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

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For the NAACCR Pathology Data WG and the NAACCR CAP Checklist WG * 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
- <u>http://www.hl7.org/</u>
- The HL7 standard itself
- HL7 Version 2.x

HL7 version 2.x Example:

PID|1||123456789^^^ S\$\000039^^^ LR|McMuffin^Candy^^ Ms.|...<CR> PV1|N||||594110NY^Attending^Doctor^^ DR|...<CR>

HL7 Version 3.0

 Clinical Document Architecture (CDA)- allows for transmission of images.

NAACCR Volume V, Version 3.0 Summary

- 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 □VolumeV(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

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

Message Segment Sections

Mostly unchanged except ...

Minor errors/typos
 Few NAACCR Usage changes (e.g., Rto 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, <u>margins</u> for *Invasive ductal carcinoma* and Ductal carcinoma in situ both have Anterior, Posterial, 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: <u>http://hl7api.sourceforge.net/</u>
- 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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