

E-general consent: development and implementation of a nationwide harmonised interactive electronic general consent

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Background

According to the Swiss Law on Research in Humans, the re-use of routinely collected genetic and non-genetic data and samples from patients for research purposes requires the consent of patients. So far, a paper-based “general consent” process with a handwritten signature has been established at all five Swiss university hospitals; this allows the further use of data and samples once the patient has received the respective consent information and given consent.

To integrate the general consent process into the hospitals’ daily work, different time-points for contacting the patients had to be considered. These time-points are usually regulated by the admission services. However, the need of additional paper documents for patients requires additional resources in terms of printing, assigning, explaining, collecting and transferring data into the clinic system. Although significant resources were invested in establishing the general consent, use of the paper-based process did not achieve the anticipated general consent coverage of 80% required for a meaningful data pool for personalised health research. Analysis from 2016 to 2017 at the University Hospital Basel showed that 25.5% of patients in the outpatient and inpatient sector (44,437 out of 174,113) returned a decision. Even though 85.8% of patients returning a decision (38,159 out of 44,437) agreed to share their data and samples, we need to make more effort to enlarge the general consent patient pool supporting the success of research initiatives in personalised health. Uncoupling the general consent from the admission and reducing the need of resources would be a crucial step to complement the current general consent process.

Goals

The goal of this project is to develop the general consent process further for a more flexible and admission-independent electronic request. This will create more options for contacting the patients at different time-points and, if required, by various personnel, resulting ultimately in a larger pool of patient data. A digital interactive presentation of

the general consent information enables us to address different patient groups and to present specific information accordingly. To make sure that patient needs are effectively met, patient representatives will be involved in the development of the electronic presentation of the respective information.

Results from a 4-month pilot project testing electronic consent presented under the same conditions as the paper documents suggested that this approach is well accepted by patients. Even though the study did not reach the predetermined sample size because of technical difficulties, the electronic consent rate (84.6%) was not different from the consent rate with the established paper process (85.5%) during this time. Encouraged by this positive outcome, we aim to develop an interoperable professional grade electronic general consent solution with consolidated technical support.

Significance

The intention to develop a harmonised nationwide interactive electronic general consent process is well accepted and highly appreciated by the key stakeholder groups involved in the general consent implementation, including all Swiss university hospitals, the Swiss Clinical Trial Organisation and SwissPedNet. The additional support by Swissethics and the Swiss Academy of Medical Sciences are another important factor for successful realisation of this project.

The project uses the possibilities arising from digitalisation to propose new technical solutions to the presentation of general consent information in standardised terms, in order to better address patient needs depending on age, language, health and mental status. Making the process technically more flexible optimises the process of recruitment of inpatients or outpatients, independent of designated hospital personnel. To propose sustainable solutions, the project takes into account Swiss legal requirements and the specific needs of the involved university hospitals, as well as values and preferences of patients involved.

As it addresses a central bottleneck in the Swiss Personalised Health Network initiative, this project was selected to be one of the financed infrastructure development projects. It has the potential to significantly advance the de-

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velopment of a functioning Swiss Personalised Health Network and to tailor one of the central prerequisites for data exchange and interoperability for research purposes.

Disclosures

Prof. Dr Pauli-Magnus reports grants from the Federal Council, during the conduct of the study.