EDUCATION PLATFORM

Seminar Series:

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

Q&A from the session

"Registries"

May 07, 2025

- Recommendations and obligations for the creation of registries by further use of health-related data with general consent (GC) and with specific consent
  - Fully covered in the presentation of Anne Lübbeke-Wolff, please see the provided session material (presentation, video recording):
    - This is one point in the registry regulation regarding consent of data subjects. So there are two types for the creation of a registry. E.g. you want to create a registry for research, there is either the GC or the specific consent.
    - The GC can be used in case of further use of routinely collected health related personal data, but ONLY of routinely collected data during the stay of the patients in the hospital. So making use of the GC, only data that were routinely collected can be used to create the research registry.
    - If you also want to follow up on your patients and you ask them e.g. by sending out a questionnaire one year after the stay in hospital (additional non-routine health related personal data is collected), it's not covered by the GC. So then you need a specific consent.
    - That is also the reason why we advise people when they start a registry to prepare a specific information with consent for the registry. Although it is more work, but in our experience it very much helps to successfully create a registry, because when you inform the potential data subjects about your registry, you have a conversation with them and you can engage them. You can explain what you're going to do. We feel that the subjects are much more interested in the registry and its use. And it creates another link between the team and the patient/ data subject. So we have seen a lot of benefit, patients/ data subjects are much more willing to sign a specific consent for a specific disease or problem than the general consent.

- Tree years ago we set up a small clinical outcome registry for surgical purposes (quality measurements). The data protection authority (Kanton Zurich) gave us the requirement to ask patients for their consent to collect their data in the registry. If we now use the data from the register for further use in research, we clearly need the general consent for 'further use'. Conversely, general consent does not allow us to collect the data in the registry, so we need two consents. I understood from your presentation that consent to the registry is not required in Switzerland. Is this correct?
  - Answered during the session by Anne Lübbeke-Wolff:
    - No, what is not required from the Ethics committee is that they say yes or yes, you can do the registry. So the advisory opinion at the time of registry creation is just an advisory opinion, but not if they don't say yes you can do the registry or no you can't do the registry. This is one thing. You can always create a registry if you want to. You don't need the Ethics Committee to allow you to do that.

- But if you collect the data and you want to use them for research purposes, then you you will need the Ethics Committee and you will need the approval for the reuse of the data. And at that point in time, it would have been better to have asked beforehand because you may have ended up with a registry which is not conform to what they would like to have.

- You may come to the phase where you want to use the data of your registry (independent on the type) and then you have to apply again to the Ethics Committee for reuse of your registered data, that you have collected and that were part of your registry regulation or construction plan. And when you submit it here to the Ethics Committee, they are very happy to link your submission for reuse to the original documents that you provided to them for the advisory opinion. It's much easier than to understand the construction of the registry and link that to it.

- So you can either reuse the data from patients that gave consent (specific or general) or you can reuse the data from patients where only part of them gave consent. Because in some registries with long existence, you have quite a number of patients that may have never consented because consent was not necessary in the 90s or 80s or the legislation / regulation or consent form has changed over the years. So especially in older registries, it's sometimes complicated. So in these cases you may have to use the HRA Article 34 when you submit for the reuse of the data. Of course you should aim at having as much consent as possible, but you never will. It is because regulation / legislation has changed, and so the longer the registry exists, the more complicated it becomes. There's another option, you may also want to do a study in which you are not only using the registry data that were originally in the registry, but you may want to add additional variables such as blood samples or use of sensors, which you are not routinely collecting in your registry. So then it's a new application of course. And then you will have to have new patients to be informed. You will have to create a new patient information and consent for this specific study.

- You may also want to nest a randomised trial in your registry and take advantage of the registry infrastructure. And then again, this is a different kind of application of course and you need a specific patient information and consent anyway. Also here it is always useful to have added the basic information about the registry to the Ethics Committee beforehand.

- Which BASEC template should be used in preparing for the ethics reviewing a study protocol for a registry study?
  - Answered during the session by Anne Lübbeke-Wolff:

    - So yeah, there are three situations. One is when you describe the registry and the other is when you apply for a registry based study which is not the same thing.
    - In a registry based study you may only make use of part of the variables and you only make use of part of the outcomes and so on. So you have to write a protocol here as well as for every other new study. So you describe the purpose an study question, the background to it, and there is a template here from the Ethics Committee that is provided and I think it's on the Swiss ethics webpage. Even so, in case if you want to reuse the data with consent or reuse the data without consent (HRA Art. 34). And for these different situations there are different templates provided.

- What types of changes should be reported to ethics committees in the case of a registry? And when?
    - Answered during the session by Anne Lübbeke-Wolff:
        - So here the Ethics Committee requests that we submit the registry regulation or the plan about the construction of the registry every five years again to them. Because there may be changes in the variables or you may have added another control or a new patient reported outcome.
        - And also of the information that is delivered to the patients/ data subjects can be improved. So we have gone with our registry over several versions of patient information / consents and over the years e.g. the text of the information that is provided to the patients/ data subjects has become more patient-friendly.
        - So there are lots of different areas where there may be changes on the registry as well as the process of creation and that`s why at least every five years submission of changes/ amendments is requested here.

- How can data quality and data interoperability in registries be ensured?
- Could you please elaborate on the quality assurance activities for the data in the registries.
- A challenge in non-mandatory registries is missing data and quality - what recommendations do you have for improve this?
    - All three questions asked to and answered during the session by Anne Lübbeke-Wolff:
        - So data quality is crucial. As I said before, that concerns first of all the input side from the registry, of course, but then also the output side of the registry. There are documents on quality criteria for registries. There was an EU funded project in which you can find the different areas/ criteria.
        - One of the very important quality criteria is the coverage of the registry. So let's take a national registry, e.g. the Swiss Arthroplasty registry, they always publish on the coverage. The coverage means in that case geographical-wise. So of all the hospitals in Switzerland that perform that intervention, how many provide data to the registry? That is the coverage.
        - And then you have the completeness of the procedure, which means of all the interventions performed in Switzerland, how many are recorded in the registry and that is for primary surgery, about 96%. To be able to report on this you need a reference source, that is you need another data source to give you the numbers of interventions performed or the number of patients with the disease or so. So you need source of validation and if you prepare an annual publicly available report, you have to write this in that report. So coverage and completeness are important.
        - There's also data specific completeness, completeness of outcomes, and you can have it for all types of data.
        - Another aspect is accuracy. So how accurate is the information you have, let's say on smoking history or lifestyle factors or other variables. So there are also procedures to test accuracy of your information. If you link your data to others, then you need to check the link ability. How well can you link your procedure with the complication, e.g. - how many cases are you able to link.
        - And then on the output side, you should look at the categories you report, are they nationally or even internationally recognized among the institutions?
        - I advise you to use classifications that are commonly used, like international classifications for medications, classifications for medical devices, classifications for diagnosis and so on. This will increase the quality.

- Requirements when wanting to share samples/data with institutions outside of the study?
  - In general find the material of the HRO lunch session "Data governance and protection: How to navigate the regulatory jungle" on April 17, 2024: Data governance and protection: How to navigate the regulatory jungle - Tools & Resources as well as the material of the HRO lunch session "Data sharing and open research data – details for HRO projects" on November 13, 2024: Data sharing and open research data – details for HRO projects - Tools & Resources

- How is the regulatory procedure recommended for international registers in which a Swiss site participates but the lead institution is located outside Switzerland (other regulatory requirements)?
  - Answered during the session by Anne Lübbeke-Wolff:
    - So this is more complicated. You if you want to participate in an international registry, you have to contact your legal department because there's a need for data transfer agreement or at least you have to check that. This is a very important point because it depends.
    - There might be requirements for de-identification of the data or maybe it's possible to send identifiable patient data outside of the country.
    - But in any case, you need to contact not only the Ethics Committee, but also the legal department for these contracts and the documents.
    - The new document by swissethics links to that sort data transfer agreements, which are templates from SPHN and you can get help from that, but it may not be sufficient. So I really advise you to see what the legal department tells you?

- When do you think will we get the first registry outputs from SPHN?
  - Answered during the session by Anne Lübbeke-Wolff:
    - I have no idea since I am not involved in this project.
    - But what I can tell you is registry outputs / registry production is really something you have to be very patient for a long time. You may have created your data of very good quality, the best quality you could get, well it's never perfect, … But when you arrive at producing your first report, looking at the data for the first time, make an annual report and then you move on to scientific publications….this is really a great moment. And the gain from that is exponential. So hang in there!
    - And have a good team, I always advise a clinician who wants to create a registry to have a data manager to get to do it together in the team.

- General consent (Forschungskonsent im Spital)
  - This is another HRO topic – please find the material of the HRO lunch session "Mastering Consent: Key insights into general and informed consent for HRO projects" from October 2, 2024: Mastering Consent: Key insights into general and informed consent for HRO projects - Tools & Resources