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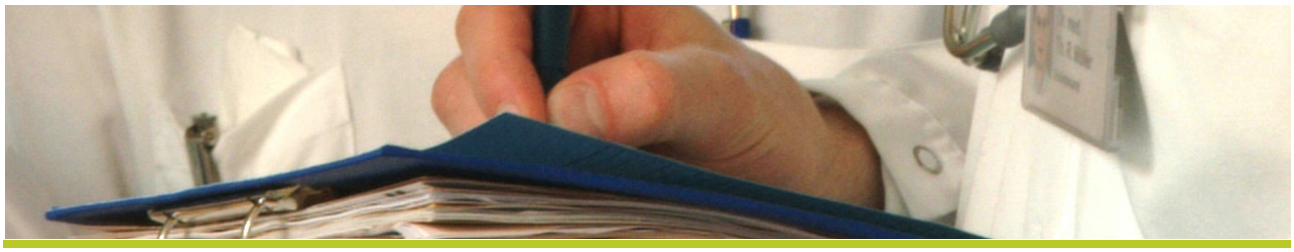

SCTO Forum Clinical Research 2015:
General consent – Yes! But how?

The collection of biological material and patient data and their further use is essential for diverse human research areas. With the introduction of the Human Research Act (HRA) in January 2014, the issue of how to obtain a general consent from patients and donors for the further use of their data and biological material in research raised major discussions. The Forum Clinical Research 2015 has been dedicated to this discussion involving major stakeholders. Patients, biomedical ethicists, data protection delegates, authorities and researchers were asked to share their opinion.

The programme developed and directed by the SCTO attracted over 90 invited representatives of the major stakeholders in Swiss clinical research. The event took place on 28 January 2015 in Bern and was moderated by Susanne Brauer, PhD. Prof Dayer, President of the SCTO, opened the 5th Forum Clinical Research and welcomed the audience.

General consent: current examples

During the first session, the SCTO member institutions demonstrated their approach to obtain general consent from their patients

All six member institutions presented their own (planned) process of obtaining as many general consents as possible from their inpatients and outpatients in compliance with the law.

The concepts and methods already in use, or anticipated within the individual institutions, are similar. Basically, they strive to follow the national law and its ordinances and they carefully exploit all instruments to have the patients' data protected and the decision about consent or referral at disposal for all investigators at any time. It is crucial to involve all clinics, IT departments and patient administrations at the very beginning and to follow an accurate communication plan. Staff who inform the patients and ask them for general consent must be adequately trained.

The long-term financing of the implementation of the general consent process remains an open issue. Additional qualified staff is needed to address all patients and a minimum of 15 minutes must be devoted to inform the patients and donors appropriately. In Lausanne, for example, a team of almost 8 staff members is solely in charge of contacting and informing patients.

Details about the concepts and methods of each institution can be found in the slides provided on the SCTO website.

Statements from the Federal Office of Public Health (FOPH) and swissethics and open discussion with the audience and the speakers

Michael Gerber from **FOPH** stated that the principle of a general consent stands at the crossroads between protection of personality and the interest of scientific research. The legislature decided to make a risk-adapted approach to take account of the self-determination of each person, i.e. the patient and donor may decide whether they give consent to the use of their samples and data in research, whether their data must be anonymised or coded, if they want to receive information about any future incidental finding, etc. Following the discussions heard during the forum, the variety of decision-making seems to be too differentiated and challenges not only the researchers and institutional IT applications, but also the patients concerned.

Dr Jürg Müller, President **swissethics**, recommended having a common approach between all ECs approving general consent forms from their institutions. Similar procedures and information to the population should be available throughout Switzerland. For example, the right of information is handled differently by individual ECs, depending on the emphasis between the patient's legal rights and the researchers possibilities to fulfil their obligations.

The audience named further **obstacles**:

- The models developed so far should be shared with all cantonal and regional hospitals, and even with the general practitioners. For meaningful and unbiased usage the data and samples have to represent the entire Swiss population and thus a national solution might be required.
- The "institution biobank" is not regulated within the law – only the use of the samples thereafter. Harmonisation and regulation is needed.
- How to practically proceed with general consents given by parents for their children once the children are grown up and may decide on their own?
- The researcher pertains the legal obligation towards the right of information of incidental findings, which he/she cannot necessarily fulfil in all cases and it is currently unclear how this can be solved. For example, the traceability to the donor is only theoretically possible, a researcher in the lab cannot necessarily establish the link between a finding and a possible diagnosis.
- How to proceed with retrospective research and use of data? Currently the legal framework allows no further usage as new requirements cannot be met.

What is the situation in Europe? How does Switzerland fit into Europe?

General consent in Europe in comparison to Switzerland

Prof Beat Rudin, Data Protection Supervisor of the Canton of Basel-Stadt provided an insight into the complex legal situation.

In Europe, there is currently no overriding regulation regarding general consent for research purposes. However, the EU is working on a new basic regulation for data protection for all member states. This may be relevant for Switzerland in future.

Anyway, the regulations between Switzerland and the EU should not differ too much in order to allow exchange of samples and data across the borders. The appropriateness of both levels of data protection, i.e. the Swiss level versus the European level and vice-versa, will be important.

An important instrument will be the proper process of coding of samples. However, the combination of varied coded data sets will allow the traceability back to the individual. With the anonymisation of data, the right of information cannot be guaranteed and the claim on the implementation of this right remains difficult when it comes to coded samples.

In Switzerland, the use of general consent is, in principle, permitted. Patients and donors give consent to the uncertainty, which is acceptable as long as this is clearly stated in the information brochure and/or general consent form. The patient has the right to withdraw his/her consent at any time and without providing reasons.

An outlook: In the future dynamic models might be applied to obtain consent, e.g. donors have the possibility to get informed actively about on-going research projects with their samples, and in case of disagreement, they may withdraw their consent. It is conceivable that in future we will have either a dynamic *information* model where the donor must actively withdraw his/her consent or a dynamic *consent* model where a re-consent would be necessary for new projects.

Future technical challenges

What technical challenges will large data and sample collections and all their links bring? And what are possible solutions?

Prof Christian Lovis, Division of Medical Information Sciences from HUG, stands up for **BigData**.

BigData is still unclearly defined. It is the convergence of large amount of data, the usual understanding of it, but also of new characteristics such as streamed data, distributed heterogeneous sources, time persistence,

and complex semantics, to name a few. Thus, BigData addresses numerous new challenges, such as distributed analytics, knowledge management or variable data quality.

One of the fundamental characteristics of BigData is its capacity to allow developing a new theoretical framework to support research without knowing the research question "a priori", such as the traditional hypothetico-deductive approach. Streams of data exist; they can hardly be changed or improved, such as social networks data streams, or environmental data. What instruments can be developed to capture and use these data streams to address health or public health challenges? How to search, aggregate, and cross-reference large streamed data flows? Similarly to meteorology and climatology, the science of correlation and causality in medicine will have to evolve to complex models.

In conclusion:

- We need new models to manage consent. Research social networks and direct participation of citizen, such as crowed research, might be amongst the solutions to investigate. The old time of signed consent on a piece of paper is dead.
- Real anonymisation of individual data is no more possible, and in any case impossible for tissue and other bio-material.
- BigData must not be seen as an engineering challenge of "volume and velocity". It is a scientific challenge that requires new approaches, new science and new theoretical frameworks.

What are the expectations of the patients and what do the researchers need?

The forum concluded with a panel discussion in which *Karin Holm*, representative of a patient organisation, *Prof Samia Hurst*, biomedical ethicist, *Prof Hans Ulrich Bucher*, neonatologist and researcher, and *Prof Aurel Perren*, researcher and biobank expert, presented their opinions to the audience.

Patients often have a huge interest in clinical research as they know first hand how life changes with a specific diagnosis. They need cures and hence, the majority of them has a positive attitude towards research. However, patients want to become addressed and involved. The self-determination of each person as given by the law is very much in the meaning of patients. It should, however, not impede research.

The **ethical** approach to the general consent for research includes a paradox: primarily patients must be protected, but at the same time, they also want research for their cure. Trust plays a key role in each person's decision-making: patients and donors will only consent to research if they trust their physician and the institution behind. Clear regulations on how and when material or data will be shared must be regulated, communicated and implemented with conviction. An institutional trust governing the access to data and samples could be the solution. Respecting cultural differences is very important. If the research community wants to reach the entire population, this must be considered in information brochures and consent forms.

Within **neonatology** and the maintenance and care of cohort registries the new law challenges the researchers. A cohort registry is only meaningful if data from > 95% of the population can be collected, otherwise one cannot make valid conclusions. However, under the new law, this is hardly achievable. For research with sampled data and material neonatologists often use the clause of article 34 as the request for consent to e.g. parents who just lost their child is considered to be unreasonable or even impious. Quality control is essential too, but it is not reflected in the HRA.

From the **biobank's** perspective, the possibility to give a general consent for further use of biological material and data is a major step for research and researchers. For the time being, the resources to better respond to the legal requirements are lacking – and it is not known who should pay for it. Infrastructures must be established to deal with all opportunities and limitations consented by patients and donors. Full transparency regarding the use of the material and data must be guaranteed.

Prof Pierre Dayer appreciated the lively debate during the forum. Very meaningful issues have been raised. The SCTO will keep track of the progress and assist with nationwide solutions.

All presentations of the Forum 2015 are available at www.scto.ch.

Save the date:	**Wednesday, 17 June 2015** **6th SCTO Symposium in St. Gallen: «Clinical / nursing / research – a convergence of two disciplines»**