Safe Effective & Secure Medical Device Interoperability – Can we make sense of all these standards?!

Todd Cooper, AFC! “Standards Guy” ~ March 2020
First: Some Definitions  *(standards guys love acronyms!)*

**SDO:** Standards Development Organization ... ISO / IEC / IEEE / IHE / HL7 / ... 

**SES:** Safe, Effective & Secure ... simple reference to “JWG7” standards  
*Community focus: quality, regulatory & legal concerns*  [think “process guys”]

**MDI:** Medical Device Interoperability ... “from the device interface” / MD2MD @ bedside  
*Community focus: research & engineering*  [think “tech guys”]

**SDC:** Service-oriented Device Connectivity ... SOA for MD2MD interoperability @ bedside

**SDPi:** Service-oriented Device Point-of-care Interoperability ... IHE “Profile” of SDC

**FHIR:** Fast Healthcare Interoperability Resources ... HL7 standard taking world by storm!
Does it have to be this hard?
The Problem of *SDO & Standards Multiplicity*

**Problem #1:** *All these SDOs ... all these standards = Confusing Complexity*

*Impact:* Need a “Standards PhD” to sort out what is relevant from what is noise

**Problem #2:** *SES & MDI Communities ... don’t work well together!*

*Impact:* Their standards are also developed in *decoupled parallel universes*

**Problem #3:** *Requirements inconsistently specified, not “CA Ready”, not integratable*

*Impact:* Companies have to spend huge ... inefficiency & status quo rut

**Problem #4:** *Real-world products have to achieve this integration in an ad hoc manner*

*Impact:* Companies have to form “requirements management” teams and tools ...
Ultimate Problem ...

*Companies have finite time and resources for product development!*

Ultimate Impact ...

*Use standards? Forget it!*

After 40 years of effort, SES MDI doesn’t exist!
Is there hope?!

As we ponder the NEXT 40 ...
What do standards guys do to “make sense of it all”?

Write more standards ... of course!

+ Build frameworks ...
JWG7 “SES Guys” standardized their own framework

The JWG7 SES “Temple Diagram” identifies core topic / subject areas …

… standardized in 81001-1 …

… over which you can “make sense of” specific standards …

… all with a process / quality / regulatory / legal “SES” community subject focus
What about the “MDI Guys”?

Consider the **SES MDI “Hanging Gardens” Framework** ...

User Narratives / Use Cases / Requirements
- Reference Architectures / Frameworks
- Device / Health Software Specializations
- Key Interoperability Properties & Controls (PRACtical SES)
- SDPi+FHIR Profiles / IGs

IEEE 11073-1072x -10799 ModSpecs
IEEE 11073-1070x PKP (Safety)
- 20701 – Architecture and Protocol
- 10207 – DIM and Service Model
- 20702 - MDPWS
- 2070x – HTTP/2, REST, IoT, DDS, ...

Devices on FHIR
- HL7 FHIR

Physical Layers (Ethernet, Wi-Fi, BT, etc.)

SES MDI Plug-n-Trust Interface

(More @ https://confluence.hl7.org/x/4ijxB)
But does this truly help or just add to the confusion?!

“Beauty is in the eyes of the beholder” … in this case, Standards guys!

… the Gardens help “make sense” of specific standards from different SDOs … in a pragmatic real-world product context … … all with a combined technical & process “SES MDI” community subject focus

(More @ https://confluence.hl7.org/x/4ijxB)
Yes! There is hope ... the *Gemini SES MDI Project!*

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**IHE-HL7 Gemini MDI SDPi+FHIR – Project Update**

for

Joint IEEE / HL7 / IHE Working Group Meetings

*2021.01.27 (Finalized 2021.02.19)*

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*FHIR is a trademark of Health Level 7, International.*

*SDC is a registered trademark of OR.NET*
The Hanging Gardens framework provide a perspective on the various standards and specifications that are integrated into each individual product’s interface …

One Layer & One Standard at a Time!
Innovators Hope: Requirements Integration

The Hanging Gardens framework can also enable a much simpler, streamlined requirements pathway through *through each standard’s needs & capabilities* ...

... the *Happy Path* charts *traceability* from the interface back to each standard specification and their *requirements*

How hard can it be?!
In the absence of a clearly defined Requirements Interoperability model to enable connection between standards...

How hard can it be?

PRETTY HARD!!!

(via Ad Hoc Requirements Integration)
Standards Guys’ Challenge @ SES MDI RI

Gemini SES MDI Project Focus (2021/Year 3):

Challenge #1: Standards are inconsistent in how they specify requirements
Focus Area: Establish a Requirements Interoperability Model & Inter-Standard Mappings (Capabilities “API” + Needs / Dependencies)

Challenge #2: Crafting standards specifications that support RI & “Happy Path” Tracing
Focus Area: Create authoring tools that transparently capture the computable artifacts necessary for standards integration automation

Challenge #3: Conformity Assessment reports that are “Regulatory Submission Ready”!
Focus Area: Generate test plans & test scripts that ensure verification of requirements + traceability & CA to <X> standards & specifications

Challenge #4: HTML-based “continuous build” publication supporting implementation
Focus Area: Develop publication tooling that enables frequent (daily) updates & inter-standard integration / navigation
Next Step: **Requirements Interoperability Pilot**

RI Pilot tasks include:

- **Crafting an interoperability semantics UML Metamodel (including OMG ReqIF)**
- **For each standard, drafting representative set of requirements using metamodel**
- **Creating inter-standard requirements mapping “links”**
- **Validate ability to trace “Happy Path” from interface to implemented standards**

**Gemini SES MDI RI Pilot Standards** could include:
- Use Cases: Silent Bed & Isolation Point-of-Care
- “MD-SOA” & MDIRA/ICE Architectures
- IEC 80001-1 2\(^{nd}\) Edition
- IHE SDPi+FHIR Profile & MDIRA Profiles
- IEEE 11073-10700 Participant Key Purposes standard
- IEEE 11073 SDC Core Standards
Next Step ... for YOU!

Many opportunities to participate & learn & shape the future of SES MDI:

✓ **Medical Device Industry Promotion Foundation @** [www.medif.or.kr](http://www.medif.or.kr)

✓ **Smart Medical Device Standard Expert Forum @** [project.medif.or.kr/subList/10000003198](http://project.medif.or.kr/subList/10000003198)

✓ **Gemini SES MDI Project @** [confluence.hl7.org/display/GP/Community+Engagement](http://confluence.hl7.org/display/GP/Community+Engagement)