From Inspiring Narratives ... ... to Plug-n-Trust

A Joint HL7-IHE Gemini SDPi+FHIR Device Interoperability Project Proposal

2020.05.12
From Inspiring Narratives to Plug-n-Trust

**Establishing a framework strategy for ...**

1. Capturing detailed requirements from *use narratives* in a clear and computable manner;
2. Enabling *mapping & traceability* & simulation through each technology and quality specification layer;
3. Testing *V&V conformity assessment* at the interoperable component and system of interoperable products level

... an ecosystem of trusted, safe, effective & secure, plug-and-play device & health software solutions using

*SDC/SDPi + FHIR*
Journey so far ...

... recent history
ISO/IEEE 11073 SDC – 15 Year Journey

2004
- BMBF Vision SOMIT FUSION / OrthoMIT
  Foundation for the idea of interoperability

2004
- TekoMed
  Feasibility study to prove the SOA approach for medical devices

2004
- Dienst-Orientierte OP Integration (DOOP)
  Networking project with various medical vendors to implement DPWS and demonstrate interoperability

2010
- BMBF-OR.NET
  A project funded by the German Ministry of Education and Research to consolidate all medical device interoperability research activities in Germany

2011
- OR.NET Consortium
  An association of different stakeholders in medical device interoperability

2013
- OR.NET, Berlin, 15/04/2015

2015
- IEEE 11073-20702
  Standard approved Medical Devices Communication Profile for Web Services

2017
- IEEE 11073-10207
  Standard approved Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication

2018
- IEEE 11073-20701
  Standard approved Service Oriented Medical Device Exchange Architecture & Protocol Binding

NOTE: This roughly parallels the timelines for IHE Devices Domain & HL7 Devices WG
IHE SDPi – Building on the ISO/IEEE & HL7 Core

SDC@IHE 2019 Initiative laid the foundation for IHE

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

profile family for “PRACTical” device-to-device interoperability


https://wiki.ihe.net/index.php/SDC@IHE_White_Paper
2020 Joint HL7-IHE Gemini Project

Device Interoperability using Service-oriented SDPi + FHIR™

A Joint HL7-IHE Gemini Program Proposal

2020.04.21

FHIR is a trademark of Health Level 7, International.

SDC is a registered trademark of OR.NET
Gemini Project Deliverables & Governance

One set of cohesive, coordinated deliverables

1. **IHE SDPi Supplement** – published 2020 JUL, PAT/CAT testing Q3/4 ‘20
2. **HL7 DoF IG** supporting **SDC integration & Alerting** – ballot in 2020
   ✓ DoF IG (proposed) for *Device Information Consumers* (title TBD)
3. Joint White Papers:
   ✓ “**What is a device?**” - including AI/ML SAMD, across use context geographies
   ✓ “**Safe, Effective & Secure MDI Using SDC/SDPi + FHIR**” – Quality / Regulatory / Legal Considerations
   ✓ “**Accelerating Safe, Effective and Secure Remote Monitoring and Mobile Health Interoperable Solutions**” – How do you know that a rapid response to address crisis (e.g., pandemic) challenges is safe enough, effective enough, and secure enough to allow for implementation & use?

Governance based on HL7 or IHE project home organization processes
Inspiring Narratives!
Journey starts @ Inspiring Narratives

**Gemini SES MDI Project:**

1. Functional Endoscopic Sinus Surgery / *Operating Room Integration*
2. *Quiet Hospital / Silent ICU*
3. JHU/APL *MDIRA/ICE* for Military & Disaster Casualty Care
4. Preeclampsia During Pregnancy – *Home to Clinic to Hospital*
5. (in process) “Loopers” Type 1 Diabetes – *Person-crafted Closed-Loop Control*

Gemini SES MDI Use Case home pages @ HL7 Confluence “Device Interoperability using SDPi+FHIR”/SDPi+FHIR Use Cases
Quiet Hospital / Silent ICU - Narrative

“Quiet Hospital” Story

Early through Kelly’s stay in the ICU, the ICU staff decide to deploy a “Quiet Hospital” mode. This routes alert notifications from all of the patient care devices associated to Kelly directly to the responsible nurse’s communication device with the proper information for each event. In this mode, for non-life critical events Sam can use her mobile device to temporarily pause the bedside alarm audio for a few minutes, allowing her time to go to the bedside to resolve it. After this mode is enabled Kelly immediately notices that the ICU is considerably quieter without constant alerts sounding, allowing him to get much more rest. Sam is also enjoying the relative quiet and able to better care for her patients. With quiet hospital engaged she can triage lower priority events from her mobile device, allowing her to prioritize more critical tasks with other patients without forcing Kelly to listen to the constant noise from these events in his room while he waits for her to arrive. Sam can also focus on just the notifications from her patients since the noise on the unit is lowered and all of the alerts related to Kelly are now coming to devices carried by Sam and others specifically assigned to Kelly’s care. The sound in Kelly’s room and surrounding environment has now been diminished with only critical alarms sounding from the devices assigned for his care and Sam has lower fatigue with higher patient satisfaction for her patients since she can better attend to the needs of all of her patients.

“Silent Hospital” Story

Given the success with the “Quiet Hospital” feature, the staff decide to go one step further and enable “Silent Hospital” mode a couple days later. (This works the same as Quiet Hospital but the nurse can completely reset an alert (if appropriate) and does not

NOTE: Current version of these narrative documents are available on the Gemini SDPi+FHIR Quiet Hospital Confluence pages.
SDC & Quiet Hospital/Silent ICU @ HIMSS’20 ...

SILENT ICU BY ALARM SIGNAL DELEGATION

Today

Tomorrow

~ 80 - 95 % clinically irrelevant

Reduction of alarms

Alarm Distribution

road to 1 alarming device per patient

up to 40 min. to alarm confirmation

50 % are not noticed

~ 40 different sounds in one ICU
**SDC & Quiet Hospital/Silent ICU @ HIMSS’20 ...**

**SILENT ICU BY ALARM SIGNAL DElegation**

- **Requirements**

  “Delegation” – *Safely enabling one system to annunciate alerts on the behalf of another system*

1. The alarm producer has to make **all information available** that are necessary for the remote alarm notifiers, like alert condition presence, alert manifestation, etc. **Interoperability** and semantical interpretability have to be ensured.

2. The system has to be suitable for **multiple alarm producers** and **several remote alarm notifying devices**.

3. The alarm producer has to be able to determine whether other devices are **ready to generate the alarm notification**.

4. The alarm producer has to be able to observe that the **alert is generated correctly**.

*Some more information: „A Safe and Interoperable Distributed Alarm Notification System for PoC Medical Devices using IEEE 11073 SDC“, Kasparick et al.*
**ALERT SIGNAL DELEGATION**

**USE CASE**

From IEEE 11073-10207 (BICEPS)

**ALERT SIGNAL DELEGATION** is the capability of a POC MEDICAL DEVICE to let another PARTICIPANT generate a POC MEDICAL DEVICE’s ALERT SIGNAL as primary ALERT SIGNAL in order to remotely indicate the presence of an ALERT CONDITION on the POC MEDICAL DEVICE.

- a POC MEDICAL DEVICE delegates its ALERT SIGNAL generation to another PARTICIPANT, e.g., to facilitate a silent workplace

- Delegable & Fallback Alert Signals
SDC/SDPi + Quiet Hospital / Silent ICU

Starting points & ending points understood ...

... what about the milestones from here to there?
Journey to “Plug-n-Trust”
From Inspiring Narratives to Plug-n-Trust

Establishing a framework strategy for ...

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\[ \text{SDC/SDPi + FHIR @ Quiet Hospital / Silent ICU} \]
A word about “Safety, Effectiveness & Security”

Primary focus area of SES @ SDPi+FHIR white paper project

Two+ ISO/IEC standards & guidance documents that address SES MDI across the life cycle of health software, Health I.T. & Incorporated devices.

SES Plug-n-Trust Requires Rigorous Testing

Leverage the established Device Interoperability tooling ...

**Objective:** Leverage IHE Test & Tooling to establish an SDC-enabled interoperable medical technology ecosystem where certified test reports can be directly included in regulatory submissions

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

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

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

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**NIST Device Tools**

Gemini SDPi+FHIR From Narratives to Plug-n-Trust
“SDPi+FHIR” – Introduced @ HIMSS’20...

“SDC+FHIR” – Foundation for MDI Use Cases

- Clinical / Therapeutic Applications & Protocols
- MDIRA/ICE Framework
- IHE “Device” Specializations
- IHE Participant Key Interoperability Purposes (PKIP)
- IHE SDPi “PRACTical” Interoperability
- SDC (BICEPS & SOMDA)
- MDPWS / WS-*
- HL7 V2 / FHIR

“Devices” = bundles of sensor / actuator / intelligence capability with an intended medical / healthcare purpose (includes SAMD)
Expanding the Requirements-to-Interfaces Model

- Multiple Standards / Specifications
- Multiple Organizations / SDOs
- Multiple Projects / Initiatives

Note: model is not perfect ... but very useful!
Charting the course from narratives to interfaces

**Traceability from Narrative to Plug-n-Trust Interface!**

- Each “layer” specifies requirements to be mapped to the next
- Each “layer” adds its own set of requirements
- Requirements align with **safety, effectiveness & security (SES)**

**NOTE:** Null layers allowed but generally required to achieve the SES Plug-n-Trust objective.
Charting the course from narratives to interfaces

The Challenge ...

1. Establish **computable traceability** from top to bottom (plug-n-trust) interface
2. Automate mapping and testability
3. Scale from simple to complex
4. Layer-specific and layer-to-layer (**mapped**) requirements representation
5. Lower the bar for specification creation, adoption, implementation and use
6. Maximize use of off-the-shelf open, “free”, widely adopted and used tooling
7. Ensure integration with corporate enterprise-grade tooling (including DOORS, Enterprise Architect, MagicDraw, etc.)
8. Support V-model CA and 3rd party (17025) “test houses”
9. …

“Mapping” remains the hardest nut to crack in this list of challenges. Especially across multiple standards, organizations and projects!
Charting the course from narratives to interfaces

**Tool kit options:**

1. **Gherkin / Cucumber** ...
2. **Requirements Authoring / Management**
   - OMG ReqIF
   - Eclipse RMF
   - DOORS
3. **UML Modeling**
   - Sequence / Activity / Use Case diags?
   - PlantUML
   - EA/MagicDraw
4. **Visual Studio Code, Eclipse, ..**
5. **Open source – reference implementations and test tools**
6. **NIST Devices tooling (see diagram above)**
7. **...**
Capturing Computable Use Narrative Requirements

**Question:** How to capture computable, testable requirements starting with user narratives?

- **Narrative “User Story” Text**
  - Objective: Real-world user detailed descriptions of what is to be supported; narrative may conform to a general template / questions.

- **Use Cases / Scenarios Analysis**
  - Objective: Analyze the “business case” narratives into use cases, realization scenarios & technical use cases (using standardized templates)

- **Gherkin / Cucumber Representation**
  - Objective: Standard computable use case / scenario representation. Basis for test tooling & transformation to ReqIF specifications.

- **ReqIF (Requirements Interchange Format) Representation**
  - Objective: Formal requirements modeling (including “relations” mapping) that forms the basis for bidirectional traceability + testing & tooling

**Note:** See ReqIF background information below.
Examples for tracing Narrative to Plug-n-Trust

Exemplar considerations from Quiet Hospital Narratives:

1. Identify (4) scenario-based requirements that can be verified during CA test
2. Include (4) alert priorities: Event + High/Medium/Low Alarms
3. Trace through the (4) KIP standards
4. Include both Physiological & Technical Alarms
5. Include at least (2) modalities + modality-specific alarms (e.g., AIL)
6. Include DIS, DAS & C-DAS support, scaling from simple to complex
7. Include both Quiet & Silent Hospital requirements
8. Include both SDC and FHIR endpoints

Note: SDC alert delegation integrates all four interoperability purposes & SDPI profiles
Examples for tracing Narrative to Plug-n-Trust

Example #1:
<deliver XYZ intravenously> => Infusion Pump
=> AIL alert => reportable / alertable / delegatable / pausable => ...

Example #2:
<tnbd>

Example #3:
<tnbd>

Example #4:
<tnbd>

NEXT: HIMSS’20 Showcase narratives, scripts, Google doc ...
https://docs.google.com/spreadsheets/d/1_6ow_3Cb4VhINLSqhlID-YiICpV71QfGBOWL4folo/edit#gid=845500776
“Trauma recovery in ICU” … “Quiet Hospital” …
SDPi Layer Strategy
SDPi+FHIR Technical Concept

- IHE Devices domain Technical Framework Approach Established
- IHE SDPi Supplement w/ 4 profiles under development – in parallel
- Will include content for TF-1 -2 & -3
- IHE Connectathon testing planned for 2020
IHE SDPi – Building on the ISO/IEEE & HL7 Core

IHE SDPi Profiles for “PRACtical” Device Interoperability

- SDPi Plug-and-Trust Connectivity (SDPi-P)
- SDPi Reporting (SDPi-R)
- SDPi Alerting (SDPi-A)
- SDPi external Control (SDPi-xC)

IHE “Gateway” Actors Defined

- HL7 FHIR PoCD IG
- DEC
- ACM
- SDC PKP Standards
- SDC Core Standards

“medical” interoperability purpose
SDPi+FHIR Sequence Models

From flipchart concept to IHE SDPi Transaction Sequence Diagrams ...
SDPi+FHIR Sequence Models

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SDPi+FHIR Sequence Models

From flipchart concept to IHE SDPi Transaction Sequence Diagrams ...
Options, options, options
Gemini Project: Collaboration Tooling

One set of Collaboration Tooling for One Expert Community

- HL7 Confluence @ “SDPi+FHIR” under HL7 Devices +
  - @ Gemini & @ HL7 Projects “home” page list
- HL7 JIRA for project & backlog management
- IHE-HL7 GitHub / BitBucket for managed sharing
- HL7 FHIR Zulip for SDPi (SDC) + FHIR discussions
- IHE Webex for web meetings
- Email list coordination (TBD best way to do this)
Additional Information
Use Case Analysis
Background
Use Case Analysis / Modeling Background

Use Case Analysis is well established in the engineering world ...
   All technology solution developers do it ...
   A few do it well ... most don’t!

In the health informatics world, here are a few of the current sources of guidance for how to address this phase of development, including:

- All related SDOs (e.g., HL7, IHE, ISO/TC 215 ...) have guidance
- Many national HIT programs leverage this guidance but tailor it to their needs
- Example: ISO TR 19669 *Health informatics — Re-usable component strategy for use case development*
ISO/TR 19669 Re-usable Component Strategy

Source: Draft ISO/TR 19669 Health informatics — Re-usable component strategy for use case development
IHE Use Case Analysis – Hierarchy of Concepts

IHE Use Case Analysis – Hierarchy of Concepts

OMG Requirements Interchange Format (ReqIF) “Mapping” Background
OMG ReqIF: Base Model

Figure 10.3 - Specification (Specification), requirement (SpecObject), requirement relation (SpecRelation), relation group (RelationGroup) and associated attributes (AttributeDefinition, AttributeValue)
Two requirements may have a relation to each other, for example to establish traceability between a Customer Requirements Specification and a System Requirements Specification. Having a relation is represented by an association of one SpecRelation element to two SpecObject elements, one being the source, one the target of the relation.

The two specifications that are related to each other (in the above example: a Customer Requirements Specification and a System Requirements Specification) are referred to by the sourceSpecification and targetSpecification association of a RelationGroup instance.

The hierarchical structure of a requirement specification is represented by SpecHierarchy elements.

“mapping” between Source & Target Requirements