# FAIRness for HL7 FHIR: supporting interoperability of health datasets

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## Abstract

*The FAIR (Finable Accessible Interoperable Reusable) principles have been established as best practice in the generation of health datasets for open science, research, and innovation. The FAIR4Health project (fair4health.eu) aims to encourage FAIRification and reuse of research data generated by publicly funded research projects. The Research Data Alliance (RDA) research community organization aims at building the social and technical infrastructure to enable open sharing and re-use of data. FAIR4Health and the RDA FAIR data maturity model WG initiated the HL7 FAIRness for FHIR implementation guide (IG) project to provide guidance on how to assess the FAIRness of health data sets with the RDA FAIR Data Maturity Model and support delivery of FAIR health datasets using the HL7 FHIR standard.*

*In this paper, we present how we applied the guidance of the HL7 FAIRness for FHIR IG on selected PhysioNet datasets and reflect on the experience gained by discussing the recommendations of the IG on how to use HL7 FHIR resources to advance the FAIRness of health data sets.*

## 1. Introduction

The FAIR (Finable Accessible Interoperable Reusable) principles have been established as best practice in the generation of health datasets for open science, research, and innovation [1]. FAIR4Health (www.fair4health.eu) has been funded by the European Commission for 2018-2021 to encourage FAIRification and reuse of health data generated by publicly funded health projects and advance FAIR practices in health care accelerating and catalyzing processes of institutional change. FAIR4Health has defined a FAIRification workflow to FAIRfy health datasets within healthcare institutions [2], and has created, and now validates, a multicenter platform for the FAIRification and reuse of health data sets by Privacy Preserving Data Mining (PPDM) algorithms. FAIR4Health works on FAIR certification roadmap.

The Research Data Alliance (RDA, rda-alliance.org) is a global research community organization established in 2013 by the European Commission, the American National Science Foundation and National Institute of Standards and Technology, and the Australian Department of Innovation. The goal of the RDA is to build the social and technical infrastructure to enable open sharing and re-use of data. The RDA FAIR data maturity model WG developed the FAIR data maturity model including a set of qualified FAIR assessment indicators in 2020 [3].

FAIR4Health and the RDA FAIR Data Maturity WG initiated the HL7 FAIRness for FHIR IG project [4] to develop an implementation guide (IG) to explore how to deliver FAIR health data sets using HL7 FHIR (www.HL7.org/FHIR). Specifically, the IG aims to provide guidance on how to assess the FAIRness of health data sets using the RDA FAIR Data Maturity Model and to help researchers deliver FAIR health datasets using the HL7 FHIR standard. In the process of creating the IG, the FAIRness for FHIR IG team has collected and analyzed a large and diverse set of examples and use cases to populate the associated FHIR resources. These efforts illustrate how FAIRness can be implemented, assessed, and potentially improved through the use of the HL7 FHIR standard.

For more than 20 years, PhysioNet (physionet.org) [5] has been a world-renowned medical research data repository for Complex Physiologic Signals to advance research and education supported by a strong international community. In this paper, the HL7 FAIRness for FHIR IG is used to assess the FAIRness of two Physionet datasets: NInFEA [6] (Non-Invasive multimodal Fetal ECG-Doppler) and MIMIC-IV-ED (emergency admissions) [7]. We propose ways to improve their FAIRness using the HL7 FHIR standard. The next sections present our methodology and the results of the assessment. Then, the recommendations of the HL7 FAIRness for FHIR IG are discussed drawing conclusions and proposed next steps.

## 2. FAIRness for FHIR IG Methodology

Using the FAIRness Assessment criteria of RDA we studied health datasets including those selected from PhysioNet and associated publications that describe the creation, presentation, license, and intended use of these

datasets. Then, we explored how FHIR resources such as Library, Citation, or ResearchStudy may describe the (meta)data of the health dataset. Selected information, available in the description of the datasets and related scientific publications, was mapped to HL7 FHIR resources. The effort and the cost of providing rich metadata in HL7 FHIR were evaluated. Figure 1 presents the overall methodology.

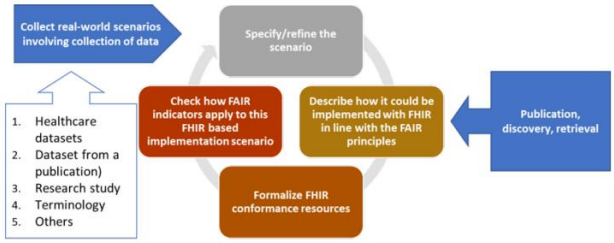


*Figure 1: FAIRness for FHIR methodology.*

## 3. Results

The RDA FAIR data maturity model was used to assess the FAIRness of the NInFEA and MIMIC-IV-ED datasets available on the PhysioNet repository. We found that NInFEA fulfills the FAIRness assessment criteria for (I)nteroperability and (R)eusability through community standards, while it is quite advanced in (F)indability and (A)ccessibility using open free to implement protocols for data and meta data access. On the other hand, MIMIC-IV-ED fulfills the indicators for Findability and Accessibility, while it lacks Interoperability and Reusability. Employing HL7 FHIR could further improve the interoperability and reusability of the datasets, particularly as it concerns machine readability/process of license and provenance information. The next sections further analyze the specific datasets. The full assessment matrix for the two datasets is available online [8].

### 3.1. NInFEA

Non-Invasive multimodal Fetal ECG doppler dataset of Antenatal cardiology research (NInFEA) includes 60 entries from 39 pregnant women, between the 21st and 27th week of gestation [6]. Each dataset entry comprises 27 electrophysiological channels (2048 Hz, 22 bits), a maternal respiration signal, synchronized fetal trans-abdominal pulsed-wave Doppler, and clinical annotations provided by expert clinicians during signal acquisition. The dataset is freely available for download at PhysioNet (physionet.org/content/ninfea/1.0.0/). The open-access NinFEA publications include the details of methodology to explain how the dataset was created and how it can be used for calibration. The publication includes additional clinical data not available in the dataset present on PhysioNet. A separate file provides machine-accessible study level metadata for the reported dataset in .csv (human) and JSON (machine) format mentioning terminology sources.

The scientific publication, the dataset, and the associated metadata were reviewed against the RDA criteria for FAIR assessment. The overall assessment at the study level is that arguably all essential FAIR assessment criteria of the RDA FAIR data maturity model are met. However, we have identified areas for improvement especially regarding interoperability, which will benefit from use of the HL7 FHIR standards. HL7 FHIR enables more detailed representation of FAIR metadata at the anonymized patient level for method and context, which is currently limited to the full text of the publication (HTML and PDF formats) and is not readily machine-readable. In retrospect, making data FAIR is an iterative process guided by the priority of the RDA maturity indicators. Optimal level of FAIRness should be determined by understanding the requirements of the community for the applicable use case. There are multiple options offered by FHIR resources that can be further profiled. Comparing alternative technical options for FAIR Implementation depending on the intended use and extent of metadata is recommended.

Currently, the NinFEA dataset is available as a single binary file. The data collection metadata can be captured as a *Citation* or *Library* FHIR resource (see for example hl7eu.onfhir.io/r4/Library/ninfea-1). There is also the possibility that the dataset be made available as a collection of FHIR resources. This, in part, depends on the granularity that needs to be addressed in the context of the specific use case. Taking a curator approach, we looked more closely at the features that would push upwards the bar of FAIR implementation for the NInFEA dataset. Notably, significant effort has been invested on preparing the dataset. Could we ask more? What FAIR improvements could be made by implementation of the FHIR standards? Can the FAIR metadata be enhanced at the study and patient level? Several observations were made during the initial FAIR assessment:

- The metadata provided for the dataset can be further extended harnessing the full text paper.
- Richer metadata would facilitate repurposing for future reuse of the dataset beyond calibration. However, enriching the metadata largely depends on the use case to be addressed.
- Developing FHIR resources and storing the dataset in a FHIR server would allow easier access to more researchers, further pushing the envelope for interoperability of PhysioNet datasets.
- Information on data provenance and license to be included in metadata with appropriate resources.
- Publishing information on the structure of the data and the associated clinical information would advance best practices.

In retrospect, there is a tradeoff between the richness of study level metadata, the effort required to prepare the dataset, and the complexity of FHIR infrastructure employed.

## 3.2. MIMIC-IV-ED

MIMIC-IV - Emergency Department (MIMIC-IV-ED) is a dataset published in June 2021 and contains emergency department (ED) admissions at the Beth Israel Deaconess Medical Center (Boston, MA, USA) between 2011 and 2019 [7]. At the time of writing, version 1.0 of MIMIC-IV-ED contains de-identified data from 448,972 ED stays. The dataset is freely available for download on PhysioNet.

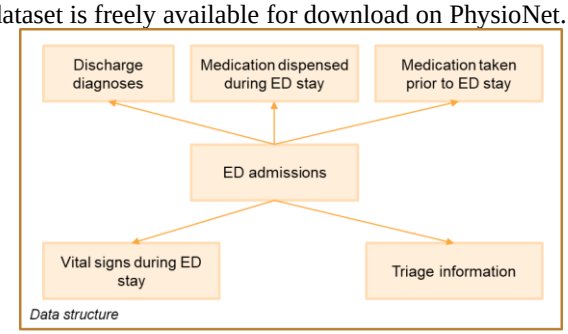


*Figure 2: Simplified MIMIC-IV-ED data structure.*

MIMIC-IV-ED follows a star-like structure around the *edstays* table (see Fig. 2), which contains two identifiers through which the other tables are linked: *subject_id* referring to a patient and *stay_id* referring to an ED stay of a patient. Five additional tables provide information documented during a patient's stay at the ED: discharge diagnoses (*diagnosis*), medication taken prior to the ED stay (*medrecon*), medication dispensed during the ED stay (*pyxis*), information collected at the time of triage (*triage*), and aperiodic vital signs measured during the ED stay (*vitalsign*). A description of each table and its elements, including background, license, access, and citation information is at the MIMIC-IV-ED page at PhysioNet.

*Table 1: RDA Assessment for MIMIC-IV-ED.*

| | FINDABLE | ACCESSIBLE | INTEROPERABLE | REUSABLE |
|---|---|---|---|---|
| **RDA Indicators** | 7/7 Fully implemented | 11/12 Fully implemented | 3/12 Not/partly implemented | 2 /10 Not/partly implemented |
| **Pros** | Globally unique DOI; Data access instructions and license. Search engine | Access via resolvable identifiers. HTTP GET; Authenticate/ authorize | Data .csv format. Metadata refers to and qualifies other data (MIMIC-IV) | License info in metadata. Data in a machine-processible format |
| **Cons** | | Metadata retention not clearly stated | No FAIR-compliant vocabularies. No standard know-ledge representation | No machine-processable license; No provenance. No standard data model |

The initial FAIRness Assessment using the RDA FAIR data maturity model indicators available here [8] and is summarized in Table 1. The RDA data maturity indicators for Findable (7/7) and Accessible (11/12) are fully implemented with the provision of a globally unique DOI and the (meta)data being available over http/get. The datasets are indexed by the PhysioNet search engine. Limited number of indicators are fulfilled for Interoperability (3/12) and Reusability (2/10). MIMIC-IV-ED provides no annotations from FAIR vocabularies at the data model level. Moreover, it does not use a standard and machine-interpretable reuse license. Additionally, the dataset does not follow a standard data model. The HL7 FHIR standard could contribute to improve the Interoperability and Findability of MIMIC-IV-ED. First, FHIR provides a standardized data model to which MIMIC-IV-ED can be mapped without any extensions. Second, FHIR allows to exchange both data and metadata in a standardized, machine-readable format and includes support for using FAIR-compliant terminologies. Furthermore, some metadata such as the description of the data tables and items would become redundant, as each FHIR resource already includes these semantics.

A FHIR server can serve MIMIC-IV-ED (meta)data via the FHIR REST API (Figure 3). This would enable (meta)data discovery via FHIR SEARCH operations using search criteria (e.g. "retrieve all ED stays of patient X", "which patients were discharged from the ED with diagnose Y"). Overall, HL7 FHIR can improve the FAIRness, machine-readability, and interoperability of MIMIC-IV-ED.

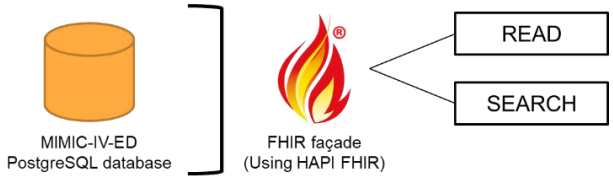


*Figure 3: Delivering MIMIC-IV-ED over HL7 FHIR.*

## 4. Discussion

The HL7 FAIRness for FHIR IG provides a number of recommendations that would help improve the FAIRness of health datasets. For **Findability**, the IG calls upon the attention of implementers to the organizational and technical infrastructure that is connected to the broader ecosystem to register globally unique and persistent identifiers of resources in public permanent register (e.g. doi.org/28). It also highlights the role of the community in defining rich metadata associated with the use case at hand that can be used in effective FHIR SEARCH. Moreover, the dataset should be associated with semantically coherent and machine resolvable metadata that have a life span potentially longer from the data itself. Metadata should be registered or indexed as a searchable resource based on community guidance and include the dataset identifiers.

Considering advanced infrastructures like PhysioNet, we envision their extension to include FHIR servers and use case specific implementation guides that cite FHIR profiles and FAIR compliant terminology servers.

Community-driven FHIR IGs associated to use case(s) formalizing FHIR profiles, FAIR vocabularies, and conformance resources may be part of the future versions of repositories like PhysioNet.

With regards to **Accessibility** indicators, the requirement for an open, free, and universally implementable protocol (A1.1) that allows as required for authentication and authorization (A1.2) is supported by the *HL7 FHIR RESTful API*. The requirement for metadata and data to be separate resources is supported by HL7 FHIR, while the number and type of actual resources in use may depend on the use case. **Interoperability** criteria call for the use of a formal, accessible, shared, and broadly applicable language for knowledge representation. HL7 FHIR works with CQL, FHIR Path, SNOMED CT Compositional Grammar and supports community-wide common vocabularies, profiles, and conformance resources to represent context of use. FHIR implementers should determine what are the qualified references to other resources needed for sufficient contextual knowledge.

Improving FAIRness with HL7 FHIR calls for a FAIR-compliant vocabulary registry managed by a FHIR terminology service and be referenced a community-driven use case specific FHIR IG

To advance **Reusability**, communities should define what metadata are sufficient to describe data and make them reusable and formalize those choices with FHIR conformance resources documented in FHIR IGs. Different technical options can be considered for metadata and data to be released with a clear and accessible *data usage license*. *Citation, copyright, security labels, and consent, etc.* are some of the options offered by HL7 FHIR. References to the license for published FHIR resources is recommended. Implementers are encouraged to use the *HL7 FHIR Provenance* resource to convey detailed provenance information for data and metadata, context of creation and use.

HL7 FHIR works with other domain-relevant community standards to ensure sufficiently rich metadata and interoperability for the datasets. In all cases however, a community supported FHIR IGs referencing logical models, vocabularies, context of use, etc. is necessary to advance clarity in interoperability and deliver high quality FAIR health data. In this sense, the work developed here takes steps in the direction of linking health datasets from around the world to allow reliable data analysis and reproduce research done using FAIRified datasets.

## 5. Conclusions

HL7 FHIR can improve FAIRness and advance interoperability of health datasets. This is important even when only the metadata of the dataset is publicly available.

At the time of this writing, the HL7FAIRness for FHIR IG is at the final stage of development and will balloted in January 2021. The IG provides guidance on assessing the FAIRness of health datasets using the RDA FAIR data maturity model and offers guidance in the FAIRification of health datasets using the HL7 FHIR standard. Therefore, the recommendations provided can help accelerate the collaborative use of standards and terminologies in the FAIRification process. It also helps guide the decision how deep and broad the FAIRification process should be, considering cost in time and effort required and depending on the applicable use cases. Finally, the HL7 FAIRness for FHIR IG will provide input to the FAIR4Health Roadmap for certification of health datasets to further accelerate the operationalization of the FAIR Data principles.

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