Fast Healthcare Interoperability Resources (FHIR) in a FAIR Metadata Registry for COVID-19 Research

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Abstract. Adopting international standards within health research communities can elevate data FAIRness and widen analysis possibilities. The purpose of this study was to evaluate the mapping feasibility against HL7® Fast Healthcare Interoperability Resources® (FHIR)® of a generic metadata schema (MDS) created for a central search hub gathering COVID-19 health research (studies, questionnaires, documents = MDS resource types). Mapping results were rated by calculating the percentage of FHIR coverage. Among 86 items to map, total mapping coverage was 94%: 50 (58%) of the items were available as standard resources in FHIR and 31 (36%) could be mapped using extensions. Five items (6%) could not be mapped to FHIR. Analyzing each MDS resource type, there was a total mapping coverage of 93% for studies and 95% for questionnaires and documents, with 61% of the MDS items available as standard resources in FHIR for studies, 57% for questionnaires and 52% for documents. Extensions in studies, questionnaires and documents were used in 32%, 38% and 43% of items, respectively. This work shows that FHIR can be used as a standardized format in registries for clinical, epidemiological and public health research. However, further adjustments to the initial MDS are recommended – and two additional items even needed when implementing FHIR. Developing a MDS based on the FHIR standard could be a future approach to reduce data ambiguity and foster interoperability.

Keywords. Metadata Standards, COVID-19, FAIR data, HL7 FHIR, Fast Healthcare Interoperability Resources, Syntactic Interoperability, Infrastructure

1. Introduction

The NFDI4Health Task Force Covid-19 (TF C19) is a project conducted by partners of the National Research Data Infrastructure for Personal Health Data (NFDI4Health). TF C19 aims to develop a FAIR (findable, accessible, interoperable and reusable) data

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infrastructure for COVID-19 research in Germany and to foster cooperation between clinical, epidemiological and public health communities [1,2]. To gather information from different health data sources on COVID-19 (studies, questionnaires and documents), a metadata schema (MDS) was created and published [3,4].

Fast Healthcare Interoperability Resources ® (FHIR®) is a standard introduced in 2011 by Health Level Seven International (HL7®). It is used in health information technology and provides an information model that is composed of various distinct blocks of information, called resources. Resources intend to provide a definition of the structure and content to cover the information needs of most health information systems. Information not covered by the core resource data model can be captured by an extension mechanism allowing to store and exchange additional structured data. References are used to link resources to each other, while profiles define further rules and constraints on top of standard resources. As FHIR complies with reusability, composability, scalability, performance, usability, data fidelity and implementability principles, it is worthwhile to investigate supporting FHIR in a system [5]. FHIR is mainly used in clinical care, but there are also uses in health research [6,7] and a clinical trials registry [8]. To date there is no FHIR based common registry to gather health data and improve cooperation between clinical, epidemiological and Public Health domains.

Therefore, this paper investigates the feasibility of mapping the MDS to the FHIR standard to enable syntactic and semantic interoperability for NFDI4Health.

2. Methods

Items from the NFDI4Health TF COVID-19 MDS [4] were mapped for each MDS resource type (study, questionnaire, document) to the FHIR standard. The MDS contains two types of items, depending on the resource type they apply to: general and studies specific items. General MDS items were each mapped to the FHIR resources ResearchStudy, Questionnaire and DocumentReference while studies specific items were only mapped to ResearchStudy using FHIR resources of the most current version of HL7 FHIR Version Release 4 (FHIR® R4, v4.0.1) as mapping target [9]. Two mappers (SK, CV), both medical doctors with experience in FHIR, performed the MDS-to-FHIR resource mappings independently after analysis of each MDS item. Incongruities were discussed and solved within a larger mapping team (SK, CV, MLÖ, MLE, ST) resulting in a consolidated version of the mapping, followed up by a feasibility analysis. In some cases, this required further input from a FHIR expert (JS), or MDS expert (AS). Evaluation of the FHIR mapping was done by calculating the percentage of mapping in each category for each MDS resource type and across resource types. Mapping results were categorized based on previous literature as follows [10]: 1) Available as standard resource, 2) Available as extension, 3) Mapping to FHIR not possible

3. Results

Forty-four distinct items from the MDS were split into general (n = 21) and studies specific items (n = 23) resulting in a total of eighty-six items to map [11]. Details on MDS resource types, FHIR resources and availability in FHIR can be found in **Table 1**.

Table 1. NFDI4Health TF COVID-19 MDS-FHIR mapping, N (%)

MDS resource types	FHIR resources	Available as standard resource	Available as extension	Mapping to FHIR not possible	MDS items
Studies	ResearchStudy	27 (61)	14 (32)	3 (7)	44
Questionnaires	Questionnaire	12 (57)	8 (38)	1 (5)	21
Documents	DocumentReference	11 (52)	9 (43)	1 (5)	21
	Total	50 (58)	31 (36)	5 (6)	86

Among all 86 mapped items, 50 (58%) were available in FHIR as standard resources. Further 31 items (36%) were available as extensions. Five (6%) of the MDS items could not be mapped to FHIR. Analyzing the mapping across MDS resource types, 94% of the MDS items could be mapped either with standard FHIR resources or extensions. Mapping was possible for 93% of the MDS items for studies, and 95% for questionnaires and documents, respectively. **Figure 1** illustrates the availability of MDS items in FHIR.
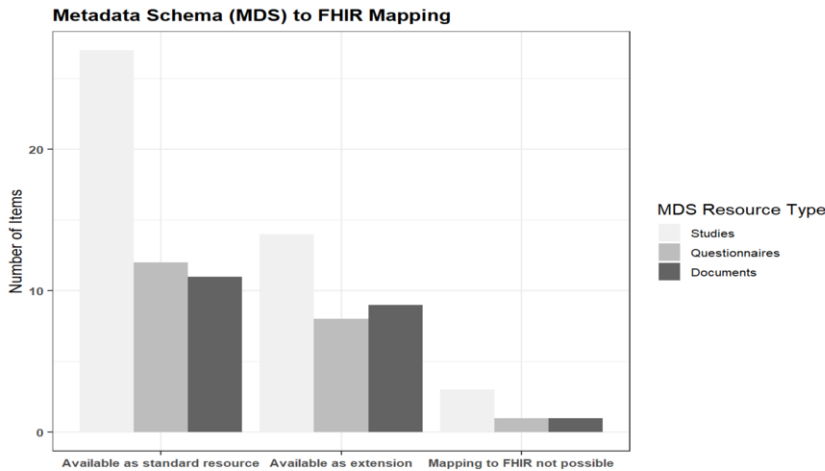

Figure 1. Number of mapped items by MDS resource type and mapping categories.

Some MDS items could not be mapped to FHIR. A mapping of the MDS items "study_status" and "study_analysis_unit" with their respective corresponding mandatory FHIR elements "ResearchStudy.status" and "Group.type" (ResearchStudy is referencing to the Group resource via ResearchStudy.enrollment) was not possible due to incompatible differences in each required value set. Building an extension would not permit to obviate the use of the value sets because of their binding strength. The MDS item "resource_type", relevant for all MDS resources, was not mapped since the selection of the MDS item "resource_type" is followed by a conditional metadata mapping to the appropriate FHIR resource.

In order to use the FHIR resources Questionnaire and DocumentReference, the following items had to be added to the MDS due to the FHIR cardinality: "Questionnaire.status", "DocumentReference.status".

4. Discussion

Existing FHIR resources guarantee the coverage of common requirements but can be expanded in most of the cases using customized extensions [5]. We were able to map the majority of MDS items to FHIR either by using standard resources or custom extensions (94%) demonstrating the flexibility of this standard and its suitability to our use case. However, FHIR resources are designed based on the 80/20 rule (20% of requirements satisfying 80% of the use cases), as well as on reusability and composability principles. With a greater number of extensions needed (36% of the items), we might also lose the proximity to the standard and hinder the compatibility with other systems. Furthermore, analysis of the MDS items showed for example that some definitions are still ambiguous. In some cases, different concepts are covered in a unique item which might lead to complex conditional mappings. Additionally, mapping of two items was not possible because of incompatible value sets between MDS and FHIR. Adjustments of the MDS are recommended and in some cases even needed to ensure compatibility with FHIR. Generating a metadata schema based on FHIR would allow an easier integration of further standards used in various research communities while lowering the amount of FHIR extensions. The current FHIR ResearchStudy resource has a low maturity level (i.e., future changes to this resource are likely) and has a focus on clinical trials. In 2022 HL7 will release a new FHIR version. Previews of the next version show that the ResearchStudy resource will be suitable for studies beyond clinical trials [12]. Therefore, future mappings within our use case could be even more feasible. However, the exact release date is not known and main German health initiatives and projects such as the Medical Informatics Initiative Germany are using FHIR R4 [13] and compatibility is one major aspect within our the NFDI4Health initiative. Further developments should also target bridges to the OMOP data model with its focus on research databases [14].

5. Conclusions

The NFDI4Health TF C19 metadata schema supports a FHIR mapping and therefore can be used for different types of health resources from different research communities. A mapping of the MDS using FHIR standard resources and elements was feasible in more than half of the cases. In most of the cases where FHIR standard elements were not available, FHIR extensions were used. Five items could not be mapped and made MDS adjustments necessary. By creating a COVID-19 registry supporting FHIR, collection of structured data, findability and analysis could be leveraged in different health research communities. We plan to profile FHIR resources based on the mapping of the next metadata schema version (currently under development) and implement the created profiles. For the main project of NFDI4Health, we plan to use FHIR as a basis for a new common metadata schema, enabling syntactic interoperability and facilitating the seamless integration of further standards to ensure semantic interoperability.

Acknowledgments and Competing interests

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