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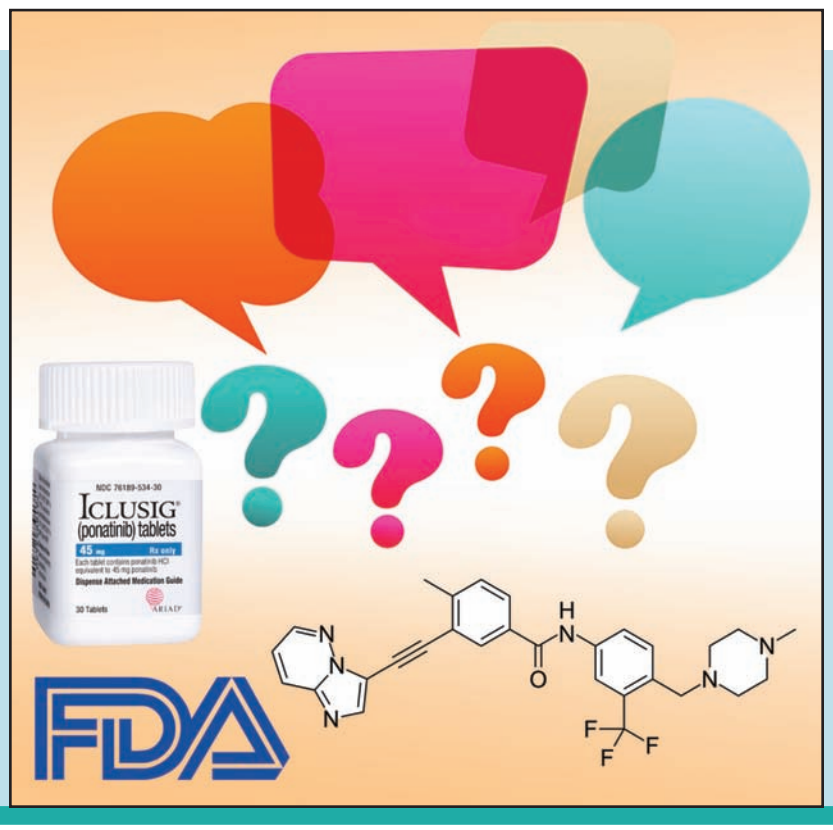

The Ponatinib Problem:

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.

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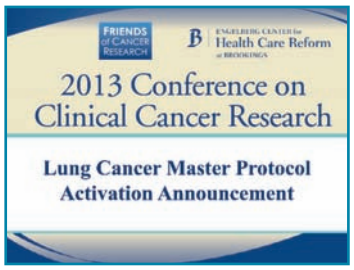

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Central Line Care Bundle Benefits Ambulatory Pediatric Cancer Patients p. 30

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PERIODICALS

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.

"It is 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.

"When we think of how to improve the quality of cancer care in the United States, we can point to all of these aspects of care that need improvement in addition to the clinical measures that we use to measure the quality of care."

The new survey, which was presented at the American Society of Clinical Oncology's Quality Care Symposium, coincides with the release of the Institute of Medicine's recent "Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis" report (***OT 10/10/13 issue***).

The report's authors identified "engaged patients" as one of six components of a conceptual framework to improve the delivery of cancer care.

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."

Five Domains

While the CAHPS survey does not deal with the costs of treatments, it does offer oncology teams a way to measure patients' perceptions of their performance in five domains:

- Affective communication (the behavior of clinicians towards patients);
- Shared decision-making;
- Enabling patient self-management;
- Communication about therapy; and
- Access to care.

"The feedback we have received from practicing oncologists is that this is very important," said Kathleen Yost, PhD, a Mayo Clinic health sciences researcher who helped develop and test the survey instrument. "They want to know how their patients are perceiving the care that is delivered."

Soliciting patients' perspectives on their care has been slowly building steam for years, but it took on new importance last year when the Centers for Medicare & Medicaid Services started paying hospitals based in part on their patient experience scores. CMS's Hospital Value-Based Purchasing Program uses each hospital's scores on the Hospital-CAHPS (HCAHPS) survey to determine the hospital's pay rate.

Meanwhile, physician pay is also beginning to be tied to patient satisfaction

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→CLL

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inhibition is rapid in CLL. The white blood cell count goes way up, and ultimately comes down."

The drug induces an 80 percent nodal response and 72 percent overall response. "Almost all refractory/relapsed CLL patients respond," Coleman said. "The drug is potent. It hits the lymph nodes rapidly, but does not have as much impact on blood counts."

Initial studies found a PFS of 17 months, with overall survival not yet reached. Side effects, he noted, include explosive diarrhea, pneumonia, and transaminase increases.

Researchers are now testing combinations of idelalisib with rituximab, bendamustine, or both rituximab and bendamustine. "These combinations get an 80 to 90 percent response in nodes, and an 80 percent response in lymph counts, and the addition of other drugs to idelalisib hits cells as they get into the peripheral blood," he said.

Pivotal studies in idelalisib in CLL are ongoing. Coleman predicted that the drug would be approved in the next year or two.

Ibrutinib

Btk is another essential element of the BCR signaling pathway, and potent inhibitors of Btk, such as ibrutinib, block BCR signaling and induce apoptosis, he explained. In a Phase Ib/II study in CLL, about 85 percent of patients responded to ibrutinib.

"Relapsed/refractory patients showed virtually the same response rate. More than three-quarters seemed to respond, which is remarkable. We now have two drugs—idelalisib and ibrutinib—with amazing response rates," said Coleman.

"We now have two drugs—idelalisib and ibrutinib—with amazing response rates."

Ibrutinib leads to an estimated PFS rate of 96 percent at 26 months, with an estimated 92 percent PFS for those with no deletion 17 p or 11q, he continued. "Again, these are remarkable results, almost identical to idelalisib."

Coleman noted that ibrutinib studies at Ohio State led by John Byrd, MD, have found a 100 percent response rate among CLL patients, with sustained improvement seen among patients with pretreated cytopenia.

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.

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."

"Almost all refractory/relapsed 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

CDC Updates Program to Prevent Chemotherapy-Related Infections

The Centers for Disease Control and Prevention Foundation has launched an updated version of **www.preventcancerinfections.org**, a comprehensive online program to raise awareness among patients, caregivers, and health care providers about steps that can be taken to prevent infections during chemotherapy treatment, part of the "Preventing Infections in Cancer Patients" program.

The evidence-based, interactive online program, funded in part through a CDC Foundation partnership with Amgen, is designed to assess a cancer patient's risk for developing leukopenia (and subsequent infections) from chemotherapy, and direct educational materials to that patient about how to stay healthy while receiving therapy.

"It is designed to empower patients to know how to protect themselves and reduce their chances of getting an infection," Lisa C. Richardson, MD, MPH, Director of the Division of Blood Disorders and Medical Officer at the CDC who led the development of the site, said via email. Research revealed that patients were more concerned about other common side effects like hair loss and nausea than they were about infections, she explained. "Patients were also not aware of actions they could take to help protect themselves during treatment."

Patients can take an online assessment—either on their own or with their health care provider—to determine if they are at low- or high-risk of infection. There is also an assessment for caregivers. Educational materials including health tip sheets, posters, fact sheets, postcards, and videos are available on the site.

Additional resources specific for clinicians include:

- A "Basic Infection Control and Prevention Plan for Outpatient Oncology Settings," which includes key policies and procedures that will ensure that a facility meets or exceeds minimal expectations of patient safety (**Pub #22-1028**);
- A poster stressing the importance of cancer patients getting the flu shot with the slogan: "Cancer is a fight. Don't let the flu knock you down" (**Pub #22-1463**); and
- A postcard stressing the importance of cancer patients getting the flu shot (**Pub #22-1462**).

→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."

> "While the initial focus of CAHPS has been for public reporting, we should ask, 'How can we use these powerful voices from patients to make changes in the delivery of health care?' That's what I would like to see happen."

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 cancer 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.

"While the initial focus of CAHPS has been for public reporting, we should ask, "How can we use these powerful voices from patients to make changes in the delivery of health care?" he said. "That's what I would like to see happen." For example, institutions could set goals to achieve specific scores on various Cancer CAHPS questions and develop quality improvement programs to ensure that those scores are met or exceeded.

Survey Development

The survey development team, headed by American Institutes for Research (AIR), conducted 14 focus groups with patients and two with family member caregivers to identify the aspects of care most important to patients, explained Steven Garfinkel, PhD, the AIR Institute Fellow who headed the project. Representatives from cancer centers, oncology professional associations, and a technical expert panel of oncologists, nurses, and patients also gave input about the content of the questionnaire.

The survey's field test, conducted with patients from six cancer centers around the country earlier this year, generated a response rate of 48 percent. "One of the things about a condition-specific survey is that the respondents are very invested in their illness so it is a very salient survey for them," Garfinkel said.

Although the survey instrument was designed for use in any cancer care setting, the field test was limited to large centers, he noted, adding that the developers are now seeking funding to test it in smaller cancer centers and outpatient oncology practices.

Unlike most patient experience surveys, Cancer CAHPS asks patients to report on how their cancer care decisions were made, whether their caregiver team helped address emotional problems related to cancer and treatment, and whether they were instructed to call their clinicians immediately if certain symptoms or side effects developed.

Ready to Use

The survey has not yet received the CAHPS trademark and uses the CAHPS name as a prototype with permission of the CAHPS Consortium. The developers at AIR and the Mayo Clinic are hoping that other cancer care organizations, including cancer centers of all types and independent oncology practices, will use it and share their data for the final analyses needed to obtain the trademark.

> Cancer CAHPS asks patients about their experience with the full range of treatments regardless of care setting, and it is designed to be used by any providers of cancer care, from large academic cancer centers to independent practices.

"We have had discussions with various organizations about possibly using it, and we are asking people who want to use it to send us their de-identified data set so that we can do further analysis on it," Garfinkel said.

The instrument and advice about how to sample, field the survey, and analyze the data are available from Garfinkel (*sgarfinkel@air.org*) and the AIR-Mayo Clinic development team.