IEEE STANDARDS ASSOCIATION

IEEE

P1752 Working Group Meeting

Sponsored by IEEE Engineering in Medicine & Biology (EMB) Standards Committee

Please mark your attendance at:
https://tinyurl.com/yc3oxg6q
(see chat window)

- 23 October 2018
- Teleconference

Attendance

- This document shows attendance from previous calls **https://tinyurl.com/yc3oxg6q** (link in the chat window of join.me). **If you attended the call, please verify that your name is listed**
  - If not, email simona@openmhealth.org
- **Put your name and affiliation in the chat window for attendance today.**
  - If your name is not listed, or if you are joining only via phone, please email simona@openmhealth.org with "P1752 WG call" as subject
- Attendance is important for determining voting rights, so please remember to "check in"
- Voting rights are granted according to the P&P after attending two consecutive calls and by explicit request to the Secretary

IEEE Patent Policy

Participants have a duty to inform the IEEE

- Participants shall inform the IEEE (or cause the IEEE to be informed) of the identity of each holder of any potential Essential Patent Claims of which they are personally aware if the claims are owned or controlled by the participant or the entity the participant is from, employed by, or otherwise represents

- Participants should inform the IEEE (or cause the IEEE to be informed) of the identity of any other holders of potential Essential Patent Claims

Early identification of holders of potential Essential Patent Claims is encouraged

Slide #1

Ways to inform IEEE

- Cause an LOA to be submitted to the IEEE-SA (patcom@ieee.org); or
- Provide the chair of this group with the identity of the holder(s) of any and all such claims as soon as possible; or
- Speak up now and respond to this Call for Potentially Essential Patents

If anyone in this meeting is personally aware of the holder of any patent claims that are potentially essential to implementation of the proposed standard(s) under consideration by this group and that are not already the subject of an Accepted Letter of Assurance, please respond at this time by providing relevant information to the WG Chair

Slide #2

Other guidelines for IEEE WG meetings

- **All IEEE-SA standards meetings shall be conducted in compliance with all applicable laws, including antitrust and competition laws.**
  - **Don't discuss the interpretation, validity, or essentiality of patents/patent claims.**
  - **Don't discuss specific license rates, terms, or conditions.**
    - Relative costs of different technical approaches that include relative costs of patent licensing terms may be discussed in standards development meetings.
      - **Technical considerations remain the primary focus**
  - **Don't discuss or engage in the fixing of product prices, allocation of customers, or division of sales markets.**
  - **Don't discuss the status or substance of ongoing or threatened litigation.**
  - **Don't be silent if inappropriate topics are discussed … do formally object.**

For more details, see *IEEE-SA Standards Board Operations Manual*, clause 5.3.10 and *Antitrust and Competition Policy: What You Need to Know* at http://standards.ieee.org/develop/policies/antitrust.pdf

Slide #3

Patent-related information

The patent policy and the procedures used to execute that policy are documented in the:

- ***IEEE-SA Standards Board Bylaws*** **(http://standards.ieee.org/develop/policies/bylaws/sect6-7.html#6)**
- ***IEEE-SA Standards Board Operations Manual*** **(http://standards.ieee.org/develop/policies/opman/sect6.html#6.3)**

Material about the patent policy is available at
http://standards.ieee.org/about/sasb/patcom/materials.html

If you have questions, contact the IEEE-SA Standards Board Patent Committee Administrator at patcom@ieee.org

Determination of Quorum

https://tinyurl.com/yc3oxg6q

Approval of Agenda

1. Attendance
2. Call for Patents
3. Approval of agenda (if quorum present)
4. Updates from subgroups
5. Discussion: upcoming activities
6. Other business

Approval of Prior Minutes

(August 28)

Update:
Physical Activity and Mobility (PA&M) Schema Subgroup

Physical Activity & Mobility (PAM) Sub-group

1. We are making progress on the following tasks
   - Task 1: Discussed about raw data
     - How this might influence schema development and/or modification
   - Task 3: Defining use cases
     - We are brainstorming on use cases
     - We will discuss on how use cases will be utilized in a clinical or research environment
     - How to map use cases to OmH schema data elements

2. Next Meeting: Thursday Oct 25, 2018 (11am to 11:45am Eastern Time)

Use Cases

- General population
  - An individual with moderate cardiovascular risk
  - Physical activity guideline for Adults
  - Physical activity guideline for Children and Adolescents
- Individuals with spinal cord injury
  - Fitness Guideline
  - Cardiometabolic health guideline
- Key aspects of use cases across population
  - Steps
  - Moderate and vigorous intensity (Duration and Bouts)
  - Activity counts (tricky)

Update:
Sleep Schema Subgroup

Sleep Schema Subgroup Update (pg.1)

- **Preparation of drafting schemas**

(1) Drafted a list of mapping between sleep schema name vs. sleep attributes

(2) Subgroup reviewed/commented/discussed the mapping list

Here is the link to the list of mapping:

https://ieee-sa.imeetcentral.com/omh/folder/WzIwLDEwMjY4MDc3XQ/WzIsNjIwNjY0NTRd/

(3) Discussed/Determined the approaches of the schema drafting:

Two groups: One focusing on quantitative measures; The other on subjective measures;

Sleep Schema Subgroup Update (pg.2)

- Information included on the list of mapping:

  -Schema ID;

  -**Schema Name**;

  -Sleep Attribute(s) **with units**;

  -**Associated Sleep Attributes**;

  -Use Case ID;

  -**Types of Measures (e.g. Trend/Statistics(over a sleep session/episode, weekly, monthly), real time);**

  -**Measure(s) Acquired: Time Interval (beginning timestamp, end timestamp) or Time Point (timestamp);**

  -**Measure(s) Reported: Effective Time Interval or Effective Time Point;**

  -**Body Site(s);**

  -**Health Events/Conditions;**

  -Location/Setting;

  -Device/App Info (e.g. manufacturer, name/model, serial number);

  -**Clinical Data Standards (e.g. SNOMED, LOINC code);**

Sleep Schema Subgroup Update (pg.3)

- **Next Step ---- Sleep schema development:**

  ---Based on a couple of example schemas, the group will discuss/ understand;

  ---Task group1 will draft the schemas;

  ---Entire group will review/comment on the draft schemas;

  ---Task group2 will start to work on subjective schemas;

- **Sleep Schema Subgroup Meeting Slides/Minutes:**

http://sites.ieee.org/sagroups-1752/sleep-subgroup-meeting-materials/

- **Next Subgroup Meeting: Nov 6, 2018 11:30am to 12:30 pm**

Discussion:
Minimum Metadata

mHealth Data Standards Landscape

- Device-centered standards that also deal with data
  - HL7 FHIR Device resource (aka schema) and provenance
  - IEEE 11073 family of standards
- EHR-centered data standards
  - HL7 FHIR Observation and other resources (aka schemas) and provenance
- Consumer or domain-specific standards
  - Consumer Technology Association published protocols for validating heart rate and step count devices, and 2 standards on sleep measures nomenclature and definitions
  - Others…

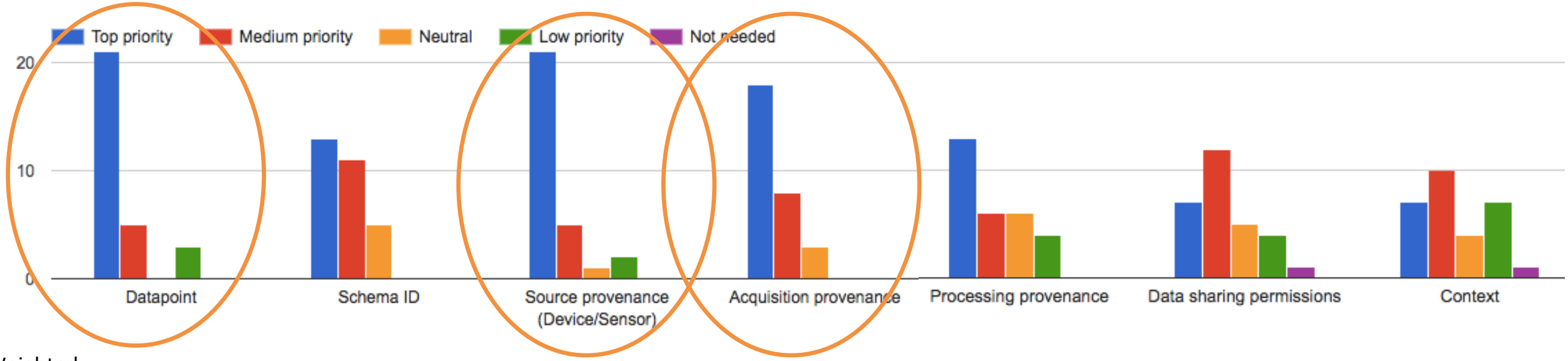
After We Build It, Will They Come?

- Potential drivers of adoption
  - Carrots: efficiency, simplicity, reusability, meaningfulness…but only if others also use them
  - Market dominance: e.g., VHS over Betamax, etc.
  - Sticks: most standards are adopted by some entity that is sufficiently large and influential
    - As a mandate imposed externally (e.g., FDA requiring CDISC submission standards for clinical trials data)
    - Adopted internally as a de facto requirement (e.g., radiology PACS manufacturers jointly developing and adopting DICOM)
- mHealth field is fragmented, global, spans several pre-existing market sectors, complex and rapidly evolving
  - Most effective driver is likely to be an external stick

Potential Sticks and Their Use Cases

- "Device" regulation
  - US FDA's new Pre-Certification program for software as a medical device (SaMD): certifies companies rather than products, relies on post-market surveillance of "real-world performance"
  - To conduct surveillance at scale, FDA needs devices to have data and metadata standards
- Health IT regulation
  - 21st Century Cures Act (2016) assigned US Health and Human Services/Office of the National Coordinator for Health IT (ONC) the responsibility for health IT and data standards for US health care system, and for NIH's Precision Medicine Initiative (PMI/All of Us)
- Open mHealth being strongly considered by both FDA and ONC as a standard to recommend/mandate
  - Simplicity and pragmatism are being appreciated
  - Need a minimum metadata model for policy makers to consider

Minimum Metadata: Survey Responses (n=30)



	Datapoint	Schema ID	Source provenance (Device/Sensor)	Acquisition provenance	Processing provenance	Data sharing permissions	Context
Weighted average	4.4	4.2	4.6	4.5	4.0	3.7	3.5

Minimum Metadata Categories

- Datapoint ID and Schema ID
- Source Provenance – *from what* did this datapoint come from
- Acquisition Provenance – *how was this datapoint acquired*
- Defer for later
  - Processing provenance – *how was this datapoint computed*
  - Data sharing permissions and record
  - Context (some elements may end up in above categories)

Datapoint/Schema ID

- Metadata about the datapoint itself, e.g., Datapoint ID, User ID, Creation date-time (timestamp or time interval) definition: the date time that the data point was created on the system where data is stored
- Metadata about the schema to which the body of the datapoint complies, e.g., Schema Name, Schema ID, Namespace, Version, URL.

Source Provenance (static provenance, “from what”)

- Metadata about the device or sensor from which this datapoint was obtained, e.g., a fitness band, smartwatch, smartphone, app. If sensor data is obtained from a smartphone's onboard sensor, then the smartphone is considered the device/sensor. If data is obtained from a separate sensor that is then communicated to the smartphone, then the smartphone is NOT a device/sensor.
- The app that generated this datapoint is also a source, i.e., Software as a Medical Device (SaMD). The algorithm(s) that generated the datapoint is deferred to Processing Provenance.
- Examples of source provenance include
  - Device Name, Model, Version, Manufacturer ID (e.g., using Unique Device Identifier, UDI)
  - Application name, Application version, OS, Manufacturer

Acquisition Provenance (dynamic provenance)

- Metadata about how the datapoint was acquired, e.g.,
  - Source (reference to device)
  - Source creation date-time definition: The date time (timestamp) of data creation at the source
  - Source last modification date-time definition: The date time (timestamp) of last data modification at the source
  - Sampling rate and regularity
  - Sensor body location
  - Whether on dominant hand
  - Modality (sensed, reported)
  - Type (prompted, initiated, missed, abandoned)
  - Etc.

Context

- Metadata context goes in the header
- Data context goes in the datapoint itself

	Datapoint/Schema ID	Source	Acquisition	Processing
In Header		Country? Regulatory status?	Electromechanical (signal strength, connectivity…)	Data quality (e.g., error ranges, missing data, imputation)
In Datapoint itself	Clinical context, e.g., blood glucose relation to meals Units Type of measure			

Comments and Issues

- Type of disease – OmH is data focused, and the same data can relate to many different diseases
- Security – is an issue for the overall system, not a particular datapoint/stream
- Others?

Metadata Next Steps

- Tasks
  - Agree on minimum categories and their scope
  - Define and enumerate properties
  - Define and enumerate value sets for properties
- Process
  - Will conduct metadata work in main WG meeting (ie no subgroup)
  - Will coordinate with other initiatives on how best to move forward to achieve an official standard *that is adopted*
    - May involve a face-to-face meeting, collaborations outside of IEEE
    - Will need to follow IEEE policies

Balloting Timeline

- Will discuss with subgroups offline

Future Work

Summary of Action Items

Future Meetings

Upcoming Meetings

- Main WG
  - Nov 13: 8 AM (Pacific)
  - Nov 27: 8 AM (Pacific)
  - Dec 11: 8 AM (Pacific)
- Sleep subgroup
  - November 6, 2018 8:30am to 9:30 am (Pacific)
- PA&M subgroup
  - October 25, 2018 11 to 11:30 am (Eastern)

Adjournment