Cancer registers have been important tools in primary and secondary cancer prevention and play an increasing role in assessing the quality of health care. Analyses based on national medical birth registers have shown that maternal smoking during pregnancy has detrimental effects on the fetus and on subsequent child health. Data from drug prescription registries linked to other health registers can monitor the long-term effects of drug use in the population, including the discovery of previously unknown side effects.

The list of important results from register-based epidemiological research could go on for several pages. Health-related databases are also increasingly used for monitoring quality of care. The Nordic countries have since a number of years developed 'health care quality register' comprising all patients treated for a specific disorder or with a specific intervention. Analyses of these have improved the construction of orthopaedic prosthetic devices, reduced the likelihood of infection after cataract surgery by 50%, and radically improved the prognosis in childhood cancer.

All record-based research and monitoring of health-care conditions demand a delicate balance between maintaining integrity and anonymity of patients while enabling important research to improve people’s health and quality of care. International ethical guidelines give an important basis for researchers as well as legislators to accommodate basic ethical principles in policy and practice that by necessity may vary between countries.

Under the current EU directive, it has been possible to add or modify the European data protection rules in order to adapt to national conditions. This has led to varying interpretations of the directive across Europe. As a result, data transfer across borders is difficult. But it has also enabled national legislation to maintain and develop research capacity and health-care monitoring using national databases according to existing practices in several countries.

But this may change. The European Data Protection Directive 95/46/EC, is currently being reviewed. In short, the review is intended to harmonize rules for data protection across Europe in order to facilitate the flow of data across borders, and to enhance privacy protection. One ambition is to strengthen the individual’s right to be personally informed and to be able to decide whether or not to be included in health-related research databases.

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Carinci et al.1 propose new ways to protect identities such as ‘privacy enhancing technologies’ (PETs) and by the use of ‘trusted third parties’ (TTPs) to handle the data exchange between data owners. While such measures have been discussed and investigated thoroughly, and should definitely be implemented whenever appropriate, there is a danger that regulators see these measures as a panacea for solving the problems at stake. The encryption of data used in PETs precludes the retrieval of personal data at a later point in time, and TTPs may be legally obliged to use only encrypted data in common data repositories. Hence, using data in new research, or adding new data to an existing follow-up may become more difficult or sometimes impossible.

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The revision of the EU directive was discussed at a Nordic conference on register-based research in Reykjavik in June 2011 and at the World Congress on Epidemiology in Edinburgh in August 2011. Feelings were strong in both instances, and leading scientists in epidemiology and public health research urged participants to contact national representatives to take action to ensure that the upcoming proposal will not jeopardize the use of personal data in future health research.

A plea for action requesting improvements in favour of health monitoring was raised on these pages already several years ago by Verschuuren et al.2 for the Work Group on Confidentiality and Data Protection, addressing the issue to the European Commission. But the Commission has paid little attention to the points made by the Work Group. That is why we fear that the current efforts toward harmonization of European data protection laws could pose serious threats to public health research and monitoring in some countries.

It is easy to agree with Carinci et al.1 that a comprehensive framework for data protection is fundamental to harmonize access to data for EU health monitoring. It is equally important that epidemiological research using record linkage can be maintained in countries that have facilitated this, while possibilities for international data sharing is strengthened throughout Europe. But until we see concrete ways to reconcile the two needs—flexibility and harmonization—we feel the current legislation, enabling register-based research, should be retained.

References


