

New EU Data Protection Regulation may have major consequences for patients in Europe



We welcome the European Commission's initiative to reform data protection legislation.

However, if the amendments proposed by the European Parliament (particularly of Articles 81 and 83) are adopted, health and scientific research may be severely threatened.

Action is required now

EU Ministers are in the process of discussing amendments right now, and negotiations between the Council and Parliamentary Representatives will take place later 2015. A final text, adopted by both the European Parliament and the Council, is to be expected late 2015 or early 2016. It is vital that the provisions affecting research are carefully drafted to ensure that the Regulation strikes an appropriate balance between facilitating the safe and secure use of personal data in research and the rights and interests of individuals.

Sooner or later, we are all patients

This is about preventing diseases and developing safe treatments for all of us. Scientific research generates important benefits by improving our understanding of health and disease. As citizens and healthcare consumers, we are all patients and beneficiaries of prevention programs. Progress in healthcare development is based on a chain of donations of information. Yesterday's patients donated knowledge to today's patients, and today's patients donate knowledge to tomorrow's patients. A break in the chain of donation of information would have a devastating effect on current and future patient care and disease prevention.

Personal data is crucial for improving public health and healthcare

Personal data, such as individual patient records, is a vital resource for research that benefits society and saves and improves patients' lives. Personal data allows researchers, for instance, to compare various factors (such as lifestyle) and incidence of disease at an individual level. Breakthroughs made possible by these studies include identification of the link between smoking and lung cancer and the treatment of infection in unborn babies.

It is therefore alarming that the proposed amendments would make much of the research involving personal data at best unworkable (by severely hampering options for collecting, using and sharing data from registries and bio banks) and at worst illegal.

How will the European Parliament's amendments prevent health research?

The proposed amendments would:

- prohibit the use of data for other than pre-specified purposes. Under the proposal, personal data will be collected and processed for specified purposes only and may not be used for a purpose incompatible with the original purpose. This will restrict the use of large historical data bases, originally collected for a specific purpose.

What type of research would the European Parliament's amendments put at risk?

Two examples of research discoveries that would not have been made without historical patient data:

Heart attacks caused by radiotherapy for breast cancer.

In Europe, 40 women are diagnosed with breast cancer each hour. Fortunately, the vast majority of these women survive the disease. Radiotherapy decreases the risk of breast cancer recurrence but carries severe side effects. In 2013 a team of British, Danish and Swedish researchers published an EC-funded study of heart attack risk among women receiving radiotherapy treatment for breast cancer. The study showed an increased risk for heart attacks with increasing doses of radiation to the heart. The results of the study have been incorporated accordingly into radiation therapy practice. Breast cancer patients were identified through cancer registries and subsequent heart attacks through in-patients registries.

Cervical cancer caused by human papillomavirus (HPV).

HPV infection is extremely common and around 80% of sexually active women will have been infected before age 50. However, only a small proportion will develop cervical cancer precursor lesions which in their turn may lead to invasive cancer. In many EU member states cervical screening programmes have reduced the number of invasive cervical cancers and deaths by 50% to 80%. Through connecting cancer register data with developed screening methods and research findings, a strong connection between HPV infection and cervical cancer was seen. By development of effective vaccines against cervical cancer and offering HPV vaccination to all young girls in several EU member states, a more profound prevention of cervical cancer is achieved and the health effects will grow with generations to come.

- prohibit the use of identifiable personal data in scientific research without specific consent. Researchers only use identifiable data without consent where other approaches are not practicable, and this is currently only allowed subject to ethical approval and strict confidentiality safeguards. To conduct their studies researchers sometimes require details such as age, postcode and health condition information which, taken together, may reveal the identity of an individual. A research project may contain register data from 1,000,000 individuals, and administering informed consent for each analysis would be practicably impossible and ethically questionable.

How do researchers safeguard confidentiality?

Research using personal data should only take place within a robust ethical and governance framework to ensure that an individual's personal data is only used in research when this is proportionate to the potential benefits for society as a whole. Researchers are given access to personal data only under strict confidentiality controls, which have been effective in preventing misuse and harm to data subjects.

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