

FHIR – Overdue Standard for Radiology Data Warehouses

FHIR – Überfälliger Standard im radiologischen Data-Warehouse

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ABSTRACT

Background In radiology, technological progress has led to an enormous increase in data volumes. To effectively use these data during diagnostics or subsequent clinical evaluations, they have to be aggregated at a central location and be meaningfully retrievable in context. Radiology data warehouses undertake this task: they integrate diverse data sources, enable patient-specific and examination-specific evaluations, and thus offer numerous benefits in patient care, education, and clinical research.

Method The international standard Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) is particularly suitable for the implementation of such a data warehouse. FHIR allows for easy and fast data access, supports modern web-based frontends, and offers high interoperability due to the integration of medical ontologies such as SNOMED-CT or RadLex. Furthermore, FHIR has a robust data security concept. Because of these properties, FHIR has been selected by the Medical Informatics Initiative (MII) as the data standard for the core data set and is intended to be promoted as an international standard in the European Health Data Space (EHDS). **Conclusion** Implementing the FHIR standard in radiology data warehouses is therefore a logical and sensible step towards data-driven medicine.

Key Points

- A data warehouse is essential for data-driven medicine, clinical care, and research purposes.
- Data warehouses enable efficient integration of AI results and structured report templates.
- Fast Healthcare Interoperability Resources (FHIR) is a suitable standard for a data warehouse.
- FHIR provides an interoperable data standard, supported by proven web technologies.
- FHIR improves semantic consistency and facilitates secure data exchange.

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ZUSAMMENFASSUNG

Hintergrund In der Radiologie hat der technologische Fortschritt zu einem enormen Anstieg der Datenmengen geführt. Um diese Daten während der Befundung oder späteren klinischen Auswertung effektiv nutzen zu können, müssen diese an einer zentralen Stelle aggregiert und im Kontext sinnvoll abrufbar sein. Diese Aufgabe übernehmen sogenannte radiologische Data-Warehouses: Sie integrieren vielfältige Datenquellen, ermöglichen eine patientenspezifische und untersuchungsspezifische Auswertung und bieten damit zahlreiche Vorteile in der Patientenversorgung, Ausbildung und klinischen Forschung.

Methoden Der internationale Standard Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) eignet sich besonders für die Implementierung eines solchen Data-Warehouses. FHIR ermöglicht einen einfachen und schnellen Da-

tenzugriff, unterstützt moderne Web-basierte Frontends und bietet aufgrund der Integration medizinischer Ontologien wie SNOMED-CT oder RadLex eine hohe Interoperabilität. Zudem verfügt FHIR über ein robustes Datensicherheitskonzept. Aufgrund dieser Eigenschaften wurde FHIR von der Medizin Informatik Initiative (MII) als Datenstandard für den Kerndatensatz ausgewählt und soll auch im European Health Data Space (EHDS) als internationaler Standard vorangetrieben werden.

Schlussfolgerung Die Implementierung des FHIR-Standards in radiologischen Data-Warehouses ist daher ein logischer und sinnvoller Schritt hin zu einer datengetriebenen Medizin.

Kernaussagen

- Ein Data-Warehouse ist essenziell für datengetriebene Medizin, klinische Versorgung und Forschungszwecke.
- Data-Warehouses ermöglichen effiziente Integration von KI-Ergebnissen und strukturierte Befundvorlagen.
- Fast Healthcare Interoperability Resources (FHIR) ist ein geeigneter Standard für ein Data-Warehouse.
- FHIR bietet einen interoperablen Datenstandard, unterstützt durch bewährte Web-Technologien.
- FHIR verbessert die semantische Konsistenz und erleichtert einen sicheren Datenaustausch.

Introduction

A medical data warehouse is an essential building block for implementing data-driven medicine in hospitals and research [1].

In the clinical context, a data warehouse not only provides relevant patient and examination data for clinical care but also serves as the basis for clinical decision support systems (CDSS). A CDSS can help prevent medical errors and ensure efficient and safer care [2].

In radiology, in particular, technological progress has led to a significant increase in the volumes of data collected from every examination [3]. AI systems can help reduce the radiologist's workload [4], but image-based AI systems usually provide the results in the form of DICOM secondary captures, which have to be retrieved individually and assessed by the diagnostician in the PACS system. A radiology data warehouse not only enables users to clearly compile AI results from a range of sources in a consistent way but also allows users to integrate these results directly in a structured report template. A data warehouse is also necessary for storing structured reports independently of the producer of the report.

Not only does setting up a data warehouse support the primary clinical use of data but it also allows for secondary use of data for research and quality improvement studies [5], as well as to train robust AI algorithms [6]. Comprehensive, interoperable, and semantically annotated data sets enable the time-saving testing of hypotheses in retrospective analyses, from which generalizable knowledge can be generated that will benefit future patients [7]. Particularly for translational research and rare diseases, it is important to aggregate data from across locations [8]. For this reason, the German Federal Ministry of Education and Research (BMBF) has launched its medical informatics initiative (MII), which aims to improve patient care and research through the establishment of data integration centers (DIC). A DIC stores the core data set in Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) format [9]. Initially, this included mainly administrative data. However, the core data set is currently being expanded to include an image core data set as part of the OMI project.

Fast Healthcare Interoperability Resources (FHIR, 2014) is the fourth and current standard in data exchange from the Health Level 7 (HL7) organization; it was preceded by HL7v1 (1987,

proof-of-concept), HL7v2 (1988, current version HL7v2.9), HL7v3 (never properly established due to lack of backward compatibility and complexity). Compared to previous versions, it is based on modern and widely established concepts for data exchange and data storage, such as the Hypertext Transfer Protocol (HTTP) and representational state transfer application interfaces (REST APIs) (► **Table 1**) [10]. In the FHIR standard, data are stored in resources, which are based on general concepts in healthcare (e.g. patient, observation, encounter, diagnostic report, imaging study, questionnaire, questionnaire response, see ► **Table 2**). This granular data storage reduces the complexity of the data without losing any information. Via a REST API interface, different applications (desktop, browser, app) and different user groups (doctor, nursing, controlling, research, patient) can access and, if properly authorized, modify data. FHIR also enables semantic enrichment of the data through the integration of medical ontologies and terminologies such as SNOMED-CT, LOINC, or RadLex.

FHIR therefore provides an ideal foundation for a radiology data warehouse. This article presents an overview of FHIR and explains how to use FHIR to build a radiology data warehouse.

► **Table 1** Web standards.

HTTP(S)	Hypertext Transfer Protocol (Secure), a protocol for transmitting data over the Internet, often used for web communications. With HTTPS, data exchange is encrypted.
REST-API	A REST API is a set of rules and conventions for creating and interacting with web services. It enables communication between the application and the server, and supports data manipulation using standard HTTP methods.
TLS	Transport Layer Security is a cryptographic protocol designed to ensure secure communication over a computer network.
OAuth	Open Authorization is a framework for securely authorizing third-party applications to access user data without sharing their passwords.

► **Table 2** Overview of FHIR resources.

Patient	Contains information about a patient, including demographics, medical history, and contact information.
ImagingStudy	Describes a medical imaging procedure, such as an X-ray or CT scan, and includes information about the patient, the imaging process, and the results.
Observation	Contains measurements or observations made during a medical examination or treatment, such as radiation dose or bone density.
Questionnaire	Defines questions and possible answers used for collecting patient data or, for example, structured reporting templates.
QuestionnaireResponse	Contains the responses by a patient or doctor to a questionnaire (see above).
ServiceRequest	Represents a request for a medical service, such as a laboratory test or radiology imaging.
DiagnosticReport	Contains reports of diagnostic examinations or tests, including interpretations and results.

► **Table 3** Document standards.

CDA	CDA is a specific implementation and subset of HL7v3 that focuses specifically on the structure and exchange of clinical documents. The focus is on presenting patient information in a consistent way, including patient history, observations, and other health data. While CDA documents conform to the principles and structures defined in HL7v3, HL7v3 actually covers a broader range of standards for healthcare communication that goes beyond clinical documentation. In contrast to HL7v3, CDA is quite widespread as a document standard.
DICOM-SR	DICOM Structured Reporting (DICOM-SR) is a standard for organizing and exchanging structured information (e.g. text or numbers) in medical imaging [13]. DICOM-SR enables the use of ontologies and terminologies (LOINC, SNOMED-CT, RadLex, ► Table 5) to enable the semantic interpretability of the data.
DICOM-SC	DICOM Secondary Capture (DICOM-SC) is a special data format in the DICOM standard for medical image data. It is used to store image data derived from primary images, often through image processing or conversion to another format such as JPEG. These secondary images can be used for reference purposes or reporting.

Overview of current standards in radiology

Interoperability, as defined by the Healthcare Information and Management Systems Society (HIMSS), is the ability of different information technology systems and software applications to communicate with each other, exchange data, and use the exchanged information [11]. Data interoperability plays a critical role in data-driven medicine, in general, and data warehouses, in particular.

Interoperability is based on two basic concepts: syntax and semantics. *Syntax* refers to a system of rules according to which data are organized. In a linguistic context, these rules correspond to a grammar. The *syntax* enables the defined processing of data between different IT systems. A *syntax* enables users to define document standards (► **Table 3**), such as Extensible Markup Language (XML), JavaScript Object Notation (JSON), Clinical Document Architecture (CDA) for clinical documents or DICOM Structured Reporting (DICOM-SR) [12, 13]. How such data are exchanged between different systems is defined in a data exchange standard, such as DICOM, HL7v2, HL7v3 or FHIR (► **Table 4**).

While *syntax* ensures the formal correctness of the data, *semantics* deals with the interpretation of the data, i.e. what the data elements actually mean and how they are understood in a particular context. Semantic interoperability thus ensures not only that data can be transmitted correctly but also that they can

► **Table 4** Standards in data exchange.

DICOM	In a radiology context, DICOM has established itself worldwide as the main standard for the exchanging, storing, and displaying medical imaging [14]. DICOM ensures interoperability between different imaging devices and health information systems, and it enables collaborative diagnostics and treatment planning, as well as seamless exchange of radiology data.
HL7v2	HL7v2 is currently the most widely used standard for the exchange of clinical and administrative data between different healthcare systems [15]. However, its purely text-based exchange format makes it difficult to exchange complex data sets with semantic information.
HL7v3	HL7v3 is the successor to HL7v2 and is based on the Reference Information Model (RIM), which defines a standardized, abstract representation of health data and their relationships, and thus adds semantic interpretability of the data to HL7v2 [16]. However, HL7v3 is known for its complexity and requires significant resources and expertise to implement, which is why HL7v3 has never been adopted widely.
FHIR	The main difference between FHIR and its predecessor HL7v3 is the modular approach to structuring data. FHIR breaks down healthcare information into individual components, called resources. These resources can be flexibly combined and extended, allowing adaptation to new healthcare requirements without disrupting existing implementations.

► **Table 5** Relevant terminologies and ontologies.

SNOMED CT	SNOMED CT (Systematized Nomenclature of Human and Veterinary Medicine – Clinical Terminology) is an ontology used worldwide to encode clinical terms and concepts; it provides common language for the exchange of health information [17].
RadLex	RadLex is an ontology developed by the Radiological Society of North America (RSNA) because SNOMED CT does not contain many specifically radiology terms. RadLex provides a common language for describing imaging findings, procedures, and anatomical structures. RadLex is also available in German [18].
LOINC	LOINC (Logical Observation Identifiers Names and Codes) is a terminology and defines terms and concepts related to the exchange of medical laboratory observations, clinical measurements, and other health observations [19]. LOINC has now been integrated in the RadLex Playbook and provides a universal standard for terminology related to radiology requirements and results [20].

be interpreted correctly in various (IT) systems. Medical terminologies or ontologies (SNOMED CT, LOINC, RadLex, ► **Table 5**) define the semantics and thus form the basis for correctly interpreting medical data [21].

A *terminology* is in this context simply a list or collection of terms and their definitions. These terms may include medical diagnoses, procedures, anatomy, diseases, symptoms, or other relevant concepts [22].

An *ontology* is a formal, explicit specification of a common conceptualization in a particular domain. It represents the entities (concepts) in this domain and the relations between the entities in a structured and organized manner [23].

Integrating the Healthcare Enterprise (IHE)

Launched in 1998, Integrating the Healthcare Enterprise (IHE) is a global initiative aimed at improving the interoperability of healthcare information systems. IHE does not define its own standards but develops integration profiles based on existing standards to enable seamless information exchange [24]. An overview of the FHIR profiles developed can be found at <https://wiki.ihe.net/index.php/Category:FHIR> [25].

FHIR (Fast Healthcare Interoperability Resources)

Need for FHIR

HL7v2 was introduced in its first version in 1988 and despite continual further development has some methodological limitations (current version: Version 2.9, released in 2019 [26]). In particular, this includes the lack of consistent semantics, which leads to variability in the interpretation of data and makes it difficult for sys-

tems to interpret data consistently [27]. In simple terms, an HL7v2 message can be compared to an Excel spreadsheet. Subsequent additions or changes to cells or interpreting what exactly is in a cell is not necessarily clear.

To remedy these shortcomings, the HL7v3 standard was developed. At the time of development, more modern transfer protocols, such as Hypertext Transfer Protocol (Secure) (HTTP(S)), Simple Mail Transfer Protocol (SMTP), or Minimal Lower Layer Protocol (MLLP), were adapted for data exchange (► **Table 1**) [28]. In addition, the reference information model (RIM) was intended to ensure the semantic interpretability of the data [29]. However, the internal documentation is already inconsistent, which understandably led to a lot of criticism [30]. The complexity of RIM requires a great deal of expertise for implementation, which delayed projects and resulted in considerable costs [27]. These reasons, as well as the lack of backward compatibility with HL7v2, meant that HL7v3 was never widely implemented by the industry and HL7v2, despite its weaknesses described above, continues to be the most widely used technology for transmission of clinical data.

Introduction to FHIR

These fundamental problems with HL7v2 and HL7v3 prompted HL7 to develop a new standard for data exchange, which is simpler in its implementation, semantically consistent, and based on modern web standards with established security concepts such as Transport Layer Security (TLS) and Open Authorization (OAuth) (► **Table 1**). This has made it much easier to develop new applications and has led to wider acceptance in the IT industry and among healthcare providers [31].

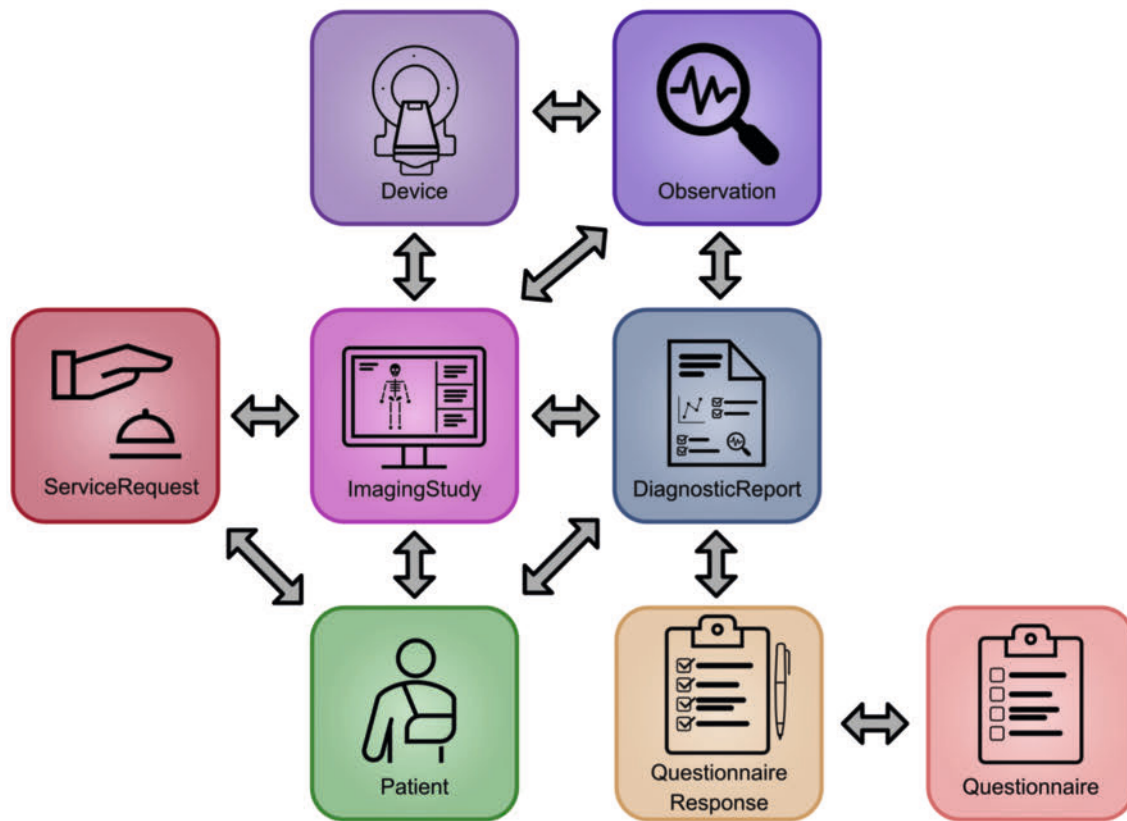
The development of FHIR officially began in 2011, and since then it has continued to evolve with iterative versions appearing regularly, including the current version FHIR Version 5 released on March 26, 2023. In order not only to meet the current requirements of the healthcare industry but also to provide a basis for future advances in the exchange of health data, further development is taking place hand in hand with the healthcare industry.

Main features and principles

The aim of developing Fast Healthcare Interoperability Resources (FHIR) was to create a standard that is capable of handling the complexity of data exchange in the healthcare sector.

The main difference between FHIR compared to its predecessor HL7v3 is the modular approach to structuring data. Health information is broken down into individual components also known as resources. Examples of resources include Patient, ImagingStudy or DiagnosticReport. These resources (► **Table 1**, ► **Fig. 1**) can be combined and expanded as needed, allowing flexibility while maintaining a standard and meeting changing healthcare needs without impacting existing implementations.

Another key issue for FHIR is interoperability. This is ensured by the use of standardized terminologies (e. g. LOINC) and ontologies (SNOMED CT, RadLex) (► **Table 5**). In addition, FHIR applies widely used, vendor-independent web standards such as HTTP(S), JSON and XML, which promotes seamless integration in existing web-based systems and makes it easier to develop new applications.



► **Fig. 1** Example illustrating a potential combination of FHIR resources.

This allows data from different healthcare applications, systems, and devices to be securely exchanged and interpreted.

In addition, FHIR has robust security and privacy features that meet regulatory requirements for healthcare. It includes authentication, authorization, and encryption mechanisms to protect patient data and ensure secure information exchange.

Choosing an open standard based on established technologies encourages continued development, which will lead to continued improvement of FHIR and keep the standard relevant – not only for the present but also for the future.

Considerations when setting up a radiology FHIR data warehouse

FHIR server

The key component of a FHIR data warehouse is the FHIR server, where data are stored in the form of FHIR resources and can be retrieved as such (online transaction processing, OLTP). There are a variety of providers for FHIR servers: free open source variants [32], as well as solutions from commercial providers that are offered on premise (locally) or in the cloud (e.g. SMILE-CDR, Google, Microsoft, Amazon, Apple).

One example of an open source option under the Apache Software License 2.0 is the HAPI-FHIR server [33]. In addition to a pub-

lic test server (<http://hapi.fhir.org/>), a local instance can be set up very easily. If a local Docker instance is installed [34], the HAPI-FHIR server can be downloaded and started using simple commands [33].

Technical considerations

FHIR's resource-oriented architecture enables radiology data to be organized systematically. The FHIR resources that are most relevant for structured and interoperable representation of radiology data in a data warehouse are Patient, ImagingStudy, Observation, Device, Questionnaire, QuestionnaireResponse, ServiceRequest and DiagnosticReport (► **Table 2**, ► **Fig. 1**).

Integration with legacy systems

In order to store data on the FHIR server, these data have to be converted into FHIR resources. Since not all manufacturers offer a FHIR interface as standard, there is a need to convert to FHIR resources if you want to extend the FHIR data warehouse to include such sources. There are several open source solutions for converting messages from HL7 format to FHIR [35, 36].

However, the inconsistencies and lack of semantic uniqueness of the HL7v2 messages described above require the conversion to FHIR resources to be adapted to specific messages. The conversion from DICOM-SR is somewhat easier because DICOM-SR already includes semantic coding.

Structured reporting

FHIR questionnaires are also ideal for structured reporting thanks to their modular structure based on “items” (i.e. questions). The German Radiological Society (DRG) is therefore in the process of expanding its report templates to include FHIR questionnaires. An easy-to-use web-based platform for building FHIR-based report templates is available at <https://drg-befundvorlagen.uniklinik-freiburg.de>.

Integration of AI results

If the results of AI algorithms have been stored in a FHIR data warehouse, it is possible to assign them to a corresponding question in the FHIR questionnaire via a semantic mapping by using the codes assigned in an ontology or terminology. This question field can then be filled automatically when the report is created, and it only needs to be validated by the radiologist.

Outlook: Semantic web in the FHIR data warehouse

The resource-based architecture of FHIR allows data to be stored in the resource description framework (RDF) format [37]. RDF is part of what is known as the “semantic web,” which Tim Berners-Lee described in 2001 [38, 39]. RDF works together with SPARQL (SPARQL Protocol and RDF Query Language), a query language, and OWL (Web Ontology Language), a language for defining data structures on the internet. RDF uses a simple structure, also known as “triples”, which consists of “subject”, “predicate”, and “object”, to represent data, concepts, and relationships in a uniform manner. Subject and object represent nodes, which are connected by the predicate with an edge. The subject is the starting point of the triple, e.g. a person, and the predicate establishes a relationship between subject and object (similar to the verb in a sentence). The combination of predicate and object describes the subject. This structure of nodes connected by edges makes it possible to combine information from different sources into a large, linked data set, which is also known as a knowledge graph [40]. Although these knowledge graphs can be queried using SPARQL, such queries are quite complicated and are not usually intended for end users [41]. The future may hold some relief in this regard based on AI systems that can convert simple language to SPARQL queries [42].

Knowledge graphs and FHIR RDF therefore also have great potential for secondary data analysis (online analytical processing, OLAP) in the medical context, and they provide a semantic basis for using artificial intelligence in healthcare, such as explainable AI applications [43].

Conclusions

FHIR, as a standard for a radiology data warehouse, opens up perspectives that have the potential to significantly improve primary data evaluation in clinical routine. This is done by integrating heterogeneous data sources such as decision support systems and AI results, which not only increases the quality of data analysis but

also simplifies workflows for radiologists. In addition, the high level of interoperability of FHIR enables the creation of inter-institutional and translational data exchange, which promotes the creation of a cross-institutional knowledge database in line with the semantic web.

Although integrating data from legacy systems that do not support the FHIR standard is challenging, the expected synergies from a semantically consistent and defragmented data warehouse justify the effort with significant improvements in the quality of patient care.

A data warehouse based on FHIR is therefore a major step on the important path towards data-driven medicine.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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