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A patient perspective: Talking about the Swiss General Consent

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To get an understanding of the patient perspective on the General Consent (GC), RA Watch Editor Séverine Méance met with Philipp do Canto from the Swiss Multiple Sclerosis Association (MSA).

Can you introduce yourself and the organisation(s) you represent?

I am a member of both the board and the scientific advisory board of the MSA. MSA supports people living with MS, supports scientific research, and provides its 15,000 members with independent information about their condition. I am also partner at the legal firm Public Sector Law, based in Zurich and Brussels. My focus lies on the healthcare sector, including projects in data-driven medicine.

What do you think about the need for a GC?

GC is very important for both spheres, that of the patient and of clinical research. Although not every patient is aware of the full implications of consent, GC is a fundamental element for patients as part of the regulatory and ethical approval process designed to ensure transparency and safety in all research projects. A long-lasting debate in the search for a nationally recognised standard highlights the difficulties associated with GC, but also the significance of such a declaration.

What consequences do you expect with its use?

On the positive side, I hope it will foster research and further promote Switzerland as a centre of scientific excellence. On the downside, I anticipate that the GC will continue to be perceived as a free pass for any type of use, and that patients will not be able to keep track of the use of their data.

What do you think about a national and harmonised version?

In today's scientific landscape, research is rarely carried out as single-centre studies. When a study is multicentric, the way it more often is, the use of multiple versions of GC forms may lead to an unnecessary administrative burden. Keeping in mind that medical professionals and researchers have to comply with regulation on human research on a Swiss national level (i.e. the Federal Act on Human Research or on Genetic Testing in Humans), I do not see any rationale for multiple, centre or cluster-focused versions of GC.

We have one set of legal standards applied to consent – e.g. of minors, or people deemed incapable of giving consent – and clinics and patients need to therefore develop a common understanding about GC nationwide. So it is a positive sign that the major centres are working to use a common standard (i.e. the version published in February 2019).

What positive aspects do you foresee, and what could be improved?

The brevity of the current form containing two pages of information is certainly a plus. I do not think that patients in Switzerland would feel comfortable with a declaration extending over 10 pages or more, as you often find in some clinics or other European countries, such as in the UK. The disadvantage of a shorter form is, of course, its lack of precise, necessary information.

A patient may consent to one set of data being used, but not be aware that their consent could be applied to other sets of data collected during subsequent consultations, at the same hospital. This GC to use data collected at further hospital visits would then raise questions. It is possible to agree on data use if the patient is aware of its content, for instance if they were treated for a sports injury. But later on, the same patient could be treated for a sensitive illness and potentially be reluctant to grant consent. But, in reality, the already consenting patient will not be asked again for their consent. In order to address such uncertainties, the concept of dynamic consent is promising: patients should be enabled to manage their consent independently, at later stages.

Furthermore, very little explanation is given in the current GC form on the background of a standard research project. Patients may also want to know more precisely where, when, and how they can withdraw their consent. Transparency on data use (meaning its traceability and feedback on it) is merely theoretical if clinics do not provide patients with a digital interface. The technology of today allows for much more feedback to patients. In the future, it will be absolutely crucial to every person to know where and in which data set their data (e.g. their DNA profiles) is stored.

What are your perspectives about the next steps for its implementation? What are your hopes?

As a lawyer, I hope our Swiss regulator will provide clarification regarding the handling of GC, in the planned revision of research law. Although there is no need for the Federal Council to change the detailed rules on consent in the law itself, it has announced that it will address the lack of transparency and the low level of cooperation among the stakeholders in the revision of the federal ordinances on human research. This may have some implications regarding GC as it plays out in the daily operations of a clinic, such as better and technology-supported means to communicate among the parties involved.

As for the importance of data protection in the EU, we also need to closely monitor further developments abroad. Brussels will remain a strong driver for compliance and regulatory issues regarding data management in human research. Technology enables us to build bridges, crossing over into new territory, but they need to be safe enough for patients to use them.