National law on cancer registration in Switzerland: Background information from NICER and the cantonal cancer registries regarding the use of explicit patient consent for cancer monitoring

Introduction

On 7 December 2012 the Federal Office of Public Health (FOPH) released a draft of a national law on cancer registration in . This marked the start of a public consultation process that will end on 22 March 2013. The draft law distinguishes between two categories of monitoring data ("basic variables" and "additional variables"), each linked to different data protection regimes ("veto right" for basic variables; "explicit patient consent" for additional variables).

Wide discussion throughout Europe on the use of informed consent regimes for the purpose of cancer monitoring concluded that informed consent regimes do not work in population-based disease monitoring . The National Institute of Cancer Epidemiology and Registration (NICER) of Switzerland and the representatives of the Swiss cantonal cancer registries hereby describe concerns regarding these issues and point out the conditions that are needed to continue effective cancer monitoring in this country.

Individual informed consent and its risk for cancer registration in Switzerland

We are deeply concerned regarding the actual plan of the new law to submit the collection and transfer of essential cancer variables to the principle of explicit patient consent. This regulation will hinder the comprehensive and unbiased monitoring of cancer in Switzerland. In 1994, the *Eidgenössiche Expertenkommission für das Berufsgeheimnis in der medizinischen Forschung* carefully evaluated the cancer registration processes in Switzerland (Art. 321bis Swiss Civil Code). As a conclusion they authorized physicians, hospitals and laboratories to deliver cancer monitoring data to the cancer registries if no opposition was claimed by previously informed patients*[3]. The texts for informing the patients were elaborated together with the Swiss Association for [4]. This system worked well, and with this authorization, on their end the Swiss cancer registries guaranteed strict confidentiality and anonymization of all data. We propose that this confidentiality regime should be continued.

NICER and its partners already pointed out the fact that obtaining explicit informed consent from cancer patients would be an arduous if not impossible . Not only we will need to contact several thousand people every year, including families of patients already deceased, but we might also cause harm to those patients (mostly elderly patients with co-morbidities) who are ignoring the fact that they have cancer or pre-cancerous . Cancer registries have no direct access to patients and receive automated notice of cancer diagnoses from laboratories and pathology institutes. Any break in this automated process will reduce the exhaustiveness of recording and lead to biased cancer information, which will then no longer be useful for epidemiological purposes and research studies at a national level. These arguments are broadly described in international [-13].

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*General information about cancer registration delivered to patients in hospitals/health centres/medical cabinets via brochures, posters, flyers, etc.

Asking each cancer patient for informed consent will seriously threaten to jeopardize all the Swiss cancer registries. Regulations of the same sort have led to the closure of cancer registries in Germany and Hungary and disabled the cancer registration in . In the United Kingdom a regulatory initiative that required informed consent for cancer registration led doctors to stop reporting cancer cases to the cancer registry; as a consequence, urgent legislation was required to prevent the national registry from being crippled and .

The importance of keeping complete population-based records

The benefits of keeping complete population-based records have been shown repeatedly over the past 50 years. If we now put in place a restrictive new law on cancer registration in Switzerland, it will have some major consequences on the quality, accuracy and exhaustiveness of epidemiological cancer research in Switzerland. Crucial public health research studies—such as local and national high-resolution studies on the access to care, quality of diagnosis and treatment, or cancer risk by occupation—could no longer be conducted. Innovative and promising research linking registries with other databases, such as the Swiss national cohort study, will become difficult or even impossible. Furthermore, informed consent will also conflict with existing cantonal laws and regulations governing the registries' activities and processes in each canton.
Finally, the proposed new law on cancer registration will increase costs substantially and will cause delays, with no better safeguarding of confidentiality.
For the record, the proposed new EU directive on data protection currently contains three articles exempting research conducted with cancer registry data from explicit patient [2]. Based on these considerations, we strongly believe Switzerland should go into the same direction.

Conclusions

Cancer is a major public health threat in Switzerland; this justifies the collection of complete and unbiased population-based data for monitoring purposes. In this case, the legal view on the security of personal data should be subordinated to the legitimate need to improve public health by preventing disease, establishing screening programs, improving health care and avoiding health risks. With the current draft on the new cancer registration law, these main objectives will definitely not be reached!

In order to achieve these objectives, it is crucial to exempt the collection of basic and relevant additional cancer data from the need of patients' explicit consent. In Switzerland and abroad, the well-established practice of "presumed consent", which has proved to be an adequate and balanced alternative to individual informed consent, protects the patient's privacy, guarantees the public's right to be informed and enables high-standard scientific research to the benefit of the health of the population.

The new law on cancer registration should consolidate cancer registration processes in Switzerland and support the development of an effective cancer monitoring system; it should not add barriers to it.

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