Cancer Care in Crisis

BY PEGGY EASTMAN

A n aging population and rising cancer incidence, along with increasing scientific complexity and rapidly escalating costs, are placing the U.S. cancer care system in crisis mode. That is the conclusion of a new report from the Institute of Medicine, which aims to chart a new course through the current system described as too often fragmented, unresponsive to patient preferences, and not making sufficient use of palliative and hospice services.

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U.S. Cancer Care Facing Crisis, Notes New IOM Report

Key to Improvement: Renewed Focus on Patient-Centered Care

BY PEGGY EASTMAN

WASHINGTON—An aging population and rising cancer incidence, along with increasing scientific complexity and rapidly escalating costs of care, are placing the U.S. cancer care system in crisis mode, according to a new report from the Institute of Medicine (IOM). The comprehensive document, “Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis,” released here during a public webinar, describes a care system that is fragmented, delivers care that often does not meet patient preferences, and underuses palliative care and hospice services.

The numbers alone documented in the report show why the country’s cancer care is in a crisis that is likely to worsen if steps aren’t taken to reduce its potentially devastating consequences: Today some 14 million Americans have been diagnosed with cancer, and more than 1.6 million new cases are diagnosed each year. By 2022, projections are that there will be 18 million US cancer survivors, and by 2030 cancer incidence is expected to rise to 2.3 million.

The number of older Americans—those most likely to develop cancer—is expected to double between 2010 and 2030, contributing to an expected 30 percent increase in the number of cancer survivors from 2012 to 2022 and a 45 percent rise in cancer incidence by 2030. The cost of cancer care, which is escalating much faster than that of other sectors of medicine, is expected to rise from $125 billion in 2010 to $173 billion by 2020, a 39 percent increase. In 2004 that cost was $72 billion.

Update from 1999 Report

The IOM report, which sets forth a detailed framework for improving the quality of cancer care, updates a 1999 report from the institute, “Ensuring Quality Cancer Care,” which called for improvement in the technical quality of cancer care, use of evidence-based guidelines, organized collection of electronic data, quality monitoring, and better access to care for all cancer patients.

The 2013 report focuses more intensively on patient-centered care aligned with patients’ values and preferences (including end-of-life care); better coordination and less fragmentation of care; problems inherent in treating an aging population with comorbid conditions; failure to use evidence-based care; over-utilization and inappropriate use of care; and an expected oncology workforce shortage.

“We do not want to frighten or scare anyone. ... that is not our intent,” said Patricia A. Ganz, MD, Chair of the 17-member multidisciplinary IOM committee that wrote the report. Rather, said Ganz, Director of Cancer Prevention and Control Research at UCLA’s Jonsson Comprehensive Cancer Center and Professor of Health Policy and Management at UCLA’s Fielding School of Public Health, the committee’s intention was to make recommendations that would help lead to better coordination of complex cancer care that is in line with what the patient wants and that avoids wasteful and unnecessary care.

In her preface to the new report, she writes: “Sadly, the key [1999] recommendations regarding implementation of evidence-based care and quality monitoring have had limited uptake, and are needed even more today due to the expansion in cancer diagnostics, imaging, and therapeutics in the past decade, as well as the expected growth in the number of new cancer patients.”

is superior.” He added that pCR is an acceptable endpoint in these studies: “In HER2 disease, pCR is associated with improved long-term outcomes.”

Side Effects Profile

Industry representatives and ODAC members discussed the side effects profile of pertuzumab in detail. In NEOSPHERE, the most common grade 3 or higher adverse events for the pertuzumab regimen were neutropenia, febrile neutropenia, and diarrhea. Potential cardiac adverse events were especially worrisome, said ODAC member Deborah K. Armstrong, MD, Associate Professor of Oncology at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University School of Medicine.

In TRYPHAENA, which investigated the tolerability of pertuzumab, trastuzumab, and anthracycline neoadjuvant regimens, no new or unexpected cardiac adverse events were observed in any of the study arms, according to Genentech data.

Also of concern to ODAC members was how neoadjuvant pertuzumab regimens would be used in clinical practice: “How exactly am I going to give it to a patient?” said ODAC member James Liebmann, MD, Assistant Professor of Medicine in the Department of Medicine at the University of Massachusetts.

Baselga said there are multiple regimens that are used with HER2 therapies, with no single conventional approach. “Part of our task is to think about how we will actually use the drug,” noted Sekeres.

ODAC members agreed that information on the drug label for the new indication would be key. Pazdur said FDA is working on an internal initiative to make the label for drugs approved via the accelerated-approval pathway clearer and more understandable—free of what he called “code language” and “gibberish.” He said that if the agency approves pertuzumab for the new neoadjuvant indication, the label would most likely specify that it be used in patients who meet the criteria of those studied in the NEOSPHERE trial.

ODAC’s Abstaining Member: Tito Fojo

The ODAC member who abstained from the vote, Tito Fojo, MD, PhD, Program Director for Medical Oncology at the National Cancer Institute, said he had problems with the study methodology of NEOSPHERE, including its small size, the fact that the majority of patients enrolled were outside the United States, and the use of an unproven surrogate endpoint.

Pazdur noted that there is no perfect new drug application. “Every application has its warts, folks,” he said. “This is what we have. Should we wait five years for more data? We’re looking at an agent that may prevent metastatic disease.”

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In many ways, she continued, “oncol-
gy care is an extreme example of the best
and worst in the health care system today,”
because it provides highly innovative, tar-
ged care alongside escalating costs that are
not always justified by evidence-based
studies.

The earlier report was considered “somewhat revolutionary” in the oncol-
gy community when it came out, Ganz
said, in that it called for major changes in
the health systems delivery infrastructure.

Since the new IOM report focuses more
on the individual cancer patient, the in-
formation emphasizes that patients want
to be involved and should be involved in
their care: “They want to be told the truth
about their care, even though it may be
uncomfortable or unpleasant,” said Ganz.

“Advances in understanding the
biology of cancer have increased the amount of
information a clinician must master to treat
cancer appropriately.”

Physicians, therefore, need to talk to
patients in depth at the time of diagno-
sis about their preferences, a conversation
that will lead to better compliance, better
outcomes, and fewer complications.

“We understand that physicians are
stretched thin,” said Ganz, but if this con-
tonation takes place early, it can be
valuable not only in respecting patients’
wishes, but also in eliminating wasteful
and futile care. “So often patients are
not given an opportunity to voice their
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Another member of the IOM commit-
tee, Noma L. Roberson, PhD, a retired
cancer research scientist at Roswell Park
Cancer Institute who also participated in
the webinar, said she came to appreciate
fully the value of patient-centered care—
including information gathering and shar-
ing and communication—on a personal
level when her husband was diagnosed
with prostate cancer.

Added committee member Mary D.
Naylor, PhD, RN, FAAN, the Marian
S. Ware Professor in Gerontology and
Director of the New Courtland Center
for Transitions and Health at the
University of Pennsylvania School of
Nursing: In focusing more specifically
and intentionally on patient-centered
care, it is important for health care pro-
fessionals to look carefully at the new
face of cancer and aging. Older cancer
patients are most likely living with mul-
tiple comorbid conditions, she said, and
family members—whom she called the
“invisible workforce”—are probably pro-
viding much of their care.

Extend Patent Protection
The new report does not suggest changes
to the current clinical trial system, but it
does recommend extending the patent
protection as an incentive for companies
that elect to test new cancer drugs in sec-
tor studies of older populations. Ganz
noted that older people are often excluded
from trials not because of age per se, but
because of comorbid conditions.

The report also recommends exploring
different forms of payment models for
oncology services, such as bundled pay-
ments and the oncology medical home:
“There are new models of care that have
not been fully evaluated, but they have
promise,” she said.

Reactions
American Society of Clinical Oncology
President Clifford A. Hudis, MD, hailed
the findings of the report, noting in a
statement (ASCO was also one of 14
sponsors of the new report): “We com-
mend the IOM for this landmark re-
port and will work with policymakers,
patients, health IT groups, and the onco-
yology community to implement its
recommendations.

“For oncologists, continuously improv-
ing the quality of cancer care is at the core
of our mission. This report provides im-
portant strategies we can use now to reach
this goal, and ASCO already has efforts in
place that will advance many of the IOM’s
recommendations.”

Hudis, Chief of the Breast Cancer
Medicine Service at Memorial Sloan-
Kettering Cancer Center, also referred
to ASCO’s Quality Oncology Practice
Initiative (QOPI), launched in 2006, as
the first national program to help oncol-
yogy practices improve the quality of their
care. He also cited ASCO’s 2011 recom-
mendations to improve physician-patient
communication on the full range of op-
tions for patients with advanced cancer,
and the organization’s new CancerLinQ,
an initiative to help achieve a continuous
learning system in oncology.

The National Coalition for Cancer
Survivorship (NCCS), another sponsor
of the report, also hailed the findings.
NCCS cites federal legislation, H.R.
2477, the Planning Actively for Cancer
Treatment (PACT) Act for Medicare
patients (which mandates a written care
plan), as a step toward realizing the
IOM’s vision of patient-centered care for
older cancer patients. PACT has been
introduced by Reps. Lois Capps (D-CA)
and Charles Boustany, Jr., MD (R-LA).

“The PACT act and this ground-
breaking IOM report have sent clear sig-
als that change in the cancer care system
is necessary, and we now have consensus
on where to start,” said Shelley Fuld
Nasso, NCCS Senior Director of Policy.
“We have an opportunity to make can-
cer patients, and the system that cares
continued on page 14

Report Recommendations

1. Provide patients and their families with understandable information
about cancer prognosis, treatment benefits and harms, palliative care,
psychosocial support, and costs.
2. Provide patients with end-of-life care that meets their needs, values,
and preferences.
3. Ensure coordinated and comprehensive patient-centered care.
4. Ensure that all individuals caring for cancer patients have appropri-
ate core competencies.
5. Expand the breadth of data collected in cancer research for older
adults and patients with multiple comorbid conditions.
6. Expand the depth of data collected in cancer research through a
common set of data elements that capture patient-reported outcomes,
relevant patient characteristics, and health behaviors.
7. Develop a learning health care information technology system for
oncology care that enables real-time analysis of data from cancer patients in
a variety of care settings.
8. Develop a national quality reporting program for cancer care as part
of a learning health care system.
9. Implement a national strategy to reduce disparities in access
to cancer care for underserved populations by leveraging community
interventions.
10. Improve the affordability of cancer care by leveraging existing
efforts to reform payment and eliminate waste.

Multidisciplinary Committee

The multidisciplinary committee that wrote the report included:

• Chair: Patricia Ganz, MD, UCLA Jonsson Comprehensive Cancer Center
• Harvey J. Cohen, MD, Duke University Medical Center
• Timothy J. Eberlein, MD, Washington University Medical Center
• Thomas W. Feeley, MD, MD Anderson Cancer Center
• Betty J. Ferrell, FAAN, PhD, MA, FPON, City of Hope National Medical Center
• James A. Hayman, MD, University of Michigan
• Katie B. Horton, George Washington University School of Public Health and Health Services
• Arti Hurria, MD, City of Hope National Medical Center
• Mary McCabe, RN, MA, Memorial Sloan-Kettering Cancer Center
• Mary D. Naylor, PhD, RN, FAAN, University of Pennsylvania School of Nursing
• Larissa Nehlyudov, MD, Harvard Vanguard Medical Associates
• Michael N. Neuss, MD, Vanderbilt-Ingram Cancer Center
• Noma L. Roberson, PhD, Roswell Park Cancer Institute
• Ya-Chen Tina Shih, PhD, University of Chicago
• George Sledge, Jr., MD, Stanford University
• Thomas Smith, MD, Johns Hopkins Medicine
• Neil Wenger, MD, UCLA
FDA Actions for Abraxane, Arzerra, Generic Capecitabine, and Tafinlar/Mekinist Combination

The U.S. Food and Drug Administration has expanded the approved uses of Abraxane (paclitaxel protein-bound particles for injectable suspension, albumin-bound) to treat patients with late-stage pancreatic cancer. Abraxane, a chemotherapeutic drug that slows tumor growth, is intended to be used with the chemotherapy drug gemcitabine in patients with pancreatic cancer that has spread to other parts of the body. Surgery is currently the only option to permanently remove or cure pancreatic cancer.

“Patients with pancreatic cancer are often diagnosed after the cancer has advanced and cannot be surgically removed,” Richard Pazdur, MD, Director of the FDA’s Office of Hematology and Oncology Products in the Center for Drug Evaluation and Research, said in a news release. “In these situations, and in situations when the cancer has progressed following surgery, options like Abraxane can help prolong a patient’s life.”

The drug, which is marketed by Celgene, was reviewed under the FDA’s priority review program, which shortens the time to complete a drug’s review and aims to deliver a decision on marketing approval designation for drugs that may offer major advances in treatment or provide a treatment where no adequate therapy exists within six months under the Prescription Drug User Fee Act. Abraxane was also granted orphan product designation for pancreatic cancer because it is intended to treat a rare disease or condition.

Abraxane’s approval was based on a clinical trial of 861 patients randomly assigned to receive Abraxane plus gemcitabine or gemcitabine alone. Patients treated with Abraxane plus gemcitabine lived 1.8 months longer than those treated with gemcitabine alone, on average, and progression-free survival for the patients receiving the drug combo was also 1.8 months longer than patients receiving gemcitabine alone.

The most common side effects for patients receiving the combination were neutropenia, thrombocytopenia, fatigue, peripheral neuropathy, nausea, alopecia, peripheral edema, diarrhea, pyrexia, vomiting, rash, and dehydration. The most common serious side effects were pyrexia, dehydration, pneumonia, and vomiting. Additional clinically important serious side effects included sepsis and pneumonitis.

Abraxane is also approved to treat breast cancer (OT 12/10/05) and non-small cell lung cancer (OT 12/10/12).

Arzerra Granted Breakthrough Designation for Previously Untreated CLL

The agency granted breakthrough therapy designation for Arzerra (ofatumumab) to be used in combination with an alkylator-based therapy (such as chlorambucil) for the treatment of patients with chronic lymphocytic leukemia who have not received prior therapy and are not candidates for 7-10-13

tumor protein 53 (p53), which is associated with cancer progression. (Photo credit: National Cancer Institute)

Tafinlar/Mekinist Combination Granted Priority Review for Metastatic Melanoma

The FDA granted priority review designation for the combined use of Tafinlar (dabrafenib) and Mekinist (trametinib) for the treatment of adults with metastatic melanoma with a BRAF V600 E or K mutation. Both Tafinlar (a BRAF inhibitor) and Mekinist (a MEK inhibitor) were approved as single agents earlier this year (OT 6/25/13 issue).

The FDA’s priority review designation shortens the time to complete a drug’s review and aims to deliver a decision on marketing approval designation for drugs that may offer major advances in treatment or provide a treatment where no adequate therapy exists within six months under the Prescription Drug User Fee Act (PDUFA). The FDA has assigned a PDUFA target date of Jan. 8, 2014 for the Mekinist supplement and Jan. 9, 2014 for the Tafinlar supplement.

The applications for both drugs are based on data from a randomized Phase I/II study comparing combination therapy with dabrafenib and trametinib with dabrafenib monotherapy in adults with BRAF V600E and V600K mutation positive metastatic melanoma.

Use of dabrafenib and trametinib in combination is investigational and has not yet been approved elsewhere in the world. The combination therapy for adult patients with metastatic melanoma with a BRAF V600 mutation is also under review in Europe according to standard timelines for regulation and approval.

Both drugs are marketed by GlaxoSmithKline.