**Orders & Observations**

**September Working Group Meeting**

**September 19 – 23, 2016**

**Meeting Minutes**

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| **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** |
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# Monday

## Q3 / Q4 – FHIR/OO/InM/MnM

See meeting minutes by FHIR Infrastructure that hosted a joint session on WORKFLOW.

# Tuesday

## Q1 - OO

### Agenda

* Micro/susceptibility in FHIR
* Future of US Lab realm guides / FHIR IG / DAF
* Future plans for Lab Order Model

### Micro/susceptibility in FHIR

* <https://github.com/Healthedata1/OO-on-FHIR-Micro-Profile/wiki/1.-Home>
* This will have to move to the HL7 github space eventually
* Looking at the logical model:
  + This uses the observation part in the DiagnosticReport
* We no longer have a grouping mechanism in the DiagnosticReport – we should open a tracker item for that;
* Reviewing the list of items for a micro report:

1. A status – is that at the report or at result level? – needs answer!
2. Category of LAB – we should support child concepts of LAB (no longer in the event pattern, so we can define at granular level, it is in DiagnosticReport with example binding)
3. this should be subject rather than patient, so we can accommodate non-living samples like food, water, soil, surface swabs etc
4. should be date/time or range
5. reporter – is that organization or person? (= performer in base resource)
6. result – how to handle when test could not be performed?
7. order reference to at least the ID – should this be a choice ? So for paper orders, can just refer to the ID on the paper – but we always have the filler order (in the lab system, so that will have to be there) – cannot be a choice, because you can have more than one request and need to keep that straight, so no choice for datatype – how do we identify which result goes with which order in the current DiagnosticReport?

* POC testing example: can manually enter the result into the system via middleware to the EHR; so will not be on the result at that time – so #10 should not be mandatory
* The report ID is assigned by the filler, it may be different from the filler DiagnosticRequest.Identifier
* Not mandatory, but must support:
  + Placer ID - isn’t this a reference to the DiagnosticRequest or actually an identifier assigned to the DiagnosticReport?
  + Specimen – why is this not mandatory – is it because of cancelation?
* Looking at specimen resources – will need to review and bring in the updated Specimen DAM information – make specimen resource a goal for FHIR STU4
* Change formatted text report to attachment?
* More discussion on this topic will be in OO on FHIR call 2 -3 PM EST on Thursdays!
* Andrea to do a double check the CLIA elements – if not in the core, then can we do US extension?

### Future of US Lab realm guides / FHIR IG / DAF

* <http://hl7.org/FHIR/us/daf/2016Sep/daf-core.html>
* Had prepared FHIR representations of LOI -> DiagnosticRequest and LRI -> DiagnosticReport during DSTU1
* At minimum need to update these to the current resource patterns in STU3
* Should see if we have a US Patient (birth sex vs administered gender)
* USLab is not linked on the profiles page (it actually is, but not on the title of it, but in the document reference type (Trial Use)

### Future plans for Lab Order Model

* DAF scope is larger than just labs – but need to coordinate with that project for lab related topics
* Also need to update, if needed, AFTER the LOI/LRI ballot in Jan2017 – then may be create the IG and plan on FHIR ballot in Sept2017 at the earliest
* DAF #1265 listed as awaiting approval
* For Wed Q1: need to check if existing PSS would cover, or if we need a new one

## Q2 – OO/PHER/Rx/RCRIM

### Agenda

* RCRIM Update
* 2017 ONC ISA Feedback review

Joint with PHER (no), Rx (no), RCRIM, FHIR (no), HCD (no)

### RCRIM Update

* The reaffirmation vote on ICSR went well
* SPL v 7 has been the major activity
* Discussion about more work in devices and SPL application against devices
* Met with Rx yesterday about product quality and substance – consider PSS for FDA project under IDMP
* CPM discussion about re-balloting about SPL v8 in regards to food items (Elaine’s requirements efforts were reviewed by FDA and found that current version already had all they need.)
* In FDA there have been discussions with Center for Food and Applied Nutrition, but no effort seen at this time
* Want to avoid that there is an effort to create a FHIR IG to avoid SPL support
* Any work on CPM or SPL at the moment? Had discussion with Rx about use of FHIR and application of updated for requirements into CPM, if there is anything?
* IDMP implementation – will that have effect on CPM?
* Have business cases with requirements were submitted and balloted
  + have European version of SPL, substance related
* Integration into care plan etc.
  + May need to review if we need to split out artifacts and that could be changes to CPM
  + Gaps identified are expected by Jan ??
* Implementers are asking what about applications in FHIR - how would we address this – in parallel or in sequence
* SPL is not known across all stakeholders in Europe, but implementers asking the long term question about what to invest in at the beginning at the process
* SPL has been implemented for 10 years with worldwide pharmacy industry, should be implementable
* IDMP is conceptual data model of what we need, which is missing in FHIR at this point
  + What technology will be best in 10 years for the use cases we already know about
* Medical devices are part of the discussion – UDI registry – whatever the drugs do, devices should do the same
* Across US underpinning efforts are precision medicine and use of cloud, NCI collaborating with ???, FDA
* It took 20 years to get regulation for data submission standard (CDISC???) and using BRIDG as model for oncology and imaging as model for basis for precision medicine for digital path, biomarkers, clinical genomics etc. – focus needs to be decision support systems based on precision medicine – underlying standards have proven merit, so how much change in the technological basis will affect these efforts
* Continue with current technologies and explore in pilots existing standards in FHIR to see, if it can work
* Has FHIR-I made commitment to migration SPL to FHIR? Not sure…
* FHIR is not yet normative;
* ICSR is a normative message that was evaluated as an adverse event FHIR resource, there was pushback on the development – currently don’t have a resource that would cover this area

### 2017 ONC ISA Feedback review

Hans prepared: Look for yellow highlights (differences to prior version) or blue comments (were proposed before, but not incorporated) applicable to our WGs. see:

 (OBJECT IS NOT PRESENT)

## Q3 – OO

### Agenda

* IHE Profile LCC related change requests
* Harmonization Proposal for HL70078 / ObservationInterpretation
* Performing Lab Location in summary C-CDA (support CLIA requirement)

### IHE Profile LCC related change requests

*  (OBJECT IS NOT PRESENT)
  + Goal here is to establish relationship from current order to either:
    - Order group
    - Order
    - Result
  + Where in the message structure is the appropriate place to add the new segment – ok to add before Observation, or would it need to go to the very end after container?
  + Postpone till Wednesday Q4, when Hans can be on

* (OBJECT IS NOT PRESENT)
  + Questions: What replaces the status that no longer applies when the time period expires? Should we define a default status, the prior status or?
  + Will the receiver be expected to update the status when the current status expires? Does the receiver have the responsibility to compare the date range and recognize when the status no longer applies?
  + We added a sentence explaining that when the date range is no longer applicable, the status should be treated as unspecified, because the element is an optional element, so could also not be specified.
  + Motion to approve as adjusted Riki Merrick, Jim Harrison, no further discussion, against: 0, abstain: 0, in favor: 7

Harmonization proposal for HL70078

* (OBJECT IS NOT PRESENT)
* Deprecated codes remain active for backwards compatibility – however the codes that we never added to either v3 or v2 do not have a high likelihood of ever being used, so marking them as inactive (or not adding them at all) may be more correct - if we don’t add them, then the view of the codes is not harmonized and would have to be explained somehow
* We should add a statement that once harmonization between v2 and v3 has finally been achieved, the related FHIR vocabulary should also be updated to match
* Motion to accept as currently prepared from content perspective – proposal editor to seek advice about submission format, since there are separate forms for v2 and v3 changes, but since this is about harmonizing across v2 and v3, will be better if kept in single proposal – Riki Merrick, Patrick Lloyd
  + no further discussion
  + against:0, abstain:1, in favor: 6

Performing Lab Location in summary C-CDA (support CLIA requirement)

* Lab Location = performer address question for C-CDA from SD (to satisfy 42 CFR 493.1291(c)(2) = CLIA to identify performer)
* Certification bodies stated this should be in the author element of the result, but in C-CDA you have author in header for the document vs adding authors to the individual sections of the C-CDA document. This is in the summary of the lab results in the C-CDA – so the author of the C-CDA is the EHR-S, not necessarily the lab.
* From ordering perspective we use performer, from resulting point of view we use author, but we have not really considered the use case of summary reporting before.
* Author can be added to the result sections in C-CDA, definition of author
* Motion to use performer to represent this CLIA requirement – Patrick Lloyd, Rob Hausam,
  + no further discussion,
  + against: 0, abstain; 0, in favor: 6

## Q4 – OO

### Agenda

* SDC Update
* IHE Profile US Lab realm guide gap analysis

### SDC Update

* See slides
  + 
* Questions/Notes:
  + Can SDC handle cancer reporting? – yes, has been tested in CA cancer registry
  + CAP is working on creating eCC as FHIR SDC resources
  + Split into special data element (SDCDE) specific profiles for dealing with data elements only, while for complete reporting like cancer or adverse event use the full SDC profile
  + New IHE SDC profile is being published next month
  + Looking for detail of differences between IHE and FHIR version of the SDC:
    - 
  + Direct message from LIS to downstream entity – are you looking at CLIA requirements?
  + No work on that yet; will be looking into that

### IHE Profile – US realm Lab guides gap analysis

* Location of all files and background material: <http://wiki.ihe.net/index.php/IHE-SNI_Lab_Harmonization>
* this is where updates will be made after today’s review, so go here for latest version!
* Overall notes:
* Tab colors:
  + green – no differences, that cause issues (if differences, IHE Profile transactions less constrained than US realm Lab guides) – several of those are because the segments are not defined in IHE Profile specifically, so would assume to use underlying base standards
  + yellow – differences found – need review
  + no color – not quite finished
* Each tab describes either the message structure or a segment or datatypes
* On each tab the first 6 columns describe the requirements as defined in US realm Lab guide column 7 lists the DELTA and columns 8+ list the respective IHE transaction definitions from the PaLM Technical Framework for LOI/LRI or LCSD for eDOS
* Field colors:
  + Red – IHE profile definition more constrained than US realm Lab guide
  + Yellow – pre-adoption or other differences where impact needs to be evaluated
  + Orange – found technical correction in either IHE-Profile or US realm Lab guides
* LOI: 
* eDOS: 
* LRI – to be completed – apologies…
* Discoveries / discussion:
  + IHE Lab transactions are inside the hospital, hence no need for support for the additional patient information including NK1,DG1 etc
  + IHE Lab does not support simple ACK – only application level ACKs
  + LCSD sends in batch – it also supports ONLY REPLACE functionality and has application level acknowledgements at the message level
  + For the atomic observation messages eDOS does not differentiate between numeric, categorical (both are lumped together into M08, instead of using both M08 and M09) and calculated (M11), which is not supported at all in eDOS
  + LCSD has been implemented in several hospitals and ambulatory settings in France as well as for communications between reference laboratories
  + In LCSD MFI-2 functions as the release number for the replacement catalog
* Looking at Francois’ LCSD to eDOS to FHIR comparison:
  + Orange highlights items
  + Red highlights items that are missing in both compared to
* Next Steps:

# Wednesday

## Q1 – OO

### Agenda

* Workgroup health
* Nutrition
* Project Insight
  + Check if we need new PSS for balloting update to Specimen DAM (Project 892) – goal is Jan2017 cycle, so deadline for submission is 10/9/2016
  + Check if we need a PSS for the US Lab on FHIR work
  + Check if we will need a PSS for LRI / LOI / eDOS / ELR R2 (might have to look in PHER for this one) – goal is Jan2017 cycle, so deadline for submission is 10/9/2016

### Workgroup Health

* Workgroup health SSD SD = <http://gforge.hl7.org/gf/download/frsrelease/1207/14652/SSD_SD-WorkGroupHealth_2016Sep.pdf>

### Nutrition

* Nutrition Dam publication
  + Publication Request was shared with the group, and the materials are ready to forward to Lynn
  + Motion by Margaret Dittloff / Jean Duteau to approve the publication request.
    - Against: 0 Abstain 0 In Favour 6
* Discussed moving forward with a second STU ballot for the Nutrition order v3 messages, incorporating DSTU comments and updates from the DAM ballot.
  + Motion by Margaret Dittloff / Jean Duteau to approve a NIB for a STU ballot for Jan 2017
    - Against 0 Abstain 0 In Favour 8
* One outstanding STU comment for Nutrition order models – Comment 483
  + Move to find persuasive and apply the approach of the pharmacy models to the complex rate instructions for enteral nutrition orders. Margaret Dittloff / Jean Duteau
    - Against 0 Abstain 0 In Favour 8

### Project insight

* Review <http://healthlevelseven.projectinsight.net/l.aspx>

(tips=<http://www.hl7.org/documentcenter/public/wg/projectServices/Project%20Insight%20Tip%20Sheet_2011.doc>)

* project 892 = Specimen DAM - covered the initial specimen DAM work, and has since been archived. We want to pull in the updates from the BRIDG gap analysis, and ballot for Jan 2017.
  + Motion by Freida Hall / Margaret Dittloff to reopen and update the existing project, if we are allowed to do that. Otherwise we will need a new PSS.
    - Against 0 Abstain 0 In Favour 7
* project 1113 = US Realm FHIR Lab Profile - Wish to update to STU 3 and incorporate learning from LRI/LOI/eDOS to create US Realm Lab Implementation Guide
  + Motion by Margaret Dittloff / Ken McCaslin to update the project scope, planned ballot timeline and milestone dates as documented in project insight.
    - Against 0 Abstain 0 In Favour 7
* Projects 922, 792, 973 = LOI / LRI /eDOS – plan another STU ballot for Jan 2017.
  + Motion to update project insight to reflect that plan by Freida Hall / Ken McCaslin.
    - Against 0 Abstain 0 In Favour 7

Other project insight updates reviewed and updated milestone dates documented in Project insight

* 1067 – Lab Order Conceptual spec – next ballot plan Sept 2017 – project dates updated to reflect.
  + Moved by Ken McCaslin / Margaret Dittloff
    - Against 0 Abstain 0 In Favour 7
* 1194 – Pastoral Care – dates moved out to reflect resource constraints.
  + Moved by Ken McCaslin / Margaret Dittloff
    - Against 0 Abstain 0 In Favour 7
* 1115 – Order Service – STU will expire in February. OMG cycle to provide comments back will be later than February.
  + - Motion to request a one year extension of the STU period to Feb 2018, by Ken McCaslin / Freida Hall. Against 0 Abstain 0 In Favour 6
* 1096 - EHR-S Func Reqs Doc for Laboratory Interoperability Transactions - EHR-S Func Reqs IG for LOI
  + Moved next milestone dates out. We were not sure this was still actively being worked on – check with Riki to see if this should be put on hold

## Q2 – OO/AP/II/CG/BRIDG

### Agenda:

* CG Update
  + Ballot update
  + Review sub groups
  + Fhir connectathon
* ASCO ObservationInterpretation issue around Indeterminate/Equivocal
* II Update
* BRIDG
  + Bio specimen and OO collaborative work
* CG question

### Clin Gen Update

* See slides
  + 
* Sequence resource and new profiles for genetics in FHIR STU3 – a lot of good feedback, working on implementation guidance document (rather than an IG) – it is in CORE, but not in IG section, there is a pointer http://hl7.org/fhir/2016Sep/sequence.html – will need to add more pointers from the resources to it
* V2 Clin Gen Lite guide – still need to move officially from OO to Clin Gen in project insight
* DAM based on clin sequening use cases – finding commonalities – separate calls lead by Gil – plan to ballot in 2017
* Handling coding systems questions
  + how to do a pre-coordinated question
  + do at end of agenda – time permitting
* Connectathon tested several use cases

ASCO ObservationInterpretation issue around Indeterminate/Equivocal

* ObservationInterpretation = HL70078 = FHIR value set are all affected - indeterminate / equivocal issue
* See slides:
  + 
* Marginal vs tech reasons for not being able to make determinations
* In V3 vocabulary:
  + Move “equivocal” to same level as “indeterminate” and replace “indeterminate” with a new term “cannot be determined”.
  + Pathology has a list of flavor of grey zone results – there is medical legal reason for them.
  + From reporting requirements the term in the package insert must be used.
* Harmonization proposal for these terms was submitted before and reviewed and current state is result of that.
* Difference between “indeterminate” and “cannot be determined”?
* Cannot be determined = test started, but failed
* The current “indeterminate” definition describes a situation that covers both “cannot be determined” as well as “equivocal”
* That is different from “test cannot be performed” – where there is NO result.
* Three levels: specimen unsatisfactory – that does not generate a result either
  + Need:
    - Positive / Negative / equivocal / cannot be determined
* Current “indeterminate” definition covers both “equivalent” and “cannot be determined”, so create these two as children
* Harmonization deadline is 10/14
* Jeff will draft examples for “cannot be determined” and “equivocal”

### BRDIG Update - Specimen

ADD Wendy’s slides

* Plan is to ballot the updated specimen DAM in Jan 2017 – the old specimen PSS was closed but will see, if we can reopen, if not will need a new PSS before 10/9
* Once the specimen DAM has been published work on updating the specimen FHIR resource based on elements defined in the DAM

### Housekeeping

* Keep as joint on agenda – CG, BRIDG – will check with II, if still interested to be here, since they missed today

### CG Question

* How do they represent the diagnostic result that was a test for the existence of an allele, and, if present, is it heterozygous or homozygous?
* Clinvar is a database of alleles, with an id representing the allele. Currently there are LOINC codes for some alleles, but it is a very large set and there are unlikely to ever all be in LOINC.
* Question – How do I say: Do this test and determine if this ClinVar variation exist?
* One example is CCR5
  + CCR5 – screen for a specific allele in that gene (protection against HIV)
  + Present, or not present. If present is it heterozygous or homozygous
* Clinvar id identifies the allele (it is an allele database)
* Discussion ensued about the choices to represent this with observation, including the potential use of observation component.
* Need to check with Eric Haas to gather his thoughts, and potentially consult with FHIR methodology.
* Will schedule a future discussion in either OO or OO on FHIR, and invite CG

## Q3 – PC/OO/FHIR/CQI/CDS

Hosted by Patient Care. See Patient Care for additional minutes.

### Agenda

* PlanDefintion resource
* eDOS on FHIR / Catalog work
* AdverseEvent
* Housekeeping

### PlanDefinition resource

* Started with knowledge artifacts of care plan, order sets and ?? to provide decision support rules – goal is to share definitions of artifacts
* First used extensions for this purpose, then added the resources in STU2 – merging of order set and protocol and decision support rule into planDefinition resource
* Does not support the format representation
* Have a few CD engines using this to express rules, want to update the guidance document that is related to this – using an apply function -> planDefintion plus patient -> create a care plan with related resources
* Guidance response captures optional things that could be done, that we currently not have captured (not as strong as a proposal)
* Deconstructed the GuidanceResponse resource element and created activityGroup = set of actions that you may or may not perform –in current continuous build

### ActivityDefintion

* Got lots of ballot comments on guidanceResponse, so will have some changes
* Pharmacy question
* NCCN – oncology template creation – got guidance on how to use PlanDefintion and activityDefintion
* One : many drugs are represented in each individual activityDefinition – that gets applied to the medicationOrders that can be referenced in the carePlan
* PlanDefinition can carry JUST what will be done, it will be applied to a CarePlan, that is applied to the patient
* But drug is a thing, activityDefinition is for an action – the drug is referenced as part of the activity
* activityDefinition is a template for producing a medicationOrder
* Need to update definition of product in Activity – should be “what can be administered when the activity is applied”
* Can dosageInstruction replace the current way dosage is described in activityDefintion, else there will be a lot of extensions?
* Relationship between activityGroup and ActivityDefintions = set of options defined by the activityDefinitions
* Can we add a diagram? Yes
* CarePlan team will need to review these resources and see how this relates and get folks on the calls:
* CDS: Wed at 12:00 PM ET; sub-workgroup for prep of the ballot recon resolutions – will share information
* Optionality is implied and how would the rules be coded – can they be specified?
* In the PlanDefintion can describe the temporal, grouping etc – when realized into guidanceResponse these definitions are carried forward to the patient
* If you have multiple activityDefinitions, then does that create the activityGroup?
* Referral to mental health
* Set current patient, time, medications,
* Separated into 2 resources, so carePlan can use ONLY the PlanDefinition and not the optional activityDefinition
* CarePlan can reference any Request resources, and activtyPlan?
* Scheduling 2 drug cycles both every 28 days, but for the first one day 2 and 5 and the other at day 7 and day 12 etc…

### eDOS on FHIR

* Lab Catalog: <http://healthedatainc.com/go-ftp/publish/labtestcatalog.html>
* Slides:
  + 
* CDS is interested in working on the global aspect of catalog
* Catalog = formulary, so Rx is also
* Medication resource might need some tweaking in order to create the catalog
* Ned to see what is universal and what are specializations between domains and then country specific within domain as well
* The PSS is excluding the actual order, not the catalog about medications
* No timelines set – order catalog specification with order service is in OMG submission phase – November is initial draft, final in 8 month
* activityDefinition has category to define the kind and how to transform this activity into a resource
* the receiver of the catalog must/can then further modify the information into the order entry system, as there may be more than one lab to order test A from
* Medication list of what is be reimbursable by insurer

### AdverseEvent

* RCRIM is defining the AdverseEvent resources on FHIR – have calls on Fridays 10 AM ET
* Need to be sure it is not ONLY defined from research angle, also and how does that overlap with adverse reaction and allergy/intolerance
* Clinical aspect relevant to the patient record – condition and allergy
* adverseEvent resource is about the reporting and tracking of the
* can adverseEvent be included in the patient record – we have to include this in the record
* fracture = condition, cause of the fracture is the adverseEvent described and there are pieces institutionally that are not reportable outside

### Housekeeping

* Will keep same set up for next WGM

## Q4 – OO/PHER

### Agenda

* ELR R2 and LRI balloting (Hans/Riki)
* Immunization proposal (Rob Savage/Craig Newman)
* LCC CP for new fulfillment message in OML^O21 (Riki/Jim)
* V2.9 Proposal - Harmonization proposal new trigger event/structures (Hans)

### ELR R2 and LRI balloting

* Objective is to update ELR 2 and integrate with latest LRI
* The plan is to ballot in Jan2017 and also addressing NAACR ballot comments and integrate Clinical Genomics as well.
* Currently LOI/LRI/eDOS team have calls Tuesdays 3 – 4 PM ET
  + Will need to increase to 3 – 5 PM ET for Tuesday AND possibly add the Thursday 3 – 4 PM ET calls;
  + PHER calls are 4 – 5:30 PM ET – use the first part of PHER when there are PHER specific questions from that work
* Will ELR be published as profile in a single document? Three alternatives:
  + 1) LRI + ELR + CG + NS in one document where profiles become subsequent chapters
    - Base LRI
    - Delta for ELR = PH
    - Delta for Clin Genomic
    - Delta for Metabolic screening
    - Delta for Cancer Reporting may be?
  + 2) LRI document and then one separate document for each that references the base LRI – delta
  + 3) LRI document and then one separate document for each that includes the base LRI – cumulative.
* Scope for future – harmonize content for HAI and LRI
* PHA will not work so well with delta documents – so that is not a good
* Motion to adopt full document structure Craig Newman, Patrick Lloyd, no further discussion, against: 0, abstain: 2, in favor: 9
* NACCR document: Lori Havener is their standards person, Ted Klein wrote the document, Wendy Blumenthal and Wendy Scharber
  + These are folks to reach out to and request they be on the call, if questions come up
* There are also other specific ELR specific comments
  + Do those with PHER folks
  + On the first ELR call introduce the ELR/LRI ballot and schedule and then start the DSTU comments on 10/6 with ELR DSTU comment review
* Call logistics for the Thursday calls
  + Use the PHER number and their web tool
  + Introduce new schedule next week and get the meetings going the first week of October.
* For CG we (Hans and Riki) are working with Clem McDonald
  + Use of repeating OBX-5
  + Use of OBX-4 syntax
    - Dan to talk with Clem to see, if they could not use the OG.2 and OG.3 elements for their organization
* When one of the profiles needs to be updated can declare the specific content that is up for ballot
* Per feedback from HQ, easier to have a new PSS that focuses on this integration effort.
* Motion to start new PSS – Owner OO, intent is for Co-sponsors PHER (will discuss on the next PHER call) and CG (Riki to reach out) – On Thursday next week OO for vote; Riki Merrick, David Burgess,
  + Discussion:
    - Do we need PHER keep ELR as project for ELR R1 – Freida will check with publishing, so hold it for now.
  + What about creating a micro profile and pulling that out of LRI base? Do we want that right now or later?
  + Freida checked with HQ – publishing agreed to do new PSS for the large document
  + Against: 0; Abstain: 0; In Favor: 10
* How to structure the document – overall introduction of the larger scope with references to the context profiles later in the document
  + - Introduction
      * Explain structure, overall purpose, etc.
      * Use case set being supported (Ambulatory, Reportable Results, ….. context profiles)
    - Base Definition
      * ORU Profiles
      * Control Profiles – mutually exclusive within profile type
        + NG/GU
        + RN/…
        + Etc.
      * Acknowledgment Profiles
        + General Acknowledgement
        + Advanced Application Acknowledgement
    - Content Profiles – multiples allowed in one message
      * Micro
      * CG
      * NS
      * NAACCR
      * (…)
    - Context Profiles – mutually exclusive – delta - declares profiles above that are valid.
      * ELR
      * Ambulatory (old LRI)
      * (Inpatient)
* The context profile of ambulatory is current LRI = use case description; and need to drop “ambulatory” from title
* ELR R2 project expires Dec 2016

### Immunization proposal

* dB tracker [#850](http://www.hl7.org/memonly/dbtracker/display_detail.cfm?trackerid=850)
  + Chapter 4a reference clean up regarding references to Table listing MSH-9.1
    - see document 4A.7, 4A.7.1
  + We did check that the codes V01, V02 and V03 have been marked as deprecated in HL70003.
  + Motion to update 4A.7, 4A.7.1 to be
* to update 4A.7 and 4A7.1 to be:

## Vaccine Trigger Events & Message Definitions

### Vaccine administration data

Immunization information systems (IIS) that maintain vaccination records need to be able to transmit patient-specific records of vaccine administration to other health information systems to provide access to the record at the time healthcare is given and to allow tracking of progress in reaching age-appropriate immunization coverage. The unsolicited update is the result of a vaccine administration update or delete. This message permits the transmission of immunization records from care providers to immunization registries. Messages containing immunization records carry patient identifying information in the PID segment. They may also carry parent or guardian information in the NK1 segments to help identify a child. The RXA segment is used to report the details of the immunization event: the type of vaccine (e.g., DTaP, polio, MMR), the date administered, the sequence (1st, 2nd, etc.), the amount (e.g., 0.5 ml), and location and provider of the immunization. In addition, the RXA provides a place to record the lot number, manufacturer and date of expiration of the immunization. The RXA can also be used to report the fact that a specified immunization was refused. This section references two tables (CVX and MVX as referenced in [HL7 Table 0396 – Coding Systems](file:///C:\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\8CXE3V7V\V282_CH02C_CodeTables.doc#HL70396) in Chapter 2C, Code Tables) maintained by the U.S. Centers for Disease Control and Prevention (CDC). These tables are recommended in the U.S. for identifying the immunization in field RXA-5-Administered Code and the vaccine manufacturer in field RXA-17-substance manufacturer name.

* Craig Newman, Riki Merrick, no further discussion, against: 0, abstain: 0, in favor:

### LCC CP for new fulfillment message in OML^O21

* How is the relationship created between the request for the review, the result of the review to the original result?
* Currently this is a phone call and the lab reports on the outcome
* If they re-run the test, would that be a new result or an updated result? New result
* If the original result needs to be changed, how is that handled?
* The REL can declare the target of the relationship between the source = current order to the target = order group (ORC-4), order (OBR-2 or OBR-3), result (OBX-21)
* The order message has separate OBX that can be included, AOE-OBX, OBX/SPM and prior resultOBX – how is that handled – this would require support for use of OBX-21 to uniquely identify the individual observation. Why would it not be sufficient to just send the prior result to be evaluated in the result\_Prior group?
* Couldn’t this be done with an OBX that uses the specific LOINCs that gives the question of what should be evaluated – need to ask Jim to get the background – also review the minutes from when we discussed this before.
* During the FHIR workflow discussion if came up, if the lab can ask, if there is enough specimen for a re-test – could this be used there, too?
* Several questions for Jim, also re-review the prior minutes where OO made this recommendation to use REL instead of OBX with LOINC and reporting the OBX-21 ID in OBX-5 – will take up on a call

# Thursday

## Q1 - OO/Templates/CDS

### Agenda:

* Ordering Service Update (SOA)
* Templates Update
* Review the ordering service model
* V2.9 Harmonization proposal

### Ordering Service update (SOA)

* Work proceeding – using alternating calls to harmonize
* Work is published here <http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=142>
* Letter of intent has closed at OMG
* Initial submissions are due Nov 7 – expect the deadline to slip 6 months to accommodate catalog exchange, should not be a concern
* What lab tasks can be ordered (either as push or pull)
* In future FHIR will work sooner with SOA to adjust – but this time a little delayed since ordering service started much sooner
* Have separate projects and put the ordering service as dependency and start them parallel
* For catalog project have 3 levels:
  + overall structure
  + formulary / pharmacy
  + lab
* Ordering service was not written FHIR specific, as work flow was just starting –the RFP specifically asked to address FHIR: provide SOAP and REST binding and identifying if FHIR works or not – and now got updated to require FHIR
* Major significant change (project intent, a lot of the dates) requires new PSS
  + Current PSS talks about ordering of order set – this is slightly different from catalog
  + If we include formulary, would need to add in pharmacy
  + This PSS includes the OMG process, so if we use this, all work product would be going to OMG
  + Do we also need II input? since focus shifted to FHIR – need to reach out
* Setting up a convenience panel is an issue in FHIR workflow to support the nesting
* Definition of order service catalog – collection of orderable items viewable to physician
* OMG participation ensures that there are technical specifications, open source code, if submitter choses, AND implementations of the specification with feedback on the base standard – FHIR is a choice as implementation of the order service model
* Logical model – content – project into FHIR resources
* Will we need to include FMG involvement?
  + Only if we need new resources or profiles, they will want to be in the loop and for some may be FHIR-I
* Update the project description to include some more detail for referencing eDOS as lab content input –there is a difference between the catalog being exchanged between organizations and making the catalog items viewable for ordering in the organization and have additional considerations to do
* Reach out to Jose (pharmacy) – use the OO on FHIR meeting as coordination point to get pharmacy and ordering service
* Need to consider how this links to the ordering workflow once completed
* For content look at FHIR catalog: <http://ig.fhir.me/Healthedata1/fhirlabtestcatalog/index.html>
* Look at the same time next WGM and also invite II and pharmacy representation for Q1 Thursday

### Template updates

* Working on extension of the template STU for ballot Jan2017 allows people to share templates across paradigms) – incorporating feedback from prior versions
* Working with FHIR people to get management of resources and extension comparable to how templates are managed – versioning for example
* Thursday Q3 and Q4 there are tutorials on creating templates in user environment using Art décor and Trifolia (constraining existing templates)
  + MDHT is also available
  + IHE Europe is using Templates STU for international sharing of templates and in different languages – encourage that in the US as well
* Remain as join for this quarter? Templates has other joint sessions with pharmacy, SD and CGIT – if we can invite
* Main templates meeting is Friday Q1 – if OO has no quorum, might be a good idea

### Review the ordering service model

* Figure 12 in order service SFM as published
* Platform independent model:
* <https://healthservices.atlassian.net/wiki/display/WGS/HSPC+OMG+Ordering+Service+RFP+WG>
* UML files are the normative artifacts of the specification
* At this level can use any standard
* How would the formulary be represented here? This is the ordering part – the catalog part still has to be developed
* This supports the physician creating an order from components as well as feedback on the ordered item, if needed.
* Service interface level:
* Query update – harmonization with FHIR diagnostic order look up;
* Order entry lifecycle was made independent from the fulfillment of the order, so services can implement independent.
* Are copy to providers included? - will need to look at the metadata
* Order management used to group it all into a single interface, but need to be renamed – Order/result manager at the provider level (unlike the external communications about the result)?
* Order service catalog may similarly have 2 levels – within organization and getting this from the outside filler
* Updating the Order Service PSS – Lorraine to get from Dave Hamil

### V2.9 Harmonization proposal

* Need to add PSS ID for general v2.9 maintenance = #773
* OSU message was originally used as ACK, but there is always a need to do unsolicited update, so we created a new OSU message structure, so new structure identifiers were assigned and those turned out to already be used in chapters 4 and 7, so we had several event types that were used in several triggers,
* So we added all the event codes – passed harmonization, but realized during harmonization that the corresponding message structure codes also need to be updated – OO needs to review the codes and then send this to InM for approval.
* NEW codes and suggest we deprecate the older values that are unique, but apply to different events
* Document to be submitted (without updated format yet):
  + 
* Motion to approve as presented Lorraine Constable, Jerry, further discussion: reformat format to new template format – approved by motioners, against: 0, abstain: 1, in favor: 8
* FYI: The search function for milestone date was added to project insight ☺

## Q2 – OO/FHIR

### Agenda

* FHIR planning
* FHIR STU3 ballot reconciliation

### FHIR Planning

* STU3 publication deadline by Nov 27
  + Have 142 open tracker items
  + MUST complete disposition of the ballot items (82 items)
  + Main FHIR editor is out, with limited backup – so schedule is at risk, unless we can get some implementation resource from FMG – bring up to FHIR-I also
* The hope is to increase the maturity level of observation upon completing the ballot reconciliation, so should be our main focus
* Cross resource query need – see tracker #[12148](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_id=677&tracker_item_id=12148)
  + Looking for input to support search across different resources that could contain the same content - for example condition and observation overlap
  + Gathering use cases and requirements, build into base spec (used to have, but was taken out, since too ambitious in the past)
* Graham, Rob and Eric were working on aggregated observation queries (e.g. mean systolic RR of the patient, also across population for a specific observation)
  + Show how to consistently form the query and represent the results of the queryResonse, focused on the patient specific first - Dan Vreeman also interested – will continue that work and publish suggested implementation on Grahame’s blog
* LRI on FHIR vs DAF – need to create new US Lab IG update to STU3 and based on updated v2 work in Jan2017
  + Likely target Sep2017
* Catalog
  + Will be on same PSS as ordering service with updated description and scope and request that II and pharmacy working groups are co-sponsors
  + eDOS on FHIR – need additional FHIR editor in order to produce the artefacts
    - bring up at FMG and FHIR-I
* LOI on FHIR – Ordering Service cooperation, was not on specifically discussed
* Workflow
  + Task has assignments to OO – those be FHIR-I UNTIL they are referred from there to OO, except when the items were applied to OO specific resources

### FHIR ballot reconciliation

* 82 comments
* Richard Cavenaugh’s comment on VitalSigns profile = [#10748](file:///C:\Users\HB036784\Documents\SRO\HL7\Orders-Observations\o%09http:\gforge.hl7.org\gf\project\fhir\tracker\%3faction=TrackerItemBrowse&tracker_id=10748)
  + Vital signs will be the core of wearables, which is global market and provide information to and from EHR-S
  + Find and get the value signs in ANY system, so we decided on 13 LOINCs to create a core profile as MINIMUM set (was reviewed by CIMI)
  + Issue is some countries don’t use LOINC, which adds overhead to those countries to map to LOINC
  + Yes, generally agnostic to a specific terminology, but we expect profiles to constrain to specific terminologies
  + Could we provide the mappings from the mandated LOINCs to for example SNOMED CT codes – that is possible
  + Potentially could use SNOMED CT codes instead, especially with the offer of IHTSDO to allow use in HL7 standard implementations, when finalized
    - May not go through
    - Specific license for that may be confusing for this
    - Future of representation of observables in SNOMED CT as possible outcome of the collaboration agreement effort
  + IHTSDO and Regenstrief are working on mapping, but it is to SCT expressions, which is the only way to express the granularity expressed in LOINC
  + Use “magic value” instead of code in the text
  + Reviewing workgroup – add OO to FGB
  + Clearly explain that these mandatory LOINCs are mappable within the codeable concept
  + Motion of not persuasive with mod: a large portion of community is supporting LOINC, the codes assigned are the fixed set, there is support for mapping, which we anticipate will happen to communicate additional clinically appropriate codes, from LOINC or other code systems – for exact text see tracker – Lorraine Constable, Ken McCaslin, no further discussion, against: 0, abstain: 0 on favor: 17 – non-substantive, resolved-change required
* 29 in person resolutions, 8 on observation = Clem McDonald = 7 and Lloyd McKenzie
* 18 comments on observation
  + #[11115](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_id=677&tracker_item_id=11115):
    - ReferenceRange.meaning cardinality should be 0..1 and add another element to capture the group of people it applies to
    - There is a need to describe the type of reference range = normal, high, critical etc. AND limiting specific groups of the population
      * Deprecate .meaning
      * Add 2 new elements:
        + .type 0..1 extensible binding to types in existing value set (normal, recommended, etc)
        + .appliesTo 0..\*, example binding to the values in existing value set of meaning minus codes describing Type
      * Motion Bobby Halperin, Grahame Grieve, no further discussion, against: 0, abstain: 0, in favor:17 – compatible – substantive, resolution-change required
  + #[11113](file:///C:\Users\HB036784\Documents\SRO\HL7\Orders-Observations\o%09http:\gforge.hl7.org\gf\project\fhir\tracker\%3faction=TrackerItemBrowse&tracker_id=11113):
    - Observation Category – may cause more confusion – seems to be a fixed value set – was discussed in DAF that way
    - Category is helpful to organize things, but we don’t all use the same vocabulary across domains for the individual use cases for grouping to decide on what granularity to use
    - Can still create an indexing system on these different categories
    - Motion to find not persuasive with mod – update documentation principal intent of category is on finding and indexing rather than processing – Riki Merrick, Ken McCaslin, no further discussion, against: 0, abstain: 0, in favor: 17 – non-substantive, resolution – change required

## Q3 - OO/CS/PC

### Agenda

* CS Business
* Allergy related vocabularies
* Ballot reconciliation on Assessment Scales reaffirmation
* ISA 2017 feedback

### CS Business

* No active work at the moment
* Question: How does it compare to the clinical statement in CDA?
* CDA has separate fork on clinical statement, but may add in select parts to improve CDA, where there is no scope expansion

### Allergy discussion

* Drug allergy classification expert panel member visiting (need to get details from Russ)
* DoD Allergen Terminology usage Analysis slides:
  + 
* Brand name may be useful for look-up, but not needed for the allergy description
* Look for the minimally group to support for food and environmental terms using SNOMED CT (SCT)
* Create a starter set with about 500 terms with good coding would reduce a lot of data quality issues
* Cerner dataset supports these findings
* Even for ingredient SCT sufficient - found mostly simple 1:1 mapping to RxNorm (UMLS already has this mapped)
* For free text entries that were common, mapped some of those as well
* Multi-ingredient products were counted at ingredient level – when capture information as precise as captured (brand name with multiple ingredients, then if identified ingredient, clarify in the coding which of the ingredients is actually the allergen
* Jay working on combining the analysis into a report
* Most important is the active ingredient for the allergies
* One thing to look at is compare code to free text for accuracy – may not always match
* <http://wiki.hl7.org/index.php?title=File:Allergy-counts.xlsx>

### Assessment scale ballot reconciliation

* Several of the comments are about publishing issue – where elements that are published in normative edition did not transfer over in to the re-affirmation ballot
* #5 - scored system categories: there are 2 kind of ways you can show assessment scale result – assigning a normal range, vs assigning an ordinal scale with more points
  + Motion to adjust the document with the proposed disposition – not persuasive with mod – Michael, Dave,
    - further discussion:
      * comment from Greg, please explain the disposition comment – the point of the categories is to explain that there are 2 kinds of scores where you have a range, and another where there is – will give the editor the leeway to update
    - Against: 0, abstain: 7, in favor: 14
* #14 – text and picture does not match – for derivationExpr there is a comment that it is an open issue – so we agree, but how to solve it, either make it conformant to Clinical statement by removing derivationExpr or remove the statement that it is conformant to clinical statement –
  + Motion to adjust the text to remove conformance to clinical statement sentence and harmonize with CS Michael, Russ,
    - no further discussion,
    - against: 0, abstain: 11, in favor: 10

### Review ISA 2017 feedback document

* Feedback to ONC is due Oct 24, 2016, HL7 Policy Advisory Committee is looking for feedback by end of this week
* Vocabulary focused standard, content, syntactic
* Organized by use cases
* About 80% of the 2016 submitted comments by HL7 were not addressed, so plan is to submit the same comments, unless they were addressed
* Overall on vocab – copy from other quarter
* For medication allergy:
  + Based on analysis remove UNII and ND-FRT when SCT is mentioned
  + Use a constrained list of RXNorm and SCT specifically as a starter set based on analysis several large data sets (DoD, VA and Cerner) – HL7 PC WG is working to get finalized list)
* RxNorm would be ingredient plus may be MIN for medication; for food and environmental just use subset for SCT
* For Laboratory:
  + Security/ consent to be added to the
  + Problematic to clarify between orders and resulted tests – that has been done

## Q4 – OO

### Agenda:

* FHIR ballot reconciliation

### FHIR ballot reconciliation

* #[11132](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemBrowse&tracker_id=11132):

Can AOEs get a date?

AOEs are handled in DiagnosticRequest.supportingInformation, which is a reference to any type of resource, including an observation, which carries date – under aka AOE is listed – withdrawn by submitter

* #[11131](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemBrowse&tracker_id=11131):

Specimen missing from DiagnosticRequest; when placing order you often already generate the information about the specimen to be collected, including an identifier that is linked to the order

This is a duplicate to #[10589](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemBrowse&tracker_id=11119), which we discussed on last week’s OO call

* #[11119](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemBrowse&tracker_id=11119):

What is the difference between DiagnosticRequest and ProcedureRequest?

ProcedureRequest describes what needs to be done – in v3 we included in the definition that it alters the patient, but that is may be too narrow a definition, while diagnosticRequest orders something to be reported about – not always straight forward – e.g. a colonoscopy is a diagnostic procedure, during which a polyp may be found and subsequently removed – but even if not explicitly done, that would be a follow on order for that procedure…

A diagnosticRequest produces a diagnosticReport, what is the product of a procedureRequest? In a system it is a clinical note,but that does not currently exist in FHIR, so currently using observation resource or document (pretty “heavy”)

This was listed only under Patient Care, we added OO as reviewing working group and will need to schedule a call to resolve – in preparation for the call collect different reasons why you would use what, if possible.

# Friday

## Q1 - OO

### Agenda:

* 2017 ISA

### 2017 ISA

Reviewed further comments from OO that were applied to the attached document.

