Connecting the Clinical IT Infrastructure to a Service-Oriented Architecture of Medical Devices

Björn Andersen[1], Martin Kasparick[2], Hannes Ulrich[3], Stefan Franke[4], Jan Schlamelcher[5], Max Rockstroh[4], and Josef Ingenerf[1]

[1]*Institute of Medical Informatics, University of Lübeck, 23562 Lübeck, Germany,* lastname@imi.uni-luebeck.de

[2]*Institute of Applied Microelectronics and Computer Engineering, University of Rostock, 18119 Rostock, Germany,* firstname.lastname@uni-rostock.de

[3]*IT for Clinical Research, University of Lübeck, 23562 Lübeck, Germany,* firstname.lastname@itcr.uni-luebeck.de

[4]*Innovation Center Computer-Assisted Surgery, University of Leipzig, 04103 Leipzig, Germany,* firstname.lastname@medizin.uni-leipzig.de

[5]*OFFIS – Institute for Information Technology, 26121 Oldenburg, Germany,* firstname.lastname@offis.de

Abstract

The new medical device communication protocol known as IEEE 11073 SDC is well-suited for the integration of (surgical) point-of-care devices, so are the established HL7 V2 and DICOM standards for the communication of systems in the clinical IT infrastructure. An integrated operating room and other integrated clinical environments, however, need interoperability between both domains to fully unfold their potential for improving the quality of care as well as clinical workflows. This work thus presents concepts for the propagation of clinical and administrative data to medical devices, physiologic measurements and device parameters to clinical IT systems, as well as image and multimedia content in both directions. Prototypical implementations of the derived components have proven to integrate well with systems of networked medical devices and with the clinical IT infrastructure, effectively connecting these heterogeneous domains. Our qualitative evaluation indicates that the interoperability concepts are suitable to be integrated into clinical workflows and are expected to benefit patients and clinicians alike. The upcoming HL7 FHIR communication standard will likely change the domain of clinical IT significantly. A straightforward mapping to its resource model thus ensures the tenability of these concepts despite a foreseeable change in demand and requirements.

Index terms—

Medical Device Interoperability; Integrated Operating Room; Clinical Information Systems; IEEE 11073 SDC; Medical Communication Standards; Computer-Assisted Surgery

Acronyms

ACR-NEMA American College of Radiology — National Electrical Manufacturers Association.

BMBF German Federal Ministry of Education and Research.

CDA Clinical Document Architecture.

CIS clinical information system.

CITI clinical IT infrastructure.

DEC Device Enterprise Communication.

DICOM Digital Imaging and Communications in Medicine.

DIM Domain Information and Service Model.

DOD Demographics and Order Distributor.

DOG Demographics and Order Gateway.

DOP Demographics and Order Provider.

DOR Device Observation Reporter.

DPWS Devices Profile for Web Services.

FHIR Fast Healthcare Interoperability Resources.

HL7 Health Level Seven.

HMI Human-Machine Interface.

ICCAS Innovation Center Computer-Assisted Surgery.

IHE Integrating the Healthcare Enterprise.

IT information technology.

ITI IT infrastructure.

LOINC Logical Observation Identifiers Names and Codes.

MDPWS Medical Devices Communication Profile for Web Services.

MDS Medical Device System.

NFC near field communication.

OR operating room.

PACS picture archiving and communication system.

PCD Patient Care Device.

RAD radiology.

REST Representational state transfer.

SDC Service-oriented Device Connectivity.

SOA service-oriented architecture.

SOMDA service-oriented medical device architecture.

SQL Structured Query Language.

1 Introduction

The operation of a hospital is supported by a multitude of information systems. In order for clinical, administrative, or imaging data to flow seamlessly from one department to another, various communication standards for information exchange in the clinical IT infrastructure have been defined and established. Medical devices, however, have grown to accommodate ever more functionality whereas hardly being interconnected to exchange data.

In order to overcome this interoperability deficit, many research efforts have been undertaken in recent years. Of these efforts, some were focused on the *integrated operating room* [1, 2] as a particularly challenging clinical environment that requires device connectivity. However, focusing only on one domain – information systems *or* devices – can only ever be half the solution for the interoperability problem.

With the ambition to devise a comprehensive concept addressing this issue, the German national flagship project *OR.NET* on safe and dynamic networking of medical devices and clinical information systems was launched. OR.NET essentially aimed for point-of-care medical device interoperability including but not limited to the integrated operating room (OR). To achieve this goal, a service-oriented architecture built on modern communication technology has been employed whereas legacy systems have been connected as well.

The scope of the project is very wide so that aspects other than the connection of this architecture to the clinical IT infrastructure are covered in additional articles of this special issue as well as in previous publications. The extensive requirements analysis explicitly involved assessing the need for interoperability between devices and IT systems [3]. The resulting service-based architecture of medical devices is described in detail by Kaspar-

ick et al. [4] whereas the integration of devices with real-time requirements is discussed by Pfeiffer et al. [5]. These novel integration concepts also have an impact on risk management that is analysed by Janß et al. [6] together with proposals for new methods for type approval of devices. Additional efforts have been undertaken to standardise the communication protocols developed in OR.NET [7] as well as to develop concepts for operators to demand and integrate these solutions into clinical reality [8]. Finally, the concepts were validated at several demonstrator sites in order to validate their viability [9].

The scope of this work in particular is the interface of two intrinsically different domains – systems of networked medical devices and clinical information system networks. In order to benefit from data exchange over the boundary between both, e. g. patient demographic data, clinical findings, or documentary information, interoperability needs to be accomplished on three levels [10]:

Foundational interoperability, also *technical interoperability,* the ability of machines to exchange data,

Structural interoperability, also *syntactic interoperability,* the ability of a machine to read data that has been exchanged, and

Semantic interoperability, the ability of a machine to interpret data that has been read.

Leveraging the benefits that a standardised communication protocol for medical devices offers over proprietary solutions, we describe solutions for both directions of this inter-domain communication.

The following section introduces communication standards for clinical information systems as well as the newly introduced medical device communication standards with a strong

focus on the modelling of the common elements. How the communication between both worlds can be realised is described in section 3 for patient and administrative data, section 4 for device observations, and section 5 for medical imaging. The results of implementing these concepts can be found in section 6 and their evaluation in section 7. Finally, a conclusion is given in section 8 together with a discussion of subsequent work.

2 Communication Standards in Medical Informatics

For an integrated OR, two different networks segments need to be considered: the medical devices network and the clinical information systems network. Due to security and safety issues [11], these networks shall be strictly separated [4]. Nevertheless, data has to be exchanged between both. And beside the network separation, there is another challenge: The communication protocols of both domains are inherently different. Whereas the communication inside the clinical IT infrastructure (CITI) is based on standards like Health Level Seven and Digital Imaging and Communications in Medicine, the OR.NET project introduced a new communication protocol specification for medical device-to-device communication, standardised within the IEEE 11073 Health Informatics series as the so-called IEEE 11073 Service-oriented Device Connectivity (SDC) family. Its purpose is to complement information system communication standards rather than to compete with them, but it still has to provide mechanisms for transferring basic patient and administrative information as well as device observation data in order to connect both domains.

2.1 Clinical IT Infrastructure Communication

Nearly every business process in the domain of healthcare can be supported by information technology (IT). Specifically care providers with complex inner structures, such as large hospitals, therefore need protocols for electronic data exchange between their diverse departments and multi-vendor subsystems. Well-established communication standards include *Health Level Seven (HL7)* for administrative and clinical tasks as well as *Digital Imaging and Communications in Medicine (DICOM)* for images and related content.

2.1.1 Health Level Seven

Introduced in the late 1980s, HL7 provides structural standards for the exchange of electronic health and related data to support clinical practice and management. These facilitate the communication of patient demographic, order management, and billing information (among others). For conveying the semantics of the data being exchanged, they largely rely on the use of external controlled vocabularies such as *Logical Observation Identifiers Names and Codes (LOINC)*. Whereas the version 3 (V3) of HL7 [12] that is based on a comprehensive *Reference Information Model* only experiences widespread use in the *Clinical Document Architecture (CDA)*, the simpler and less-constrained version 2 (V2) [13] continues to dominate message-based data exchange. Specifying only the data structure, both versions are agnostic of the communication protocols at lower abstraction layers.

Recently, a third major installment of HL7 has been brought forward: The *Fast Healthcare Interoperability Resources (FHIR)* [14] provide a flexible way of defining data structures using *resources*, modular building blocks that can be refined to cover various data exchange

scenarios.

2.1.2 Digital Imaging and Communications in Medicine

For medical image interchange, DICOM [15] is the single widely-recognised standard. It has its origins in the *American College of Radiology — National Electrical Manufacturers Association (ACR-NEMA)* standard, a manufacturer independent format for medical image interchange, which came up in the early 1980s following the increasing importance of digital modalities [16].

Whereas the core of the standard still defines how medical images can be exchanged, displayed, and managed, DICOM as a whole has grown over the last 24 years from 750 to more than 5600 pages [15], not only to reflect the ever growing complexity of modalities and related IT systems, but also by expanding into many areas beyond the original scope of medical image communication. These areas include worklist management for passing along administrative information, e. g. patient demographic data, during the whole imaging workflow, consistent image presentation via presentation states, and DICOM Structured Reporting, which may not only be used for creating diagnostic imaging reports, but also for transmitting semantically interoperable image annotations, such as radiation dose information [17].

2.2 Service-Oriented Medical Device Architecture

HL7 and DICOM are well-suited for the communication of information systems and modalities, but they are neither designed nor appropriate for the specific needs of device-to-device communication as many use cases, e. g. safe remote control, are not covered. A third major

series, the *ISO/IEEE 11073 Health informatics – Medical / health device communication standards* [18] have been developed for this purpose and complement the aforementioned. Their original point-of-care medical device communication protocol, however, specifies point-to-point connections that since desisted to represent the state of technology. Consequently, another sub-series within the IEEE 11073 has been developed in order to employ modern technology for the communication of medical devices [19].

The *IEEE 11073 SDC family* follows the paradigm of a *service-oriented medical device architecture (SOMDA)* derived from the service-oriented architecture (SOA). It consists of three standards:

IEEE 11073-20701 Standard for Service-Oriented Medical Device Exchange Architecture & Protocol Binding [20]

IEEE 11073-20702 Medical Devices Communication Profile for Web Services (MDPWS) [21]

IEEE 11073-10207 Domain Information & Service Model for Service-Oriented Point-of-Care Medical Device Communication [22]

The communication technology and the data structure are therein separated to facilitate exchangeability of either or both. Part 20701 thus only defines the universal architecture and the binding of part 20702 describing the technical transmission details and part 10207 containing the domain-specific definitions for the modelling of medical devices.

MDPWS describes mechanisms for dynamic discovery of devices and services, data exchange, etc. based on the OASIS standard *Devices Profile for Web Services (DPWS)* [23]. Additionally, medical device-related extensions and restrictions are defined, such as mechanisms for safe data transmission (e. g. single-fault safety), transmission of data streams (e. g.

waveforms), or compact data transmission. More detailed information about MDPWS can be found in [24].

IEEE 11073-10207 specifies the Domain Information and Service Model (DIM) to describe the medical devices' capabilities and interactions: Measurements, parameters, alerts, remote control operations, etc. are modelled and annotated with terms from (external) controlled vocabularies. This further separation ensures that the data structure can contain a variety of semantics that are elsewhere precisely defined. In this model, the coding system defaults to the IEEE 11073-10101 Nomenclature [25], but the use of LOINC, SNOMED CT, etc. is also permitted.

2.2.1 Contextual Information

In addition to the device functionalities, different relationships between the medical device and its environment need to be modelled in order to put the exchanged information *into context*, i. e. to modify its semantics through encompassing information. The following context descriptors are especially relevant in a point-of-care setting:

Location Context describes the physical location of a device,

Ensemble Contexts define groups of medical devices that fulfil a purpose together, for example an endoscopic camera with its light source or even a whole endoscopy rack,

Patient Context contains information about the patient being treated, and

Workflow Context that comprises clinical and administrative information about the procedure and the workflow.

The latter two context descriptors can be used to transfer data from the clinical information systems that is relevant to point-of-care devices. Beside instance identifiers, e. g. social security number, passport id, or driving licence number, the *Patient Context* can contain *Patient Demographics Core Data*. This basic information includes family and given name, date of birth, and sex.

The *Workflow Context* can enclose an *Order Detail* element. This part represents required administrative information about the treatment such as the patient being treated and the order placer number. Additionally relevant clinical information (e. g. anamnesis) and danger codes (e. g. infections) can be added. Such information can be displayed to the clinical staff within the OR or even be used for the configuration of medical devices.

Before the introduction of SDC, only powerful devices implementing DICOM or HL7 have had access to patient and order-related information. The new protocol standards, however, enable even resource-constrained devices to receive a basic subset of this data. They do not have to implement multiple stacks to communicate with both the information systems and the other medical devices. And if a device does not process contextual information at all, it is not necessary to implement all of the contexts explained above.

Furthermore, the DIM allows for contextual information to have different states of association. It is thus possible for a device to be, for example, associated with one workflow it is currently operating in while being pre-associated with another one that is to follow.

According to this concept of handling and transferring contextual information, devices can provide remote control operations for particular contexts. Using these operations, other network participants can push contextual information to the device. Otherwise the device itself has to invoke services provided by other network participants providing such informa-

tion. Advantages and disadvantages of both variants are also discussed in sections 3.2 and 3.3.

3 Data Propagation from Clinical IT Systems to Medical Devices

The inherently different communication protocols used by the CITI domain and point-of-care devices lead to major difficulties wherever data needs to be exchanged between them. Point-of-care settings including but not limited to the OR greatly benefit from the electronic propagation of patient demographic data, avoiding manual input on every device. Furthermore, a certain amount of order management information facilitates data retrieval as well as observation data consolidation if available in the device domain.

In the OR setting, there are also use cases demanding the display of laboratory findings or preoperative diagnostic information. Additionally, the preparation of a procedure could be further simplified by using this information not only for display but also for context-aware, i. e. patient-, physician-, and procedure-specific, device initialisation.

Yet, implementing an HL7 communication stack and being integrated into the clinical IT network overburdens the majority of point-of-care medical devices and undermines the network separation. It is therefore necessary to mediate between the realms, so that all actors can continue to communicate using their native exchange protocols.

3.1 From Message-Based Data Exchange to Context Generation in a SOMDA

Before approaching the issues of syntactic and semantic interoperability, the difference in communication paradigms has to be overcome: Information contained in messages from the CITI side must be made available to a loosely coupled device ensemble in the SOMDA. In the case of patient demographics and order management, that is achieved by interpreting this data as contextual information that semantically modifies the state published by the participating devices, turning information into knowledge.

In order to avoid the tedious manual selection of all devices that are to operate in the same context, this section assumes that the devices are grouped in an ensemble or preferably a *session*, a dedicated assemblage of devices working together within the scope of a procedure. A general discussion of session management in the SOMDA can be found in [4]; this paper assumes that it is handled by a Session Manager component.

The task of assigning devices to a patient and to a procedure is thereby simplified to only expanding the existing context by patient and order information. To that end, a gateway component is specified that connects to the CITI network as well as to the networked system of medical devices. It implements an HL7 V2 interface and therewith receives patient and order data from the clinical information systems, which it then stores locally.

The preferred message format for this HL7 communication is defined by the global initiative *Integrating the Healthcare Enterprise (IHE)* through integration profiles and transactions that are to be implemented for specific use cases. Their IT infrastructure (ITI) technical framework specifies patient identity and encounter management in transactions ITI-30 and

-31, whereas order placer management is covered in transaction RAD-2 of the radiology (RAD) technical framework. The gateway adheres to these specifications.

In the next step, the context is generated from the received data. This requires parsing the received data and mapping the content extracted from the message fields into the attributes of the context objects. Demographic information is represented in the patient context whereas encounter and order information becomes part of the workflow context.

The only user interaction that is needed in the process is the selection of the ensemble/session context(s) the patient and workflow context will be assigned to. This can be implemented in various ways: interaction with a computer terminal, scanning a patient's wristband that has a bar code and/or a near field communication (NFC) tag, etc. Ideally, the user interface for this interaction is the same that is used for the generation and propagation of a session context.

In the following sections, two propagation strategies for patient and workflow context are discussed. Section 3.2 describes an approach where the Demographics and Order Gateway (DOG) pushes the context data to every device in the ensemble. An alternative solution using a publish/subscribe pattern is proposed in section 3.3. This second design is based on a dissemination protocol for electronic health records [26] and enhanced by multi-session support. Both strategies can be implemented to comply with the IEEE 11073-20701 communication protocol whereas each is suited for a distinct set of clinical use cases. Figure 1 illustrates the component interaction described above that is the prerequisite for both the following variants of realisation.

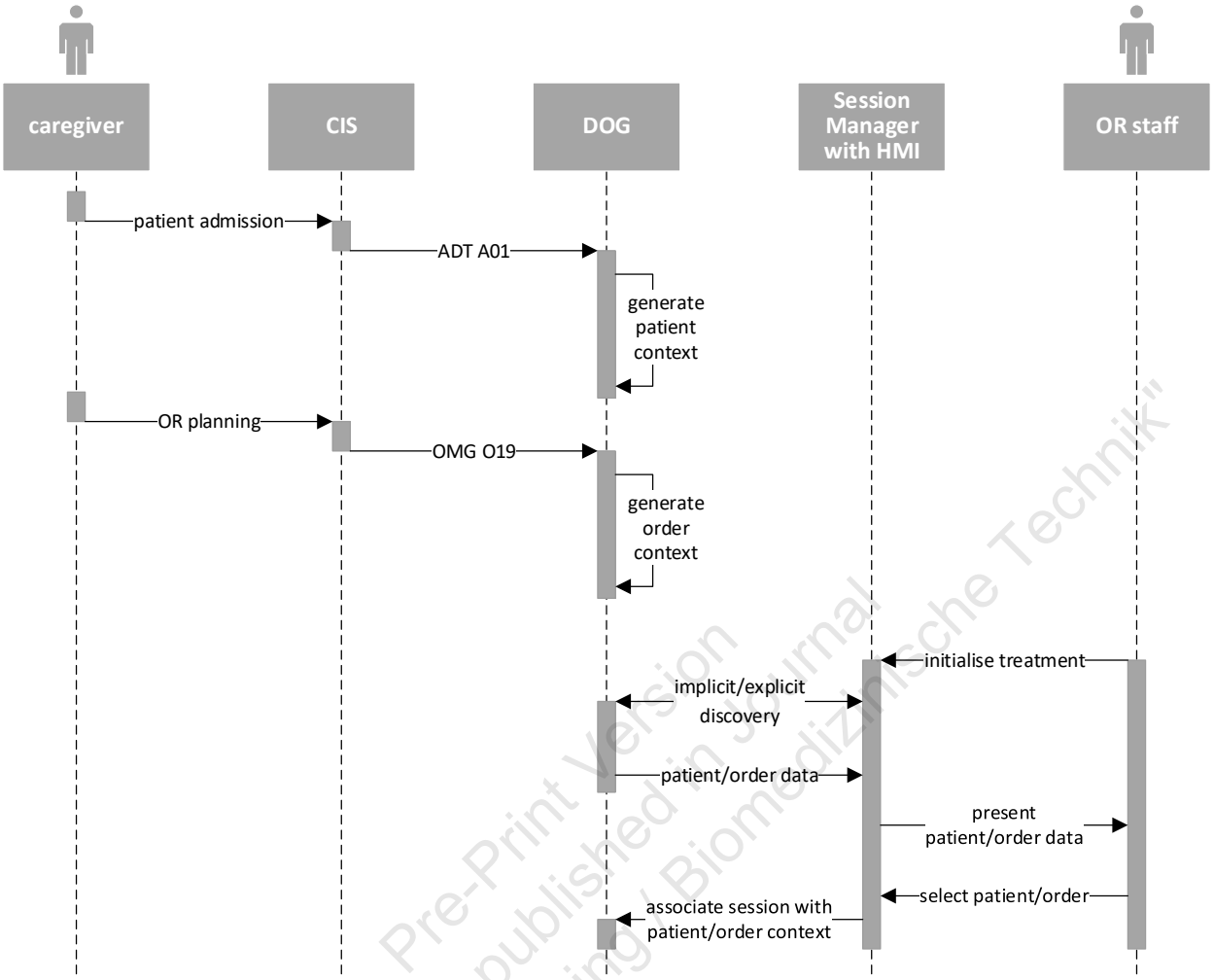

Figure 1: Sequence diagram detailing generation and association of context states. Patient demographic and order data is sent to the gateway following a trigger event. The context generated thereafter is associated through user interaction. It is herein assumed that the Human-Machine Interface (HMI) is part of the Session Manager.

3.2 Demographics and Order Distributor (DOD)

If the gateway is to manage the context distribution to the devices, it needs to compile and and maintain a list of devices operating within the same ensemble, patient, and workflow context. (This is simplified if the gateway is part of a central entity that also manages

the session context.) Using the control functionality described in section 2.2.1, the gateway pushes the patient and workflow context to those devices that support it, upon which previously associated context information is either disassociated or overwritten.

Consequently the gateway also needs to ensure that the context and association states of all devices involved are kept up-to-date, re-distributed if a device encounters and recovers from a fault, distributed to devices that join at a later stage of the procedure, and disassociated or removed upon leaving the ensemble. Figure 2 visualises the interaction pattern induced by the implementation of the gateway as an active distributor of context data.

Whereas this centralised approach removes the need for (passive) service providing medical devices, especially those that are small and resource-constrained, to implement additional service consumer functionality and context handling business logic, it also entails the diffusion of responsibility from the devices to the central component: The gateway needs to constantly monitor all devices and react accordingly. This requirement, however, is in conflict with the idea of loose coupling in a SOMDA and forces a centralist architecture upon an inherently distributed systems engineering approach.

3.3 Demographics and Order Provider (DOP)

This alternative approach [27] has the gateway act only as a provider of contextual information, leaving the retrieval and management of the context and association state to the devices. The gateway therefore publishes a device representation on the network that identifies itself as a context provider and expresses a patient and workflow context associated with an ensemble/session context. To provide information for more than one device ensemble, the

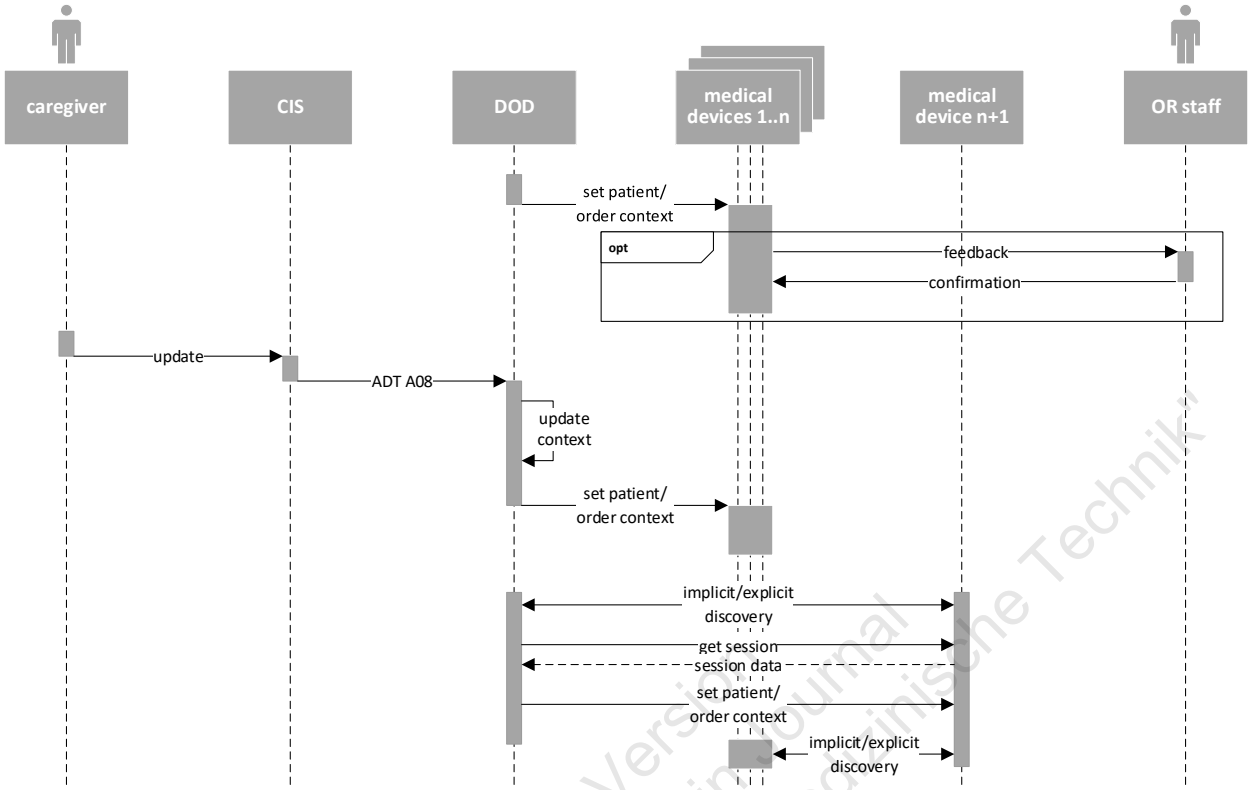

Figure 2: Sequence diagram of active data distribution; the DOD pushes the context to the devices. Changing the current association state can be implemented to require user confirmation. On update or a device $n+1$ joining the session late, the information needs to be pushed again. This diagram does not depict the prerequisite session management.

gateway can publish an arbitrary number of instances as long as the mapping of ensemble identifier to patient, encounter, and order identifier remains injective.

Devices are then notified of the provider instance belonging to their ensemble/session or, in the case of later device additions to the ensemble, can now probe for the provider instance. Depending on the complexity of the device in question, this can be an automated procedure or initiated through user interaction. Adhering to the SOMDA paradigm, the device then subscribes to the context and association states of the provider and is thus instantly informed

and automatically kept up-to-date through episodic notifications. The process is depicted in figure 3.

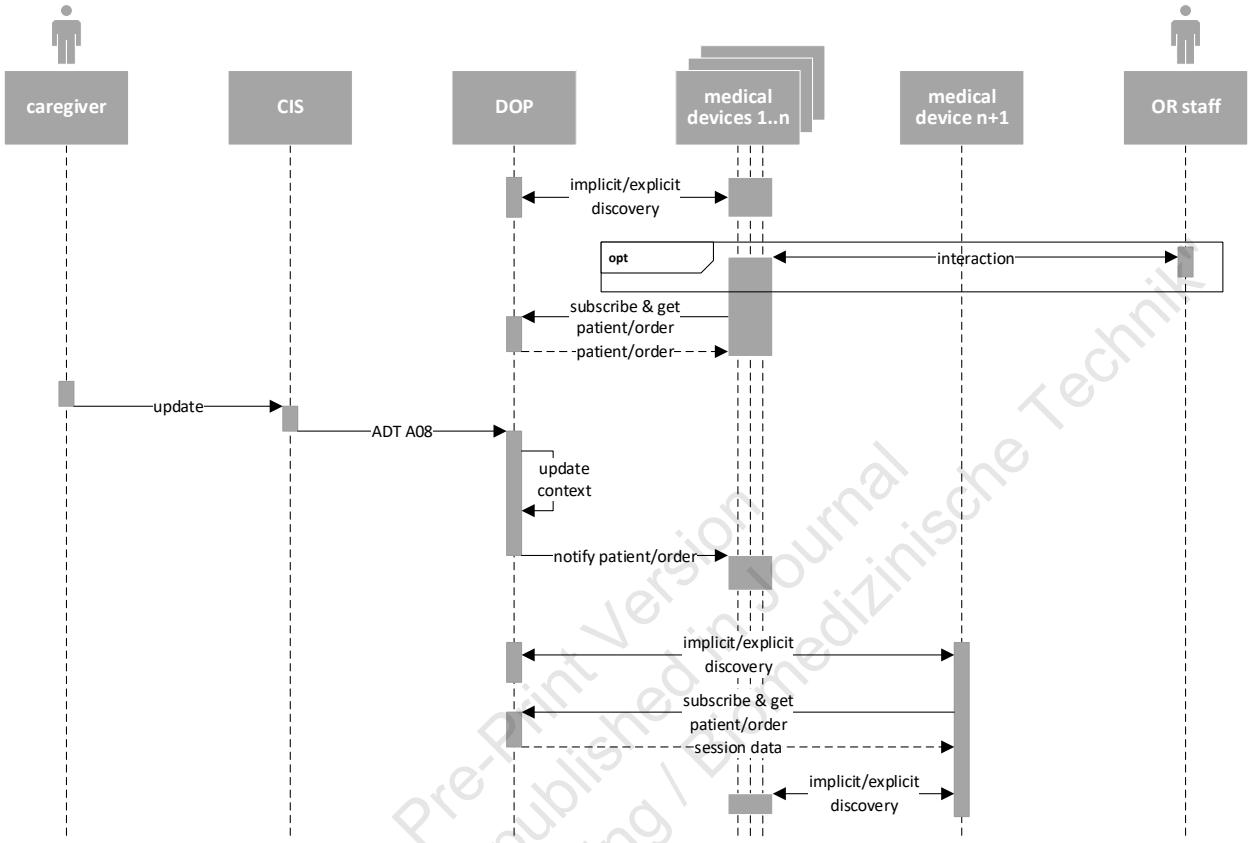

Figure 3: Sequence diagram of passive data provision; the devices subscribe to context data from the DOP. This can be implemented to require user initiation. On update, the devices are automatically notified. A device $n + 1$ joining the session late subscribes in the same way. This diagram does not depict the prerequisite session management.

This management strategy makes efficient use of the SOMDA principles and has a high fault tolerance due to the distributed responsibility for correct behaviour. These benefits, however, come at the cost of requiring even resource-constrained devices to implement a certain amount of context acquisition business logic.

4 Reporting Device Observations to Clinical IT Systems

Many point-of-care medical devices, especially in the OR environment, measure and generate large amounts of physiological observations, operational parameters, and alerts. Oftentimes, these *observations* are relevant not only at the time of measurement. Their persistence and continued use have the potential to better inform later stages of the care-giving process, to measure and improve the quality of care and documentation, and to be reused for clinical research through data analytics. Administrative processes such as billing, device maintenance, or tracking of materials consumption can also be simplified. It is therefore highly advantageous to transmit device data to the CITI domain for persistence and further use. However, the same impediments as described in the previous section need to be addressed – in reverse direction.

4.1 From Raw Device Data to Aggregated Reports and Findings

Not only are the communication protocols very different, the CITI is also commonly ill-equipped to handle raw device observations, much less large amounts of it. Besides the obvious need for aggregation, this also introduces the opportunity to implement smart analytic functionality at the interface between SOMDA and CITI networks, thereby generating useful knowledge.

This led to the specification of another component, which may or may not be integrated with the gateway described in 3. This *Device Observation Reporter (DOR)* is to record data through direct communication with the medical devices in the SOMDA and generate an

output that is readable and reusable in the CITI domain. It therefore needs to retrieve the data using one of the services defined in the IEEE 11073 SDC specifications: A simple *get* operation allows for the retrieval of a single value whereas the *subscribe* mechanism facilitates receiving episodic or periodic updates to the value of interest.

In its simplest possible implementation, the reporter then aggregates this data and sends it to a clinical information system using HL7 V2. A more appropriate solution lets a user interact with the reporter to select the signals that are to be recorded and the method of aggregation. A human actor can choose, for example, a simple time line, mean or median of a value, or more complex computations involving an arbitrary number of signals and values from different devices. DOR implementations for clinical use may also include analytic functionality that automatically assesses the raw device observations to deduce clinical findings, which can be used to support (computer-assisted) diagnosis [28] and therapy.

The reporting of device data also requires integration into the clinical workflow and business processes as well as system interoperability. For correct record target identification, the patient and workflow context state under which an observation is recorded must be used for generating the identifying segments in a HL7 V2 message. Observation and parameter values that have been recorded and aggregated from the device metrics are then mapped to the message structure as recommended by the IHE in their Patient Care Device (PCD) transaction PCD-01, thereby introducing syntactic interoperability with the clinical information system. In order to preserve the meaning of content and thus ensure semantic interoperability as well, the descriptive coding from the IEEE 11073-1010X series on Nomenclature is retained in the generated message [29].

With respect to the deployment of a recording component, three distinct integration

scenarios are depicted in figure 4 and described in the following sections.

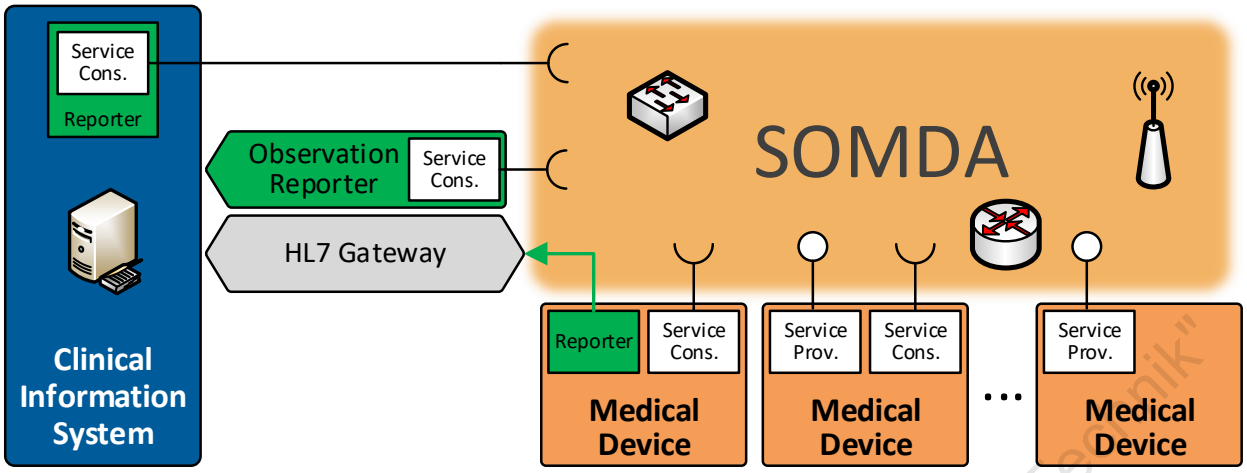

Figure 4: Component diagram depicting three integration scenarios for the recording component (green) as either (1) part of the medical device, (2) a stand-alone gateway connecting SOMDA and CITI, or (3) part of a clinical information system (CIS).

4.2 Medical Device with Integrated Reporting

One solution is the integration of reporting functionality into the device firmware. This variant is already commercially available today but does not commonly involve the retrieval of data from more than the device that is hosting this service [8]. These solutions, being described for example in the Device Enterprise Communication (DEC) profile by the IHE in their PCD framework, offer a high degree of freedom for implementers as they are not necessarily constrained by the IEEE 11073 SDC intermediate communication. They can also be tailored very specifically to the communication needs of the device in question, however, are commonly implemented as proprietary software that fails to leverage the benefits of the openly standardised SOMDA and the usage of associated coding systems.

4.3 Generic Observation Reporter as a Stand-Alone Component

A more flexible variant is the implementation of the reporter as a device-independent component and participant in the SOMDA [30]. It uses the IEEE 11073 SDC protocol to gather observations and operating data, serving as a generic gateway to the CITI domain. This solution exhibits the advantage of manufacturer-independence over available gateways that exist redundantly for every proprietary protocol in today's hospital IT landscape: It enables aggregation over all devices that employ SDC and thus receives well-described data that is annotated with terms from the IEEE 11073 Nomenclature or other controlled vocabularies.

An implementation of this kind features either a front-end that allows for user-defined post-coordination of device data into finding reports or even elaborate business logic for automatic evaluation that can be adapted to the needs of the operating health care provider. Whereas being a promising approach for future product development, this functionality is also very complex to be implemented and type approved.

4.4 Reporting as Part of the IT Infrastructure

The integration of the reporting into a communication server or information system that is part of the IT landscape rather than the device domain constitutes a third approach for deployment. In this case, the need for gateway components is obsoleted as the IT systems become participants in the SOMDA themselves. At the same time, it would render the separation of CITI and device networks nigh impossible. As this is not recommended in a traditional clinical network setting for safety and security reasons, this integration scenario has only marginal areas of applicability as of today.

5 DICOM Configuration over SDC

For the transmission of images from modalities inside the operating room, e. g. images from a C-arm X-ray unit, as well as for the intraoperative display of images from previous examinations, the incorporation of DICOM devices into the SOMDA is essential. For this task, a novel integration concept was developed during the OR.NET project: The information that is required to configure the DICOM devices is transmitted via SDC, so that the devices may then initiate classic DICOM communication.

In general, the DICOM standard already addresses the issue of device configuration. A solution for managing the configuration of all DICOM devices inside a clinical network has been developed and published as Supplement 67 Configuration Management [31] and is now officially part of the DICOM standard (part 18). The mechanisms of DICOM Configuration Management are, however, not directly applicable to devices in the loosely coupled SOMDA that is implemented by the SDC standards. The core problem is the requirement to have a central configuration server that manages the configuration of all devices inside the DICOM network. Whereas this reflects the reality of most classical DICOM setups, it is fundamentally different from the idea of SDC, in which each device manages and provides distributed information locally.

DICOM configuration management was therefore used as a basis to design a new device model for DICOM devices within SDC. Figure 5 shows the important elements of this model as an entity relationship diagram. Notably, all fields that are only meaningful in a centralised setup have been removed as well as some fields that are already contained in basic SDC entities and would have otherwise been redundant duplicates. Further modifications

were necessary to accommodate technical parameters of DICOM configuration management previously unavailable in SDC; for a detailed description see [32].

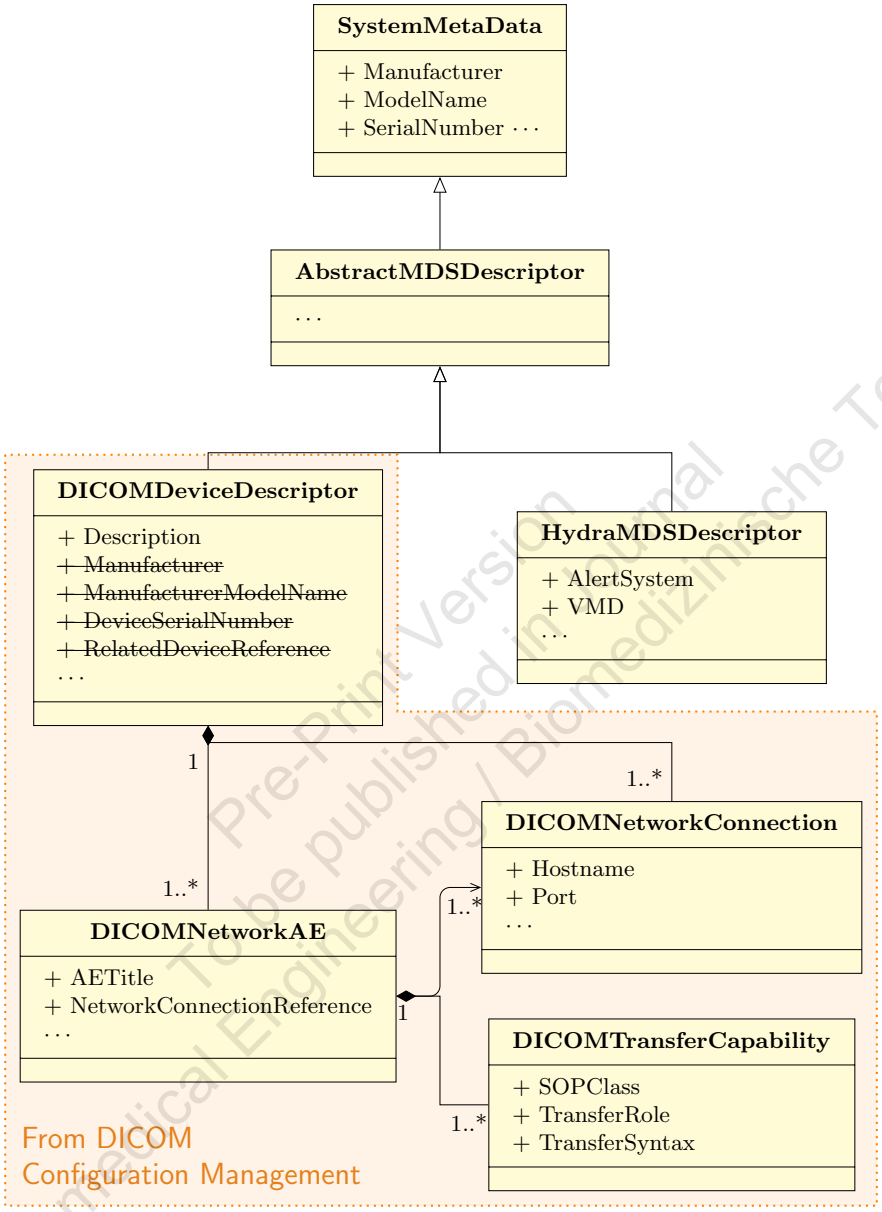

Figure 5: Information model excerpt based on adaptations of DICOM Configuration Management [32]. The DICOM device descriptor is an optional item within the device model. It is derived from the same abstract descriptor as any other Medical Device System (MDS).

5.1 DICOM Gateway

The DICOM device model described above allows for the integration of SOMDA-capable DICOM devices into the OR network. However, this alone does not resolve the issue of integrating DICOM participants that are located outside the OR network, for example a picture archiving and communication system (PACS). These need to be accessible from within the OR for planning and navigation as well as for persisting intraoperative image data generated during the procedure, e. g. from an endoscope or microscope. The solution is to employ a gateway that resolves two separate issues:

1. Routing DICOM connections/associations between the OR and the information systems network.

2. Managing the configuration information of non-SDC DICOM devices and providing it to the devices within the SOMDA.

Such a gateway was implemented and evaluated [32] as part of the OR.NET project. A similar gateway was specified for HL7 messages, operating as a proxy for communication to and from HL7-capable devices within the SOMDA.

6 Results

The implementation of the concepts described in sections 3, 4, and 5 resulted in reference prototypes of a Demographics and Order Distributor, a Device Observation Reporter, and a DICOM Gateway that were evaluated in the setting of a clinical demonstrator environment. It was thereby achieved to effectively connect the domains of clinical IT infrastructure and

medical devices in the operating room and to provide interoperability solutions for the most important use cases that require inter-domain communication.

The gateway for patient demographic and order data makes the transmission of this information easier, safer, and more reliable than the manual input that is customary today. At the same time, the availability of device observations for clinical information systems enables reuse, improved documentation, and clinical research. In contrast to previous reporters, the standardised communication protocol for medical devices allows for the aggregation over devices from different manufacturers in a uniform representation. In addition, the precise annotation with terms from controlled vocabularies facilitates semantic interoperability and thus further increases the potential for machine-processability of the collected device data. The configuration management extension for DICOM as well as the gateway leverage this previously existing standard to be more easily deployable within a SOMDA.

The feasibility of these concepts provides the opportunity for software vendors to implement commercial solutions based on the herein described components. In a productive clinical setting, the different types of gateways can be realised as either a single component, separate entities, or even using a distributed deployment strategy.

7 Evaluation

The herein proposed concepts allow for exchanging data between the device network and the clinical IT network. Prototypical implementations of the required components and gateways were realised within the scope of clinical demonstrators, which were established in the OR.NET project. These implementations served as prototypes to evaluate the associated

design decisions.

During presentations of the demonstrator site at the Innovation Center Computer-Assisted Surgery (ICCAS) in Leipzig, a questionnaire survey with CITI managers of eleven German hospitals was conducted. The participants were recruited from two events for professional audiences: the German Spring Conference for Clinical IT and the Symposium for Medical Technology. The essential data integration features of the demonstration OR were interactively explored prior to the survey.

This concept evaluation approach allowed for the structured gathering of feedback. The questions focused on the context distribution and demographics gateway paradigm as well as the generic stand-alone DOR approach, on the latter especially with respect to the relevance of maintenance data and device observations for the CITI. Hence, both directions of data integration were addressed. Besides that, future demands and risk management issues were considered, see [33] for details.

The automated and standardised transfer of patient demographics and order data from the CITI to the medical devices, implemented at a centralised touch screen in the OR, has been considered useful to streamline the workflow and also to increase patient safety, especially by obsoleting the error-prone and time-consuming manual entering of data. Vice versa, the reporting of maintenance data and measurements to the CITI, implemented by a generic DOR, has been considered useful to improve device maintenance workflows and to simplify post-operative documentation.

The demonstrator implementations have proven the technical feasibility of the integration approaches, and the first qualitative evaluation has indicated their suitability for clinical workflows and their potential benefits for daily clinical routine. In summary, these concepts

are expected to improve the integration of CITI and device networks over proprietary solutions in terms of comprehensiveness and flexibility.

8 Conclusion and Future Work

This work has introduced concepts for the integration of medical device and clinical information system networks and shown their expedience. The results are going to introduce manufacturer-independent interoperability into clinical environments and thereby improve the quality of care as well as the efficiency of care provision.

At the same time, there are other promising developments in the field. As introduced in section 2, Fast Healthcare Interoperability Resources (FHIR) constitute an important evolution of communication standards for clinical IT systems. Following years of largely unsuccessful promotion of HL7 V3, this upcoming approach is considered to be a suitable successor of the HL7 V2 exchange standard. FHIR is not technically an enhancement of its predecessor but a new approach that combines a new technology stack including RESTful communication and noSQL storage with useful concepts from the previous messaging standards. It therefore seems to be the *best-of-breed* approach for future information exchange in clinical IT infrastructure.

Considering medical device communication, FHIR's approach of modelling point-of-care devices has tremendous similarity to the IEEE 11073-10207 Domain Information and Service Model (DIM). Both standards have been designed in the same period of time and it is obvious that they have mutually influenced each other during the process. Consequently, mapping efforts have already been undertaken from this DIM to the corresponding FHIR

resources [34]. The proposed transformation offers a simple and robust customisation of resources using profiles and extensions, the tools and methods provided by FHIR.

It is thus conceivable to implement a gateway component to translate between SDC and FHIR similar to the components described in sections 3 and 4, or to develop a communication library that natively handles both protocols. Whereas FHIR does not offer all the device-specific features that are included in SDC, it is nevertheless much better suited for (limited) device integration than previous HL7 standards. In addition, the possibility of communicating device data using FHIR can facilitate the pooling of detailed observation and other data in *clinical repositories* in order to enable the secondary use of routine data and conduct clinical research. The latter will further benefit from the expansion of these repositories to include other related information, e. g. corresponding (genetic) data from biobanks etc. [35].

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