Achieving a Seamless Pathway to Plug-and-Trust Medical Devices

Editorial Note:

- I (THC) added a ToC for navigation during drafting. We can keep it or punt for the final version. Note that for navigation during content development, there is an outline navigation bar to the left of the document that can be used.

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1. Executive Summary

- What is the reality that this will actually be adopted and implemented by industry? (Vs. yet another failed MDI standards program?) What value drivers are new / different?
- What are we "selling" here?
- Approach that enables (for the first time) an ecosystem of products that addresses both the technical & process aspects
- Explicit section on medical device security
- Message: How is this different from device connectivity we've seen in the past? Why should I care now?!
- Message: National Program Coordination ... this is a key DRIVER of UPTAKE ... how can we advance this effectively? Move to a top-level topic ...
- Regulatory Affairs Story:
- Key stakeholder engagement: National governmental bodies & regulatory agencies
- Add Conformity Assessment to product CA certification (required by national bodies & healthcare providers ...)
- Vendor independent interoperability (with regulatory pathway addressed)

2. A Short History of Medical Device Interoperability

Ed. Content:

- Audience very well may approach this Story document with a "Yeah, I've heard all this before" — We need to address why this is any different than before
    - Learned over decades / not re-inventing the wheel
    - Technical vs. Business problems … now we address integrated solutions to both

2.1 1980 - 2000

As communications technology has evolved, the methods electrical/electronic medical devices[1] use to communicate has evolved as well. The first methods medical devices used were actually analog signals that were used to communicate measurement values such as heart rate and blood pressure from the devices at the bedside to central stations.

2.1.1 Point to Point Solutions

In order to meet the data needs of evolving Anesthesia Record Keeping (ARK) Systems, Clinical Information Systems (CISs) and early Electronic Health Records (EHRs), devices were equipped with RS-232 ports which would export data to these consuming systems. Similar to the networking solutions, the data exchanged was totally proprietary and limited to reporting of measurements and in some cases alerts due to the low bandwidth of the RS-232 approach. Note that many of these solutions continue to be supported today.

[1] In the context of this document electronic medical devices typically refers to devices for monitoring and therapy (patient monitors, infusion devices, ventilators, etc.) that are not imaging devices (X-Ray, MRI, CT, etc.)

In the mid 1990s the Medical Information Bus (MIB) effort took hold within the IEEE EMBS branch. The goal was to create a standardized serialized point-to-point communications stack that would replace vendor proprietary approaches. Development of the standard has gone through a number of iterations which, unfortunately, did not gain commercial success. The MIB efforts were the predecessor of the current set of IEEE 11073 standards which are discussed later in this document.

The DICOM (Digital Imaging and Communications in Medicine) protocol was developed in this general timeframe as a mechanism of exporting data from imaging systems using the RS-485 standard. In the early days this was primarily a point to point approach.

2.1.2 Network Solutions

As digital communications technology became more available in the late 80's and early 90's medical device companies started to evolve from the analog approach and use both proprietary and non-proprietary methods of networking devices digitally. For example Hewlett-Packard (now Philips) developed a totally proprietary approach called SDN (Signal Distribution Network), while Siemens (now Draeger) used SDLC (Synchronous Data Link Control) which was initially developed by IBM. In all cases, the data exchanged using these hardware protocols was completely proprietary.

Toward the end of the 1990s, manufacturers started to migrate away from their previous generation networking approaches and started to adopt Ethernet using TCP/IP or UDP/IP as their lower layer (physical layer, data link layer, network layer, transport layer) approach. As in previous generations everything else was proprietary including the syntax and semantics of the data.

2.2 2000 - 2020

The use of Ethernet based networking and the need to feed data to Information Systems led most manufacturers to develop gateways that integrated the data from multiple devices from their proprietary networks and converted that data into HL7 based output streams, which primarily addressed the issue of syntax.. Inevitably the various HL7 based implementations were similar but not the same which required additional work to convert one approach to another.

In parallel a number of companies saw a commercial opportunity to create systems that addressed the issue of collecting data from diverse medical devices, integrating that data and feeding that data to various clinical applications. These vendors, such as Nuvon, Capsule and Bernoulli devised various ways of collecting data from a mix of RS-232 and Ethernet based devices and systems. For the most part these solutions would export this data also using a gateway with an HL7 based export approach.

Around 2005 a number of vendors and clinical provider organizations joined together as a Domain under the IHE organization to develop a more consistent, consensus based version of an HL7 based approach to communication of device data to clinical IT systems. This group, known as the IHE PCD (Patient Care Device) Domain released a draft specification within 2 years which has since achieved broad acceptance with many commercial implementations.

The draft specification, which is now final, not only provided specific recommendations concerning the consistent use of specific HL7 fields and messages it also specified the use of the IEEE 11073-1010x nomenclature standards to ensure consistent semantics, Subsequently this group has developed similar specifications for the communication of alerts, data from infusion devices, etc.

2.3 2020 and Beyond

Currently the situation is much the same as it was in 2015. Medical device vendors of stand-alone devices provide RS-232 based interfaces to their devices typically using proprietary syntax and semantics. Medical device vendors of networked devices use Ethernet or WiFi coupled with gateways that comply with the IHE PCD flavor of HL7 which have undergone testing at IHE Connectathon events. Device integration firms such as Philips/Capsule, SPOK, ASCOM, Cerner and Nanthealth, etc. have also converged on using the IHE PCD standards in their products.

Looking forward it is clear that the same way that medical device gateway interfaces have become more standardized, the medical device communication interfaces need to become more standardized and interoperable. Any efforts to create the necessary ecosystem of interoperable devices will be driven by the value these solutions bring.

3. What Type of Interoperability?

3.1 The Definition of Interoperability

The typical definition of interoperability comes from IEEE which defines it as: “the ability of two or more systems or components to exchange information and to use the information that has been exchanged.” So in order for 2 devices to be interoperable all you need to do is figure out how to convert what one device is saying into something the other device can understand no matter how great the effort. This is a relatively low bar, and is somewhat representative of the current reality - something that has been termed “dysfunctional interoperability”.

Our objective is to go beyond the current state of interoperability and achieve “plug-and-trust” interoperability, where medical devices can exchange data with other medical devices and applications without the need for data conversions, so that they can understand each other and interoperate with each other out of the box. In addition we want medical device data to flow seamlessly to/from health IT systems. In order to achieve this, we need to look at the different aspects of interoperability.

3.2 The Aspects of Interoperability

In order to achieve Plug-and-Trust Interoperability these various aspect of interoperability must be mastered:

- Technical Interoperability - this refers to the physical layer, data link and transport layers of a data communications solution.
- Syntactic Interoperability - this refers to the formatting of the data - how the data is arranged within the data packet.

- Semantic Interoperability - this refers to how meaning is communicated, typically via an established way of coding values.

Some models of interoperability recognize additional aspects of interoperability, namely, Pragmatic, Dynamic and Conceptual aspects which we define as Plug-and-Trust Interoperability that builds on the above interoperability aspects and supports ways of identifying devices such that one device can 'trust' that the other will behave in an expected and agreed upon manner and can be used safely in the intended application.

4. Value of Medical Device Interoperability

Ed. Content: Intent is to connect with primary stakeholders WHY THEY SHOULD CARE. + to connect with previous studies - both cost #'s and priority use cases … THAT REQUIRE AN ECOSYSTEM OF PnT Products

In the world of medical device interoperability there are 2 key studies that have been conducted into understanding the benefits. One investigation was conducted by the West Health Institute (WHI) on "The Value of Medical Device Interoperability[2]". Another report on the topic "The Real Value of Medical Device Interoperability in Hospitals[3]" from Unity Consulting and Innovation.

The following is an excerpt from the report prepared by the West Health Institute. "This report examines areas of waste in health care that can potentially be eliminated through greater medical device interoperability and the adoption of commonly accepted standards for interoperability. Waste reduction through greater medical device interoperability would lead to increased efficiency, improved quality and more affordable care. Commonly adopted standards can accelerate the move towards greater medical device interoperability and potentially reduce the cost of achieving interoperability.

With all of the caveats associated with estimating the value of a process improvement not yet deployed, our combined top-down and bottom-up modeling suggests that annual savings in excess of $30+ billion may be liberated by widespread adoption of functional interoperability for medical devices. To realize the benefits, providers, payers, medical device manufacturers and the government will need to collaborate and partner to promote the development and adoption of seamlessly interoperable devices. Industry trends are already driving providers and payers to converge and share risk through care coordination, clinical integration and improved population health management. Stakeholder collaboration is expected to provide a strong platform for accelerating adoption of medical device interoperability and realizing its associated benefits.

Similarly the research done by Unity Consulting resulted in additional benefits for Medical Device Interoperability (MDI). "Medical Device Interoperability (MDI) is seen as a major determinant for smooth, efficient processes in healthcare. In general, it is expected that MDI simplifies the work done by physicians and nurses, improves productivity and performance, and may significantly improve the patient outcome and care.

The top five use cases were Isolation Room, Digital Charting, Ward Round PoI, Quiet ICU Wards and Integrated UI. Of these, Isolation Room and Quiet ICU hold the most promise in MDI development. (Use cases that can benefit from MDI are further discussed below). We also expect

[2] The Value of Medical Device Interoperability
[3] The real value of Medical Device Interoperability (MDI) in hospitals

that the Operating Room as well as the emerging area of "Hospital at Home" will benefit greatly from open interoperability.

The top five overall benefits of MDI were increased patient safety, increased process efficiency, improvement of the job attractiveness, support of (digital) innovation, and improvements of existing products."

4.1 Value to the Patient

The key value to the patient is the safety that is achievable if the overall solution conforms to the same standards and has been exhaustively tested. Safety also derives from technical capabilities built into the SDC technology which include specific features that address safety and security.

Other value benefits include specific use cases that take advantage of MDI such as:

- Quiet / Silent ICU: The ICU can be a very noisy environment which leads to disruption of patient rest and staff dissatisfaction. This use case supports the reporting of alerts directly to staff and their ability to manage alerts remotely without noisy alerts sounding at the bedside or central station.
- Hospital @Home: The ability to take care of a patient remotely has advantages to the patient who is able to recover in a familiar environment as well as to the healthcare organization which can free up resources for other patients. While the advantages of obtaining data from remote devices is clear, it is even more important to be able to remotely control these devices and remotely diagnose these devices if they are miles away from the clinician.
- Reduction of Adverse Events - The WHI report identified that the reduction of adverse events due to safety interlocks would have obvious clinical benefits to the patient. In addition this would also impact the providers and payers.
- Reduction of Testing - Due to the lack of interoperability and information flow many duplicate tests are performed. MDI could substantially reduce the inconvenience to patients and costs to providers and payers.

4.2 Value to the Clinical User

The study done by Unity Consulting investigated a large number of use cases to see which one had the most promise for MDI. They ended up with 5 key use cases, however many others can benefit. Some use cases include:

- Support for Charting: As previously discussed this was the starting point for many device integration efforts. However much more can be accomplished that just sending data to the EHR/EMR for charting. A reverse path may help reduce the load on the clinical staff.
- Isolation Point-of-Care: Patients that are placed in isolation, for example due to Covid 19, need staff to don protective equipment and remove it each time they enter the room. This takes considerable time and cost. With MDI it would be possible to adjust many medical devices from outside of the room.
- eICU: MDI can enable more choice in selection of equipment used in a remote ICU, typically called the Electronic Intensive Care Unit..
- Device automated control: MDI can enable the development of intelligent algorithms which can control therapeutic devices or even settings on monitoring devices.

In addition interoperability can enable advanced applications including:

- Analytics (predictive, real-time, …)

- Real-time decision support
- Advanced 'closed-loop' clinical applications:
    - Ventilator weaning
    - Medication administration
    - Blood pressure or other parameter management
- Smart Alarming
- etc.

4.3 Value to the Provider/Responsible Organization

Typically the Provider/Responsible Organization (RO) is interested in the economic impact of interoperability. This covers aspects such as safety, efficiency and cost. From a purely financial standpoint, the WHI report identifies that ROs are the largest benefactors of increased medical device interoperability with approximately 90% of the overall financial benefit captured.

- **Safety:** From an RO perspective increased safety can lead to greater patient satisfaction, reduction in patient length of stay, reduction of exposure to lawsuits, etc.
    - SDPi based solutions take advantage of various safety oriented features that are built into the standard.
    - Risk management support for the ISO/IEC 80001 series of standards has already been considered.
    - Agreements around how devices should behave as good citizens have been developed and documented in a number of IEEE Participant Key Purposes (PKPs) standards.
    - Applications that improve patient safety are more easily implemented and deployed.
- **Efficiency:**
    - Ability to achieve clinical system functions with fewer devices that can be combined
    - Lower integration cost / improved system quality
    - Reduce infrastructural inertia (middleware systems)
- **Cost:** Due to an enhanced sustainability focus of Electronic equipment, there is also a paradigm shift in the design specification of Active Medical Devices.

  In the past, specifically those devices which serve a growing demand of professional applications in hospitals of other healthcare providers, have always been investigated in financial terms with the traditional Net Present Value (NPV) approach. If the outcome was positive, usually the design project received approval.

  Unfortunately this approach came under pressure due to the fact of limited resources in both materials, starting from precious metals via semiconductors towards the availability of sufficient, qualified personnel, being responsible for installation and maintenance of the Medical Device during the Use Phase, which might span a decade or beyond. As a consequence of that, another approach became more dominant, called least life-cycle cost (LLCC). It focuses on all associated costs over the entire life cycle, from cradle to grave. While a NPV focus is limited to the manufacturer's aspects to be profitable, the LLCC approach goes far beyond. In comparison of two candidate Devices it figures out the one with the most favorite overall resource consumption and thus the highest level of environmentally friendliness or cost per function.

  As such the concept helps to minimize overall healthcare spending of society without compromising performance. Under the aspects of Interconnectivity of medical devices,

the LLCC point will be reached, once the function of integrating that functionality into the healthcare service provider network runs seamlessly without an involvement of IT experts during installation and maintenance. Therefore interconnectivity of medical Devices plays a key role in smart resource utilization.

4.4 Value to the Device Manufacturer

Buy-in from the manufacturer's side will be key to adoption of interoperability technologies to address the increased awareness of Providers/Responsible Organisations that interoperability is a key prerequisite to deliver timely clinical information. Unfortunately there are numerous hurdles to be tackled before device manufacturers are able to truly adopt interoperability. One of the major hurdles is inertia. Manufacturers are comfortable with the proprietary interoperability solutions that they already have in the marketplace. In most cases the ecosystem knows how to deal with these proprietary solutions, though it is not without issues such as cost and buying into specialized integration solutions. There is also a challenge coming from the long intervals between major device updates or replacements which represent opportunities for adoption of new technologies such as SDPi.

Yet there are benefits to the manufacturer as well. The WHI white paper identifies approximately $2 Billion of savings to the industry (in 2013) if interoperable solutions were adopted. Most of the savings would come from a reduction in testing effort. Today each combination of devices must be tested and functionality verified in order to receive FDA approval resulting in M:N combinations that need to be tested. Note that these tests must be redone with every new release.

With proper conformance testing in place using well documented standards this can be reduced to 1:1 testing with a much higher probability of success and safety than we currently experience. We also expect that with more formal conformance tests in place, the regulatory agencies will be much more inclined to accept these tests and reduce or eliminate pairwise testing.

4.5 Value to Public Agencies

Increased and open interoperability will also benefit public health especially in the collection of data to support public health research to support improved policy. Consistent semantics starting with the bedside and transferred to EHRs or other data repositories using technologies such as SDPi will support these needs.

5. Core Challenges & Concepts

Ed. Content: review points from the SDPi white paper; consider renaming the section title to "Why is MDI so hard?" or "Addressing both technical & business challenges" or "Device Interoperability is mostly a business challenge"

For example: Ecosystem of Interoperable Plug-and-Trust Medical Technology Products, Technology Perspective (MDI), Quality Perspective (SES), SES+MDI Integration
The role of Remote/External Control

6. Plug-and-Trust Device Interoperability - SDC & SDPi

Ed. Content: Briefly describe the main character of the story SES MDI SDC/SDPi+FHIR. The ECOSYSTEM PATHWAY STORY.

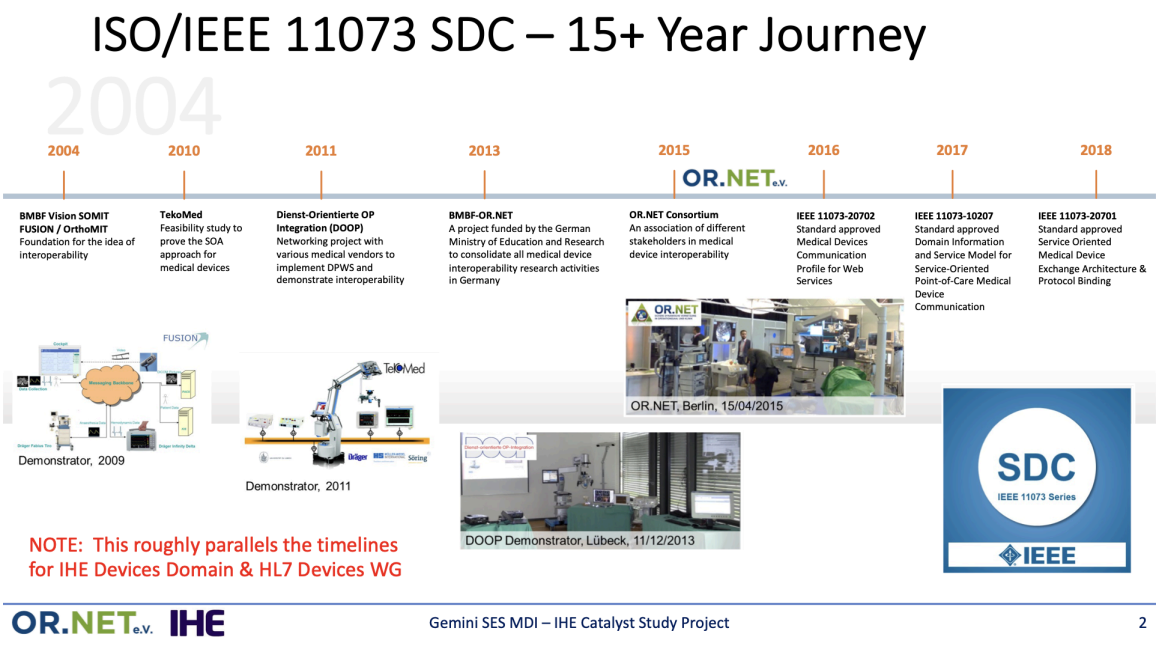
6.1 Overview

As previously described, the current reality is a world where each device speaks its own language resulting in a virtual Tower of Babel. There is some consistency at the point of feeding this data to enterprise systems using the IHE DEV communication profiles. This current state of Dysfunctional Interoperability has many negative side effects which create hurdles to enabling new clinical applications and can also create safety related hazards. These have been previously discussed in this document.

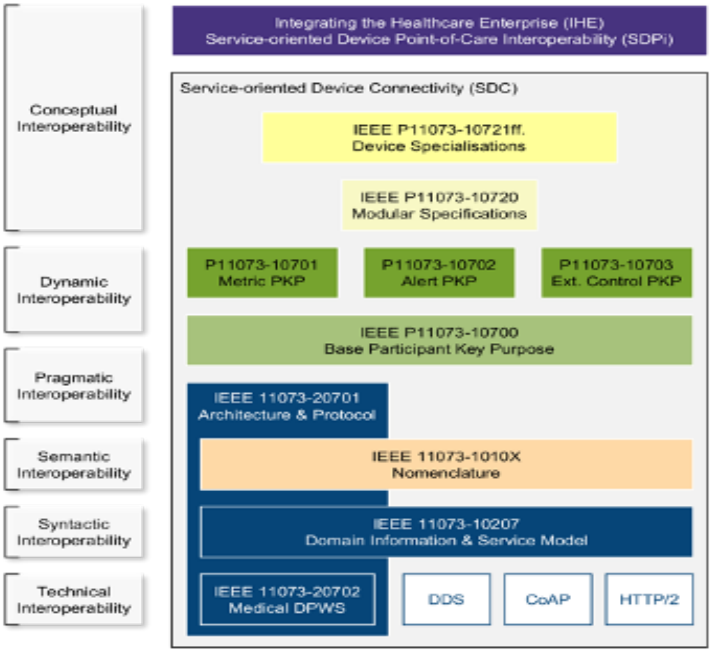
Looking forward there are a number of technologies that can be applied which can get us to our objective of Plug-and-Trust Interoperability.

6.2 IEEE 11073 - SDC Series of Standards

The IEEE 11073 service-oriented device connectivity (SDC) family of standards defines a communication protocol for point-of-care (PoC) medical devices. The main purpose is to enable manufacturer-independent medical device-to-device interoperability. Furthermore, interconnection between medical devices and medical information systems is enabled.



IEEE 11073 SDC is based on the paradigm of a service-oriented architecture (SOA). The IEEE 11073 SDC family of standards currently comprises three parts: Core Standards, Participant Key Purpose (PKP) standards, and Devices Specialisation (DevSpec) standards.



6.2.1 Core Standards

The Core Standards consist of a transport standard, ISO/IEEE 11073-20702, called Medical Devices Communication Profile for Web Services, a Domain Information and Service Model (ISO/IEEE 11073-10207), and Architecture and Binding definition (ISO/IEEE 11073-20701).

6.2.2 PKP Standards

PKPs describe process requirements according to the role of a network participant. While P11073-10700 defines the Base PKP with basic requirements for participating providers and consumers, the three additional PKP standards focus on specific functionalities:

- Providing and consuming information in terms of metric data (IEEE P11073-10701),
- Providing and consuming alerts (IEEE P11073-10702), and
- Providing and consuming external control functionalities (IEEE P11072-10703).

PKPs[4] are thus independent from the particular medical devices and their concrete medical use case. However, they mainly restrict the IEEE 11073 SDC Core standards to enable safe and interoperable medical device systems and to facilitate the approval process.

6.2.3 Available SDC Development Resources

In addition to the experts that participate in the IEEE 11073 PoCD SDC Subgroup, there are other organizations and resources available to parties interested in developing SDC based solutions. These include open source implementations of the standard written in various languages such as Java, C++ and Python. There is also OR.NET e.V.[5] which is an association which brings together industrial specialists, clinical staff and researchers intent on realizing open integration in the OR of the future, as well as in other areas of acute medicine around the use of the SDC standard. There are also plans to develop standardized verification tooling and scripts which would lead to common conformance assessments.

[4] Note that currently 11073-10702 and 11073-10703 are under development.
[5] https://ornet.org/en/

6.3 IHE DEV DPI SDPi Profile

The SDPi 1.0.x[6] supplement is the first publication from the joint IHE-HL7 Gemini device interoperability project, with close cooperation between the IHE and HL7 Devices groups and the Devices on FHIR team. It comprises four profiles to cover four primary aspects of device interoperability:

- SDPi-P - Plug-and trust interoperability; foundational communications including security provisions and device discovery as core capabilities
- SDPi-R - Reporting of medical information from the device (e.g., infusion pump drug dose rate, or patient exhaled O2)
- SDPi-A - Alerting support, including support for medical device alerting "DAS" systems
- SDPi-xC - Device-external Control; (future profile)

Gateways are also defined for the current IHE DEV Enterprise-facing profiles:

- Device to Enterprise Communication (DEC)
- Alert Communication Management (ACM

Requirements are formalized in a new truly "computable way (e.g., see requirement blocks in TF-2: Appendix A); this will greatly facilitate both integration of specification requirements into product requirements management tools as well as provide for traceability and coverage from test scenarios back to specification requirements to referenced standards and to use cases

The Service-oriented Device Point-of-Care Interoperability (SDPi) profiles mark a major milestone not only for IHE Devices technical framework portfolio, but for open standards-based device informatics in general:

- SDPi marks the first time after 40+ years of effort across multiple standards organizations (starting with IEEE in the early 80's) and across multiple international initiatives that a comprehensive, cohesive set of device-to-device plug-and-trust interoperability specifications have been published;
- SDPi completes support for the three IHE Devices use case areas: Patient Care Devices (for Enterprise integration), Personal Connected Health (for home & mobile), and now Device Point-of-care Interoperability (for high-acuity point-of-care interoperability);
- SDPi integrates standards profiles from multiple organizations, including ISO/IEEE 11073, HL7 FHIR & V2, and ISO/IEC JWG7, as well as others;
- SDPi fully leverages new publication technologies and tooling, such as AsciiDoc and Github automation to advance the state-of-the-art in computable specifications, supporting "requirements interoperability" for enhanced traceability and coverage determination, and enabling "regulatory submission ready" conformity test reporting.

Incremental version development with continuous integration are key aspects of how this supplement was developed and will be maintained, targeting minor releases quarterly and annual major releases

6.4 OR.NET

OR.NET is an association of more than 35 manufacturers and institutions, primarily based in Germany but with a world-wide presence, with the goal of developing and promoting SDC based products. The following is from their website:

[6] https://profiles.ihe.net/DEV/SDPi/index.html

"OR.NET e.V. is a registered association bringing together industrial specialists, clinical staff and researchers, all intent on realizing open integration in the OR of the future, as well as in other areas of acute medicine. It is our vision to establish safe and dynamic device-to-device communication using state-of-the-art information and communication technology. Medical equipment is automatically integrated in a device network within the OR, the ICU or the emergency room via plug-and-play.

Following 15 years of research, the enormous relevance of our approach became transparent in the OR.NET project funded by the German Ministry BMBF (until 2014), not least through the participation of more than 50 directly funded project partners and an equal number of associated project partners. The technical outcome of this project was made public in 2018, in the form of three IEEE 11073 SDC standards enabling manufacturers to make their products integrable.

Establishing these SDC standards is a declared goal of our association. In addition to prominent publicity work, it identifies and discusses key topics in individual workgroups. Topics currently being addressed through the set-up of demonstration and test centres include requirements for the open network regarding approval, development and initial operation."[7]

6.5 Testing and Public Demonstrations

6.5.1 Testing Events

Devices that comply with the SDC standards have been tested against each other at various Plugathons sponsored by the OR.NET organization. In addition, testing at IHE sponsored Connectathons is planned for 2024.

6.5.2 Public Demonstrations

There have been numerous public demonstrations of SDC technology at work. Most recently there have been public demonstrations at the HIMSS22 Interoperability Showcase where the applicability of SDC based technology was demonstrated as a mechanism to remotely control medical devices for a patient in isolation.[8] In addition there was a public demonstration at the DMEA in April 2022[9] which focused on the applicability of the SDC based devices in the operating room. Similar public demonstrations are planned for 2023.

6.5.3 Clinical Evaluations

- <clinical projects ... Charite Berlin for example>

6.6 Security at the Core

<expand on Plug-and-TRUST>
<addresses both security technology & related standards + global operationalization>

[7] https://ornet.org/en/services-2-3/
[8] https://www.draeger.com/Library/Content/ICU-patient-care-in-an-isolation-room-himss-2022-wp-dmc-101791-en-us-2002-1.pdf
[9] https://ornet.org/en/2022/04/13/4760/

6.7 Safety at the Core

<expand on Plug-and-TRUST>
Safety aspects built in
PKPs

7. Product Conformity Assessment

Ed. Content: CA is not an option for establishing an ecosystem of PnT "decoupled" products; it is a requirement for adoption by public agencies, national health programs, healthcare providers, for recognition by regulatory agencies, etc. MANUFACTURERS already use CA for many aspects of their products & their QMS; foundational to TRUST for "decoupled" products PnT'ing at the point-of-care. Need to be based on ISO 17000 stuff + coordinated with NIST; IHE provides a proven pathway for this testing. Dynamic verification of CERTIFICATION and other status.

7.1 EU MDR Conformity Assessment of Interoperable Devices

Conformity Assessment for Medical Devices in Europe follows the provisions of the Medical Device Directive (MDR) 2017/745. Active medical devices for diagnosis – the primary candidates for interoperability – are predominantly in risk classes IIa or IIb. Most common for those categories are Annex IX procedures, which are split into an initial Review of the Technical Documentation followed by a 2-Stage onsite assessment of the Quality Management System. Key content of the Technical Documentation is evidence for the compliance with the General Safety and Performance Requirements (GSPRs). From a total of 150+ requirements, about 80 are applicable for the above Medical Devices. Compliance statement is usually based on the consideration of about 12…20 individual standards, including Quality Management, Basic Safety and Performance, EMI, Risk Management, Usability, Biocompatibility, Labeling, Packaging, Life Cycle Processes Medical Software, dedicated Product standards and - last but not least - Interoperability.

In order to filter incomplete document sets, and manage their workload, the Notified Bodies are obliged to conduct a pre-assessment, before the application is finally accepted. On top of that an essential part of the content covers a term which is just cited once within the regulation : Information security.

Due to a lack of applicable basic requirements, the Association of German Notified Bodies for Medical Devices - with support from industry and academia - set up a task force to compile a dedicated checklist. Applicable for any kind of software, either SaMD or embedded, Cybersecurity will be assessed via separate checklists covering generic = QMS and specific = per product requirements. It is available in English as a free, public download from the webpage of the association.

Usually the Annex IX Conformity Assessment Procedure is backed up with preclinical, laboratory Type Testing of Safety (IEC 60601-1 /-2-XX), EMI (IEC 60601-1-2), Cybersecurity (IEC 60601-4-5) Penetration and Interoperability Tests (IEEE 11073 SDC). The latter one will be complemented by Installation Validation at the Healthcare Service Providers premises under real-term environmental conditions. Usual lead-times are 6 months for the preclinical tests and 12 months for Annex IX procedures.

8. Enabling Regulatory Acceleration

Ed. Content: Major value add to developers and adopters is the integration of "regulatory submission ready" CA test reports + continuity across the ecosystem of what the vendors actually submit, starting in the EU with the MDR & NB's (Bothe) & U.S. FDA.

Global story starting with EU & US engagement ...

8.1 EU MDR and Interoperability

The EU Medical Device Regulation[10] uses the terms interoperability and the related term compatibility.. The main requirement can be found in Annex I, Chapter I Clause 14.5:

> *Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.*

8.2 US FDA and Interoperability

The US FDA has an active program and involvement in medical device interoperability. It maintains a web page (Medical Device Interoperability | FDA[11]) which outlines the various efforts it has either initiated or participated in since 2010. Notably the FDA actively participates in a number of standards development efforts including IEEE 11073 SDC, IEEE 11073 PHD, AAMI/UL 2800 and AAMI WG03 Interoperability.

From the manufacturer's perspective the FDA final guidance on Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices[12], in 2017 was a key milestone. This document provides clear guidelines for designing for interoperability. It also supports the aspirational goal of plug and trust devices.

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[10] https://eur-lex.europa.eu/eli/reg/2017/745/2020-04-24

[11] https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-device-interoperability

[12] https://www.fda.gov/media/95636/download

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OR.NET - Secure Dynamic Networking in the Operating Room and Clinic
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