Enabling Artificial Intelligence in High Acuity Medical Environments

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Acute patient treatment can heavily profit from AI-based assistive and decision support systems, in terms of improved patient outcome as well as increased efficiency. Yet, only very few applications have been reported because of the limited accessibility of device data due to the lack of adoption of open standards, and the complexity of regulatory/approval requirements for AI-based systems. The fragmentation of data, still being stored in isolated silos, results in limited accessibility for AI in healthcare and machine learning is complicated by the loss of semantics in data conversions.

We outline a reference model that addresses the requirements of innovative AI-based research systems as well as the clinical reality. The integration of networked medical devices and Clinical Repositories based on open standards, such as IEEE 11073 SDC and HL7 FHIR, will foster novel assistance and decision support. The reference model will make point-of-care device data available for AI-based approaches. Semantic interoperability between Clinical and Research Repositories will allow correlating patient data, device data, and the patient outcome. Thus, complete workflows in high acuity environments can be analysed. Open semantic interoperability will enable the improvement of patient outcome and the increase of efficiency on a large scale and across clinical applications.

Keywords: context-aware medical technology; big data; IEEE 11073 SDC; HL7 FHIR; surgery

Introduction

Methods of artificial intelligence (AI) are increasingly applied in many fields of healthcare, e.g. for image processing to support the diagnosis of diseases like tumours, in genetics, etc. [1]. Lots of research progress has been achieved in recent years. The first AI-based assistive systems have already started to be used for regular patient care [2], [3]. However, AI-based assistive and decision support systems for patient treatment in high acuity environments with high impact on patient safety and clinical

outcome, such as the operating room (OR) or the intensive care unit (ICU), are highly underrepresented. Two prime reasons are the lack of availability and suitability of medical device data due to missing open communication standards, and the high regulatory/approval requirements for AI-based systems. This article focuses on the first aspect.

Data is the most important resource for AI applications. In high acuity environments, this includes information about the composition of the medical device ensemble, vital signs measured by the devices, their current state of operation, etc. On the one hand, information provision is necessary for the actual decision making in the particular situation and, on the other hand, this data is needed for any machine learning process. While the first aspect can only be achieved with interconnected medical devices at the point of care (PoC), the second requires a seamless data transition from the medical devices to Clinical Care and Research Repositories. We will show how vendor-independent interoperability based on open standards can empower innovative AI-based assistive and decision support systems. Our goal is to enable AI for the OR and ICU as well as for PoC medical device deployments in general.

State of the Art

Artificial Intelligence (AI) is emerging in the medical domain and becomes ever more important. In their survey, Jiang et al. [1] analyse the current research in terms of the addressed diseases and the kinds of input data being considered in recent AI literature. They conclude that the leading three disease categories are neoplasms, neurological, and cardiovascular diseases. The three most frequently used kinds of input data are diagnostic imaging (>3,000 PubMed-listed papers between 2013 and 2016), genetic data (>1,100 papers), and electrodiagnostic data (diagnostic methods based on electrical activity of human body, like electrocardiography (ECG), electroencephalography

(EEG), and electromyography (EMG); >900 papers). Other types are mentioned less than 100 times in AI literature between 2013 and 2016. Monitoring and physiologic data is not used frequently, although many hospitalised patients' vital signs are being monitored. This might be an indicator for poorly available or unsuitable medical device data as proper communication standards have been missing. In contrast, the well-established DICOM standard for medical images might be one reason for their frequent usage.

Maier-Hein et al. [4] discovered that large-scale data science is not as quickly introduced into interventional medicine as into other medical domains. For the vision of Maier-Hein et al. of a 'Surgical Data Science', they point out that one of the immediate challenges is the availability of data. During a surgical procedure, a large amount of data is generated, but it is usually neither captured nor annotated using standardised vocabulary [5].

The lack of interoperability and the lack of standardised data models and communication protocols is often highlighted as one of the major challenges or problems for AI in healthcare [6]. Especially, the fusion of heterogeneous data from multiple sources is challenging without widely-used standards [7]. Raghupathi et al. [8] identify the challenge that "healthcare data is rarely standardized, often fragmented, or generated in legacy IT systems with incompatible formats."

Even researchers from IBM Watson and Google DeepMind indicate that "the challenge lies in harnessing volumes of data, integrating the data from hundreds of sources, and understanding their various formats. [9]" and that "open standards and true interoperability" are the key-enablers [2].

We conclude our state of the art study by citing the analysis of Dimitrov [10]: "The biggest technical barrier to achieving this vision is the state of health data." It

states that data fragmentation in silos and a lack of "standardized vocabularies and message formats" are major problems.

Problem Statement

Following the analysis of current challenges and problems for AI in healthcare, we make the case that two main problems have to be solved for large-scale application.

- Hypothesis 1: Fragmentation of data, unavailable data, and data being stored in isolated or proprietary silos are responsible for a low *quantity* of input data for AI in professional healthcare.
- Hypothesis 2: Missing or lost explicit semantics, like data types, units of measure, acquisition context, temporal annotations, etc. considerably decrease the *quality* of input data for AI in professional healthcare.

Hypothesis 1 deals with the unavailability/inaccessibility of medical data. As a sufficiently large amount of data is crucial for most AI applications, it is necessary to overcome this problem to enable the potential of medical device data for AI applications. Due to the high amount of necessary data, it is typically indispensable to make use of different data sources.

However, the – ideally (semi-)automated – integration of heterogeneous data sources without annotation to get high quality data sets is a difficult and error-prone task. Modern AI methods are generally able to work with unstructured, untagged, and uncorrelated input data. However, understanding the structure and semantics of the input is then as well part of AI-training process. Given semantics therefore reduces the complexity of the learning problem. Thus, the results are expected to be much better using semantically annotated data. Unfortunately, the capability of AI-based methods to cope surprisingly well with unstructured and untagged data of poor quality lowers the

motivation of some stakeholders to increase data quality by implementing semantic interoperability.

Both of these problems can be solved by using comprehensive standards for vendor-independent interoperability. To make medical device data available for AI applications, two steps have to be taken: Firstly, the medical devices have to be interconnected by committing to the same syntax protocol and standardised vocabulary. For this purpose, we will introduce the new IEEE 11073 SDC family of standards. Secondly, the data has to be transferred to the medical and research information systems without losing information or modifying semantics (overcoming the 'semantic gap'). HL7 FHIR is an emerging standard enabling the device-to-infrastructure transfer as well as communication between information systems. Both standards will be explained as key enabling technologies in this paper.

Interoperability for Medical Devices at the Point of Care: IEEE 11073 SDC

The IEEE 11073 Service-oriented Device Connectivity (SDC) family of standards is an emerging technology designed for manufacturer-independent interoperability of medical devices in high acuity environments [11], [12]. Today, integrated ORs or ICUs are isolated solutions by single vendors, based on proprietary interfaces. Consequently, device data is locked away inside these systems and therefore unavailable to innovative medical systems that could supply advanced assistance and decision support at the point-of-care in highly dynamic situations.

As illustrated in Figure 1, the Medical Devices Communication Profile for Web Services (MDPWS), published as ISO/IEEE 11073-20702, provides foundational interoperability, i.e. the ability of devices to exchange data. It is derived from the OASIS standard Devices Profile for Web Services (DPWS) [13] and defines extensions and restrictions with a focus on the characteristics of medical data and related safety

requirements. Whereas the extensions for *dual channel transmission* and the *safety context* primarily focus on safe remote control, the *data streaming extension* for waveforms such as ECG and EEG is also highly relevant for data access by AI-based systems.

The Domain Information and Service Model (IEEE 11073-10207) defines how the devices describe themselves and their data in the network. Together with the usage of standardised nomenclature terms, this well-defined structure enables semantic interoperability, i.e. the correct perception and interpretation of exchanged data by human users as well as by machines. Semantically well-described medical device data in large quantities can thereby unfold its potential to bring AI and big data approaches to the next level of accuracy.

In addition to the data and service model and the transport mechanism, there is a third standard (IEEE 11073-20701) that binds the services of the former to actual implementations of the interchange mechanism of the latter and thereby defines the full communication protocol. Furthermore, important references to other standards are specified therein, e.g. for time synchronisation, which is a very important factor in terms of data quality for AI and big data based applications.

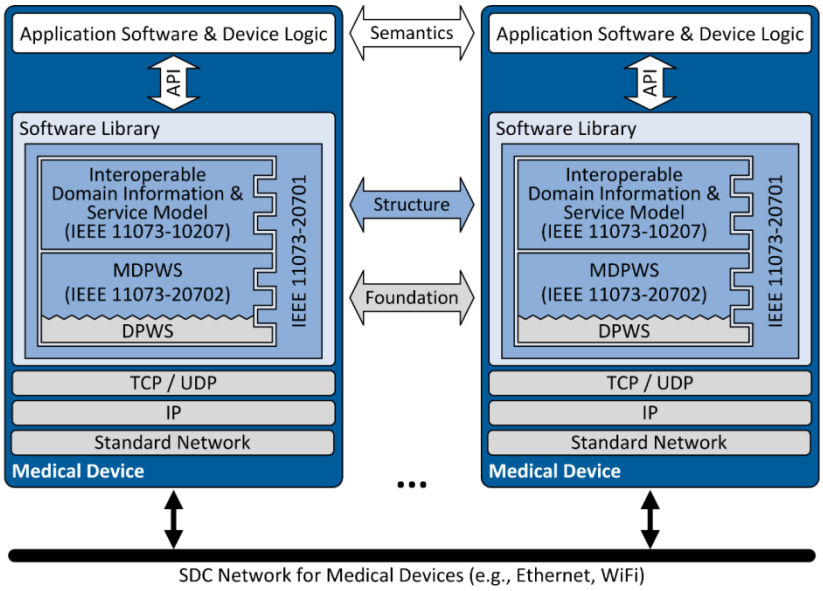

Figure 1. Visualisation of IEEE 11073 SDC standard family and levels of established interoperability [11], [14], [15].

Interoperability for Device to Infrastructure Communication: HL7 FHIR

Whereas the IEEE 11073 SDC family provides a comprehensive standard for the interconnection of medical devices, the connectivity to the clinical information system infrastructure is governed by another set of protocols. In the worst case, device data is locked out of this ecosystem by the aforementioned semantic gap between both worlds. Early efforts to overcome this resulted in proprietary outward communication of device data that only integrated with clinical information systems through custom interfaces. In response to these data silos, *Integrating the Healthcare Enterprise (IHE)* defined the *Patient Care Device* transaction PCD-01 that transforms device data into the *Health Level Seven (HL7) Version 2 (V2)* message format that dominates clinical IT systems' message exchange to this day. Much of the data and its acquisition context, however, was lost in this transformation, ultimately limiting the usefulness of the data for the purpose of clinical research [16]. Version 3 (V3) of the HL7 standard overcame most of these problems through immense modelling depth, which came at the cost of high

implementation complexity. Consequently, it has hardly been adopted with the notable exception of its *Clinical Document Architecture (CDA)* [16]. Only the introduction of HL7's latest modular instalment *Fast Healthcare Interoperability Resources (FHIR)* raises hopes and expectations of a data structure syntax for clinical IT infrastructure that is not only powerful and implementable but also enables secondary use, e.g. for clinical research.

Whereas FHIR does not cover the same set of use cases as IEEE 11073 SDC, their development was mutually influenced. Therefore, mappings between these standards are far superior to, for example, the PCD-01 transaction in terms of data and context preservation. Most importantly, the semantic descriptions of the data are carried over**.** These are usually taken from internal or external coding systems that provide the necessary terms for machine-interpretability of the device data. This 'mappability' of SDC and FHIR thus has the potential to eliminate the semantic gap and make medical device data available as part of Clinical Repositories built on FHIR that integrate clinical data from various sources.

Solution Outline

In Figure 2Figure 1**Fehler! Verweisquelle konnte nicht gefunden werden.**, we outline a reference model that addresses both the requirements of innovative AI-based research systems as well as the clinical reality. In the top left part (orange box), the medical device network, e.g. in the OR or ICU, is displayed using the new IEEE 11073 SDC standards for interconnection among each other. For the data transfer to the clinical information systems (bottom left part, green box), especially future Clinical Care Repositories, the usage of HL7 FHIR is proposed. This Clinical Care Repository also stores data from other information systems such as laboratory or radiology information systems. Provided there is an informed patient consent and de-identification of personal

data, the information can be duplicated into another FHIR-based Clinical Research Repository. This data can then be used for machine learning and other AI-based systems (right part of Figure 2, blue box).

Machine learning frequently needs data that is not stored routinely during day by day clinical practice. Therefore, we introduce a second repository containing medical device data. This 'Transient' Research Repository contains data that will typically not be stored in Clinical Repositories, e.g. high-resolution technical parameters, and acts as a bypass allowing data that is usually discarded to be recorded for machine learning. There are established standards for clinical research data such as the ISO 14199 BRIDG Model [17], and favouring HL7 FHIR for this repository as well may slightly impede the computational performance, for instance, as streaming data needs to be flattened into arrays. However, it also facilitates direct linkage of the transient data to the recorded clinical data of the same case, even if stored on a different server (repository link in Figure 2). This data alignment feature requires only that the de-identification process preserves an anonymous case or operation identifier in both the clinical and transient data that does not enable linking to the patients' personal information in the Clinical Care Repository. Furthermore, using FHIR for both research repositories preserves the semantic descriptions of all data elements and eases the machine learning systems' data access through using the same protocol interface. Whereas not within the scope of this work, it is also conceivable to share the data in these research repositories between different institutions using FHIR, provided that issues such as data protection, informed consent, and data provenance can be solved. The IHE Profile Mobile Cross-Enterprise Document Data Element Extraction (mXDE) [18], which is based on a federated concept, outlines a possible solution.

Data augmentation is a promising approach to cope with problems like low amounts of data, irrelevant features in the dataset, etc. For example, this technique is used in the field of (medical) image classification [19]. However, for data augmentation a suitable basic dataset is necessary. Thus, data augmentation is not able to solve the two basic problems that we identified above. Nevertheless, data augmentation could later on be used for further improvement of datasets collected in implementations of the reference architecture described in this paper.

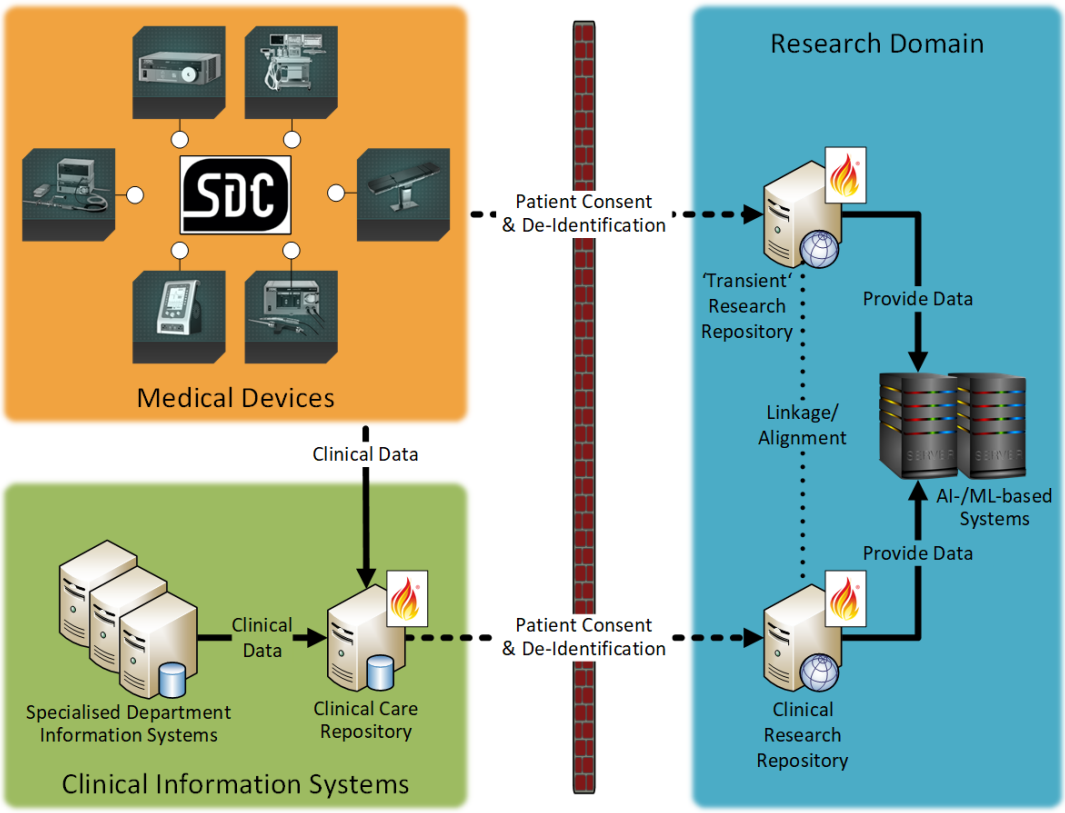

Figure 2. Conceptual overview: Medical device communication via IEEE 11073 SDC, Clinical Repositories based on HL7 FHIR, and AI-based research environment using the provided data. Abbreviations: AI – artificial intelligence; ML – machine learning.

Future applications of AI in acuity medical environments

The efforts towards a successful implementation of AI in patient treatment address two main long-term goals: an improvement of patient outcome and an increased efficiency. Whereas patient outcome is associated with increased effectiveness, reduced

invasiveness, and personalised treatment strategies, efficiency targets a reduction of cost, including time, material, as well as stress in the context of increasing health care expenses in aging societies. Methods of machine learning and artificial intelligence can improve current workflows in a broad set of applications. This comprises decision support [20], patient monitoring [21], context-aware device behaviour [22], as well as documentation and logistics.

The integration of FHIR-based Clinical Repositories and SDC-based medical devices as data sources will foster applications for the intelligent operating room. Most of the context-aware surgical assistance systems yet published rely on an explicit, knowledge-based modelling of the surgical procedures [23], [24]. These models are often trained with recordings of real interventions, and the training may also consider case-specific factors provided by a clinical information system. The intraoperative application of such models requires a processing pipeline considering workflow recognition, classification of surgical situations, and an evaluation of the situation to derive intelligent systems' behaviour. For instance, the appropriate video source for the primary surgical display may automatically be selected in endoscopic interventions based on the surgical workflow [22]. To that end, case-specific information, device data, tracking data, video streams, and sensors are interpreted, combined with knowledge about the surgeon's needs, and mapped to actions of technical systems, e.g. the video switching unit. In every processing step, methods of AI and machine learning, such as Hidden Markov Models [25] and convolutional neural networks [26], can be applied [27]. However, the training sets are yet very limited, seldomly include device parameters, measurements, or patient-specific (diagnostics) data, and need to be manually annotated due to the missing semantic interoperability of data sources and repositories. The lack of such recordings limits the applicability of advanced AI

methods. To compensate the insufficient training data, domain knowledge is explicitly modelled using for instance ontologies [28] or rule-based approaches [29], which in turn tailors the resulting assistance system to a specific clinical use case. An end-to-end training of such AI pipelines cannot be realised with limited, centre-specific datasets. A survey on machine learning and AI-technologies in clinical settings and medical research can for instance be found in [30].

With large repositories, semantic annotations, and a high quality of data automatically acquired, sophisticated AI methods and models may be trained faster and for a broader set of applications. In the evolution of medical technology, systems may be able to continuously improve with the increasing amount of training data. Starting from a rather generic model, systems may adapt to new surgical approaches and novel technologies. In the long-run, semantic interoperability between Clinical and Transient Research Repositories will enable the correlation of preoperative information, device behaviour during treatment, and the patient outcome. Hence, patient treatment in high acuity medical environments can be analysed, predicted, and improved considering the complete workflow and a comprehensive set of influential factors. By means of that, the long-term goals of improved patient outcome and increased efficiency can be achieved on a large scale and across clinical applications.

Conclusion

Methods of artificial intelligence (AI) become increasingly important in the healthcare domain – in clinical research as well as in clinical care. However, interventional medicine and high acuity care are highly underrepresented. We analysed this situation and concluded that the lack of interoperability based on open standards is one of the major problems. To overcome the challenges of unavailability of data and missing semantic information, we urge clinics to use two emerging interoperability

technologies: The new IEEE 11073 Service-oriented Device Connectivity (SDC) series of standards for interconnection of medical devices among each other and HL7 Fast Healthcare Interoperability Resources (FHIR) for the connection to information systems and Clinical Repositories. Based on these open standards, we present a reference model that enables the usage of point-of-care medical device data for current AI-based approaches. In addition, we explain how this architecture can be built upon by future applications.

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