review article

Synoptic Reporting: Evidence-Based Review and Future Directions

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INTRODUCTION

Synoptic reporting is a process for reporting specific data elements in a specific format in surgical pathology reports. Previously, surgical pathology reports were free text, highly narrative, and prone to omission of necessary data and inconsistencies in formatting.[1] Synoptic reporting not only ensures that all reports contain all necessary data elements, but also is amenable to scalable data capture, interoperability, and exchange. Efforts are ongoing to create national[2] and international[3-7] health care meaningful use standards by using cancer registries and health information exchanges for storing and accessing data. Ideally, data will be fed dynamically and seamlessly into and out of these data exchanges by using lean and streamlined automated processes.

In practice, the College of American Pathologists (CAP) has been promoting synoptic reporting for > 20 years,[8] has published protocols with both required and optional data elements for at least a decade, and has required reporting of these elements for the past 2 years as part of its Laboratory Accreditation Program (LAP) checklist.[9] The contents of the CAP protocols along with the contents of the American Joint Commission on Cancer (AJCC) TMN staging system, which the protocols use, are both copyright protected. The AJCC copyright includes all computable representations of its TNM staging system, which raises issues to be discussed later. Internationally, the Royal College of Pathology (United Kingdom), the Royal College of Pathology Australasia, the European Task Force for Structured Reporting, the American Society of Clinical Pathologists, the Canadian Association of Pathologists, and CAP have worked with the International Collaboration on Cancer Reporting to produce a standard data set for the international community.[3-7] A detailed road map was outlined by those involved in the CAP effort, which went from free-text narrative reports (level 1), to synoptic reporting (level 3), toward fully structured reporting. The final product includes discrete data embedded in laboratory information systems (LISs) and structured messaging/data exchange standards (level 6).[10,11]

Synoptic reporting has many different connotations, which depend on the stakeholder. For practicing pathologists, synoptic reporting refers to specific elements in the cancer protocols and a specific format required by the CAP LAP checklist.[9] For clinicians, synoptic reporting provides a checklist that ensures completeness of reported data elements. For registrars, researchers, and data scientists, synoptic reporting denotes a means to populate structured databases. Although substantial overlap exists, the requirements for these various stakeholders can differ. This review details the components of synoptic reporting that affect its utility for these stakeholders and the components of synoptic reporting from the perspective that synoptic reporting actually exist as two layers. These layers comprise a front-end presentation layer and a back-end computational data layer. This understanding becomes sharper as components of synoptic reporting are discussed in context throughout this review.

SYNOPTIC REPORTING FOR THE PATHOLOGISTS WHO CONSTRUCT THEM

Checklists are associated with improvement in completeness of surgical pathology reports,[11-20] although completeness rates do not exceed 90% in most studies.[12-15,21-26] Higher completeness rates (that approach 100%) are achieved by using consistent formatting of the checklist elements,[27] exclusion of all optional elements,[27] reminders when the element is missing from the report,[28] and force functions (CAP electronic Cancer Checklists).

Several features correlate with synoptic reporting accuracy. Accuracy has been inversely correlated with number of required data elements.[29] This correlation with error is strongest for those reports created by hand with or without aids,

including Word macros (Microsoft Corporation, Redmond, WA). As a result, some authors have suggested that only essential elements and a minimized data set should be required in synoptic reports to improve the accuracy and quality of data.[29] In addition, the format of the items can affect the accuracy of the report. The use of the terms no and not have been associated with decreased accuracy as a result of the user forgetting to include the terms in the report.[30] Such terms should be avoided.

Another source of error is the requirement to report related/associated data multiple times throughout the same report. For example, data elements related to AJCC staging often are duplicated within the final stage itself. This repetition introduces unnecessarily redundant efforts for pathologists to duplicate and verify data consistency and concordance. One solution is to eliminate this redundancy. Alternatively, various related selections can be bundled as one automated selection that the pathologist selects once but that a computer-assisted process repeats as necessary in the report. At present, neither the logic for this is readily available in commercial builds nor the heuristic guidelines for such logic builds. Because AJCC holds copyright on all computable representations of its TNM staging system, this may hinder development of these processes and may become more problematic as molecular data elements are further incorporated into the AJCC staging system. In addition, many anatomic pathology (AP) LISs require some technical skill by client information technology support, which may be lacking in many pathology departments. Furthermore, for clients whose synoptic reports are created by hand, such logic is nonexistent.

Many features of synoptic reporting still require more study. Unknown is whether fewer questions and a longer list of responses (and fewer clicks) performs better than more questions with fewer options. Also unknown is whether multiple question formats (single response, multiple responses, deprecated responses) or a single format for all questions affects performance. Furthermore, whether various pathologists perform differently with different formats is unknown. Alternatively the effect of free-text entry on the accuracy of the report needs additional study. Little information exists about whether data are lost or inaccurate when free-text entry is impermissible. Pathologists vary in what they consider to be adequate responses, and some pathologists routinely include more information than required in a particular protocol, and this information might be lost without the ability to use free-text entry.

Synoptic reporting user interfaces should make the process less error prone for pathologists. Such user interfaces allow pathologists to customize their system easily and rapidly. Today's AP-LISs are designed more for data management that facilitates billing and operational functionalities, with reporting functionalities developed almost as an afterthought. As a result, optimal use of synoptic reporting continues to lag behind reporting needs. In addition, today's AP-LISs are unable to decouple data entry flexibly from what is displayed in the synoptic reporting presentation layer, which creates consequences for users as discussed in the next section. With AP-LIS vendor turnaround times often taking months to years, customizations for flexible reporting functionalities can be difficult and costly for clients.

Web-based synoptic reporting user interface systems, on the other hand, decouple data entry and have shown improved accuracy of synoptic report creation in the presentation layer compared with manual methods.[28] Web-based systems also may be more flexible and easily customizable by end users for data entry. For example, free-text entries can be smartly anticipated as a response. A Web-based system that interfaces with a laboratory's information system is not only easier to update, modify, and enhance rapidly but also cheaper to build and maintain. Web-based synoptic reporting user interfaces have improved the ordering of ancillary studies and have incorporated functionalities such as diagnostic algorithms; immunohistochemical staining patterns; billing reminders; and quality assessment procedures, including the Physician Quality Reporting System.[28,31] Even with genomic reporting in cancer, Web-based systems provide for structured intuitive display and presentation through upfront data collection and automated report formatting.[32] Nevertheless, the landscape of commercially available Web-based reporting user interface platforms is sparce. Much remains to be validated with widespread client adoption, and this may take some time before more commercial Web-based reporting vendors come to market.

SYNOPTIC REPORTING FOR USERS WHO READ AND DIGEST SYNOPTIC REPORTS

The increasing volume and variety of data along with poor formatting creates a potential for information overload because the number of variables surpass the limits of human cognition.[33] With the addition of genomic ancillary testing, information overload can easily occur in the presentation layer of synoptic reports. Information overload at the synoptic reporting presentation layer can lead to users ignoring, overlooking, or misinterpreting crucial information. Several studies have already investigated ways to manage information overload with molecular pathology data.[34,35] These studies focused on the field of visual analytics, which is the science of analytic reasoning and interpretation of complex data facilitated by advanced interactive visual interfaces.[36] Visual analytics combine concepts from the disciplines of data mining, machine learning, human computing interaction, and human cognition.[37] In synoptic reports, some human factors and usability testing research has taken place but at a smaller scale than in the visual analytics research community.

Users have strong preferences about report formatting in the presentation layer of synoptic reports, although these preferences are not always correlated with more rapid or more accurate data retrieval.[38] With few exceptions,[39] most studies have suggested that expert and nonexpert readers of synoptic reports perform similarly with regard to reader comprehension and speed.[17,38-40] Readers prefer consistent formatting (same order of elements), which in turn is associated with more rapid comprehension.[39] Columned formats are preferred over justified formats and are associated with both more accurate and more rapid information retrieval.[38,39] Single-line formats are preferred and associated with more rapid information retrieval by readers than multiple-line formats (where the response is on a second line rather than on the same line as the required element).[39] This preference may be attributable to multiple-line synoptic reporting requiring more time for the reader to extract information.[39]

When the number of data elements is relatively small (eight data elements), the speed of information retrieval is improved by including only a single column of unique responses rather than a two-column table with separate headers and responses.[17,39] Alternatively, if the information in the response column is unique, expert or more experienced readers simply read down the response column without looking at the header column,[39] which contrasts with less-experienced readers who consistently refer to the headers before examining the corresponding response. Efforts to make the responses unique so that they can be identified without referring to the header section may be of value. In addition, eye tracking device studies have suggested that readers tend to view Web pages in an F-shaped pattern.[41] Presentation of data in such a pattern (eg, a single list of responses rather than as header and response pairs in a table) may also facilitate readability of the presentation layer of synoptic reports.

Shorter sentences are preferred, more accurate, and enable more rapid information retrieval compared withlonger responses.[39,42] Negative terminology (no and not) is associated with decreased accuracy because the reader overlooks the word in the report.[30] Readers are more likely to mistake responses that are similar than those that are not. For example, the terms involved and uninvolved take longer to read and are much more commonly misread than the terms positive and free.[40] Whether this applies to headers as well is unclear. When required items that are not applicable are omitted from the report, readers take longer and are less accurate[38] in determining that the item is not applicable and more often make incorrect assumptions about that item.[42]

The positioning, grouping, and pairing of response data elements may facilitate readability and comprehension through human neurocognitive/perceptive mechanisms in the synoptic reporting presentation layer. Such a mechanism is known as chunking.[43] For example, Gleason grading in prostatic adenocarcinoma is required to be reported as separate elements of primary grade, secondary grade, and summed score. Placement of all these on the same line, however, leads to both more rapid and more accurate data extraction by human readers[38] in the synoptic reporting presentation layer.

Because interoperability infrastructures for data exchange are not well developed in the data layer for synoptic reporting, much of the data exchange currently is happening in the presentation layer, which restricts flexibility for formatting in the presentation layer. For example, many

natural language processing techniques require the separation of all data items rather than the combination of responses of aggregated data elements, and these requirements are incorporated into the CAP LAP checklist requirements.[44]

As synoptic report lengths have increased, there has been growing interest in summary sections for time-constrained clinician-readers to identify key elements quickly from synoptic reports (ie, synopses of synoptic reports). Options include changing the order of the elements so that key summary features are at the beginning and highlighting/bolding key features by leaving synoptic data in their current locations. Unfortunately, with the latter option, formatting changes such as bolding have had a limited effect on the speed of information retrieval and did not necessarily improve accuracy.[40] Alternatively, the creation of separate summary sections entails the duplication of information and demands automated mechanisms repurposing to capture elements in synoptic reports and place them in the summary section to avoid error that results from manual duplication. Finally, what best content from captured data elements to include in the summary section remains unknown.

As synoptic reporting incorporates genomic data, big data constraints with information overload and data leveraging come into play.[45,46] Web-based reporting systems have shown utility for handling genomic data,[32] with data presentation more flexible than the plain flat-text constructs in electronic medical records (EMRs) produced through Health Level Seven (HL7) messaging. In genomics, discrete data are exchanged between the sequencer and analysis programs, and much of the upfront creation of genomic reports can be completed through automation with Web-based reporting systems, which results in a structured intuitive presentation in molecular information systems. In the data layer, however, exchange of molecular reporting data from molecular information systems to EMRs and data warehouses remains nondiscrete and unstandardized, which creates difficulty in assuring intent and integrity in presentation of molecular reporting data in EMRs during transfer from molecular information systems. A syntactic exchange standard like HL7 Fast Healthcare Interoperability Resources is an option, but such a framework moves only core data, and as such, discrete data elements with clinical meaning are not transmitted beyond natural language free text. In addition, summary section formats are ill-defined, with evidence lacking that compares the effect on readability among a variety of formats. In contrast, Web-based synoptic reporting user interfaces have the advantage of flexibility in customization of various formats to improve the incorporation of genomic data into synoptic reports.[47] Visual analytic tools can facilitate the evaluation, validation, and measurement of the efficacy of translating this information[48] into and out of synoptic reports.

SYNOPTIC REPORTING FOR CREATING STRUCTURED DATA SETS

Structured data sets are more amenable to computation than narrative free text and are valued by many stakeholders, most notably researchers.[10,11,16,49-54] For decades, structured data sets have been created through manual retrospective curation in the synoptic reporting presentation layer, and much of the information was free text and narrative in format. With synoptic reporting, natural language parsing through rules-based algorithms[47] can generate structured data sets from the presentation layer. However, constraints are introduced by HL7 messaging standards used to translate pathology reports from AP-LISs in the data layer into the visible layouts of pathology reports in EMRs. Certain characters such as the tilde (~) negate terms that immediately follow, which leads to inadvertent loss of terms in the presentation layer and creates the need for additional testing and validation[55] as well as the use of updated versions of HL7 (2.3 and 2.5).

Alternatively, the data layer can be leveraged by using such programs the CAP electronic Cancer Checklists to maintain the intent and integrity of discrete data elements and structured data sets.[8] To test this system, large pilot efforts are under way in Canada with the Ontario Cancer Registry[56,57] and in California with its tumor registry.[58] These programs, however, are the exception rather than the rule. Nevertheless, an advantage of this approach is that rigid translations from the structured data sets to the presentation layer of synoptic reports are alleviated, and user preferences can be accommodated more easily. The key issues in harnessing the benefits of back-end infrastructures are robust architecture, mapping, and leveraging standards that enable interoperability and data exchange of a

complete, accurate, structured data set created at scale and in real time. Mapping of terminologies to a unifying coded concept is necessary. Interoperable semantic data standards, such as standardized terminology schemas, have existed for decades in health care, but curiously few are developed in a computational ontologic framework.

Cancer type is one concept in the health care sector where there is no widespread use of a universally accepted computational coded ontologic framework. The Office of the National Coordinator mandates the use of SNOMED CT (Systematized Nomenclature of Medicine–Clinical Terms) and LOINC (Logical Observation Identifiers Names and Codes) for the laboratory. Coding schemas for cancer type, such as International Classification of Diseases for Oncology, SNOMED CT, and others exist but are not universally applied. An alternative solution is the initiative of the American Association for Cancer Research Project GENIE (Genomics Evidence Neoplasia Information Exchange) where genomic data are linked to cancer type.[59] In this system, a homegrown cancer-type ontologic framework called Oncotree was leveraged on the back end for the public genomic database cBioPortal for Cancer Genomics[60-62] that serves as the visualization tool for the project's genomic data. In effect, Oncotree was adopted and accepted as the de facto ontologic framework for the cancer-type concept across participating institutions in Project GENIE.

Syntactic interoperability of data in synoptic reports can begin with incorporation of HL7 concepts, such as clinical document architecture (CDA), to enable better messaging exchanges[55,63] of structured data sets to cloud-based cancer registries. CDA can be used to transform medical documents into extensible markup language–like hierarchical structure data frameworks that are more easily and accurately exchanged. Cancer type and pathologic stage in synoptic reports can be arranged in a similar framework through CDA with parent-child relationships for the response elements,[55] which also would be easier to exchange.

Parts of the pathology report other than the synoptic section, including addendums, amendments, consultations, and ancillary studies, have no current standards for structured reporting or interoperable data elements. As a work-around, outside ancillary reports may be scanned to corresponding surgical pathology reports without discrete data capture. CDA, perhaps on the basis of the already-developed back-end infrastructures for genomic data, could be used to extract data from these sections. When these ancillary studies are large, however, consensus will be needed on which parts should be summarized and reported. Standards for this process currently do not exist.

Question bundling also raises semantic hurdles for extraction of structured data from synoptic reports. When data are bundled, whether they should be separated or remain bundled when extracted is not always clear. To ensure semantic intent and integrity for subsequent data set extraction from synoptic reports and data reuse, all stakeholders, including pathologists, clinicians, and data scientists skilled in terminologies, should review such question items. Standards for this process currently do not exist.

Despite even with the best computational data frameworks, free-text extraction still will be necessary to ensure capture of all relevant data. Free-text extraction applies where new entities in cancer type, no existing International Classification of Diseases for Oncology or SNOMED code, or any other available unifying codified schema exist. Free-text extraction also will continue to be needed with the reporting of addendums, amendments, consultations, and ancillary studies because of the lack of current standards for structured reporting or interoperable data elements. A system of just-in-time continuous updating of structured terminology, when available, may prove useful to reduce the requirement for free-text extraction.[64]

As a final consideration, cancer registries must also evolve to keep pace with rapidly changing requirements in data management. Today's cancer registries are unidirectional and accept push messages from institutions as opposed to bidirectional feeds. Because of this one-way push-type data transfer, cancer registries cannot ensure that a specimen and its data have been previously entered into the registry by another institution or that a related specimen is not already present in the registry. The specimen-level structure rather than the individual patient-level structure with today's cancer registries is another potential problem. All the reports from the same individual are not always possible

to link together because they may have originated from many different sites that use different types of identification schemes. Currently, no mechanism is available to confirm back to the original submitting institution the existence of related specimens or daughter specimens from an original parent specimen or whether specimens were taken at different times from the same patient. Finally, even when different tumors can be linked to the same patient, cancer registries are ill-equipped to handle patients with multiple primaries, where such data may be of importance for investigating familial or germline cancer predisposing syndromes.

In conclusion, significant progress has been made in recent years in defining the features of synoptic reporting that are most important for effectively generating, reading and digesting, and creating structured data sets from synoptic reports for interoperability and data exchange. The next generation of synoptic reporting platforms, which most likely are Web-based environments, promises to accommodate the diverse requirements of various corresponding stakeholders. Nevertheless, more clinician, pathologist, and registrar/data scientist understanding and involvement are needed because their domain knowledge and insight can be put to use in recognizing which features work best to improve synoptic reporting for all stakeholders. This involvement will translate into better data presentation, interoperability and management, assurance of completeness and accuracy (including synoptic information and ancillary studies), and improved patient care.

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