HL7 CIC – Opening Plenary Session **Location:** Paris, France		**Date:** 11 May 2015 Monday **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
	See Attached Roster		
Quorum Requirements Met:			

Presentations introduced by Chuck Jaffe.

- Philippe Burnel, French eHealth update
- Nicolas Canu, Chair of European HL7
    - In France the Carte Vitale was introduced in 1999 to manage patient information and identification problems. Pharmacists are very motivated to use HL7 standards; other groups are 'stuck'.
    - ICD-10 is widely used, LOINC has consensus but not actual use. Trying to find a way to use SNOMED-CT. Building services to share value sets, conceptual domains, more.
    - France has a strong initiative to protect information for privacy. Recently it was decided to use the national SSN, issued to each citizen, to access and index all patient information.
    - Transformative health care requires paradigm changes in organizations, technology and methodology. The patient must become an empowered citizen before becoming an empowered patient.
    - **Interoperability in decentralized distributed environments requires shared knowledge and skills to adequately establish cooperating systems.**
    - Interoperability is built on users' domain, to meet business objectives, to share knowledge, not on IT. The business defines naming of concepts and modeling decisions.
- John Gachago, HL7 Africa Ambassador, low and middle income countries (LMICs)
    - Lack of investment in HI education and HIT
    - Reliable infrastructure may be absent
    - Interoperability myths
    - What is in it for me?
    - Governance and policy issues
- Bobby Jefferson, Technology in LMICs, experience with Ebola outbreaks
    - Open systems must be used because they cannot be sustained if the solution requires a payment

HL7 CIC – Multi-group Report of Activities to Highlight **Location:** Paris, France		**Date:** 11 May /2015 Monday **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

Patient Care included mention of the NI2016 showcase presentation from HL7 Nurse Group that was accepted for presentation in June 2016.

HL7 CIC – Joint Meeting with RCRIM and CBCC on Bipolar Project – Covers Substance Abuse and Mental Health **Location:** Paris, France		**Date:** 12 May 2015 Tuesday – Q1 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

Use case: prisoners released by the Criminal system now have to wait 60 days to receive substance abuse and mental health counseling.
Use case: Maternal healthcare needs post release from judicial system setting

Update from Anita: Project has been approved by TSC. James Topping has been extracting the data elements from FDA reports as part of the FDA Therapeutic Area development.

Mary Ann Slack from the FDA commented on the FDA's need for data elements. PDUFA V is a set of user-fee set of commitments with industry. Standards will facilitate efficacy analysis of new drug analysis. FDA wants to tackle this incrementally so they can get endpoints that can be used for cross-trial analysis. Approval or non-approval of a drug is the end goal of standardizing data elements.
Data elements have been synthesized and will be reviewed by the FDA before going to a clinical expert group to review them. (CERC review) Plan is to ballot in September 2015

Abstracted 220 elements from 23 trials, 55 questionnaires
Scope of the project is for Bipolar I.
This is a model of how the FDA is collecting elements to approve a drug, not a model of the condition itself. This is the set of FDA internal requirements. Want to keep the scope down to something in a reasonable timeframe, and making sure that stakeholders are engaged. Lori Simon recommended if Bipolar I and Bipolar II are done together, it would be more time-consuming upfront because most of it would already be done.

An informative DAM will be balloted. CBCC is trying to develop models that can be used for as general purpose as possible. Lot of discussion about the scope of elements needed; some of the elements may be needed for secondary analysis.

<u>Model:</u>
In the last WG meeting (January 2015) the advantages and disadvantages of a common mental health DAM vs. individual DAM for each condition was captured. After the data elements are captured the elements go to CDISC for creation.

Option 1 for separate model for each disorder
Option 2 for a combined model for mental health disorders into one model

- Common models can be harder to use because the level of abstraction is higher, and people have a harder time understanding it.
- Common models will also be harder to ballot because in ballots of changes the earlier content will also end up being reviewed and balloted.

Option 3 is a hybrid approach, where the data elements common across all areas are used across all conditions; but the elements specific to one condition will be balloted.

- But it is important to include all the common elements so that reviewers can identify with the content and not think that things are missing.

- But when they get too big and abstract, the models are not useful
- This is not an HL7 requirement for individual models.

Option 4 is for a common behavioral health model; then disease-specific condition elements can be balloted.

This is a specific use case in the FDA drug application review process. The real question is the interoperability goals of what you are trying to achieve. Are you trying to get information from a special setting, and what are you trying to achieve from the poll process?

Anita: We are trying to scope down the problem, but also trying to keep the big picture in mind to harmonize mental health model with functional profile so that implementation will have the elements.

Lori Simon: The interest of CBCC is to develop a model for mental health that is broad and reusable as possible. The FDA need for data is one use case for the use of mental health data. As you understand more and more uses of the data, that can shape the scope of the model.

- The approach is to gather as much data as possible.

Mead: If you want to model the content that is used over and over in one place, and then show the specifics in the same model, then managing it becomes tricky and takes a lot of work. The common model can change over time, and keeping the model coordinated and doing continuous refactoring is a challenge. Separate models can lead to a lack of alignment. That is a real danger. Post-hoc harmonization is a lot of work.

Lori Simon: pointed out that the data elements are the same, but the responses/values to the elements are different.

AMS: Do we maintain one information model and subset it each time we create a DAM? We're talking about an information model with a functional model. This becomes a management issue for the model.

Is it really an option to look at the elements in each type of model and see if the purposes of the models are so different? Or is there plenty of opportunity for reuse and overlap. Is this a federated model that has different parts with the need for governance?

Building views is important to consider – values of the elements and the setting of how the elements are used represent two views to consider.

For the General Anxiety Disorder project can we start moving in the direction of a general model?
For the Bipolar disorder we will continue as an individual model in order to meet the September ballot timeline.

CBCC: CBCC can continue by looking at a common model across conditions while CIC continues with their work in order to meet their timelines. CBCC is balloting in September as well.

1. Look for common elements for reuse
2. GAD – continue to move along as before, and CBCC will come to Anita to get our input. CBCC can then engage CIC. It will take too much time to harmonize all the content right now.
3. CIC will continue on and work with CBCC on areas of commonality.

We will meet again at the WGM in September. And include the BRIDG model in the discussion in September.

AMS: What made the decision for me is the fact that both the common and specific models are changing. It's just too hard to keep two changing models in alignment.

For October WGM – meet again Tuesday Q4

HL7 CIC – Update on the Max Tool – Presentation by Michael van der Zel **Location:** Paris, FR		**Date:** 12 May 2015 Tuesday – Q4 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

For October WGM – meeting again while in Atlanta

Review of Project Scope Statement

There are thoughts of considering other modeling tools for use with MAX. It is yet to be determined.

The project scope statement was approved last meeting in CIC but it didn't go further in the process. Approval is needed by Tooling Working group, DESD and TSC. It was also suggested that Publication should be a co-sponsor because the out- put will produce materials for ballot.

January 22nd was the date CIC approved the PSS.

Michael will place the PSS on the Tooling agenda for vote on Thursday during the Working Group then will send it to Dianne Reeves for submission to DESD.

Salimah will be the facilitator for the project to produce documentation

A potential risk is maintenance of the project is to be sure it is in sync with each version of the modeling tool in use.

Next Steps:
Set up a Quarter next WGM in September: Tuesday Q4 – Michael Van der Zel

ACTION:
Michael Van der Zel will place the MAX Tool (Electronic Services and Tool - EST PSS on the ETS agenda for vote on a future call
Michael Van der Zel will send the ETS Group approved PSS to Dianne Reeves to be submitted to DESD
Dianne Reeves will submit the MAX Tool PSS to DESD.
Abdul Malik-Shakir will create a communication plan to include Salimah in the discussion for developing tools.
Add the MAX Tool Discussion to the monthly CIC agenda

HL7 CIC – Trauma Project/EMS Project Updates – Presentation by Jay Lyle, Clay McMann, Other on Team **Location:** Paris, FR		**Date:** 13 May 2015 Wednesday – Q1 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves & Anita Walden
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

For October WGM – meet in Atlanta Wednesday Q1, with the need for a second contiguous Quarter to cover both projects. Either Q1/Q2 or Q3/Q4.

Trauma – passed ballot but there were substantive changes

- A reballot will take place out of cycle for the June ballot. TSC is expected to review the request for ballot during their next meeting in two weeks.
- Current standard is based on 2013 NTDB and TQIP dictionary which is out of date. Update the CDA II to 2016 dictionary. The 2017 data dictionary is just starting.
- January is a reasonable timeframe for balloting. Discuss status in OCT
- Question if to stay with the same project and complete it or just extend the current statement.
- WED Q1 is good for Trauma meeting.
- There has been discussion about quality measures. The college has submitted quality indicator to CMS but it is not based on data that is currently collected by the registry. Prophylaxis abdominal trauma patients. Not meaningful for what trauma surgeons do. Based on the percent of patients that it applies to.
- Finalizing measures should be completed prior to the 2017 data set. National Provider Index has to be created. Decided that these measures will not influence current work
- The professional societies can create their own quality measures but there is a question around if the provider can create their own indicators.

ACTION
Anita will inform the Trauma team of next steps in preparation to ballot
Jay will review the current project scope to determine if it can be extended
Jay will inform CIC when regular conference calls will take place to be added to the HL7 conference call list.

EMS Discussion

- Two negatives will need to be discussed during this session. The other comments are straight forward
- Standard Update Scheduled
- Two versions moving forward at one time the phase out and the new one. Rather than annual there will be no changes for two years.
- March 1st of 2018 will be when the next standard will be updated (next revision cycle).

<u>Adding Hospitalization Outcome to the Standard</u>

- Hospital outcomes is up for discussion but needs to be resolved this Fall. They would like to include hospital outcomes in a report maybe in the form of a discharge summary. This will be a separate CDA. Would like to extend the current project to include it.

- Jay will determine if a new project scope statement will be needed and if so it needs to go to US Task Force. .. It was decided a new project scope statement is needed so it needs to go the US Realm Task Force on Thursday for vote, then to CIC on Thursday for vote, then to DESD by the 24th

ACTION:
Jay will facilitate the New PSS starting tomorrow to obtain votes in time for the 24May PPS deadline
Anita will place notice on bulletin of change in agenda for Thursday Q1 to add EMS Vote for PSS

EMS Ballot Reconciliation

- Review of the ballot comments from EMS May Ballot. The focus is on the negative comments

VOTE
Jay Lyle made a motion to accept the disposition for item number #52
No Discussion
Clay Mann Second the motion
Abstain= 0
Against= 0
Approve = 10

Jay Lyle made a motion to accept the disposition for item number #54
Abdul Malik Shakir second
Abstain= 0
Against= 0
Approve = 10

- Review of the other comments Items 1, 2, 3, 45 and 55

Null Flavors were handled inconsistently (unknowns are null flavors instead of part of the value set in some places. It is also non in alignment, not part of the scope but it does need to be decided in the future of how they should be handled.

VOTE
Items 1, 2, 3, 45 and 55

Abstain= 0
Against= 0
Approve = 10
Jay motion to accept dispositions Items 1, 2, 3, 45 and 55
Abdul Malik Shakir second

Abstain= 0
Against= 0
Approve = 10

They will review the rest of the affirmatives on the next EMS call

HL7 CIC – Joint Meeting with BRIDG, OO, CTG & Joint Meeting with EHR **Location:** Paris, FR		**Date:** 13 May 2015 Wednesday – Q2 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves & Anita Walden
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

BRIDG update – Ballot reconciliation for BRIDG v4.0 ongoing at the meeting, along with an Architectural review of the model.

- Request made for SMEs to help reconcile the comments received from HL7 voters
- Need a set of principles or governance to keep models aligned
- Answer sets are not described in BRIDG

Each module should be driven by the domain experts. The real challenge is to integrate the domains.
BRIDG is now a stakeholder in specimen discussions – and will provide additional scope and use cases.

The BRIDG WG will set up calls and invite people to participate to resolve negative ballots for BRIDG 4.0.

Usability Meeting Ballot Reconciliation

The facilitators John Ritter and Mitra Rocca were not able to attend so presentation was presented by another co-chair
18 Affirmative 23 Negative 87 abstains 24 not voting Total in Pool 152
They will work on addressing the comments during their weekly Usability meeting
HL7 EHR-S Usability WG
Phase I – collect and perform analysis of literature (200-250 references identified)
Phase II – Engage Clinicians and other experts to develop usability framework

Not sure of the status of the White Paper

Future Releases of EHR-S

Included Data Definitions that correspond with the functionality requirements

They are currently obtaining data definitions from FHIR resources. CIC made a suggestion to use current data elements from Patient Care, CIC and other working groups instead of using FHIR. EHR will reference data elements rather than create.

In June they will start conversations around this topic once they have identified a lead.

Question was raised about how the usability standards will be used in light of Meaningful use and ONC. There are a number of groups nationally and internationally that are interested in using if for another certifying body.

EPIC was in attendance and wanted to get involved and asked about including industry usability experts.

Use Case should include Off Line connection (DOD and Home Healthcare)

Is precision maintained as data is exchanged from one system or location (decimal points).

HL7 CIC – Trauma Registry Symposium **Location:** Paris, FR		**Date:** 13 May 2015 Wednesday – Q3 & Q4 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

Non-HL7 experts from Europe invited to participate in this session to present on and discuss issues related to Trauma Registries. Speakers highlighted registry issues such as standards for the registry and other issues.

HL7 CIC – CIC Business Meeting **Location:** Paris, FR		**Date:** 14 May 2015 Thursday – Q1 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

PSS- Keith Boone

- Clinician decisions is not making it into the CCD. There is a document that is 69 pages long but it is not very relevant to the patient care in this case.
- Obtain guidance from clinician to identify criteria to automatically obtain pertinent information. Ex. All active state problems and issues from the last month. The clinicians that are receiving the document need to know what is important but it may be difficult to know the target context for those on the receiving end. In some cases you will know such as an oncology consult.
- Develop a process of outreach within HL7, and those outside of HL7 (AMA, HIMSS….). Figure out to engage, the questions and the input. Put it together in an informative fashion. Then ballot it. How long should the document be?
- Tell an engineer… The problem section includes: which criteria…, meds, and allergies. In this context include this information.

- Keith is looking for assistance in designing an engagement plan.

VOTE

Dianne Reeves motions to co-sponsor relevant and pertinent data in automatically patient summaries.
Anita Walden Second
Discussion – Resources available? Dianne and Anita expressed interest in engaging.

Approve -5
Abstain - 0
Against -0

- Goal is to have a kick off within the next month. Ballot will be in Sept or January. Suggestion was to move it to January because it may take time to engage clinicians.
- Objective of Kick off meeting- Provide overview, scenarios, and start to outline engagement plan.

- May be helpful to prioritize…what are the top items that clinicians want to see?
- US Realm project.
- Dianne Reeves will assist with clinician engagement.

EMS Discharge Summary CDA PSS

Jay Lyle

- Questions were raised about the Risk of the project. Project is driven by the funder and if the funding goes away but that is the case with many organizations.
- ARB may need to approve it because the specifications are external. Jay will talk with ARB today 3rd quarter.
- USRTF will meet at lunch today to review the PSS.

Vote

Motion Moved-Jay Lyle move to accept the PSS
Second – Dianne Reeves
Discussion- No Discussion

Approve - 4
Abstain -0
Against -0

- Jay will inform us when the PSS has been approved by USRTF and ARB.

FHIR Profile Registry
Ed Hammond

- Need a list of all Profiles.
- Ask people to sign up at the beginning of a project instead of prior to vote
- Manage of the process. Need some way of validating the profiles…ballot? A group decision of what goes into the registry. Use Facebook approach, because other organizations like it.
- Content- a set of resources that are separately contained. Some profiles are creating data elements as they are creating the profile. There will be an ultimate set of resources and drag and drop. If resource is not there create an extension which can promote reuse of resources.
- *Needed*: Identifier, description (short narrative of the purpose), set of key words, resources, steward organizations, date created, register interested parties, ballot date, history timeline (extensions creation date), track everyone who downloads, yearly update of who is using the profile (similar to UMLS), extension notifications, need a set of tools for downloading resources and profiles, point of contact.
- Sounds like 11179 requirements
- FHIR working group will be owner of participant of the project.
- Need a single steward (organization) to create the product and the maintenance of the product. The group that can make a determination that there can be extensions. If it breaks the profile then it should be a new profile.
- It is a usability and architecture question. Needs to be easy to find and current. People don't look to find out if something exists. Finding it is a chore. Maybe the registry can resolve this issue.

Should CIC create a Project Scope Statement for this project? Should FHIR workgroup be sponsor or co-sponsor. There are questions of how CIMI will be involved.

The suggestion was to hold off because of lack of resources.

PLEASE ✓ YOUR NAME AND UPDATE INFORMATION

Name		Affiliation	E-mail Address	MON 11 May		TUES 12 May				WED 13 May				THURS 14 May			
Last	First			Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Acker	Beth	VA	beth.acker@med.va.gov														
Allard	Crystal	FDA	crystal.allard@fda.hhs.gov														
Baker	JD	Sparx Systems	jbaker@sparxsystems.com														
Beeler	George	Beeler Consulting	woody@beelers.com														
Bennett	John	Lancet Technology	John.Bennett@LancetTechnology.com														
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Tolk	Chris	CDISC	ctolk@cdisc.org															
Topping	James	Duke	james.topping@duke.edu			x			x	x	x	x	x	x				
Tripp	Ed	Tripp & Asssoc	Edward.Tripp@ESTRIPP.com															
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