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Modeling the Application of IHE QRPH Profiles in Data Integration Centers: A Practical Approach with 3LGM²

Christian DRAEGER[a,1,#], Sebastian STÄUBERT[a,b,#], Alessandra KUNTZ[c], Christian HENKE[c], Alfred WINTER[a], Ulrich SAX[c,d] and Matthias LÖBE[a,b]
[a] *Institute for Medical Informatics, Statistics and Epidemiology (IMISE), University of Leipzig, Germany*
[b] *SMITH Consortium of the German Medical Informatics Initiative, Leipzig, Germany*
[c] *Department of Medical Informatics, University Medical Center Göttingen (UMG), Göttingen, Germany*
[d] *Campus-Institute of Data Science (CIDAS), Göttingen, Germany*
ORCiD ID: Christian Draeger 0000-0001-8835-4548, Sebastian Stäubert 0000-0002-7221-7415, Alessandra Kuntz 0000-0002-8259-2577, Christian Henke 0000-0002-4541-4018, Alfred Winter 0000-0003-0179-954X, Ulrich Sax 0000-0002-8188-3495 and Matthias Löbe 0000-0002-2344-0426

Abstract. The Data Integration Centers (DICs), all part of the German Medical Informatics Initiative (MII), prepare routine care data captured in university hospitals to enable its reuse in clinical research. Tackling this challenging task requires them to maintain multiple data stores, implement the necessary transformation processes, and provide the required terminology services, all while also addressing the use case specific needs researchers might have. An MII wide application of the standardized profiles defined in the IHE QRPH domain might therefore be able to drastically reduce the overhead at any one DIC. The MII DIC reference model built in 3LGM², a method to describe complex information system architectures, serves as a starting point to evaluate whether such an application is possible. We first extend the IHE modeling capabilities of 3LGM² to also support the five profiles from the QRPH domain that our experts evaluated as relevant in the MII DIC context. We then expand the DIC reference model by some IHE QRPH actors and transactions, showing that their application could be beneficial in the MII DIC context, provided they surpass their trial status.

Keywords. IHE, 3LGM², Medical Informatics Initiative (MII), Secondary Use

1. Introduction

The Medical Informatic Initiative (MII) [1] in Germany aims to make routine care data available for research. While this is an ongoing process, substantial progress was made in planning and building the underlying infrastructure. Currently, 37 data integration

[1] Corresponding Author: Christian Draeger, Institut für Medizinische Informatik, Statistik und Epidemiologie, Universität Leipzig, Härtelstraße 16-18, 04107 Leipzig, Germany; E-mail: christian.draeger@imise.uni-leipzig.de
[#] Contributed equally.

centers (DICs), each located at one of the university hospitals in Germany, are operational[2]. Extracting data from patient care data sources, transforming it towards the MII wide common data model[3], a set of HL7 FHIR profiles, and ultimately providing data for medical use cases, are among their daily tasks. To this end, extracted data is stored in the clinical domain, as well as, consented and pseudonymized, in the research domain, making multiple data storages mandatory. Metadata repositories and terminology services come in handy when working with such redundancies and providing the common data model. However, overcoming the vastly different source software systems at 37 different university hospitals, as well as satisfying all the nuances of the legal foundation that Germany's federated landscape requires, is even more challenging. To harmonize discussions on such topics within the MII, a reference model for the architecture of an MII DIC was designed. This reference model does not match the architecture or processes at one specific DIC exactly, but rather is an approximation that enables relevant comparisons to any of the 37 DICs. This DIC reference model (DIC-RM) was built with the 3LGM² [2] software, and is included in its current version, 4.5.0[4], as part of its model library. Designed to address the challenges when modeling health information systems, 3LGM² is a method that differentiates between three layers, the *Domain Layer*, the *Logical Tool Layer,* and the *Physical Tool Layer.* The latest version of 3LGM² tool also supports the use of Integrating the Healthcare Enterprise (IHE) profiles [3]. IHE profiles describe use cases utilizing standards to improve the interoperability of healthcare information systems [4] and have proven themselves especially useful when planning the IT infrastructure in highly distributed contexts like the MII. As 3LGM²'s main application is to model the information systems at hospitals, its current IHE implementation only supports profiles from the *IT Infrastructure* (ITI) domain. While profiles from the ITI domain see wide adaptation, other, less mature IHE domains, like the *Quality, Research and Public Health* (QRPH) domain might be of interest for the MII and for DICs specifically. If there was an information system model for standards-based integration of data collection operations, staff at a DIC could use it to plan a specific implementation at their site. With this in mind, our research aims to answer two questions, (1) can the 3LGM² IHE implementation be extended in a collaborative, reusable way that also addresses the IHE QRPH profiles, and (2) which profiles from the IHE QRPH domain can find meaningful, direct application in the 3LGM² reference model for MII data integration centers?

2. Methods

IHE defines different states of maturity for its profiles. As our goal was the direct application of IHE QRPH profiles in the DIC-RM, we considered limiting our research to profiles with Final Text (FT) status. This, however, was not feasible, as only three of the 24 QRPH profiles[5] have FT status. For comparison, 26 out of the 49 ITI profiles have FT status. We therefore considered all FT and Trial Implementation (TI) QRPH profiles, meaning that our results are subject to change, depending on the future development of the profiles analyzed. Profiles from QRPH cover many different scenarios, some of

[2] https://www.medizininformatik-initiative.de/en/consortia/data-integration-centres

[3] https://www.medizininformatik-initiative.de/en/medical-informatics-initiatives-core-data-set

[4] https://www.3lgm2.de/en/Downloads/3LGM2_Tool/index.jsp

[5] https://wiki.ihe.net/index.php/Profiles

which are not relevant in the MII context. As a group of experts from the MII, we therefore first reviewed which profiles from QRPH could potentially see application in the context of an MII DIC. To integrate IHE profiles into its modeling toolkit, 3LGM² uses an ontology as its knowledge base [5]. Our expert reviews identified five QRPH profiles that would be of interest for DICs in the MII. We then extended the existing 3LGM² IHE ontology by those profiles. To do so collaboratively we used WebProtégé to modify 3LGM²'s underlying IHE ontology. The resulting .rdf file can be interpreted by 3LGM² natively, providing full functionality without any source code changes. As 3LGM² ensures that all required actors of an IHE profile are present, and that only transactions between actors that are defined in an IHE profile are possible, we could now adapt the DIC-RM with profiles from both QRPH, and the ITI domain that 3LGM² already supports. The DIC-RM is an extensive model that provides detailed information on all three layers of 3LGM², as well as many different zones in which contexts a DIC has to operate. With our research question in mind, we focused our modifications on the logical tool layer in the *DIC Clinical* and *DIC Research* zone.

3. Results

While FHIR is important in the MII context, in the ITI domain to date only 12 of the most recent profiles all without FT status deal directly with FHIR, with many updating existing IHE profiles. Even with the more prominent trail status in QRPH, FHIR is not as broadly covered in this domain. The *Mobile Retrieve Form for Data Capture* (mRFD) profile addresses FHIR while updating the ITI RFD profile that has FT status already. This reflects how interconnected IHE profiles are across the different domains.

Table 1. IHE QRPH profiles, their actors and transactions, as added to 3LGM²s underlying ontology.

Abbr.	Name	Maturity	IHE Actors	IHE Transactions
CRD	Clinical Research Document	FT	Form Filler, Form Manager, Form Receiver, Form Archiver	QRPH-36, ITI-34, ITI-35, ITI-36
CRPC	Clinical Research Process Content	TI	Content Creator, Content Consumer	QRPH-20, QRPH-22, QRPH-25, QRPH-26, QRPH-27
DEX	Data Element Exchange	TI	Metadata Source, Metadata Consumer	QRPH-43, QRPH-44, ITI-18, ITI-38, ITI-51
mRFD	Mobile Retrieve Form for Data Capture	TI	Form Filler, Form Manager, Data Responder	QRPH-48, QRPH-49, QRPH-50, QRPH-51, QRPH-52, ITI-34, ITI-35
SDC	Structured Data Capture	TI	Form Filler, Form Manager, Form Receiver, Form Processor (Form Manager + Form Receiver)	QRPH-36, ITI-19, ITI-20, ITI-34, ITI-35, ITI-36

Table 1 shows the five QRPH IHE profiles that were identified as relevant in the MII DIC context by our experts. The table shows which IHE actors and transactions were added to 3LGM²'s ontology. Note that transactions from ITI were already present and could be reused. The resulting ontology is shared to anyone with a WebProtégé

account[6] and can also be found in 3LGM²'s online resources[7] build with RickView[8].

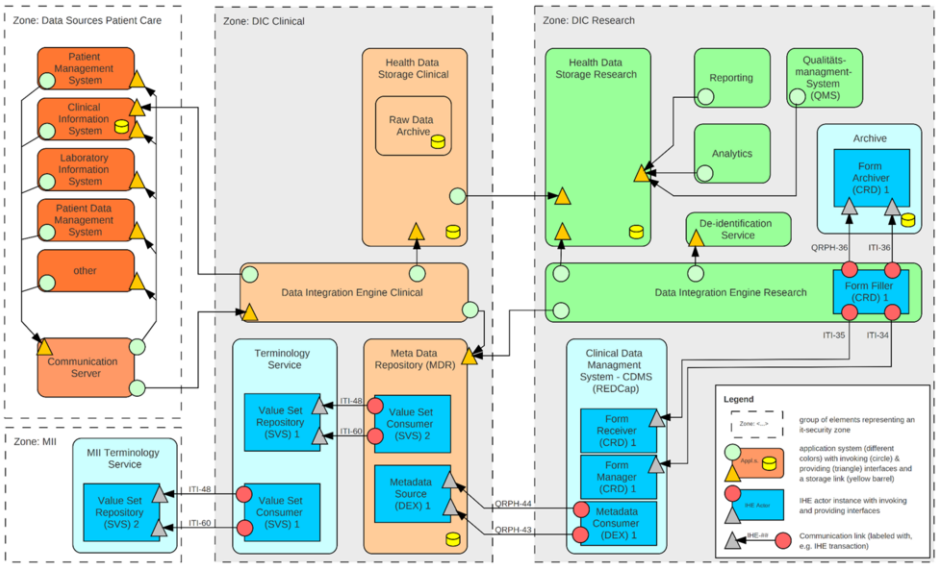

Figure 1. Exemplary MII DIC information system architecture with IHE actors (dark blue rectangles).

In 3LGM²s notation, dotted rectangles represent different IT security zones, in the DIC-RM a gray background indicates their location at a DIC. Rounded rectangles represent application systems, which in turn contain the (rectangular) IHE actors. Their (circular) interface invokes IHE transactions, as they can be provided by corresponding (triangular) interfaces. 3LGM² ensures that all IHE actors required by a profile are present, and that their transactions are invoked correctly. Figure 1 shows how the ITI profile SVS as well as the QRPH profiles DEX and CRD can extend the DIC-RM. The modified DIC-RM can be found on GitHub[9]. All new application systems added as part of our work are marked in light blue, and all new IHE actors are marked in dark blue. Figure 1 also shows how the external patient care data is loaded from the *Data Sources Patient Care* zone to the *DIC Clinical* zone which processes unconsented, identifiable medical data. It shows how the *Health Data Storage*, accessible via a FHIR endpoint, located in the *DIC Research* zone, provides consented, pseudonymized medical data using the *Data Integration Engine Research* to enable the secondary use of the initially loaded care data. We also newly defined the external *MII* zone, that contains application systems for central data sharing. Here, the ITI SVS actor can distribute centrally-managed, uniform nomenclatures as part of an *MII Terminology Service.* In the *DIC Clinical* zone an SVS actor can in turn provide a local *Terminology Service* for the *Meta Data Repository* where a QRPH DEX actor makes the metadata available to DEX actors from the *DIC Research* zone. In the research zone QRPH CDR actors have access to the *Data Integration Engine Research*. With both CDR and DEX actors a *Clinical Data Management Systems* like REDCap could prefill case report forms directly. CRD also defines actors and transactions addressing archival concerns.

[6] https://webprotege.stanford.edu/#projects/78335b01-f425-44c5-8949-0d88efaa1a25/edit/Individuals?selection=NamedIndividual(%3Chttps://www.3lgm2.de/resource/ihe/QRPH%3E)
[7] https://3lgm2.de/resource/ihe/QRPH [8] https://github.com/KonradHoeffner/rickview
[9] https://github.com/IMISE/IHE-QRPH

4. Discussion and Conclusion

Reviewing all the necessary documents to understand the functionality and resources required by an IHE profile was a time-consuming task. We were able to do this collaboratively for the smaller IHE QRPH domain and would have been unable to also evaluate the ITI domain completely in the same manner. Fortunately, the 3LGM^2 modeling tool already came with the ITI domain as part of its ontology. Starting from this ontology we were able to integrate the QRPH profiles which our experts assessed as relevant for MII Data Integration Centers (DIC)s. WebProtégé enabled us to work together collaboratively and makes our efforts easily available to others. Using an ontology as the knowledge base for IHE profiles in 3LGM² is especially beneficial, as it allows others to add new profiles without any coding skills required. In our work with 3LGM², we identified not only QRPH DEX and CRD, but also ITI SVS as relevant IHE profiles in the MII DIC context. Additionally, thanks to the integration of ITI profiles in 3LGM², we were able to understand and apply these profiles in a shorter amount of time. Correct application of an IHE profile sometimes requires inclusion of actors from different profiles and always requires specific transactions between them. By verifying all actors in a model 3LGM^2 can also increase model reliability. Our results show a model that utilizes IHE profiles available in QRPH while being built on the DIC reference model (DIC-RM). The DIC-RM portrays a common ground for DIC in the MII. Our model can therefore be used by DIC staff as a starting point for planning electronically supported data collection processes based on standardized IHE profiles at their site. Our model, however, suffers from common problems in the QRPH domain. The central DEX profile is only in trail status, meaning there are currently no implementations available, and the standard is subject to change. Due to the FHIR based MII common data model, FHIR resources are key in all MII infrastructures. Yet most QRPH profiles cannot interact with FHIR's REST API. If QRPH profiles are adapted to work with FHIR, as is happening in other IHE domains, it may be possible to have a more practical adaptation beyond just idealized reference models.

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