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Exploring the College of American Pathologists Electronic Cancer Checklists

What They Are and What They Can Do for You

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The College of American Pathologists (CAP) cancer protocols were first conceived as a resource tool for pathologists to help provide tumor reporting guidelines. The use of synoptic reports provides a way to assure completeness and consistency in reports so that they contain the necessary diagnostic, prognostic, and predictive elements needed for patient management. This information is also presented in a standardized manner that reduces ambiguity for readers. However, the data embedded in the pathology report now hold value that goes beyond immediately clinically actionable diagnostic information. The benefits of electronic cancer checklists (eCCs; now also known as electronic cancer protocols) have become clear, as capturing and storing this information as discrete (structured) data allows for data interoperability and portability. The advantages of this are numerous and include facilitation of case retrieval, teaching, research, quality metrics collection, regulation compliance, and automated data transfer to external sites such as referral treatment centers and tumor registries.

In order to make use of the eCC, the end user (the pathologist) must have access to a laboratory information system or to a third-party vendor that integrates the eCC into the pathology report.[1] The dependence on vendor support creates variability in the implementation of the eCC product, with regard to both data input by individual pathologists (Figure 1) and data presentation to end users (Figures 2 and 3). Examples of variability in input include how in-form prompts (prompts within the form) are displayed and what restrictions are placed on the inputted data (eg, numbers versus text strings), whereas examples in variability in data presentation include the ability to apply modifications like text formatting (bold, italics, underline) and other data display options (such as 2-column format versus paired indented) (Figures 4 through 6). This variability also creates a lack of transparency in the source of functionality, which can come from either the CAP or the eCC vendor.

This article clarifies fundamental eCC core capabilities to educate the pathologist community as to the available functionality, including what an end user might expect a vendor to provide. This knowledge may be used to initiate more productive user-vendor discussions to maximize use of eCCs.

WHAT IS THE eCC?

Historically, patient pathology reports have largely been unstructured free text. However, there are problems inherent to a narrative style of reporting, which include a lack of consistency in organization and the potential to miss or underreport critical data elements.[2–8] In 1986 the CAP

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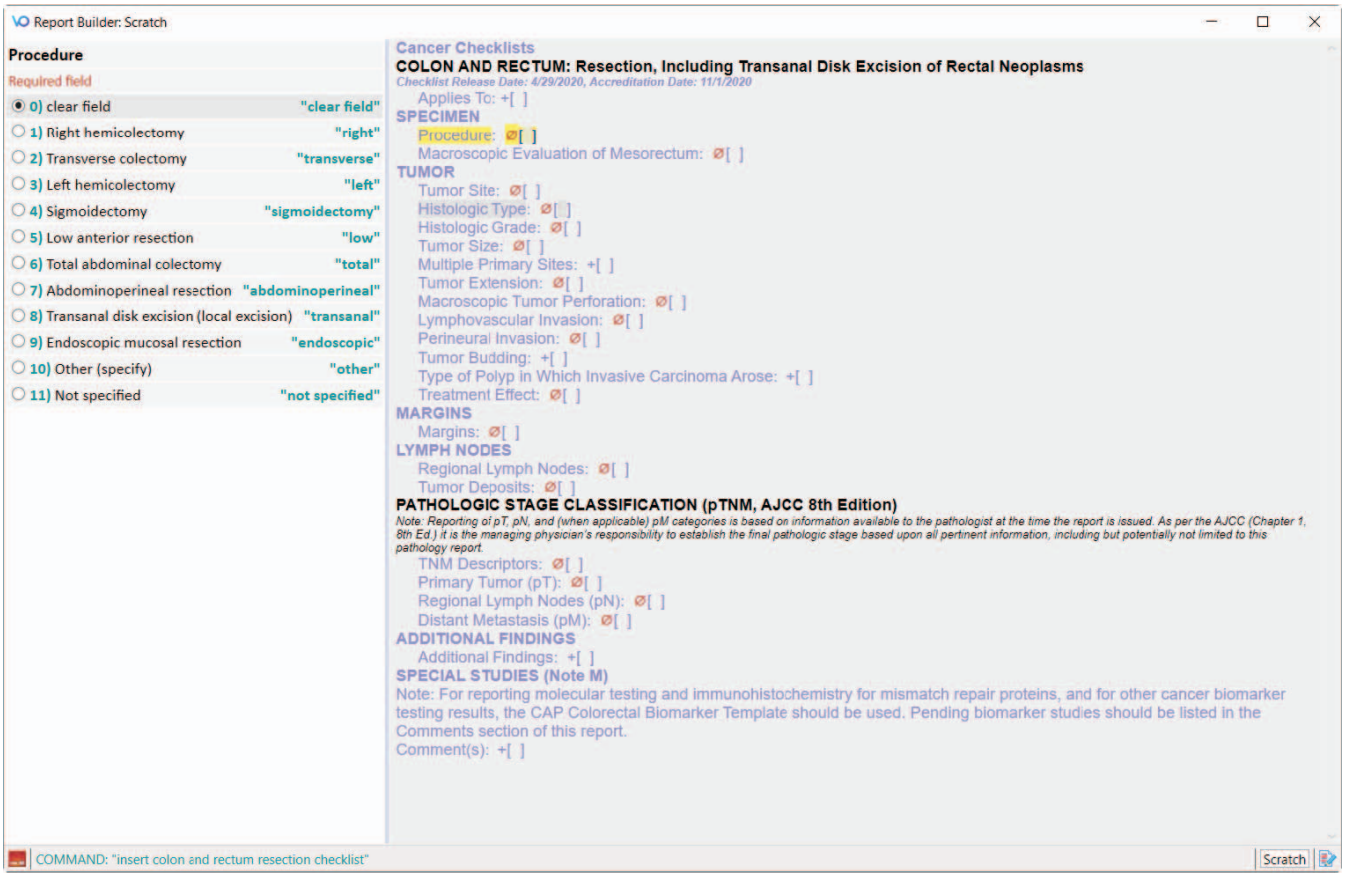

Figure 1. *Example worksheet for colon and rectum: resection electronic cancer checklist inserted into PRO Report Builder. Required questions are indicated using red slashed O, optional with light blue plus sign. Blue annotative text will not report unless a question is answered. The panel on the left displays details about the currently highlighted question, including available pick-list answers, if applicable.*

Cancer Committee addressed this issue when it established the first set of cancer protocols with its "Guidelines for Data to Be Included in Consultation Reports on Breast Cancer, Bladder Cancer, and Hodgkin's Disease."[9] As information technology advanced, the advantages of an electronic version of the paper-based cancer protocols became evident. The first electronic version of the protocols was published in 2007 with the release of a SNOMED-CT–encoded eCC and was followed by the release of the first XML-format checklist in 2009.[8,10,11] There are now electronic versions of more than 100 case summaries within the cancer protocols and cancer biomarker templates.

The eCC is a machine-readable version of the CAP cancer case summaries. It is important to note that there are differences between synoptic reports and the eCCs, which are based on a structured data capture format.[1,8] The electronic version is distributed to the vendors in a computer-readable data exchange format (an XML file) and allows for the computerization of cancer pathology data elements.[8] The use of a question-and-answer format (see Figure 1) ensures that the content is explicitly and precisely specified with a list of possible responses. This in turn ensures that the needed information is both present and valid. The format also ensures that the data are computer readable, retrievable, and processable.[12] The structured data capture interoperability thus allows transmission of discrete data in a standardized format to downstream systems such as cancer registries and other health information systems. This data identification and extraction are integral to many users.[13–19]

The following sections review some of the fundamental eCC core capabilities and the vendor role with respect to implementing these functionalities.

FLEXIBILITY IN CONVEYING INFORMATION

As stated above, the eCC is based on a question-answer set format. These codified elements have attached metadata, some of which specify whether a question is core (required), noncore (optional), or conditional (a question that becomes core based on an answer to a preceding question). The answers may be numerical or alphanumeric. An eCC vendor that can limit user input to an appropriate variable type can reduce errors by not allowing unreasonable or unintentional data entries. This limitation may be implemented by limiting responses to numbers versus text strings, but may also include limiting numbers to a range of reasonable values. Specific examples include requiring answers in free-text fields when "Other (specify)" is selected in a list-type question, limiting measurement questions (such as distance from tumor to margin) to numeric data entry, and limiting percentage answers to a positive integer less than 100. The result is prevention of inconsistent, nonlogical, or incomplete answers, and vendors are encouraged to use these metadata in their platforms.

A benefit of electronic synoptic reporting is the ability to include information that aids pathologists in accurately

COLON AND RECTUM: Resection, Including Transanal Disk Excision of Rectal Neoplasms

SPECIMEN

Procedure: Right hemicolectomy
Macroscopic Evaluation of Mesorecrum: Complete

TUMOR

Tumor Site: Transverse colon
Histologic Type: Adenocarcinoma
Histologic Grade: G1: Well differentiated
Tumor Size: Greatest dimensions (Centimeters) - 3.0 cm
Tumor Extension: Tumor invades submucosa
Macroscopic Tumor Perforation: Present
Lymphovascular Invasion: Present - Small vessel lymphovascular invasion
Perineural Invasion: Not identified
Type of Polyp in Which Invasive Carcinoma Arose: Tubular adenoma
Treatment Effect: No know presurgical therapy

MARGINS

Proximal Margin: Uninvolved by invasive carcinoma, high grade dysplasia / intramucosal carcinoma, and low grade dysplasia.
Distance of tumor from Margin: 3mm
Distal Margin: Uninvolved by invasive carcinoma, high grade dysplasia/intramucosal carcinoma, and low grade dysplasia.
Radial (circumferential) or Mesenteric Margin: Uninvolved by invasive carcinoma
Distance of Tumor from Margin: 5mm

LYMPH NODES

Number of Lymph Nodes Involved: 3
Number of Lymph Nodes Examined: 12
Tumor Deposits: Not identified

PATHOLOGIC STAGE CLASSIFICATION (pTNM, Ajcc 8th Edition)

Note: Reporting of pT, pN, and (when applicable) pM categories is based on information available to the pathologists at the time the report is issued. As per the AJCC (Chapter 1, 8th Ed.) it is the managing physician's responsibility to establish the final pathologic stage based upon all the pertinent information, including but potentially not limited to this pathology report.

Primary Tumor (pT): pT1
Regional Lymph Nodes (pN): pN1b

Figure 2. *Final output of colon and rectum worksheet for vendor 1: resection electronic cancer checklist sent from Report Builder into a Word document.*

Specimen

Procedure: Right hemicolectomy
Macroscopic Intactness of Mesorectum: Cannot be denied

Tumor

Tumor Site: Right (ascending) colon
Histologic Type: Adenocarcinoma
Histologic Grade: High- grade (poorly differentiated to undifferentiated)
Tumor Size: 6.0 x 5.6 x 2.2 cm
Tumor Deposits: Present
Number of Deposits: 3
Tumor Extension: Tumor invades the visceral peritoneum
Macroscopic Tumor Perforation: Not identified
Lymphovascular Invasion: Present
Perineural Invasion: Not identified
Treatment Effect: Present - Residual cancer with evident tumor regression, but more than single cells or rare small groups of cancer cells (partial response, score 2)

Margins

Margins: All margins are uninvolved by invasive carcinoma, high-grade dysplasia, intramucosal adenocarcinoma, and adenoma
Margins Examined: Proximal, Distal, Radical or Mesenteric
Distance of Invasive Carcinoma from Closest Margins: 1 mm
Closest Margins: Radical or Mesenteric

Lymph Nodes

Number of Lymph Nodes Involved: 22
Number of Lymph Nodes Examined: 26

Pathologic Stage Classification (pTNM, AJCC 8th Edition)

TNM Descriptions: y (post-treatment)
Primary Tumor (pT): pT4a
Regional Lymph Nodes (pN): pN2b
Distant Metastasis (pM): pM1b

CAP eCC February 2019 Annual Release

Figure 3. *Final output of a second vendor to compare with final output of the previous vendor.*

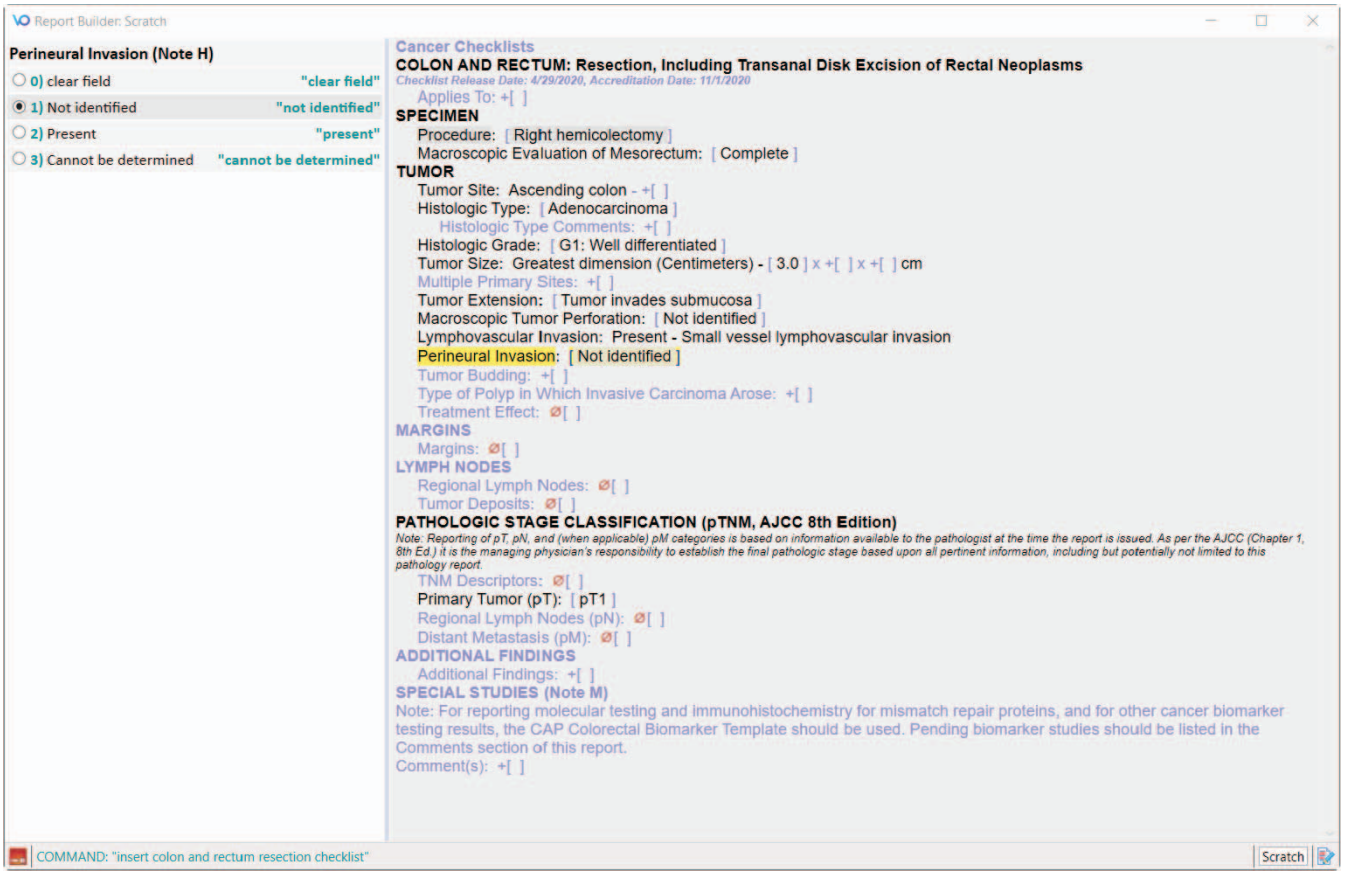

Figure 4. *Partially completed checklist. Answered questions change from purple to black text to signify that they will be reported once the checklist is completed. Red slashed O's disappear, signifying that required elements have been completed. Suggested pT and pN stages are provided to the user automatically based on answers to relevant questions.*

completing a synoptic report during the data entry phase and hide or remove that information from the final report. This includes both in-form prompts and paragraphs of detailed explanatory notes provided by the CAP protocol authors. The explanatory notes include a variety of information, such as methods for defining tumor location or methods for assessing histologic grade. Keeping these prompts would make the report appear cluttered. Vendor systems should ideally be able to handle instructions for including this information in a data entry form but excluding it from a final report. These data could be included within the XML itself, as content that is shown through a mouse-over (when the cursor goes over a point on the screen) feature, or as a stand-alone Web page accessed by a hyperlink.

The unit of measure (UOM) used in the eCC is often established by content-contributing entities (eg, American Joint Committee on Cancer) or by established medical literature. Although allowing an end user to select the UOM (eg, centimeters versus millimeters) may sound beneficial, it suffers on several levels. Notably, it introduces an interoperability source of error, as different sites may select different UOMs; it complicates data mining efforts as nonstandard variables are introduced; and it may contribute to the end user's entering an incorrect value (mistaking the expected UOM). Therefore, it is best if the eCC vendor supports only the encoded UOM, as well as clearly defining the UOM on the data entry form and the report output.

CAP laboratory accreditation standards require synoptic reporting of specified data elements using specified question verbiage. However, the formatting for the final report (the output) may be modified and optimized to meet the site-specific needs and preferences of pathologists (as users) and of other clinicians (as consumers of the information).[20] These modifications may facilitate the quality and effectiveness of clinical communication. Text formatting (eg, bold, italic, underline) may be used for emphasis of questions, answers, or section headers. Question-answer pairs may be reported either adjacent to one another, separately justified as a 2-column format, or in a paired indented model.

At a higher level, there is no uniform agreement regarding the placement of the synoptic report content within the overall surgical pathology report. Some vendor systems allow for the synoptic report to function as a stand-alone section within the diagnostic field, with or without accompanying free-text diagnostic lines. Some users may see this as desirable because it allows for succinct reporting without the potential introduction of errors inherent to data duplication. Other systems may position the synoptic report in a separate field entirely, requiring traditional free-text diagnostic lines within a diagnosis field. There should be flexibility in accommodating the position of the synoptic data within the pathology report according to the needs of the local pathology and clinician community as well as meeting national accreditation standards.

Figure 5. *Validation warnings are provided to the user in real time to ensure that data are captured correctly. The above image shows an X next to the Distance of Tumor From Margin field because this field requires a numeric entry rather than a text string. The panel on the left provides details to the user to assist with correcting data.*

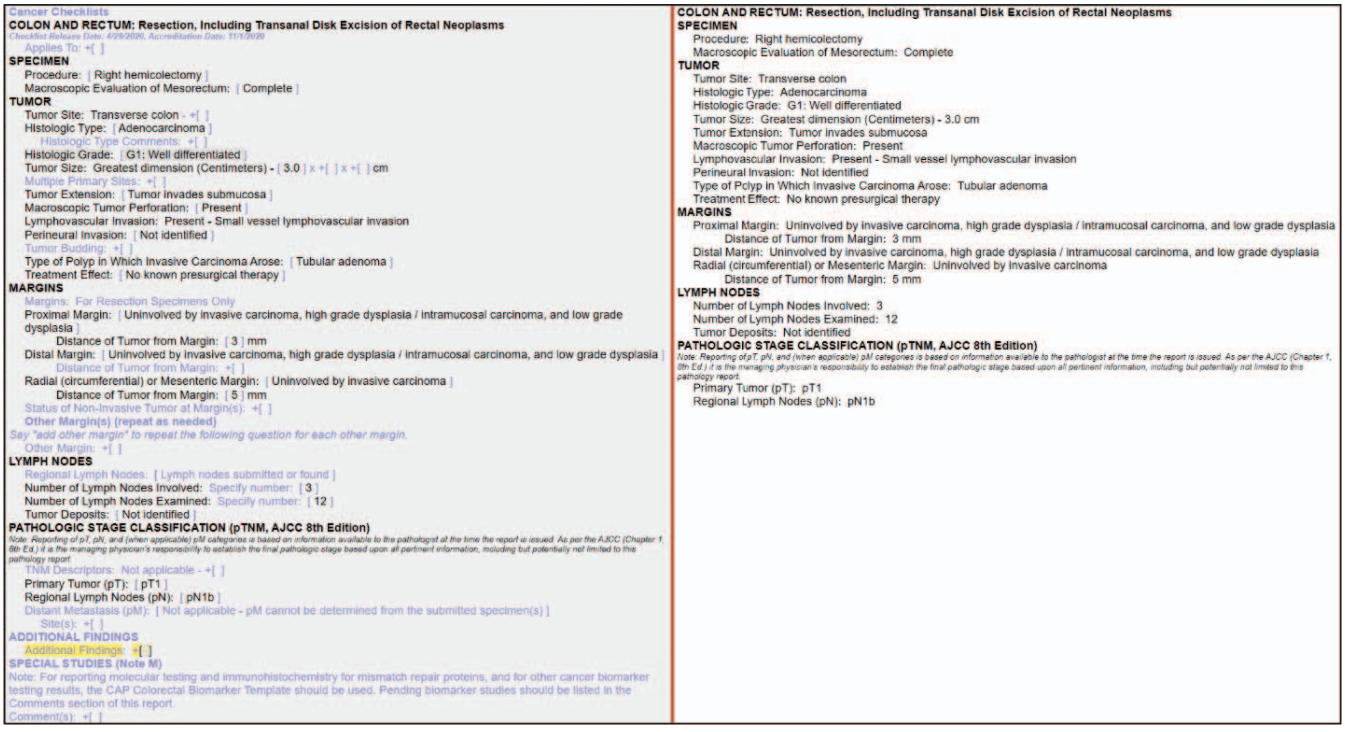

Figure 6. *Annotative text (including nonapplicable conditionally reported questions like TNM descriptors and distant metastasis [pM] in the above example) are stripped upon completion of the report.*

CUSTOMIZATION

The content of the CAP cancer protocols represents the current recommendations of the CAP Cancer Committee on what should be included for completeness and for appropriate clinical care in a pathology report for the relevant cancer. For regulatory compliance, there are some constraints on what can be changed in the CAP eCC protocols. The data element specified in the questions cannot be changed, although individual institutions can provide their own values for answers. Even so, it is recommended that the CAP Cancer Protocol or eCC nomenclature be used in order to maintain a clear and unambiguous reporting standard (as consistency of terminology is one of the benefits of this type of structured reporting).

There are often local requests for making optional elements required or adding data elements that have not yet been approved for inclusion by the Cancer Committee. Similarly, there are requests to delete optional elements or prefill some answers based on the convention at an individual institution (eg, assay type and methods in biomarker templates). Customization of the eCC templates is not prohibited; however, all eCC users and vendors must maintain any site-specific modifications they make to the templates. To maintain CAP accreditation, modifications must not alter the specific features that define synoptic report formatting or change required data elements.[21] The various vendors are inconsistent in how this is accomplished. Vendors should be able to allow such customization and preserve these modifications either prior to uploading the latest eCC release or within the end user's system after the eCC content is uploaded.

DATA ENTRY AND DECISION SUPPORT

Although the benefits of synoptic reporting are clear, a complaint has been the increased time to enter all the data elements.[22] Therefore, synoptic reporting tools should be designed to make data entry as efficient as possible. This often requires the use of rules, or automations, which means that if a certain condition is met, an automatic result or set of results happens. Toward that goal, the CAP eCC supports a question hierarchy with auto-inactivation of irrelevant questions. For example, the lymph node section of all cancer checklists begins with the option "no lymph nodes submitted or found," which, when selected, deactivates all subsequent questions in the lymph node section.

More complex rule functionality, such as assessment of margins and auto-calculation of pTNM stage, are currently underway. Auto-calculation, in addition to increasing efficiency, reduces potential error due to redundancy in data entry. For instance, in the synoptic for bladder cancer, selecting invasion into lamina propria and inadvertently selecting pathologic stage pT3 is possible without the use of rules. However, because of the complexity of some pTNM staging category calculations, auto-staging likely cannot be implemented until a vendor validation program is in place. If auto-calculations are used, there will be a need for extensive testing and verification of the validity of the calculations. Vendor platforms offering auto-staging functionality will also need to be able to auto-recalculate when data elements are modified, and respondents need to be able to override an auto-calculation if it is incorrect.

In the least, if auto-calculations prove difficult to implement, vendors may use alerts to prevent the entry of discordant data. Alerts can also be applied beyond the use case of pTNM staging. In general, answer choices for many list-item questions could trigger alerts if their selection is not consistent with previously entered data. For example, in the thyroid synoptic, if right lobectomy is selected as the procedure type, respondents should be alerted if they select left thyroid lobe as the tumor site. Alternatively, instead of triggering alerts, irrelevant list-item answer choices could be automatically deactivated based on how prior questions are answered, preventing the respondent from selecting an inconsistent answer.

DATA MINING

A key benefit of the standardized collection of data elements by specifying discrete data values is the ability to later extract this information by querying the collected data. This feature is becoming more important as the value of tumor reporting goes beyond just diagnostic information: the ability to easily extract data is critical for the purposes of case finding, cancer conference presentations, case studies, confirming accreditation compliance, teaching, quality improvement, and research. As an example of a higher-level application, integrated reporting has been identified as a critical tool for precision medicine. Precision medicine relies on matching patients to their treatments and thus requires large numbers of patients in order to reliably discover the targets and predictors of response to therapy within smaller subgroups of a single disease. By standardization of the data values and structure within a framework that can be aggregated across multiple patients from multiple institutions, the numbers needed for target discovery can be achieved. Additionally, the field of artificial intelligence is one of the exciting new areas of medicine. This encompasses the ability not only to discover targets for precision medicine, but also to develop and test clinical decision support software. The synoptic data elements can serve as scalable annotations for supervised training for artificial intelligence algorithms.[23] The ability to easily and robustly extract data is, therefore, a crucial feature provided by the eCC vendor.

SUMMARY

This article provides information about the capabilities of the eCC. By knowing the capabilities of the eCC, pathologists can be more aware of what to expect and what is possible from a prospective eCC vendor. As end users, pathologists should be aware of the advantages of eCC use, as they go beyond just simple data entry. Pathologists as end users can also help drive product improvement by working with and advising their eCC vendors to provide the functionality that will most help them provide care for the patients they serve.

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