Minutes of Joint Meetings of HL7 Health Care Device WG and IEEE 11073 Point-of-Care Committee, Madrid, Spain, Monday May 8 to Thursday May 11, 2017

Monday, 8 May, Q2

Notice of IEEE patent policies for meetings
Notice of other IEEE meeting policies regarding anti-trust and ethics considerations
(displayed IEEE slides on above topics)

Discussion of Agenda

Discussion of Minutes of San Antonio Meeting, January 2017
Follow-up on Action items from minutes:
● IEEE PHD Cybersecurity Group - we will hear presentation at present meetings
● UDI, Time management topics also on agenda for present meetings
● OpenICE requests for extensions to IEEE 11073-10201 - no new communications on this, action item continued.
● FHIR change action items achieved by Chris Courville (thanks!), forward-looking itesm to be discussed later in the Madrid agenda

VOTE: Garguilo moved (1) approval of San Antonio meeting minutes, and (2) current version of agenda (version 0.5) for Madrid meetings. Vote 12-0-0 (in favor, against, abstentions)

● Malcolm Clarke reported on recent discussions in Personal Health Device (PHD) meetings about scope of subgroups of IEEE 11073 following on member objections to creating a PHD profile for spirometry on the grounds that this is not a personal health device. Discussion about what the fundamental distinction between x73 PHD and x73 Point-of-Care Device (PoCD) subgroups. This is mainly a result of the history of the groups. Should we base the distinction on:
  ○ The protocol used
  ○ The intended context of use (hospital vs. home). This idea has some strong supporters of this position.
  ○ The intended user (patient vs. professional caregiver)
● Or should we accept that the charters have some overlap.
● ACTION: Kathryn Bennett will research the documents to the current position and background (Result: there is nothing on scope in the Committee procedures and practices). Then a consensus will be sought on the matter in the Standards Committee, and they will initiate actions to resolve it. Moved by Ken Fuchs, seconded by Chris Courville. Vote was 15-0-0 including responding online attendees).

● Daidi Zhong submitted a slide presentation on the IEEE 11073 PHD (see HL7 HCD Documents page to download)
● PCHA / Continua - Brian Reinhold talked about issues in mapping x73 to FHIR. These will be discussed in more detail on Wednesday agenda.
●

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Monday Q4

- **Action:** Brian will create HL7 GForge tickets for FHIR device issues he has identified so that they can be more readily tracked.
- AAMI / UL 2800 standards concerning interoperable medical devices, other cybersecurity-related efforts (UL 2900, Diabetes Technology Society DTSec): we will need to look into how these relate and what role x73 committees should take.
- Report from IEEE-SA (Kathryn Bennett). See meeting documents in HL7 HCD webpage: slides summary spreadsheet
- VOTE: Update the sponsorship of PARS so that a second sponsor be identified to serve as a backup and avoid delays in the process. Passed 16-0-0 including online attendees.
- Discussion on progress in nomenclature work in IHE Patient Care Device (PCD) Infusion Pump Workgroup
- Dialysis workgroup - x73 will seek further information on progress and plans
- Discussion of x73 PHD Cybersecurity work
- Discussion of Patient Care PSS on Cross-Paradigm IG Medical Device Data (more later)
-

Tuesday Q1 / Q2

- Notice of other IEEE meeting policies regarding anti-trust and ethics considerations
- P11073-10207 Presentation
    - David Gregorczyk: SDC First round ballot results, comments (see presentation)
    - Discussion of the process for handling comments - comments and resolutions should be made available, but commenters names should not be given because the process is anonymous.
    - Detailed discussion of comments and resolutions (see presentation and , when available, subsequent notes and resolutions)
    - Björn Andersen: forthcoming projects (see presentation)
    - Modular Validation Environment for Medical device Networks (MoVE)
    - International Network of Connecting Ubiquitous Assistive Technology in the Operating Room (INCUbATOR)
    - Device specializations (for Surgery)
    - Discussion of goal of test tooling covering other forms of 11073 as well

Tuesday Q3

Michael Faughn review of the DIM UML modeling tool (Presentation)

Extending model to cover 11073-SDC (BICEPS)

Considerable progress on performance and generation of a .docx version

Discussion concerning the proper endpoint of this effort. It seems like most objectives have been accomplished. Key is active use to verify and validate.

Jan W. feels that it has to be appropriate for quick edits and turn-around. Michael F. feels like it is very close to that point.

- Discussion as to whether Word document compare would provide an appropriate red-line document for review. Would be acceptable, however Michael wonders whether an XML generated documented could be compared. He will do a test and get back to the committee.
  - John Garguilo - NIST Tooling Update (Presentation)

Tuesday Q4

Paul Schluter overview of nomenclature status

Status of 10101b which includes Infusion pumps, NMT. RTLS, Event and Alert, hemodynamic parameters as well as surgical and OR devices.
- Discussion around "Power Events" proposed for the RTLS nomenclature.

Malcolm recommends making the events more explicit.

Wednesday Q1

- Review of IEEE meeting policies
- Discussion of current lack of liaison with Center for Medical Interoperability (CMI) as regrettable because SDOs cannot help them meet requirements without knowing what they are. Companies active in IEEE 11073 or HL7 and also in CMI encouraged to express this concern to CMI.

- Dialysis proposal status and intentions not known. Chris Courville will make contact with Orders and Observations members about their expectations (they will be discussing proposal in Q3).
- Malcolm Clarke reported on deliberations in PHD regarding Unique Device Identifier (UDI).
- Roadmap and planning: Elections will be needed as Jan Wittenber will be stepping down as PoCD chair

Wednesday Q2

- Election of officers for IEEE 11073 Point-of-Care Committee to be carried out. Ken Fuchs designated as Election Officer, approved by a vote of 11-0-0.
- Problems have been experienced with sponsorship signoff for submitting PARs.
  - ACTION: Identify an additional sponsor so that two people are available to sign off when needed
- Kathryn Bennett clarified, with respect to 10207 balloting in progress, that it was acceptable for changes due to new issues identified in these working group meetings to be corrected even though they were not identified in previous ballots
- Returning to topic of Center for Medical Interoperability.

- ○ **ACTION**: Ken will contact CTO, Ed Miller, to see if they would at a minimum care to identify a contact person for us to contact by email, and possibly to be added to the 11073 mailing lists.
- ● MDI Prototyping group has essentially lapsed, which affects plans for carrying forward MDAP development. Jan asks if an effort to reactivate the group is likely to bring in enough resources to finish the work. Alternatives include withdrawing the 20101 MDAP Project Authorization, allow it to lapse due to 10-year expiration at the end of 2018, or re-ballot it without change to keep it available for reference in other standards.

VOTE: Ken Fuch moved that the 20101 standard be formatted to current template and re-balloted without changes. Vote: in favor 11-0-1

Meeting of IEEE 11073 Point of Care Committee Adjourned by unanimous vote at 12:45 PM.

Wednesday Q3

Meeting of HL7 Health Care Devices Work Group convened.
Welcome and introductions
HL7 Intellectual Property Policy
Review and discussion of work group's mission, charter, and
strengths/weaknesses/opportunities/threads (SWOT) documents.

Wednesday Q4

Meeting of HL7 Health Care Devices Work Group continued.
Welcome and introductions
HL7 Intellectual Property Policy

Joint meeting with Mobile Health WG
Matt Graham and Gora Datta presented project updates
Consumer Mobile Health Application Functional Framework (CMHAFF) - many APIs in use, few meaningfully connected with standards - create a framework for standards-based API
MFAST - provide some standards for SMS-based content
Other: investigate FHIR resources to support resource and data type special needs for mobile health
HCD will continue practice of joint meetings with Mobile Health at next WGM

Further discussion of mission, charter, and SWOT documents. Consensus was to reaffirm current decision making practices, to make mission and charter emphasize semantic interoperability and device models, and generally update to better reflect current environment and activities. All agreed that detailed "wordsmithing" at the meeting would be inefficient. SWOT should list succession planning and backups for leadership roles as

a need / weakness. Another challenge is managing online conference timing challenges posed by time zone differences of Europe, east Asia and US participants.

ACTION: Rhoads agrees to draft revisions reflecting the conversation at the meeting, and present them to a workgroup phone meeting for further discussion and eventual vote. Also will check whether Statement of Understanding with CLSI is still in force.

Devices on FHIR discussion: Participation in [Madrid FHIR Connectathon](#). Preparation of issues for discussion with FHIR management group scheduled for Q1 Thursday (QA items, proposed resolutions, questions about roadmap and schedule for next major revision of specification)

Discussion of progress and remaining issues for harmonization of Personal Health Device and Point-of-Care Device FHIR approaches and profiling.

Thursday Q1

Meeting of HL7 Health Care Devices Work Group continued.

Welcome and introductions

HL7 Intellectual Property Policy

Joint Meeting with FHIR

Feedback requested on existing QA rules and procedures. Are mappings to RIM being looked at? Look at application of workflow patterns

Review of open issues with DeviceComponent and DeviceMetric resources

From FHIR representatives: Review of schedule leading up to release 4. There will be two ballots:

- Certain identified, well-proven resources will be normative, less mature resources will be identified as not yet normative and on a different ballot
- "For comment" ballot December 2017
- Q&A of FHIR Management with DEV WG on various minor clarifications and general design advice

HCD votes: make "identifier" cardinality 0..* in DeviceComponent (was 1..1). In favor 14-0-1

- make "identifier" cardinality 0..* in DeviceMetric (was 1..1). In favor 14-0-1
- Change usages of URL for 11073 nomenclature into OID. In favor 14-0-1
- There was discussion of "open-ended" codings in the resources (permitting values other than those enumerated). No vote, discussion deferred to future phone meeting

Thursday Q2

Last quarter - meeting of HL7 Health Care Devices Work Group

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Devices on FHIR discussion continued - consider additional feature proposals
Reinhold proposal for open-ended "feature vector" allowing device characteristics to be added without change to the resource definition - further discussed, but decision deferred for future discussion in phone meetings
Review of action items identified in the WGM for resolution in future phone meetings

Dialysis project Project Scope Statement - Lorraine Constable - update and discussion
Approach proposed is different from what DEV members expected and is perhaps not very aligned with other device-related V2 approaches. Includes [proposal for new V2 Segment for device data](#)
. Members will study and possible responses will be discussed in ongoing phone meetings.
Cross-Paradigm IG Medical Device Interoperability PSS - members reiterated continuing concerns about unrealistically broad scope, lack of specifics on deliverables and team. Will discuss with Patient Care WG.

Given the volume of issues accumulating for discussion at phone meetings, adding some extra time to current FHIR-focused weekly meetings was proposed and will be resolved by email.

Last Madrid WGM meeting of HL7 Health Care Devices (DEV) Working Group adjourned at end of Q2.

Session Attendee Lists

Attendees, Monday Q2

Jan Wittenber (IEEE 11073)
Chris Courville (Epic)
David Gregorczyk (Draeger)
Bjorn Andersen (University of Luebeck)
Clem McDonald (U.S. National Library of Medicine)
Ken Fuchs (Draeger)
Asim Muhammed (Philips)
Koichiro Matsumoto (Nihon Kohden)
Masato Tanaka (Nihon Kohden)
John Garguilo (U.S. National Institute of Standards and Technology)
Michael Faughn (Prometheus Computing)
John Rhoads (Philips)
Malcolm Clarke (British Standards Institute)

Attendees, Monday Q3

Jan Wittenber (IEEE 11073)
Chris Courville (Epic)
David Gregorczyk (Draeger)
Bjorn Andersen (University of Luebeck)
Ken Fuchs (Draeger)
Koichiro Matsumoto (Nihon Kohden)
Masato Tanaka (Nihon Kohden)
John Garguilo (U.S. National Institute of Standards and Technology)
Michael Faughn (Prometheus Computing)
John Rhoads (Philips)
Malcolm Clarke (British Standards Institute)

(online)
Beth Pumo (Kaiser Permanente)
Brian Reinhold (Lamprey Networks)
Daidi Zhong (IEEE 11073 PHD Chair)
J.-Üwe Meyer (MT2IT)
Kathryn Bennett (IEEE-SA)
Stefan Karl (Philips)

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Attendees, Monday Q4

Jan Wittenber (IEEE 11073)
Chris Courville (Epic)
David Gregorczyk (Draeger)
Bjorn Andersen (University of Luebeck)
Ken Fuchs (Draeger)
Koichiro Matsumoto (Nihon Kohden)
Masato Tanaka (Nihon Kohden)
John Garguilo (U.S. National Institute of Standards and Technology)
Michael Faughn (Prometheus Computing)
John Rhoads (Philips)
Malcolm Clarke (British Standards Institute)

(online)
Beth Pumo (Kaiser Permanente)
Brian Reinhold (Lamprey Networks)
Daidi Zhong (IEEE 11073 PHD Chair)
J.-Üwe Meyer (MT2IT)
Kathryn Bennett (IEEE-SA)
Stefan Karl (Philips)

Attendees, Tuesday Q1

Jan Wittenber (IEEE 11073)
Chris Courville (Epic)
David Gregorczyk (Draeger)
Bjorn Andersen (University of Luebeck)
Ken Fuchs (Draeger)
Koichiro Matsumoto (Nihon Kohden)
Masato Tanaka (Nihon Kohden)
John Garguilo (U.S. National Institute of Standards and Technology)
Michael Faughn (Prometheus Computing)
John Rhoads (Philips)
Malcolm Clarke (British Standards Institute)

(online)
Beth Pumo (Kaiser Permanente)
Brian Reinhold (Lamprey Networks)
J.-Üwe Meyer (MT2IT)
Stefan Karl (Philips)

Attendees, Tuesday Q2

Jan Wittenber (IEEE 11073)
Navid Fazel (Telexiom AG)
David Gregorczyk (Draeger)
Bjorn Andersen (University of Luebeck)
Ken Fuchs (Draeger)
Koichiro Matsumoto (Nihon Kohden)
Masato Tanaka (Nihon Kohden)
John Garguilo (U.S. National Institute of Standards and Technology)
Michael Faughn (Prometheus Computing)
John Rhoads (Philips)
Malcolm Clarke (British Standards Institute)
Chris Courville (present for last part)

(online)
Beth Pumo (Kaiser Permanente)
Brian Reinhold (Lamprey Networks)
J.-Üwe Meyer (MT2IT)
Stefan Karl (Philips)
Martin Kasparick (University of Rostock)
Daidi Zhong (IEEE PHD Chair)

Attendees, Tuesday Q3

Same as above with the exception of John Rhoads

(online)
Beth Pumo (KP)
Paul Schluter (GE)
Stefan Karl (Philips)
Brian Reinhold (LNI)
Daidi Zhong

Attendees, Tuesday Q3

Same as above with the exception of John Rhoads

(online)
Beth Pumo (KP)
Paul Schluter (GE)
Stefan Karl (Philips)
Brian Reinhold (LNI)

Daidi Zhong

Attendees, Tuesday Q4

Same as Q3,
Plus
 Adamu Haruna (Nokia)
 Swapna Abhyankar (Regenstrief Institute)
 Dantel Vreeman (Regenstrief Institute)
 William Jones (DXC)
 J. Uwe Meyer (online)
Minus
 Brian Reinhold (online)

Wednesday Q1 Attendees

Jan Wittenber
Chris Courville
David Gregorczyk
Bjorn Andersen
John Garguilo
Michael Faughn
John Rhoads
Malcolm Clarke

Online
 Beth Pumo
 Brian Reinhold
 Stefan Karl

Wednesday Q2 Attendees

Jan Wittenber
David Gregorczyk
Bjorn Andersen
Ken Fuchs
Asim Muhammed
Michael Faughn
John Rhoads
Malcolm Clarke

Online

Stefan Karl
Beth Pumo
Kathryn Bennett

Wednesday Q3 Attendees
Same as previous

Wednesday Q4 Attendees
Same as previous

Thursday Q1 Attendees
Michel Rutter (Furore)
Reinhard Egelkraut (HL7 Austria)
David Gregorczyk
Bjorn Andersen
Koichiro Matsumoto
Masato Tanaka
Nicola Ryzhikov
Dennis Patterson
Michael Faughn
John Garguilo
John Rhoads
Malcolm Clarke
Ewout Kramer
William Jones
Adamu Haruna (Nokia)
Charles Parisot (GE)
Lorraine Constable (O & O)

Online
Beth Pumo
Brian Reinhold
Paul Schluter
Stefan Karl
J. Uwe Meyer

Thursday Q2 Attendees
David Gregorczyk
Bjorn Andersen
Koichiro Matsumoto

Masato Tanaka
Dennis Patterson
Michael Faughn
John Garguilo
John Rhoads
Malcolm Clarke
Ewout Kramer
Adamu Haruna (Nokia)
Charles Parisot (GE)
Lorraine Constable (O & O)

Online
Beth Pumo
Brian Reinhold
Paul Schluter
Stefan Karl
J. Uwe Meyer