CONSULTATION RESPONSE

wellcome trust

Department of Health: Liberating the NHS: An Information Revolution

Response by the Wellcome Trust

January 2011

Introduction

1. The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.
2. There is an urgent need for a genuine information revolution to maximise the potential benefits of NHS data and we are pleased to have the opportunity to respond to this consultation on the strategy. Given the Trust's remit, our comments focus primarily on the access, use and sharing of patient data in the context of biomedical and health research.
3. We welcome the proposals set out for requirements of the new "information architecture", including interoperability; accuracy and quality of data; and mandating a unique NHS identifier, since these practical measures will support high standards in patient records that are essential to underpin excellent care in the NHS. In addition, these proposals will facilitate research using the unique data resource provided by NHS records. The use of patient data in research can bring about benefits both for society and individual patients, such as improving clinical care and enabling patients' choice to participate in research studies, therefore we consider that research merits a greater focus in the strategy.
4. We urge the Government to include improved research uses of both anonymous and identifiable patient data as a desired outcome in the final strategy. This should include implementation of the recommendations of the Data Sharing Review and addressing the current barriers to accessing patient data for biomedical research.
5. The key messages of this response are:
   - There are both societal and individual benefits to the uses of patient data for research and the use of patient data to identify individuals to take part in research studies;
   - The strategy does not acknowledge the important role of identifiable patient information in research;
   - The 'key improvement' listed for research lacks ambition and does not address the ongoing concerns around access to patient data for research; and
   - Progress on the implementation of recommendations from the Data Sharing Review has been disappointingly slow and is still required to maximise the benefits of research using patient data.

Uses of patient data in research

6. The use of information from patient records provides the foundation for much medical research, and offers significant potential to answer questions about the factors that influence health and disease. Information from patient records can be used for epidemiological research; to understand more about the causes of disease; to detect outbreaks of infectious diseases; to

monitor the safety and efficacy of drugs; and to study the effectiveness of treatments and interventions.

7. Patient records also offer a helpful starting point to identify potential participants to invite to take part in a clinical trial or cohort study. This use of data will be important to help fulfill the commitment in the Government's White Paper, *Liberating the NHS*, to "give patients more information on research studies that are relevant to them, and more scope to join in if they wish". Patient recruitment is also a factor that determines where the pharmaceutical industry chooses to invest in R&D and therefore facilitating this process could enable the UK to attract investment and maintain its competitive advantage in this area. Facilitating access to patient data for this purpose will therefore contribute to fulfilling the Government's ambitions for healthcare and life sciences as set out in the Growth Strategy.
8. We are pleased that the strategy acknowledges the importance of the use of evidence and the essential role of research in increasing quality and productivity in the NHS. However, we consider that the strategy misses an opportunity to fully address the uses of patient data for research. The 'key improvement' for research that "the quality and scope of information available for analysis and research will be considerably higher, more comprehensive and based on accurate reporting" lacks any substantial ambition. This 'key improvement' does not address many of the continuing barriers to the use of patient data in research, including a lack of clarity in the legislation, for example in the requirements of the Data Protection Act.
9. We support the strategy's aim to provide aggregated, anonymised data to researchers, since these data can underpin important research. However, while much research can be conducted with anonymised information, in some cases researchers will need access to identifiable information (see Box 1). The use of identifiable patient data for research is not acknowledged by the strategy, despite a legislative basis for this, including exemption from the common law of confidentiality under section 251 of the NHS Act (2006).

Box 1: Power lines and the risk of childhood leukaemia

Cancer registries have been used to identify 33,000 children with cancer, aged up to 14 years. The research showed that, compared with children who lived greater than 600m from a line at birth, those who lived within 200m had an increased risk of leukaemia (relative risk: 1.69). This study involved information that a child of a particular age lives in a specific postcode. These two pieces of information alone could enable the identification of an individual child. However, it would not have been feasible – or proportionate – to seek individual consent from all 33,000 children.

Continuing barriers to the use of patient data in research

10. The Data Sharing Review[1] made the following recommendations to address ongoing concerns around access to patient data for research and the identification of potential trial participants:
    - The development of 'safe havens';
    - A mechanism to approve researchers to work in these safe havens and ensure that they are bound by a strict code of confidentiality; and
    - The development of a system by the NHS to allow approved researchers to work with healthcare providers to identify patients to take part in clinical studies for which consent is needed.

11. The last Government accepted these recommendations in its response in November 2008, but the slow progress made in implementing these recommendations is very disappointing. We are delighted by this Government's commitment to the Research Capability Programme (RCP) and

[1] http://www.justice.gov.uk/reviews/datasharing-intro.htm

Health Research Support Service pilots, since we consider that these have the potential to lead to significant health benefit and drive efficiencies within the NHS, in addition to improving the recruitment of patients to clinical trials. We hope that any further financial commitment to the RCP will be supported by further action from the Government towards swift implementation of mechanisms to approve researchers and the development of systems for these approved researchers to work within the NHS. Since these developments are necessary to maximise the benefits that flow from the use of patient data in research, we consider that it would be appropriate to address them in this strategy.