Usefulness of a Synoptic Data Tool for Reporting of Head and Neck Neoplasms Based on the College of American Pathologists Cancer Checklists

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Abstract

The primary source of information that clinicians use when evaluating and managing patients with cancer is the surgical pathology report. Omission of critical information from the report is a recognized problem in pathology, especially considering the expanding amount of information, such as molecular diagnostics data, that is now routinely included in reports. To standardize surgical pathology reports, the College of American Pathologists (CAP) introduced the CAP checklists. In 2004, the American College of Surgeons Commission on Cancer mandated that 90% of pathology reports indicating a cancer diagnosis at participating centers contain all scientifically validated or regularly used data elements.

The University of Pittsburgh Medical Center has implemented synoptic reporting based on the CAP checklists for all major tumor types. We report our experience with synoptic reporting on head and neck neoplasms, demonstrating, in particular, how this can be customized according to needs of each institution.

The primary source of information that clinicians rely on when evaluating and managing patients with cancer is the surgical pathology report. Historically, the surgical pathology report included only morphologic information on the histologic type, grade, and margin involvement of the tumor. However, as our understanding of disease processes has advanced with the rise of translational and molecular medicine, so has the number of relevant diagnostic markers and parameters. The amount of clinically important information is increasing rapidly, and because much of this information factors in the diagnosis and treatment of the patient, it is necessary to describe it in the pathology report. This increase in information has caused the report to evolve into a complex document encompassing translational and molecular information such as hormone receptor status, microsatellite instability, oncogene mutations, and other information that can affect adjuvant therapy. In addition, the use of microarrays in common clinical practice is also looming on the horizon. With this immense amount of data, the surgical pathology report has to be not only accurate but also clear and complete in conveying information to clinicians.

It has long been recognized that in consistently documenting the extensive amount of important details for a wide range of tumors, relying on a pathologist’s memory is not an ideal solution. Based on a landmark study of 15,940 pathology reports of colorectal cancer from 332 laboratories, Zarbo1 reported in 1992 that essential elements such as gross tumor size, depth of tumor invasion, status of resection margins, and tumor grades were omitted in a significant portion of surgical pathology reports. This finding was reiterated for lung carcinoma reports by Gephardt and Baker2 in 1996. Differences in styles and terminology among pathologists add another layer of complexity to understanding these reports.
In addressing these concerns, Rosai\(^3\) proposed in 1993 the standardization of surgical pathology reports for major tumor types by creating a checklist format. In the ensuing years, morphologists, researchers, and informaticians have made significant progress establishing guidelines for pathology reports in the form of templates and checklists.\(^5\)\(^6\) The implementation of these guidelines gained momentum when the American College of Surgeons Commission on Cancer, which accredits more than 1,400 cancer treatment centers in the United States, mandated in its Cancer Program Standards that 90% of pathology reports at its approved cancer programs include all scientifically validated or regularly used data elements in their reports for each site and specimen.\(^7\) To facilitate implementation of this mandate, the College of American Pathologists (CAP) developed site-specific cancer protocols and checklists as a resource.\(^8\) These checklists contain required data elements that have been scientifically validated, as well as optional elements that may be clinically important.

Mohanty et al\(^9\) previously described the implementation of the checklists for hematologic and lymphoid neoplasms in a synoptic reporting tool integrated with the anatomic pathology laboratory information system (LIS) that provides a structured and preformatted method for entering clinically and morphologically relevant details of surgical specimens. This is essentially an online diagnosis worksheet that provides an intuitively designed template for data entry. It also captures the data elements into a relational database, greatly simplifying and streamlining the process of searching and retrieving data compared with information stored in plain-text reports. Increasing the accessibility of the data enhances their usefulness in clinical, translational, and basic science research. In this article, we report our experience with synoptic reporting for head and neck neoplasms.

Materials and Methods

The purpose of this project was to develop the entire set of elements in the synoptic templates for head and neck neoplasms (eg, thyroid, parathyroid, larynx) using the CAP checklists. The synoptic worksheets for thyroid and upper aerodigestive tract, including salivary gland neoplasms, are based on the respective CAP checklists (thyroid posted in July 2006; upper aerodigestive tract revised in January 2005). However, owing to the highly specialized nature of head and neck cases at our institution, there was a need for more specific worksheets, leading us to develop separate checklists for larynx, parathyroid, and neck dissection cases.

As previously described,\(^7\) we used a digital synoptic reporting module integrated into an existing LIS, CoPathPlus (version 2.5.1.83), owned and developed by Cerner DHT, Kansas City, MO. This module is available from the vendor and can be adapted to the needs of other institutions. The LIS provides a Windows-based user interface and is built on a relational database platform (Sybase). The data elements are presented under logical categories and captured as discrete values; eg, the data element for “mucoepidermoid carcinoma, low grade” exists in the synoptic value dictionary as a discrete value, allowing the user to search for just the cases with that value point populated.

The 4 distinct components within the synoptic reporting system are described in the following sections.

Dictionaries

Image 11, Image 21, and Image 31 illustrate 3 of the dictionaries. The synoptic worksheet is composed of synoptic values (created in the Synoptic Values dictionary). Each synoptic value is assigned to a synoptic category (created in the Synoptic Category dictionary). When building a synoptic worksheet, the synoptic categories and synoptic values for the worksheet must first be created in their respective dictionaries. In the Synoptic Worksheet dictionary, a synoptic category is selected and then the synoptic values assigned to that category are available to be added to the worksheet. The synoptic category that a group of values has been assigned to in the synoptic values dictionary becomes the header (editable) for that category on the worksheet, and the synoptic values become the selectable values under that header on the worksheet. The tabs in the Synoptic Worksheet dictionary allow an administrator to set rules for each group of values, such as whether a group requires a selection, cardinality, parent-child relationships between values, and how the text will display in the report.

Specimen Data Entry and Text Generation

Image 41, Image 51, and Image 61 illustrate the final diagnosis entry-edit and electronic sign-out activities, in which synoptic data entry and editing can be performed in line with editing of other diagnostic text in the report. The worksheets may be completed directly by pathologists or training staff or dictated and completed by transcription staff. Validation logic based on definition of worksheets generates warnings to staff, eg, for required groups missing a selected value or fill-ins with inconsistent formatting. After the worksheets are filled out and completed online, the system automatically generates diagnosis text from them based on specifications in the Synoptic Worksheet definition. The generated text, which is protected from editing via the word processor, can be directed to the Final Diagnosis text field or to a separate text field. Free text comments can be included in the text field above or below the protected text.

Results Interface

An HL-7 results interface can optionally be configured to transmit discrete synoptic data elements via “Z segment” extensions, along with the text-based HL-7 results.
Image 1 Synoptic worksheet dictionary interface. Categories and values, or “questions” and “answers,” are defined and then used to build the template for entering structured data. These can be inserted as related groupings. Additional logic may then be applied to groupings, eg, to require an entry or allow for multiple entries. The same tool is used for subsequent editing.

Image 2 Synoptic category dictionary interface. Categories organize the synoptic values so that they can be added to templates in groupings. They may also be accessed in constructing data retrievals or lookups.
**Image 3** Synoptic value dictionary interface. Users can create and edit values and modify their attributes, e.g., to allow numeric or text fill-ins or link Systematized Nomenclature of Medicine Clinical Terminology CT code.

**Image 4** Final diagnosis entry/edit activity. This application item is used for primary entry of final diagnosis and related text, by pathologists or clerical staff, and access to synoptic worksheet entry is integrated as a second tab. A “blank” worksheet may be automatically added to the case or defaulted based on specimen type.
Image 5 Synoptic worksheet entry interface. Templates are presented in multiple pages, as lists of related “values” grouped under “categories” as headers. Values that have been selected by the user are circled in blue. If a selected value includes a fill-in, text that is entered displays in bold blue (see A3 above). Other optional conventions shown include an off-colored band for the header and a double-asterisk (**) to denote groups that require an entry. A worksheet generates no text in the report until successfully completed.

Image 6 Final report sign-out. A completed synoptic worksheet will autogenerate text values for all selected items and insert the values into a distinct section of the final report, with categories and values in opposing columns. The synoptic text may not be edited directly. The “Worksheet” button will access the synoptic worksheet entry screen to allow pathologists to complete or otherwise edit selections, and text is then updated dynamically.
Kang et al / SYNOPTIC TOOL FOR HEAD AND NECK CANCERS

Data Search and Management Reports

A data search capability is provided via the “Infomaker wizard” tool, allowing detailed searches of the discrete synoptic data fields in combination with other specimen and patient parameters. There are also several management reports defined for obtaining information on use of synoptic worksheets, for example, by pathologist, individual worksheet, and grouping by natural language and Systematized Nomenclature of Medicine Clinical Terminology, or SNOMED, coding searches.

Results

The synoptic worksheets that we developed for head and neck neoplasms are displayed in Image 7. PDF versions of these worksheets are available online (http://www.dbmi.pitt.edu/CTSA/HNSPORE/HN_index.htm). Because the checklist for upper aerodigestive tract and salivary glands encompasses a wide range of tumors, it is several pages long, and it can be tedious to page through the online worksheet looking for the specific items of interest. This searching, in turn, can lead to errors, in part owing to the difficulty in applying rules or constraints on the entries. This may not be a problem for uncommon tumors, but owing to the large volume of head and neck surgeries performed at our institution, we see a significant number of less common cases. These issues prompted us to break out the elements specific to certain situations into separate worksheets, as illustrated by the Larynx Synoptic Template (Image 7C). We have also developed a worksheet for parathyroid tumors (Image 7D), which are not represented in the CAP checklists. Finally, the Neck Dissection Synoptic Template (Image 7E), although not specific to a certain tumor, was created to capture data with somewhat greater levels of detail than specified by CAP and streamlines the reporting for this procedure. As of October 15, 2008, there were a total of 1,233 cases of head and neck neoplasms (thyroid, 820; upper aerodigestive tract and salivary glands, 306; larynx, 90; neck dissection, 16; and parathyroid, 1) with completed synoptic worksheets.

Discussion

The pathology report is the main vehicle by which pathologists communicate with clinicians and is one of the most important factors that help clinicians to predict prognosis and,

Image 7 Image 7 Image 7 Image 7, Upper aerodigestive tract and salivary gland synoptic template. This is the template that is used when a pathologist is diagnosing a head and neck neoplasm from the upper aerodigestive region. The template is based on the College of American Pathologists (CAP) checklist for upper aerodigestive tract tumors, which is updated periodically, and the template in the laboratory information system is modified to reflect these changes.
B. Thyroid tumor resection synoptic template. This template is based on the CAP checklist for thyroid neoplasms. The synoptic dictionaries provide the flexibility to customize the worksheets, eg, to include thyroid function markers such as thyroid stimulating hormone. C. Larynx synoptic template. The larynx template is an example of a customized worksheet to incorporate data elements specific to laryngeal cancers. This template captures all CAP checklist elements but also has additional values that were added on recommendation of our clinical teams and head and neck pathologists.
**D, Parathyroid tumor resection synoptic template.** This is another customized checklist that was designed in a format similar to the existing CAP checklists. The customization of the checklists is not technically demanding and is a valuable method for ensuring that high-quality data that fit the need of a subspecialty or user community are captured at the time of sign-out. **E, Neck dissection synoptic template.** Synoptic templates do not need to be limited to specific tumors; the neck dissection synoptic template can be easily modified to capture information about lymph node excisions in other sites. Overall, these checklists represent a standardized method of capturing information on commonly recurring tasks.
performing queries against the data compared with data stored that programmers could directly apply to an application. 

The increased information has led to a better understanding of the behavior of tumors in individual patients and the development of therapies that focus on specific molecular targets. However, to apply this knowledge, clinicians must digest an ever-increasing amount of data, most of which are contained in pathology reports. Traditionally, this has been in a narrative format, but the complexity of the information that the report contains has made this format prone to errors such as the omission of resection margin and depth of tumor invasion, leading to the proposal for diagnostic checklists to ensure thoroughness. The mandate of the American College of Surgeons Commission on Cancer in 2004 spurred the adoption of the checklists that CAP developed for this purpose. Another characteristic of narrative reports is the variability in style among pathologists and institutions: especially in this age of multi-institutional care, inconsistent formatting sets another barrier in the efficient communication of data to clinicians. The CAP checklists address both of these issues, providing mechanisms to ensure that pathology reporting is thorough and uniform.

True synoptic reporting, in which the checklist data elements are captured individually, improves on this even further, for example, performing quality assurance by enabling automatic constraints on data elements in the reports. Several studies have demonstrated the effects of synoptic reports in enforcing completeness and consistency by comparing pathology reports from before and after synoptics implementation, and this has been shown to improve clinical measures as well.

The head and neck synoptic worksheets that we have implemented have been used extensively. In particular, our experience demonstrates how a synoptic reporting tool is flexible enough to be adapted to institution-specific situations and is not limited to a certain format. It is also possible to share exports of the worksheets with institutions that have compatible versions of the software. While the export files are not compatible across different LIS products, it would not be difficult to build a template using printouts of our worksheets. In addition, CAP has made some effort at standardization in this area by upgrading the cancer checklists to a database format that programmers could directly apply to an application.

Another advantage of synoptic reporting is the ease of performing queries against the data compared with data stored in plain-text format. At our institution, the synoptic tool is completely integrated into the anatomic pathology LIS and captures and stores the entries as discrete data elements in a relational database.

The main weakness of this tool is that it cannot restructure the enormous amounts of legacy free-text surgical pathology reports that many institutions have. The University of Pittsburgh has developed a different application, the Cancer Text Information Extraction System, which can assist in this process. This product, although open to data sharing through cancer Biomedical Informatics Grid compliance, is not integrated with the synoptic report database. The data extracted using this system reside in a separate database parallel to the CoPathPlus database.

The database of synoptic reports is, of course, accessible only to people who have access to the LIS. However, it can serve as a powerful resource for clinical and translational research, in addition to being mined for data to assist in the clinical decision-making process. The data can also easily be exported to a platform-independent format such as XML by addressing the database through an application programming interface and mapping the data elements to appropriately structured XML tags. Enabling the cancer registry and other resources, such as the SPORE Head and Neck Neoplasm Virtual Biorepository, to extract these data (with appropriate layers of security) prevents duplication of effort and improves their data quality as well. Sharing the data across multiple environments in such a controlled manner increases data availability by broadening the scope of people who can access it, while ensuring that patient confidentiality is not compromised. This also empowers researchers by lowering the cost of data retrieval, increases data utilization, and, ultimately, has the potential to create new synergies and applications of this information.

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