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Strengths and Weaknesses of the European Concept of Informed Consent: Theoretical Issues and Practical Examples

Nikolaus Forgó, Magdalena Góralczyk, Constantin Graf von Rex
Institute for Legal Informatics
LUH Hannover, Germany
forgo@iri.uni-hannover.de
goralczyk@iri.uni-hannover.de
constantin.rex@iri.uni-hannover.de

Abstract—**A general overview of the legal requirements for consent in health in European Union is presented and a comparison between three different usage of consent is being offered: consent for care; consent for clinical trial participation and consent for data processing. On a second stage a practical example of the strengths and weaknesses of the European concept of informed consent, the research project Linked2Safety is presented. Particular attention is being paid to the involved patients in the project, the different types of consent and the phases of the project as well as the data within the project.**

Keywords - Infromed consent, clinical tirals, patients, sensitive data, European Union framework.

I. INTRODUCTION

This article combines views on informed consent of two different European projects – one analyzing theoretical aspects of the notion, the other having practical difficulties with the concept in daily practice. The theoretical framework will examine the requirements put forth by law and ethics. The practical part unveils struggles to enable research and allowing researchers as much freedom as possible, while still safeguarding patient rights and preserving conformity with the abovementioned legal and ethical duties.

In a first stage CONTRACT [1] will be set forth and on basis of work done in this project a legal framework will be presented. In a second stage the project Link2afety [2] will be introduced and practical consequences will be explained on its example.

II. CONTRACT PROJECT

A. Project aims and background

CONTRACT: Consent in a Trial and Care Environment is an EU 7th Framework Programme project running until September 2012. The focus of the project is laid on the legal and ethical issues concerning informed consent in the context of patient care and translational research and underpinning issues of data processing. A central goal of the project is to understand how the European Data Protection Directive [3] and the European Clinical Trials Directive [4] and national implementations of both have impact on clinical research, in particular in a translational setting.

The question of informed consent is at the nexus of many obstacles with which clinical trials in Europe currently struggle. On one hand, being the essential basis of a successful patient–researcher relationship, informed consent is an indispensable condition of any trial. On the other hand however it is a serious impediment resulting from uncertainty surrounding legal requirements. It is at this juncture that CONTRACT seeks to find solutions to support researchers in both today's and future clinical practice.

One of the issues consent is currently posing before the researchers is the fact that whenever a clinical trial with participation of human subjects is to commence not one, but at least three consents have to be obtained: that is firstly for medical treatment, secondly for participation in the clinical trial and thirdly for processing the patient's personal data. The requirements for consent in all three cases will be described below.

B. Introduction to consent and its requirements

The principle of consent entails that the health professional can act only after patient's agreement on proposed treatment or trial has been obtained.

The rule of consent originates in both moral and legal theory.

Faden and Bauchamp [5] followed the distinction between the moral and legal backgrounds of informed consent and offered two distinctive meanings of the notion. In moral sense consent is an autonomous authorization securing that patient/trial subject is treated as a subject, capable of taking an autonomous choice, in opposition to being an object only.

The second understanding is the legal one – where consent is used as a legally effective measure. This stems, when it comes to care, from Anglo-Saxon law, where torts of battery and assault safeguard individual's bodily inviolability [5] – no one shall be touched, or threatened to be touched without permission. Hence, without consent the medical intervention will be seen as an illegal assault.

The legal understanding of consent is underpinned by the moral substance and is a way in which the law safeguards that substance and protects individual's autonomy.

Below requirements for consent will be analysed following the division resulting from the legal acts – firstly consent for care, secondly consent for clinical trial participation, and thirdly consent for data processing in the framework of clinical trial.

Figure 1: Types of Consent

C. *Informed consent for care*

Informed consent for care is not legislated on EU level, but falls under domestic legislation of each Member State. However, there is a certain common understanding in the Western world regarding the ethical roots of consent [6] and thus of requirements any consent for care and treatment should meet. These will be signalized here.

The notion of consent is on the one hand an important emanation of autonomy[6] and self-determination[5] of individuals. On the other hand it is also what constitutes the physician-patient relation.

On the basis of this relation physician and patient should establish whether, and if yes, to which extent, the eventual treatment or diagnostic procedure shall take place. The physician should communicate to the patient important information concerning his/her health and possible options available to him/her. The duty to inform the patient is crucial, as it allows the patient to make practical use of his/ her right and make conscious choices. The information given should be fit to the patient needs, expectations and cognitive skills.

D. *Inormed consent for clinical trial participation (research)*

Unlike consent for care, which is legislated on the Member States level only, consent for clinical trials participation has been legally implemented on the European level. The law which also defines the informed consent for that scope and standards this consent has to fulfill, is the Clinical Trials Directive.

The aim of this Directive was to set clear guidelines on the conduct of clinical trials and harmonse these European-Union-wide. Currently, after wide critic [7] the Directive is under review and a draft of Regulation [8] which shall replace it was recently introduced. Among other reasons for critic also the legislation on consent was criticized as contributing to the administrative burdens, which researchers have to face.

The Directive defines informed consent in Article 2(j) as: "decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation."

The provisions of the Directive concerning consent can be divided into two categories: the substantial requirements towards consent and the formal requirements, which have to be fulfilled to sufficiently document the process of giving consent.

The first category would include: consent being a free decision. The duty of duly informing the patient before receiving his/her consent is the second of the obligations in this category, finally the individual needs to be capable of consenting.

The duty of information is further elaborated in the Directive: as informed consent is only valid if given after being "duly informed" the Directive states the topics, which have to be addressed every time consent is being obtained. Those are:

- nature of the trial
- significance
- implications
- risks

Formal requirements for consent are written and signed informed consent form, which in addition has to be dated.

E. *Inormed consent for data processing during the clinical trial*

Both of the former types of consent are well established in the medical world, on the opposite a relatively new requirement of obtaining consent for data processing when dealing with patient data within a trial is also a necessity.

The Clinical Trials Directive points out that a clinical trial may only be undertaken if "the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with Directive 95/46/EC

are safeguarded" (Article 3 paragraph 2 (c)). By that the Clinical Trials Directive reinforces the importance of obedience to data protection norms within the clinical trial.

However on the very first step of consideration of processing of personal data in medical context a distinction has to be made between different purposes for which the data is being processed. That is important, as legality of processing of personal data relies on the legitimate purpose. Therefore processing of personal data for care and treatment has to be treated differently then processing of (even exactly the same data) for research purposes.

The Data Protection Directive knows few and defined conditions under which processing of personal data is considered legitimate: these are laid down in Article 7. If the personal data being processed is data concerning health and hence a special category of personal data, which regularly will be the case in context of both medical treatment and clinical trials, the stricter rules of Article 8 apply.

Article 8 of the Directive generally requires by its paragraph 1 that "Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life". However, according to Paragraph 3 this rule shall *not* apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy."

Consequently, data processing in context of medical care is allowed whenever it fulfills the requirements of the paragraph 3.

Processing of data for clinical trials is however not addressed by the exemption just introduced, as clinical trials do not meet the requirement of following "purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services".

Data processing in context of clinical trials therefore is only legal, if any of the conditions set up by Article 8 paragraph 2 apply. Regarding clinical trials this means that "the data subject has given his explicit consent to the processing of those data".

The Data Protection Directive defines consent as "any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed" (Article 2 lit. (h)). In case of health data the Directive requires furthermore that the consent given has to be explicit. (Article 8 paragraph 2 (a)).

Processing of the patient's health data in clinical trials hence requires as much consent as does performing medical treatment and conducting clinical trials. Again, "consent" means providing as much information to the patient as is needed for him or her to completely understand the consequences of his / her agreement (which may differ in each single case due to both objective and subjective reasons regarding the particular patient). In all the cases of consent, the information has to meet the requirements set up by the respective legal framework, in particular its purposes while taking into account the particular risks each of the legal frameworks wants to provide protection for.

As a result, "informed consent" to medical treatment means e.g. providing the patient with such information which is necessary to completely understand the risks and possible consequence of a specific treatment, hence enabling him / her to decide whether or not to take that risk. "Consent" in context of processing personal health data however means agreement after providing the patient with all that information which is needed to understand the impact of the data processing itself – regardless of any medical implications. Consequently, informed consent regarding the processing of the personal health data obviously requires different information than informed consent to trial participation (e.g. which data is collected for which purposes; whether or not it will be transferred to third parties and if yes for which reasons; how long the data will be kept etc.). Particularly, data collected for one purpose only shall not be used for a different purpose later on.

III. PRESENTATION OF THE PROJECT LINKED2SAFETY

The informed consent of patients to participate in clinical research is connected with some problems in practice. As an example for the informed consent the project Linked2Safety will be presented.

Linked2Safety is a project funded by the European Commission in the area of ICT for health. To promote clinical practice and accelerate medical research is the vision of the project. This shall be done by providing pharmaceutical companies, healthcare professionals and patients with an innovative semantic interoperability framework facilitating the efficient and homogenized access to distributed Electronic Health Records. The Linked2Safety project intends to develop a next-generation, semantically-interlinked, secure medical and clinical information space in Europe. This should allow to discover, combine and access medical resources and information contained in spatially distributed Electronic Health Records. The reuse of electronic health records in clinical research should also be improved by the project. Within the project all relevant legal and ethical problems shall be investigated. Finally, the requirements of the European data protection law also receive attention. A Linked2Safety Data Privacy Framework shall guarantee the compliance with the European and national legislation, with regard to the publication, access to and reuse of the patients' personal and healthcare data.

The ambitious goals of the project show that the informed consent is of great importance within the scope of this project. However, informed consent is not the only privacy-related issue to consider. The special feature of the project Linked2Safety is that only anonymous data will be available in the datacube-approach chosen. The data will be rendered anonymous by deletion of identifiable parameters, by accumulation and by the introduction of turbulences in the parameters which will make it impossible to recalculate the original value. The anonymous data is collected in a data cube which the data provider creates outside of the Linked2Safety platform. After the creation of the data cube it will be stored into the Linked2Safety platform. Whereas within the framework anonymous data is processed where data protectuion rules no longer apply, the necessary anonymisation of data as such is a form of processing of data, so that requirements of informed consent to be observed.

A. Involved patients and their informed consent

From a data protection legislation perspective a project like Linked2Safety could in principle be carried out without the consent of the participating patients in many cases. Under specific circumstances, medical research may also be seen as being ethically and legally acceptable without informed consent, in particular when the competent ethics committee gives approval. From an ethical point of view consent is in most cases however a crucial precondition and therefore shall be implemented into the project. Medical data of any patient not willing to take part in the project shall not be included.

Patients should be adequately informed by a trained person about the research goal, the scope of their consent and the possibility of withdrawal of their consent at any time, effective for the future. The information given to the patient must be so comprehensive that it is possible for the patient to make a free decision on a broad basis for decision. The person explaining the patients the scope of their consent and informing them about the project, needs to know the individual phases of the project (see below C.). Without a thorough investigation, it would not be possible for the patients to give their informed consent for participation in the project with their data. The patient must not be exposed to any external pressure in his decision. Patients should agree in writing to make patients aware of the importance and impact of their decision.

Informed consent also needs to be examined when data derived from databases that were not originally collected for the project Linked2Safety are involved. In such cases, patients must also have been informed that their data will also be used in future research projects such as Linked2Safety. Only if the informed consent of patients included the future use of their data, they can be used in the project Linked2Safety.

B. Different types of consent

In the case of the project Linked2Safety, the patient data are collected at the patient and anonymised afterwards outside of the infrastructure. Only anonymous data will enter the infrastructure.

Specified Consent which can be defined as consent for the use of patient data for a limited number of clearly defined research projects, is not an option for the project Linked2Safety at least for two reasons. On the one hand the development of an infrastructure needs data already existing, otherwise an infrastructure could never be developed, as the concrete usage of the data is the output and not the input of the research undertaken. In this case it is not possible to inform the patients about the usage of their data in advance. On the other hand, Linked2Safety needs data collected by the clinical partners at a time when the project was not known. Therfore the project Linked2Safety was not mentioned in the used consent forms and patient information sheets for evident reasons.

With broad/blanket consent of the patient as the data subject it is declared that his data will be used for future unknown research projects. Because of its low administrative burdens this type of consent is the best from the perspective of the researcher. Against this type of consent is alleged that the patients do not know what they agree. Some authors argue that broad consent *"cannot have legal weight because it is too general, too vague"[9]*.

As a solution to the critique of broad consent, the so called tiered consent, that provides possibility to patients to choose between providing consent to specified research, future research related to the current study, any future research, is recommended as a good solution. This type of consent tries to bring together the two other forms of consent. For Linked2Safety tiered consent would mean that the patient could select between consent for the collection, processing and use of health data only for the original research project or for the project and beyond for unknown future projects or for the project and also for specific research projects in the future but not for all. Against this kind of consent speak the same arguments used against the specified consent.

C. Phases of the project

Initially, the project is divided into different phases and in the course of these phases are different people and groups to develop the platform of the project and then work with that platform who will have access to the data involved in the project.

In the first phase of development of the platform there are only the technical partners of the project who need access to data in order to be able to develop the technical solutions provided by the project. As a rule, at this stage of the project, no real personal health data from real patients are required. Rather, the development of the platform at this time can be made with invented data or with data from publicly available sources without restriction.

In a second phase within the project's lifetime technical and non-technical partners will need to get access to the platform for evaluation and research purposes. This phase will

require at least limited access to personal data of existing persons by a limited number of internal partners and external members of the special interest group of the project. During this second phase it should be relatively easy to restrict access to personal and health data to legitimate use cases and the careful monitoring of the use of the data.

In these first two phases of the project the processing of data can be well controlled and audited. The confidentiality agreement of the project will ensure in this context, that external stakeholders will get access to relevant information in this phase only if they agree with the confidentiality agreement.

The third phase of the project, the exploitation phase, is characterized by the fact that the data within the platform will be made available to a more general audience. At this time it must be guaranteed that the data on the platform are completely anonymous and they can no longer be placed in conjunction with real people.

D. Data within Linked2Safety

The medical data of each patient do not take part in the project in a way, in which the data were collected. This data has been obtained for a specific purpose after ethics committee approval and should be kept inside the organization that produced them. The final user of the platform developed by the project will get access through the platform only on non-personalized data. Therefore, all data that are accessible through the platform of the project will be rendered anonymous. The Linked2Safety platform is unique in the sense that only anonymous data will take part in the project and there will not be any possibility to track back to the patient. The data is recorded anonymously in data cubes in the platform. It will be crucial to make sure the data cubes leaving data providers (e.g. hospitals) will be rendered anonymous. Therefore it will be necessary to implement anonymization steps related to statistics, scientific investigation and information technology science related to data mining and k-anonymity.

E. Conclusion

All personal data used in Linked2Safety was collected on the basis of properly informed consent given by the patients as the data subjects in writing. All data was collected within medical research projects that were properly announced and cleared by the competent ethics committees. The consent forms used allow the processing of personal data for the purposes of the research undertaken.

Processing is therefore legitimate and covered by the existing consent forms provided that the research undertaken in Linked2Safety is to be seen as part of the existing research project and therefore does not expand or change the research questions tackled. The tools developed in Linked2Safety wouldn't require any additional measures from a data protection perspective as the data controller, the purpose of the processing and the processing as such wouldn't change.

It is therefore vital to guarantee that the data processed for Linked2Safety will be processed in personal form on site only. They will then be aggregated and personal identifiers will be removed by the system so that no personal information will leave the site.

The consent forms might limit data providers to use gathered data for particular studies as Linked2Safety is not explicitly mentioned in the consent forms for obvious reasons.

This might allow the performance of planned clinical research showcases, provided that the showcases are tailored to be in line with the above-mentioned studies as well as relevant ethics committees approvals.

The example of the project Linked2Safety shows the different requirements of the informed consent of patients to participate in a medical research project with their data. At the same time Linked2Safety makes clear that the idea of informed consent of patients to take part in research projects could be implemented and protects –in alliance with strong anonymization – the patients' interests.

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