A Paradigm Shift - NAACCR’s Volume V Standard and the College of American Pathologists’ (CAP) Electronic Cancer Checklists

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* Since Jan. 2011 with Canada Health Infoway
Outline

- Background & History
- Development Team
- HL7 Brief
- Version 4.0 Highlights
- Challenges
- Conformance Testing Tools
- Work in Progress/Future Plans
NAACCR Pathology Data Work Group

Goal and Aims

- Develop messaging standards for transmission of electronic reports from AP laboratories to cancer registries
  - Standard – something established by authority, custom, or general consent as a model or example (Merriam-Webster)

- Overall aims: improve efficiency, reduce costs and provide a structure for future electronic pathology initiatives
Volume V - History

- Chapter in NAACCR Volume II (March 1999)
- Version 2.0 – HL7 version 2.3.1 (November 2005)
- Version 2.1 – HL7 version 2.3.1 (September 2007)
- Version 2.2 provides guidance using HL7 version 2.3.1 (February 2009)
- Version 3.0 provides guidance using HL7 version 2.5.1 (July 2009)
  - Limited synoptic guidance
- Version 4.0 provides guidance using HL7 version 2.5.1 (April 2011)
  - More detailed synoptic guidance
Working Definition of “Synoptic”

- Synoptic is a term which implies synopsis or summary; typically refers to checklists designed to ensure that key data fields are not omitted.

- The standardized and structured documentation of a Cancer Pathology Report, with common definitions, data items, and data item values.

- Jan 2009 - CAP defined specific features of “synoptic reporting formatting” (Letter to Dr. Greene, CoC Chair, by Dr. Amin, CAP Cancer Committee Chair).

- Feb 2009 - Dr. Srigley et al (J Surg Oncol;99:517-524) introduced a “Spectrum of Cancer Pathology Reporting”, -- from narrative to synoptic—the latter, fully structured, with discrete data fields, and coded.
Need for Data in a Synoptic Format

- First recognized by the CDC-NPCR through the Reporting Pathology Protocol (RPP1 and RPP2) pilot projects.
  - The RPP1 (2001) explored sending pathology reports for colon & rectum in a structured format, characterized by question and answer style pairs, where, for example, “Tumor Border Configuration” is the question (LOINC) and “Infiltrating” the answer (SNOMED CT).
  - The RPP2 (2004) addressed the use of CAP cancer checklists for three additional sites (breast, prostate, and malignant melanoma of the skin). These checklists were SNOMED CT encoded, which evolved during the project into the CAP electronic Cancer Checklists (eCC).

- NAACCR Volume V versions 2.1, 2.2, and Version 3.0 included some guidance how to transmit cancer checklist data using HL7. The new Volume V, Version 4 provides more detailed and updated information regarding how to construct such messages.
NAACCR Pathology Data WG 2010-2011
A Collaboration between Canada and the U.S.

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HL7 Brief

- Organization – Standards for Development Organization (SDO) for transmission of healthcare/clinical information
  - Over 20 years old
  - The HL7 standard itself
  - HL7 Version 2.x

  HL7 version 2.x Example:
  PID|1||123456789^^^SS000039^^^LRMcMuffin^Candy^^Ms.|…<CR>
  PV1|N|||||594110NY^Attending^Doctor^^DR|…<CR>

- HL7 Version 3.0
  - Clinical Document Architecture (CDA)- allows for transmission of images.
Focus on transmission of traditional text-based pathology reports with emphasis on specimen information (HL7 v. 2.5.1)

Sample messages provided for:
- 1) A “Simple Case” - a single reporting source, single primary with multiple specimens
- 2) A “Complex Case” - multiple:
  - primaries
  - specimens
  - types of reports

Also included - The “Older” ASCII Pipe-Delimited Format (Appendix A), last updated in Feb. 2009, Volume V, Version 2.2.
NAACCR Volume V, Version 4

Version 4.0 is comprised of ~297 pages including

- Volume V (Chapters 1-3),
  - Chapter 3: Synoptic Reporting
- Appendices
  - Data Type Definitions
  - Examples and Sample Reports
  - Questions and Answers

- Not included: ASCII Pipe Delimited Format, to be included in the forthcoming NAACCR Electronic Pathology (E-Path) Reporting Guidelines.
Paradigm Shift:
From Traditional Narrative Pathology Report Text
to Synoptic

Broadly Speaking – Three Styles of Pathology Reporting:

1) Traditional Narrative Reporting
   - Broad Section Headings (e.g., microscopic)

2) Synoptically Structured (aka synoptic like)

3) Synoptic (e.g., eCC)
Greater Nuance

- Kinds of Pathology Reports
  - Primary Reports
  - Supplemental Pathology Reports
    - Addenda
    - Amendments
  - Consultation notes (consults)
  - Autopsy reports
### New LOINC Codes for Kinds & Styles of Reports

- Labeled by a LOINC code in OBR-4* for the report

<table>
<thead>
<tr>
<th>Kind of Report</th>
<th>Style of Reporting</th>
<th>LOINC code</th>
<th>LOINC Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Report</td>
<td>Narrative Text</td>
<td>11529-5</td>
<td>Study report</td>
</tr>
<tr>
<td>Consult Report</td>
<td>Narrative Text</td>
<td>60570-9</td>
<td>Consultation note</td>
</tr>
<tr>
<td>Addendum</td>
<td>Narrative Text</td>
<td>35265-8</td>
<td>Path report.addendum</td>
</tr>
<tr>
<td>Autopsy Report</td>
<td>Narrative Text</td>
<td>18743-5</td>
<td>Autopsy note</td>
</tr>
<tr>
<td>Primary Report</td>
<td>Synoptic</td>
<td>60568-3</td>
<td>Synoptic report</td>
</tr>
<tr>
<td>Consult Report</td>
<td>Synoptic</td>
<td>60571-7</td>
<td>Consultation note.synoptic</td>
</tr>
<tr>
<td>Addendum</td>
<td>Synoptic</td>
<td>60569-1</td>
<td>Report addendum.synoptic</td>
</tr>
<tr>
<td>Pathology Report Collection</td>
<td>any</td>
<td>60567-5</td>
<td>Comprehensive pathology report panel</td>
</tr>
</tbody>
</table>

* Universal Service ID (identifies battery/types of tests/reports being ordered)
Message Segment Sections

- Mostly unchanged except ...
- Minor errors/typos
- Few NAACCR Usage changes (e.g., R to RE)
- OBR-4: LOINC Codes for Reports, including codes for some Tumor Marker Tests (Molecular Markers)

- NAACCR Standards Volume V, Version 4.0
  Summary of Changes – Posted on NAACCR Website
Chapter 3: Synoptic Reporting Sections

- 3.1 Interactions (flow diagrams)
- 3.2 The CAP Cancer Checklists
- 3.3 The CAP eCCs (Electronic Cancer Checklists)
- 3.4 Rules for Constructing the HL7 Message for CAP eCC Synoptic Reporting
- 3.5 HL7 Encoding of Specific eCCs
- 3.6 HL7 Encoding of Localized & Customized Checklists
Core Section: 3.4 Highlights

A. “The question/answer sets must be transmitted using the published CKey values for the codes (OBX-3 for all questions, and OBX-5 for coded answers). If published, standard codes must be sent as a second set of codes.“

Examples of standard codes: SNOMED-CT Core (many of these are distributed in the CAP eCC release); SNOMED-CT Extension (work is underway for a Cancer Registry SNOMED extension); LOINC Codes; NAACCR Registry Codes; ICD-O-3 Codes

• “SNOMED-CT and/or LOINC codes that are distributed as part of the CAP eCC distribution must be sent. The access mechanisms for other standard codes for the purposes of constructing and processing HL7 messages as per this Volume V Guide are under development (e.g., maps between CKeys and Registry codes).

• If there are published CKeys with no corresponding standard codes -- such CKeys can only be sent with prior approval by the receiving registry.“
What is a Ckey?

- The eCC software uses a unique key format, called the Composite Key ("Ckey"), to identify each line item in each electronic CAP cancer checklist.

- Developed to allow robust database management of identifiers for checklists, questions, and answers in data repositories.

- Ckey identifiers may distinguish similarly worded values (For example, margins for *Invasive ductal carcinoma* and Ductal carcinoma in situ both have Anterior, Posterior, Medial, Lateral, etc., margins). Each of these fields/margins has a unique Ckey value.

- The unique Ckey identifiers may be mapped to standard reference terminologies such as SNOMED CT and LOINC, and may also be used in data transmission protocols such as HL7 messages.
Challenges:
Customization of CAP Cancer Checklists

- “Discussion is underway to fully define the processes and mechanisms for
  - Local modifications and customizations of published CAP cancer Checklists
  - Best ways to disseminate and store such customized Checklists (e.g., so that others may benefit from work done locally).
- As soon as broad agreement has been reached on these topics, an update will be released to the community to provide guidance in the local modifications of checklists and the encoding of the data sent to registries.”
Challenges- cont’d: The HL7 Standard Allows for Some Freedom of Interpretation

- High degree of variability among HL7 implementations
  - Optionality and other degrees of freedom within an implementation such as Volume V
  - Saying ___ “If you’ve seen one HL7 message, you’ve seen …. One HL7 message”

- This variability has a negative impact on receivers of data
  - There must be custom-modifications for each laboratory sending data
  - Ongoing maintenance cost for many slight modifications
Conformance Testing Tools

- Conformance testing tools may help in addressing the challenges associated with the variability of HL7 2.x messages. Here are examples of three such free-ware tools:

1) HL7 Messaging Work Bench (MWB) - available at the NAACCR web site including NAACCR Conformance Profiles for Volume V (using HL7 v. 2.5.1 and v. 2.3.1) for Volume V, Versions 2.2, 3.0 and the new Volume V, Version 4.0. To download go to: http://www.naaccr.org/StandardsandRegistryOperations/VolumeV.aspx

2) HAPI Parser - open source HL7 2.x parser for Java, to download parser go to: http://hl7api.sourceforge.net/

3) Electronic Mapping, Reporting and Coding Plus (eMaRC Plus), tool developed by CDC/NPCR and their Registry Plus Development Team. For details go: http://www.cdc.gov/cancer/npcr/tools/registryplus/mp.htm
Work in Progress/Future Plans

- Molecular Markers
- Customization of Synoptic Reports, Namespaces (OIDS), and a Central Authority
- Tissue Inventory
- Synoptic Surgery Reports
- Synoptic Diagnostic Imaging Reports
- Staging Parameters
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