IHE Patient Care Devices SDC Initiative Group 2019-07-03

Integrating the Healthcare Enterprise

Enterprise

SDC@IHE White Paper Topics for Discussion



SDC@IHE White Paper

Topics for Discussion

- Core Use Case Examples June 27
- 2. SDC Standards & Functional Capabilities June 27
- 3. SDC Mapping to IHE Tech Framework Constructs July 3
- 4. Device Profiling: From general connectivity to specializations July 3
- 5. SDC CA Framework (testing & tooling) July 3

Integrating the Healthcare Enterprise

Core Use Case Examples



White paper contains:

- Four core use cases that can be used to establish the core requirements for integrating SDC-enabled devices and systems into IHE TF.
- ✓ Appendix identifying and referencing the large body of use cases that have been developed to understand interoperability of devices in high acuity healthcare contexts.

Key Questions:

- ✓ Right (4) use cases to target?
- ✓ Folded into TF-1? Where?
- ✓ Level of detail in white paper actor diag? transactions? High-level only (like QH example)?



Example #1: Functional Endoscopic Sinus Surgery (FESS)

John Miller (13yrs, m) has chronic rhinosinusitis, which is an inflammatory condition in which the nose and his left maxillary sinus is swollen and the drainage of the mucus is prevented. John's chronic rhinosinusitis doesn't respond to medication anymore. After consulting with his physician, he and his parents decide to resolve the issue with a Functional Endoscopic Sinus Surgery (FESS). The FESS will be done in as a day surgery, so that John can get home in the evening.

Before the day of the surgery, a **CT scan** is taken that is used to guide the surgeon during the surgery.

In order for the surgery to start, John is put under general **anesthesia** and monitored with a **patient monitor** by a pediatric anesthesiologist, esp. his mean arterial blood pressure which has been reduced in order to provide optimal visibility of the surgical field due to reduced capillary bleeding.

During the intervention, the Surgeon has a **constant view of the patient's vitals** (including MABP) and the **control functions** to execute the intervention.

During the procedure one of the surgical devices has a technical issue. It generates a **technical alert** which notifies the responsible biomedical technician. He/she decides to replace the device and connects it to the network where it is **automatically discovered and configured** allowing the intervention to continue.

There are no additional technical or clinical problems, the surgery is a success and John can go home with his parents.

NOTE: Proposed for the HIMSS'20 SDC Showcase Demo



Example #2: NITRD '19 MDI Use Case

NITRD.1 – Seamless changes of medical devices

NITRD.2 - Capture of data and settings

NITRD.3 – Supervisory control established

NITRD.4 – Autonomous patient therapy

NITRD.5 – Data flows through the Continuum of Care

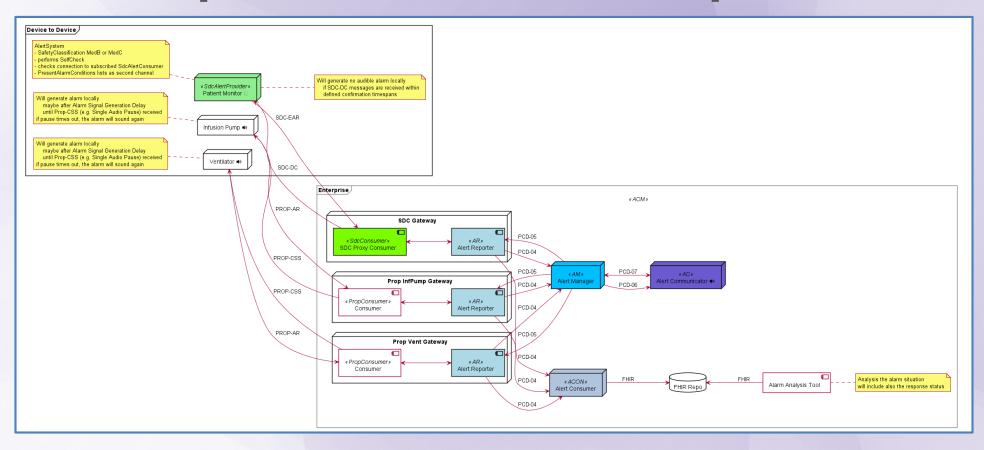
NITRD.6 - Capture of equipment configurations

NITRD.7 – Black Box Recorder

Source: https://www.nitrd.gov/nitrdgroups/index.php?title=Medical-Device-Interoperability-2019



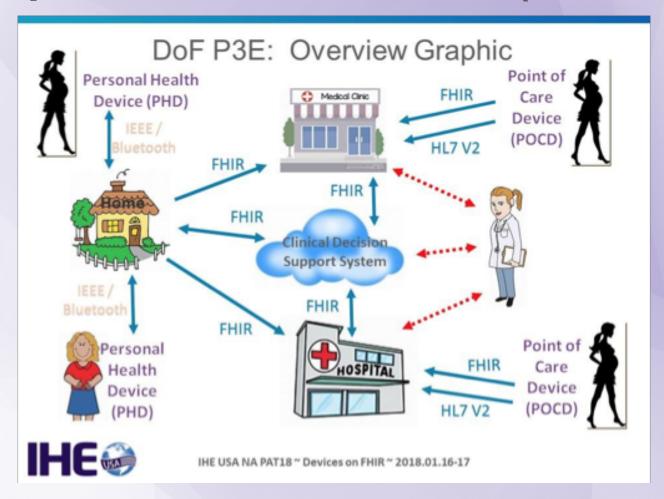
Example #3: SDC to Enterprise



Source: IHE PCD **Quiet Hospital** initiative; HIMSS'20 Showcase proposal; graphic is version 3 – work in progress



Example #4: SDC with DoF (PoCD / PHD)



Source: IHE DoF PAT '18 + HL7 FHIR DevDays

Integrating the Healthcare Enterprise

SDC Standards & Functional Capabilities



SDC Core Elements:

- ✓ Standards set (baseline & in-process)
- ✓ General Architecture (device-to-device w/ Gateway)
- ✓ TF-1 Functions: reporting, alerting, controlling.
- ✓ TF-2 Functions: Core SDC services

Key Questions:

- ✓ Safety, security & risk mitigation for Key Purposes?
- ✓ Device Specializations?
- ✓ Imaging integration?
- **√** ...



The concept of a

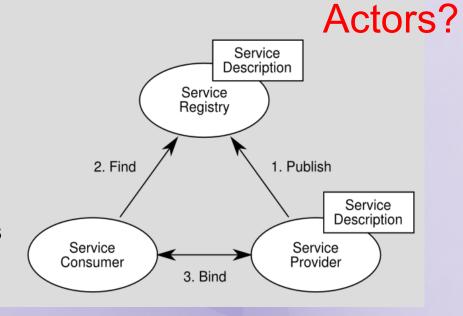
clinical workplace service-oriented medical device architecture

transfers the concept of a

service-oriented architecture

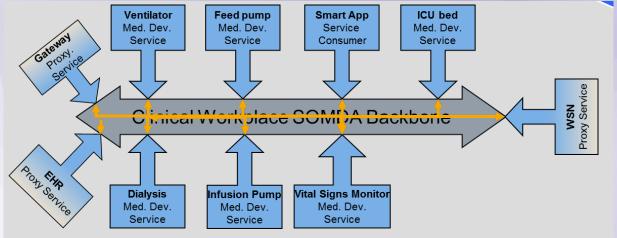
to the domain of

distributed system of medical devices for one clinical workplace.



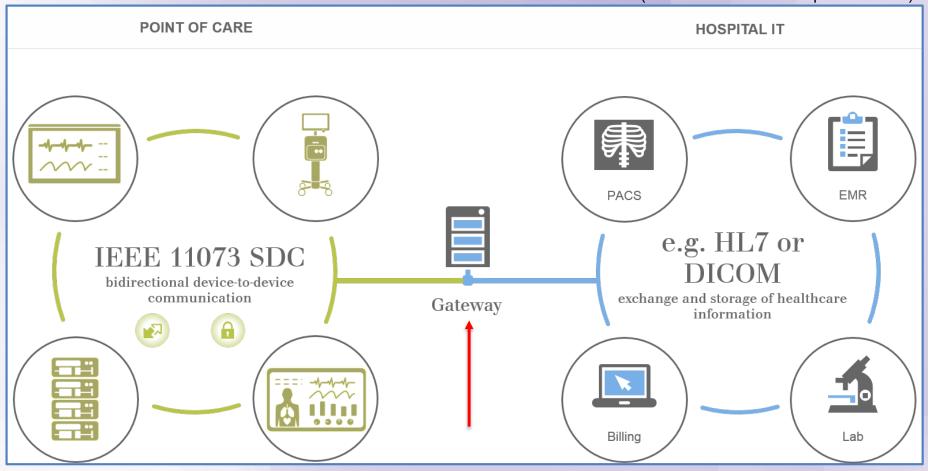
(Sources: SDC overview presentations)

Deviceto-Device





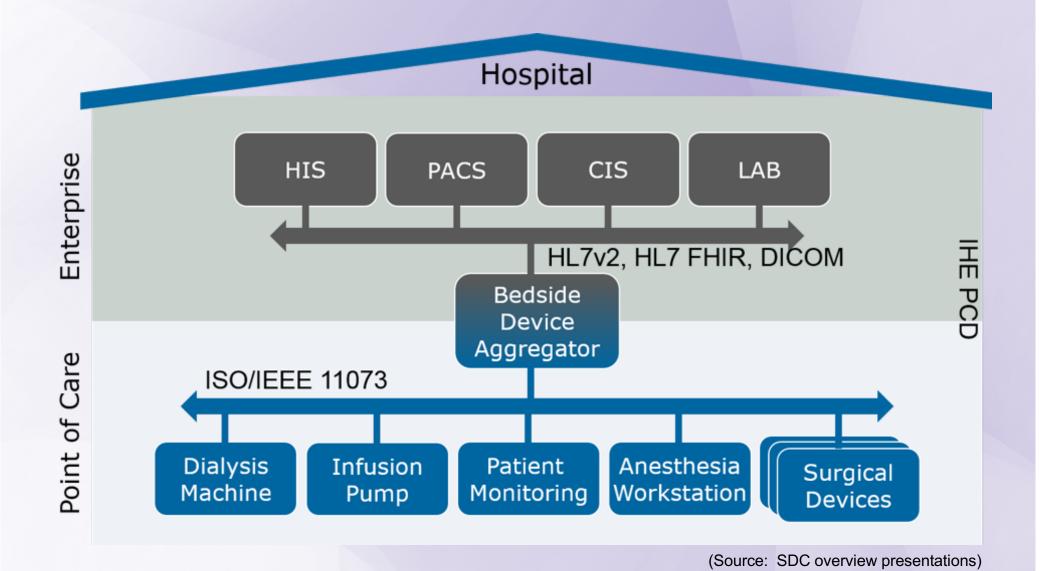
(Source: SDC overview presentations)



SDC Point-of-Care Context

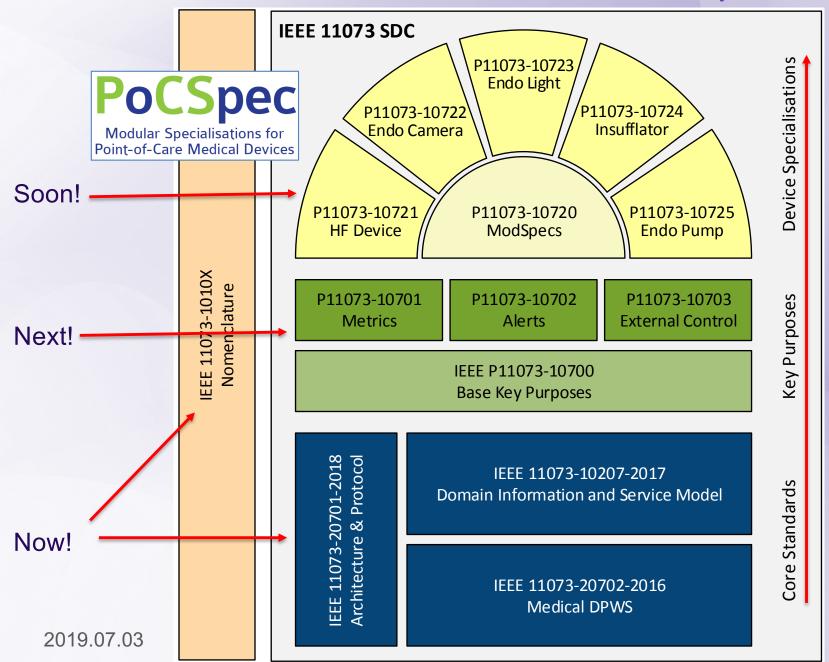
IHE "Enterprise" Context





2019.07.03





IEEE 11073
SDC Family +
Foundational
11073
semantics

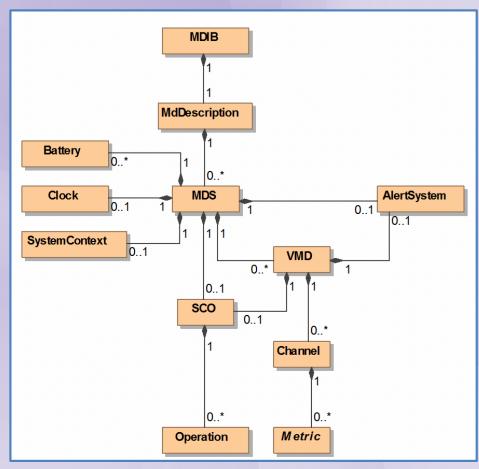
Note: SDC specializations allocated 11073 -1072x to -10799.

(Source: SDC overview presentations)

14



Based on IEEE 11073-10201 Information Model



(Source: IEEE 11073-10207)



Questions:

1. Maping of BICEPS Services to TF-2 transactions ...

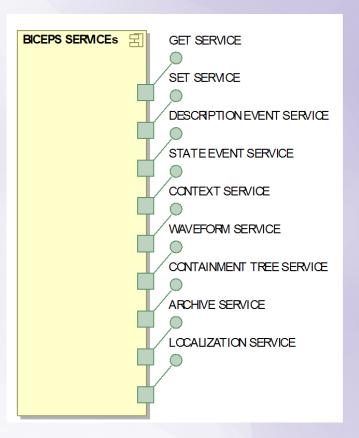
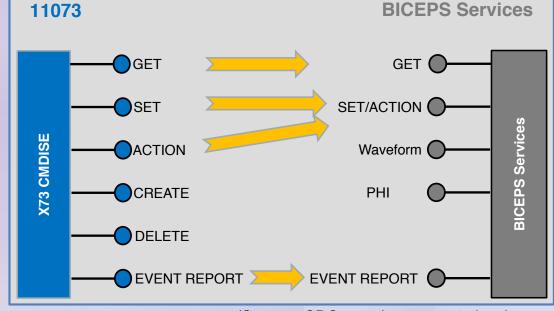


Figure 12—SERVICEs defined to let SERVICE CONSUMERs gain access to the MDIB

(Source: 11073-10207)



(Source: SDC overview presentations)



Questions:

- Map MDPWS Services to TF-2 transactions also?
- 2. Security Considerations section?
- 3. Relationship to ITI WS-* Appendix (used for DEC @ IHE-KR CAT)

■ DPWS:2009* is the core of MDPWS

- OASIS standard (since 07/2009)
- Utilizes a subset of the WS-* standard
- Covers
 - Service discovery,
 - Interface description,
 - Messaging,
 - Event propagation, and
 - Secure information transmission
- Designed for resource-constrained devices

MDPWS

 Added some missing parts e.g. safe transmission of control requests

Service 2 Client m Service z Device n Service 1 Service 2 Service v Application Specific Protocols WS-MetadataExchange/ WS-Discovery WS-Eventing WS-Transfer WS-Security, WS-Policy, WS-Addressing SOAP-over-UDP, SOAP, WSDL, XML Schema HTTP UDP TCP IPv4 / IPv6 / IP Multicast

messages

Client 1

Client 2

Device 1
Service 1

(Source: SDC overview presentations)



Questions:

1. Where to include these MDPWS extensions?

Profile options:

- 1. Binary XML?
- 2. Secure exchange?
- 3. ...

- WS-Streaming based on SOAP-over-UDP for (numeric) data streaming
- Maybe unreliable
- Multiple receivers

Waveform Streaming



- Safe & reliable data exchange based on
- WS-SafetyInformation
 - e.g. Dual Channel
- · Liveliness assurance

Patient Safety



- Access control for critical operations
- Secure transmission

Access Control



- XML Manifestation doesn't need to be UTF-8
- Optional binary XML (EXI) for reduced message sizes

Compression



- Policy assertions
- Limit options in DPWS spec
- New Device Type for Discovery

General



(Source: SDC overview presentations)

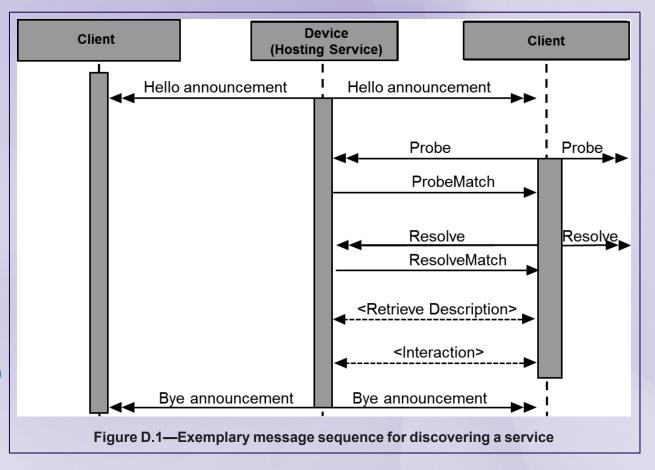


Service Description Service Registry 2. Find 1. Publish Service Description Service Provider 3. Bind

Basic Discovery & Exchange

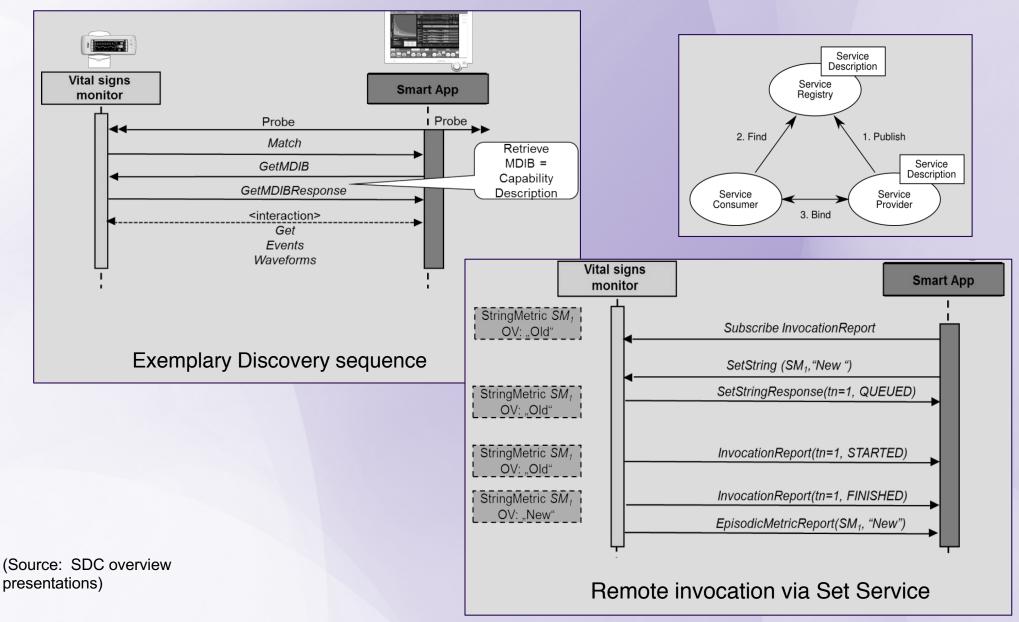
(note: distributed
"registry" architecture)

SDC Standards & Functional Capabilities



(Source: 11073:20702)





Integrating the Healthcare Enterprise

SDC Mapping to IHE Tech Framework Constructs

(Conceptual Approach Only!)



Mapping considerations:

- ✓ IHE TF Volumes & Components (traditional)
- ✓ Scale from basic SDC to specializations to therapeutic protocols & clinical workflow

Key Questions:

- ✓ Where to present SDC architecture content (TF-1 / 2)?
- ✓ Profiling: Family vs. Profile vs. Options
- ✓ How to relate to existing IHE PCD profiles for reporting, alerting and (limited) controlling @ Enterprise context?



#1 Challenge for SDC@IHE

IHE TF-1 – Interoperability Profiles:

- ✓ Perspective: Primarily clinical
- Actors / Transactions / Options / Constraints / Dependencies
- ✓ Use Cases / Process Flows / Sequence Diagrams
- ✓ General Principles / Concepts (see XDS.b ITI TF-1)
- ✓ Implementation Strategies / Considerations

IHE TF-2 – Transactions:

✓ Core tech reference detail to SDC standards

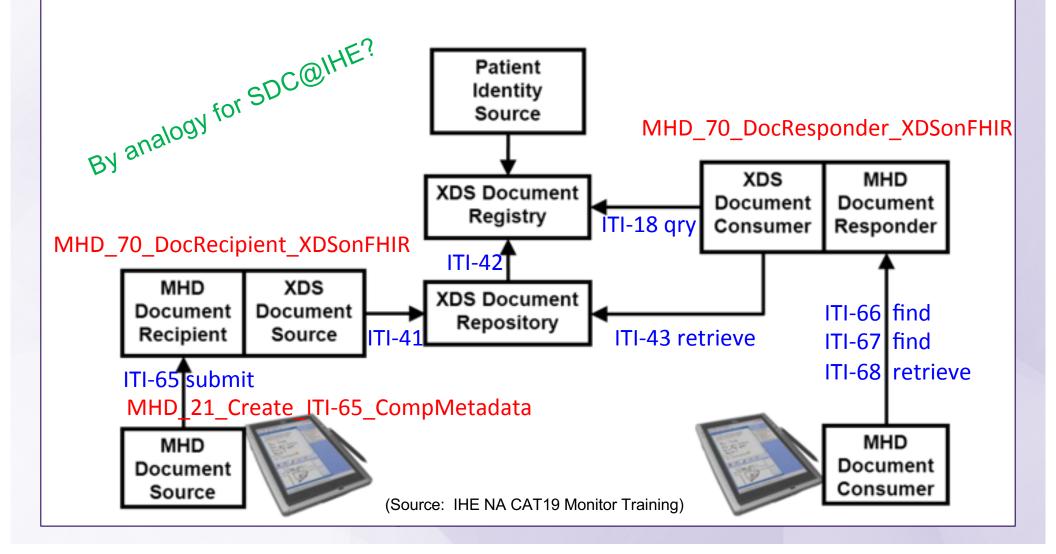
IHE TF-3 – Semantic Content:

- ✓ General terminology use to device specializations
- √ Value sets bindable to actors & transactions



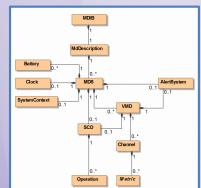
The "XDS on FHIR" Option - MHD in an XDS Environment

'Conversion' of MHD transactions into XDS transactions These are tests run by MHD actors that have this capability.



Profile(s):

✓ SDC or DPI? (analogous to XDS.b) or ICE or D2D ...



- ✓ SDC-Reporting, -Alerting, -Controlling profiles?
- ✓ Streaming as an option or a profile with options?
- ✓ Actors: Provider, Consumer, Registry ...
- ✓ Grouped Actors: Gateway, IHE PCD DEC/ACM/...
- √ Functions At clinical level ...
 - Discovery & Assoc.: Register Services, Find Services, Bind / Subscribe Services ...
 - Publish / Report: Parameters / Alerts (vs. polling)
 - Invoke Operation / Set Parameter (control)
 - Stream Waveforms
 - ... (see earlier SDC Overview slides)



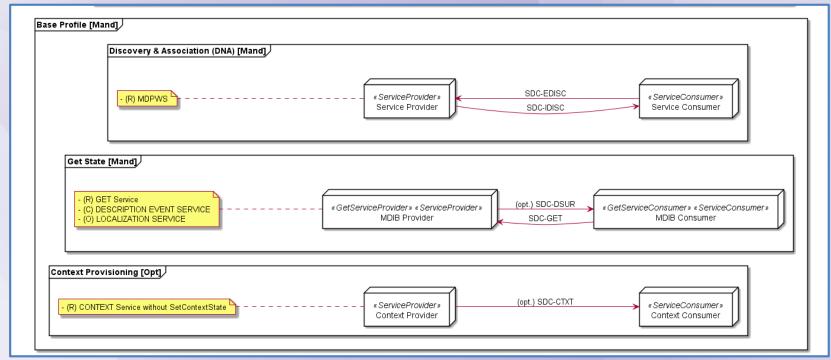
SDC@IHE Profiles

- ✓ Rationale for Multiple Profiles
 - Complexity management @ Actors, options, etc.
 - Analogous to other PCD, ITI approaches
- ✓ Base SDC Profile
 - Core SDC connectivity
 - Options incl. security, compression, streaming, ...
- ✓ Reporting / Alerting / Controlling Profiles
 - Options focused on each of the four core functions
 - Incl. grouped "gateway" actors & mapping
- ✓ SDC or DPI or ICE or D2D or ...

SDPi – Service-oriented Device Point-of-Care Interoperability (mashup of SDC & DPI)



Example Base Profile Actors & Transactions



(Source: Stefan Schlichting)

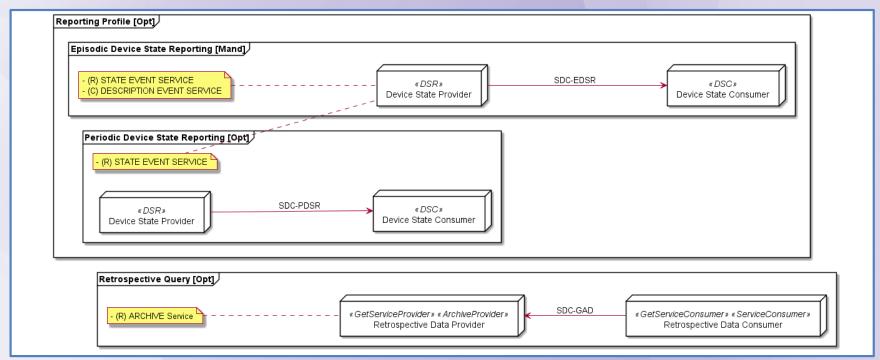
Profile: SDPi

- ✓ Basic PoC device-to-device service discovery & network organization
- ✓ Mandatory, Conditional & Optional capabilities
- ✓ Dependencies incl. CT for NTP time sync
- ✓ Includes linkage PCIM "gateway" capabilities

	Description
SDC-IDISC	SDC Implicit Discovery
	SDC Explicit Discovery
SDC-EDSR	SDC Episodic Device State Report
SDC-PDSR	SDC Periodic Device State Report
SDC-GDS	SDC Get Device State
SDC-DSUR	SDC Device Structure Update Report
SDC-CC	SDC Device Control Command
SDC-CCR	SDC Device Control Command Report



Example Reporting Profile Actors & Transactions



(Source: Stefan Schlichting)

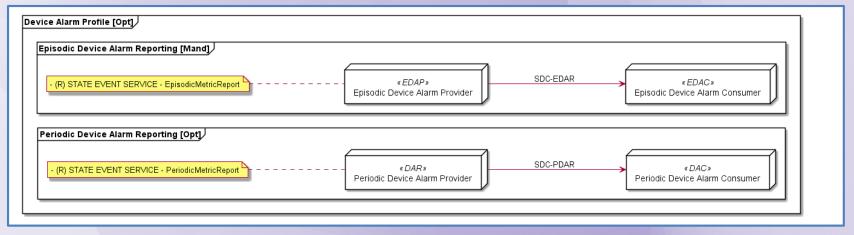
Profile: SDPi-Reporting

- ✓ Basic PoC device-to-device information exchange
- ✓ Options can include periodic updates (vs. episodic) or Archive Service to support *data logger* functions
- ✓ Includes linkage DEC "gateway" capabilities (consider bidirectional DEC + DEC:DOF use)

	Description
SDC-IDISC	SDC Implicit Discovery
	SDC Explicit Discovery
SDC-EDSR	SDC Episodic Device State Report
SDC-PDSR	SDC Periodic Device State Report
SDC-GDS	SDC Get Device State
SDC-DSUR	SDC Device Structure Update Report
SDC-CC	SDC Device Control Command
SDC-CCR	SDC Device Control Command Report



Example Base Profile Actors & Transactions



(Source: Stefan Schlichting)

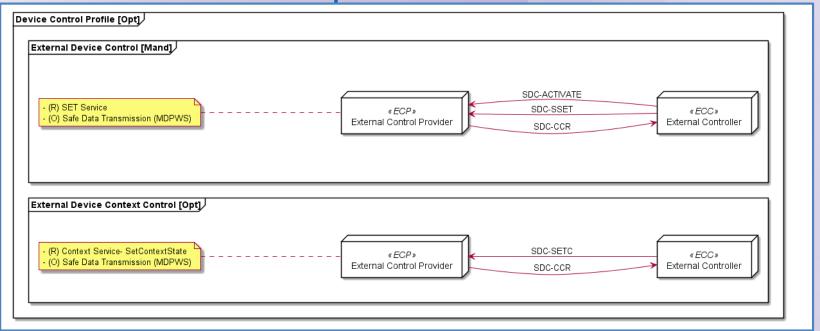
Profile: SDPi-Alerting

- ✓ Alerting support around the PoC
- ✓ Supports "alert delegation" option
- ✓ Includes linkage ACM "gateway" capabilities (see Quiet Hospital initiative examples)

Message	Description
SDC-IDISC	SDC Implicit Discovery
SDC-EDISC	SDC Explicit Discovery
SDC-EDSR	SDC Episodic Device State Report
SDC-PDSR	SDC Periodic Device State Report
	SDC Get Device State
SDC-DSUR	SDC Device Structure Update Report
SDC-CC	SDC Device Control Command
SDC-CCR	SDC Device Control Command Report



Example Base Profile Actors & Transactions



(Source: Stefan Schlichting)

Profile: SDPi-Control

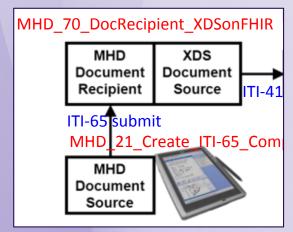
- ✓ Enables device-external control services
- ✓ Supports "safe data transmission" capability
- ✓ Could include gateway linkage to PIV

See "smart" device specializations below

Message	Description
SDC-IDISC	SDC Implicit Discovery
	SDC Explicit Discovery
SDC-EDSR	SDC Episodic Device State Report
SDC-PDSR	SDC Periodic Device State Report
	SDC Get Device State
SDC-DSUR	SDC Device Structure Update Report
SDC-CC	SDC Device Control Command
SDC-CCR	SDC Device Control Command Report



Example: XDS on FHIR



Grouped Actors:

- ✓ SDPi-R:Consumer + DEC:DOR
- ✓ SDPi-A:Consumer + ACM:AR
- ✓ SDPi-R:Consumer + IPEC:DOR (w/PCD-10 mapping)
- **√** ...

Open Questions:

- ✓ ITI WS-* compare/contrast?
- ✓ Use of NTP for SDC ref'd in SPDi @ CT dependency
- ✓ Data logging? [Archive service w/ "Syslog" gateway]
- ✓ PCIM @ SDC? [Base profile or reporting?]
- ✓ UDI@SDC ... relevance?
- ✓ SDPi, SDPi-Reporting / -Alerting / Controlling ... ???
- ✓ SDC @ DoF As a gateway option on SDPi profiles?
 - Forward reference to the PoCD DoF IG
 - Consider IHE (esp. ITI) @ FHIR-based Profiles
- ✓ @ DEC DOF include in examples, bidirectional!
- **√** ...



Device Specialization Profiling

From general connectivity to specific devices



Device Specialization Profiling

SDC device specializations:

- Rationale for device specializations in IHE TF
- ✓ IHE PCD Device Specializations: SDC, v2, DoF, ...

Key Questions:

- ✓ TF-1 Profiles? (Vent @ SDC PoC, Enterprise, Home)
- ✓ TF-3 content? (device specialization value sets)
- ✓ Cover both SDC PoC & V2 Enterprise bindings?

Device Specialization Profiling

Specializations Rationale

- ✓ Simplifies user adoption (vs. profile laundry list)
- ✓ Allows for finer control of semantic bindings to device actors and transactions
- ✓ Provides for a consistent device view across use contexts and IT tech
- Serves as building blocks for clinical workflow and therapeutic protocols
- **√** ...

Note: Always trace back to core 11073 semantics (See NIST RTMMSv2 Framework below)



IEEE 11073 SDC

P11073-10721

(Source: Stefan Schlichting)

P11073-10722 Endo Camera

P11073-10723 Endo Light

P11073-10720

P11073-10724

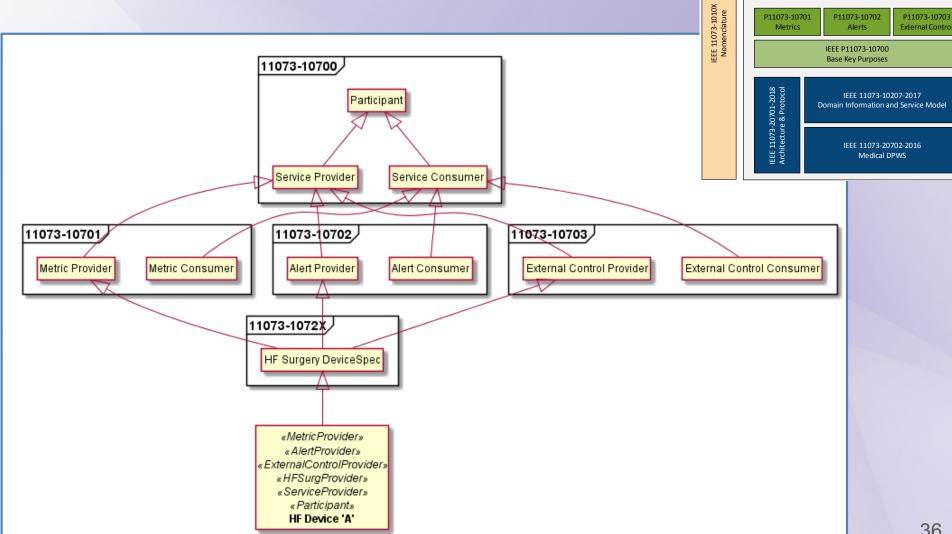
Endo Pump

Device Specialisations

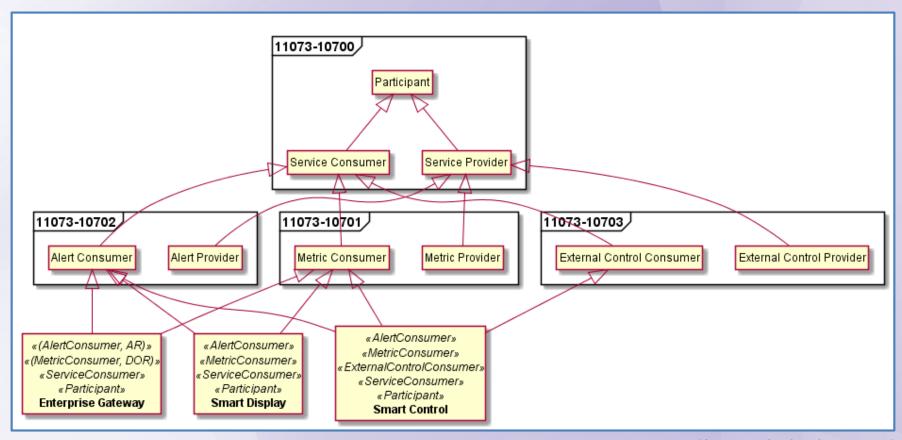
Key Purposes

Core Standards

Example: High-Frequency Surgery Device







(Source: Stefan Schlichting)

"Smart" Devices – Service Consumer & Provider

Integrating the Healthcare Enterprise

SDC CA Framework

SDC CA Framework

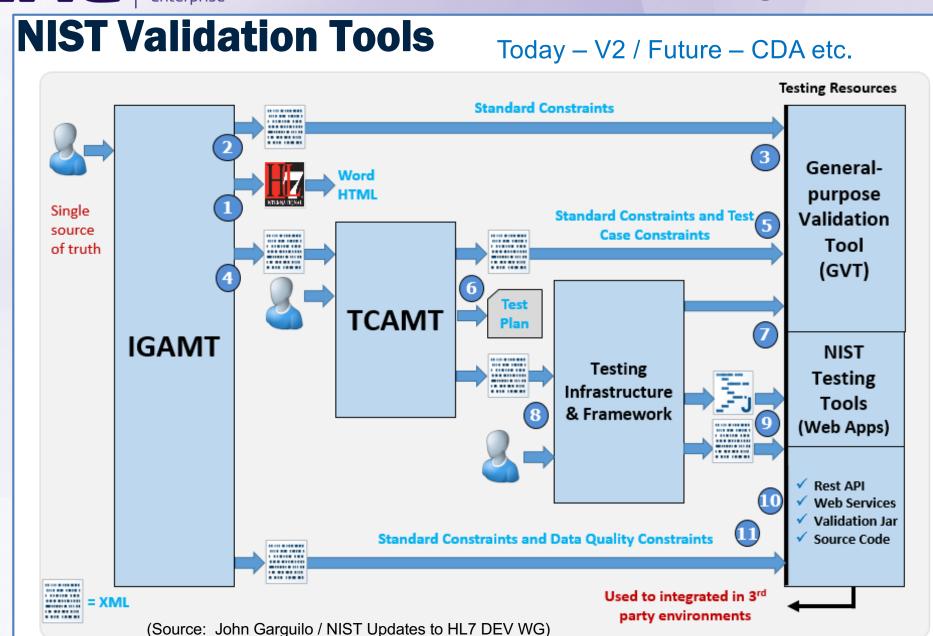
Conformity Assessment considerations:

- ✓ IHE CA Conceptual Framework (CAT to certification)
- ✓ Tooling Architecture
- ✓ Conformity at the PoC device interface as well as to enterprise endpoints
- ✓ Ensuring support path for regulatory filings?
- ✓ Interoperability across a SOMDA & Enterprise

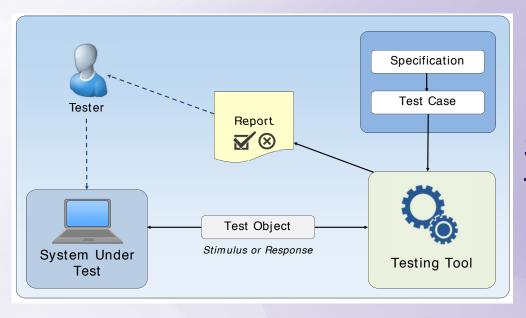
Key Questions:

- ✓ RTMMSv2 and Beyond
- ✓ Integration of SDC community "external" test tooling, esp. to Gazelle?
- ✓ Near term vs. 2+ year approach?
- **√** ...





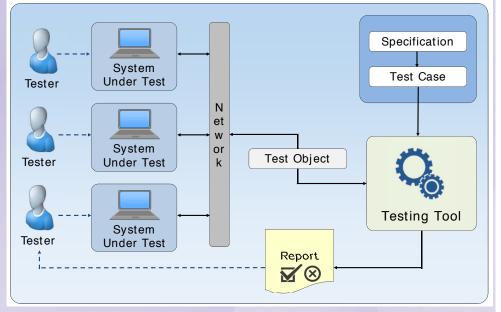




Isolated System Testing

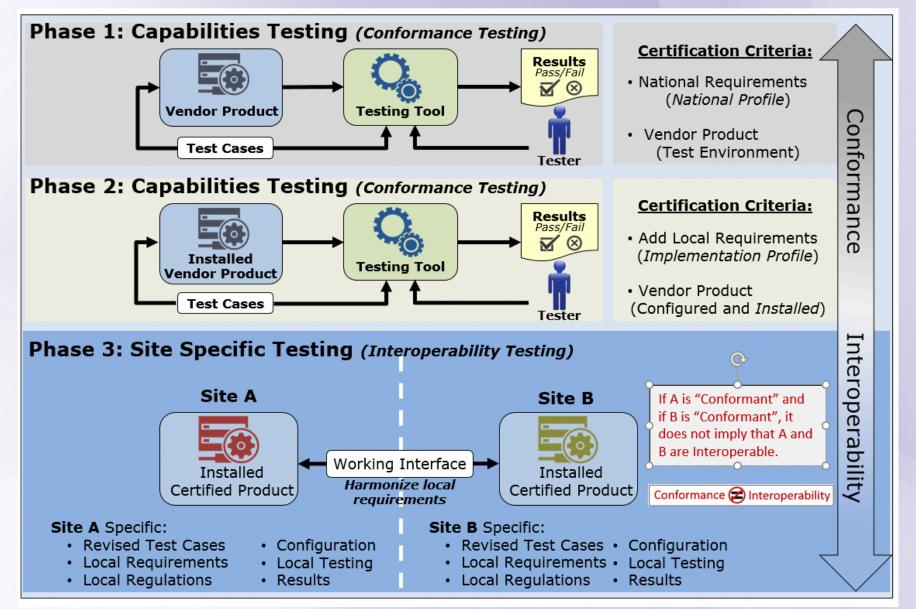
Progress from standalone to networked P2P

Peer-to-Peer System Testing (a la SOMDA!)



(Source: John Garguilo / NIST Updates to HL7 DEV WG)

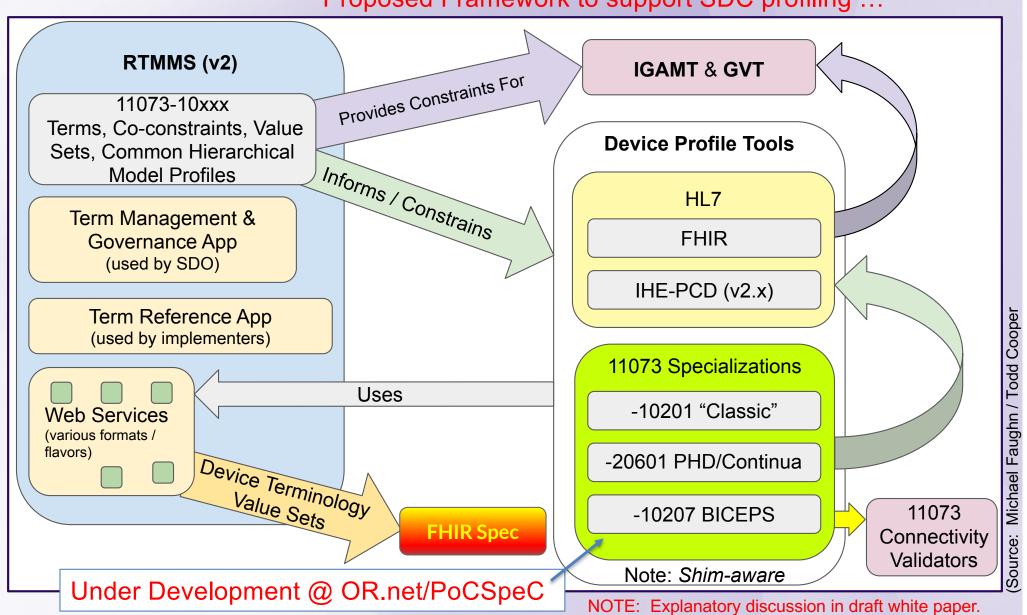




(Source: John Garguilo / NIST Updates to HL7 DEV WG)



Proposed Framework to support SDC profiling ...





Changing the Way Healthcare CONNECTS

http://www.ihe.net

Integrating the Healthcare Enterprise

Additional Information



IHE TF Elements

