.

13. Creating a flexible system for rewarding industry sector innovation

In recent work with Roche and GE Healthcare on ‘Stratified Medicines’, the Academy has deliberated the creation of a new system to reward innovation in the development of safer and more effective drugs. The concept of stratified medicines is based on the better understanding of molecular variation in disease, to define sub-types of patients for targeting new therapies. The main conclusions emerging from this work were as follows:

- It is essential for societal, as well as pharmaceutical company, benefit to relate incentives for the development of new therapeutics to pricing flexibility. Incentives might be linked to value defined after a conditional approval period.
- Following on from the Cooksey Review, there are new opportunities for public-private partnership to establish clinical utility. These opportunities include greater academic involvement in generating fundamental knowledge in exploratory drug development and the use of public infrastructure for clinical trial sample collection.
- The need to explore further the Cooksey Review proposal on conditional approval as a means to promote flexibility in assessing stratified medicines and, thereby, to reward innovation.

14. Accepting the NHS responsibility for articulating the value of innovation

The NHS must learn how to properly value innovation and to communicate that value to its stakeholders. Previous paragraphs have noted the importance of the NHS working to engage the public on issues of research and innovation, for example to communicate and reduce the risk of adverse drug reactions. In addition, the NHS has a responsibility, together with other funders of science, to do more in evaluating and demonstrating the benefits of medical science and the benefits of partnership in innovation.

What are the most significant challenges to implementing these policy measures?

15. Maintaining commitment and engagement with all stakeholders in UK biomedical research

As emphasised in previous paragraphs, realising the current opportunities in UK biomedical research requires partnership across the public, charitable and private sectors. Many of the new operating procedures required to generate and implement innovation will be challenging; they will require an increased level of resource over a sustained period, a validated system of performance monitoring to assess what is successful, and recognition that hard choices will need to be made in deciding between competing demands.

16. Facilitating uptake of industry innovation

As discussed above, there is need to improve NICE processes, together with consideration of the options for introducing new forms of early, conditional, licensing to encourage innovation. It is important to explore these options while, at the same time, ensuring that the rewards for industry innovation are not inappropriately
weakened. Generally, much could be done to encourage the public and private sectors to develop a deeper understanding of each other’s perspectives and practices. One way of achieving this is through enhancing mobility between the sectors (see next paragraph).

17. Building innovation expertise by developing, recruiting and exchanging skilled scientific staff
The recent NHS R&D reforms will help to develop scientific expertise, resource and infrastructure in the NHS more systematically. The activities of the UKCRC will help to address current deficits through identifying the priorities for research networks, infrastructure and workforce, together with the introduction of incentives for NHS research and streamlining of research governance. However, policy developments can inadvertently damage efforts to secure the next generation of biomedical scientists. For example, the effects of Medical Training Application Service, as part of Modernising Medical Careers, could reduce the supply of first-class clinical academics and impact negatively on medical research. We welcome the recent recommendations from the Tooke report and we emphasise the need for diversity, flexibility and excellence in medical training. Other recent work by the Academy has highlighted the importance for the UK of providing MB PhD training programmes and the need to support alternative career pathways by encouraging mobility between the NHS, academia and industry research sectors.

18. Building international relations
The UK faces growing global competition in innovation. In addition to the measures needed to increase UK innovation, it is vital for the UK to collaborate internationally when it is appropriate to do so. The Academy welcomes the recent approval by the European Commission and Parliament to commence the Innovative Medicines Joint Technology Initiative (IMI). The IMI represents a very important concept: large pharmaceutical companies acting together to lead European pre-competitive research in consortia with academics, smaller companies, regulatory agencies and patient groups as the essential partners in innovation. It is important for the NHS to support IMI projects. More generally, European-led policy development may sometimes represent a threat to UK innovation as well as an opportunity. For example, the EU Clinical Trial legislation has brought frustration for UK clinical academics; it is necessary for the Department of Health, with others, to be more proactive in identifying and communicating impending EU policy developments to the UK research community.

19. Developing UK coherence in policies to support innovation
The UK should build coherence in policy formulation across Government to support innovation and encourage innovative business sectors. In particular:

- The NHS in England must work with the Devolved Administrations and regional Development Agencies to ensure strategic complementarity, make effective use of limited resources (paragraph 8) and share lessons of best practice in informing policy development and sector support mechanisms.
- The Health Innovation Council is an important new entity with a core responsibility for overseeing innovation. This body must ensure that its objectives and actions are well integrated with other functions, particularly the Technology Strategy Board, which has recently adopted enhanced roles following the recommendations of the Sainsbury Review, and with the sector-specific Long-term Strategy Groups and Innovation Teams created by Government departments for pharmaceuticals, diagnostics and other medical devices.

We are grateful to Dr Robin Fears for preparing this response.

The Academy of Medical Sciences
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The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK’s strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

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