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(Accepted 19 May 2006)

Confidentiality and consent in medical research

Balancing potential risks and benefits of using confidential data

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Public health benefits arising from advances in medical research often rely on the use of personal data. How can we ensure that protecting patients' interests does not unduly hamper scientific study?

Editorial by Souhami

This article is the last in a four part series building on a recent Medical Research Council initiative relating to use of personal information in medical research

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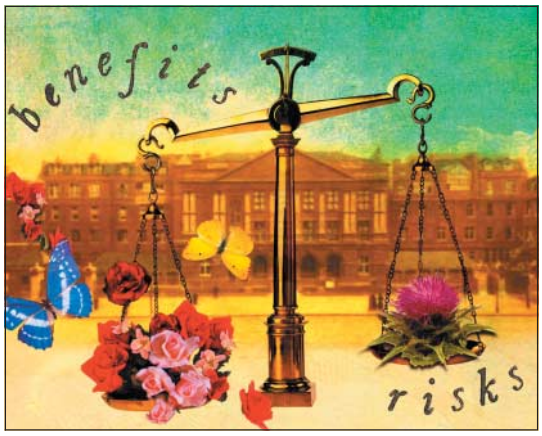
BMJ 2006;333:349–51

Confidential medical information is used in almost every type of clinical and public health research. Different research scenarios raise different practical, ethical, and legal issues, and with these come the challenges of balancing the potential risks associated with the use of personal data against the potential benefits that might be gained from the research. We consider a strategy for explicitly reviewing the balance of these potential risks and benefits when planning research.

Effect of current legislation

Changes in the laws on data protection[1–3] have had an important effect on training for medical research and on the design, costs, and feasibility of research projects. In many instances, this has improved the ways in which personal data are handled and protected the privacy of patients. There is, however, a general concern that varying interpretations of current legislation are stifling important research.[4] Widespread uncertainty among professional bodies, hospital managers, ethics committees, clinicians, medical researchers, and the public may be producing disproportionate obstacles to the use of personal data when there is not genuine risk. In some instances, interpretations of legislation seem to have been driven less by careful consideration of the likelihood of real harm for individuals than by the desire to minimise the risk of criticism for organisations.

It needs just a few such decisions to impart an extra twist to the cycle of inefficiency in the use of public money for medical research. Clearly, research should conform to good practice, but it remains appropriate to consider whether over-interpretation of data protection legislation represents another real, albeit difficult to quantify, risk to the public.



SARAH PERKINS

Balancing risks and benefits

It is essential to achieve a rational view of the real risks and benefits of research using medical records and for any regulations to be drafted and interpreted appropriately. Risks and benefits can be presented from the perspectives both of safeguarding the interests of the participants in research and of pursuing the needs of patients and the wider public for evidence on which to base healthcare decisions.[5] Individuals should not be allowed to come to harm from research that uses information concerning them, particularly since it may be future patients (rather than those whose data have been used) who benefit from such research. There is, however, little evidence that serious harm has been caused by the use of confidential records in medical research.[4]

When designing a research project using confidential data, researchers should consider the ways in which the data are to be used and the measures to be taken to protect confidentiality. They should assess the likelihood of any harm being caused to individuals and the value of

alternative approaches to protecting patient privacy and managing the risk of disclosure. Training is needed in the assessment and implementation of appropriate measures to minimise the risks of harming individuals.[4]

In the same way that mismatch may exist between the real and perceived risks to an individual from their records being used in medical research, mismatch can also occur between the real and perceived risks to the research enterprise of restrictions on the use of personal data. Again, therefore, it is helpful to consider the ways in which the data are to be used and the measures that can reasonably be taken to protect patient confidentiality without unduly hampering the research process. Irreversible anonymisation reduces the risk of breach of confidentiality, but stripping the data of identifiers may render data unusable for some research purposes—for example, by removing the potential for linking data to future diagnoses. In each case, the likely effect of alternative approaches to protecting personal data on the potential health gains from the research should be assessed, rather than applying blanket rules. If these risks and benefits can be considered in a balanced way this should not only provide appropriate protections for the privacy of individuals but should also help promote high quality research that can benefit public health.

Explicit risk-benefit assessment

How should those involved in planning research using personal data proceed in ways that protect patient privacy and respect confidentiality appropriately without unduly impeding important research? A useful starting point might be to develop an explicit assessment of risks and benefits for the proposed use of such data. Aspects of this assessment could include the type of study, nature and sensitivity of the records, and likely value of potential results. Careful consideration should be given to the sensitivity of the personal information to be used and the potential effect that the research findings might have on those in the study and on the group of people who might be affected by the findings.

An explicit assessment should help researchers to consider how best to minimise the risks of causing harm to potential participants while avoiding undue obstacles. It follows that, whenever suitable action can practicably be taken to reduce the potential risks, it should help to ensure that the resultant balance of risks and benefits is more favourable. A checklist of the potential risks and benefits considered during this planning stage could be provided to data controllers and review bodies, along with a description of the measures to be taken to minimise the risk of causing harm to individuals (including training of research staff, information for participants, and data processing and access policies[4–6]). The assessment should cover the aspects discussed below.

Potential risks to participants

Clearly, the potential for adverse effects to study participants must be borne in mind at all stages of research using personal data. Apart from putting in place systems to minimise the possibility of personal information leaking out by accident or through deliberate wrongdoing,[6] researchers need to be alert to the possibility of causing harm or distress through other means (see below).

Consent for the use of confidential records— Key considerations are whether consent is required and, if so, what form it might take.[4 5] When no contact with, or feedback to, individuals is planned, seeking consent might create anxiety without compensating benefit. When contact is required—for example, to obtain additional information or invite active participation—but it is not possible to obtain prior consent for accessing records, the planned approach must be shown to minimise the risk of causing distress. When consent for the use of confidential records is considered necessary and practicable, potential participants should be told who will have access to the data, how confidentiality will be maintained, and how the data may be used. It may, however, be appropriate to be non-specific about possible future uses because the rapid development of science and technology makes it difficult to predict all future uses (although participants could be informed that these would be consistent with the general purposes of the project).[7] In all circumstances, it is important to establish secure systems for maintaining confidentiality (such as, key coded pseudonymisation that reversibly separates identifiers from other information) and for controlling access by trained and supervised staff.[4 6]

Approaches to potential participants—When contacting potential research participants it is important to avoid inadvertently causing distress to them or their families. Checks should be made that contact details are correct, that the individual is still alive, and that there are no special reasons for avoiding contact (such as recent bereavement). Central registries could be used to check addresses and vital status, and responsible clinicians could be asked to check that there are no particular reasons for not approaching any of their patients.[8] It may also help to have the initial approach made either by the person's clinician or, perhaps more practically in multicentre studies, in the name of the clinician or some other appropriate person or organisation.

Re-use of data for purposes other than originally defined— New scientific hypotheses often arise that could be tested using existing data, but explicit consent will not have been obtained for such use. In these circumstances, the most likely cause of real harm to the people involved would be through inadvertent or mischievous disclosure of their personal data. When feedback of results is not planned (see below), and appropriate safeguards are in place to maintain the confidentiality of personal data securely, the potential for such harm is generally low. This reinforces the need to ensure that systems are in place to protect confidentiality and control access.[6]

Feedback of findings to study participants and families— The findings from studies using personal data may have substantial implications both for the individuals studied and for the wider public. Researchers must carefully prepare findings to allow access to information without causing undue anxiety. Moreover, in some types of research, it is not possible to counsel participants about the health relevance of possible findings (in which case it may be appropriate to instigate a policy of "no feedback" of an individual's results[7]). Ideally, individuals who have contributed to a study should be notified of the general findings, although this may not be appropriate when the records have been used without contact. Publication of results that highlight adverse health behaviour or other

risk indicators could lead to stigmatisation of defined groups. But, the potential for such harm to a particular group might be unavoidable and should be balanced against the potential benefits for them and others.

Potential risks for research

The main risks to research were considered in the recent Academy of Medical Sciences report on the use of personal data.[4] They stem chiefly from over-interpretation of regulations rather than from over-regulation.[4]

Obstacles due to inappropriate interpretation (or over-regulation)—Issues to consider include the need for consent when contact is not involved; the restriction of access to records for research purposes; and the loss of informativeness by irreversibly anonymising data.[4–6] These could have major costs for research and public health in terms of time, funding, and scientific value. Alternative approaches that are ethically acceptable (such as, central processing of records by researchers on behalf of the data controller, in accordance with the Data Protection Act[4 8]) should be considered during the planning and reviewing of research proposals.

Public health damage from loss or destruction of data—As well as the potential obstacles to an individual study outlined above, potentially valuable scientific material could be sub-optimally used if over-interpretation prevents the re-use of existing data or sharing of data between research groups with common interests. For example, if consent for re-use of data becomes a requirement this could mean loss (or destruction in the case of tissue samples) of large amounts of potentially valuable information. Optimising the use of data in this way is appropriate not only scientifically but also for fostering collaboration between research groups and promoting value for money. Consideration needs to be given to how the potential of data can be maximised while still protecting patient privacy and maintaining confidentiality.

Benefits

Many individuals wish to contribute to research and substantial evidence shows that those who do so not only enjoy being a part of a study but may also benefit from a health-related perspective.[4]

Impact of research findings—When developing a study, researchers should be as explicit as possible about the potential direct or indirect benefits that might be obtained for participants, defined groups in the population, and society as a whole—for example, how many lives might be saved by widespread use of a treatment in a clinical study (if found effective) and how this might affect individual patient care, public health policy, and the costs of health care. The way in which this is expressed will be determined by the nature of the study question and the outcomes being researched.

Opportunities for collaboration—Research groups may collaborate either in the same study or by sharing data between groups. Such collaboration not only has the potential to strengthen the research scientifically but provides opportunities for groups to work together on developing and testing new hypotheses.[9 10]

Summary points

Any research study involves potential risks and benefits.

Privacy of individuals should be respected, but disproportionate obstacles to using personal data in research may adversely affect public health

Researchers should make an explicit assessment of risks and benefits for the proposed use of confidential records

Conclusions

Clearly, we need to respect the privacy of individuals whose data are used in research. It is also critical, however, to consider what is practicable for a research project that may have important health implications. An explicit overview of the potential risks and potential benefits to the participants and to the planned research would facilitate a more informed review of the appropriateness of the ways in which confidential data are to be used and protected. This should help researchers to consider how best to minimise the risks of causing harm (while still avoiding undue obstacles), and help ethics committees and other guardians of confidential records to be assured that appropriate systems are in place.

This series arose from discussions stimulated through participation in the MRC's data sharing and preservation initiative, which aims to extend new and secondary research using high value research datasets collected with public funding for the public good. It will lead to a web based route map through current regulatory processes supported by guidance for good practice when using personal data for medical research (www.mrc.ac.uk/strategy-data_sharing_implementation.htm). We thank Peter Dukes and Allan Sudlow for support and advice. The opinions expressed are those of the authors.

Contributors and sources: RC has been involved in designing large scale randomised trials and epidemiological studies that have influenced international guidelines on the conduct of research and had major implications for public health and health guidelines. CD has been involved in the design and conduct of clinical trials and worked at the MRC in public health and health services research.

Competing interests: None declared.

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