The Ponatinib Problem: Debating the FDA’s Recent Market Suspension

BY SARAH DIGIULIO

Although promising early results led to the accelerated approval of the leukemia drug, recently reported longer follow-up data showed an increased risk of arterial thrombotic events—prompting the FDA to temporarily suspend marketing and sales of the drug. But, several experts told us that for some patients, the potential benefits may still outweigh the risks.
New Cancer-Specific Survey Measures Patients’ Experience of Care

BY LOLA BUTCHER

With pressure mounting for oncologists to provide patient-centered care, two major federal institutions have developed a new survey instrument that allows oncologists to measure how well they are doing.

The Consumer Assessment of Healthcare Providers and Systems Survey for Cancer Care (Cancer CAHPS) is the first cancer-specific survey instrument designed to capture patient feedback about their experience with all types of treatment in any care setting and allow comparisons across treatment centers and modalities.

The survey instrument was initiated by the Agency for Healthcare Research and Quality (AHRQ) and the National Cancer Institute, with additional financial support from the California Healthcare Foundation. It was developed by the American Institutes for Research and the Mayo Clinic.

While many cancer care providers already survey their patients, AHRQ and NCI leaders hope the new survey tool will become the standard approach for assessing patients’ experience of care.

“Is it my hope that the metrics developed through this survey would become standard metrics for quality of care that cancer care organizations will collect on a longitudinal basis,” said Neeraj Arora, PhD, Program Director for Patient-centered Care Research at the NCI.

Specifically, the report said: “The cancer care system should support patients in making informed medical decisions that are consistent with their needs, values, and preferences. Cancer care teams should provide patients and their families with understandable information about the cancer prognosis and the benefits, harms, and costs of treatments.”

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bendamustine. “These combinations get us 80 percent response in lymph counts, an 80 to 90 percent response in nodes, and diarrhea, but less intense than the diarrhea seen among patients with pretreated CLL,” Coleman said. These include pneumonia and diarrhea, but less intense than the diarrhea seen with idelalisib.

Ongoing CLL trials are comparing oral ibrutinib with intravenous ofatumumab, and also combining ibrutinib with ofatumumab. He said he also sees approval of ibrutinib within the next year or two.

In conclusion, Coleman said, “Idelalisib and ibrutinib, two potent BCR pathway inhibitors, are highly effective in both untreated and treated CLL. Both drugs work well in combination with other CLL-directed therapies, and represent a new non-chemotherapeutic approach. Both drugs have very acceptable toxicity profiles. They will profoundly change the way we approach CLL in the future.”

Gabrilove added: “PI3K inhibitors and tyrosine kinase inhibitors have an impact on CLL and other low-grade leukemias. There optimal use is unknown as of yet. In the current post-genomic era, we have a rapidly emerging armamentarium to treat proliferating diseases. Ultimately, we run out of all treatment options. These new drugs will have a significant impact.”

The frequency of Grade 3 adverse events with ibrutinib is “rather small,” Coleman said. These include pneumonia and diarrhea, but less intense than the diarrhea seen with idelalisib.

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Almost all refractory/refractory CLL patients respond to idelalisib. The drug is potent. It hits the lymph nodes rapidly, but does not have as much impact on blood counts.

—Morton Coleman, MD
CANCER CAHPS
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scores. Specialists responding to a Medical Group Management Association (MGMA) survey earlier this year said that three percent of their total compensation is based on quality measures, including patient satisfaction measures. “Quality and patient satisfaction metrics are not yet dominant components of physician compensation plans right now, but as reimbursement models continue to shift, the small changes we’ve observed recently will gain momentum,” MGMA President and CEO Susan Turney, MD, said in a news release announcing the survey results.

A challenge, however, is that the surveys used to measure patients’ experiences of care are often too broad to effectively address the concerns of patients with a specific medical condition. “We hear over and over again from our oncology colleagues that the instruments they are using are something they are required to use to collect patient data but they don’t really get to the complexities of the issues faced by cancer patients,” Arora said. “Several of the standard surveys that are being used right now do a pretty good job of getting to some of these aspects of care, but they don’t go into enough detail.”

For example, current surveys ask patients whether they were bothered by pain from their disease or treatment, but the Cancer CAHPS instrument goes beyond that and assesses whether their oncology team helped them deal with the pain.

Marlene Frost, RN, PhD, Associate Professor of Oncology at Mayo Clinic, says she expects that cancer care providers will be enthusiastic about the survey: “I think they will embrace it because it gives input about a patient’s perspective on the care. We are always trying to improve patient care, and this will help with that.”

Why CAHPS?
Since its inception in 1995, the government’s CAHPS program has developed a series of surveys to assess the performance of health plans, physician practices, nursing homes and other health care providers, but the new Cancer CAHPS is a first in several ways.

The first disease-specific survey in the CAHPS series, Cancer CAHPS asks patients about their experience with the full range of treatments—surgery, medical oncology, and radiation therapy—regardless of care setting. The instrument is designed to be used by any providers of cancer care, from large academic centers to independent oncology practices.

The CAHPS surveys are best known for allowing patients to compare providers. HCAHPS scores are posted on the government’s Hospital Compare website, while the Medicare program posts home health CAHPS scores in an online spreadsheet. Arora hopes that Cancer CAHPS will be used to inform quality-improvement initiatives.

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