

JIC Executive Meeting

Sunday 29 April 2018

13:00-17:00 local time (16:00-21:00 UTC)

Minutes of Meeting

Location: Rio de Janeiro Room, Hotel Metr pole, Maring , Brazil

Attendees:

1. Welcome, roll call, apologies

The JIC were welcomed to the meeting and the attendees, apologies and guests are recorded in the table above.

2. Minutes from previous meeting

The Chair asked the JIC to approve the minutes from the previous meeting, CHA moved to approve, and this was seconded by TCO. The minutes from 14 March 2018 were approved unanimously.

3. Agenda approval, requests for other/new business

An item on eStandards Workshop was added to the agenda and the order of items was changed.

4. Review of action items from previous meetings

- The actions on UDI to be covered during the meeting.
- Process for improving approval processes for JIC. Each organization was to signify if there was a fast track that members could represent their vote immediately. PST follow up on this.
- Adding SKMT to communications – this action has been assigned to MGL
- Draft package of materials regarding communications for MGL.
- Review HL7 paper, MGL has this as an action as part of communications.
- PSSS will be presented at Open Plenary in Brazil by DNE.
- Social media interview is still open, JMI to follow up with DSW.
- Adding IDMP to JIC communications - this action has been assigned to MGL.
- MGL to add Olympics communication - this action has been assigned to MGL.

Action 1	JMI and PST to group all Communications under one item to track.
Action 2	JMI to follow up with PST regarding all actions and updated information to be ready for the next meeting.

5. Unique Device Identifiers

The JIC were given a presentation on Unique Device Identifiers (UDI) by CHA.

Initially the work focused on addressing supply chain issues (e.g. 2010 PIP breast implants supply chain scandal). A Regulator noticed that there was no identification with medical devices and where there was a barcode; it was not necessarily being read.

The US has a UDI program, led by the FDA, as does Europe.

In Europe there is a roadmap similar to that in the US which will start in 2020, in which manufacturers will have allocated an identifier on every medical device they are trading. That will be populated in a database. There will be a time table for implementation. This is everything that is currently on the market today in Europe.

Three elements of semantics - what is the item, how to Identify, capture and share the information (which is a GS1 characteristics as well).

GS1 and ISO are close together, GS1 standards are mostly ISO compliant.

The Basic UDI-DI is the main key to access device data across EUDAMED. (See Summary of EU “Basic UDI-DI” slide for summary).

GS1 has adapted this from the standards. The idea is for this to be global as opposed to being healthcare specific. US UDI does not require traceability, but in Europe it is required.

DNE asked where the UDI definition resides, and whether it will be possible to look to GS1 to identify this? It was noted that GS1 is not a regulator. Can say our standard is fit for purpose. UDI is only defined by a regulatory agency, not by an SDO.

EHA noted that MDepinet of the FDA is doing similar work to GS1 and the two groups should be connected.

TCO asked whether there is a way to allocate IDs software as a medical device? SG responded that the US and Europe does not see this the same way. As of 2020 the EU regulation will be stricter, especially for software. Class 1 software will become Class 1A and will need to be certified.

CHA noted that multi-component devices in US do not need to be identified, whilst in Europe they will need to be.

IMDRF has a website that is publicly available and talks about the need for standards, especially for software, but makes recommendations only. There a large group demand for standards.

At this point this is informational and going forwards JIC should track this, especially for medical device identifiers.

MGL noted that the missing pieces of this are important and asked whether it should be broken down into smaller pieces? There is always a difference between regulatory vs. standards. Since the JIC has the regulators around the table it was asked whether advantage could be taken of this in ISO/TC 215 and collaborate with TC210 and TC62. Something to consider.

Action 3	CHA to bring cross SDO collaboration on UDI back to the JIC when the timing is suitable.
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6. ISO Workforce Technical Specification

The document attached above was presented to the JIC by Beverley Knight of Infoway. It provides tasks, roles, skills, and competencies for those who want to work in terminology in healthcare organizations. Canada has started to develop a certification process around this.

JIC Opportunities and call for action:

- Explore integration of the specification within educational programs being offered by JIC members.
- Pursue some collaboration with WHO so that at least a precis of this specification might be made widely available to low and middle-income countries.

EKE asked what focus is and was informed that the terminology is the focus. It doesn't specify the curriculum, but rather focuses on what skills are needed, and the curriculum will then be developed from this. This will help education providers know where the gaps are and help employers understand what is really needed to do this job. It is managing expectations.

MNU noted that IHE offers some levels of training and now is launching a webinar, this could be an opportunity for collaboration.

BKI noted that for NIH this is connector and would like to follow up.

Action 4	BKI to follow up with BKN with regards to collaboration with NIH.
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DNE suggested this be promoted to use with national member bodies as part of the ISO/TC 215 and do an article with ISO Focus using Canada as the use case.

EKE noted there are opportunities for qualified personnel in digital health and that it is very important to create career pathways.

RDH supported the need for expansion beyond TC 215 within digital health. Having a certification has benefits and it is up to the NMB. It would be good to have training materials to be able to sell the products, and the JIC could be used as a vehicle for free sales pitches, similarly to what was done with PSSS.

EHA noted that this was presented to HL7 and there is value in it. It is a temporary solution and there are many terminologies with political overheads e.g. RxNorm. The transition across terminology to modes is another issue. The JIC should consider looking at ontologies and look beyond the well-known clinical terminologies.

PAS informed the JIC that in CEN there are topics around national and regional repositories for both payment and clinical services, but there are also issues with identifying a unique ontology or terminology to support these repositories with integrated data. Integration of data is an important discussion which is needed.

Action 5	SGO to share the ISO Workforce Technical Specification presentation with CEN.
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MGL informed the JIC that WG3 and WG6 may be able to work together on this area.

JMI said the document references healthcare organizations and employees and then talking about education – what is the scope of what this document applies to? SNOMED International works to find best people for terminology work and maintenance of the terminology, so is this of benefit to SI.

BKN informed the JIC that this specification is designed for the workforce and is geared towards people working on projects who both need to understand terminology and to implement it. It goes to the level of being broader for each terminology and is more about understanding and being able to apply this. There is value to have each organization to integrate some of the items listed in the specification.

A question to consider is how could this be made available to low and middle-income countries (LMIC)?

MGL: Request ISO/CS to make this available to LMIC.

Action 6	ISO/CS to make the specification available to LMIC.
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Action 7	DNE to contact ISO regarding an article in Focus on the Technical Specifications, in the form of an interview with BKN and Kelly Abrams.
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7. Olympics Initiative

MNU provided the JIC with an update regarding the Olympics Initiative, based on the attached presentation.

8. JIC Signature Events

RDH presented the JIC a summary of major events leading to and conducted within JIC. The key steps to where the JIC is today were:

- National e-health programs 2005 (National eHealth Leaders).
- IATA Conference 2006 (Vendor perspectives).
- GHITS Summit 2007 (clinical perspectives from a provider point of view and provider organizations). Major outcome with ISO/TC 215, CEN/TC 251 and HL7 to come up with a charter for the JIC started in 2007.
- GHITS Summit (Client/Patient perspectives in 2008).
- GHITS Summit 2009 (Sustainable Healthcare IT Funding).

Action 8	MNU and RDS to discuss possible actions to obtain missing GHITS information from HIMSS.
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Some observations and conclusions were as follows:

- Evolving roles of national/supranational eHealth programs –institutionalisation of core eHealth services
- Cornerstone roles: patient and provider identifiers, patient summary, ePrescription and, for many, a health insurance/EHR access card
- Others include: shared EHR, identification & security management frameworks, maintenance of clinical terminology & code sets
- Use of certified EMR systems to improve the quality of clinical care → needs for measures to support and encourage “meaningful use” of such systems
- eHealth standards should support business sustainability & complementary uses of healthcare data (cost reduction; healthcare safety, quality, effectiveness; energy efficiency; environmental protection)
- Effective application of standards requires coordinated work on 5 key areas:
 - (1) Use case definition and prioritisation
 - (2) Base standards development
 - (3) Profile development and maintenance
 - (4) Conformance test plans and tools
 - (5) Sharing of best practices in deploying eHealth projects
- The return on investment (ROI) for healthcare IT does not go to healthcare organizations - the benefits flow to citizens and payers
→ community funding support for adoption and use of Health IT may be essential, but funding standards is not as ‘attractive’ as funding new technology or science
- Sustainable funding models should be developed by governments - Incentives should be provided to healthcare organizations where EHRs have effectively been utilised
- Evolution of business strategy driven by technology in the broader business environment
→ threats/opportunities for organisations and traditional ways of business
→ significant challenges/ barriers for Health IT standardization to participate in this business environment
→ Challenges/barriers include IP rights & costs to users of ISO/IEC/NMB business models
- The JIC operates between SDOs - how can its activities relate to formal adoption and national coordination?
- Common reliance on volunteer effort with knowledge and skills sets across SDOs – need to harness this more effectively

- A proactive posture for elevating awareness of Health IT standards based on SDOs includes:
 - Interacting with government
 - Working with industry
 - Providing user education, and
 - Developing certification standards

A review of the JIC's activities was presented as follows:

- Working group on prioritisation & process for health IT standards development proposals → ISO adoptions of global standards
- Engagement with WHO & others on eHealth Standards for Low & Middle-Income Countries – sponsorship of LMIC report
- Representation at WHO eHealth Architecture workshops and engagement with WHO/ITU on eHealth planning guidelines
- Representation of JIC participants at WHO sponsored events:
 - WHO Forum on Health Data Standardization and Interoperability
 - Joint Inter-Ministerial Policy Dialogue on eHealth Standardization
- Representation and opportunities to participate on international collaboration projects initiated by US-ONC and EU/EC
- Support for EU e-Health INTEROP, establishment of eHealth standards platform in Europe and subsequent eStandards work
- Completion of PSSS & support for OHI initiative.

The JIC discussed how best to move forwards

MNU suggested possible signature events such as the GHITS Summits or other offsite meetings to bring more focus back.

EHA noted that the JIC started with HL7, ISO/TC 215 and CEN/TC 251 and asked what can the JIC can do more strongly together than separately.

BKI suggested that the JIC continue to provide detailed reports at ISO/TC 215.

Action 9	PST to add Signature Events to the next meeting agenda for discussion of their resumption.
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9. SKMT Update

HGR gave the JIC an update on SKMT.

There are currently instructions on how to upload information and any further ideas are welcome. SKMT is going to produce a user video.

There is an FAQ section to support any questions, which is also used to collect any issues with the tool. There is an internal Google group document repository. The SKMT team has fixed the bugs and now are looking at suggestions. Requesting the JIC to review the list of suggestions and putting priorities around this.

Next steps are to consider how to get organizations to use this tool.

On a weekly basis the SKMT is cleaning the information and retiring terms.

The number of terms is going up versus the number of definitions against them is going down. There are now only 33 terms with more than 5 definitions.

MNU also noted that the JIC and SKMT have formalized the SKMT agreement with the University of Sherbrooke.

Action 10 HGR to discuss at the next SKMT governance committee to identify the priorities and to present these to the next JIC meeting.

10. eStandards follow up by JIC (for information) – Robert Stegwee

SGO informed the JIC that eStandards is moving forward in Europe and that CEN had a follow up in their May meeting.

RST noted that the Roadmap has been re-worked for the eHealth standards group and that it will come back to the Autumn meeting of the key stakeholder group and that he is pushing forward to get the document published alongside an opinion paper.

Highlights from the eStandards Workshop:

1. Support the full Health Informatics Standards life cycle
2. Target joint engagement in key initiatives to get expression of needs from the four perspectives identified
3. Explore the eStandards CGA-model to make sure the Health Informatics Standards community supports bottom-up digital health innovation
4. Position processes around PSSS and SKMT as a means to support the life cycle and CGA-model
5. Keen to evaluate the eStandards recommendations within the OHI context

It should be ensured that the JIC members deliver standards supported by the users and community.

RST: Proposed next steps:

1. Revisit the eStandards roadmap methodology
2. Engage OHI initiative to review the roadmap
3. Consider the eStandards recommendations in setting up PSSSS maintenance and engagement

DNE noted that there has not been much movement on this for six months and asked, if the JIC is to be involved what the communication process and timeline are.

MNU suggested that, as there has been a time lag between the original presentation and now, it is up to the JIC to discuss how to move this forward. The OHI and PSSS already have a commitment and JIC is reviewing the eStandards. There are teams of members already meeting regards this offline. The JIC now needs to review what to do with the roadmap and it was suggested that the JIC take this particular item and share it with colleagues

Action 11 JIC to share the eStandards roadmap with their colleagues.

Action 12 PST to add eStandards to the next JIC agenda.

CCH informed the JIC that HL7 Europe have been active in consolidating the work and reaching out to stakeholders. There are different umbrella organizations within EU pharma and a wide range of stakeholders with different agendas and different priorities. Making the roadmap for these groups is very important for them. They are also working with the PH Alliance who are very keen to focus on the inequalities. There are a lot of different applications of the framework – there are three main groups:

- the Directive for health
- the IT(?)
- the consensus process of ehealth stakeholders.

Action 13 JMI to organize a call for RST and the PSSS team.

Action 14 MNU to discuss the next steps for OHI.

11. PSSS Maintenance

There was no discussion of this item at the meeting.

12. Build a list of what the JIC should do in the next 2-5 years.

- a. MNU: Additional JIC Signature Events
- b. MNU: Support the establishment of Standards Collaboratives nationally around the world (e.g. as per Canadian model)
- c. BKI: Establish genomics as a cross SDO JIC activity
- d. DNE: Develop additional Standards Sets
 1. Genomics
 - Cybersecurity
 - Mental health
 - Opioids
 - Virtual health
- e. HGR: Address problems with implementation e.g. terminology mapping, conformance testing
- f. CHA: Investigate standards uptake and use, and establish feedback mechanism
- g. SGO: Initiate a review of standards alignment across SDOs
- h. SGO: Investigate SDO alignment of standards to support health and wellness apps.
- i. PAS: Investigate uptake of standards sets to determine how they address the need.
- j. BKN: Develop a marketing program to describe the benefits of implementing standards in eHealth programs, and how it can make a difference to an individual.
- k. EHA: World has changed significantly since JIC has come together, look at what everyone else is doing
 1. Determine how the JIC can support and influence the success of government implementations of standards developed collaboratively by SDOs.
 2. Establish a program to ensure future standards development is done amongst SDOs without duplication or competition, drawing collaboratively on the skills and knowledge available across SDOs.

Action 15	PST and JMI to create and distribute a survey based on the list above and distribute to the JIC for their feedback.
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13. General discussion

DWA suggested that there be a review the membership of the JIC and asked whether the JIC has the relevant stakeholders? The JIC should perhaps consider adding regulators to the group.

14. New Business - Deferred

There was no new business put forwards.

15. Next meeting and adjournment (adjourned 17:35)

The meeting adjourned at 17:35 local time.

The next meeting is a teleconference, on Wednesday 11 July at 20:00 UTC