Introducing New College of American Pathologists Reporting Templates for Cancer Biomarkers

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The College of American Pathologists (CAP) has been developing guidelines on cancer data reporting for more than 25 years, with more than 80 regularly updated cancer case summaries now available for pathologists’ use. The protocols consist mostly of traditional data elements determined by gross and microscopic examination, but many of the case summaries within the protocols also include short sections on “ancillary testing.” As the frequency of biomarker testing and its importance in managing patients has grown, however, these results are no longer considered ancillary. The growing number of details related to this testing add to the length and complexity of the cancer resection report. Another problem with including biomarker testing in the cancer case summary is that the results are often not available at the time the primary cancer resection report is completed, either because they are still pending or because they are ordered later.

In response to requests from pathologists to address these issues and streamline the CAP cancer protocol case summaries, a multidisciplinary group was assembled in 2012 to establish guidelines for reporting biomarker assays. The Cancer Biomarker Reporting Workgroup was composed of a steering committee and 3 initial site-specific expert panels charged with developing pilot biomarker reporting templates for breast, colorectal, and lung cancers. Panel members participated from a variety of organizations, including the CAP, the Association for Molecular Pathology, the American Society of Clinical Oncology, the Centers for Disease Control and Prevention, the American Joint Committee on Cancer, the North American Association of Central Cancer Registries, and other organizations. The workgroup goals were to establish reporting guidelines for commonly ordered biomarkers, create stand-alone reporting templates, and improve consistency and completeness of results reporting to assist tumor registrars and others involved in data collection, exchange, and surveillance.

This issue of Archives of Pathology & Laboratory Medicine introduces new reporting templates for lung and colorectal cancer biomarkers (the template for breast cancer was harmonized with the recent update to the American Society of Clinical Oncology/CAP guideline for HER2 testing subsequent to the writing of this editorial and was completed in late 2013). These 3 templates incorporate standards based on existing guidelines as well as expert consensus where formal guidelines do not exist. These draft templates were reviewed by the CAP Cancer, Molecular Oncology, Immunohistochemistry, and Pathology Electronic Reporting Committees, followed by formal public comment and field-testing periods.

Also see pages 166 and 171.

These reporting templates are intended to encompass all important data elements for routinely assessed tumor markers and are designed to be incorporated into electronic reporting systems. They mirror the format of the CAP cancer protocol case summaries, listing required and optional elements (with optional items designated by a plus [-] symbol). Required data elements should be reported only if testing for that particular marker has been done and the result is available to the pathologist. Identifying an element as required is for reporting purposes only and is not intended to mandate specific testing for individual patients. All elements in the colorectal and lung templates are currently optional, although this may change in future versions as new evidence emerges. At this time, only the breast template includes required elements (in accordance with American Society of Clinical Oncology/CAP reporting guidelines).

As with the case summaries, report formatting is determined by the individual laboratory based on laboratory information system capabilities and institutional needs and should follow the CAP synoptic reporting definition. Synoptic reporting of results is strongly recommended by CAP and the American College of Surgeons Commission on Cancer, and will soon be required by other accreditation programs, such as the National Accreditation Program for Breast Centers (James Connolly, MD, written communication, February 14, 2013). The templates are divided into “Results” and “Methods” sections. The “Results” section lists specific test results for that individual patient and should be reported in synoptic form. Items in the
“Methods” section generally do not change from patient to patient and may be reported in either synoptic or narrative format.

The templates list many possible results for those laboratories choosing to use a paper-based report and therefore appear lengthy in written form, but most laboratories will incorporate them into their laboratory information system, and the final report will be relatively short. An example is included in the Figure for illustration.

Completion of the template is the responsibility of the laboratory performing the biomarker testing and/or providing the interpretation. When both testing and interpretation are performed elsewhere (eg, a reference laboratory), synoptic reporting of the results by the laboratory submitting the tissue for testing is also encouraged to ensure that all information is included in the patient’s medical record and thus is readily available to the treating clinical team.

The templates will replace the “Ancillary Studies” sections that currently are in the corresponding CAP cancer protocol case summaries; the corresponding section data elements and related explanatory notes will be removed from the existing CAP protocols. Duplicate reporting is neither expected nor required. Separating the reporting of biomarker results from the primary cancer resections will reduce the number of incomplete reports and will allow for a more efficient template revision process.

Following the successful completion of these 3 pilot templates, the Cancer Biomarker Reporting Workgroup has been charged with developing new templates and revising existing ones. Working closely with its participating stakeholder organizations and with the CAP Pathology & Laboratory Quality Center, the standards-setting arm of the CAP, the committee will assess the need for reporting templates in other sites and appoint expert panels as needed to create new templates. Similar to the cancer protocols, these templates will have regular planned revisions based on user feedback and evolving evidence. Users are strongly encouraged to comment on these templates and suggest ideas for new ones. Feedback may be provided by sending an e-mail message to CProtocol@cap.org.

Just as the CAP cancer protocols represent a standard for cancer reporting, it is hoped that these report templates will introduce a new standard for biomarker reporting. Given the frequency with which new testing methods and markers are being incorporated into clinical practice, these templates are expected to be increasingly important in aiding pathologists in their roles in patient management.

References


