Beyond the paradox of interoperability in open health data standards

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Abstract

In response to the proposal of Tsafnat et al. to converge towards three open health data standards, this viewpoint provides a critical reflection on the proposed alignment of using OpenEHR, FHIR and OMOP as the default standards for clinical care and administration, data exchange and longitudinal analysis, respectively. We argue that besides the focus on open standards, we need to consider the ecosystem of open source implementations in choosing an appropriate standard for a given context. We discuss two specific contexts, namely standardization of i) health data for federated learning, and ii) health data sharing in low- and middle income countries (LMICs). Specific design principles, practical considerations and implementation choices for these two context are described, based on ongoing work in both areas. In both cases, we observe a strong convergence towards FHIR as the primary standard, while OMOP and OpenEHR are currently […some word …]. We propose a number of additional points to guide developments in this area.

Keywords: OMOP, OpenEHR, FHIR, secondary use, data platform, digital platform

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1. Looking beyond the paradox of interoperability

"A paradox of health care interoperability is the existence of a large number of standards exists with significant overlap among them," say Tsafnat et al., followed by a call to actions towards the health informatics community to put effort into establishing convergence and preventing collision (Tsafnat et al., 2024). To do so, they propose to converge on three open standards, namely i) OpenEHR for clinical care and administration; ii) Fast Health Interoperability Resources (FHIR) for data exhange and iii) Observational Medical Outcomes Partnership Common Data Model (OMOP) for longitudinal analysis. They argue that open data standards, backed by engaged communities, hold an advantage over proprietary ones and therefore should be chosen as the steppingstones towards achieving true interoperability.

While we support their high-level rationale and intention, we feel their proposed trichotomy does not do justice to details that are crucial in real-world implementations. This viewpoint provides a critical reflection on the their proposed framework in three parts. First, we reflect on salient differences between the three open standards from the perspective of the notion of openness of digital platforms (de Reuver et al., 2018) and the paradox of open (Keller and Tarkowski, 2021). Subsequently, we present our findings in designing and implementing health data platforms in two specific contexts, namely i) platforms for federated learning on shared health data; and ii) health data platforms for low and middle income countries (LMICs). We conclude with …

2. The paradox of open for health data standards

Besides the paradox of interoperability put forward by Tsafnat et al., we argue that open standards are a necessary, but not sufficient condition for convergence of health data standarization. We posit that open source implementations of components, libraries etc. constitute another necessary condition for establishing a flourishing health data sharing platform and associated ecosystem for any given context, be it regional, international or within a specific sub-domain like pandemic preparedness. Research on digital platforms underline the importance of the platform openness, not only in term of open standards, but also in term of extensibility of the code base, availibility of complements to the core technical platform (in our case the data standard itself) and availibility of executable pieces of software (de Reuver et al., 2018). Only when the majority of these aspects of digital platforms are fullfilled can we resonably expect that the platform will indeed be longlived.

In what they call the paradox of open, Keller and Tarkowsi argue that this conventional approach of open standards and open source flourish under two types of conditions (Keller and Tarkowski, 2021). First, projects where many people contribute to the creation of a common resource have proven succesful. This is the story of Wikipedia, OpenStreetMap, Blender.org, and the countless free software projects that provide much of the internet's infrastructure. Indeed, Tsafnat et al. have explicitly taken into account that "an engaged and vibrant community is a major advantage for the longevity of the data standards it uses," which has informed their proposal to converge towards OMOP, FHIR en OpenEHR. However, the emphasis on open source implementations is somewhat overlooked. This point is only mentioned in passing and indirectly, when Tsafnat et al. reference work done by Reynolds and Wyatt who already argued in 2011 "… for the superiority of open source licensing to promote safer, more effective health care information systems. We claim that open source licensing in health care information systems is essential to rational procurement strategy" (Reynolds and Wyatt, 2011). We believe that a realistic assessment of the current position of an open standard within the wider context of availability of complementary components and open source implementations is equally important when choosing which standard to adopt.

This point is related to the second condition put forward by Keller and Tarkoswki, namely that the conventional open approach has proven fruitful when "opening up" is the result of external incentives or requirements, rather than voluntary actions. This is the story of publicly-funded knowledge production like Open Access academic publications, cultural heritage collections in the Public Domain, Open Educational Resources (OER), and Open Government data. A canonical example in the birth of the GSM standard, which was mandated by European legislation.[1] Reflecting on this perspective on openness, we observe a salient difference between FHIR vis-a-vis OpenEHR and OMOP, namely that the former is the only one that has been mandated (or at least strongly recommended) in some jurisdictions. In the US, the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) has introduced a steady stream of new regulations, criteria, and deadlines in Health IT that has resulted in significant adoption of FHIR (Firely, 2023). In India, the open Health Claims Exchange protocol specification - which is based on FHIR - has been mandated by the Indian government as the standard for e-claims handling (ind, 2020; hcx, 2023). The African Union recommends all new implementations and digital health system improvements use FHIR as the primary mechanism for data exchange (Tilahun et al., 2023), but doesn't say anything about the use of, for example, OpenEHR for administrative point-of-service systems.

These external incentives have resulted in a large boost in both commercial and open source development activities in the FHIR ecosystem. One such example is the speed with which the Bulk FHIR API has been defined and implemented in almost all major implementations (Mandl et al., 2020; Jones et al., 2021). It has also led to more people voluntarily contributing to FHIR-related open source projects, which has resulted in a wide offering of FHIR components across major technology stacks (Java, Python, .NET), thereby strengthening the first condi-

[1] See https://en.wikipedia.org/wiki/GSM#Initial_European_development for details.

tion. By comparison, OMOP and OpenEHR have not yet profited from external incentives to spur the adoption and thereby growing the ecosystem beyond a certain critical mass. To illustrate this, a search on GitHub on "FHIR" yields 8.2 thousand results, "OMOP or OHDSI" one thousand results, and "OpenEHR" yiels 400 results.

- The majority of OMOP components are run by Observational Health Data Science and Informatics (OHDSI) ...Say something that OMOP still has a relatively large ecosystem, with R libraries, pyOMOP etc.
- The OpenEHR, however, seems subscritical. We are not judging the content and approach of OpenEHR, but there are just so few implementations.

Hence, we stress that beyond the evaluating the instrinic structure of an open standard and the community that supports the standard, we need to take into account the wider ecosystem of open source implementations, complementary components etc. From this wider perspective on the whole ecosystem around a standard, FHIR stands out as having the diverse and rich ecosystem because it has been mandated in certain jurisdictions. This is relevant when comparing these standards in real-world implementations. We now turn to two specific use cases c.q. contexts where these considerations are at play.

3. Standarization of health data for federated learning

The current fragmentation in health data is one of the major barriers towards leveraging the potential medical data for machine learning (ML). Without access to sufficient data, ML will be prevented from reaching its full potential and, ultimately, from making the transition from research to clinical practice. Data like this is hard to obtain, because health data is highly sensitive and its usage is tightly regulated.

Federated learning (FL) is a learning paradigm that aims to address these issues of data governance and privacy by training algorithms collaboratively without exchanging the data itself (Rieke et al., 2020; Teo et al., 2024). Based on ongoing work with the PLUGIN healthcare consortium (https://plugin.healthcare, in Dutch) we have detailed an architecture for FL for secondary use of health data in the Netherlands. Starting point for this implementation are the National Health Data Infrastructure agreements for research, policy and innovation for the Dutch healthcare sector, which have been adopted at the beginning of 2024 (Health-RI, 2024). Figure 1 shows a high level overview of the platform, which comprises three areas (multiple use, applications and generic features) and a total of 26 functional components (for details please refer to (Health-RI, 2024)).

The principle of FL has been actively researched and developed within the Dutch healthcare community. The first proof-of-concept of the so-called Personal Health Train (van Soest et al., 2018) ultimately led to the open source vantage6 platform (Smits et al., 2022). One of the prerequisites of this architecture is that organizations that participate in a federation of 'data stations' use

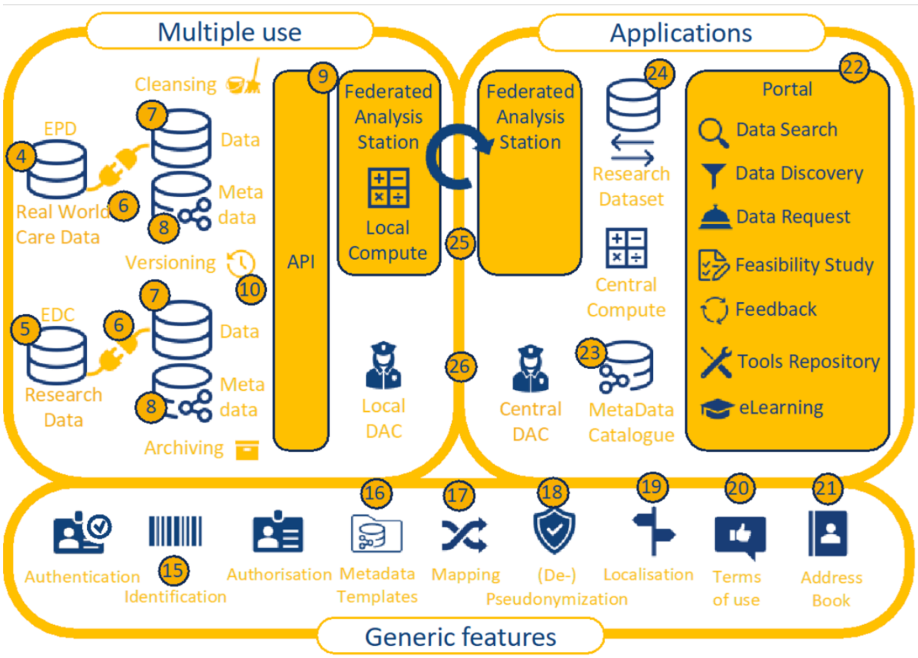

Figure 1: Reference architecture for the Dutch health data infrastructure for research and innovation (Health-RI, 2024)

the same common data model to make the data Findable, Accessible, Interoperable and Resusable (FAIR). These FAIR data stations comprise components 7, 8 and 9 in Figure 1, i.e. the data, metadata and APIs, respectively, through which this the data station can be accessed and used. FHIR has been chosen as the common data model quite early in the development because of its practicality, provenance of RESTful APIs out of the box, support of many healthcare terminologies and flexibility through the profiling mechanims (Choudhury et al., 2020). This solution design has gained traction since then. The CODA platform, which aims to implement a similar FL infrastructure in Canada, compared OMOP and FHIR and chose the latter as it has been found to support more granular mappings required for analytics (Mullie et al., 2023). The fair4health project has implemented also based on FHIR, but using a different open source framework for federated learning (Sinaci et al., 2024).

Using the FHIR standard for persistent storage for longitudinal data in such FL architectures may strike many as counterintuitive. Another common approache takes OMOP as the the common data model more in line with the proposal of Tsafnat et al. Reports of real-world implementations based on the OHDSI-OMOP stack include a global infrastructure with 22 centres for COVID19 prediction models(Khalid et al., 2021), FeederNet in South Korea with 57 participating hospitals (Lee et al., 2022), Dutch multi-cohor dementia research with 9 centres (Mateus et al., 2024), the European severe heterogeneous asthma research collaboration (Kroes et al., 2022).

Given that conceptually OMOP can be viewed as a strict subset of FHIR, hybrid solutions using OMOP and FHIR combined have also been reported, such as the German KETOS platform (Gruendner et al., 2019), and the preliminary findings from the European GenoMed4All project which aims to connect clinical and -omics data (Cremonesi et al., 2023). A collaboration of 10 university hospitals in Germany have shown that standardized ETL-processing from FHIR into OMOP can achieve 99% conformance (Peng et al., 2023), which confirms the feasiblity of the solution pattern where FHIR acts as an intermediate sharing standard through which data from (legacy) systems are extracted and made available for reuse in a common data model.

One could argue that the distiction between FHIR amd OMOP becomes less relevant if data can be effectively stored in either standard. We are hopeful that initiatives like https://omoponfhir.org indeed will foster convergence rather than collision between these two standards. In the case of PLUGIN, however, we had other considerations to opt for FHIR.

First, we find that the mechanism of FHIR Profiles can be tied to concept of late binding commonly applied in data lake/warehouse architectures: allow ingest of widely different sources, and gradually but more constraints and validations as you move closer to a specific use case. If machine learning is the primary objective for secondary use, we want to be able to cast a wider net of relevant data, rather than having very detailed data. Late binding in data warehousing is a design philosophy where data transformation and schema enforcement are deferred until as late as possible in the data processing pipeline, sometime even until query time. This approach contrasts with early binding, where data is transformed and structured as it is ingested into the data warehouse. Put differently, we defer from transforming data at the point of ingestion (ETL - Extract, Transform, Load), but rather apply transformations when the data is accessed for analysis (ELT - Extract, Load, Transform).

FHIR Profiles are a key mechanism for defining, constraining, and extending FHIR resources to meet specific use cases and requirements in healthcare data exchange. We FHIR Profiles to create increasingly more strict standardized data models to ensure consistent and accurate data representation across the various use-cases. Combining this mechanism with late binding, we use a solution pattern whereby the zones of the lakehouse (more on that later) correspond to FHIR profiles with increasingly more specific constraints. This principle is visualized as concentric circles (see below).

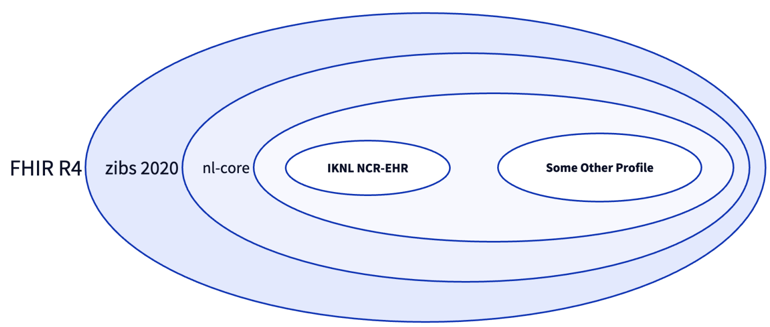

Figure 2: Principle of late binding with FHIR profiling mechanism

The advantages of this design is that it allows for greater flexibility. During the initial ingest of the data, we only require the data to conform to the minimal syntactic standard defined by the base FHIR version (R4 in the diagram). As the data is processed, more strict checks and constrains are applied, whereby ultimately different profiles can co-exists next to one another (the two most inner circles), within a larger circle with fewer strictions. This approach does not support the extension mechanism of FHIR, so we need to be cautious if we decide to use that.

The main disadvantage in using FHIR in this way pertains to the need for upgrading the whole ELT pipeline when upgrading to a new primary FHIR version, for example R5. However, we expect that the development time required to upgrade FHIR versions is significantly less than the initial migration to FHIR.

- Add more arguments here ...[Melle]

4. Health data standards in low- and middle income countries

It is a widely held belief that digital technologies have an important role to play in strengthening health systems in LMICs. Yet, also here the current fragmentation of health data stands in the way of scaling up digital health programme beyond project-centric, vertical solutions into sustainable health information exchanges. And also here, many have called to converge towards open standards (Mehl et al., 2023). Based on our direct involvement in implementing and designing health data platforms in sub-Saharan African countries, and in line with the approach put forward by Mehl et al., we emphasis the need for convergence not only on i) open standards, but also on ii) open technologies (similar to our arguments discussed in the above), iii) open architectures (doucmentation, using open standards, of reusable enterprise architecture patterns for health systems) and iv) open content (representations of public health, health system or clinical knowledge to guide implementations).

Many sub-Saharan African countries have adopted the OpenHIE framework (ope, 2022) as the architectural blueprint for implementing nation-wide health information exchanges (HIE) (Mamuye et al., 2022), including Nigeria (Dalhatu et al., 2023), Kenya (Thaiya et al., 2021) and Tanzania (Nsaghurwe et al., 2021). While the OpenHIE specification is agnostic to which data standard should be used, in practice the digital health community in the global South have *de facto* converged towards FHIR as the common data model, not only for data exchange, but also for point-of-service systems to support clinical care and administration, and persistent, longitudinal storage of data in the so-called Shared Health Record to facilitate both primary and secondary reuse (Cascini et al., 2024). The adoption of FHIR as the default standard for all three domains is fueled by the widespread availibility of open-access software infrastructure which enables and end-to-end integration. To illustrate this, consider For example, the Open Health Stack (OHS) consists of a new suite of digital public goods, including a software development kit for building FHIR-native apps on Android, and analytics tooling to generate insights from FHIR data. This solution design blurs the distinction between the three original domains for health data standardization.

Arguments to add:

- explain that we don't see OpenEHR playing any role of significance. Largest open source EHR implementations working with own data models. Unlikely this will change any time soon (Syzdykova et al., 2017)
- instead, we see that FHIR is in fact being adopted as a point-of-service system. this is possible because data is of lower complexity and the majority of smaller health facilities are resource constrained anyway –> moving towards a scenario where an app used by the health care worker is the system of record. Here we see a convergence of the three domains put

forward by Tsafnat: the Shared Health Record serves as the back-end of the system-of-record, it provides a transactional, persistent storage engine for enabling information exchange and it is the longitudinal data that is used downstream for analytics, monitoring etc.

- explain example OHS/OpenSRP: maternal care
-
  - explain there is lot of complementatry open technologies and open content, to get going
  - and SDK to build apps
  - Clinical workflows which can be configured in a FHIR-native front- and backend
  - InstantHIE to deploy a swarm of containers to provision all relevant components
  - leverage open source data & analytics components to build data stations/data warehouses at any scle
- also technical advantages of FHIR
  - explain that because FHIR is based on web technologies, it lends it self serverless implementations, separation of storage and compute(ref composable data stack); and downward scaleability (running in the browser)
  - how does this relate to ontologies/graph-based? FHIR can be expressed in graphs (Gebreslassie et al., 2023)]

5. Conclusion and outlook

- We underline the need for open data standards as a necessary condition to achieve interoperability
- It is not a sufficient condition
- Suggestion: can we maken OMOP and OpenEHR benefit from the open technologies on FHIR? We think that through making open source reference implementations, such as OMOP-on-FHIR (what's EHR equivalent of that?) we can
- MPC as next step up from FL
- More than a decade later, we observe that only a very small fraction of health IT systems are based on open source, the majority of which are used in LMICs which we will discuss later (dig, 2024).

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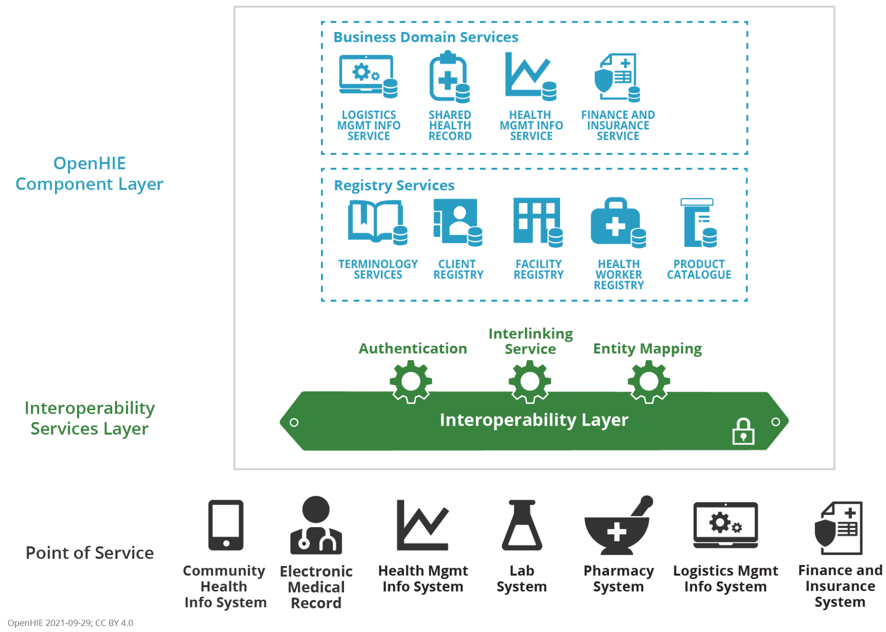
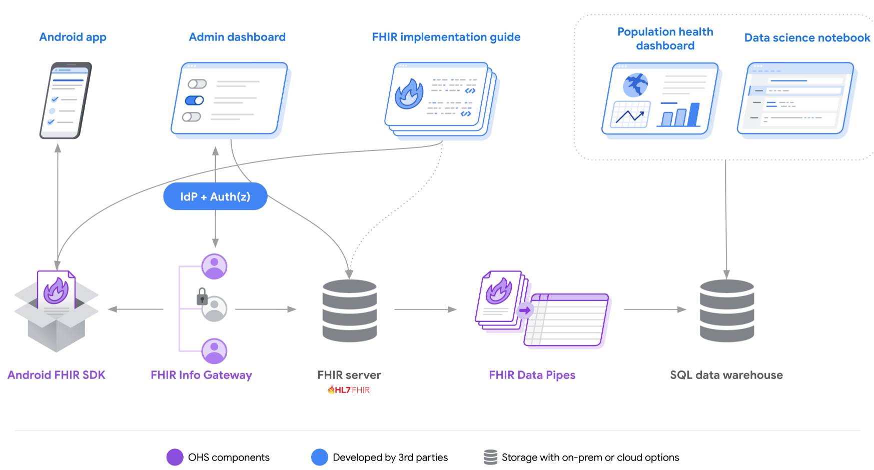


(a) a)



(b) b)

Figure 3: The OpenHIE reference architecture (a) and themain components in the Open Health Stack (b).

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