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)

- 13 November 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 and of priori minutes (if quorum present)
4. Updates from subgroups
5. Discussion: upcoming activities
6. Other business

Approval of Prior Minutes

(September 18 and October 23 -- deferred)

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 3: Defining use cases
     - Completed brainstorming of use cases
     - Discussed how use cases may be utilized in a clinical or research environment
     - Discussed how to map use cases to OmH schema data elements

2. Next Meeting: Thursday Nov 29, 2018 (11am to 11:45am Eastern Time)

Use Cases and Relation to Schema

- Reviewed existing schemas
  - Step Count, MET
- Modified PA Schema (Simona)
  - Activity - METS

Code Writer

```
{
    "$schema": "http://json-schema.org/draft-04/schema#",

    "description": "This schema represents a single episode of physical activity.",
    "type": "object",
    "references": [
        ...
    ],
    "definitions": {
        "activity_name": {
            "$ref": "activity-name-1.x.json"
        },
        "length_unit_value": {
            "$ref": "length-unit-value-1.x.json"
        },
        "kcal_unit_value": {
            "$ref": "kcal-unit-value-1.x.json"
        },
        "time_frame": {
            "$ref": "time-frame-1.x.json"
        }
    },

    "properties": ...,

    "required": [
        "activity_name",
        "effective_time_frame"
    ]
}
```

Update:
Sleep Schema Subgroup

Sleep Schema Subgroup Update (pg.1)

- **Preparation of drafting schemas**
  - **Discuss/Align on the followings:**

    Data end users, roles of a sender & a receiver, aggregated data vs. real time data

  - **Quantitative sleep measure schemas:**

(1) Draft/Discuss one sleep schema example (SOL) provided by Simona

(2) Updated the list of mapping between sleep schema name vs. sleep attributes based on the WG metadata and sleep schema example discussions

Sleep Schema Subgroup Update (pg.2)

Here is the link to the updated list of mapping:

https://ieee-sa.imeetcentral.com/omh/folder/WzIwLDEwMjY4MDc3XQ/WzIsNjIzMjc5MTVd/

Qualitative sleep measure schemas:

(1)Gather references to qualitative sleep measures;

(2)Gather references to existing framework from Open mHealth;

- **Formed two task groups:**

---Quantitative sleep measure

---Qualitative sleep measure

Sleep Schema Subgroup Update (pg.3)

➢**Next Step**

Quantitative sleep measure task group:

---Review the updated list to make sure every proposed schema name with measures included is meaningful to the end users;

---Draft the schemas based on the SOL example;

Qualitative sleep measure task group:

---Review/update the use cases for qualitative sleep measures;

---Review the references to the qualitative sleep measures;

---Review the existing framework for the subjective measures from Open mHealth;

---Draft/Discuss qualitative sleep measure schema (start with one);

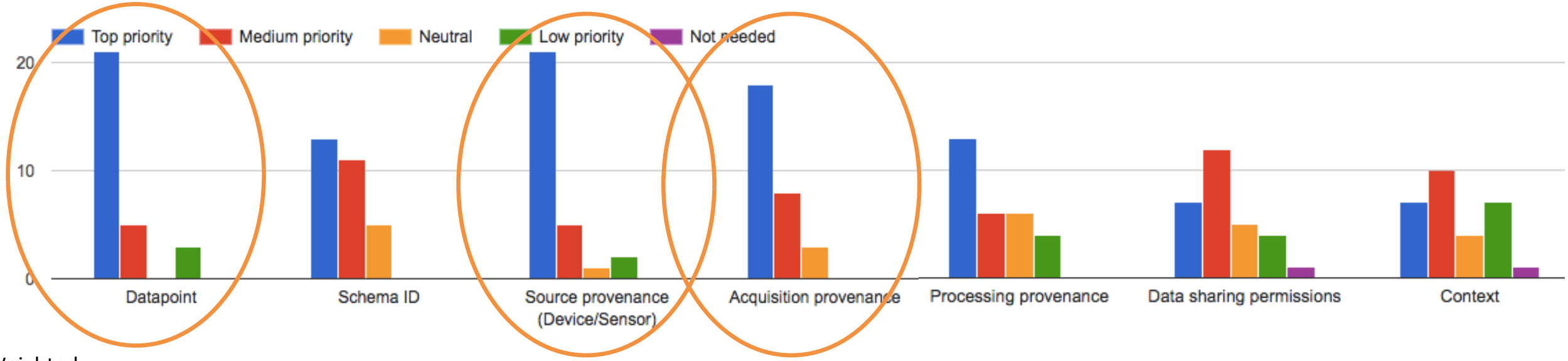
Discussion: Minimum Metadata (continued)

Drivers of mHealth Data Standards Adoption

- mHealth field is fragmented, global, spans several pre-existing market sectors, complex and rapidly evolving
  - Carrots and market dominance approaches less likely to be effective
  - Most effective driver is likely to be an external stick
- 3 categories of use cases and corresponding potential sticks

Use Case Category	Example	Potential Stick
Device regulation	FDA Pre-Cert program needs data/metadata standards to conduct real world monitoring	FDA
Clinical care	Clinician reviews mHealth data from patient in device-agnostic way	Office of the National Coordinator for Health IT (ONC)
Clinical research	Digital biomarkers need to be standardized across studies, and for market approval	ONC, NIH, FDA

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)

Metadata Next Steps (from last call)

- Tasks
  - Agree on minimum categories and their scope √ (done on 10/23)
  - **Define and enumerate properties**
  - Define and enumerate value sets for properties
- Process
  - Will conduct metadata work in main WG meeting (ie no subgroup)
  - Will inform joint agency meeting that is being planned

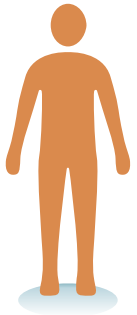
Datapoint/Schema ID

- Metadata about the datapoint itself
  - What do we need to know about the datapoint?
- Metadata about the schema to which the body of the datapoint complies
  - What do we need to know about the schema of the datapoint?

- Illustrative use case…

Increasing Physical Activity to Reduce CV Risk

Patient with moderate CV risk

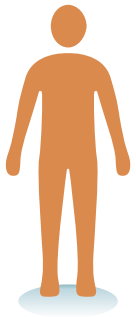


Primary Care Physician

Joint Goal Setting

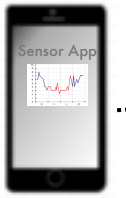
AHA/CDC guidelines: 150 minutes moderate activity per week → 4000 steps per day

Data Prescription

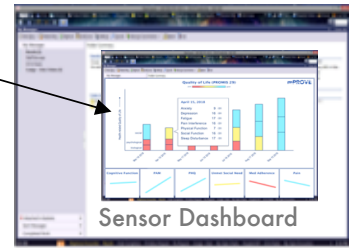


+

FHIR-enabled EHR



Joint Data Review



FHIR-enabled EHR

Datapoint/Schema ID

- Metadata about the datapoint itself
  - What do we need to know about the datapoint?
- Metadata about the schema to which the body of the datapoint complies
  - What do we need to know about the schema of the datapoint?

- Illustrative use case
  - Category: clinical
  - Scenario:
    - 1) clinician reviewing physical activity result
    - 2) developer building decision support system that uses this result
  - Digital biomarker: “physical activity”

Datapoint: What Do We Need to Know?

Metadata Category	Needs	Metadata Required
Datapoint	Which datapoint is this?	datapointID
	Whose datapoint is this?	userID
	When was this datapoint created?	creation_date_time
	What does this value represent?	Schema ID and schema metadata
	When is the effective time of this data?	[in the datapoint itself]

Datapoint Metadata in Header Schema

```
"properties": {
   "id": {
      "description": "The identifier of this data point. We strongly recommend this to be a globally unique value.",
      "type": "string"
   },
   "creation_date_time": {
      "description": "The date time this data point was created on the system where data is stored.",
      "$ref": "#/definitions/date_time"
   },
   "schema_id": {
      "description": "The schema identifier of the body of the data point.",
      "$ref": "#/definitions/schema_id"
   },
   "user_id": {
      "description": "The user this data point belongs to.",
      "type": "string"
   },
[...]
```

Schema: What Do We Need to Know?

Metadata Category	Needs	Metadata Required
Schema	Which schema does this datapoint follow?	schema namespace and name
	What is this schema about?	annotation to controlled term
	Which version of the schema?	schema version
	Where can I find this schema ?	url
	What *can* be said with this schema?	[in the schema itself]
	What *must* be said?	[in the schema itself]
	In what units?	[in the schema itself]
	How is effective time handled?	[in the schema itself]

Schema-id Schema

```
"properties": {
    "namespace": {
      "description": "The namespace of the schema. A namespace serves to disambiguate schemas with conflicting names.",
      "type": "string"
    },
    "name": {
      "description": "The name of the schema.",
      "type": "string"
    },
    "version": {
      "description": "The version of the schema, e.g. 1.0.",
      "type": "string"
    },
    "url": {
      "description": "A URL to retrieve the schema. If a URL is not specified, it is assumed that the schema can be located using other means.",
      "type": "string",
      "format": "uri"
    }
  }
```

Sample Instance


```
{
  "header": {
    "id": "123e4567-e89b-12d3-a456-426655440000",
    "creation_date_time": "2013-02-05T07:25:00Z",
    "schema_id": {
      "namespace": "omh",
      "name": "physical-activity",
      "version": "1.2",
      "url": "http://www.openmhealth.org/schema/omh/physical-activity-1.2.json"
    },
    "user_id": "user1432",
    [...]
  },
  "body": {
  }
}
```

Your input – Define and enumerate properties

- Describe your own use case
  - Is it regulatory, clinical, and/or research?
- What do you need to know about a specific digital biomarker result to make full use of it?
  - categorize your need
    - Datapoint ID
    - Schema ID
    - Source provenance (from what did this datapoint come from?)
    - Acquisition provenance (how was this datapoint acquired?)
    - Other (including processing provenance (how computed), context)

Future Work

Summary of Action Items

Future Meetings

Upcoming Meetings

- Main WG
  - November 27: 8 AM (Pacific)
  - December 11: 8 AM (Pacific)
- Sleep subgroup
  - December 4, 2018 8:30am to 9:30 am (Pacific)
- PA&M subgroup
  - November 29, 2018 11 to 11:30 am (Eastern)

Adjournment