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Research Networks in the Digital Healthcare Environment: A Review



Teaching hospitals and academic institutions which band together to conduct research reap the benefits of the increasing digitalisation of healthcare. In this article, we examine the attendant benefits and challenges, with particular focus on electronic health records and the privacy issues relating to patient data. We review the permissions-based sharing model for patient data as an optimal solution which allows flexibility in adapting the individual hospital's digital infrastructure to the challenges and needs of different types of research networks and projects.

Rise of the Research Network

Research networks can come about in many ways. At the highest level, there are inter-governmental bodies and international associations; at the other end, you have clinicians from two hospitals sharing research data. The common factor is in bringing different organisations together to work on resolving a common problem and working on common research. Each party might bring resources such as manpower, best practices, clinical and treatment expertise, equipment and infrastructure, software systems, IT systems and infrastructure, or a patient pool or a repository of patient data, to the table.

The benefits of forming a research network are clear. 80% of clinical trials experience delays, often for recruitment-related reasons¹. Having a consortium of research organisations means the network may access a larger pool of patients, combining the outreach potential of all the individual sites. Equally importantly, it will gain access to experts in a variety of fields, and to facilities offering other treatment methodologies.

Research networks also offer the potential for more efficient approvals from institutional review boards (IRBs) or ethics committees. When sites are within the same jurisdiction, only a single approval may be required for the various sites in the entire network.

Not every hospital's research department is funded well enough to be able to afford state-of-the-art equipment, which can run into the millions of pounds. Not every research institute has access to experts in every field required by the research topic. Within a network, resources and costs may be shared. A software solution for management of a clinical trial, or electronic data capture, or the very structure of the shared data, need only be purchased and implemented once to benefit the entire network. IT infrastructure solutions may also be shared: virtual servers enable quick modular expansion of networks, overseen by shared IT and data protection specialists.

For the clinician working at a site in the network, this means a higher potential to run trials on innovative new treatments, with a higher probability to get useful and meaningful results.

Rise of Digitalisation

All of the benefits we have mentioned only became possible with the advent of digitised patient data in the form of hospital electronic health records (EHRs). Many healthcare institutions around the

world are investing in improving their IT infrastructure to improve patient care and the ability to utilise patient data for research. HIMSS EMRAM statistics show that more and more hospitals around the world are moving into higher levels of digitalisation^{2,3}. Among other benefits, digitalisation allows huge efficiency gains, transparency of the number of patients, hospitals and treatments, and improved interoperability and "connectedness" for administrative, clinical, and research tasks. Data from trials may be mapped and made comparable. The interrogation and analysis of records and results becomes instantaneous and exhaustive. A complete health record empowers patients with full information about their health. Studies have demonstrated that hospitals with exceptional levels of digitisation showed significantly higher scores for a patient's experience of care⁴.

Most importantly for our discussion, digitalisation offers more avenues for the integration and harmonisation of digital patient data across institutions and IT platforms. This allows digitalisation in healthcare to reap the benefits of its initial investment not only for clinical care but also in revolutionising clinical research.

A Unified Patient Data System?

There are many models for how the network's data should be designed, stored and queried in a unified way. Different types of networks will have different needs. There are networks which are formally linked, for example the Swiss Personalized Health Network (SPHN). This is a network which includes universities and university hospitals across Switzerland, set up for the "development of a nationally coordinated data infrastructure ensuring data interoperability of local and regional information systems with special emphasis on clinical data management systems enabling effective exchange of patient data"⁵.

There are also networks which come together just for the fulfilment of single research projects, and networks which are more persistent, such as the SAIL Databank in Wales, set up to provide 20 years of person-based population health data for research⁶. Then there are the national and inter-governmental bodies and international associations, which are explicitly set up to support data collection and accessibility with a view to accelerating clinical development. Examples of this are PCORnet, the National Patient-Centered Clinical Research Network⁷ in the US; and ELIXIR, an intergovernmental organisation which manages and coordinates bioinformatics data and resources across 21 EU member states and 180 research organisations⁸. We show a general overview of a hospital network architecture common to all these example types in Figure 1.

In structuring a research network's patient data, the key questions to be asked are:

- How should individual patient data privacy be preserved? What permissions do the parties have to use in sharing which data?
- Should the data be collected into a single data warehouse? How can the platform scale up to include new members modularly?
- What mappings, transformations, harmonisations or enrichments need to be performed to bring all the data to the same level for queries?
- How can the data be kept current and "useful" (up-to-date)?

Hospital Network Architecture

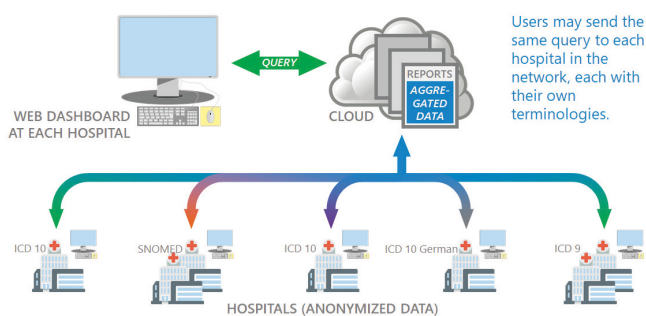


Figure 1: A general architecture common to all hospital networks.

Patient Data Privacy

Decisive among these points is the principle that the patient is the owner of their own data and should have the power to decide what elements of their data are shared with whom. This principle is enshrined in the privacy regulations of many countries, notably in the European Union's General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679)⁹. GDPR also codifies the idea that data should only be accessed for very clearly delineated purposes, and for as short a time as possible. All of this should already be taken into account in the management of a patient database within a single hospital, but adds an extra layer of complexity when dealing with data shared with a research network. The challenge is to ensure that permissions given on a lower level, such as a general practitioner's office or hospital, "carry through" upwards into the larger research network, so that individual data subjects do not lose control over what happens to their data, but also that the network neither gains – nor loses! – privileges it may have in using a patient's data.

Concretely, what this asks is: who can query a patient's data, and what results can they receive from a query. One option might be to work only with anonymised data. Anonymised data is, by definition, no longer personal data in the legal sense, as it has undergone the removal of a defined set of key elements relating to personal, identifiable information. This means it may be queried free of personal data privacy issues. For the sake of this article, we assume that HIPAA safe harbour protections¹⁰ are also implemented here, removing the potential for triangulation and identification of individuals belonging to small populations.

Some hospitals do implement additional privacy protections for their patients, in the form of voluntary limitations on the use of even anonymised data, based on specific consents given by the patient. The individual hospital's responsibilities regarding patient data will have to be respected and taken into consideration. All these provisos being taken into account, this "anonymised model" would essentially allow anyone to query the unified database and get meaningful results. However, the model falls down on identifying a patient for enrolment, the crucial step for a clinical trial.

A second option might be to ensure that the explicit consent for patient identification for enrolment in clinical trials in the wider hospital network is included in the standard permissions request to the patient when registering them in a hospital's EHR system. This will allow queries of identifiable patient data and seems necessary in every case where anonymisation of data makes no sense. However, this still requires ethical commission approval in certain countries.

In all of this, it is clearly necessary that a permissions structure with roles and attendant access rights is built into the tool that queries patient data throughout the network. This ensures that only

relevant, authorised personnel at every level may gain access to the type of data that is necessary for them to discharge their function. An additional protection is the use of anonymised records throughout the system, allowing local staff the possibility to re-identify patients locally from the anonymised records ("Anonymised Identification"¹¹). As examples: a clinician at hospital A may query the database of hospital B but will only receive a count of the results rather than individual records; whereas a clinician in hospital B may run the same query for their own hospital and gain anonymised records; whereas again a clinician in hospital B who has permission from an IRB or ethics commission may run the query on records in their own hospital and receive fully identifiable records.

Additional considerations relate to imagery and genomic data in a patient record. Both are de facto not anonymous and require either a different model again, or adaptation to fit into this model. For example, if the EHR stores details of whether specific genetic variants are present for each patient, rather than the entire genome itself, then those may be queried anonymously.

Data Harmonisation and Standardisation

The benefit implied by the formation of a research network is the ability to perform research queries across all the systems of the member institutions. However, it is inevitable that each hospital's EHR system will have different data standards and use different terminologies and codes. To achieve the desired benefits, the network will have to find ways of querying patient data in a harmonised way.

Take the example where hospital A records a medication with generic medicine names, whereas hospitals B and C record it using different branded medicine names. Our proposed solution is to run the query using query statements specific to the local dictionaries, and combining these statements into a single query to get a complete report back. This allows a single semantically interoperable query to be targeted at every hospital's own system without needing to massage data into overall buckets.

Data Access

How would the data itself be accessed for queries? Currently, within a single institution, it is already difficult to create complex queries without IT support and to send them across siloed departmental divides. Given the plethora of EHR systems types within a research network and the continuing necessity for data firewalls between network members, it is hard to imagine a query system that is a simple expansion of the current process. To search on a large scale across multiple institutions in the entire network requires a query system interoperable with all their systems and sits "on top" of the existing EHR systems, able to send queries to all of them. Authorised personnel thereby gain access directly via a locally installed front-end without additional IT resource requirement. This supports the argument for our proposed data harmonisation solution (above) and also helps scalability (below).

Keeping Data Current

Depending on the field of research, it can be essential to have access to immediate data across the network, for example, for research that requires finding trial candidates who have not yet been given conventional treatments. The emergency room setting is a typical example for the need for on-the-spot data availability. As a patient enters the emergency room and is evaluated, certain clinical conditions such as antibiotic or pain treatment need to occur without delay. For a clinical trial targeting these patients, it would be crucial to recognise the eligibility of the patient before conventional antibiotic or pain treatment is initiated. This requires the members of the research network to commit to keeping their data up-to-date

and available for query – and that the overall network's systems can accommodate this.

Scalability

The concept of an interoperable query system sitting on top of the existing site systems also helps the scalability of the system. In this paradigm, adding a new site partner to the research network simply means adding search terms appropriate to the local dictionary in another member's EHR system node in the query architecture. This allows members to still manage their own systems. As these nodes may even be virtual servers in the hospital's IT infrastructure, speed of implementation may be quicker, manpower resources required for implementation may be fewer, and costs may therefore be less.

Conclusion: Characteristics of a Research Network's Patient Data Infrastructure

We have reviewed the current state-of-the-art system for querying patient data from across a network of members of a research network in a unified way, and a way which allows flexibility in adapting the digital infrastructure to the challenges and needs of different types of research networks and projects. Important components are permissions-based sharing, the maintenance of patient data privacy via anonymisation (while still allowing local identification of candidate patients), and semantic interoperability during the query process from a platform sitting on top of site EHR systems.

With all this, a research network member hospital can flexibly choose to what extent they share data, allowing them to conform to minimum levels of data privacy in every case, while allowing maximum use of their patient data; for example, trial recruitment without sharing personal data outside of the hospital.



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