

JIC Executive Meeting

Wednesday 6th July 2016

20:00-21:00 UTC

Record of Discussion

Location: Teleconference via GoToMeeting

Meeting documentation:

<https://confluence.ihtsdotools.org/display/JIC/2016-07-06+-+JIC+Meeting>

1. Welcome, Apologies.

The Chair welcomed the Council members to the meeting. Apologies are noted above.

2. Minutes of last meeting (20160501 – face-to-face in Amsterdam)

Approved. An abbreviated 'Record of Discussion' will therefore be posted on the JIC website.

3. Agenda approval, requests for AOB

Agenda approved. No new business was raised.

4. Review of actions from previous meeting

Action list: <https://confluence.ihtsdotools.org/display/JIC/JIC+Action++List>

Outstanding Actions:

- **20160501-01, JIC Standard Set Work – Patient Summary:** DSW to contact the WHO re clinical engagement for Standard Set work.
Update on 20160706: DSW reported that he has a call with WHO next week, so will report progress on the next call.
- **20160501-02, JIC Standard Set Work – Patient Summary:** PSSS group to prepare updated materials so that a focused call for clinicians can be issued. *(see item 6 below)*
- **20160501-03, Unique Device Identifier:** UDI document to be updated with a chapter and annex *(see item 7 below)*
- **20160501-04, Unique Device Identifier:** Final review by small group should include the HL7 representations. *(see item 7 below)*
- **20160501-05, Unique Device Identifier:** JIC Member Review (ALL) *(see item 7 below)*
- **20160501-06, FHIR:** A FHIR discussion to be added to the agenda in November, including what HL7 want from the JIC and SDOs.

- **20160501-07, e-Standards Development Lifecycle Discussion:** Comment and or approval to be sought from each SDO (ALL) (*see item 8 below*)

5. JIC Standards Set Work – Patient Summary

An executive gave the following presentation:

[JIC PSSS key points for discussion](#)

They said that the work-plan would be revisited to look at timelines, and that the sub-groups next call was scheduled for the next week. They stated that they would email to update to the JIC after that meeting re an update on timelines. An executive on the PSSS group agreed that good progress was being made and that the consulted physicians understood the patient profile for a use case, and they looked forward to finishing up this stream of work over the summer. On the questionnaire, an executive on the PSSS group explained that it came about in the joint CEN/ISO meeting in Amsterdam, thinking that ISO attendees could be consulted as to what they consider to be a patient summary, to help with guidance aspects of what to put in a summary set. A draft was sent locally for input from the CEN and ISO working groups, along with the JIC standard set sub-group, and also to the e-Standards project. They are updating the questionnaire and he hopes to complete it over the next month or so. It is an attempt to ‘horizon scan’ and make sensible guidance for standard sets.

An executive on the PSSS group ran through *Discussion Point 1: (On ownership and governance)*

An executive said that it was correct that the JIC can't own the Standards Set so it should be a formal SDO, with a wide coverage (like ISO or IHE). Another executive agreed, saying that the JIC will produce a considered piece of work and they had imagined that ISO would then manage it, supported by IHE profiles. An executive said that HL7 need to give their perspective, as this is a thorny issue considering that profiling is also happening with FHIR. And also, the issue is that some standards are free, whereas others are on a subscription basis, so their business model needs to be considered. An executive on the PSSS group supported the idea of ISO being the home for it, being complementary to the ISO reference portfolio work. In terms of ownership and maintenance, it is hard to define until we know what the final content the JIC produces will be. They questioned what would be necessary to maintain, other than as standards and use-case requirements change, so whoever takes this on will have to repeat multi-SDO work to update this. An executive asked how ISO could maintain something unless it was a TR? They stated that there would need to be a mechanism - like a TR or whitepaper - so it goes through ISO/TC215. An executive agreed, saying the issue is that the JIC is ‘laying track’ at the same time as writing. The JIC has already said in its Charter that it does not create standards. The question is important to ask, but they stated that the final work would be more informative than normative, so it may not require maintenance. It will be guidance for the next time, but the answer will always be different depending on whose domain it is, and where the experts are. An executive said in legal terms, recognising that there is a series of activities that flow from this, the JIC does need credit and the material should be freely available (which it wouldn't be as a TR in ISO). They asked is there a mechanism to put it up publicly on the JIC website – perhaps as a report? It could then flow into ISO as a TR. The organisations of the JIC could be joint owners, although some on the Council are acting as individuals rather than just for their corporations. They stated that the earlier point about HL7 was valid too. An executive said they hoped that all JIC members would sign off on the work, though they wouldn't underestimate the importance of further maintenance to ensure relevance is kept. There would need to be

a “custodian” on behalf of the JIC. Another executive agreed, saying that one of the first premises of the work that it would be freely available.

To summarise, the JIC Chair said that the JIC needs to finish the work, have the JIC’s SDOs sign off on it, and then have it shared on the website. A discussion can then be had in Norway about the on-going process of ensuring relevance, and how we manage maintenance and changes to the initial report. We can adapt as we go along. If someone then steps forward as a custodian (such as ISO) then that can be addressed in the future. Those on the call agreed with this approach.

To conclude, an executive on the PSSS group said there needs to be some statements to this effect in the delivered document to help stave off any questions. The chair of the PSSS group agreed to ensure this happened.

Action 1	The Chair of the PSSS group to include a statement about ownership and maintenance in the final Standards Set documentation.
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Point 2 (Conformity Assessment)

An executive on the PSSS group said that they wanted to note that the slide talks about the question of harmonizing to a single standard, or instead compiling “all relevant standards.” Their Standards Identification Task Group has put together the criteria for including standards within the standards set, but they are talking more about a “master set” where the aim is to eliminate overlaps as much as possible. So the approach his group is taking is to identify this master, or initial common set. It was agreed to update the wording accordingly.

An executive said they would like it to refer to conformity processes of the SDOs involved, rather than being up to the JIC to develop a new process. An executive on the PSSS group replied that we could all assume that the Conformity Assessment work will include recommendations on a framework, a lot of it drawn from ISO. The question is - how far beyond that does the JIC go? What standards will end up on the master list, as some have very strong conformance, and others do not? Another executive suggested as a matter of process – how far does the JIC go, and how far do others go? Assessment is the next step, and the JIC is merely trying to come up with a framework. The JIC needs to decide when to hand it over, without creating harmonization issues further down the track. Another executive agreed to this, saying that there are great experts in the group that should establish a framework to resonate with everyone. They said they were now comfortable with the answers to this issue that were given on this call.

Point 3 (Standard set v’s IHE profile)

An executive on the PSSS group asked - can we articulate what we are trying to accomplish – not singling out IHE as it could also be relevant to FHIR and the work of other SDOs? Can we articulate what we hope to achieve, and how can we convince our market that we have raised the bar to a higher level, and how do we define that level? An executive replied that with IHE you start out with a use-case, and then look at the available standards, reduce overlaps and define how they will be used, so in this case it does sound a lot like an IHE profile. Producing something less prescriptive or rigorous than an IHE profile, which is more general but may therefore be seen as lesser in quality. The thing to be careful about is – have you done a full job? As if you can make those decisions then why not do it within IHE? Another executive on the PSSS group replied that they thought there was a lot to be said for disentangling the standards set from IHE profiles – they didn’t think the standards set had the authority to pick a particular thing or to say it’s harmonizing, so in their opinion - to identify what they are, and where they are, is a valid thing for the standards set. To go beyond that, however, raises issues about authority and what people can expect. Another executive agreed, saying that standards sets have to recognise that there are some decisions that

cannot be made globally but that it can narrow the choices. It then means that conformance becomes a little less tractable. The executive on the PSSS group agreed – saying this was all going to go back to other PSSS group, assembling this ‘master list.’ They agreed that the JIC only has the authority to identify overlaps. Another executive on the PSSS group agreed, saying they will start to apply the criteria once the use case is done. Another executive said that European e-Standards Project has been having discussions about the European Health Interoperability work where they say that there is a standard set but there is also something called the “Realisation Scenario.” They are still trying to figure out how the two are different. They offered to leave the discussion open and contribute to it from a European e-Standards perspective. Those on the call said they would be interested to hear more on this.

6. Unique Device Identifier (UDI) update

An executive reported that DICOM has been putting through a change proposal, basic idea to include UDI as a storable field in images, with recalls etc. Discussion over how formatted it should be, and it was decided that the best way was to just store the human-readable form, as any device interested in UDI will have to parse human-readables. Format quoted reference from FDA that they should all be ISO/646 characters, with no limitations in length.

7. eStandards Development Lifecycle Discussion

Notes: A revised endorsement statement was circulated to JIC executives on 3rd May 2016, asking for each SDO to follow its internal process to endorse the deliverable in the context of the JIC and accept (or reject) the revised wording in attached document. Alternatively, if organizations were also willing to provide an individual letter of endorsement for this deliverable, this was also welcomed.

An executive reported that they had received endorsements from GS1 and one from CEN, so they were still waiting on others (though they apologised for not following up further due to other commitments). The JIC Chair stated that the IHTSDOS’s process would be completed next week. Another said that the European Commission had accepted the deliverable from a project management point of view. They had mentioned to them that he was reaching out to the JIC and the Commission had welcomed this warmly.

Action 2	A follow-up to be sent to those SDOs who have yet to respond.
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8. New business

No new business was raised.

9. Adjournment

The meeting was adjourned after the Chair thanked the attendees for their time.

10. Next meeting

Confirmed as a teleconference on Wednesday 28th September 2016 (20:00-21:00 UTC)