IHE Germany
SDC / SDPi Plug-a-Thon -
Overview Briefing

20-21 October 2020
IHE Germany – SDC / SDPi Plug-a-Thon – Briefing

IHE Plug-a-Thon Basics

From ISO/IEEE 11073 SDC to IHE SDPi to PATs & CATs

Orientation Tour: IHE Technical Framework & SDPi Profiles

Real-world Narrative: Pandemic Patients in an Isolation ICU

SDC/SDPi PAT – Objectives
First ... Term Usage & Assumptions

**SDC**  
**Service-oriented Device Connectivity**  
Family of ISO/IEEE 11073 SDC standards  
Assumption: PAT participants have a working understanding of SDC

**SDPi**  
**Service-oriented Device Point-of-care Interoperability**  
Set of (4) IHE technical framework profiles based on ISO/IEEE 11073 SDC standards  
Assumption: PAT participants may have some working knowledge of IHE & TF profiles

**PAT**  
**Plug-a-thon**  
IHE testing event intended for early, informal exploration of new tech & new profiles  
Assumption: PAT participants may have background in “hackathons”, plugfests, etc.

**CAT**  
**Connectathon**  
IHE formal interoperability testing event for published profiles; includes independent monitors, test management tooling; published results  
Assumption: PAT participants may have background in formal test invents
Isn’t a well architected family of standards sufficient?

The needs of an implementation community are often both narrower than the set of possible applications that are covered by foundational / core standards, such as ISO/IEEE 11073 SDC, as well as broader in scope requiring additional standards to be integrated.

1 Not to be confused with an HL7 FHIR Profile, which is similar in concept but very different in application
IHE Process Overview

Source: https://www.ihe.net/about_ihe/ihe_process/
IHE Plug-a-thon (PAT) Basics

IHE Test Events – Pathway to CA & Certification!

- Rigor: Low
  - Iterative testing process based on use cases
  - Similar to Hackathon
  - Standards and code in development
  - Code will change on-site

- Rigor: Medium
  - Structured, Peer-to-Peer testing
  - Conformance
  - Multiple standards
  - Established standards
  - Code might change on-site

- Rigor: High
  - Selected IHE Profiles in Final Text
  - ISO accredited test labs
  - Strict version controls of product & tools

Targeted at software engineers… not marketing

• Open forum to ask questions, explore boundaries, learn what...
Orientation Tour: IHE TF & SDPi Profiles


https://wiki.ihe.net/index.php/SDC@IHE_ White_Paper
5 Structure of the IHE Technical Frameworks

The IHE Technical Frameworks define specific use of established standards. They are updated annually and maintained regularly through the identification and correction of errata. The Technical Framework volumes are augmented by supplements and change proposal documents as described in Section 8. The latest versions of Technical Framework documents are always available at http://www.ihe.net/Technical_Frameworks.

The Technical Framework for each domain consists of several volumes:

- Volume 1 provides high-level overviews of each profile, the use cases it addresses, the actors involved, and references to the Transactions and Content Modules used.
- Volume 2 provides detailed technical descriptions of each IHE Transaction.
- Volume 3 provides detailed technical descriptions of each IHE Content Module.
- Volume 4 describes National Extensions to the Technical Framework such as country-specific code sets or national patient privacy requirements.

Source: https://www.ihe.net/uploadedFiles/Documents/Templates/IHE_TF_General_Introduction.pdf
Orientation Tour: Example – IHE DEC Profile

TF-1 Profile calls out TF-2 Transaction(s) – may add usage constraints

TF-2 Common Transaction Message Elements Specified Once in Appendices

NOTE: Only message profiling specifications included, relying on references to base message standards for all additional details.
Orientation Tour: Example – IHE DEC Profile

TF-3 Bindings only generally specified in DEC profile & DEV-01 Transaction

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IHE DE SDC/SDPi PAT – Lübeck DE – October 2020
Orientation Tour: IHE TF & SDPi Profiles

Service-oriented Device Point-of-care Interoperability (SDPi)

✓ Four profile specifications:
  • SDPi-P for Plug-and-Trust Interoperability
  • SDPi-R for Reporting Medical Information
  • SDPi-A for Alerting
  • SDPi-xC for External Controlling

✓ Three IHE DEV TF Volumes:
  • TF-1 Profiles / use cases / actors / …
  • TF-2 Transactions / MDPWS messaging
  • TF-3 BICEPS content modules / device specializations

See draft SDPi Supplement Word Document for additional content detail & outline (https://github.com/IHE/sdpi-fhir/tree/master/SDPi%20%20Supplement/SDPi%20Rev%201.0)
Orientation Tour: From Volume 1 to 2 to 3

SDPi TF Supplement Vol.1 Integration Profiles

SDPi-P Profile
- Profile Actors & Transactions & Content Modules
- Profile Actor Options
- Profile Overview (Concepts & Use Cases)
- SES Considerations

SDPi-Reporting Profile ...

SDPi-Alerting Profile ...

SDPi-xControl Profile ...

Appendix A: Requirements Management for Plug-n-Trust Interoperability

Appendix B: ISO/IEEE 11073 SDC Requirements Coverage
- <including ISO/IEEE 11073 SDC ICS tables>

Appendix C: Device Point-of-care Interoperability Use Cases
- <including Gherkin detail & links to Compendium etc.>

SDPi TF Supplement Vol.2 Transactions

DEV-23 Announce Network Presence
- Scope
- Actor Roles & Referenced Standards
- Messages (at BICEPS level w/ links to Appendix A)
- Protocol Requirements
- SES Considerations

DEV-24 Discover Network Participants

DEV-44 Invoke Medical Control Services

Appendix A: ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative)
- SDC/BICEPS to SDC/MDPWS Message Specifications
- Messages for BICEPS Discovery Model
- <specific MDPWS message links>
- <example exchanges & library calls>

MDPWS Message Detail in Appendix

See SDPi Supplement (1.0) document in the IHE sdpi-fhir Github repository for full details.
Orientation Tour: From Volume 1 to 2 to 3

**SDPi TF Supplement Vol.1 Integration Profiles**

*SDPi-P Profile*
- Profile Actors & Transactions & Content Modules
- Profile Actor Options
- Profile Overview (Concepts & Use Cases)
- SES Considerations

*SDPi-Reporting Profile*

**SDPi TF Supplement Vol.2 Transactions**

*DEV-23 Announce Network Presence*
- Scope
- Actor Roles & Referenced Standards
- Messages *(at BICEPS level w/ links to Appendix A)*
- Protocol Requirements
- SES Considerations

*DEV-24 Discover Network Participants*

**SDPi TF Supplement Vol.3 Content Modules**

*DEV Semantic Content Modules*
- General Device Content Considerations
  - *SDC / BICEPS Semantic Content*

*DEV Specialization Content Modules*
- Device: Infusion Pump
  - *SDC / BICEPS Content Module*
- Device: Ventilator
- Device: Physiologic Monitor
- Devices: Surgery *(new)*
- Devices: Anesthesia *(new)*
- Devices: Dialysis *(new)*

See SDPi Supplement (1.0) document in the IHE sdpi-fhir Github repository for full details.
Orientation Tour: From 11073 SDC to SDPi

• <diagram with cathedral & where specific standards content is profiled in TF-1 & TF-2 & TF-3>

• BICEPS MDPWS SOMDA PKP SPECIALIZATIONS
Orientation Tour: From 11073 SDC to SDPi

- Initially, map to **TF-3 DEV Content Modules / Device Specializations**
- Can include content **before** specializations published
- Eventually, may inform IHE DEV Device-Specific Profiles

- Pre-publication, will reference in SDPi SES sections (TF-1, -2 & -3)
- Post-publication, can fully integrate requirements into SDPi (incl. TF-1 Appendix B conformance)
- **NOTE:** (4) profiles are aligned with these (4) key purposes

- SDC/BICEPS (-10207) Referenced in all (3) volumes (TF-1, -2 & -3)
- SDC/SOMDA (-20701) Referenced in TF-1 & TF-2
- SDC/MDPWS (-20702) Referenced primarily in TF-2 (esp. Apdx. A)
Orientation Tour: IHE Profile Actor Diagrams

**IHE Actor**
“information systems or components of information systems that produce, manage, or act on health information”

**IHE Abstract Actor**
Specifies behavior that is shared across / inherited by a set of IHE Actors (actor name in italics & dotted line around concrete actors)

**Profile “External” Actor**
Indicates actors that are outside the scope of the profile but interact with profile actors (dotted box) Note: actor may be defined in other profiles

**IHE Grouped Actor**
Indicates actors that integrate with other actors to provide their functionality (two rectangles joined side-by-side)
Orientation Tour: SDPi-P (Plug-and-Trust)

SDPi-P Actor Model

NOTE: SOMDS Participant actors may be devices, system applications, SAMD, “smart apps” ...
Orientation Tour: SDPi-P (Plug-and-Trust)

SDPi-P Actor Model

SDPi-P Options (partial)

Table 10.2-1: SDPi-P – Actors and Options

<table>
<thead>
<tr>
<th>Actor</th>
<th>Option Name</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOMDS Participant</td>
<td>No options defined</td>
<td></td>
</tr>
<tr>
<td>SOMDS Provider (See Note 1)</td>
<td>Streaming Option</td>
<td>DEV TF-1 10.2.1 Streaming Option</td>
</tr>
<tr>
<td></td>
<td>[Editor's Note: Which can be waveform or other content, but is that in SDPi-P vs. here? And should we have a waveform option? What about SCO or polling mode type support options?]</td>
<td></td>
</tr>
<tr>
<td>Safe Data Transmission Option</td>
<td>DEV TF-1 10.2.2 Safe Data Transmission Option</td>
<td></td>
</tr>
<tr>
<td>Compact Representation Option</td>
<td>DEV TF-1 10.2.3 Compact Representation Option</td>
<td></td>
</tr>
<tr>
<td>Patient Context Management Option</td>
<td>DEV TF-1 10.2.4 Patient Context Management Option</td>
<td></td>
</tr>
<tr>
<td>Archive Service Option</td>
<td>DEV TF-1 10.2.5 Archive Service Option</td>
<td></td>
</tr>
<tr>
<td>Localization Service Option</td>
<td>DEV TF-1 10.2.6 Localization Service Option</td>
<td></td>
</tr>
<tr>
<td>Ensemble Participation Option</td>
<td>DEV TF-1 10.2.7 Ensemble Participation Option</td>
<td></td>
</tr>
<tr>
<td>SOMDS Consumer (See Note 1)</td>
<td>Streaming Option</td>
<td>DEV TF-1 10.2.1 Streaming Option</td>
</tr>
<tr>
<td></td>
<td>Safe Data Transmission Option</td>
<td>DEV TF-1 10.2.2 Safe Data Transmission Option</td>
</tr>
<tr>
<td></td>
<td>Compact Representation Option</td>
<td>DEV TF-1 10.2.3 Compact Representation Option</td>
</tr>
<tr>
<td></td>
<td>Patient Context Management Option</td>
<td>DEV TF-1 10.2.4 Patient Context Management Option</td>
</tr>
</tbody>
</table>

SDPi-P Options (partial)
Orientation Tour: SDPi-P (Plug-and-Trust)

### SDPi-P Actor Model

- **SOMDS Provider** (MDIB, Services, ...)
  - SOMDS Consumer (consuming MDIB info, invoke services, ...)
  - SOMDS THIR Gateway
  - SOMDS V2 Gateway
  - SOMDS Sensor Gateway
  - SOMDS Smart App Platform

- **Non-SOMDS Systems**

### SDPi-P Transactions

<table>
<thead>
<tr>
<th>Actors</th>
<th>Transactions</th>
<th>Initiator or Responder</th>
<th>Optionality</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOMDS Participant</td>
<td>[Editor’s Note: TBD specific transactions abstract actor]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOMDS Provider</td>
<td>Announce Network Presence</td>
<td>Initiator</td>
<td>R</td>
<td>DEV TF-2.3.23</td>
</tr>
<tr>
<td></td>
<td>Discover Network Topology</td>
<td>Responder</td>
<td>R</td>
<td>DEV TF-2.3.24</td>
</tr>
<tr>
<td></td>
<td>Discover BICEPS Services</td>
<td>Responder</td>
<td>R</td>
<td>DEV TF-2.3.25</td>
</tr>
<tr>
<td></td>
<td>Discover System Context and Capabilities</td>
<td>Responder</td>
<td>R</td>
<td>DEV TF-2.3.26</td>
</tr>
<tr>
<td></td>
<td>Manage BICEPS Subscription</td>
<td>Responder</td>
<td>R</td>
<td>DEV TF-2.3.27</td>
</tr>
<tr>
<td></td>
<td>Notify Change in System Context and Capabilities</td>
<td>Initiator</td>
<td>O (See Note 1)</td>
<td>DEV TF-2.3.28</td>
</tr>
<tr>
<td></td>
<td>Publish BICEPS Update Reports</td>
<td>Initiator</td>
<td>R</td>
<td>DEV TF-2.3.29</td>
</tr>
<tr>
<td></td>
<td>Retrieve BICEPS Content</td>
<td>Responder</td>
<td>O</td>
<td>DEV TF-2.3.30</td>
</tr>
<tr>
<td></td>
<td>Set Provider State</td>
<td>Responder</td>
<td>O</td>
<td>DEV TF-2.3.31</td>
</tr>
<tr>
<td></td>
<td>Retrieve Archive Data</td>
<td>Responder</td>
<td>O</td>
<td>DEV TF-2.3.32</td>
</tr>
<tr>
<td></td>
<td>Retrieve Localization Information</td>
<td>Responder</td>
<td>O</td>
<td>DEV TF-2.3.33</td>
</tr>
<tr>
<td></td>
<td>Announce Network Departure</td>
<td>Initiator</td>
<td>R</td>
<td>DEV TF-2.3.34</td>
</tr>
<tr>
<td>SOMDS Consumer</td>
<td>Announce Network Presence</td>
<td>Consumer</td>
<td>O</td>
<td>DEV TF-2.3.23</td>
</tr>
<tr>
<td></td>
<td>Discover Network Topology</td>
<td>Initiator</td>
<td>R</td>
<td>DEV TF-2.3.24</td>
</tr>
<tr>
<td></td>
<td>Discover BICEPS Services</td>
<td>Initiator</td>
<td>R</td>
<td>DEV TF-2.3.25</td>
</tr>
</tbody>
</table>
Orientation Tour: SDPi-P (Plug-and-Trust)

Example of an SDPi-P transaction exchange ...

NOTE: Definition of “BICEPS” abstraction level for SDPi transactions.

For a full set of profile-specific MDPWS sequence exchanges, see:

https://confluence.hl7.org/display/GP/SDPi+Technical+Framework+Models
Example of an SDPi-P transaction MDPWS sequence

For a full set of profile-specific MDPWS sequence exchanges, see:

https://confluence.hl7.org/display/GP/SDPi+Technical+Framework+Models
NOTE: Transactions are drawn to the dotted box around the gateways, indicating that they can be either Provider and/or Consumer SDPi-R actors.
Orientation Tour: SDPi-A (Alerting)

SDPi-A Actor Model

SOMDS Consumer
DEV-AA Establish Medical Alert Exchange
DEV-CC Retrieve Medical Alert Status
DEV-DD Manage Medical Alert Delegation
DEV-FF Update Alert Acknowledgement Status

SOMDS Medical Alert Consumer
DEV-BB Publish Medical Alert Update
DEV-EE Delegate Medical Alert

SOMDS Provider
SOMDS Medical Alert Provider

SOMDS ACM Gateway

DEV-04
DEV-05

SOMDS V2 Gateway

DEV ACM
Orientation Tour: SDPi-xC (External Control)

**SDPi-xC Actor Model**

- **SOMDS Consumer**
  - DEV-AA Manage Medical External Control
  - DEV-BB Invoke Medical Control Services

- **SOMDS Medical Control Consumer**

- **SOMDS Provider**

- **SOMDS Medical Control Provider**
Real-world Narrative: Isolation ICU

Pandemic Patients in an Isolation ICU – EUA Remote Control Narrative

In dealing with severely infectious patients, healthcare workers (HCWs) are at a significantly greater risk of infection than the overall population due to their frequency and time in contact with the infected patients. The HCWs will enter the patient room to administer care to the patient and manage the therapeutic equipment. This management of the patient’s therapy may require frequent device adjustments which may be delayed due to the need for the HCWs to protect themselves by donning PPE prior to entering the patient room and doffing the PPE upon leaving. This donning and doffing processes can exceed 15 minutes depending on the specific PPEs used. A recent study (Suen, 2018) reported times of 7 minutes for donning and 10 minutes for doffing, with the doffing process providing the opportunity for “considerable” self-contamination.

Infectious diseases confer a synergistic burden on and risk to the patient due to the requirements for isolating the patient (Abad et al., 2010) including poorer care and impaired coordination of care, (Mehrotra et al., 2013), significantly fewer HCW and family visits (relative to patients not on precautions) (Morgan et al., 2013), increased rate of adverse events (Stelfox et al., 2003) and increased depression (compared to other inpatients). (Day et al., 2011). The use of remote control and monitoring can be used to eliminate some treatment delays, reduce the infection risk to the HCW, and help preserve the limited supplies of PPE and improve patient care.

Critically ill patients with an infectious disease will often require monitoring with physiologic monitors and therapeutic support with ventilators and infusion pumps. As previously explained, entering the room to view parameters or adjust any settings can require 15 minutes for something that may take less than 1 minute. Medical devices that support open interoperability technology can provide remote access to view parameters and adjust settings thereby increasing efficiency, saving the costs of the PPE and most importantly increasing the safety of the HCW.

Source: Adapted from AAMI CR Proposal: “Emergency Use Guidance for Remote Control of Medical Devices"
Real-world Narrative: Isolation ICU

Pandemic Patients in an Isolation ICU – Scenarios?

For the purposes of this PAT, what scenarios are of greatest interest?

1. Participant Discovery / Security / Service Exchange?
2. Patient / Participant Association (Patient & Location & Workflow context establishment)?
3. Alert delegation / Alert Limit Adjustment / Alert confirmation / Silence ... ?
4. Which devices, systems, applications? Monitors, vents, pumps, central … others?
5. Integration with EHR or other system?
6. Use of IHE-based FHIR profiles for integration with non-SDPi / non-SDC SOMDS systems?
7. ...

Other Use Cases / Scenarios? (e.g., surgery focused)
SDC/SDPi PAT – Objectives

1st IHE SDPi Testing Event!!!

Build SDC / SDPi Competency for Implementer Community

Validate SDPi Profiling Approach (Actors & Transactions & SDC ...)

Advance SDC / SDPi Testing & Tooling strategy into 2021!
Additional Information
Hanging Gardens: **After SDPi 1.0** ...

**NOTE:** Profile Titles are notional – hopefully useful too!

**IHE (Official) Profile Types:**
Transport, Content, Workflow
Or a combination of all (3)

**Other types?**
Architecture (SOA, MDIRA, SDC, ....?)
Single domain / multi-domain?