College of American Pathologists Cancer Protocols: From Optimizing Cancer Patient Care to Facilitating Interoperable Reporting and Downstream Data Use

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Abstract

The College of American Pathologists Cancer Protocols have offered guidance to pathologists for standard cancer pathology reporting for more than 35 years. The adoption of computer readable versions of these protocols by electronic health record and laboratory information system (LIS) vendors has provided a mechanism for pathologists to report within their LIS workflow, in addition to enabling standardized structured data capture and reporting to downstream consumers of these data such as the cancer surveillance community. This paper reviews the history of the Cancer Protocols and electronic Cancer Checklists, outlines the current use of these critically important cancer case reporting tools, and examines future directions, including plans to help improve the integration of the Cancer Protocols into clinical, public health, research, and other workflows.

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Introduction

As a patient begins a journey of cancer treatment, the pathology report and associated biomarker results represent the starting data set that will drive that patient’s care. While traditionally pathology reports have been narrative-style unstructured text with variable content depending on the institution, the College of American Pathologists (CAP) has provided its Cancer Protocols to guide pathologists in creating synoptic cancer reports. Cancer Protocol-generated reports contain consistent content across institutions, record the data in discrete fields, and allow standardized sharing of these data with other organizations. A computer-readable version of these enables programs to use this information for decision support, prognosis, research, and public health reporting. Rather than manually scanning reports for specific parameters, such as tumor size and grade, computers can query databases for this content and use analytics to provide patient-specific prognostic and therapeutic information. Additionally, the use of data exchange standards allows for interoperability and information sharing under the 21st Century Cures Act.

Background

By the mid-1970s, it was recognized that the variation in reporting of cancer specimens by pathologists was problematic. Reporting was often handwritten and narrative, which created the potential to underreport or omit critical data elements needed for patient management. During this time, the American College of Radiology (ACR) had been conducting their own patterns-of-care studies with the goal of improving the quality of care by establishing guidelines for best management practices through peer consensus review and engaged with the CAP around the importance of cancer pathology reports to these efforts.1

The CAP Cancer Committee proceeded to form the Patterns of Care Steering Committee in the late 1970s, which later evolved into the Committee on the Pathologist as a Consultant in Cancer Patient Management in the early 1980s. Through the work of these groups, the Cancer Committee conducted their own studies with the aim of standardizing pathologic reporting and establishing the role of the pathologist as a consultant whose objective should be to provide the appropriate information needed for patient treatment.1

Work in this area led to the formulation of pathology practice protocols, ultimately culminating in the publication of the first set of Cancer Protocols in 1986 titled “Guidelines for Data to Be Included in Consultation Reports on Breast Cancer, Bladder Cancer, and Hodgkin’s Disease.”2,3

Protocols for different cancer types were steadily developed throughout the ensuing years. These included a background documentation section (which was a list...
CONTEXT

Key Objective
To promote understanding of the College of American Pathologists (CAP) Cancer Protocols and their critical use in cancer patient care, and advance collaboration and interoperability in the cancer domain through standardized structured reporting and data exchange.

Knowledge Generated
The CAP Cancer Protocols contain guidance and standardized clinical content that support best practices in cancer patient care. The CAP electronic Cancer Checklists (eCCs) allow for that content to be integrated into vendor systems and pathologist workflow to ensure report completeness, and to enable downstream structured data transmission, queries, analytics, quality assurance, research, and use in cancer surveillance and health system planning.

Relevance
The use of standardized structured data sets for pathology cancer reporting has been shown to improve patient care and clinical outcomes. The use of the Cancer Protocols and eCCs enhances patient care in addition to interoperability and data exchange through health information technology standards utilization and advancement.

The Cancer Protocols were encoded content in a common database format. By 2009, the Cancer Protocols were released for the first time in eXtensible Markup Language (XML) format. The CAP electronic Cancer Checklists (eCCs) are computer-implementable versions of the Cancer Protocols and Biomarker Templates that can be used for cancer reporting and direct patient care through middleware software, laboratory information systems (LISs), and electronic health records (EHRs). The eCC templates contain question-answer sets and fill-in parameters needed to create the diagnostic patient report. The presence of a question-answer format ensures that the content is explicitly specified and that the needed information is both present and valid. Once filled out in a data entry form (Fig 2), the data can be stored discretely within a vendor or other database. Thus, the eCCs provide several advantages as compared to paper-based synoptic reporting related to the ability to capture and store standardized structured data and ensure completeness of reports.

CURRENT USE

The Cancer Protocols were first designed as a resource tool for pathologists providing guidelines for cancer reporting and ensuring that all relevant data elements would be reported via standardized terminology. Ultimately, the use of synoptic reports is a quality assurance measure that ensures completeness and consistency: reports contain the necessary diagnostic, prognostic, and predictive elements needed for patient management. Through this standardization, ambiguity is reduced improving communication between pathologists and treating clinicians and allowing for more streamlined patient care.

Initially, the Cancer Protocols were largely based on the work of the Cancer Committee members with multidisciplinary input. Currently, the Protocols are developed and maintained by a multidisciplinary panel of experts (ie, Cancer Protocol Review Panels) with input from members of liaison organizations, the CAP House of Delegates, and other user feedback.

The Pathology Electronic Reporting Task Force (now the Pathology Electronic Reporting [PERT] Committee) was created in 2007 to oversee and guide the development of the electronic version of the Cancer Protocols, including refining the user interface and assisting in data modeling. The work of the PERT Committee further ensures that the cancer reporting information is both standardized and up to date and remains practical and usable for pathologists using electronic reporting through laboratory software systems.

The Cancer Protocols and eCC are under constant revision by the Cancer Protocol authors and review panels, keeping
Surgical Pathology Cancer Case Summary

Protocol posting date: February 2020

INVASIVE CARCINOMA OF THE BREAST: Resection

Select a single response unless otherwise indicated.

Procedure, Laterality, and Site may be listed separately or on 1 line.

Procedure (Note A)
___ Excision (less than total mastectomy)
___ Total mastectomy (including nipple-sparing and skin-sparing mastectomy)
___ Other (specify): ____________________________
___ Not specified

Specimen Laterality
___ Right
___ Left
___ Not specified

+ Tumor Site (select all that apply, as appropriate) (Note B)
+ ___ Upper outer quadrant
+ ___ Lower outer quadrant
+ ___ Upper inner quadrant
+ ___ Lower inner quadrant
+ ___ Central
+ ___ Nipple
+ ___ Clock position (specify): _____ o’clock
+ ___ Distance from nipple (centimeters): ______ cm
+ ___ Other (specify): _____________________
+ ___ Not specified

Tumor Size (Note C)
___ Microinvasion only (≤1 mm)
___ Greatest dimension of largest invasive focus >1 mm (specify exact measurement) (millimeters): ___ mm
   + Additional dimensions: ___ x ___ mm
___ No residual invasive carcinoma
___ Size of largest invasive focus cannot be determined (explain): __________________________

Note: The size of the invasive carcinoma should take into consideration the gross findings correlated with the microscopic examination. If multiple foci of invasion are present, the size listed is the size of the largest contiguous area of invasion. The size of multiple invasive carcinomas should not be added together. The size does not include adjacent ductal carcinoma in situ (DCIS). For any carcinoma larger than 1.0 mm but less than 1.5 mm, the size should not be rounded down to 1.0 mm, but rather rounded up to 2.0 mm, to ensure that the tumor is not miscategorized as pT1mi.

Exception to the size rule – if two histologically similar carcinomas are within 5.0 mm of each other, measure from outer edges of the two. For staging purposes radiologic findings can be used for pT category.
in step with changes in tumor classification systems, staging parameters, and biomarkers. Core elements must be included for the report to be complete and must meet established scientific level of evidence criteria for protocol inclusion, while optional (noncore) elements are proposed parameters that are still being evaluated and may eventually be promoted to a core element. For example, tumor budding in colorectal carcinoma is currently an optional element but could be promoted to a core element for some tumor stages. Definitions and criteria used by pathologists are also continuously updated in the protocols’ Explanatory Notes sections based on feedback from end users and quality studies.

The electronic version of the CAP Cancer Protocols is seeing more widespread use in recent years. The number of licensed full-time equivalent pathologist users of the eCC has grown over the last 6 years from 1,000 to 6,400. This represents about 35%-40% of all practicing anatomic pathologists in the United States and Canada. Additionally, approximately 45% of hospitals with > 400 beds in the United States are licensed to use the eCC for diagnostic pathology cancer reporting, and 49 of the 50 states in the United States have laboratories using the eCC.

The eCC uses a Structured Data Capture (SDC) format that offers some notable advantages over paper-based synoptic reporting. The United States Department of Health and Human Services’ Office of the National Coordinator for Health Information Technology created SDC in 2013 to provide a standardized format for clinical data capture, transmission, and sharing. The CAP eCC was first released in SDC-XML format for vendor implementation and use in February 2019. This format ensures that data are computer-identifiable, retrievable, and processable and uses a standardized data set lexicon (Fig 3).

Reporting using structured data is advantageous as it facilitates easier case retrieval and data transfer by supporting extraction of data elements with standard and discrete values. Without this, there is a lack of uniformity in
cancer reporting that can affect the ability to extract data because of the diversity of terms used or nonuniform selection of reportable elements. Although natural language processing (NLP) tools and machine learning capabilities have become more sophisticated, they are still not sufficiently powerful to successfully and accurately mine all unstructured cancer data with consistent precision and sensitivity. The use of the CAP Cancer Protocols can improve the yield of NLP by standardizing the language; however, this does not entirely solve back-end data harmonization issues. Ideally, information is captured as discrete data upfront with a controlled vocabulary, such as with the Cancer Protocols and eCC, preemptively eliminating misinterpretation of the data that may occur during manual abstraction, NLP, and coding translation processes. Fidelity of these report data is critical for patient management and for numerous downstream uses including cancer surveillance, research, education, analytics, quality assurance, and health system planning.

Dependence on clinical vendor implementation adds another variable to standardization, and so, greater attention to vendor engagement is now helping to mitigate this. Over the past 2 years, most pathology and LIS vendors have successfully implemented the eCC in SDC format. Collaborative efforts with vendors are ongoing to render the Cancer Protocols efficiently and accurately as data entry forms and reporting tools, with a primary goal to reduce the cycle time from protocol release to implementation. One of the challenges is that many vendors are required to transform the current SDC format into their proprietary system. Improvement of that process and adoption of newer technologies to address any shortcomings is an ongoing goal.

Additionally, significant efforts are ongoing through a cooperative agreement with the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR) and a recent grant with the California Department of Public Health (CDPH) California Cancer Registry. The collective work toward the development and implementation of standardized structured reporting (SSR) across laboratories and health systems shares a goal of automated, direct transmission of cancer case data to centralized cancer registries. Activities include reconciling clinical cancer reporting with cancer registry data.
collection standards, cooperative work on metric development and measurement for cancer reporting from laboratories to registries, promotion of use of technical standards such as SDC for more automated transmission of cancer report data to registries, and alignment on biomarker and other key data capture components.

The CAP is also engaging with the Ontario Health—Cancer Care Ontario, the North American Association of Central Cancer Registries (NAACCR), the National Cancer Institute—SEER, the American Joint Committee on Cancer (AJCC), ASCO, International Collaboration on Cancer reporting, the University of Nebraska Medical Center, the ACR, and the WHO International Agency for Research on Cancer to improve alignment of release scheduling, to develop common coding practices (eg, International Classification of Diseases for Oncology, Third Edition (ICD-O-3), Minimal Common Oncology Data Elements, and SNOMED CT), and to adjust the flow and automation of cancer case identification both for clinical use and for capture into cancer surveillance systems.

**FUTURE**

Continuing to build on the current momentum to improve the data capture, reporting, and portability, there are plans to further use the expanded capabilities of the SDC format for both direct patient care and downstream data use purposes. One of the goals is to provide rule capability within the SDC format that will allow dependencies of different questions and answers to be evaluated in real time when the form is being filled out. Stage classification, for instance, can be calculated from answers to the specific staging parameters that are collected while filling out the data entry form that creates the report. Setting relationships between SDC question and answer metadata enables the program to automatically calculate stage classification and check for inconsistencies within the completed cancer patient pathology report. This functionality is similar to that of consumer tax preparation software, where branching logic changes questions that are relevant to the respondent according to their responses and may constrain possible answers to be consistent with the other reported elements. The challenge is that the rule information is supplied generically within the SDC format, but successful implementation relies on the specific vendor system capabilities. Vendors could choose to offload some of these tasks to an outside application program interface or other similar technologies. This would streamline data entry by the pathologist and ensure internally consistent data in the pathology report.

As noted in the background review, the initial electronic protocol version used SNOMED CT as the basis for terminology. That tight coupling was abandoned because of the need for new terms that were not available in SNOMED CT. However, there is an ongoing effort to map CAP cancer protocol data elements to other terminologies, including ICD-O-3 and NAACCR Site Specific Data Items, and a project to SNOMED-encode the CAP Cancer Protocols, including creation of new SNOMED CT precoordinated observable concepts for accurate mapping.\(^{21}\)

Importantly, there is a significant push to address the future of downstream interfaces and systems to make the best use of these data. The most obvious model for this is public health for cancer reporting and quality measures that is currently in place in Canadian provinces, such as Ontario, in parts of California, and in work with the CDC NPCR. Quality indicators generated from structured pathology databases can be used to compare practice patterns across jurisdictions, institutions, and even individual providers.\(^{22-24}\)

However, future use of these electronic data applies to both patient care with real-time implementation for treatment and research use for analysis of discrete pathology report data to registries, and alignment both for clinical use and for research use for analysis of discrete pathology report.
data. For example, Sluijter et al\textsuperscript{25} looked at whether using SSR could affect clinical outcomes in patients with colorectal cancer. They determined that SSR improved patient care by providing more complete, higher quality reports that led to more effective care delivery and better patient outcomes. In addition, there is work underway at the CAP to develop frameworks for cancer biomarker reporting that would span tumor types for both immunohistochemistry (eg, programmed death-ligand 1) and genomic measures (eg, Tumor mutational burden - High and Microsatellite instability - High) and as to consider how to most effectively combine molecular results and digital images to optimize clinical review of these data to help inform treatment options. Discrete data for these elements can also allow for computational analysis to assist the treating physician with the selection of appropriate therapies and provide prognostic data useful in patient care.\textsuperscript{26}

The current interfaces for public health follow the NAACCR Volume V standard in Health Level Seven International (HL7) v2.x messages for transmitting discrete pathology report data.\textsuperscript{27} Future possibilities include interfaces based on the Integrating the Healthcare Enterprise (IHE) SDC profile,\textsuperscript{28} including HL7 Fast Healthcare Interoperability Resources FHIR-based transmissions (eg, SDC on FHIR).\textsuperscript{14,29} These evolving technical profiles have been tested in IHE-Connectathon activities and demonstrated at Healthcare Information and Management Systems Society, Inc. Interoperability Showcases to validate their robust functionality and translation into practice in the real world. The desired application and outcome would be reconciling EHR, SDC, and other future data format use with cancer registry software and other surveillance tools, allowing for the automated push, transfer, and ingestion of these data in an accepted standardized format. Even as this area is undergoing sustained growth and development, current adoption of newer technologies has been slow because of the persistence of legacy systems with outdated interfaces which still meet institutional shorter term clinical needs.

Additionally, genetic analysis has become critical to defining some tumors and to identify specific therapies. For some cancers, there is a standard set of testing, and synoptic reports have been created to allow these data to be recorded as discrete data. This field is rapidly expanding such that having these data as discrete data will be necessary to allow decision support to analyze the burgeoning

\textbf{FIG 4.} Vision of an interoperable future for cancer data exchange, patient care, and downstream data use. Multidisciplinary reports are currently issued in varied formats, and translation and integration of these may be limited by the allowable outputs from their electronic health record systems. We envision harmonizing reporting structures using a technical standard such as Structured Data Capture (SDC) to be used in direct patient reporting and to communicate these data accurately and effectively to downstream data users.
amount of data and to assist the clinician in identifying possible options. The SDC format is capable of handling a variety of data structures that may be needed to collect these types of data, but determining an agile standard to collect and transport these data is still a work in progress.

A vision for the future of cancer data exchange shares in the basic principles behind the eCC, as evolution toward an automated system of cancer reporting aiding pathologists and clinicians in their workflow and in patient care that is also synchronized with downstream data use needs. The SDC framework can help achieve this through integration into vendor systems to capture pretreatment clinical information and export data to downstream systems (Fig 3). To have a successful data exchange ecosystem where clinical cancer reports are automatically subsumed by the cancer surveillance and research communities, we must continue to strive for an agreed-upon reporting structure based on standardized content and technical frameworks (Fig 4). These technical frameworks may also include nonrelational database structures, such as an XML database, that could retain the XML object and use newer technologies for querying.

SUMMARY
The CAP Cancer Protocols and eCCs have evolved from paper forms to a relational database to the current SDC-XML format which allows metadata to manage the complex relationships between multiple tumor data elements. Cancer Protocol’s electronic reporting and adoption has steadily grown in the clinical domain, with ongoing evolution of use by downstream data consumers such as the cancer surveillance community. This trend is continuing to close the gap, providing accurate and detailed cancer reports in a computable form needed for the next generation of data-driven cancer care and personalized medicine.

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