Association of Medical Research Charities' response to the Ministry of Justice Call for Evidence on the Review of the Balance of Competences between the United Kingdom and the European Union: Information Rights

Tuesday 1st July

The Association of Medical Research Charities (AMRC) is a membership organisation of the leading medical and health charities funding research in the UK. Working with our members, we aim to support the sector's effectiveness and advance medical research by developing best practice, improving public dialogue about research and science, and influencing government to ensure the best research can go ahead and be translated into new treatments.

Medical research charities exist because the public choose to donate their money to support research to develop new treatments and cures. In 2013, AMRC members invested £1.3 billion in health research in the UK.

Access to patient data is essential for medical research and, ultimately, for saving lives. The information held about patients in their medical records can be used to research the causes of disease, monitor survival rates, study the effectiveness of treatments and interventions, and identify appropriate participants for clinical trials. In other words, patient data holds the key to medical progress. And patients want to share their data for this cause. In 2011, in a survey of 990 people in the UK, 80% said they would consider allowing a researcher confidential access to their medical records.[1]

We agree that protecting privacy is crucial. The Data Protection Regulation must strike the right balance between protecting personal data whilst enabling life-saving research. We believe that it is possible to encourage the safe and secure sharing of data to facilitate research whilst protecting patient confidentiality so patients can be confident that the personal nature of their information is respected.

Due to our interest in this issue, we would like to respond to Question 4 from this Call for Evidence:

What evidence is there that proposals for a new EU Data Protection Regulation will be advantageous or disadvantageous to individuals, business, the public sector or any other groups in the UK?

If implemented the European Parliament's amendments to Articles 81 and 83 would seriously impact on scientific research in the UK, including health research and the social sciences. The European Parliament position that emerged from amendments made by the Civil Liberties, Justice and Home Affairs (LIBE) committee would make much research involving personal data at worst illegal, and at best unworkable.

The original draft Regulation proposed by the European Commission struck a crucial balance, setting out a proportionate mechanism for protecting privacy, whilst enabling health and scientific research to continue. It included a requirement for specific and explicit consent for the use of personal data concerning health, but provided an exemption from consent for research, subject to certain safeguards in Article 83.

The LIBE Committee's amendments to Articles 81 and 83 – now adopted by the European Parliament – significantly reduce the scope of the exemption for research. For example, the use of personal data

[1] Ipsos MORI (2011), Public support for research in the NHS. http://www.ipsos-mori.com/researchpublications/researcharchive/2811/Public-support-forresearch-in-the-NHS.aspx

concerning health in research without specific consent would be prohibited or become very difficult in practice.

Consent is a crucial ethical principle and researchers will seek consent or use anonymised data where possible. However, it is not always feasible to seek consent, particularly where it is required to be specific and explicit. Where this type of research does take place, it is subject to ethical approval and strict confidentiality safeguards, and the identity of individuals is often masked.

If implemented, the European Parliament's amendments would put at risk significant European investments in genetics, cohort studies, biobanks, disease registries and the use of routinely collected data, and associated progress towards understanding society, health, and disease that delivers real patient benefit.

We hope that the position of the European Council and subsequent trialogue talks can recalibrate the balance between protecting privacy and enabling research that has been lost in the Parliament's amendments.

These are just a couple of examples from our member charities of hugely valuable studies which would be severely impacted by the EU Data Protection Regulation:

UK Collaborative Trial of Ovarian Cancer Screening
Researchers need to be able to contact potential participants to invite them to take part in studies. For example, the UK Collaborative Trial of Ovarian Cancer Screening contacted 1.2 million women by post to invite them to take part. More than 200,000 postmenopausal women without ovarian cancer consented to take part in this study on the effectiveness of screening techniques for ovarian cancer. Were the LIBE committee's amendments adopted, specific consent would have been required to identify and contact the 1.2 million eligible women, even before inviting them to take part in the study itself. This would make recruitment for valuable large-scale studies such as this very difficult and costly to conduct.

Tracking Parkinson's study
Tracking Parkinson's is the world's largest ever in-depth study of people with Parkinson's. It is a 5-year project which aims to speed up the search for a cure by finding 'biomarkers', many of which circulate in the blood. Participants complete questionnaires, donate blood samples and have their Parkinson's symptoms carefully monitored at regular hospital appointments and give broad consent for these data to be shared with researchers. The information and samples collected in the study are made available to researchers studying Parkinson's all over the world free of charge. This study would become unworkable under the LIBE committee's amendments since the form of consent is very narrow.

If you would like to discuss our comments further please contact Rachael Mann at r.mann@amrc.org.uk