Considerations on General Consent in paediatrics

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The general goal of the initiative launched by the Swiss Personalized Health Network (SPHN) is to establish the infrastructure needed to collect and provide data and samples from Swiss residents, to ultimately support personalised approaches to healthcare.

For the paediatric population, the project "Harmonizing health-related data and biospecimens across paediatric hospitals" was set up to create a common database of health-related variables to be collected from inpatient children in Switzerland, and to develop a consensus among all major paediatric hospitals on which data and which samples should be stored. Through this project, a unified data structure and list of target samples, which could support future high-quality research projects in paediatrics, will be generated. General consent (GC) in paediatrics would allow for this data to then be available for research.

In 2018, a working group – consisting of paediatricians, adolescent physicians, a patient advocate and health lawyer, and a representative from the group of HIV-positive adolescents – was convened by the Swiss Academy of Medical Science (SAMS). This group created a fact sheet and a checklist on the topic of what to consider when seeking general consent for research in the paediatric population. In January 2019, both documents were shared with and reviewed by SwissPedNet (Swiss Research Network of Clinical Pediatric Hubs) members, representing paediatricians conducting clinical research in Switzerland.

Under what circumstances is obtaining GC in paediatrics permitted?

GC aims to support the use of routine data and samples that are gathered as part of regular medical care for research. According to the Human Research Act (HRA), art. 22ff, research projects requiring data and/or samples from patients should be of potential benefit to the participating population. This, however, is rarely the case for children and adolescents as diseases are rare and long-term benefits often unclear.

However, importantly, the paediatric population should not as a result be excluded from research. Without data and samples from children, research projects cannot be conducted in this age group, and results obtained from research on adults, in general, cannot be extrapolated for children. The use of routine data and samples from this vulnerable group in fact serves to minimise the burden of research on them, by reducing their need to undergo additional visits and unpleasant interventions, while still potentially informing better approaches to future medical care. Therefore, processes and strategies should be implemented to obtain GC in children and adolescents.

What kind of written information is required for the paediatric population?

From a legal perspective, written information from the legal representative of a patient is central to the consent process, including for children and adolescents. As such, when children are younger than 14, their parents (or their legal representative) can decide on their behalf, taking into account the interests of the child, based on their knowledge and beliefs. It is, however, recommended that children and adolescents be “age-appropriately” informed about the study and give their assent verbally. If the patient is 14 years or older, both the adolescent patient and their parents are expected to indicate their consent in writing.

For many studies, this written information – which can be offered in as many as three to four types of format suited to the different types of addressee – is considered necessary:

1. The first, addressing the parent or legal guardian of children and adolescents: This version usually is similar to patient information for adults, but its greeting and wording are adapted, e.g. “your child is being approached to participate in…”.
2. The second, addressing adolescents between 14 and 18: the content of this version corresponds to the patient information for adults, but the greeting is adapted, e.g. in German, French, or Italian, the address will be informal (using “Du” or “tu”). If appropriate, the unchanged written information prepared for adults can be given to youth aged 16 and older.
3. The third, addressing children of 11 to 13: In this version, the language is deliberately simplified, shorter, avoiding complex scientific or medical terms, and the facts are explained according to the patient’s age. In addition, visual representations can be used.

4. Sometimes, depending on the study, a fourth type of written information is created to address children younger than 11. This form is typically very short (less than a page), relies as much as possible on drawings, and uses simple words to explain the study.

Double consent, always together with parent or guardian

According to the HRA (art. 23), teenagers older than 14 have the right to decide for themselves whether they wish to participate in a study that poses minimal risks. GC processes could be interpreted as being of minimal risk, as the patient's data are already available in the electronic patient record and their biosamples are "leftover" material. Nevertheless, the working group recommends double consent for youth of this age, meaning that the parents (or legal guardians) should be included in the GC. The working group's reasoning is that the long-term effect of the use of these data and samples, progress in medical diagnostics, and the possibility that personally relevant findings may be generated in the future may affect the decision, and these eventualities cannot be fully evaluated by teenagers. Of course, when the teenager reaches legal adulthood at 18, they can independently reconsider and potentially withdraw their previously granted approval.

Recommending temporary consent

Intensive discussions took place about the issue of re-consenting children and adolescents when they reach adulthood. The working group decided that a GC should only be valid until the donor of data and samples reaches adulthood, i.e. until their 18th birthday. Nevertheless, technical hurdles hinder implementation of this recommendation and may substantially delay the use of longitudinal data for the paediatric population.

Over the years, the attitude towards the use of data and samples may change, as may the related research opportunities and their impact on society. From this perspective, using data and samples from a neonate or child for an unspecified period of time may be problematic. This topic remains pertinent and should be reviewed periodically.

Conclusion

The paediatric community is ready to implement a GC process within children's hospitals, countrywide. Although all SwissPedNet member institutions started with different information and consent forms, SwissPedNet decided to initiate a harmonisation process based on the template for adults, version 2/2019, issued by unimedsuisse.

The problem related to the transition to adulthood and to the transition from dual to single consent remains and needs to be revisited in the future.