

IHE

Integrating
the Healthcare
Enterprise

Health Device Interoperability *Standards “Families Revisited”*

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Discussion Agenda

MDI Standards Families – Intro. to 15 Year Scoping Review

U.S. Army MDRC MDIRA Project (Steve Griffiths)

IHE SDPi Use Cases

IHE PCD 2.0: Opportunities & Challenges

Open Discussion

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1st Consider 4 Core Use Cases ...

#1 Functional Endoscopic Sinus Surgery – OR Integration

#2 NITRD / FDA MDI Scenario (military evacuation)

#3 IHE PCD “Quiet Hospital” – Device to Clinician & Back Again

#4 Preeclampsia During Pregnancy (PDP) Across the Continuum of Care

NOTE: SDC focuses on High-Acuity Contexts: OR, ICU, ED

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

FESS narrative includes the following component use cases:

- SDC/FESS.1 Surgeon view of patient vitals
- SDC/FESS.2 Surgeon control of OR table and lights
- SDC/FESS.3 Surgeon control of surgical tools
- SDC/FESS.4 Device reports technical issue to responsible BMET
- SDC/FESS.5 Seamless exchange of Medical Devices

Example #2: NITRD '19 MDI Use Case

From the online narrative ...

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: Quiet Hospital

Sam, a nurse in University Hospital's high-acuity intensive care unit is continuously bombarded with alert sounds emanating from a variety of medical devices including infusion devices, ventilators, nurse call systems, patient monitors and/or associated central monitoring systems. This can result in alarm fatigue, especially since only a portion of these alerts are intended for her. In addition, Kelly – one of Sam's patients, hears many of the same alarm sounds increasing his overall level of stress as well as interrupting his rest.

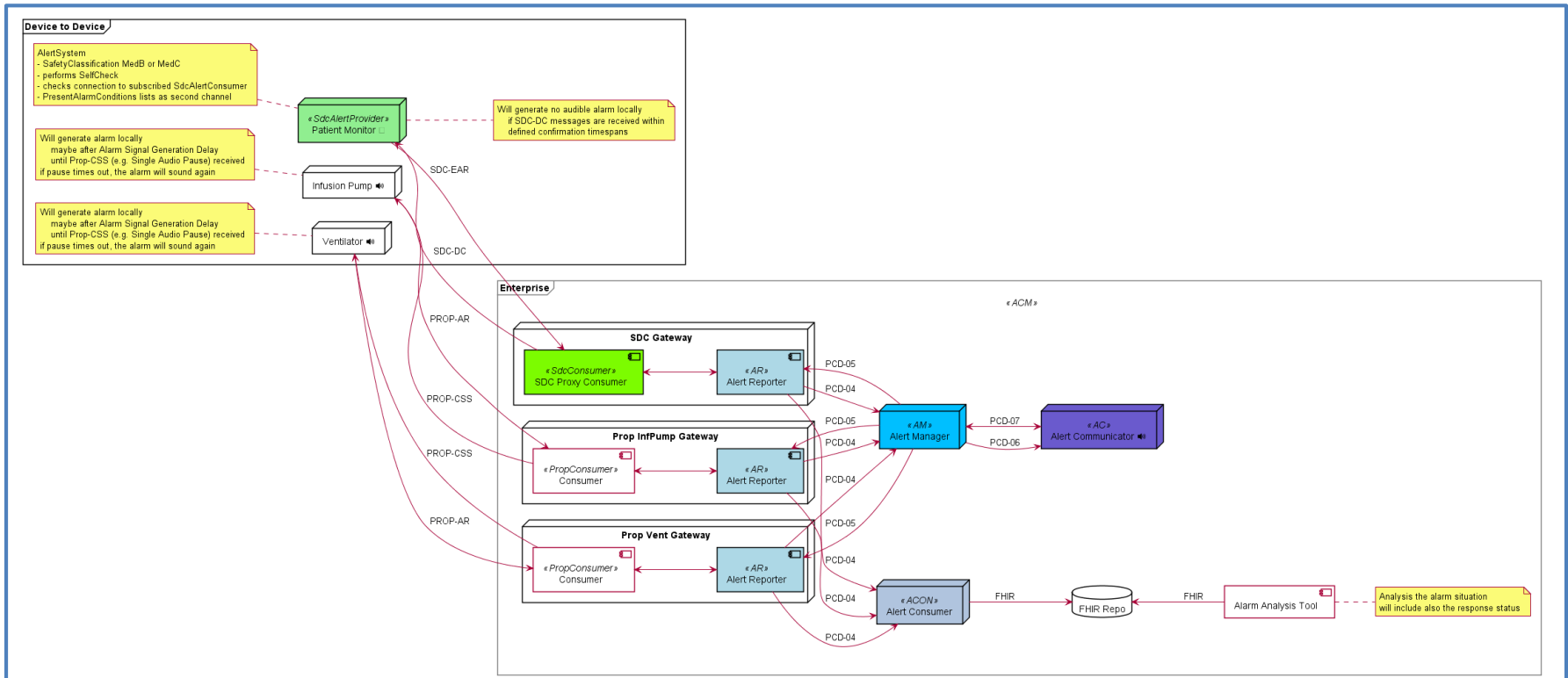
The Quiet Hospital (QH) introduces the concept of "Alarm/Alert Delegation" which allows one medical device (usually SaMD) to act as an alarm proxy for other medical devices/sensors. For example, an SpO2 monitor, blood pressure monitor or infusion device on an SDC network can delegate its alarm signaling to a local patient monitor (on the same network). In turn, a ventilator and the patient monitor can delegate their alarm signaling to a central station. The central station (acting as a PCD AR or via an independent SDC device gateway acting as an AR) can, in turn, delegate the function of alarm signaling to an alert communications manager which sends alert notifications directly to Sam's smart phone or another personal device. This can result in reducing or eliminating the noise level in the care unit as well as the potential for alarm fatigue. The reduced noise level also reduces Kelly's level of stress and allows for uninterrupted periods of rest.

Given the possibility of communication errors or system failures which could affect patient safety, appropriate feedback loops must be in place to mitigate any hazards that may result in dropped Alerts or other malfunctions.

Finally, in order to support longer term alert logging and analysis of alert patterns a separate SDC to FHIR gateway can be installed to capture the alert traffic and "serve" results to interested applications.

NOTE: Isolation ICU extension also included

Example #3: SDC to Enterprise



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

4 Core Use Case Examples

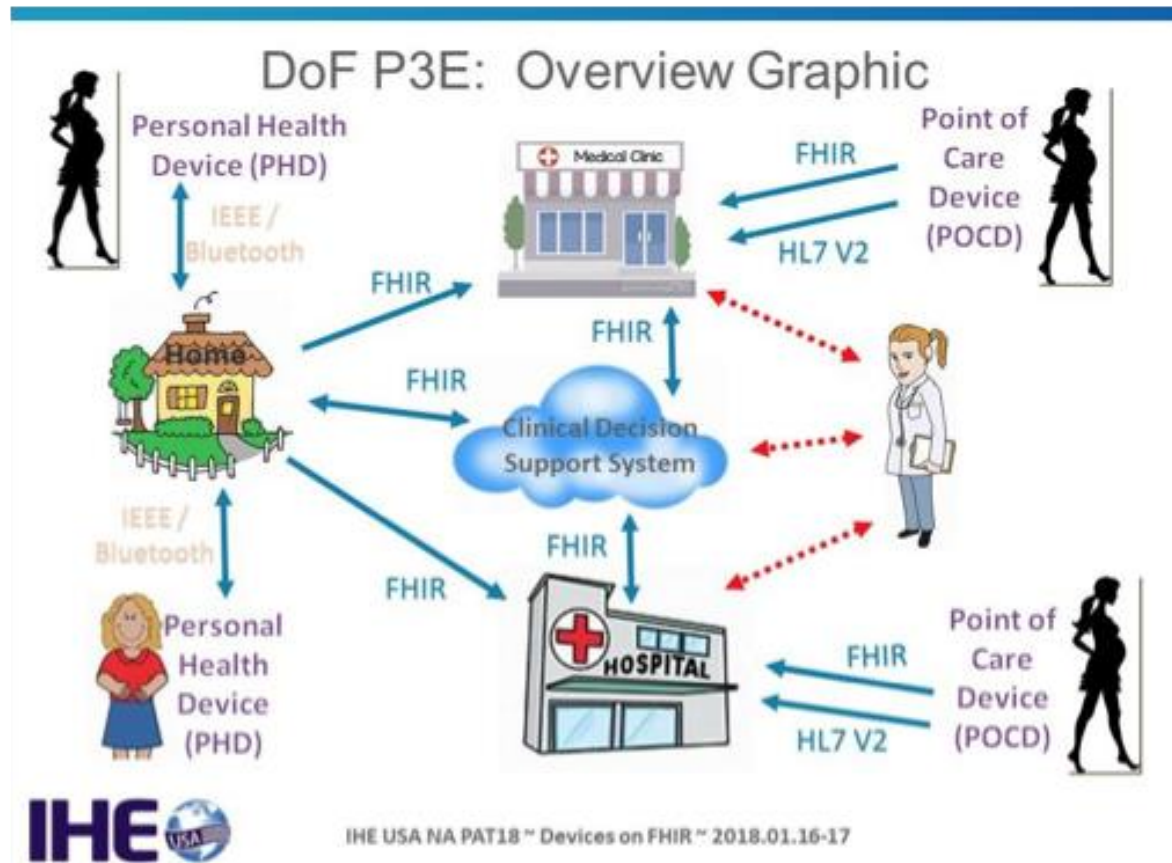
Quiet Hospital narrative includes the following component use cases:

- SDC/QH.1 Device alert signal delegation to single-pt. alert aggregator
- SDC/QH.2 Single pt. alert aggregator alert signal delegation to multi-pt. aggregator
- SDC/QH.3 Device alert signal *delegation* to Alert Communication Manager
- SDC/QH.4 Multi-pt. aggregator to Alert Communication Manager
- SDC/QH.5 SDC to FHIR Gateway.
- SDC/QH.6 Alert Communications Manager to care-giver Alert Communicator
- SDC/QH.7 Alert Communicator failure
- SDC/QH.8 Alert Communications Manager failure
- SDC/QH.9 Multi-pt. aggregator failure
- SDC/QH.10 Single pt. aggregator failure

Example #4: Preeclampsia During Pregnancy (PDP)

*Holly, a pregnant mom, goes to the **clinic** for a **regular check-up** where hypertension + proteinuria are detected resulting in a diagnosis of preeclampsia. She is **monitored** for preeclampsia (hypertension) during the remainder of her pregnancy utilizing a **personal health device** (PHD) blood pressure monitor and urine analyzer. A **Clinical Decision Support (CDS) system** is integrated to help with the real-time monitoring of Holly's condition. During Holly's final pre-natal exam, it was determined that the infant was under stress and an **emergency C-section** was performed. After delivery (postnatal) everyone expected her blood pressure to return to normal within a few days or weeks; however, to ensure this is the case, as part of her discharge Holly is prescribed to continue her **home monitoring** regimen and the CDS system oversight is also continued. Shortly after her discharge, Holly's BP spikes which is detected by the CDS and the physician is alerted to action. It's a good thing that she was being actively monitored. The problems were quickly identified, her caregivers alerted, and she was re-admitted to hospital before the condition progressed to eclampsia and seizures.*

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



Source: IHE DoF PAT '18 + HL7 FHIR DevDays

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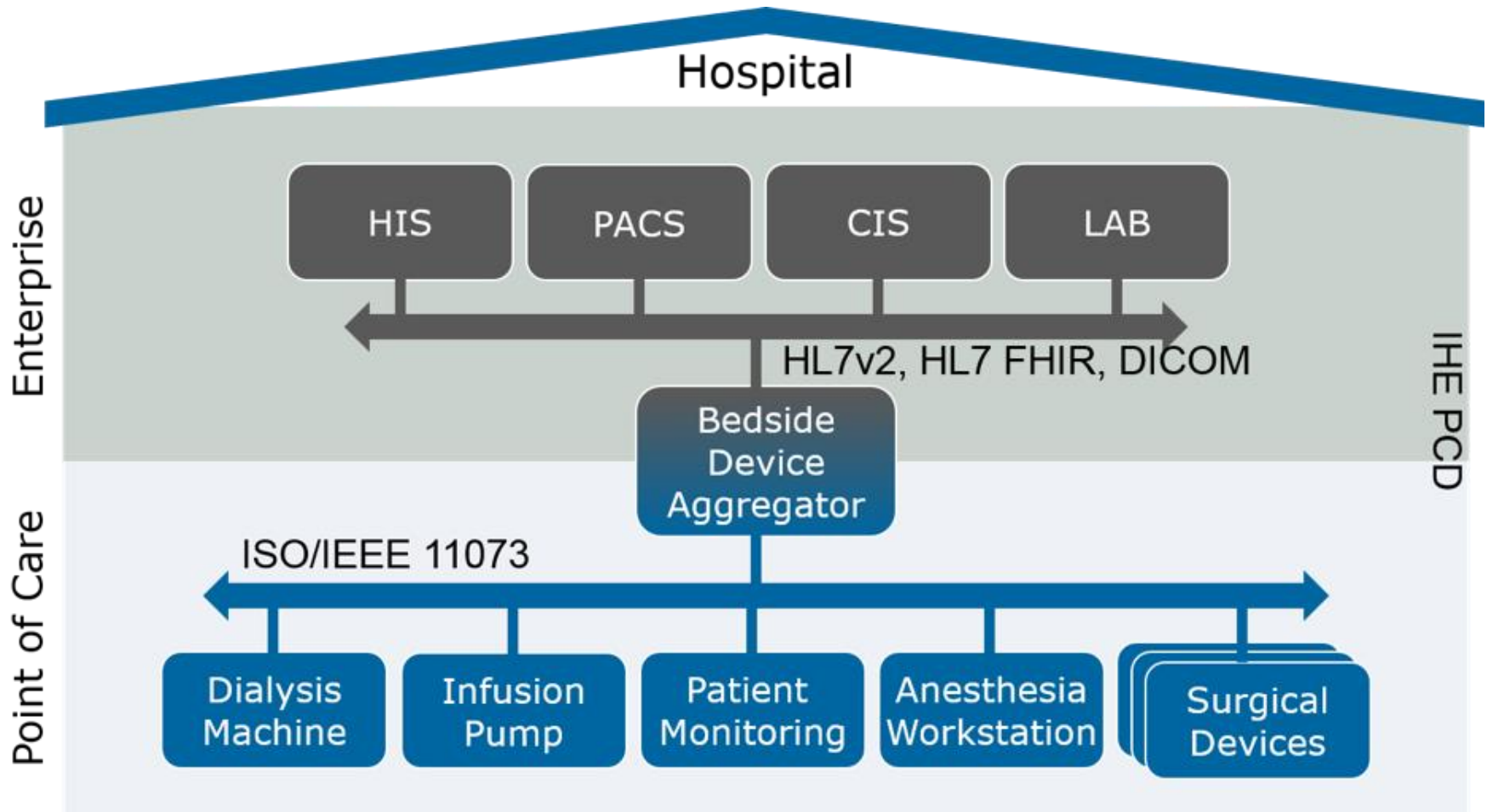
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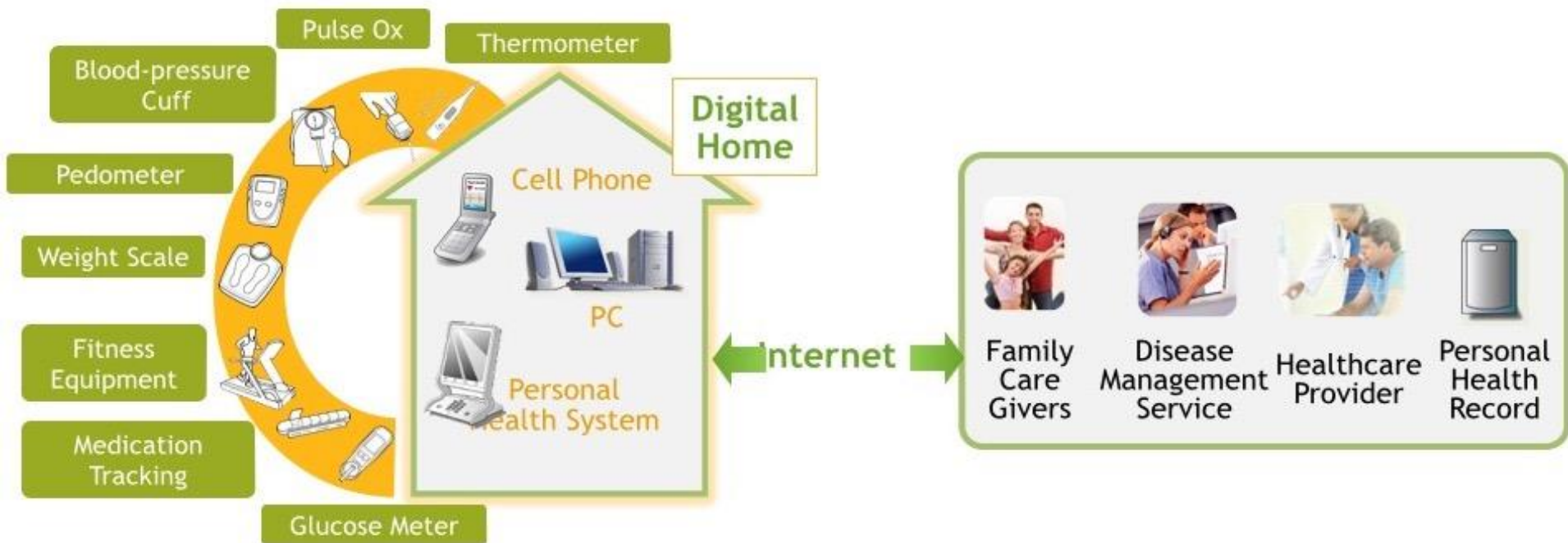
Open Discussion

SDC Standards & Functional Capabilities

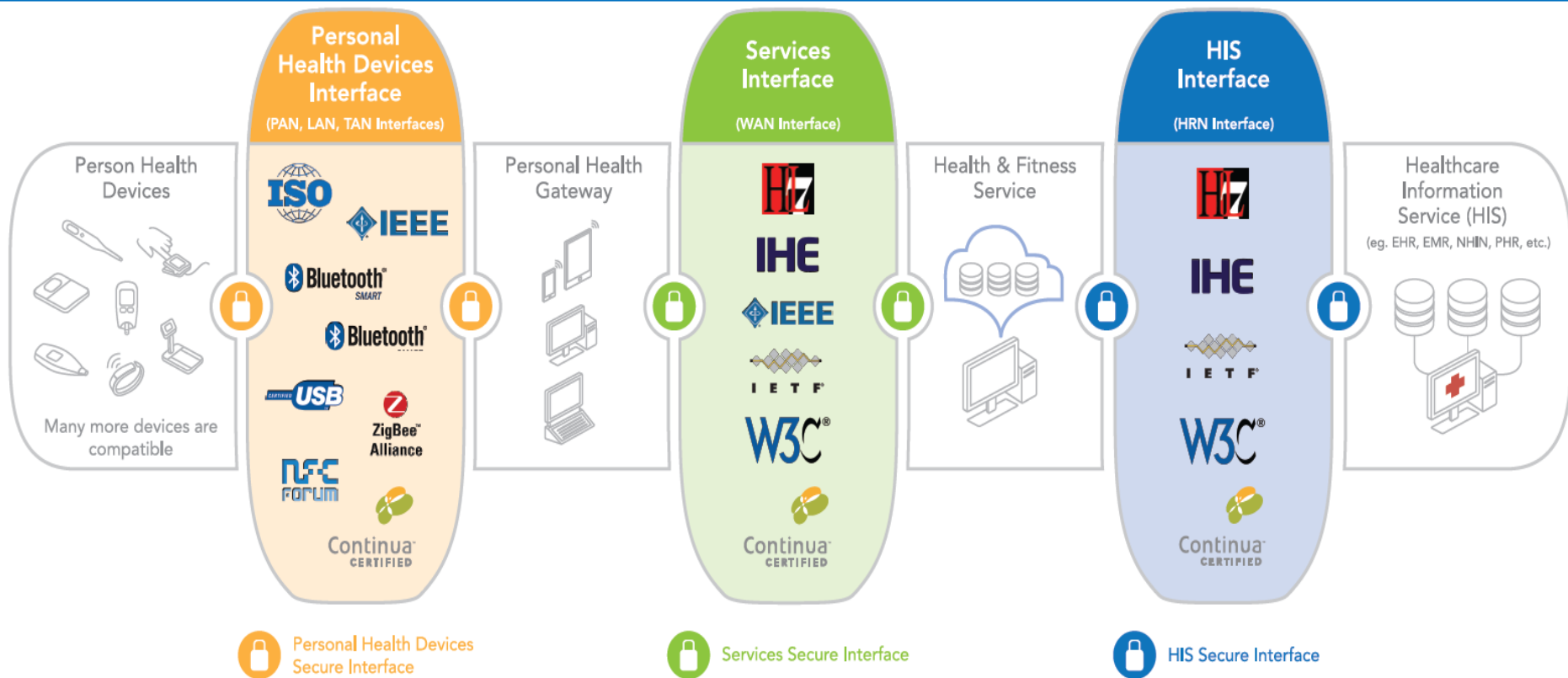


(Source: SDC overview presentations)

Continua Interoperability Ecosystem ...



Currently part of HIMSS / PCHAlliance “Continua”



Download @ www.pchalliance.org/continua-design-guidelines

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- **Use Cases** - both that are distinct to a specific use context and that involve two or three and require cross-context coordination
- **Use Contexts** - are the (3) suggested appropriate or should there be a further breakdown?
- **Risk => Criticality => Regulatedness**: Clearly this is involved in all three use contexts, but at different levels?
- **User** - professional clinician to personal grandpa or family caregiver
- **Technology** - esp. with the advent of Medical IoT, mobile FHIR-based, AI/ML MD ... EMBS SC initiatives? Etc.
 - Consider RWE needs of FDA and others @ AI MDs ... melding a few of the above aspects
- ...

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