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Data Exchange Standards in Teleophthalmology: Current and Future Developments

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Abstract. Background: Teleophthalmology services are considered capable of supporting screening, early diagnosis, and monitoring of leading causes of blindness on a global scale. Therefore, standards and best practices are needed to seamlessly exchange medical ocular images and related data among relevant stakeholders with maximum interoperability. Objectives: This paper provides an overview of current standards in the field of store-and-forward teleophthalmology data exchange and further developments in this area. Methods: A literature review was conducted for healthcare standards with a focus on data exchange in ophthalmology. Results: IHE, HL7 FHIR, DICOM, and clinical terminologies are considered the most important standards, providing distinct concepts, solutions, and guidelines for ophthalmology. Conclusion: Available standards provide the necessary base for teleophthalmology on technical and semantic interoperability, but practical use is limited due to missing process interoperability resulting in proprietary interfaces of vendors and rejection by ophthalmologists. Further investigations should analyze processual needs on ophthalmology data exchange standards.

Keywords. Telemedicine, Ophthalmology, Health Information Interoperability

1. Introduction

The digitization of medicine is currently transforming healthcare systems worldwide and opens opportunities to implement more efficient and effective decentralized patient management approaches. This trend has been significantly accelerated by the ongoing COVID-19 pandemic on a global scale [1].

The increasing implementation of telemedicine has rapidly accelerated the research and development of Information and Communication Technology (ICT) and related

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intelligent medical diagnostic systems, which further broaden the opportunities for telemedical applications. The medical field of ophthalmology is particularly affected by this development since it is heavily dependent on digital imaging and communication.

Ophthalmology is the medical specialty with the highest proportion of digital diagnostic data acquisition in medicine. It has been shown that outsourcing community-based ophthalmic care to teleophthalmological services can effectively reduce demands on hospital eye services and dramatically reduce referrals and streamline care [2]. The technical requirements for telemonitoring in ophthalmology are fully available for vitreoretinal disease (e.g., macular degeneration, diabetic retinopathy) or glaucoma by using optical coherence tomography (OCT), retinal cameras, or digital perimetry. Thus, telemedical services are considered capable of supporting screening, early diagnosis, and monitoring of leading causes of blindness on a global scale.

Telehealth in general comprises the remote delivery of medical services via ICT and has shown significant progress in applications for early diagnosis and monitoring of known conditions and accessibility of ophthalmology care [3]. New innovative image acquisition modalities, high-performance computing, new analytical means through artificial intelligence as well as e.g. continuously improving smartphone cameras and mobile access to high-speed internet even in very remote areas enable new teleophthalmology opportunities.

Based on telehealth communication, the following specific teleophthalmology approaches can be identified [4]:

1. Synchronous teleophthalmology, e.g., live consultation in video calls and/or live image acquisition related to both physician-physician communication and physician-patient communication (often also referred to as “teleconsultation” or “virtual patient visit”).
2. Asynchronous teleophthalmology, e.g., store-and-forward acquired medical data to ophthalmology experts for assessment (often also referred to as “telediagnosis”)
3. Hybrid teleophthalmology: e.g., store-and-forward is used for image acquisition, analysis is done remotely by an ophthalmologist, and the final report and follow-up plan is conducted via synchronous video call with the patient.

Due to the strong dependence on image-based information, asynchronous communication or data exchange is still much more common in teleophthalmology [5,6], independent of the related model of care, which might be screening, triage, consulting, and remote supervision [7]. Asynchronous image acquisition and analysis have been successfully implemented in the past in several ophthalmologic applications, where standardized imaging is available to establish a diagnosis or judge the clinical course of ocular disease. Specifically, the monitoring of age-related macular degeneration based on high-resolution optical coherence tomography (HR-OCT) enables remote diagnosis and treatment recommendations. HR-OCT is capable of generating retinal thickness maps and reliably diagnosing macular edema requiring intravitreal injections of VEGF-R2 inhibitors to restore vision [8]. Another example is telemonitoring of diabetic retinopathy as implemented in the UK 20 years ago and now widely applied on a global scale [9]. Patients suffering from diabetes mellitus require professional assessment of retinal vasculature on an annual basis to exclude or monitor proliferative diabetic retinopathy. For this purpose, mobile imaging units are used to acquire color photographs of the retina. The photographs are then assessed by an eye care professional in a remote reading center. If the retinal disease is confirmed, patients are referred to the hospital for laser treatment.

Along with those user requirements, standards and best practices are needed to seamlessly exchange ophthalmic images and clinical information among relevant stakeholders with maximum technical (enable to share information among parties), semantic (understand what is shared among parties), and process (understand why information is shared among parties) interoperability. This paper is intended to provide an overview of the current research status for store-and-forward data standards in the field of teleophthalmology and further developments in this area. It is out of the scope of this work to provide details on specific ophthalmological image formats and their related parameters or representation.

2. Methods

This paper analyzes well-known standards and best practices for healthcare data exchange and relates them to the domain of teleophthalmology considering a store-and-forward modality for typical routine use cases of screening and remote supervision. A focus literature review was conducted by the authors on Medline PubMed and Google Scholar on general healthcare data standards with search terms "telemedicine", "telehealth", "data exchange", "teleophthalmology", "tele ophthalmology" and "data standards" considering results published since 2010. Identified standards were further analyzed on their related websites and investigated according to "ophthalmology or eye-related scenarios", i.e., to find specific results for the related domain of ophthalmology and the use cases of exchanging necessary medical information for remotely analyzing images of the eye. The results were structured as follows: Each identified standard consists of a general introduction about its main objectives. Then a more detailed view of the standard on teleophthalmology is provided. Finally, a short relation to other standards is given and how the standard is maintained and further developed.

3. Results

3.1. Integrating the Healthcare Enterprise (IHE)

Integrating the Healthcare Enterprise (IHE) is an international non-profit initiative, that establishes processual and implementation guidelines for clinical data exchange with the overall aim to maximize technical and semantic interoperability of involved information systems [10]. The organizations' members comprise healthcare professionals and software vendors of healthcare IT who jointly develop integration profiles that are published as "Technical Frameworks". Along with the eye care domain, IHE published the "Eye Care Technical Framework", which (in its current version) consists of the following integration profiles: Charge Posting (CHG), Eye Care Evidence Documents (ECED), Eye Care Displayable Report (ECDR) and Unified Eye Care Workflow (U-EYECARE).

The Unified Eye Care Workflow [11] is of special importance as it describes the clinical workflow of basic patient data exchange for continuity and integrity in clinical eye scenarios. The main goal of the profile is to provide a structure on how actors like the Picture Archiving and Communication Systems (PACS; for storing, accessing and displaying the images), Electronic Health Record Systems (EHR; for clinical information), Practice Medical Systems (PMR; for scheduling and billing information) and eye care diagnostic imaging and testing equipment (e.g., fundus cameras, slit lamps) should communicate and interact for eye-related clinical workflow scenarios. The profiles include "real-world scenarios" that target a certain system configuration: "EHR Supports DICOM Modality Worklist and Integrates with a PACS", "EHR Supports DICOM Modality Worklist, Image Storage and Display (no PACS)" and "EHR Implements HL7 Only (No DICOM Support) and Integrates with a PACS)".

These approaches enforce the detailed listing and description of the required actors and their communication via the definition of transactions. Based on these scenarios [11], software vendors are provided with a standards-based approach on how existing standards like HL7 or DICOM need to be implemented to fulfill the profile's stated communication requirements and therefore guarantee interoperability on all levels. With the ongoing four-step annual development cycle of IHE (1. Use case definition of clinical and technical experts; 2. Technical experts developed communication specifications; 3. Industry implemented specification as IHE profiles; 4. Vendor system tests on connectathons) and the domain committee for "Eye Care", IHE is continuously improving and adapting the Technical Frameworks for ophthalmology.

3.2. Health Level Seven (HL7)

Health Level Seven (HL7) provides several healthcare data standards for medical information. While the legacy message standard V2 lacks semantic dynamics for the medical field [12], HL7 V3 provides a more flexible messaging structure utilizing the Extensible Markup Language (XML) and the HL7 Reference Information Model (RIM) for representing generic clinical concepts. However, the design of HL7 V3 RIM follows a "design by constraint" approach, i.e., a complex information model (RIM) needs to be constrained to fit for purpose (e.g., to comply with legal regulations). In general, V3 is still conceptualized as a communication standard based on messages.

In contrast, the latest HL7 standard FHIR (Fast Healthcare Interoperable Resources) was completely redesigned moving away from a rigid messaging standard to a web service standard, therefore, following a "design by addition" paradigm [12,13]. FHIR defines Resources as distinct, identifiable structures for clinical concepts (e.g., the resource *CarePlan* describes the delivery of care for a particular patient) which can be used to represent specific patient data and offers flexible access to such data items through a standardized RESTful web interface. FHIR offers Implementation Guides (IG) to describe how FHIR resources should be used to solve a particular clinical problem.

For specific eye-related scenarios, FHIR currently incorporates only resources for *VisionPrescription* (defining glasses and contact lenses for patients) but is also working on an IG for ophthalmology [14]. The current proposal of the IG incorporates four main use cases: (1) Fundamental representation of ophthalmic and related clinical and administrative data elements in FHIR (clinical findings, diagnoses, therapeutics); (2) Data exchange between ophthalmic diagnostic (e.g., OCT machines) and EHR/EMR; (3) Data exchange between the various EMRs of different eye care providers (e.g. data exchange between patients with chronic conditions who are co-managed by optometrists and ophthalmologists); (4) Specific scenarios: e.g. sending selected data elements to a research institute or referral of a patient to a clinical trial.

The respective IG is not yet released by FHIR as it is still in development and currently available in Version 0.1.0, thus it is still affected by frequent changes and not ready for productive use. In general, HL7 FHIR is the trend of health information data exchange for loosely coupled and standardized services as proposed by IHE and should be considered for teleophthalmology applications concerning all communicating actors.

3.3. Digital Imaging and Communications in Medicine (DICOM)

The Digital Imaging and Communications in Medicine (DICOM) standard is indispensable for any imaging or processing procedure in medicine, e.g. for magnetic resonance imaging (MRI), computed tomography (CT), or OCT. Besides the document-file standard to store medical images including all necessary meta-information (e.g., image material and full metadata), the standard also offers services for the communication and data exchange of medical images. The DICOM Message Service Element (DIMSE) is responsible for the communication of data-exchanging parties. The data model separates information and knowledge as known from HL7 (attributes and relations of medical concepts represented as Information Object Definition, OIDs). Suitable actions that can be used to process OIDs are called Service Elements (SE). Since actions like *querying images* are frequent, DICOM groups common sets of SEs for OIDs into Service-Object Pairs (SOP). The Modality worklist is responsible to request and organizing image procedures, thus it needs to communicate with several components like EHRs, PACSs, RISs. As an extension, DICOMWeb [15] is a standardized web-based RESTful interface for DICOM. With DICOMWeb it is possible to query, retrieve, store, and execute other actions through REST-calls, resulting in structured XML or JSON responses that might also include the related DICOM image(s). Queries can be specified by parameters, e.g., it is possible to query a series of DICOM images in a specific size and/or file format (e.g., providing a JPG thumbnail of an image) according to the users` needs via the web interface.

The American Academy of Ophthalmology recommends the following DICOM supplements for ophthalmology [16]: DICOM supplement 5, 91, 110, 130, 143, 144, 146, 152, 168, 173, 197, and 1811. The usage of DICOM for ophthalmology images can be considered the state-of-the-art standard for managing image-related data exchange. A working group for ophthalmology in DICOM (WG-09) exists that is working on the related supplements for eye care. DICOM updates get published four to five times a year. Members of the open community are encouraged to submit their change proposals or new work item proposals.

3.4. Healthcare Terminologies

To unambiguously identify medical knowledge like diagnoses, therapies, medications, symptoms, and many others it is necessary to provide a unique and comprehensive vocabulary instead of unstructured free text. Therefore, healthcare terminologies are considered the main contributor to fostering semantic interoperability, as they even allow the software to interpret and utilize structured medical documentation.

Systematized Nomenclature of Human and Veterinary Medicine ‒ Clinical Terms (SNOMED-CT) [17] with currently comprises about 350.000 standardized medical multilingual concepts and about 1.3 mil relationships, is considered the most extensive collection of clinical terms. SNOMED-CT is maintained by International Health Terminology Standards Development Organisation (IHTSDO) and requires a license to be used in production systems. Technically it is structured as ontology, which represents a knowledgebase as a set of concepts (with its properties) and its relations. Each concept is designated a unique identifier and it is common to link synonyms for related terms.

Besides SNOMED-CT a variety of healthcare-related terminologies for different use cases exist, e.g., Logical Observation Identifiers Names and Codes (LOINC) for medical procedures, International Statistical Classification of Diseases and Related Health Problems 10 (ICD-10) for diagnoses or RxNorm for prescriptions and medication [18]. Since the beginning of 2022, the new ICD-11 is available. With about 135.000 entries, ICD-11 (as well as its predecessor ICD-10) is used to classify diagnoses and is also widely used for remuneration of clinical services. The Unified Medical Language System (UMLS) combines several controlled medical vocabularies like SNOMED-CT, ICD-10, and about 200 others to provide one unique ID across all vocabularies.

Information-related standards like FHIR use terminologies within their resources, as a *CodeableConcept* Resource and thus link the related term with the indented terminology concept ID and terminology OID.

Regarding ophthalmology, SNOMED-CT offers a wide range of ophthalmologic concepts (~9,500 terms and ~5,200 synonyms) that are used for reports, metadata, or any other documentation to record e.g., diagnoses, procedures, and medication in ophthalmology.

SNOMED International as the main maintaining organization provides new releases of the terminology twice a year with new added concepts and relations.

4. Discussion

The adaptation of data standards for existing and potential teleophthalmology applications is crucial for seamless and interoperable data exchange. Standards and best practices like IHE, HL7 FHIR, DICOM, and clinical terminologies such as SNOMED-CT enable rapid and dynamic development, integration, and maintenance of new teleophthalmology components that can be integrated into existing information system infrastructures and workflows. In addition, new possibilities for data processing and further (automatic) analysis of provided data are enabled, e.g., as a service for analyzing images according to known anomalies and disorders (e.g., through artificial intelligence), which might get integrated into existing infrastructure and adheres to all technical, regulatory and security requirements. Further, the flexible data structures also streamline distributed data utilization, e.g., needed for post-processing machine-learning also considering federated learning [19].

HL7 FHIR is used for data exchange along with the information space (workflows considering patient-related data like reports, studies, etc.) and DICOM or DICOMWeb for data exchange along with the image space (managing all image-related data with all related metadata and related workflows like post-processing). The modern design of those standards with its modular data representation and flexible access through well-known RESTful web interfaces turns them into an ideal standard for agile-driven developments even in the field of ophthalmology, e.g., to implement the proposed transactions from the IHE Unified Eye Care Workflow. Considering the use case of remotely analyzing images of a patient's eye in combination with mobile image acquisition modalities, the web-based healthcare standards with accessible terminologies offer a valuable toolbox for new applications while guaranteeing required interoperability. However, past teleophthalmology projects identified a lack of proper workflow integration in teleophthalmology as the systems often could not align to the proposed processes: E.g., SNOMED CT still lacks synonyms for ophthalmologic concepts hindering to finding the right codes during routine practice which often lead to the rejection of using SNOMED CT by ophthalmologists or to substitute the terminology with locally maintained concepts lists [17]. Future teleophthalmology solutions might utilize FHIR interfaces with workflow support (e.g., utilizing FHIR *Workflow* resource) for more convenient and flexible data integration for clinical information as well as DICOMWeb interfaces for flexible requesting orders and providing images.

To coordinate the development and avoid overlaps among the standards, the DICOM joint working group *WG-20: Integration of Imaging and Information Systems* and the *Imaging Integration Working Group* (IIWG) of HL7 work on the common objective to optimize and align the links between DICOM and FHIR. E.g., the imaging workflow in FHIR is related to clinical information (utilizing the *ImageStudy* resource) but not to the images. To query the image(s), *ImageStudy* further provides another resource *Endpoint* which consists of an *address* property that can define the DICOMWeb path of a certain image for its practical retrieval. *Endpoint* additionally includes the *connectionType*, which could be e.g., *dicom-wado-rs* (web access to DICOM objects using restful services) or *dicom-qido-rs* (Query based on ID for DICOM Objects) or any other used service for data retrieval.

Although the specification of DICOM with its supplements is open accessible and usable, there is still a gap in providing a mandatory image-related standard to software and hardware vendors in ophthalmology as they often rely on proprietary interface formats [20]: Most vendors confirm DICOM support, but very few vendors support the specification according to the defined standard, which hinders interoperability in teleophthalmology. As stated by several publications, there is a strong recommendation from experts for vendors of ophthalmology systems to strictly adhere to data standards and contribute to reaching a more unified structure and fostering interoperability [16,20]. Due to the rapid progress in imaging hardware (new cameras or other imaging acquisition modalities with better image quality) and new methods in software-based processing (cloud computing, artificial intelligence), future data exchange standards in ophthalmology must also be able to deal with possible new data protection-relevant aspects, for example when processing images of eyes, which represents biometric data that might uniquely identify a patient. Current standards like FHIR or DICOMWeb consider common data protection and privacy aspects along with web security methodologies.

In the field of teleophthalmology, new technologies require to have flexible interfaces that enable communication and data exchange between both remotely located parties, i.e., physician and patient (or physician and physician) as well as physician and image-acquiring devices (or any other diagnostic device). The basis for such data exchange is provided by the web-based standards HL7 FHIR and DICOMWeb. Although the standards, together with IHE and medical terminologies facilitate achieving technical and semantic interoperability, there is still a gap to seamlessly map ophthalmology workflows along with a patient use case with process interoperability.

This paper aimed to provide an overview on established data exchange standards in teleophthalmology and their future directions, however, this overview is not exhaustive and is primarily focused on the store-and-forward communication modality and interoperable data exchange in ophthalmology. Similar areas, such as radiology, often rely on similar concepts with slight adaptations. Thus, it can also be adapted for the field of ophthalmology, especially for general topics like e.g., privacy and security in medical data exchange.

Further investigations in this area might consider the user requirements of teleophthalmology with a focus on process-related requirements.

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