Many steps make up the mile: Towards a harmonised General Consent within Switzerland

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A journey of a thousand miles begins with a single step. This Chinese proverb comes to mind when one is considering the project of introducing a harmonised General Consent (GC) in Switzerland. Nobody knows where the journey will take us, but this much is certain – with the harmonised GC, adopted in 2019 by the university hospitals, the first step has been taken.

Introduction: Taking the first step

A journey of a thousand miles begins with a single step. This Chinese proverb comes to mind when one is considering the project of introducing a harmonised General Consent (GC) in Switzerland. Nobody knows where the journey will take us, but this much is certain – with the harmonised GC, adopted in 2019 by the university hospitals, the first step has been taken.

The large amounts of data that hospitals produce daily represent a huge potential for medical research and innovation. Human Research in Switzerland 2018, a report on the research projects evaluated and approved by the Swiss ethics committees in 2018, shows that a significant portion of medical research today is made possible by the reuse of routinely collected data. A structured and transparent use of this data, taking into account the legitimate interests of protecting patients, is therefore an important contribution to medical progress.

Following the coming into force of the Human Research Act (HRA) in 2014, all five university hospitals have taken the opportunity to create a GC for the further use of data for research. Its introduction was taking place on a decentralised level, as the introduction in each institution was dependent on the approval of the respective ethics committee. This meant different solutions for the GC in the different university hospitals – whereby each of the implemented solutions was approved by the responsible ethics committee – and was therefore compliant to the HRA. After this initial and decentralised introductory phase, it was soon realised that national patient-centered research projects using health related data should be based on a harmonised consent solution.

Harmonising the different approaches of the various institutions and stakeholders involved is a complex undertaking. The major challenge lies in the fact that digitisation itself is a decentralised process that is

inherently in constant conflict with the idea of centralised or harmonised solutions. This is all the more true as patients, hospitals, and researchers alike are constantly confronted with new possibilities, requirements, and risks stemming from the digital world.

A first milestone in the harmonisation efforts was reached in 2019: After intensive discussions, the version 2 of the GC template was published. The template was prepared by a working group of university hospitals and received a joint adoption by unimedsuisse, the Swiss Academy of Medical Sciences, and swissethics. It can be downloaded on the websites of **unimedsuisse** and **swissethics**.

The GC 2019 template finds the balance

When drafting the GC 2019 template, the focus was on making it conform legally with the HRA and be comprehensible to patients. In view of the complexity of the legal framework and terminology that is barely comprehensible to laypersons, a balance had to be found between describing legal details with precision and remaining understandable.

At the same time, the applicability had to be taken into account. For example, contacting a patient in the event of “incidental findings” – i.e. in the event of new findings or treatment options for them – can not be guaranteed, because in reality it is not always possible to locate former patients, years on. Yet, it is mentioned as an aim in the information. It is a question of honesty to make visible the practical limits and not to make false promises to patients.

The greatest benefit of the harmonised template lies in improving the protection of patient interests. This is achieved above all by the fact that with the GC 2019 template, the approval solution has become the standard. The contradictory approach, which is possible according to the HRA and has also been used in previous consensus solutions, has been abandoned. This contributes to the patients' understanding of the meaning of their individual decision and goes along with the EU General Data Protection Regulation (GDPR).

From a research perspective, the main advantage of the harmonised GC is that it simplifies research cooperation between different institutions and thus meets the current research settings in multicentre studies.

Last, but not least, the GC 2019 template will serve as a common basis for the further development of research infrastructures or innovative approaches for public participation in research. These include the projects of the Swiss Personalized Health Network (SPHN) with the development of IT interfaces, as well as electronic consent or – further in the future – the development of a dynamic consent system.

Developing governance as a core task

Currently, the harmonised GC 2019 template is being put into practice in university hospitals and several other institutions. This practical process is as important as the template itself. The implementation of appropriate governance in everyday hospital life is a complex undertaking that includes a wide variety of clinics, hospital-wide IT processes, and careful documentation. As a change process, it affects questions of corporate culture as well as the attitude of the individual researchers.

The unimedsuisse working group has addressed the common issues of implementation and has drawn up **a series of recommendations for applying the GC template**. They are available to be downloaded from the website of unimedsuisse. These explanations of how the GC 2019 template can be interpreted and applied are intended to facilitate its implementation. The recommendations explain, for example, what “no”, “yes”, and “no status” mean in concrete terms and how the patient data can be used according to the documented choices.

The recommendations pay specific attention to those patient groups in particular need of protection – namely children/adolescents and persons incapable of judgement. It provides a feasible approach to still include vulnerable patient groups for health related research projects considering actual hospital resources. If the process of consenting is designed appropriately, it is possible to apply the GC 2019 template to all these groups of patients. While some hospitals choose this solution, other hospitals differentiate the information provided, according to the patient's age.

The actual implementation, however, always remains the responsibility of the individual hospitals themselves. They must bear in mind that there is still no uniform practice among the regional ethics committees. To this end, it can be useful for hospitals to clarify their solutions individually with the ethics committee responsible for them.

Conclusion: Empowering the patient as the future challenge

The harmonised GC template represents an important step forward, setting a standard and allowing for convergence in practice. Following the adoption of the harmonised template, the focus at this stage is on its implementation in the hospitals. The recommendations that have been worked out among university hospitals should provide assistance in this regard. However, they do not relieve hospitals of the need to reflect on and shape governance within their institution. In a further stage, the experiences of implementation will have to be compiled and incorporated into further development of the GC.

But the development of the GC is not only a question of regulation and governance, forms, and procedures. It is embedded in the wider social and individual setting. The lay person as the general public are also on this journey of a thousand miles, as they are deeply affected by these issues. No matter how elaborate the consensus solution in hospitals, it cannot work out if patients cannot handle their own data and if they do not feel capable enough to make informed decisions. The development of the GC thus remains closely linked to the digital competencies and empowerment of the lay population. By developing public templates and procedures of the GC, university hospitals seek to contribute to this competence as well as to building trust in their institutions.