McMahon Publishing

Clinical Oncology news

Advances in Cancer Care

CLINICALONCOLOGY.COM • APRIL 2008 • Vol. 3, No. 4

New ESA Restrictions Raise Concerns Over Impact on Anemia Rx

An FDA advisory panel's recommendation last month that erythropoiesis-stimulating agents (ESAs) no longer be used in patients with curable cancers or in those with metastatic breast or head and neck malignancies has oncology experts questioning how to apply the ruling to clinical practice.

The panel's decision was prompted in part by data from two new studies linking ESAs to increased mortality in patients given the drugs for chemotherapy-induced anemia (CIA).

"I understand part of the panel's logic—if ESAs boost mortality in some cancer patients, then it stands to reason that the drugs should be reserved for palliative care of anemia in those patients when they have terminal disease," said Jim Koeller, MS, professor of pharmacy,

see **ESA LIMITS**, page 28 ▶

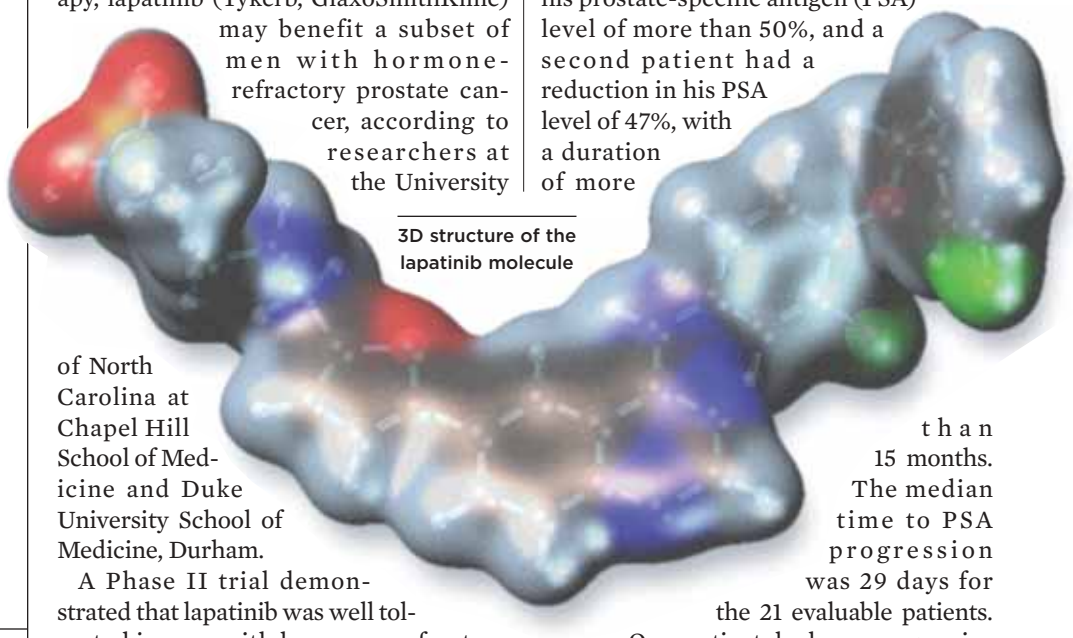
Adjuvant Imatinib Promising for GIST

Orlando, Fla.—The first trial of imatinib (Gleevec, Novartis) as adjuvant therapy for patients with primary high-risk gastrointestinal stromal tumors (GISTs) showed excellent results after one year of therapy, with an overall survival rate of 97% at three years. The findings were reported by Ronald DeMatteo, MD, vice chair of the Department of Surgery and head of the Division of General Surgical Oncology at Memorial Sloan-Kettering Cancer Center in New York City, at the 2008 Gastrointestinal Cancers Symposium (abstract 8). This compares favorably with historical controls, he said. The trial, called the U.S. Intergroup Phase II Z9000 trial, was funded by CTEP

see **IMATINIB**, page 17 ▶

Lapatinib May Benefit Some Men With Prostate Cancer

San Francisco—Used as single-agent therapy, lapatinib (Tykerb, GlaxoSmithKline) may benefit a subset of men with hormone-refractory prostate cancer, according to researchers at the University of North Carolina at Chapel Hill School of Medicine and Duke University School of Medicine, Durham.



3D structure of the lapatinib molecule

A Phase II trial demonstrated that lapatinib was well tolerated in men with hormone-refractory prostate cancer. One of the 21 evaluable patients given the drug had a reduction in his prostate-specific antigen (PSA) level of more than 50%, and a second patient had a reduction in his PSA level of 47%, with a duration of more than 15 months. The median time to PSA progression was 29 days for the 21 evaluable patients. One patient had nonprogressive

see **LAPATINIB**, page 3 ▶

POLICY & MANAGEMENT

Coming of Electronic Age:

Medicine Needs To Go Digital

For nearly two decades, there has been a buzz about electronic medical record (EMR) systems, but adoption and implementation of EMR systems has not happened swiftly. Today, 90% of U.S. physicians and more than 66% of hospitals still use paper records.

Digital Health Information Lags

Presidents have touted EMR systems since 1994 as part of their State of the Union addresses, and the government has put investment dollars behind the effort. So why have EMR systems been slow to catch on? Experts have cited four major reasons: fragmented health care infrastructure, misaligned financial incentives, lack of good software and cultural resistance by physicians ("Doctors Slow to Digitize Records," David Kohn, *The Baltimore Sun* March 2, 2008).

see **DIGITAL**, page 21 ▶

Bendamustine HCL (Treanda, Cephalon) approved for CLL.

See page 21

New Treatment for CLL Approved

The FDA has approved bendamustine hydrochloride (Treanda, Cephalon) for injection for the treatment of patients with chronic lymphocytic leukemia (CLL). In a randomized, international, multicenter, open-label study of 301 treatment-naive patients with CLL, those who received the drug had better clinical outcomes compared with patients treated with chlorambucil (Leukeran, GlaxoSmithKline).

Specifically, patients receiving bendamustine hydrochloride had a significantly higher overall response (59% vs. 26%; *P*<0.0001), a higher complete response rate (8% vs. <1%), and a significantly longer progression-free survival (18 vs. 6 months; hazard ratio, 0.27; *P*<0.0001).

Patients receiving bendamustine hydrochloride also had a longer duration of response than patients who received chlorambucil (19 vs. 7 months). The most common adverse events in the trial were myelosuppression, fever, nausea and vomiting.

POLICY & MANAGEMENT

Record Keeping

DIGITAL

continued from page 1 ▼

Two separate electronic health systems are being developed in the United States: electronic health records (EHRs) and EMRs. The EHR is an individual's medical record in digital format owned by the patient. This record is portable and is updated with each medical visit. While corporations and patients are eager to develop EHR systems, physicians, hospitals and the government are investing in EMR systems, which are kept in each clinician's office as a record of service and include relevant medical history. The two systems may or may not be able to speak to one another. The term EHR may be described by health informatics experts as a global concept, whereas EMR is often used to define a discrete localized record. To add to the confusion, both terms are often used interchangeably.

No matter how you choose to define it, however, the United States is one of the last developed countries to adopt electronic medical records. Germany is virtually 100% digitized, and Canada is 50%. National health systems have better coordination of information and data storage and retrieval. According to an article in the March 27, 2008, *Baltimore Sun,* U.S. health care is a "$2 trillion industry, staffed by 700,000 doctors, most of them essentially small, independent business people who are generally not paid by their customers, but by insurance companies."

Creating Health Information Solutions

Virtually every other industry has exploited technology in a revolutionary way. Apple changed multimedia; Amazon revolutionized retail; and Google democratized access to knowledge (Tom Friedman, *The World Is Flat,* Farrar, Straus, and Giroux, New York, 2005). By contrast, EHRs tend to be faithful representations of paper records.

> ***No matter how you choose to define it, the United States is one of the last developed countries to adopt electronic health care records.***

Clinicians need to lead the way and do better than just replicating the paper medical record. Without making it more versatile, it is unlikely that physicians will invest $40,000 to $60,000 to get digitized. It is unreasonable to expect small businesses to invest in technology that does not result in direct revenue.

Blake Lesselroth, MD, assistant professor of medicine and medical informatics, Portland VA Medical Center, in Oregon, has investigated what it will take to encourage physicians to invest in going digital and has identified three requirements. "First, the record must include tools, such as information filters, and pre-appraised resources to address pressures of a busy practice. Second, we need context-dependent decision aids to support problem solving. And third, we should borrow innovative ideas from other industries" (*Medscape J Med* 2008;10:45). His ideas create open-source development communities sponsored by government and corporate entities with bioinformatics from clinical educators and input from frontline clinicians.

Many major institutions such as Boston's Brigham and Women's Hospital are modernizing on their own dollar to advance electronic records. Brigham and Women's Hospital reported an 88% reduction in serious medication errors in the early years of adoption. It is critical to provide support for physician practices to upgrade and go digital to enhance medical practice.

The Department of Health & Human Services has opened its electronic health record demonstration project to physicians in 12 communities. Under the demonstration, payments over the five-year period may be up to $58,000 per physician or $290,000 per practice. While this project aims to improve patient care, it only affects a tiny percentage of the medical community. It also will do little to create a usable network. For more information, visit www.cms.hhs.gov/Demo Projects EvalRpts/downloads/2008_Electronic_Health_Records_Demonstration.pdf.

Efforts to create electronic solutions need to consider the big picture. Making business decisions regarding electronic applications for medical practices without the participation of other providers, insurers and local hospitals will not result in an integrated approach to managing patient data. It is important to avoid creating thousands of unnetworked EMR systems that will not have the potential impact to assist physicians in providing care, reducing costs and eliminating errors. Perhaps Dr. Lesselroth is providing greater vision and leading us down a better path.

Benefits Abound

EMR systems offer several benefits, including the potential to improve health care quality, reduce medical errors, minimize the duplication of services and provide an annual cost savings of $80 billion, according to Dr. Lesselroth.

EMR systems can also expedite the delivery of health care including emergency treatment at hospitals. In some cases, EMR systems have reduced the length of hospital stays because of immediate access to critical patient data.

Not only do electronic records significantly reduce paperwork and documentation errors, they also allow for much quicker universal access to and navigation through a patient's medical record. Information can be readily transmitted and retrieved for use in patient care, quality and risk management, performance reporting and even e-prescribing. Billing and coding processes are supported with efficient and effective e-systems, thus simplifying administrative processes. In addition, consumers can access individualized patient-specific information about their medical history and review and manage their own health care information, through a security-enhanced Web portal.

Just last month, Aetna Inc., launched a Web-based search site that allows customers to generate information about disease risks, medical costs and local doctors using their electronic health records. Of course, privacy and security concerns exist, but patients are eager to become better informed and to take charge of their own health care decisions.

Physicians appreciate having information about their patients readily available to them. The Veterans Affairs health programs have invested in a fully integrated, unified system that enables doctors to review more than 5.5 million patient records anywhere in the United States (Patricia Barry, "Going Digital," *AARP Bulletin*, March 2008). Others are slow to adopt and shell out the funds needed to develop digital health information. It is time to give up individualization and begin to look at the intersection between technology and medicine in an open, collaborative and networked way.

—Mary Lou Bowers, MBA, President and CEO, and Rhonda M. Gold, RN, MSN, Director

Mary Lou Bowers, MBA, *and* **Rhonda M. Gold, RN, MSN,** *are members of the advisory board for* **Clinical Oncology News** *and represent The Pritchard Group, LLC (www.thepritchardgroup.net).*

Barriers to Implementation Of e-Records

- Privacy and security concerns
- Lack of consistent national data standards
- Lack of technology standards for interoperability
- Resistance of clinicians to embrace technology
- Inadequate support for office-based providers
- Productivity misperceptions
- Insufficient returns on investment
- Minimal reimbursement and/or funding