

**Report on the
Reporting Pathology
Protocols Project for Breast
and Prostate Cancers and
Melanomas**

Executive Summary

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Introduction

RPP1

In 2001, the Centers for Disease Control and Prevention’s National Program of Cancer Registries (CDC-NPCR) funded two states, California and Ohio, to conduct a pilot study, the Reporting Pathology Protocols (RPP1) project, which evaluated the use of structured data entry for cancer pathology reports for submission to cancer registries for colon and rectum cancers. Typically, pathology reports are in a text format with data item-specific information contained in the narrative. See <http://www.cdc.gov/cancer/NPCR/informatics/rpp/>.

RPP2

In 2004, CDC-NPCR funded a second pilot project, the Reporting Pathology Protocols Project for Breast and Prostate Cancers and Melanomas (RPP2) with three CDC-NPCR cancer registries and four anatomic pathology laboratories in California, Pennsylvania, and Maine. The purpose of the RPP2 project was to use and enhance the data collection systems of registries funded by CDC-NPCR so that discrete data can be received electronically from anatomic pathology laboratories using the College of American Pathologists (CAP) Cancer Checklists for cancers of the breast, prostate, and skin (melanomas only). The RPP2 project participants developed a software data entry program of the CAP Cancer Checklists for these cancers for use by pathologists in the participating hospital anatomical pathology laboratories. The data were converted into a Health Level 7 (HL7) messages with SNOMED Clinical Terms® (SNOMED CT®) codes and transmitted to the cancer registry.

The RPP2 project evaluated the use of the SNOMED CT Encoded CAP Cancer Checklists (SECCC) in the participating laboratories for submission to cancer registries for cancers of the breast and prostate, and melanomas. The CAP has developed 42 (as of 2004) site-specific cancer protocols containing 64 checklists for use by the pathology community to improve the quality and completeness of information in cancer pathology reports.

The intent of this project was to—

1. Standardize and implement new means of transporting pathology data for cancers of the breast and prostate, and melanomas to cancer registries.
2. Increase the expertise and acceptance of synoptic reporting in the cancer and pathology communities.
3. Provide feedback to CAP’s Cancer Committee and other groups on improvements and implementation of the CAP Cancer Checklists.
4. Evaluate the strengths and limitations of implementing the SECCC for breast and prostate cancers, and melanomas.

The CDC-NPCR registries participating in this project included the California Cancer Registry (including C/NET Solutions), the Maine Cancer Registry, and the Pennsylvania Cancer Registry. The California Registry collaborated with the City of Hope laboratory;

the Maine Cancer Registry collaborated with the Maine Medical Center and Dahl Chase laboratories; and the Pennsylvania Cancer Registry collaborated with the University of Pittsburgh Medical Center. Additional project participants included two software vendors (Cerner CoPathPlus and Elekta's Impac Software), and SNOMED International[®], a division of the College of American Pathologists.

Results of RPP2

This project was successful in standardizing and implementing the electronic transmission of pathology data for cancers of the breast and prostate as well as for melanomas using the CAP Cancer Checklists. For example, software was developed collaboratively and installed to use the breast, prostate, and melanoma CAP Cancer Checklists in the participating anatomical pathology laboratories. The RPP2 project team developed an HL7 specification including generic message components, as well as those for carrying data from the CAP Checklist coded questions and answers.

Specifically, the project team agreed on the structure of the HL7 message for both the core HL7 segments and the observation segments that correspond with the data or concepts from the CAP Checklists. As the team developed the message structure, there was open dialogue between the group and the CAP Cancer Committee. Any issues or concerns raised during this process were shared with the CAP Committee. The data was converted into a standard HL7 Version 2.3.1 message and transmitted to the participating cancer registry, which then evaluated the associated data comparing the traditional narrative pathology report with the checklist data. The *Reporting Pathology Protocols Project for Breast and Prostate Cancers and Melanomas HL7 Implementation Guide* is available at: http://www.cdc.gov/cancer/npcr/npcrpdfs/rpp_report_121605.pdf.

This report gives a summary of the RPP2 activities, including descriptions of the workgroup teams, reports and documents developed from these activities, and the challenges and issues that were identified. The evaluation of the strengths and limitations of implementing the SECCC was initiated successfully and is described in Appendix F in the main report. A great deal was learned about the optimal electronic structure of pathology reports using the CAP Cancer Checklists, and how it differs from the structure of traditional text-based reports. The key findings and recommendations are noted below.

Key Findings and Recommendations

1. CAP Cancer Checklists incorporated into software systems: The initial CAP Cancer Checklists were designed for paper and in many cases did not account for the checklist concepts that need to be included in the software design. Both the paper checklists and the encoded checklists are updated periodically. This highlights the need for a system or a tool to accommodate the needs of anatomical pathology (AP) laboratory information software (LIS) vendors in handling the multiple CAP Checklist updates and to encourage semantic interoperability. There is also a need to assess the CAP Cancer Checklists from the perspective of information technology and adjust the checklists as appropriate.

Recommendation: The CAP should design and implement an electronic version of the CAP Cancer Checklists to interface with AP LIS vendor systems and promote interoperability. The CAP Cancer Checklists, in future versions, should be structured to be consistent with software design. [Editor's Update: During the project, the SNOMED CT[®]-encoded CAP Cancer Checklists (SECCC) evolved from a series of Microsoft[®] Word files to one Microsoft Access[®] file. The SECCC has evolved into the CAP electronic Cancer Checklists (eCC), which contain SNOMED CT codes in an XML format. See

http://www.cap.org/apps/docs/committees/cancer/cancer_protocols/Overview_CAP_Cancer_Checklists_090115.pdf]

2. Choice of coding system: For the purpose of encoding the pathology reports in the CAP Cancer Checklists, the first RPP project used LOINC as the question codes and SNOMED CT as the answer codes. Initially, the RPP2 team agreed to this pattern, and codes for the project Checklists were requested from the Clinical LOINC Committee. However, project participants expressed concerns about this pattern and noted that the SECCC contained SNOMED CT codes for both the questions and the answers. It was also noted that SNOMED CT is the vocabulary for pathologists, and was more appropriate. The decision was made and implemented to use the SNOMED CT codes for both the question and answer codes. While this was implemented for the project, the issue involves a variety of national and international standard setters and remains unsettled among stakeholders.

Recommendation: National and international standard-setting organizations including CAP and LOINC should work together to integrate LOINC codes into the CAP Cancer Checklists while concurrently incorporating the CAP Checklist concepts into the LOINC database. [Editor's Update: In January 2009, the CAP released an electronic version of the CAP electronic Cancer Checklists (eCC). Collaborative efforts are underway to incorporate the LOINC codes into this tool, as well as the corresponding SNOMED CT codes.]

3. Concept codes versus line identifiers: Two basic approaches can be used to represent the checklist questions and answers. The first approach, which was used in this project, was to assign semantic codes that represent clinical concepts across a variety of different checklists or other use cases. In practice, this means that the codes can repeat across

many checklists (e.g., the code for “Histologic Type”), or even within the same checklist (e.g., for repeating questions). Using this approach, project software participants were able to translate the CAP Checklist data items into the appropriate cancer registry data item. However, during the course of the project, it was observed that this approach creates problems when end users of the CAP Checklist pathology reports query the data.

Recommendation: To simplify querying, a preferred approach might be to assign simple checklist line-item identifiers for use in data transmission and storage. The design of the electronic version of the CAP Checklists should consider a combination approach, using both line codes and semantic codes for maximum flexibility. [Editor’s Update: These issues are being addressed in the new version of the eCC.]

4. Implementation and Testing: Although a common project implementation guide was developed, pathology laboratory and cancer registry software participants had difficulty complying with those specifications, in part because of the complexity of the code HL7 Version 2.3.1 and because software development was taking place as the guidelines were being developed. The implementation involves extracting data from a custom checklist data repository, possibly modifying data to match the project HL7 specification, and writing the conformant data to specific locations in the HL7 message.

In summary, writing HL7 code specific to an implementation guide is extremely difficult, and errors cannot be detected without software compliance tools. Specifically, after the HL7 project specifications were developed in word processing and spreadsheet software, the project explored the use of conformance testing software, HL7’s Messaging Workbench (MWB). Project specifications were entered into this tool and errors in the project HL7 specifications were discovered. Project implementation specifications were adjusted to conform to the discovered errors and to comply with the conformance testing rules. The MWB was deployed late in the project cycle and participants did not use it to assess message conformance. Rather, the more traditional approach of reading the code was taken to achieve project compliance. Consequently, many of the project HL7 segments, fields, and components were ignored and the participant’s previously developed HL7 specification or data format was used unmodified. In other cases, the RPP specification was attempted but was implemented incorrectly. As a result, thousands of MWB-generated validation error messages of many types came from the participants.

Recommendation: Pathology and cancer registry organizations should consider developing conformance testing tools to accompany HL7 Version 2.x implementation guides for the transmission of CAP Cancer Checklists. [Editor’s Update: The CAP is modifying the eCC to generate data-entry screens automatically from a standard XML representation of each checklist, in concert with the XML representation of the message profile. This eCC application could produce internally validated and correct HL7 messages as a standard output option from the data-entry form. These HL7 messages could be sent directly to participating cancer registries, or could be stored as a text blob in the host database systems for transmission at a later time.]

5. Registry and hospital software systems: Cancer registries and pathology laboratories use a variety of different commercial and custom software systems. The systems used for

sending and receiving HL7 messages are among the most diverse, and are very likely to use proprietary software tools and code. For the CAP Cancer Checklists, custom and site-specific HL7 messaging procedures are needed to move data to and from site-specific database tables and the HL7 message itself. Standardizing the HL7 message format, and implementing the format for the CAP Cancer Checklists, will allow the registries and laboratories to agree on the information that should be sent so cancer registries and other data receivers can be assured of receiving a reasonably consistent set of checklist information.

Recommendation: The North American Association of Central Cancer Registries (NAACCR), in collaboration with other data transmission standard-setting organizations, should develop HL7 implementation guidance for the CAP Cancer Checklists. The current NAACCR guidance for the transmission of pathology reports is primarily for traditional text-based reports. [Editor's Update: NAACCR has incorporated some guidance in the form of questions and answers related to the CAP Cancer Checklists, and is exploring the possibility of providing additional guidance.]

6. Accuracy and completeness of data in the CAP Cancer Checklist versus text-based reports: Pathology reports developed as part of this project using the January 2005 CAP Cancer Checklists are generally equivalent to data found in the traditional text-based pathology reports when assessed for accuracy and completeness. The majority of the cases from different specimen sites showed a high percentage of matches between the CAP Checklists report and text-based pathology report. In general, the discrepancies between the checklist and text-based reports appeared to be minimal. The version of the CAP Checklists used for this project did not contain many tumor marker data items needed for cancer registries.

Recommendation: To improve the accuracy and completeness of checklist reports, CAP should assess the utility of the data elements included in the January 2005 CAP Cancer Checklists for breast and prostate cancers and melanomas. [Editor's Update: The CAP Cancer Checklists are updated frequently. A major revision is taking place to be consistent with the seventh edition of the American Joint Committee on Cancer (AJCC) *Cancer Staging Manual* and will include selected tumor markers.]

7. Multiple cancers within one pathology report: Cancer registrars need to create a report or abstract for all cancers because some specimens contain more than one primary cancer. Project participants agreed to transmit a CAP Checklist report for all cancers (breast, prostate, and melanomas) within the particular pathology report. Cancer registrars need information about the number of reportable tumors to get the sequence number of the cancer in question and for case-finding purposes. Guidance within the pathology community on how to handle multiple cancers within a single specimen seems limited and amorphous. Concurrently, within the cancer registry community, the rules for determining multiple cancers are site-specific and complex. Pathologists may be unaware of these rules, and some rules are not necessarily clinically relevant.

Recommendation: The CAP Cancer Committee and the cancer registry community should address how best to define and code multiple cancers within a single specimen.

8. Pathologist use of the CAP Cancer Checklists: Pathology department procedures and the completeness of data collected for the checklists both impact the utility of the CAP Cancer Checklists and subsequently their use by pathologists. Compliance rates for the use of CAP Checklists are generally higher in pathology laboratories that require the use of checklists for reporting. Some of the participating project pathology laboratories already required the use of locally developed structured pathology reports, and the staff at these laboratories was more inclined to use the CAP Checklists.

Recommendation: CAP, as part of its laboratory accreditation program, should consider requiring the use of CAP Cancer Checklists, and identify potential organizational business practices and policies that could impede the ability of cancer registries and pathology laboratories to use CAP Cancer Checklists effectively.

9. Challenges and barriers to implementation of CAP Cancer Checklists: Challenges to the successful adoption of the CAP Cancer Checklists included the usability of the electronic versions of the checklists, staffing resources, technology and technical infrastructure, funding, and organizational procedures. Some of the participating pathologists already were using locally developed synoptic reports, and the number of additional keystrokes to complete the new CAP Checklists made adopting them more difficult. The design of the electronic input or entry software for the CAP Checklists is critically important.

Recommendation: Anatomical pathology laboratory information software vendors should solicit input from pathologists and other key stakeholders during the design or revision of the electronic versions of the input sections of the CAP Cancer Checklists. [Editor's Update: CAP is in the process of designing paper and electronic input tools for the CAP Cancer Checklists.]

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