

Use of Patient Data in Medical Research Call for Evidence

Introduction

Medical research using patient data has had a long and successful history in the UK and has provided vital knowledge on the causes of disease and the effectiveness of treatments. The Academy of Medical Sciences 2003 report 'Strengthening Clinical Research' is one of several recent documents to highlight the opportunities for population-based research presented by the presence of the National Health Service and the advent of large patient databases.

However, there appears to be widespread concern that advances in this field are increasingly inhibited by unnecessary constraints on the use of patient data. These include confusing legislation and professional guidance, bureaucracy of process and a lack of engagement between patients, data controllers and researchers about their mutual needs and concerns.

Medical confidentiality and appropriate consent are important entitlements that must be protected by an ethically sound regulatory framework. Technological developments in database management present ever more sophisticated research opportunities. It is crucial that measures to preserve confidentiality and ensure appropriate consent adapt rapidly and in ways that allow research to proceed effectively.

As part of its continued interest in ensuring a regulatory environment that is conducive to developing the UK science base, the Academy of Medical Sciences is launching a study to examine the current and future situation regarding the use of patient data in medical research. The outcome of this study will be a report suitable for policy makers and other interested parties, to be published in late Spring 2005.

Scope of Study

The study will:

- Analyse the development of the present position regarding the use of patient data and the necessity and requirements for this kind of research
- Analyse the advantages and problems of the national and international regulatory environment in this area.
- Make recommendations for dealing with key issues of consent, security of data, confidentiality and public engagement.

The study will not:

- Provide practical guidance on how to negotiate the current environment governing the use of patient data in research
- Consider the use of human tissue as governed by the Human Tissue Bill, although it will consider the implications of this legislation.
- Provide practical guidance to clinicians on obtaining patient consent.

Call for evidence

The working group invites written evidence on:

- The historical and current situation regarding the use of patient data in research, including examples of the positive and negative impact of regulatory changes on various research practices.
- What lessons can be learned from international practice and regulations in this area.
- Key issues of consent, including:
 - the principles and practicalities of opting out;
 - the agents who can/should obtain patient consent;
 - the principles and practicalities of various forms of consent, including informed and generic consent;
 - ownership of data.
- Key issues of confidentiality and data security including:
 - the appropriateness and feasibility of reversible and irreversible anonymisation in various research practices;
 - the potential benefits and risks of database linkage;
 - the retention of data.
- Issues relating to public engagement, understanding and opinion, particularly with regard to potential differences between social and ethnic groups
- How mutual understanding between patients and researchers might be engendered.
- Areas where more research is needed.

Those submitting a response may like to illustrate their evidence with practical examples of how good and bad practice relating to the use of patient data has impacted on research activities and outcomes.

Guidance for submitting evidence

The working group invites submissions of 5 pages or fewer, in which references to the appropriate literature are provided and any additional data are included as an appendix.

The Academy may publish submitted evidence in parallel with the final report. Please indicate if submissions should not be made publicly available in this way.

This is a public call for evidence and the working group would be grateful if it could be brought to the attention of any relevant groups or individuals who may not have received a copy directly.

The deadline for submissions is **Friday 10 December 2004.**

Evidence should be submitted, in preferably both hard and electronic formats, to:

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