

**Department of Health: A Consultation on the draft NHS Constitution****Response by the Wellcome Trust**

October 2008

1. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending over £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. The Trust is pleased to provide comments on the proposed draft NHS Constitution. In March, the Trust wrote a letter to David Nicholson, Chief Executive of the NHS, urging for health research to be recognised in the future vision for the health service and for research and health innovation to be embedded in the NHS Constitution. The NHS is uniquely placed to support UK health research – with over 50 million people represented, involvement of patients will be extremely beneficial and their medical information provides a valuable resource for the research needs of the UK, particularly as Connecting for Health is rolled out. It is from this research perspective that we respond to the relevant consultation questions below.
3. The Trust welcomes the specific inclusion of research in the Constitution key principles. However, we suggest the Constitution could provide greater detail to ensure that research is recognised as a permanent and underpinning feature of the NHS. There has been significant momentum behind research in the NHS of late, most recently with the research announcements made in the NHS Next Stage Review and the preceding *'60 years of research in the NHS benefiting patients'* publication. The NHS Constitution provides a timely opportunity to consolidate and build on this momentum to ensure that research becomes a fully integrated rather than an annexed function of the NHS.
4. In summary, the main points detailed in our response below are:
  - emphasising the importance of research in the Constitution;
  - raising public awareness of research;
  - encouraging patient involvement and clarifying the use of patient information in research; and
  - ensuring that the NHS provides world-class training and ensures adequate capacity building for health research.

**Question 4: Are the statement of purpose and set of principles right? Are there any principles that should be added?**

5. The Trust is pleased that the Constitution recognises the NHS's *'commitment to innovation and the promotion and conduct of research'* among the guiding principles of the NHS, which formally incorporates research in the NHS's agenda. However, we suggest that including research in a principle of its own would raise its prominence. In addition, biomedical research is a collaborative endeavour with collective ownership: we suggest that including a reference to the NHS's commitment to collaborating with other organisations concerned with research could strengthen this statement.

**Question 6: Is it useful to bring together all of the key public and patients' rights and pledges?**

6. By consolidating existing rights and pledges, the Trust sees the main function of an NHS Constitution as engaging the public with the health service. The inclusion of research in the Constitution provides an opportunity to increase public awareness and understanding of the benefits of research. The current format is perhaps not ideal for the purpose of public engagement – although the Constitution itself is a concise document, the inclusion of key information in the *Handbook* and statement of accountability may mean that such details are not communicated to the public in the most effective manner.
7. Although the document '*Your Guide to the proposed NHS Constitution*' provides a useful overview of the Constitution for the public, it does not mention research at all. The Trust recommends that this is changed to ensure that the importance of research is consistently acknowledged and communicated in all associated documents.

**Question 8: Is the list of pledges right? Which are most helpful?**

8. The pledges concerning informed choice for patients have clear implications for patient involvement in research, which are articulated in the *Handbook to the draft NHS Constitution*. When defining these pledges, the *Handbook* includes the measures announced as part of the NHS 60th anniversary celebrations to inform patients and encourage participation in relevant research. We welcome this position. In order to ensure that patient involvement in research is enduring rather than a sub-definition of a wider pledge, the Trust suggests that the role of patients in research could be articulated in the actual Constitution document rather than its current position in the *Handbook*.
9. It will be important to ensure that there is not seen to be a conflict between the patient's '*right to privacy and confidentiality*' and the use of patient information for research that will improve human health. The *Handbook* states that '*patients can expect that a health professional or a research professional who owes the same duty of confidentiality as a health professional may use records, in confidence, to identify whether they are suitable to participate in approved clinical trials*'. We welcome this statement which we hope will be a first step towards clarifying best practice for the use of patient records for research.
10. At the moment, there is considerable uncertainty about the processes that should be used when information from patient records is required for research. The Trust has been working with the Royal College of GPs to develop guidance around the issues in general practice. We hosted a workshop in May 2008 with GPs, researchers and patient groups and hope to publish guidance later this year.
11. Following discussion at the meeting, and the *Handbook* statement, we consider it will be important to introduce a formal process of accreditation, including sanctions, to place 'approved researchers' under the same duty of confidentiality as a health professional. This is in line with the recommendations of the Data Sharing Review, published by the Information Commissioner and Mark Walport, Director of the Wellcome Trust, in July 2008. It would be useful if the *Handbook* (or the Department of Health) could give further guidance as to how this might be achieved. We would also argue that this process of approval should cover all research uses of identifiable patient information, rather than only recruitment to clinical trials. We would be happy to discuss these issues with you in more detail.

**Question 11: Is the list of staff pledges right? Which are the most helpful?**

12. The Trust welcomes the pledge to provide staff with '*well-designed and rewarding jobs*' and '*personal development, access to appropriate training for their jobs, and line management support to succeed*'. The *Handbook* includes in its definition of the first of these pledges a reference to the Government's continuing work in modernising careers for doctors and others involved in delivering services for the health service. For staff involved with research, it is important to ensure that the NHS provides world-class training and ensures adequate capacity

building for health research, and we suggest that this pledge should make direct reference to this need.

**Question 13: Do you support the proposal to publish a separate statement of accountability? How can we make this most helpful?**

13. The consultation document states that a statement of accountability will be published alongside the final draft of the Constitution, which will make clear who takes decisions concerning the health service, and on whose behalf. The Trust welcomes this as part of the public engagement purpose of the Constitution, though we believe that the Constitution will be most effective if it is used as a set of guiding principles for patients, staff and the public rather than being used dogmatically to hold the NHS to account, for example by setting targets.
14. Regarding the area of research, it is crucial that the statement of accountability takes account of the roles of the National Institute of Health Research (NIHR) and the Office for Strategic Coordination of Health Research (OSCHR) in the management of research in the NHS, particularly for the measures contained in the *Handbook* regarding patient involvement in research. There is currently insufficient information contained in the Constitution and its associated documents on how and by whom this is to be implemented; the Trust would welcome further details on this matter.

**Question 15: Is the level of detail in the *Handbook to the NHS Constitution* right?**

15. The *Handbook* elaborates on elements of the NHS Constitution and provides a useful summary of how the various pledges and rights are to be interpreted. However, in the management and coordination of research in the NHS, the *Handbook* does not mention the role of NICE and OSCHR: the Trust's initial letter to David Nicholson in March stressed that it would be important for an NHS Constitution to take account of the roles of these organisations. Acknowledging the role of these organisations in the *Handbook* would help increase public awareness of how research is managed and conducted in the NHS.

**Question 16: How can we best ensure that there is widespread awareness of the Constitution among the public, patients and staff?**

16. The NHS 60th anniversary announcements and the NHS Constitution provide a useful starting point to raise the profile of research among the public. As the Constitution is implemented and in the future, it will be vital to build on this to increase public awareness about the importance of research, and the need to use patient records to inform research. We suggest that further activities are considered to maintain momentum in this area.