

No worries with new cancer biomarker templates

Anne Ford

October 2013—For anyone worried about the new CAP reporting templates for cancer biomarkers, Patrick L. Fitzgibbons, MD, has an important message: Don't panic.



**Dr.
Fitzgibbons**

"These are nothing new," says Dr. Fitzgibbons, a pathologist at St. Jude Medical Center, Fullerton, Calif., and chair of the CAP Cancer Biomarker Reporting Committee. "We're not adding anything. The templates will look very familiar to users of the CAP cancer protocols. They shouldn't be considered a significant burden."

On Oct. 1, two new templates for reporting the results of biomarker testing for colorectal cancer and lung cancer were posted online at www.cap.org/cancerprotocols. (They were published June 28 online in the Archives of Pathology & Laboratory Medicine.) A similar template for breast cancer biomarker testing will be released later this year and reflect the latest update to the CAP/American Society of Clinical Oncology guideline for HER2 testing, published online Oct. 7 (see story, page 1).

Each of these cancer protocols had previously contained a section titled "Ancillary Studies." The word "ancillary" has been changed to "biomarker," and these sections have been made into separate, freestanding templates. The only changes made were to standardize how patient data are reported.

"It's become a little out of date," Dr. Fitzgibbons says, to categorize biomarker testing results as mere ancillaries to the main protocols. "These biomarkers are becoming essential to treating the patient. They're not really ancillary. They're even more important than some of our traditional parameters. In some cases, they're the drivers of the patient's treatment," he says.

Another reason for the separate templates: "Those studies are often not completed at the time the cancer resection is reported, so the pathologist filling out the cancer checklist for the primary resection can't complete the case summary because these other results aren't yet available. So you always have something pending."

In what Dr. Fitzgibbons calls a "horizontal rather than a top-down approach," the Cancer Biomarker Reporting Workgroup (now committee) that created the new templates consisted of members from several groups, among them tumor registries, ASCO, Association for Molecular Pathology, American Joint Committee on Cancer, and National Comprehensive Cancer Network. The draft templates were posted for public comment, and those comments were taken into consideration while the templates were being finalized.

One of the workgroup's primary goals was to make the protocols easier to use. "We tried to standardize the basic formatting and language used in the reports," Dr. Fitzgibbons says. "One of the things we learned is that there's wide variation across laboratories in terms of how they structure their reports, and that causes a lot of confusion among end users, such as tumor registrars, who want to compare one lab's results to another's." Registrars continue to struggle, he says, with the spectrum of reporting practices, trying to get the data into a format they can analyze. "So there's been a lot of requests that we do something to make these a little more homogeneous."

It'll be much better for the analysis of cancer data."

The workgroup kept the needs of pathologists and laboratories in mind as well, not just those of tumor registrars, clinicians, and other end users, he adds. "Each template has two sections. One is a results section and will reflect only results of the testing that was done, even though there might be many markers that could be done. The second section is the methods section, and methods typically don't change from specimen to specimen. So laboratories will be able to use a boilerplate to complete that portion of the template; it could be put into a macro and wouldn't have to be filled out every single time."

But won't the main cancer protocols still ask for biomarker information, thus resulting in duplicated effort? "All the ancillary material itself will eventually be entirely removed from the cancer protocols," Dr. Fitzgibbons says. "We won't be asking for the same information twice."

As a further helpful feature, each of the new templates will contain a set of notes that will provide educational material as well as further interpreting and reporting guidance. "So there's an educational value to these besides the reporting template itself," Dr. Fitzgibbons points out. "For the breast template, there was quite a bit in the existing cancer protocol, so that one is quite a bit longer than the colon and lung templates, which will gradually expand to include more and more of this educational material."

On a final note of reassurance about the latest change in cancer reporting, he reminds users that "only the breast template has required elements. The entire lung and colon templates are optional," that is, not required by the CAP Laboratory Accreditation Program or the American College of Surgeons Commission on Cancer.□

[hr]

Anne Ford is a writer in Evanston, Ill.