"What is a device, really?!"

The term "device" gets used all the time, but what do people really mean?

In the standards world, we get pretty serious about our definitions, sometimes "coming to blows" over the right way to describe something. The same is true for most other communities that have their own set of Terms of Art. And when you are talking about specialized communities, they often come to agreements around group scopes that allow them to reuse a given term, but to make sure its use is generally clear based on the context in which is used.

In the health device informatics world, this starts with the core term: Device.

Historically we have had many ways of trying to disambiguate its use, including point-of-care device vs. personal health device, regulated medical device vs. healthcare device, devices that require specialized hardware vs. general purpose platforms (including mobile devices), embedded firmware vs. software applications, etc. The medical device interoperability (MDI) community often gets so focused on how a "device" interacts with the world around it, the fact that MOST devices used to deliver care do NOT have communications interfaces ... like flashlights or face masks. BUT they are managed, part of supply chains, tracked, many times "regulated" by public agencies, etc. To be sure, 10, 20, 30+ years ago these distinctions were fairly effective at allowing industries and standards organizations focus on specific areas without bumping into each other ... too much.

With the recent sea change in technology and its use in healthcare and ... "devices" ... these lines of distinction have become increasingly blurred.

Is it still a "device" when it is a software app running on some virtual blade server somewhere in the cloud that integrates AI/Machine Learning technology to determine when Joe should be told to go to the emergency room at his local hospital? What if it is a closed-loop algorithm running in an app on a mobile phone that reads continuous glucose monitor DEVICE readings and dynamically adjusts an insulin pump DEVICE dose settings? If an emergency responder uses a pocket flashlight he just picked up at a convenience store to check the pupils of someone who was just knocked off their bike by a car ... is that flashlight now a medical device? The list is getting longer and longer ...

Sorting out the various nuances of meaning that are currently associated with the term health "device" and coming to a common understanding as to how best to use it when creating standards and other materials related to ... devices ... is a good thing, especially for the two IHE and HL7 working groups whose names are simply "Devices"!

The focus of the paper being proposed here is to do just that. Note that the intent is ...

NOT TO ANSWER THE QUESTION, "What is a device??!

But to discuss the overloaded nature of the term as it is used today and to propose a set of principles and ground rules for how it should be consistently used in the Gemini SDPi+FHIR specifications and other materials.

NOTE: This topic was first raised within the IHE-HL7 group during the HL7/IHE/IEEE WGM 2019 September, in the presentation "X73 Standards Family Scoping - Atlanta 2019-09-17 FINAL.pdf". The rebranding simplification of the IHE and HL7 Devices working groups + the broadening of the scope of the IHE Devices group to include technology used across contexts (hospital to clinic to home), motivated the need to come to a better understanding of the usage of this term, especially within this community.

If you need a definition ...

<recognizing this challenge, recent SDPi+FHIR presentations have used a simplified "layman's" expression ... see Tobias/Cooper HIMSS'20 slide + reference Hanging Gardens model graphic & page>

"bundles of sensors, actuators and intelligence with a healthcare purpose"

<start with the IMDRF formal "medical device" definition (use 81001-1 as a reference)>

<pull apart the medical purpose (and thus regulatedness) ... vs. other stuff ... including software!>

<introduce the AI/ML and similar challenges>

ADD: If you need a list ... <nomenclature standards ...>

What's the story on SAMD and VMDs?
Discuss virtualization of "devices" from the early 90's Virtual Medical Device (VMD) construct in ISO/IEEE 11073-10201, to the more recent (and increasingly important) Software as a Medical Device 

Consider: Digital Therapeutics

Current debate in this area includes trying to clarify - establish a definition - for Digital Therapeutics. As always, the end points make the discussion easy: Clearly a cloud-connected app that provides mental health therapy is a DTx, and an app integrated into a ventilator platform that provides a closed-loop controller function is not. However, the middle ground gets murky - can you say that DTx is only SaMD? Or are there instances when it is architecturally deployed on generic hardware components (e.g., a VR set) that constitutes SIMD but is still far from a classical medical device (e.g., infusion pump)?

Discussions in ISO/TC215/WG11 Health Informatics - Personalized Digital Health, are actively working to craft language that works for all stakeholders, from developers / vendors to users to regulators to advocacy groups, including the development of a technical report on the subject of DTx Health Software, as well as joint discussions with IEC/SC62A (home of 60601 standards) on a formal definition of DTx and where that should be integrated into existing and new standards (e.g., updates to 82304-1 and -2, 62304, 81001-1, etc.).

Content Considerations

From the 2019-09 HL7 WGM (here is the presentation) & 2019-10 IHE Devices meetings:

- 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? Architectures?
- Risk => Criticality => Regulatedness: Clearly this is involved in all three use contexts, but at different levels?
- Quality – including process requirements (e.g., ISO 13485)
- User - professional clinician to personal grandpa or family caregiver
- Technology - esp. with the advent of Medical IoT & Clinical IoT and Io<everything>T, mobile FHIR-based, AI/ML MD ... EMBS SC initiatives? Etc.

- Consider RWE needs of FDA and others @ AI / ML MDs ... melding a few of the above aspects

- Architecture – Is there a clear delineation between device subsystems that allow for "containment" of critical (high risk) functions to one system component (e.g., the dialysis subsystem with SIMD) and other elements, such as education or user interface to software applications (general health software & SaMD) that are running on a general purpose platform?
- Communication Devices:  
  - e.g., mobile "device" - "device used in a clinical setting" but not a regulated medical device (at ACM: Edge devices / end-point communication devices)
  - Google Glass ... VR / MR / AR technology
  - Note: in ACM a "dashboard" can be an endpoint "device"
- Connected vs. Disconnected (not connectable)
- HIT Infrastructure "devices" vs. health / medical purpose (sensor/actuator/intelligence) "device"
  - Including ID & location devices (e.g., RFID)

Cameras ...
  - e.g., for patient assessment in an isolation room

Project Roadmap & Status

Paper Roadmap

1. Develop a joint HL7-IHE Gemini Paper  
   - Informal paper that is developed and approved as a working group internal document
   - Primary intent is to come to a set of principles or guidance for how the IHE and HL7 Devices working groups can use the term "device" in a consistent manner
   - May be elevated to a formal balloted Gemini paper at a later date
   - Will ensure that the use of the term is consistent in the Gemini SDPI+FHIR and related specifications and related materials
   - Home working groups: IHE Devices (DPI) and HL7 Devices
   - Supporting working groups: HL7 mHealth; IEEE 11073 Standards Committee
   - TARGET: Ballot 2020 Q3

2. ISO/TC 215 Coordination  
   - May be circulated to ISO/TC 215 WG2 and ISO/IEC JWG7 for informational purposes only.

Development Status

1. IHE Devices  
   - Work item was approved at the DEV monthly plenary WebEx meeting 2020.04.29 (search for "DPI")

2. HL7 Devices  
   - PSS Proposal to be submitted by Friday, 2020.05.22
3. **Gemini Project Coordination**
   - Paper included in the original set of work products approved at the 2020.04.21 Steering Committee Meeting
   - TBD process & IP details on how and where to "publish" a Gemini paper; in this case it might simply be on the SDPi+FHIR program home confluence page as a WG approved document.

"What is a 'medical device'?' Paper

This section contains the content of the paper. Outline sections can be started here and then linked to subpages as content gets developed.

**Title:**

*What is a "device"?*

**Subtitle:**

Disambiguating the term "device" in health informatics

or

...

**Executive Overview**

<summarize / bullet anticipated content here>

**Scope & Organization**

**Introduction**

<.... sections ....>

<problem statement and a bit of historical context>

<Dimensions Contributing to Defining "Device">

<Use Context Specific Guidance - Principles>

<Conclusion / Summary section>

<.... annexes ....>

<Bibliography>