

The inconsistent ethical oversight of healthcare quality data in Switzerland

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Introduction

Although evidence-based medicine has led to much progress, there remains significant unwarranted variation among treatments that clinicians and health systems routinely use in practice, and deficiencies regarding all key aspects of healthcare [1]. The insufficient protection of patients from unjustified harms and burdens from clinical care has been identified as a “profoundly serious moral problem” [2]. As a result of this situation, healthcare systems are increasingly using routinely collected health data to achieve continual improvement in healthcare and to answer questions about treatment efficacy and effectiveness [3]. Although such activities to improve care and patient safety are urgently needed, questions persist about how healthcare improvement activities using health data should be regulated.

As a result of the sharp distinction made between clinical research and clinical practice by ethical oversight systems around the world following various scandals in the last century, whether a healthcare improvement activity using health quality data receives ethical oversight often depends on whether it is classified as “research” or “quality control”. Research involving humans requires approval from an independent ethics committee, fully informing participants and obtaining their written consent, but there is no equivalent process for non-research activities. This situation can result in inconsistent ethical oversight of healthcare improvement activities, and has also raised concerns that the oversight system itself may undermine efforts to improve patient care by “protecting” patients from research that does not undermine their interests or rights [2]. As the Swiss healthcare system increasingly looks to derive knowledge from clinical practice and use this knowledge to drive the cycle of continuous healthcare improvement, it is important to consider whether the current regulation of healthcare improvement activities using health quality data appropriately balances the need to protect individual participants against the social value of improving health care.

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Healthcare quality data collection in Switzerland

Nationwide quality indicators are collected and published by two key organisations in Switzerland to provide stakeholders and the general public with transparent information about healthcare quality and to serve as a basis for continuous quality improvement.

Federal Office of Public Health (BAG)

Utilising routine data from the Federal Statistical Office, the BAG publishes the Swiss Inpatient Quality Indicators (CH-IQI) for every acute care hospital in Switzerland. The development of the indicators is a coordinated process with Germany and Austria, which allows results to be compared between the three countries. Quality indicators include case numbers, mortality in certain diseases, proportional values (e.g., caesarean section rate) and selected length of stay [4].

National Association for Quality Development in Hospitals and Clinics (ANQ)

To complement the BAG official quality indicator set, the ANQ also coordinates and implements quality measurement for hospitals and clinics at the national level. ANQ is supported by the cantons, the hospital association, Santé-suisse (umbrella organisation of health insurers), the Federal Social Insurance Funds, and the Swiss Conference of Health Directors. The basis of ANQ’s activities is article 32 of the Federal Act on Health Insurance, which requires service providers and funders to periodically review the effectiveness, appropriateness and efficiency of services by use of scientific methods. ANQ’s national quality contract has been signed by all Swiss hospitals and clinics, and requires them to collect a wide range of quality indicators (e.g., wound infections, falls, hospital readmission, repeat operations, patient satisfaction, etc.) in acute medicine, rehabilitation and psychiatry in accordance with the ANQ measurement plan [4]. Two data levels can be distinguished within the ANQ measurement framework: (1) data concerning patients, and (2) data concerning hospitals and clinics.

Ethical oversight of healthcare quality data in Switzerland

Medical research became comprehensively regulated for the first time at the federal level in Switzerland in 2014, with the implementation of the Human Research Act (HRA). The HRA applies to research “concerning human diseases and concerning the structure and function of the human body” which involves, among other things, health-related personal data (article 2). The HRA does not apply to research involving anonymously collected or anonymised health-related personal data (article 2), whereas research involving non-anonymised health data is required to obtain approval by an ethics committee.

The HRA typically only allows nongenetic health-related personal data to be reused for research purposes in uncoded form “if informed consent has been given by the person concerned”, or in coded form if the person concerned has “been informed in advance and have not dissented” (article 33). The HRA also allows for so-called *General Consent* (*Generalkonsent*) under certain conditions, where a person agrees to the use of their data and samples for future research projects subject to future ethical review. There are ethical and legal concerns that general consent undermines specific informed consent [5], but the Swiss Academy of Medical Sciences and the Swiss Ethics Committees for Clinical Research have endorsed general consent and have developed a suggested template for *General Consent* in Switzerland [6].

However, if these consent requirements are not met, the reuse of data for research purposes may be permitted without consent in exceptional cases if “(a) it is impossible or disproportionately difficult to obtain consent or to provide information on the right to dissent, or this would impose an undue burden on the person concerned; (b) no documented refusal is available; and (c) the interests of research outweigh the interests of the person concerned in deciding on the further use of his or her biological material and data” (article 34). The example of activities using ANQ quality data nicely highlights the implications of this current regulatory framework in Switzerland.

Collection and use of ANQ data for “quality control” purposes

At the start of data collection, ANQ sought legal advice and determined that hospitals and clinics are not required to obtain ethical approval from an ethics committee or informed consent from patients for the collection of ANQ data. Although no official documents resulted from this legal advice, ANQ provides three justifications for this position: (1) the data collection is required by the Federal Act on Health Insurance to allow the effectiveness, appropriateness and efficiency of services to be scientifically reviewed; (2) ANQ is not conducting “research” and therefore its activities do not fall under the HRA; and (3) ANQ and its evaluation institutes at no time have access to the key of personal identifiers (held by the hospitals and clinics), but only to the data in its anonymised form (personal correspondence, Dr Luise Menzi, Head of ANQ Rehabilitation, 20 December 2017).

Secondary use of ANQ data for “research” purposes

Whereas the first right to publish the results of the nationally comparative measurement lies exclusively with ANQ, which will decide whether and in what form the results are to be published, data are also archived to allow for them to be reused in the future for scientific purposes [7]. Under article 11(1) of the ANQ data regulations, ANQ is permitted to share only fully anonymous data for reuse in research; however, as ANQ measurements do not generate completely anonymised data, ANQ itself is not currently permitted to share data [8]. Data that are not fully anonymised are the responsibility of the relevant hospitals and clinics. If these coded data are reused for research purposes, it falls under the HRA and Data Protection Act [8], and requires ethical approval from the responsible ethics committee. For patient-level data, the person concerned must “have been informed in advanced and have not dissented”, unless the ethics committee allows for the use of the data without of consent under article 34 of the HRA.

Discussion

At present, ethical oversight is handled very differently in Switzerland for healthcare improvement activities using the same quality data, depending on whether they are classified as “research” or “quality control”. However, these activities can often not be reliably differentiated from each other.

At the core of the current inconsistent ethical oversight is the sharp distinction made by regulations between “clinical research” and “clinical practice”. However, it has been acknowledged by the Swiss Ethics Committees on research involving humans (swissethics) and the Swiss Academy of Medical Sciences that research cannot always be clearly differentiated from non-research [5, 9]. Indeed, although the HRA defines “research” to mean a “method-driven search for generalisable knowledge” (article 3), attempting to distinguish “research” and “quality improvement” based on the rigor of methods (internal validity) and generalisability (external validity) of the findings is typically unconvincing [10]. This also appears to be the case with “research” and “quality control” activities using ANQ data in Switzerland: both are using rigorous scientific methods, both are attempting to derive knowledge from clinical practice to improve healthcare, and both activities publicly publish their results. It is therefore difficult to see the justification for these activities receiving vastly different levels of ethical oversight.

Whereas the HRA does not apply to research involving anonymous data, ANQ data are not fully anonymised but are “coded data”; personal identifiers have not been “irreversibly masked or deleted” as required for anonymisation by article 25 of the Human Research Ordinance. Although ANQ and its evaluation institutes at no time have access to the key of personal identifiers (held by the hospitals and clinics), but only to the data in its anonymised form, this is also the case for “research” using the data and simply confirms that the data have been correctly coded according to article 26 of the Human Research Ordinance (“data are considered to be correctly coded [...] if, from the perspective of a person who lacks access to the key, they are to be characterised as anonymised”). As a result, it appears that one of the justifications ANQ provides for not requir-

ing ethical approval or consent for the collection and use of ANQ data is not correct. Because ANQ data are not fully anonymised, neither “quality control” nor “research” activities are currently legally exempt from ethical review simply because of the type of data being used.

The fact that ANQ data collection is required by the Federal Act on Health Insurance probably provides a legal justification for hospitals and clinics to collect patient level ANQ data without patient consent (article 13 of the Data Protection Act). Although the reuse of this data without consent for research purposes may also be permitted in exceptional cases under article 34 of the HRA, typically, the person concerned will need to be informed in advance of the use of their data for research purposes and not dissented. Although the wording of article 33(2) appears to permit “passively informed”, obtaining a signature by the patient has been recommended as it is the only way to prove that the patient has been informed [11]. It is also unclear why these activities should be treated differently with regards to patient consent and notification. It has been argued that it may be ethically acceptable for certain healthcare improvement activities to be conducted without patients’ consent, but these arguments do not distinguish between “research” and “practice” and also assume ethically robust oversight practices [2].

Conclusion

The ethical oversight system in Switzerland currently places a higher standard of ethical oversight on “research” in comparison with “quality control” activities using the same quality data. However, these activities cannot often be reliably differentiated from each other and the inconsistent ethical oversight of these activities needs to be reconsidered. The level of ethical oversight healthcare improvement activities using health quality data receive should depend on the risk that they pose to participants, not whether the activity is labelled “research”. It is increasingly recognised that some form of ethical oversight is desirable for most initiatives aiming to improve the quality of healthcare [12]; however, we do not think that the correct solution is to simply expand the current research oversight system as a research ethics committee will not always be the best mechanism to achieve this. Further consideration needs to be given to how regulations can be revised in a way that ensures that healthcare improvement activities using the same quality data in Switzerland are not either overregulated on one side (potentially undermining efforts to improve patient care) or completely without control on the

other (potentially exposing patients to unjustified risks or burdens).

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Potential competing interests

The authors have no other competing interests to declare.

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