Joint IHE Laboratory/Anatomic Pathology meeting

May 31, 2012 - Paris

C. Daniel (ADICAP, ASIP Santé, INSERM)
F. Macary (ASIP Santé)
Agenda

- Image management (H. Solomon)
- Brief proposals defined in collaboration across domains
- Harmonization of CDA implementation guides, MDHT
Anatomic Pathology Technical Framework

- **Current Technical Framework - Revision 2.0**
  - Vol. 1 (PAT TF-1): Integration Profiles
  - Vol. 2 (PAT TF-2): Transactions
  - These volumes provide specification of the following profile:
    - Anatomic Pathology Workflow (APW)

- **Supplements for Trial Implementation**
  - To be tested at subsequent IHE Connectathons.
  - Supplements extend the IHE Anatomic Pathology Technical Framework, Rev. 2.0 for Trial Implementation.
  - Anatomic Pathology Reporting to Public Health (ARPH) - Published 2010-07-23
  - Anatomic Pathology Structured Reports (APSR) - Published 2011-03-31
    - APSR Value Sets Appendix - Published 2011-03-31
Adapting LAB integration profiles to Anatomic Pathology domain
2012-13
Change proposals/Profiles/White papers

- Content profile -> Structured orders *(with LAB, RAD?)*
- Integration Profiles *(with RAD, CARD)*
  - Anatomic Pathology Reporting Workflow *(APRWF)* (G.Rodriguez – Satec)
- White papers
  - *Device automation integration profile (with LAB, ITI)*
  - *Inter-departments workflow (with LAB, ITI)*
  - *Telepathology (with ITI)*
    - *Opinion request (content and workflow)*
  - Relationships between pathology/radiology/endoscopy
  - Sharing templates/terminology *(with ITI)*
Sharing observations across domains

C.Daniel (ADICAP, ASIP Santé, INSERM)
W.Li (INSERM)
[APSR] – Anatomic Pathology Structured Report

- Joint IHE and HL7 anatomic pathology initiative
- Content profile providing templates for building Anatomic Pathology Structured Reports in all fields of anatomic pathology (cancers, benign neoplasms as well as non-neoplastic conditions)
  - CDA documents including Anatomic Pathology observations bound to images or regions of interest
  - Shared or exchanged within a community of care providers using existing integration profiles defined by IHE Information Technology Infrastructure
[APSR] – Anatomic Pathology Structured Report

- Clinical Use Case to implement this profile
  - Sharing/exchanging APSR for surgical pathology
  - 21 CDA templates (Document Content Modules)
    - Generic APSR template
      - All organs & fields of anatomic pathology (inflammatory, vascular, traumatic, metabolic diseases as well as cancer)
    - 20 organ-specific APSR templates
      - Cancer-specific organizers covering 85% of incident cancers
  - 490 observations & procedure templates
    - 21 procedure templates
    - 469 observation templates (including molecular biology observation templates)
Experiment of MDHT

- Open Health Tools Model-Driven Health Tools (MDHT) Project is a wide-ranging open source effort to promote interoperability in healthcare infrastructure.
- A common modeling framework and tools that support seamless integration of design, publication, and runtime artifact creation. Allows the creation of computable models of the templates in UML. These models can be used to produce:
  - Template Specifications (DITA, XHTML, PDF, Other)
  - Conformance/Validation Tools
  - Model Driven Code Generation
  - Schematron
- The project has already built models from the following specifications:
  - HL7 Continuity of Care Document
  - HITSP C83 Sections and Entries
  - IHE Patient Care Coordination Technical Framework
  - HL7 Common Document Types
  - HL7 Consolidated CDA (DSTU Dec 2011)
  - HL7 CDA IG : Public Health Case Reports (US Realm)
  - HL7 CDA IG : Personal Healthcare Monitoring Report (PHMR)
MDTH Architecture

- CDA
  - Includes
  - 1 CDA support
  - 2 CDA templates
  - 3 HITSP & IHE

- HI7 Core
  - Includes
  - 1 HL7 V3 Datatype
  - 2 MIF->UML support
  - 3 HDF

- Terminology Services
  - Includes support terminology sets

- Custom Tools
  - Includes
  - 1 UML Table Editor
  - 2 New Project Wizards
  - 3 New CDA templates
  - 4 Property Editors

- EMF
  - Eclipse Modeling Framework
    - Includes
    - 1 EMF Core
    - 2 EMF Edit
    - 3 EMF Code Generation
    - 4 Validation Framework

- DITA Document generation
  - Includes generation of DITA xml files

- Document Publishing
  - Includes generating documents using DITA-OT

- Model to Model Transformation
  - Includes generating Java source code for models and the constraints

- Validiation Suite
  - Includes testing instances of CDA and non-CDA models.
Example
Implementation guide of the Breast APSR (french edition)
APSR contains 6 sections

- Header
  - Reason for AP procedure section [0..1]
  - History of present illness section [0..1]
  - Active problems section [0..1]

- Clinical information section [0..1]
  - Specimen clinical information entry [0..*]

- Intraoperative observation section [0..1]
  - Specimen intraoperative observation entry [0..*]

- Macroscopic observation section [0..1]
  - Specimen macroscopic observation entry [0..*]

- Microscopic observation section [0..1]
  - Specimen microscopic observation entry [0..*]

- Report textual summary section [0..1]

- Diagnosis section [1..1]
  - Specimen diagnosis entry [1..*]

- Procedure steps section [0..1]
APSR Template Architecture

Generic APSR Template

- Specific Colon Template
- Specific Breast Template
- Other Organs Templates
Create ACP Project (1)
Create ACP Project (2)
Create ACP Project(3)
Add new template(1)
Add new template(2)
Add new template(3)
Generic Header Constraints
Generic Body Constraints
Entries containing specimen-based organizers and « problem »-based organizers

```
<ClinicalDocument>
  <structuredBody>
    AP <section>
      <text>
      AP <entry>
        specimen information <organizer>
          specimen collection <procedure>
          problem <organizer>
            AP <observation>
              clinical laboratory <observation>
              image(s), comment(s) related to the specimen or group
            sub- <section>
        image(s), comment(s) related to the observation
      image(s), comment(s) related to the problem
    Body of the report:
    1 to 6 AP sections
  human-readable content of a section
  machine-readable content:
  a specimen or group of specimens
  properties of a specimen
  a problem investigated
  has as sub-observation
```

The header of the report provides all contextual information (acts, participants, patient, report type, template, id, time & version …)
Specimen-based organizers and «problem»-based organizers in MDHT
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<th>Multiplicity</th>
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<th>Value</th>
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Code System-PATHLEX
Value Set Version

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**Properties**

**Select Code System:** PathLex

**Documentation**

**Name:** Sein-Grade histologique (CCIS)

**ID:** 1.2.250.1.213.1.1.4.88
## Value Set Code

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### Diagram

- **Value Set Code**: 743
- **Concept Code**: 743
- **Concept Name**: Sein-Grade histologique (CCIS) Bas grade
- **Code System**: PATHLEX
Select Code System
MDHT: Automatic generation of the implementation guide - e.g. Breast APSR

Implementation Guide for CDA Release 2
Compte Rendu Structuré d’Anatomie et de Cytologie Pathologiques (CR-ACP) du Sein

PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY
Sein Specific Body Contraints

[ClinicalDocument: templateId 1.2.250.1.213.1.1.1.1]

1. SHALL conform to Sein Specific Header Contraints template (templateId: 1.2.250.1.213.1.1.1.1)
2. SHOULD contain zero or one [0..1] component (CONF-171)
   a. Contains exactly one [1..1] 1Section Informations Cliniques (templateId: 1.3.6.1.4.1.19376.1.8.1.2.1)
3. SHOULD contain zero or one [0..1] component (CONF-196)
   a. Contains exactly one [1..1] 2Section Examen Extempore (templateId: 1.3.6.1.4.1.19376.1.8.1.2.2)
4. SHOULD contain zero or one [0..1] component (CONF-203)
   a. Contains exactly one [1..1] 3Section Description Macronscopique (templateId: 1.3.6.1.4.1.19376.1.8.1.2.3)
5. SHOULD contain zero or one [0..1] component (CONF-210)
   a. Contains exactly one [1..1] 4Section Description Histopathologique (templateId: 1.3.6.1.4.1.19376.1.8.1.2.4)
6. SHALL contain zero or one [0..1] component (CONF-217)
   a. Contains exactly one [1..1] 5Section Conclusion- Diagnostic (templateId: 1.3.6.1.4.1.19376.1.8.1.2.5)
7. MAY contain zero or one [0..1] component (CONF-820)
   a. Contains exactly one [1..1] 6Section Techniques (templateId: 1.3.6.1.4.1.19376.1.8.1.2.6)

Sein Specific Body Contraints example

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
   xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
   <realmCode code="FR"/>
   <realmCode code="FR"/>
   <typeId root="2.16.840.1.113883.1.3"/>
</ClinicalDocument>
```
5_ Section Conclusion- Diagnostic

[Section: templateId 1.3.6.1.4.1.19376.1.8.1.2.5]

1. SHALL conform to aep 5_ Section Conclusion- Diagnostic template (templateId: 1.3.6.1.4.1.19376.1.8.1.2.5)
2. SHALL contain zero or one [0..1] code (CONF-218)/@code="22637-3" Diagnostic anatomopathologique (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-219)
3. SHALL contain zero or one [0..1] text (CONF-220)
4. SHALL contain zero or one [0..1] title = "CONCLUSION" (CONF-221)
5. SHALL contain zero or one [0..1] entry (CONF-223)
   a. Contains exactly one [1..1] Entry Donnees De Conlusion Relatives Au Prelevement (templateId: 1.3.6.1.4.1.19376.1.8.1.3.5)

5_ Section Conclusion- Diagnostic example

```xml
<?xml version="1.0" encoding="UTF-8"?>
```
Observation templates

Sein Observation ACPO1ISO102

[Observation: templateId 1.3.6.1.4.1.19376.1.8.1.4.9]

1. SHALL conform to acp Observation Anatomie Ou Cytologie Pathologique (ACP) template (templateId: 1.3.6.1.4.1.19376.1.8.1.4.9)
2. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF-317)
3. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-325)
4. SHALL contain zero or one [0..1] code (CONF-318)/@code="437" Sein-Type histologique de lesion neoplasique maligne invasive (CodeSystem: 1.3.6.1.4.1.19376.1.8.2.1 PATHLEX) (CONF-319)
5. SHALL contain zero or one [0..1] effectiveTime (CONF-320)
6. SHALL contain zero or more [0..*] id (CONF-321)
7. SHALL contain zero or one [0..1] interpretationCode (CONF-322), where the @code SHALL be selected from (CodeSystem: 2.16.840.1.113883.5.83 ObservationInterpretation) (CONF-323)
8. SHALL contain zero or one [0..1] methodCode (CONF-324)
9. SHALL contain exactly one [1..1] statusCode (CONF-326)/@code="completed" (CONF-327)
10. SHALL contain zero or more [0..*] value with data type CD (CONF-328), where the @code SHALL be selected from ValueSet Sein-Type histologique de lesion neoplasique maligne invasive 1.2.250.1.213.1.1.4.74 DYNAMIC (CONF-329)
11. MAY contain zero or one [0..1] performer (CONF-330)
a. Contains exactly one [1..1] Laboratory Producer (templateId: 1.3.6.1.4.1.19376.1.3.3.1.7)
12. SHOULD contain zero or one [0..1] entryRelationship (CONF-331)
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<th>Severity</th>
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Instances of observation templates

Sein Observation ACPO1SO102 example

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<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
    classCode="OBS" moodCode="EVN">
    <templateId root="1.3.6.1.4.1.19376.1.8.1.4.9"/>
    <templateId root="1.3.6.1.4.1.19376.1.8.1.4.9"/>
    <id root="616067975" extension="MDHT"/>
    <code code="437" codeSystem="1.3.6.1.4.1.19376.1.8.2.1"
        codeSystemName="PATHLEX" display="Sein-Type histologique de lesion neoplasique maligne invasive"/>
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        <high value="2012"/>
    </effectiveTime>
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            <high value="2012"/>
        </time>
    </performer>
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        <addr/>
    </assignedPerson>
</observation>
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## Value sets

### Sein-Type histologique de lesion neoplasique maligne invasive

<table>
<thead>
<tr>
<th>Concept Code</th>
<th>Concept Name</th>
<th>Code System</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>688</td>
<td>Carcinome infiltrant canalaire</td>
<td>PATHLEX</td>
<td></td>
</tr>
<tr>
<td>689</td>
<td>Carcinome infiltrant lobulaire</td>
<td>PATHLEX</td>
<td></td>
</tr>
<tr>
<td>690</td>
<td>Carcinome infiltrant autre</td>
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</tbody>
</table>

Value Set: Sein-Type histologique de lesion neoplasique maligne invasive - 1.2.250.1.213.1.1.4.74

Code System: PATHLEX - 1.3.6.1.4.1.19376.1.8.2.1
Joint IHE Anatomic Pathology/IHE Laboratory/HL7 Clinical Genomics

Harmonization process APSR/Clinical genomics

CDA templates

C. Daniel (ADICAP, ASIP Santé, INSERM) – W. Li (INSERM)
Use case

Protocol for the Examination of Specimens from Patients with Neuroendocrine Tumors (Carcinoid Tumors) of the Colon and Rectum

Protocol applies to well-differentiated neuroendocrine tumors of the large bowel and rectum. Carcinomas with mixed endocrine/glandular differentiation, poorly differentiated carcinomas with neuroendocrine features, and small cell carcinomas are not included.

Based on AJCC/UICC TNM, 7th Edition
Protocol web posting date: February 1, 2011

Procedures
- Local Excision

*Ancillary Studies (select all that apply) (Notes E and H)
  - ___ Ki-67 index
    - ___ ≤2%
    - ___ >2% to 20%
    - ___ >20%
  - ___ Other (specify): ________________________
  - ___ Not performed

*Additional Pathologic Findings (select all that apply) (Note I)
  - ___ Tumor necrosis
  - ___ Other (specify): ________________________

*Comment(s)
**Protocol for the Examination of Specimens From Patients With Non-Hodgkin Lymphoma/Lymphoid Neoplasms**

Protocol applies to non-Hodgkin lymphoma/lymphoid neoplasms involving any site except the central nervous system, bone marrow, mycosis fungoides, and Sezary syndrome.

**Based on AJCC/UICC Protocol web posting**

**Procedures**
- Biopsy
- Resection of lymph node

**Authors**
Jerry W. Hussona, MD

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**Immunophenotyping (flow cytometry and/or immunohistochemistry) (note E)**

- Performed, see separate report: __________________________
- Performed
  - Specify method(s) and results: __________________________
  - __________________________
- Not performed

**Cytogenetic Studies (note E)**

- Performed, see separate report: __________________________
- Performed
  - Specify method(s) and results: __________________________
  - __________________________
- Not performed

**Molecular Genetic Studies (note E)**

- Performed, see separate report: __________________________
- Performed
  - Specify method(s) and results: __________________________
  - Not performed
Joint IHE/HL7 AP/Clinical Genomics

- Defining a common set of observation templates for molecular biology
- Managing these observations
  - Common Data Elements (metadata repository)
  - Value sets
  - Terminology (LOINC, PathLex)
- Using the same modelling tool: **Model-Driven Health Tools (MDHT)**