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HHS Cites Imperatives for Electronic Records

Among groups with 50 or more physicians, more than two thirds (68%) have adopted electronic medical record systems. But for groups of five or fewer, only 12% have adopted EMRs, and among solo practitioners and small groups of two physicians, only 1% have adopted EMRs, says David Brailer, MD, PhD, national health information coordinator for the U.S. Department of Health and Human Services.

To Brailer, these small groups, which make up roughly half of all practicing physicians in the United States, are “the elephant in the room,” explaining that if they don’t adopt EMRs, the government’s plan to establish an interoperable seamless computer system that links all components of the U.S. health care system will be useless. President Bush appointed Brailer to his position last year and gave him a mandate to create this system and get physicians to adopt EMRs nationwide.

The challenges Brailer faces are significant. One of the most daunting involves finding a way for the government to support those physicians who operate in small groups. These doctors are either too busy or don’t have the management resources to take a deliberate and detailed approach to installing information technologies. Conversely, large groups, which often dominate their markets, have capital set aside for EMRs, and can plan for IT implementation.

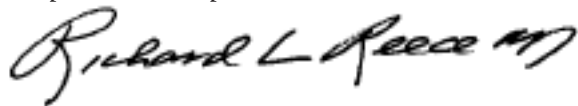
Another hurdle involves what Brailer calls the interoperability challenge. Most hospitals and doctors’ offices have customized systems that cannot communicate with other customized systems. These disconnected proprietary silos, as Brailer calls them, cannot serve as the foundation of an interconnected system.

To overcome these obstacles, Brailer says there are three building blocks that need to be added to the health care system to support interoperability. The first of these blocks is to develop communication and interoperability standards so that physicians will be able to make intelligent decisions about which EMR systems to use.

The second and perhaps most significant building block involves finding a way to give financial support to physicians to adopt EMR systems. Currently, many of the smallest physician practices cannot afford an EMR.

The last building block involves establishing regional health organizations, which would be networks of hospitals, health plans, and physicians in any given market that can adopt the particular technologies to fit the peculiarities and specifications of their market.

Clearly, these obstacles and building blocks represent a formidable challenge to Brailer, physicians, and the entire health care system. But fortunately, Brailer insists his mission is to let the marketplace, rather than the government, drive the process of computerization.



Richard L. Reece, MD

Editor in chief

Phone: 860/395-1501

Fax: 860/395-1512

E-mail: Rreece@premierhealthcare.com

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Publisher

Premier Healthcare Resource, Inc.
150 Washington St.
Morristown, NJ 07960
888/457-8800; Fax: 973/682-9077
publisher@premierhealthcare.com

Editor

Joseph Burns
508/495-0246
editor@premierhealthcare.com

Neil Baum, MD

Urologist
New Orleans

Daniel Beckham

President
The Beckham Co.
Physician and Hospital Consultants
Whitefish Bay, Wis.

Thomas M. Gorey, JD

President and CEO
Policy Planning Associates
Crystal Lake, Ill.

Michael B. Guthrie, MD, MBA

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Premier, Inc. and
Premier Practice Management
San Diego

Harold B. Kaiser, MD

Allergy & Asthma Specialists, PA
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Nathan Kaufman

President
The Kaufman Group
Division of Superior Consultant Co. Inc.
Physician and Hospital Consultants
San Diego

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Evidence-based Medicine
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Peter R. Kongstvedt, MD

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Roanoke, Va.

Bernard Rineberg, MD

Physician Consultant
BAR Health Strategies
New Brunswick, N.J.

James M. Schibanoff, MD

Editor in chief
Milliman Care Guidelines
Milliman USA
San Diego

Jacque Sokolov, MD

Chairman
Sokolov, Sokolov, Burgess
Scottsdale, Ariz.

New Treatment Options Available

For patients, screening for colorectal cancer is the key to reducing the burden of this disease, the third most common cancer and the second most common cause of cancer mortality in the United States. Fortunately, the number of medical and surgical options continues to rise, offering hope to patients when a cancerous lesion is detected.

One important new development is the chemotherapy regimen known as FOLFOX: oxaliplatin added to a 5-fluorouracil (5-FU)/leucovorin chemotherapy regimen. "Given the findings of a series of recent large clinical trials, FOLFOX has proven to be our most effective chemotherapy regimen for first-line treatment of metastatic colorectal cancer," says Richard L. Schilsky, MD, a medical oncologist and professor of medicine and associate dean for Clinical Research at the University of Chicago. In the adjuvant setting, FOLFOX has also improved disease-free survival of colon cancer, but its effect on rectal cancer remains unknown.

Monoclonal Antibodies

The introduction of two new monoclonal antibodies also represents a significant advance in medical therapy for colorectal cancer. One is bevacizumab (Avastin), which is directed against vascular endothelial growth factor. "Several randomized clinical trials have demonstrated that adding bevacizumab to standard chemotherapy for patients with metastatic colorectal cancer leads to an improvement in survival," states Schilsky, noting that some trials were begun before the use of FOLFOX. But earlier this year, clinical trial findings indicated that adding bevacizumab to FOLFOX in the second-line treatment of patients with metastatic colorectal cancer also results in improved survival.

"Given these findings and the strong support of FOLFOX in general, most medical oncologists today would use FOLFOX with bevacizumab as the first-line therapy of choice," Schilsky says. The benefits of using bevacizumab in adjuvant therapy are now being studied.

Last year, the FDA approved a second monoclonal antibody, cetuximab (Erbix). Several studies indicate that adding cetuximab, which is directed against the epidermal growth factor receptor, to second-line chemotherapy will result in an increased tumor response and a delay in tumor progression, Schilsky says.

Ongoing studies are evaluating whether FOLFOX plus cetuximab offers better outcomes than FOLFOX plus bevacizumab, as well as whether the addition of cetuximab to FOLFOX and bevacizumab improves outcomes over FOLFOX and bevacizum-

ab that patients receiving capecitabine had outcomes that were as good as patients receiving IV chemotherapy, with somewhat less toxicity," he explains. Ongoing clinical trials are addressing whether capecitabine can be substituted for 5-FU/leucovorin in the FOLFOX regimen in order to simplify therapy for patients.

At the annual meeting of the American Society of Clinical Oncology, held in Orlando in May, presenters provided confirmatory data on these new drugs, Schilsky reports. Other interesting findings included data from a few clinical trials showing that the use of irinotecan, another active drug in colon cancer, is not effective in the adjuvant setting, he says.

"Data was also available from an eagerly-awaited study employing a new biological therapy, PTK787, an oral drug that is an inhibitor of the

Each time a new oncology drug is approved, oncologists face a whole new set of questions regarding how to optimize its use.

ab alone. Both first-line therapy and adjuvant use are being studied.

Other Therapies

In another area of recent research, the value of capecitabine (Xeloda), an oral form of 5-FU, has continued to be highlighted. "Capecitabine, which came on the market in the late 1990s initially as a treatment for breast cancer, has been shown in randomized studies to be as good as 5-FU/leucovorin in the first-line treatment of metastatic colorectal cancer," Schilsky observes. "Furthermore, an adjuvant therapy study published in the June 30, 2005, issue of the *New England Journal of Medicine*, found

vascular endothelial growth factor receptor," Schilsky says. "Data indicated that the effectiveness of FOLFOX in the first-line treatment of metastatic colorectal cancer was not enhanced significantly when PTK787 was added. This is somewhat of a setback, both in the development of that particular drug and in the development of antiangiogenic therapy, because oncologists were hoping that PTK787 might offer an alternative to bevacizumab as an antiangiogenic strategy."

Medical oncologists now find it more complicated to select a treatment option for colorectal cancer because more options have become

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available, Schilsky says. “Each time a new oncology drug is approved, oncologists face a whole new set of questions regarding how to optimize its use,” he says. “For years, 5-FU/leucovorin therapy was essentially the only option for colorectal cancer patients, either in the adjuvant setting or in the advanced disease setting. Now we have all these new drugs and all these potential ways of combining them.”

In deciding among options, Schilsky says, oncologists are driven by clinical trial data. “We focus on the findings, the patient population, the magnitude of the benefit, and the risks,” he comments. “But unfortunately, there are always gaps in our information. We try to fill in those gaps by extrapolating data from one setting to another and by using good clinical judgment. We strive to make the optimal recommendation for each individual patient by analyzing the clinical situation, the risks, and the patient’s ability to tolerate the toxicity of treatment.”

Less Invasive Surgery

The foremost element of surgical treatment of colon cancer is removal of the cancerous lesion, but options that are less invasive than traditional incisional surgery are now used if the cancer is found at an early stage.

Many colonic polyps can be removed colonoscopically using electrocautery techniques. “Colonoscopic removal is appropriate if the cancer is a T1 lesion, if its appearance under the microscope is either well-differentiated or moderately differentiated, if

vessels or lymphatic vessels,” notes Marc I. Brand, MD, assistant professor of surgery and director of the Sandra Rosenberg Registry for Hereditary Colon Cancer at the Rush University Medical Center in Chicago. Surgical removal is indicated when the polyp cannot be removed safely colonoscopically or if the polyp contains an invasive malignancy that does not have all the favorable pathologic features listed above.

Similarly, early-stage rectal cancers may be removed with transanal endoscopic microsurgery (TEM), a technique involving a magnifying scope and special instruments, rather than an abdominal incision. “TEM allows surgeons to reach tumors that are higher in the rectum than can be reached with conventional transanal excision, and visibility is improved because of the magnified scope,” Brand observes. About 40 centers around the country are capable of performing TEM, he says.

A rising number of surgeons also are using laparoscopy to treat colon cancer. “Recent research has suggested that colon cancer outcomes—in particular, recurrence rates—are similar for patients undergoing the conventional open surgery approach and those undergoing laparoscopy,” Brand says. “As a result, the technique has been growing in popularity.” Gastroenterologists and their patients can consult www.colon-surgeryinfo.com to locate a surgeon who offers this approach.

Benefits of laparoscopy include decreased pain, shortened hospital-

tion, and fewer adhesions forming inside the abdomen, which may translate into a decreased occurrence of bowel obstruction after surgery.

Increased Accuracy

The downside is that a surgeon using laparoscopy will find it more difficult to see smaller growths in the colon. “Surgeons rely on the gastroenterologist’s description of the location of the lesion as seen during colonoscopy,” Brand observes. “But since there are no landmarks inside the colon, it is easy to describe a location inaccurately.”

Gastroenterologists can improve surgical accuracy by tattooing lesions at the time of colonoscopy, making them visible to the surgeon. “If gastroenterologists inject the tattoo ink deep in the colon wall, the ink will be visible on the outside wall of the colon, which is what the surgeon sees,” Brand offers. “Also, the tattoo should be placed in three or four locations in a circle around the lesion, rather than in just one spot, which may be hidden by the fat surrounding the colon.”

Another recent trend is the use of colonic stents in patients who have a colonic obstruction from colon cancer. “Traditionally, colonic obstruction was treated with two surgical procedures,” Brand explains. “The first involved a colostomy, and the second reconnected the bowel. The time between surgeries ranged from six weeks to six months, and the tumor was removed during one of these surgeries. Now, a colonic stent is placed during colonoscopy to relieve the obstruction without colostomy. So, only one procedure is needed—for tumor removal.”

Placement of colonic stents is a cutting-edge yet straightforward technique that gastroenterologists should consider. “Some gastroenterologists are using stents in other areas, but may not use them for colon obstruction,” Brand says, adding that gastroenterologists using stents in

Guidance from gastroenterologists may make high-risk patients more receptive to preventive surgery.

the edge of the tumor is at least two millimeters away from the cautery line where the polyp was removed, and if the polyp has not invaded the blood

ization, and quicker return to normal function. Other potential benefits include less likelihood of hernias in the incision, decreased wound infec-

other areas can place these stents with minimal additional training. “By suggesting to the surgeon that the obstruction be stented prior to surgery, gastroenterologists can simplify the surgery for patients.”

High-Risk Patients

While less invasive options are being explored, Brand notes a trend toward more aggressive surgery for patients with hereditary colon cancer, the goal being to prevent future malignant occurrences. “Given new understanding about patterns of cancer recurrence in high-risk patients, patients with hereditary colon cancer may require more extensive surgery than what is necessary to treat the known growth,” he says. “For example, several years ago a female patient at high risk who developed right-sided colon cancer would have the right half of her colon removed. Now, we might remove both sides of the colon as well as the uterus and ovaries to prevent the development of a cancer that might not be recognized until an advanced stage.”

Brand emphasizes that gastroenterologists can help their patients by understanding surgical options and, when applicable, preparing their patients for the possibility of extensive surgery. “High-risk patients are more receptive to the idea of preventive surgery if they have been prepared for that recommendation by their gastroenterologist,” he says. “Then, when they meet with the surgeon, they are not suspicious of the recommendation.”

Evaluating Techniques

More advanced rectal cancer requires pre-operative treatment with radiation and chemotherapy followed by formal removal of the rectum (proctectomy), Brand continues, while rectal cancers at a moderate stage might be treated with proctectomy but not with radiation. Different surgical techniques may be used for proctectomy, and this surgery can affect the

likelihood of local recurrence of the cancer. “For example, in total mesorectal excision, certain anatomic planes are developed so that the rectum is removed with an envelope of fascia, which helps to better contain the cancer and results in lower local recurrence rates,” Brand explains.

Researchers are also exploring the use of techniques that can lead to more accurate staging of colorectal cancer. For example, sentinel lymph node biopsy, commonly used in breast cancer and melanoma, may hold some potential for colon and rectal cancer. The sentinel lymph node is the first node that filters fluid from a given area, and is therefore

Prevention studies have largely been driven by oncologists, but partnering with gastroenterologists on these studies would enhance their value,” Schilsky says.

the most likely to capture cancerous cells. A biopsy performed on the sentinel lymph node, which is identified via injection of tracer fluid, obviates the need to remove and biopsy all lymph nodes near a tumor.

“Removal of all lymph nodes from the armpit of a breast cancer patient can result in lymphedema, a serious complication due to the alteration in the lymphatic drainage system,” Brand explains. “But lymphedema is not a problem when lymph glands in the abdomen are removed. Therefore, the value of sentinel lymph node biopsy in colon and rectal cancer will depend largely upon whether it will lead to more accurate staging than current staging techniques.”

Already, better preoperative staging has been achieved in rectal cancer via the use of ultrasound. “Ultrasound has enabled surgeons to make more informed decisions regarding the most appropriate option for each patient,” says Brand. “Now, researchers are exploring the

use of three-dimensional rectal ultrasound to see if it provides surgeons with more accurate information.”

Eventually gastroenterologists will begin to play an important role by participating in prevention studies involving high-risk patients. “Prevention studies have largely been driven by oncologists, but partnering with gastroenterologists on these studies would enhance their value,” Schilsky notes, adding that most oncologists are interested in strategies to prevent cancer in high-risk populations but don’t see those patients in their practices. “Working with gastroenterologists can help ensure that prevention studies are

performed and that strategies shown to be beneficial are adopted in clinical practice,” he says.

A Continuing Relationship

Another way in which medical oncologists and gastroenterologists can work in partnership is in the follow-up of patients post-operatively. “Patient who have had one colorectal tumor remain at high risk of developing subsequent tumors and therefore need life-long surveillance,” Schilsky points out. “Once patients complete adjuvant therapy, the physician following their health is often the oncologist. But the gastroenterologist, by virtue of doing surveillance colonoscopy, continues to play a major role in the management of that patient. Therefore, gastroenterologists and their oncology colleagues need to maintain good continuing relationships.”

—Reported and written by Deborah J. Neveleff, in North Potomac, Md. More information on physician practice strategies is available on our Web site (see page 8).

Cautions on Implementing an EMR

By Neil Baum, MD

Many physicians are adopting electronic medical record systems, and most have made the transition without too much trouble. But others have horror stories to tell about the experience when new systems don't work well. Or worse yet, when a new system doesn't work and the company that makes the system stops answering your calls for support.

Many physicians, hospital executives, and others consider Jeffery Daigrepoint, a consultant with The Coker Group, health care consultants, in Alpharetta, Ga., to be one of the nation's leading independent and objective experts on EMRs.

Daigrepoint emphasizes that there is a steep learning curve to make an EMR work before physicians will be able to enjoy the benefits of this electronic marvel. He cautions that EMR implementation success depends on solid preparation by training physicians and staff to use the tools and by preparing them emotionally for the change.

Homework Required

The most successful implementation occurs when the practice allows plenty of time to use the program before going live. In every practice in which Daigrepoint has served as a consultant, the physicians agree that it was a mistake to rush the implementation. In fact, many times physicians wish they had provided more time for training and learning the program than they had allotted. The minimum time to practice with the pro-

gram before going live should be four months. Doctors and staff can familiarize themselves with the program on a home PC or after office hours in the office.

Also, Daigrepoint suggests allowing staff and physicians to voice their concerns about implementation. Your staff may worry, for example, about losing their jobs, and the doctors may be concerned about a decrease in productivity during the early phases of implementation. You can allay such fears by reassuring staff of job security and by allowing the physicians ample time to become accustomed to the new processes required of the EMR.

with the program, I used it with every third patient, then every other patient, and finally with every patient. Of course, there were still times when I would encounter a problem and would temporarily return to paper and then complete the EMR at the end of the day.

Starting Slowly

Another way to encourage physicians to get comfortable with the EMR is to have them begin using the EMR with tasks that don't require significant changes in office processes. A doctor who uses e-mail should quickly get the hang of the EMR

The most successful implementation occurs when the practice allows plenty of time to use the program before going live. In fact, many times physicians wish they had provided more time for training and learning the program than they had allotted.

Coker recently surveyed several practices about their EMR experiences and asked what they would do differently. The top response was, "Would have spent more time on training and preparing."

In my practice, the first few days of having an EMR consisted of using the program only twice: once with the last patient in the morning and once with the last patient in the afternoon. Each of the first two patients required nearly an hour to complete the visit using the EMR. I told the patients that they were the first to experience the new technology and that the visit would be a longer than usual. Most patients were understanding.

When I became more comfortable

messaging system, for example. From there, he or she can move to automating incoming faxes, then adapt to prescription writing, reviewing lab reports, and then move to the more complex point-of-care documentation with a patient. These simple tasks help physicians become confident with the system and facile with the computer without significantly affecting productivity.

Daigrepoint recommends having regular meetings with physicians, the office manager, and any staff involved with the implementation. It is important to allow all staff to vent frustrations, provide suggestions, and let the group know about deficiencies that need to be commu-

Neil Baum, MD, is a urologist in New Orleans and the author of Marketing Your Medical Practice Ethically, Effectively, and Economically (Sudbury, Mass.: Jones and Bartlett Publishers, 2004). Readers may contact him at neilb89@aol.com.

Smoothing the Way

Jeffery Daigrepoint, a principal of health care consultants the Coker Group, in Roswell, Ga., and head of the Coker Technology Division, specializes in integrating information systems for medical practices. He also is the author of *Automating the Medical Record* (Chicago: 2004, AMA Press).

He suggests physicians take a number of steps to help ensure that the implementation of the EMR in your office will go smoothly. Typically, a physician group will work with a consultant to ensure success. Initially, the consultant will assess the readiness of your practice for an EMR, including doing a physical inventory of your hardware, a review of the existing infrastructure, and a study of what you may need. The goal of this phase will be to fully understand the specific operational characteristics and corresponding priorities of your practice. The consultant then likely will provide your practice with a recommendation for an appropriate technology solution and a qualified vendor.

The consultant should help your practice understand the following issues about installing an EMR:

- How to leverage technology to increase your revenue
- How your practice can succeed with an EMR
- Why physicians fail to use EMRs effectively
- How to avoid compromising productivity
- What implementation challenges you can expect
- Strategies for converting your paper records to digital format
- Getting a return on your investment
- Hidden fees and recurring costs
- How to successfully convert or disconnect your existing systems
- Operational challenges (specific to your practice) that need to be addressed before undergoing the transition
- Practice-specific interfacing requirements.

The most important of these factors involves understanding the true cost. The true cost of owning and implementing technology, especially an EMR, can be difficult to ascertain because it does not appear on the vendor's proposal. For example, during the first few weeks of implementation, your productivity will decrease as your practice acclimates to the new technology. Converting to a paperless environment is a big change, and you will need to commit a substantial amount of resources to the process. Practices need to fully understand the economic ramifications of this decision. Given the substantial cash outlay, other costs, and unforeseen expenditures, consultants should provide a thorough analysis that includes recommendations on how to contain costs.

nicated to the vendor's technical support department.

While becoming accustomed to a new EMR is a significant hurdle in any practice, there may be other barriers to overcome as well. Some of these obstacles may involve your relationship with your system vendor. For all issues regarding a vendor,

experts advise physicians to get all promises in writing. Ask the vendor for a locked-in fee for your annual service contract, for example. Agree to a limit on the percentage that fees may increase (for example, 1% or less than the Consumer Price Index) within a year. If additional training is necessary, agree on the availability

and cost of additional training. Consider requesting a discount off the annual maintenance cost once your use of the vendor's support staff levels off.

Staff Experience

Also, ensure that the vendor's trainers are not the company's newest staff members. You don't want to be learning while they are. Daigrepoint suggests that these staff have at least two years of experience in their current role with the vendor.

It is reasonable to request that the vendor accept responsibility that the hardware and software meet your performance expectations for at least 90 days after the installation and going live with your EMR. You don't want to start the performance clock during the learning phase but only after the program goes live.

Since most practices have a practice management system (PMS), ensure that it will work with your EMR and specify the vendor's responsibility regarding the interface. Otherwise, the interface can be costly.

Most EMRs need to be tweaked or adjusted once the program is used in practice. Daigrepoint suggests you request at least 50 hours of specialized support at no charge and a reduced rate for the first year following installation.

Finally, the computer business is fraught with risk, and many vendors have cash flow problems. Therefore, it is important to get a written agreement that the vendor will pay to establish an escrow account to protect you in the event of bankruptcy, liquidation, or sale.

Installing an EMR can be a daunting experience, but taking the right steps in advance can smooth out some of the bumps that are inevitable.

—For more information, readers may contact Daigrepoint at 800-345-5829 or by e-mail at jdaigrepoint@cokergroup.com. More information on physician technology strategies is available on our Web site (see page 8).

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