Conclusion & Recommendations
From the workshop on EHR4CR platform deployment in Swedish Hospitals context seen from ethical and legal perspective

Hosted at AstraZeneca R&D, Mölndal, Sweden September 1st, 2014

Meeting objectives

The purpose of the meeting was to discuss, deepen understanding, and further clarify ethical and legal issues with the EHR4CR platform and EHR services seen from Swedish & European legal perspectives for facilitate Swedish Hospital deployment to the EHR4CR platform.

Participants

- *Lars-Olof Eriksson,* Parexel and representing Gothia Forum/Sahlgrenska University Hospital, Gothenburg
- *Ulf Malmqvist,* Region Skåne Hospitals, Lund
- *Mats G Hansson*, Professor of Biomedical Ethics, Centre for Research Ethics & Bioethics, University of Uppsala
- *Jane Reichel*, Professor of Administrative Law & the Centre for Research Ethics & Bioethics, University of Uppsala
- *Elof Dimenäs*, Know IT, Gothenburg (representing service provider perspective)
- *Gopal Sondur*, Know IT, Stockholm (representing service provider perspective)
- *Martin Dugas*, Institute of Medical Informatics, University of Münster, Germany (Leading the EHR4CR hospitals sites in Europe)
- *Brecht Claerhout*, CEO of Custodix, Belgium (Leading the EHR4CR technical platform development)
- *Mats Sundgren*, Coordinator of EHR4CR project, AstraZeneca R&D, Mölndal

(Invited but excused: Anders Ekbom, Karolinska University Hospital, Kaj Stehlöf, Sahlgrenska University Hospital, and Gunnar Klein (University of Örebro)

Conclusion & Recommendations from the meeting

The meeting was successful in order to provide understanding of the EHR4CR project objectives and deliverables. The meeting achieved clarity on how data flows for Protocol Feasibility Service (PFS) and Patient Identification Recruitment Services (PIR) are operating on the EHR4CR platform together with EHR4CR governance measures to secure trustworthy use of EHR data for supporting clinical research. Based on EHR4CR key design & operating principles that include:

- The EHR4CR platform only analyses de-identified Electronic Health Records (EHR) at participating hospital sites and is only connected to a dedicated repository approved by each hospital for EHR4CR use (Clinical Data Warehouse, CDW);
- That for PFS and PIR services, only patient counts (totals and sub-totals) are returned from each hospital to the central EHR4CR Platform, never patient level data;
- The EHR4CR platform never stores nor communicates data about single data subjects and, for the PIR service, data about individuals who might be invited into a study remain internal to the hospital and abide by its local governance rules;
- EHR data is only shared - within the hospital - with a clinical research team if the patient has given that specific consent;
- EHR4CR platform fully complies with state of the art advanced security framework (cross-organisation Web Services) and other relevant aspects.

A consensus was reached by participants at the meeting that the EHR4CR platform and services take adequate measures to secure patient privacy and comply with Swedish privacy protection rules, and that there are no formal barriers for Swedish Hospitals to connect to the EHR4CR platform and services.

Recommendations to the EHR4CR project relating to communication based on the information disclosed at the workshop.

- For stakeholders new to the EHR4CR project, simplify the the structure, function and operations of the EHR4CR platform. Transmit the "Big Picture" and avoid too many details and make it easy to understand for stakeholders.

- It is evident that the EHR4CR project has solicited input from many cross-country stakeholders, identified potential ethical and legal issues and challenges and indeed has addressed many, if not all of them, already. There is a need to make this more obvious to new discussion partners and reviewers, for example in a table format where each issue is highlighted in the left hand column and the EHR4CR approach explained in the right hand column, making it easy to review and understand.

- EHR4CR operating procedures presently exclude the aggregation of query result data from patient groups where less than 5 patients are available in a Clinical Data Warehouse (CDW). The reason for this is that the volume of aggregated data is too low and may pose a risk to identify patients. However, there was consensus in the workshop that this would exclude using the system for "rare diseases" which would be unfortunate since trials in small patient populations are particularly challenging when it comes to identification and qualification of patients to clinical studies. The group suggested reviewing this area again with "rare diseases" in consideration and suggested some additional steps that can be utilized to protect patient privacy within in small patient groups.

- Articulate the value proposition for EHR4CR in a clear and concise statement.

- Explain and communicate what values EHR4CR is protecting in the design, operations and organization suggested for the system.

- For healthcare systems that are joining EHR4CR as data providers, service providers and/or end users suggest and promote that these organizations should position themselves as "Learning Health Care Systems". A guiding map would be necessary to help these organizations take action and foster the development of a "learning health care system" designed to generate and apply the best evidence of health care choices for each patient and patient groups; to drive the process of clinical development as a natural outgrowth of patient care and to ensure innovation, quality, safety and value in health care. This approach would include a clear communication plan and openness towards patients that clinical, diagnostic and laboratory data are being used in a professional and ethical way for research purposes to continuously improve care.

- Although the EHR4CR project group indeed has representation form patient groups the workshop members questioned whether the inclusiveness can be broadened and suggested that more patient advocacy and support groups should be invited to the concept and engaged by the system. There may be unforeseen benefits and avoidance of unidentified issues by engaging these groups more broadly. It is also in line with the growing global trend of patient engagement in clinical research.

- Clarify the legal entity and the organization and representation of the governing institute for EHR4CR i.e. the European Institute for Innovation through Health Data.

- It was highlighted that "aggregation" of unidentified data is key for personal data protection. However, different groups within and between countries have different views and definitions on what data aggregation means and EHR4CR should protect patients adequately. Therefore, it was suggested that the "Data Protection Board" should be consulted and invited to review the operating procedures and the rollout of EHR4CR in Sweden to allow them to become a collaborative stakeholder and support the use of aggregate unidentified data to support research and development.

- Consider drafting "General Consent" for health care provider systems to use for new and existing patients where it is clearly stated that de-identified aggregated health care data is being used by these "learning institutions" for research and development, for the purpose of improving care to their patients. It should be clearly stated that only aggregate data is being used and that no patients can be identified when data is used this way, except following their explicit consent to participate in a clinical trial. Examples of these "General Consents" are available from many health care systems particularly in the U.S. The implementation of "General Consent" can be done in a stepwise approach over a 1-3 year period.

- Be more open and explicit on the problems and issues EHR4CR is trying to address so people, amateurs and experts alike, clearly understand the value of making this work seamlessly. Facts and figures should be included in this problem statement.

- Politicians may be "concerned" (not sufficiently understand why and how) health care organizations are "selling" reports on aggregate patient data. Therefore, it is suggested politicians are adequately invited and educated on what EHR4CR is all about.

- "Get your hands on the constant change" in life science and particularly clinical development allowing the EHR4CR institute leadership and project group to act proactive rather than reactive when issues may occur.

September 17th, 2014

Mats Sundgren, on behalf of all participants of the work shop.