Published in : Q J Med (2014), vol. 107, n°1, pp. 3-5
DOI: 10.1093/qjmed/hct236
Status : Postprint (Author's version)

DATA PROTECTION REGULATION AND THE PROMOTION OF HEALTH RESEARCH: GETTING THE BALANCE RIGHT - COMMENTARY

R. Fears[1] H. Brand[2], R. Frackowiak[3], P.-P. Pastoret[1,] R. Souhami[4] and B. Thompson[5]

From 1FEAM, Brussels, Belgium, 2European Alliance for Personalised Medicine, Brussels, Belgium, 3Medical Sciences Committee, Science Europe, Brussels, Belgium, 4Academy of Medical Sciences, London, UK and 5Wellcome Trust, London, UK
Address correspondence to Or R. Fears, Policy Advisor, FEAM, Palais des Academies, Rue Oucale 7, 7000 Brussels, Belgium. email: info@feam.eu.com

Health research is essential for better public health and health care. However, the use of personal data in research could be put under threat by amend-ments recently adopted by the European Parliament.

Individual patient records provide a vital resource for health research for the benefit of society. These records form the basis for observational studies of the factors influencing health and disease and help researchers identify suitable participants to invite them to take part in clinical trials concerning their condition. Jt is equally essential to make most use of the research that has already been completed. By re-using patient research data where appropriate, participants in trials are then assured that the data they contribute help to further knowledge without unnecessary duplication of research.[1]

Jn the European Union (EU), the use of patient data in research in Member States is governed by the Data Protection Directive, which has been criti-cized as overly complex, sometimes ambiguous and presenting an obstacle to epidemiological and other research. Furthermore, variability in the implemen-tation of the EU Directive in different countries has impeded the collection and use of complete, accur-ate and homogenous data in multi-centre studies, for example using diabetes registries.[2] The Directive is now being revised as a General Data Protection Regulation (DPR) with the objectives to harmonize data protection within the EU, facilitate the flow of data across borders and enhance privacy protection. Although reservations had again been expressed at the potential for jeopardizing the use of personal data in health research,[3] the proposed reforms did initially offer new opportunities to researchers, enabling international collaboration by streamlining the currently complex data protection rules. The European Commission's draft DPR acknowledges that research generates valuable knowledge for so-ciety and includes an important exception to enable the sensitive personal data-including health data-to be processed for research without consent under certain conditions.[4]

However, during passage of the draft DPR through the European Parliament, the lead Committee on Civil Liberties, Justice and Home Affairs (LJBE) has voted to amend the research provisions. There are serious concerns that some of these amendments, in particular removing the exceptions

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from consent for the use of identifiable data in research, would hinder health research dramatically.[5] Statements by the Federation of European Academies of Medicine (FEAM),[6] by FEAM with the Wellcome Trust[7] and by Science Europe[8,9] have drawn attention to what is at risk. The societal benefit of health research will not be realized if the DPR does not succeed in creat-ing a legal framework that strikes an appropriate balance between facilitating the safe and secure use of personal data in health research and the rights and interests of individuals. Particular prob-lems likely to be caused for patients and researchers have been exemplified with regard to rare disease registries.[10]

FEAM, the Wellcome Trust and Science Europe, together with the European Alliance of Personalised Medicine, recently organized a discussion event in the European Par I iament to bring together interested parties from the pub I ic and private research sectors, patient groups, ethics committees and legislators. The goal was to ascertain what is needed from the DPR to keep health research alive in the EU.[11] A summary report has been pub I ished by the orga-nizers 12 and in the present paper we highlight some of the key points and emerging issues for the collaborative endeavour of health research.

It was clear from the meeting that there is wide-spread mutual interest in achieving the right balance between protecting the individual and encouraging popu la ti on-based research. The right to personal privacy must be balanced with the right to health-care and other interests such as access to a healthy environment and the efficient use of taxes. Satisfying these multiple rights requires effective use of per-sonal data in research, within a facilitative adminis-trative framework, standardized procedures and a clear legal context-these are the challenges for the DPR. Researchers use anonymized data when-ever possible but pseudonymized data (key-coded to protect privacy while permitting justified access) are sometimes needed for research; one example is the EU Collaborative Oncological Gene-environ-ment study (http://cogseu.org). Identifiable data are also essential for particular research purposes, for example for long term follow-up (such as in research on uncommon childhood illnesses) and where re-searchers need details such as post code, age and information on a health condition, that together could disclose an individual's identity.

Specific, explicit, informed consent for the use of data in research may not always be practicable, for example in disease registries and biobanks, research on rare diseases, the statistical re-evaluation of data using new techniques or with refined hypotheses, and in monitoring a range of variables over ex-tended periods. Tens of thousands of records are often necessary for these large scale studies. Nonetheless, health research in the EU is conducted within a robust ethical framework, using validated procedures for safe processing of personal data. Ethics committees play a central role in balancing risks and benefits of research and ensure that data will be collected and used in a way that is also pro-portionate to the potential benefits to society as a whole. Thus, the provisions of the DPR must take into account the wider context of the many other safeguards, guidelines and regulations that already provide the framework for health research activities. It is important to clarify any contradictions in EU policy that arise within this complex environment. For

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example, the proposed LIBE amendments to the D PR seem to be at variance with the requirements of the EU Cross-Border Directive which specifies that data have to follow the patient.

The report of the meeting[12] discusses these and other issues in more detai I, focusing on what is sti II controversial and what needs clarification. The adoption of such damaging amendments by the LIBE committee must energize the medical commu-nity to contribute to the debate. It is crucially im-portant to ensure that any new legislation takes account of the societal benefits of health research and the existing safeguards in this area so that new obstacles to research are not introduced, intention-ally or inadvertently into the final text. Some key points in this regard are summarized in Box 1.

In conclusion, in many respects the EU has a strong, productive health research base. However, the European Parliament's amendments pose a sig-nificant threat to the benefits that this research can deliver for healthcare and public health, and to the EU as a globally competitive environment for health research. To ensure these amendments do not become law, it is essential for researchers to con-tinue explaining to the public and policy-makers why health research is important and that patient data are an essential core resource. It is now impera-tive to set the balance between the public good arising from health research and the protection of the individual so that patients and the pub I ic con-tinue to benefit from scientific advances and to bu i Id on the longstanding experience of many European centres of excellence for data processing. It is also prudent to devise a proportionate regulatory frame-work that is sufficiently flexible to cope with future changes in collecting, analysing, aggregating and transferring data. As noted previously,[13] this has been a busy time for EU policy-makers in terms of legislation affecting health and research, and the re-search community has a continuing responsibility to analyse and debate the options for building the health research enterprise.

Box 1 : What is needed in the DPR ?

1. Article 83 of the European Commission DPR proposal and associated provisions for scientific in-clude an exception from consent for the use of identifiable data in research-should be maintained. There are some research circumstances when it is necessary to use identifiable data without consent and the DPR should permit this, provided that there is no practicable alternative and that appropriate safeguards such as ethics committee approval are in place. The UBE committee's amendment to Article 81 that restricts the processing of health data for research must therefore be rejected.

2. Pseudonymized data must be handled proportionately by the DPR, taking into account the minimal risk of re-identification when robust safeguards are in place.

3. There must be a limit to the administrative burden placed on researchers and administrators. For example, a single data protection impact assessment should be sufficient for processing operations that present similar risks, in line with the UBE committee's amendment to Article 33.

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4. The DPR should facilitate cross-border transfer of personal data for health and research purposes and the text should be amended to ensure this.

Source documents : Refs. 6-9, 11 and 12.

Acknowledgements

We thank Nessa Childers MEP, Stephen McMahon (Irish Patients Association), Greg Rossi (European Federation of Pharmaceutical Industries and Associations) and Jean-Marie Maloteaux (Academie Royale de Medecine de Belgique) for their contributions to the European Parliament Roundtable. Conflict of interest: None declared.

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