EDUCATION PLATFORM

Seminar Series:

Facts and pitfalls of observational studies - How to plan and conduct HRO projects

Q&A from the session

"Mastering Consent: Key insights into general and informed consent for HRO projects"

Oct 02, 2024

- How is the GC handled in different University Hospitals? Are numbers available on how many of the patients have a GC status (approved or refused) and how many have an unknown status within the different departments of the Inselspital? Maybe there are departments with excellent implementation that other departments may learn from.
    - Different strategies are in place among hospitals:
        - GC mailing (+/- convocation documents) +/- collection of the GC form during the admission process
        - Distribution of the documents during the visit (during the admission, by the medical doctors or nurses, …)
    - Best combination: GC mailing coupled with pro-activity of collaborators within the services to collect GC of patients that didn't answer
    - No numbers at hand for other hospitals than CHUV – depending on the hospital, they might be more or less easily available
- Informed consent: how bad is it if, for example, the location is missing, or if the patient has noted the year of birth instead of 2024 and we only find this out when the patient is already back home? In which cases is an NTF sufficient and in which cases must the consent form be sent home for a second signature?
    - Procedure at CHUV (might differ at other hospitals):
        - Option 1: call the patient, ask to clarify. If the patient agrees, correct the GC form (put visa and date on it) and send a copy of the corrected GC form to the patient. Write a comment about it in the research consent app.
        - Option 2: send an explanation letter and a new GC form to the patient
- Informed Consent Process - what are the most important aspects for the ethics committee; what are common ethics audit findings
    - Information modalities to ensure that patients autonomy is respected (clarity of the information sheet, how the information is given, how and when consent is collected)
    - Good governance procedures to ensure patients protection and confidentiality.
    - Revocation procedure and description of what happens to samples/data after revocation
    - Education of professionals within hospital to inform/answer patients
    - In case of oral consent – document the oral script

- What aspects should to be addressed in an IC SOP? What's different from IC process in ClinO projects?
    - Our focus is on HRO projects. However, in general one can say that for ClinO you ALWAYS need a specific consent, whereas in HRO projects a general consent might be enough. See presentation for more details.
    - Swissethics has templates for IC; and see question above
- Informed consent for further use of data and samples: in which cases is the 'further use' informed consent necessary and in which cases can biological studies be considered as 'sub-studies' in the protocol?
    - As soon as a new research question is answered, it has to be authorised by an ethics committee and patients need to give consent for this use of their samples and data.
- When can data be transferred to other databases? What if samples are shipped to other biobanks, potentially outside the EU?
    - In principal: if the data protection conditions in the destination country are at least as stringent as those applied in Switzerland
    - AND patients have consented to further use
    - Always make sure that all necessary contracts and agreements are in place!
- Short and concise participant information documents and how to create specific template documents or videos usable for specific topics in the information process
    - We cannot give detailed guidance on this, the time is too short. Swissethics has a lot of useful templates. In general: patient information has to be understood by everybody – you could give it to somebody you know outside of research to test or ask patients to revise these supports.
- Are general consents always specific to an Institution or can it be extended as general for research? For example: if ETH has samples left over from a clinical trial with a hospital, can they do further research with the leftovers of patients that have a general consent of that hospital or does ETH need their own general consent?
    - In any case, the general consent applies to the institution where patients are treated, where their data and samples are collected. Leftover samples issued from another study can only be used if patients have consented to this further use in the initial consent. GC doesn’t apply for the use of leftover samples collected in previous research studies.
- Are pseudonymised data still personal data if you do not have access to the key?
    - As long as there IS a key, it does not matter if you have access to it, the data is still coded/pseudonymised personal data
    - Further comment to that from the audience: To specify: ECs see data as coded if a key EXISTS, even if the researcher has no access to the key or gets data only in coded form for a research project
- Implementation of the e-consent inside hospital and outside hospital. How can the signature process be done electronically in a simple way? What are the options? How can patient identification be achieved outside of the hospital?
    - e-consent concept still has to be developed. Authentication steps are critical.

    - Different groups are at the moment developing possible ways of working with e-consent.

- Practical aspects difference between further use with and without consent
    - There is a difference. If you will reuse data of patients for whom you don't have a consent, you will use the protocol template for data reuse without consent in which you will ask for a waiver consent and justify it. In BASEC, in section 3, you need to tick on consent to be sought no consent-Art.34 HRA even if you have just one patient without consent.
    - If all patients have consent, then you will use data reuse with consent protocol template and you don't need to ask for any waiver of consent. In BASEC, in section 3, you need to tick on prior consent/general consent exists.
- Do we need the consent of patients to use their fully anonymized data?
    - No, for fully anonymised clinical data, no consent is needed. However, before anonymisation, you have to exclude all patients that are opposed to the secondary use of their data. Note that complete anonymisation of clinical data is not easy.
- What changes with new law?
    - We can't go into detail here. Please have a look at the SCTO training on Oct 28th (https://sctoplatforms.ch/HRA-online-seminar)
- Why the new HRO article on general consent and the mandatory reminders/reconsent at majority was deleted?
    - We do not know the reasons, sorry.
- I do not understand the difference between identified data (specific consent) and coded data (General consent) in secondary use of data (HRO3). Can you help me out?
    - Identified data is data that has personal attributes like name and date of birth, so that the identity of the person is known. That's the reason why you need a specific consent. When data are coded, the investigator doesn't see any identifying data and the participants can't be identified without having the coding key, which explains why the regimen of consent is less stringent.
- If only a voluntary questionnaire is collected (and no other data), can you do without a specific consent, as filling out a questionnaire may be seen as implicit consent?
    - Depends on what you want do afterwards: for opinion or quality data, no consent is needed, since it is no research
    - In research projects: If the answers are fully anonymous, yes, probably
- Do you foresee a „monitoring" process for general consent?
    - CHUV process regular monitoring on general consent data. These quality checks are essential to ensure the quality of data concerning registered consents and ensure that patients decisions are respected.
- Does GC for prospective studies mean that we can submit the project to the Ethics Committee, indicating that we would like to conduct a prospective study with secondary use of data, and then collect daily routine practice data only using GC (+ small info about the study)?

    - Prospective use of general consent is only valid for projects using data from routine care (HRO3). If that is what you need, yes, that's ok (include a short information sheet about project). This procedure has been authorized by the EV Vaud (is it the case elsewhere in Switzerland?).

- The emergency department is a common entry possibility for patients. e.g. at CHUV? Is the GC provided to patients there? It seems to be a department where GC is not easily collected.
    - Emergency department is not the best place in general as patients may be stressed or not in a good general status; CHUV patients will receive documents after the visit via post.
    - On the other side, patients have a lot of time in the emergency waiting room, and some patients report that it would be a good place to distribute GC and let them read GC documents/sign GC.
- Is it sufficient to check GC status just before data collection (and not again just before data analysis)?
    - It's essential to check GC status just before the analysis starts!
- Who is responsible to check whether GC status changed and puts it in the system?
    - At CHUV, GC status changes are received by the Research consent unit, and collaborators register the changes in HORUS Consent application.
- How fast is the GC answer entered into the electronic patient file? Is it done immediately, after days/ months? Who is doing that to have a smooth process?
    - At CHUV, as soon as a consent status is registered in the consent app, the information about the positioning is adapted in the patient file.
- how do you detect revocations in your Systems, how often do you communicate those to the Investigators, and how?
    - As soon as a revocation is received, it is registered in the consent app and emails are automatically sent to the investigators that have included the patient in their project.
- Is eConsent function planned to be integrated into the HORUS app?
    - CHUV is exploring the possibilities to develop a dynamic consent platform, with one part on HORUS consent and one part on a patient platform.
    - Aim: adapt GC modalities to patient needs and instore a more eco-friendly and sustainable GC process.
- Regarding the answer about identified data (for HRO3 projects): if I work in a hospital I always have identified data, or not? So it means that I always need a specific consent?
    - In patient folder, data are identified. It is needed for patient care.
    - If you want to use clinical data for research purposes, it is recommended to use coded or anonymised data (depending on the project). In rare cases, data remain identified. The format of data/sample dictates consent needs.
- Do we need to actively and regularly update the general consent status of each participant?
    - If the patient does not say anything, status will stay as it is
- For prospective study with secondary use of data (using GC) is this small info about the study mandatory or recommended?

    - It's requested by the EC-VD. It offers transparency for patients.
- In the context of HRO2, can we recontact patients by email to propose them new research projects?
    - Prospective project: you anyway need to talk to your patients directly, so there is no other way than contacting and asking them directly
    - The way how you ask participants has to be in the protocol.
- For HRO3 projects, should patients be informed about which projects use their data and samples?
    - They don't have to be informed proactively, but they have the right to ask how and for which projects their data are used.
    - This information is not so easy to track. That's one of the reason why the CHUV developed the HORUS app.
- What additional steps are needed to ensure data protection when transferring data abroad to a destination country for research purposes, where data protection laws are not as strict as in Switzerland, aside from having a signed GC?
    - If data protection laws are not as strict as in Switzerland, GC cannot be used. You have to make patient sign a specific consent before transferring data/samples. In any case, a DTUA/MTA has to be contracted. The list of countries with a legislation ensuring an adequate level of protection is available on the swiss Confederation website (Liste des États PFPDT (admin.ch))
- With Art 34 , HRO3, dead patients: is it possible to collect genetic data? and samples?
    - Art 34 is not applicable to projects where there's a collection of data/samples (HRO2). However Art 34 may apply for secondary use of genetic data and samples.
- How do you proceed with consents of children, when they turn 18? Is your procedure different depending on who signed the consent (child after age of 14 or parents)?
    - At CHUV, every patient that had a GC form completed during childhood receives a new adult consent form 1 month after the 18th birthday (independently of a new hospital visit). As long as the adult form is not signed, the following regimen are applied:
        - If the GC form was signed by the parents: samples and data cannot be used anymore for research purposes.
        - If the GC form was accepted and signed by the patient when adolescent (14-17 years old), samples and data can still be used for research purposes, however no genetic analysis can be done on samples.
        - If the minor GC form was refused, the refusal remains valid
- So far I have managed clinical trials phase 1 to 4, I would like to know the difference in consent in an observational study.
    - General consent or specific consent, depending on the project --> see presentation for details