Informed Consent and Data access issues

Sunday 3 May 2020 12:49

Agenda	Minutes
Description	Consent registration in biobanks and registries is primarily done on paper with scanned copied stored in their management systems. For the EJP RD Virtual Platform (VP) there is a need to have machine readable consent information available. We would like to discuss the development of the use case for machine readable consent using ADA-M and consider if there are related and complementary systems available. Time permitting, we can also look at related task of further development of ADA-M to link to existing ontologies such as DUO and ICO to anchor the ADA-M clauses in an ontological representation.
Objectives	• Development of the Machine-Readable consent use case • Overview of existing systems and technologies • Develop the roadmap for inclusion in the EJP RD Virtual Platform
	Day 1 (04/05/2020)
Participants	**Rapporteur: Annalisa Landi** **Participants:** You can **paste Screen Captures** of the Participants:

• Annalisa Landi • Yanis Mimouni • Benoit Miotto • Bruna DesSantosVieira • Catherine Champseix • Céline Angin • Christian Ohmann • Christina Reimann • Esther van Enckevort • Florian Gleich • Franz Schafer • Kejla Musaraj • Leroux Dorothee	• Mariapia Iermito • Michael Nitzlnader • Petr Holub • Sara Vianello • Sonia Pavan • Viviana Giannuzzi • Francesca Frexia • Jose M Fernandez • L Pasquier • Carles Garcia • Nancy Lynne Mah	• Marc Hanauer • Karl Kreiner • Gonzalo Sofio • David Llyod • Alexander Binder • Mary Wang • Astri - eurohuntington • Coralea Stephanou • Maria Xenophontos • Nancy Lynne Mah • admin aphpneckerhospital • Jaume Català

	Minutes
	• E. van Enckevort starts the parallel session highlighting the objectives identified for the Use Case on Informed Consent and the focus on informed consent for biobanks and registries and the relationship with Task 11.1 and with the ADA-M software tool and data structure. Starting from the limitations of ADA-M and of the existing informed consent forms used for biobanks and registries (paper forms), an use case on machine readable consent will be developed by using ADA-Mand tested with biobanks and registries and researchers working on them. • A discussion starts following the presentation of E.van Enckevort.
	DISCUSSION C.Garcia: • *Through the Virtual Platform we can access e.g. samples in a biobank. Would the informed consent form be checked automatically?* E. van Enckevort confirms that the idea is to automatically check if the request for accessing samples meets the requirements. The system will not fully automate access to samples/data since it cannot automatically check all conditions. (e.g. if a request would deny access to the sample for clinical use) • *When you talk about consent, do you refer to any legal basis?* E. van Enckevort explains that it is more related to the informed consent for medical research not the consent for processing personal or special categories of data as part of the GDPR. However, the consent for the processing of data within research activities (e.g. biobanks) is something we have to cover in the use case too. C.Angin: • *Will the patients have access to ADA-M or only professionals will be allowed to do so?* E. van Enckevort replies that the professionals in biobanks, registries, hospitals involved in the informed consent process will manage the ADA-M software but working together with the patients in creating profiles. • *As registry do we need to connect with this platform/link with this software?* E. van Enckevort replies that it is one of the aspects we need to work out in the use case. How do we enable you to provide us with you profiles? We would find the best way to do this, sometimes it might depend on the preferences of the professionals. P.Holub:

- *In principle is not necessary being connected but describing the consent with appropriate terms ADA-M. It also depends on the support the use case may provide both offline and online operation modes. Consent clauses could be also created in a structured way.* E. van Enckevort agrees and adds that ADA-M could be the tool makes the things easier by avoiding technical and legal definitions. It could be used online without downloading a software in the system and it may be linked to registries and biobanks.

E. van Enckevort:

- *Do biobanks and registries prefer having an online tool or a tool storing locally in the system?* C.Angin replies that they are trying to avoid having different applications for different purposes (difficulties, a great number of passwords) especially for professionals using different computers and networks. Having an online application may be better but should be integrated directly into the registry to make things easier for everyone. E. van Enckevort agrees and introduces the concept of integration. P.Holub reports his experience with the AAI developed within BBMRI and ELIXIR – for all the services provided people have just single identity and could use their home institution credentials. M.Iermito adds that an online application could be better and could avoid the time-consuming activities (such as the downloading of papers). D.Leroux agrees that a full integrated tool would be better. M.Nitzlnader continues that he promotes the federated approach too – having a web application with the possibility to store things on a local site.

P.Holub:

- *Are you willing to offload this type of information? Are you willing to store the informed consent elsewhere? What would be the acceptable scenario you would go into as a registry to be created in the EJP RD virtual platform? In the past, EUPID proposed to do consent-management for all the rare disease patients all over Europe because they need consent for the PPRL and they could do all informed consent but they notice that typically the hospitals need the informed consent for their purposes as well.* E.van Enckevort replies that people will be able to offload the information and that the tool may help creating the machine readable consent and having the record in the registry in order to held information locally, perfectly integrated with the registry.

P.Holub:

- *Within EUPID they would like to create a central consent where patients may change the terms and conditions and exercise their GDPR-related rights. What would be your preferences from the legal perspective, not only from the technical perspective?* M. Iermito adds a consideration: we could make machine-readable only part of the information, personal information should be kept confidential while sharing the others (e.g. things that patients are willing to allow and things that patients are not willing to allow). P.Holub replies that the discussion is more related to the informed consent than to the data sharing. He adds that people (e.g. investigators) are more willing to keep the consent locally and we should consider GDPR requirements (e.g. who is the controller). E.van Enckevort highlights that a lot of people are willing to help this use case and asks P.Holub to join the group.

P.Holub:

- *Suggestion: to pilot the use case once developed and before finalising it in a couple of registry for a reality check.* M.Nitzlnader fully agrees with P.Holub and with a proof of concept implementation in order to see what fits for the needs and how the system can be integrated. E.van Enckevort agrees with the suggestions of piloting the use case involving some biobanks and registries too, it seems the best way to move forward.

M.Wang:

- *Does this online tool already exist?* E.van Enckevort replies that ADA-M also goes with Windows and Mac applications but it is not still online. P.Holub adds that developing such a tool would not be so hard. M.Nitzlnader asks if there is an intention to develop an online tool. E.van Enckevort replies that he will be in contact with the person of GA4GH responsible for the ADA-M development.

M.Wang :

- *Is there a tool compatible with dynamic consent? Is there some kind of structured consents?* M.Nitzlnader replies that it is the reason why we are pushing the idea to create a federated consent and to integrate different systems.

E.van Enckevort:

- *How many are already working on dynamic consent? Do you have idea on how that should work?* M. Iermito replies that, within the Besta Institute, they start talking about dynamic consent but the discussion is still ongoing and the idea has not been implemented yet. M.Nitzlnader adds that it is important to develop dynamic consent also to allow patients to change their minds to exercise their rights and thus to be compliant with the GDPR. Otherwise patients may give the consent to be re-contacted. M.Iermito adds that clinicians often prefer the paper forms because they encounter problems with the applications and we could help them solving the problems. M.Nitzlnader concludes that it is important that patients may be re-contacted.

CONCLUSIONS

- Having an application online integrated with the registry/biobank is preferred (easy to use)
- Piloting the use case involving some biobanks and registries
- Patient management of consent should be taken in consideration especially with reference to GDPR requirements
- Identifying information needs to stay within control of the institute obtaining consent
- Dynamic consent is being consider by some institutes, our solutions should be compatible with this

Day 2 (05/05/2020)

Participants

Rapporteur: Annalisa Landi

Participants:

You can **paste Screen Captures** of the Participants:

• Annalisa Landi • Yanis Mimouni • Alain Veroles • Annalisa Trama • Anthony Brooks • Beatriz Gòmez CIBERER • Belén Lòpez • Bruna DesSantosVieira • Catherine Pouzat • Esther van Enckevort • F Turon	• Gibson J Spencer • Giorgia Totonelli • Victoria Guttierez Valle • Haitam Abaza • Yi Hong • Jaume Català • Johann Bauer • Keeva Cochrane • Kejla Musaraj • Leo Schulze • Lorena Casareto	• Marta Del Alamo • Maria Sanches • Viviana Giannuzzi • Kodra Yllka • Michael Nitzlnader • Astri Arnesen • Steve Canahm • Sara Lonzano • Janet Vos • Alessandro Sulis • Odonovan • Marc K Wadsley • Pim kamerling • David Llyod	• Anne Sophie Lapointe • Pablo Alarcon • Ssegovia • Milena Greczan • Manila Boarini • Marina Mordenti • Helen Parkinson • Christina Fasser • Rajaram Kaliyaperumal • Laura Lee Cellai • Dennis Kadioglu • Laura (Spain) • Valerie Deprez • Mariapia Iermito

Minutes

- E. van Enckevort starts the parallel session summarising the discussion held the day before and draw the conclusions from the first session.

DISCUSSION

A. Brooks:

- *Will the pilot testing be done for some biobanks and some registries or for only one of the two categories?* E. van Enckevort replies that they have not decided yet but having a combined biobank and registry could work. A. Brooks says that ADA-M is only what can be done with a thing (e.g. patient, sample, all database). People using ADA-M within biobanks identify a couple of things that may be implemented/needed and so ADA-M may be used for both biobanks and registries within EJP RD but it should be decided if it should be tested for both as pilot based on the objectives identified for the pilot.

S. Lonzano:

- *In EUROCAN they are working on how to develop the consent. The challenge is not to read properly the consent but to be able to define a consent to use patients' data for several studies. They are discussing to have a general consent/one-time consent that is difficult to make machine-readable and could be misleading if made machine readable. The challenging is to use these data for several studies and not going back to the patients asking the consent each time. This is why she does not understand how machine-readable consent could help.* E. van Enckevort suggests the use of dynamic consent in this case in order to have interaction with the patients instead of obtaining a broad consent. To clarify how ADA-M works and could help within this use case, A.Brooks shows the excel summary of the software ADA-M and the profiles that could be created by each data owner. Use conditions – informed consent is represented by the ADA-M profile. Around 40 items are included (e.g. type of purposes, countries) with information on the use "unrestricted" or "limited" and with the possibility to enter free text.

S. Lonzano:

- *Is it more feasible to do this with the consent? The access will be more related to the governance. Is ADA-M working in all languages?* A.Brooks replies that ADA-M unfortunately is not working in all languages now but it could be implemented/improved. He continues that she can make not only one profile but she could make a generic ADA-M profiles applying to the registry or a more detailed specific profile describing particular studies. It is not related only to data consent but also to data use conditions.

Y.Mimouni:

- *Have you considered the Blockchain-enabled consent? Did you envisage the possibility to use a blockchain technology for developing the consent?* E. van Enckevort replies that she personally did not have an in depth look at it, that they have people with the authority to authenticate the consent (e.g. the hospital) and that having the patients be part of this process would conflict with patients 'rights/anonymity/double-blind. She sees a couple of issues with blockchain and any specific thing that blockchain could solve compared with existing solutions. Y.Mimouni adds the link of a recent publication on the use of blockchain technology used for consent management in the chat.

B.DesSantosVieira:

- *Is ADA-M going to adopt DUO ontology, or publish a new ontology? Or are both not related at all?*
  E. van Enckevort replies that there is the idea to link the DUO Ontology with the ADA-M, investigating the gaps and looking in the other existing ontologies what could be useful and implemented. A. Brooks continues that some work has been done already with DUO on that. It is supposed to having a look at the last version of the DUO ontology and to consider how to integrate DUO because it should be extended significantly to be used in ADA-M (it presents some limitations). The informed consent ontology will be evaluated as well. The aim is to

update ADA-M to version 2.0 and to use the ontology aiming to capture the elements needed. EJP seems the best place to do this all together.

A.Brooks:

- *Would anyone else be involved in the development of the use case?* E. van Enckevort fully agrees with the proposal of A.Brooks to involve other people in the group and Y. Mimouni provides the link of the helpdesk as well as the email addresses of Esther and Michael. A.Arnesen expresses her interest in working in this group ad patient advocate. She explains the point of view of patients, they will to know how the can contribute with their data (it is a question of trust). The importance of the broad consent needs to be communicated to patients. A.Brooks replies that it is not the aim of the use case but it could be useful to include the consideration coming from patients on why the consent should be broad and not narrow. A.Brooks asks A. Arnesen to take the lead of this effort. All agrees that it is something that could be investigated further and implemented in the use case. E. van Enckevort is struggling how to integrate this in the work of Pillar 2 and Y.Mimouni suggests that a collaboration with the Pillar 3 (patients empowerment) may be foreseen.

D.Llyod:

- *Does EUPID offer a utility for Patient management that might fit with EJP-RD?* E. van Enckevort replies that EUPID is one of the tool part of EJP RD, a pseudonymisation tool not covering the consent part. M. Nitzlnader clarifies that the EUPID Services will cover consent management in particular for functionality that is related to the EUPID Services (e.g. the registration of patients, the transition of patients and their data to other contexts). There is an agreement with Petr Holub within EJP RD to use a federated approach for the consent management. Consents concerning EUPID Services functionality like the registration of patients and the transition of data will be referred to the EUPID Services Consent Management.

V.Deprez:

- *EUPID works on pseudonymisation, not anonymisation, right?* E. van Enckevort replies that it works primarily on pseudonymisation. A. Brookes adds in the chat that it is "anonymisation IN CONTEXT" (I.e., to users the data are anonymous, but to EUPID it is pseudonymised. M. Nitzlnader continues the discussing giving an overview of what EUPID is and gives his availability to discuss further by email.

E. van Enckevort:

- *Michael, would you like the give an overview of the architecture?* M. Nitzlnader summaries the overall architecture of the application and how it can be provided within EJP RD. There is a need for further investigation of ADA-M in order to fit it with the EJP RD needs.

A.Brooks & M. Nitzlnader asks questions to participants:

- *How you manage consent? What are the bottlenecks of consent?* Mary (Paris) replies that her colleague works with patients and data management and they find difficulties in re-contacting patients – difficulties to reach patients once they go home (it is difficult to maintain their interest). V.Deprez adds that in the modern world in which we live, it would be good indeed having patients receiving links and being able to give consent through mobile phones or technologies. A.Brooks agrees and continues that it is a dynamic approach and that ADA-M structure or something like ADA-M should be used for the interaction with the patients. Y. Mimouni adds that ADA-M may be used to provide this e-consent solution but for sure there are other issues regarding the legal aspects that should be defined and that the Ethics Committee has to approve related to the e-consent.

V.Janet:

- *With biobanks and registries, we often obtain broad consent. Before actual use of the data/ materials, the ethics committee needs to review whether the requested data/material use fits with the consent given by the patient (at least this is the case in the Netherlands). Consent is not black and white in that sense. Can we indicate this as well with ADA-M?* E. van Enckevort replies that this could be possible and ADA-M can give some constraints but it will have not the authority to answer ethical questions. E. van Enckevort continues that ethical questions may not be solved by the software, you still need the ethics approval. A.Brooks adds that the free text sections of the ADA-M can help with answers that are not YES or NOT, no-predefined options may help on this.

CONCLUSIONS

- People willing to be involved in the Use Case on Informed Consent group may contact Esther Van Enckevort <e.j.van.enckevort@rug.nl> or Michael Nitzlnader <michael.nitzlnader@ait.ac.at> or the EJP helpdesk
- Inclusion of patients representatives in the group and investigation of their perspective (e.g. why broad consent and not narrow?)
- ...

Upcoming actions & Assigned persons / Planner

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