BEYOND THE SCHEMA
Tips for Conforming to the HL7 aECG Standard for the digital submission of ECGs

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Realized:

Fabio Badilini
A.M.P.S. LLC
badilini@amps-llc.com

With the contribution/review of:

Barry D. Brown
Mortara Instrument, Inc.
barry.brown@mortara.com

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General points

- For each *code* element, is there a *codeSystem* attribute?
  - (example: <code code= "93000" codeSystem="2.16.840.1.113883.6.12">)

- Each *codeSytem* must be an OID, either from a public vocabulary or defined in a private vocabulary.
  - (example: *<code code=* "93000" *codeSystem=*"2.16.840.1.113883.6.12">)

- For each *id* element, is there a *root* attribute?
  - Are all the *root* attributes in the form of an UID? A UID can be in the form of an OID or UUID.

  - An *id* includes a mandatory *root* attribute and optional *extension* attribute. The *root* must be included, and is a UID. The combination of the *root* and *extension* must be universally unique. Note that for some objects, like the subject id, the *extension* actually is required even though the HL7 schema doesn't enforce that requirement.

- Is the format of ALL the timestamps correct?
  Warning: the format of timestamps must be one of those:

yyyy	*(ex: 2002)*
yyyymm	*(ex: 200210)*
yyyymmdd	*(ex: 20021015)*
yyyymmddhh	*(ex:2002101508)*
yyyymmddhhmm	*(ex:200210150855)*
yyyymmddhhmmss	*(ex:20021015085544)*
yyyymmddhhmmss.mmm	*(ex:20021015085544.123)*

  Example: (*< low value=*"1"> *<high value*="1"> *<center value*="1">) would be accepted by a schema validator……… but not by the warehouse. Be careful when calculating timestamps. It is highly recommended to use built-in timestamp objects for computing timestamps. It is difficult to take care of all the cases like leap years, days in the month, etc., even when adding as little as 1 second to a timestamp. A common mistake is if a 10 second ECG starts 50 seconds past the minute, the ending time is 0 seconds past the next minute, not 60 seconds past the starting minute.

annotated element

- Is there at least one ECG (i.e. a *series* element) ?
- For the available *series*, you should include 12 leads (whenever possible according to what are you studying)
- Have you included a valid *code* and OID for the *code* element?
  Warning: the *code* value MUST be fixed to the following value
  <code code= "93000" *codeSystem=*"2.16.840.1.113883.6.12">
- Have you included a valid OID for the *root* attribute in the *id* element?
- If you have included the *confidentialityCode* element, have you specified a valid OID for the *codeSystem* attribute?
  Warning: There is not yet a public vocabulary for this *codeSystem*.
- Have you specified a valid timestamp in the *effectiveTime* element? Note this is the time corresponding to what is used in the statistical analysis dataset.
- If you have included the *reasonCode* element, have you specified a valid OID for the *codeSystem* attribute?
  Warning: There is not yet a public vocabulary for this *codeSystem*.

subjectFindingComment element

If you have included the *subjectFindingComment* element:
- If you have included the *code* element, have you specified a valid OID for the *codeSystem* attribute ?
  Note: you can either use your own vocabulary or you can also use an HL7 domain like 2.16.840.1.113883.5.4 (ActCode vocabulary).

relatedObservation element

- If you have included *relatedObservation* element:
  Have you specified a proper OID for the *codeSystem* attribute in the *code* element?
  Note: you can either use your own vocabulary or you can also use an HL7 domain like 2.16.840.1.113883.5.4 (ActCode vocabulary).

timepointEvent element

This is the *code* for the visit, study day, or something similar. It is used to group related ECGs together in the Warehouse. Core labs have to place it because this is REQUIRED by Warehouse.

- Does your *timepointEvent* (visit) include a *code* element?
  Warning: The *code* element is not required by the schema.
- Have you included a proper OID for the codeSystem attribute in the *code* element?
  Warning: This is the *code* naming the timepoint event. This could be the visit number, study day, etc. The set of timepoint event *codes* is usually defined by the protocol. There is not (and probably never will be) a public vocabulary for this *code* because the intention is to let the core lab or sponsor to define their own coding system (locally defined).
- If you have included the *effectiveTime* element, have you specified a valid timestamp? Note this is the time of the whole visit.
- If you have included the *reasonCode* element, have you specified a proper OID for the *codeSystem* attribute?
  Warning: There is not yet a public vocabulary for this *code*.

trialSubject element

Reminder:
 - the subject ID is placed in the *id* element under the *trialSubject* element. The *id* element is mandatory and thus a schema <u>validator</u> would notify whenever it is missing
- The Warehouse will name the subject using the extension attribute of the *id* element. The *root* is required by the schema but unused in theW (yet).

- Have you included a valid OID for the *root* attribute in the *id* element?
  A client-specific vocabulary should be used for this OID. Ideally, this should be assigned by the sponsor organization.

- If you have included the *code* element, have you specified a valid OID for the *codeSystem* attribute?
  Warning: you can either use your own vocabulary or you can also use the HL7 vocabulary 2.16.840.1.113883.5.111.

subjectDemographicPerson element

- If you have included the *subjectDemographicPerson* element:
  If you have included the *administrativeGenderCode* element, have you specified a valid OID for the *codeSystem* attribute?
  Warning: you must use the HL7 vocabulary: 2.16.840.1.113883.5.1. (administrativeGender)

treatmentGroupAssignment element

- If you have you included *treatmentGroupAssignment* element:
  Have you specified a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: : There is not a public vocabulary for this *codeSystem*,. It is expected that this will be a locally defined vocabulary – probably tied to the protocol..

clinicalTrial element

- Have you included a proper OID for the *root* attribute in the *id* element?
- If you have included the *activitytime* element, have you specified a valid timestamp?

clinicalTrialProtocol element

- If you have included the *clinicalTrialProtocol* element:
  Have you included a proper OID for the *root* attribute in the *id* element?

sponsorOrganization element

Reminder: If you have included the *clinicalTrialSponsor* element, the *sponsorOrganization* element is mandatory.

- If you have included the *sponsorOrganization* element:
  If you have included the *id* element, have you included a proper OID for the *root* attribute?

trialSite element

- If you have included the *trialSite* element:
  Have you included a proper OID for the *root* attribute in the *id* element?

trialInvestigator element

- If you have included the *trialInvestigator* element:
  Have you included a proper OID for the *root* attribute in the *id* element?

series element

- Have you included a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: you MUST use the HL7 vocabulary 2.16.840.1.113883.5.4 (ECGOservationSeriesType vocabulary).
- If you have included the *id* element, have you specified a valid OID for the *root* attribute?
  Warning: this *id* should be different from that of the AnnotatedECG element (which uniquely identifies the aECG file). Both are important and both must be universally unique. There will be cases in the Warehouse where we need to identify the aECG file separately from the individual *series*.
- Have you included a valid timestamp for the *effectiveTime* element?

seriesAuthor element

- If you have included the *seriesAuthor* element:
    - If you have included the *id* element, have you included a proper OID for the *root* attribute?

seriesPerformer element

- If you have included the *seriesPerformer* element:
    - If you have included the *id* element, have you included a proper OID for the *root* attribute?

manufacturedSeriesDevice element

Reminder: If you have included the *seriesAuthor* element, the *manufacturedSeriesDevice* element is mandatory.

- If you have included the *manufacturedSeriesDevice* element:
    - If you have included the *id* element, have you included a proper OID for the *root* attribute?
    - If you have included the *code* element, have you included a proper OID for the *codeSystem* attribute?
      Warning: There is not yet a public vocabulary for this *codeSystem*,.

sequenceSet element

- Are all simultaneously recorded leads grouped together in a single *sequenceSet*?

- Does each sequenceSet have a single time sequence and one or more voltage *sequences*?

- Do all sequences have the same number of samples?

sequence element

- Do you have one and only time sequence per *sequenceSet*?
- Is the *codeSystem* for the time sequence *ECGObservationSequenceType* with OID 2.16.840.1.113883.5.4?
- Do you have at least one voltage sequence per *sequenceSet*?
- Does the *code* for the voltage sequence from MDC, OID 2.16.840.1.113883.6.24?

controlVariable element

- Have you included a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: currently the only recognized vocabulary for ECG control variables is MDC, OID 2.16.840.1.113883.6.24.

annotationSet element

- If you have included *code* element, have you specified a proper OID for the *codeSystem* attribute?
  Warning: There is not yeat a public vocabulary for this *codeSystem*,
- If you have included the *activityTime* element, have you specified a valid timestamp?

assignedEntity element

- If you have included the *assignedEntity* element:
  If you have included the *id* element, have you included a proper OID for the *root* attribute?

representedAuthoringOrganization element

- If you have included the *representedAuthoringOrganization* element:
  If you have included the *id* element, have you included a proper OID for the *root* attribute?

identification element

- If you have included the *identification* element:
  If you have included the *id* element, have you included a proper OID for the *root* attribute?

assignedAuthorType element

- If you have included the *assignedAuthorType* element:
  If you have included the *id* element, have you included a proper OID for the *root* attribute?
  If you have included the *code* element, have you included a proper OID for *codeSystem* attribute?
  Warning: There is not yet a public vocabulary for this *codeSystem*.

annotation element

- Have you included a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: you should use (whenever possible) the public domain vocabulary 2.16.840.1.113883.6.24 (MDC)

supportingRoi element

- If you have included the *supportingRoi* element:
  Have you included a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: you MUST use the public domain vocabulary 2.16.840.1.113883.5.4 (ActBoundedROICode vocabulary).

boundary element

- Have you included a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: you MUST use the MDC vocabulary, OID 2.16.840.1.113883.6.24.
- Does the *code* match one of the *sequence* codes in the *series*?

relativeTimepoint element

- If you have included the *relativeTimepoint* element:
  Have you specified a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: There is no public vocabulary for this *codeSystem*,.

protocolTimepointEvent element

Reminder: If you have included the *relativeTimepoint* element, the *protocolTimepointEvent* element is mandatory.

- Have you specified a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: There is no public vocabulary for this *codeSystem*.

referenceEvent element

Reminder: If you have included the *relativeTimepoint* element, the *referenceEvent* element is mandatory.

- Have you specified a proper OID for the *codeSystem* attribute in the *code* element?
  Warning: There is no public vocabulary for this *codeSystem*.