The CenterWatch Monthly

October 2011 A CenterWatch Article Reprint Volume 18, Issue 10

EHR integration could change the game for clinical research

Benefits include faster data entry, validation, easier AE reporting

By Sue Coons

A few short years ago clinical research sites struggled with moving their paper systems to electronic form. The automation added efficiencies, but information often had to be re-entered into different systems, adding the possibility of mistakes and taking time from patient care.

Now, a different kind of electronic integration is poised to redefine how sites conduct their research studies and gather data. Proponents say this integration can eliminate duplication of data, reduce the overwhelming administrative costs of conducting a study and create more valid data. It also can help researchers follow patients to track possible adverse effects long after a study is complete. Even the FDA has taken an active interest.

What is at the center of all this attention? The electronic health record (EHR).

EMRs vs. EHRs

Although many people use the terms EMR (electronic medical record) and EHR interchangeably, the concepts are different, said Dave Garets and Mike Davis, authors of an HIMSS Analytics white paper, "*Electronic Medical Records vs. Electronic Health Records: Yes, There is a Difference.*"

"EHRs are reliant on EMRs being in place, and EMRs will never reach their full potential without interoperable EHRs in place," they said.

An **Electronic Medical Record**, they said, is an application environment composed of the clinical data repository, clinical decision support, controlled medical vocabulary,

Eight Core Functionalities of the EHR

In May 2003, the Department of Health and Human Services (HHS) asked the Institute of Medicine (IOM) to provide guidance on the key care delivery-related capabilities of an EHR system. The resulting report, "*Key Capabilities of an Electronic Health Record System,*" identified eight care delivery functions essential for such records to promote greater safety, quality, and efficiency.

Health information and data: EHR systems with a defined dataset that includes such items as medical and nursing diagnoses, a medication list, allergies, demographics, clinical narratives and laboratory test results can ensure improved access to at least some types of information needed by care providers when they need it.

Results management: Managing results of all types electronically has several distinct advantages over paper-based reporting in terms of improved quality of care.

Order entry/order management: The benefits of computerized provider order entry have been well documented, with the strongest evidence of its clinical effectiveness seen in medication order entry.

Decision support: Computerized decision support systems have demonstrated their effectiveness in enhancing clinical performance for many aspects of healthcare, including prevention, prescribing of drugs, diagnosis and management and detection of adverse events and disease outbreaks.

Electronic communication and connectivity: Improved communication among care partners, such as laboratory, pharmacy and radiology, can enhance patient safety and quality of care and improve public health surveillance. Electronic connectivity is essential in creating and populating EHR systems, especially for those patients with chronic conditions who characteristically have multiple providers in multiple settings that must coordinate care plans.

Patient support: Patient education has demonstrated significant effectiveness in improving control of chronic illnesses.

Administrative processes: Electronic scheduling systems for hospital admissions, inpatient and outpatient procedures and visits not only increase the efficiency of heathcare organizations, but also provide better, more timely service to patients.

Reporting and population health management: Having clinical data represented with a standardized terminology and in a machine-readable format would reduce the significant data collection burden at the provider level, as well as the associated costs, and would likely increase the accuracy of the data reported.

order entry, computerized provider order entry, pharmacy and clinical documentation applications. The data in the EMR is the legal record of what happened to patients during their encounter at the CDO and is owned by the CDO.

An **Electronic Health Record** is a "subset of each care delivery organization's EMR… is owned by the patient and has patient input and access that spans episodes of care across multiple CDOs within a community, region or state (or in some countries, the entire country)."

Government incentives

Seeing the potential of the EHR, the Department of Health and Human Services (HHS) asked the Institute of Medicine (IOM) in 2003 to provide guidance on the key care delivery-related capabilities of an EHR system. The resulting IOM report, "*Key Capabilities of an Electronic Health Record System*," identified eight core EHR functionalities (see graphic).

The American Recovery and Reinvestment Act put another spotlight on EHRs in 2009 by authorizing incentives through the Health Information Technology for Economic and Clinical Health Act (HITECH) for using the technology. The Medicare and Medicaid EHR Incentive Programs are designed to provide incentive payments to eligible professionals, hospitals and critical access hospitals (CAHs) as they adopt, implement, upgrade or demonstrate "meaningful use" of certified EHR technology.

Eligible health professionals can receive up to $44,000 over five years under the Medicare program and up to $63,750 over six years under the Medicaid program. They must show that the EHR technology is certified and that the use of the EHRs made specific improvements in patient care delivery. The information on finding certified EHR technology is available on the Centers for Medicare and Medicaid Services' (CMS') web site. To qualify for the incentives, providers, rural hospitals and CAHs must meet a set of core objectives and choose from a menu set of objectives. The lists are available for download on the CMS web site.

Clinical research sites also may have some negative pressure to look at EHR integration. "If you look at what is available today, largely you see departmentally focused solutions that solve part of the process in conducting a trial. The reason you see adoption around those kinds of marginal solutions is that there is not much of a tax for being inefficient. NIH has funded whatever process is required to make the clinical research activity successful," said Michael Nolte, general manager at GE Healthcare IT, in Boston, Mass.

He predicts this will change because of budget pressures. "Organizations are going to be faced to take a broader look at all the activities that go on around clinical research," he said. "They are going to want to look at the administrative pieces of how these activities are conducted. They are not going to be able to do that without a portfolio-wide snapshot. They won't be able to aggregate data in a meaningful way otherwise."

To this end, GE now offers Centricity Research, an enterprise-class clinical research management solution that links a patient protocol manager with research billing compliance.

How EHR integration works

The Clinical Data Interchange Standards Consortium (CDISC), based in Round Rock, Texas, has been working for years to find a way to use the data held in EHRs for research purposes. The nonprofit's mission is to develop and support global, platform-independent data standards that enable different information systems to work together to improve medical research and related areas of healthcare. Using one definition, data standards are documented agreements on representations, formats and definitions of common data. These standards improve data compatibility, consistency and efficiency of data collection.

For its initial efforts, CDISC focused on a tightly defined set of activities and data set standards: exporting the continuity of care document (CCD), created by standards organizations Health Level 7 (HL7) and ASTM International, from the EHR. "We took the

Hospital system adoption of EHRs (2009)

	Small hospitals (<99 beds)	Mid-sized hospitals (100-399 beds)	Large hospitals (>400 beds)	Overall*
Basic EHR system	5%	8%	16%	7.6%
Comprehensive EHR system	1%	2%	3%	1.5%

*Weighted average

Source: Jha, A. et al. New England Journal of Medicine, 2009 (April 16)

The CenterWatch Monthly
ISSN 1556-3367

Editor-in-Chief Cheryl Appel Rosenfeld
Drug Intelligence Tracy Lawton
Production Holly Rose

The CenterWatch Monthly is published monthly by CenterWatch. Annual subscriptions start at $399.

For inquiries regarding subscriptions:
CenterWatch Customer Service
Tel: (866) 219-3440, Fax: (617) 948-5101
Email: customerservice@centerwatch.com

CenterWatch Main and Editorial Offices:
Tel: (617) 948-5100 Fax: (617) 948-5101
Email: editorial@centerwatch.com

CenterWatch

snapshot, called the CCD, which is well-known in the healthcare world. In fact, it is a requirement for meaningful use," said Landen Bain, CDISC liaison to health care.

Today, with an electronic data capture (EDC) system, a study coordinator would typically gather some information from the electronic health record, write it down on a piece of paper, go over to the EDC system log-in and re-enter that data, Bain explained. The Retrieve Form for Data-capture (RFD) integration profile, developed by CDISC and Integrating the Healthcare Enterprise (IHE), allows the study coordinator to bring the case report form directly in front of her through the EHR. "She doesn't have to leave the EHR," said Bain. "She doesn't have to deal with a separate laptop or a separate website. She doesn't have to sign into a different system. Authentication is carried through."

In the integration, the CCD goes from the EHR to the EDC system. The EDC system applies pre-populated data elements to the case report form, and then the case report form pops up in the EHR session. "We are saving double-data entry," Bain said. "We are saving dealing with multiple systems, and we are automating the workflow between the healthcare and the research functions."

CDISC's Healthcare Link approach, which Bain emphasized is a public domain, standards-based solution rather than a solution offered by a vendor, tackles workflow automation issues as opposed to what he calls the "extractive data grab." "We integrate the workflow of the study coordinators at the healthcare sites and the electronic health record," he said.

Sites now can enter data into the pre-populated form no matter what the EDC system is, said Robert Barr, chief technology office of Nextrials, a clinical research software and services provider based in San Ramon, Calif. "The user doesn't have to have training and memory of different systems. The effort is streamlined so the studies are happening more quickly. The data is more accurate, too, because it is coming directly from the EHR." A copy of that data also is being sent to an independent archive. "This is being considered electronic source in some of the standards."

The profile itself is elegant in its simplicity, Barr said. "While the EDC and EHR communicate with each other, they still maintain their own security and their own separation, which means that the EHR is not exposed in itself to the regulatory requirements of the EDC system (21 CFR Part 11), and the EDC system is not modifying anything in the EHR so HIPAA requirements don't come across to the EDC system."

Benefits for sponsors, sites

One benefit of the EHR integration is that it creates an electronic source document. This "fringe benefit" of the Healthcare Link may turn out to be its most important part, Bain said. "Sponsors go through a very tedious process of source document verification. They send people to the sites. These people sit down, they look at a piece of paper, they look at the EDC system and they see where everything came from."

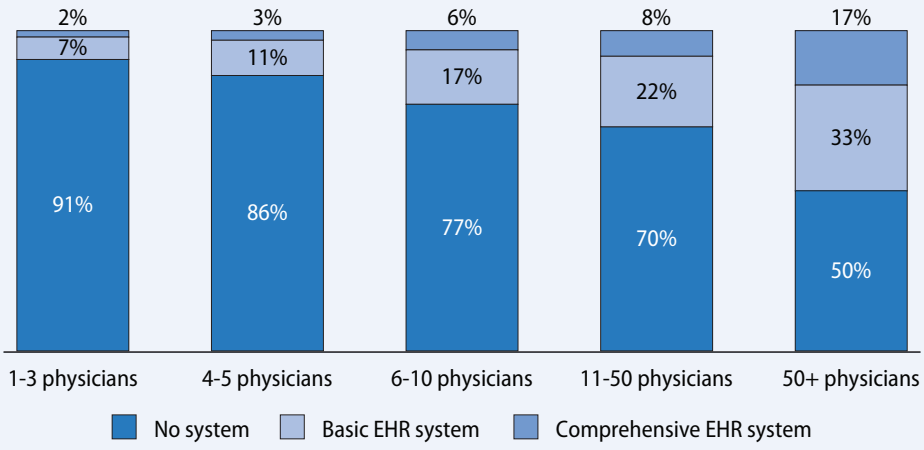
With the integration, the sponsors should be able to do that electronically. "This would save sponsors enormous sums of money in terms of sending monitors to visit sites. Remote source document verification could turn out to be truly a revolutionary benefit."

Data is entered into the system and patient records more quickly, often while the patient is still in-house. Nextrials now sees a surge in client traffic at the end of the month as sites scurry to input patient information into their systems. This results in discrepancies in time as far as when the data was collected and entered, Barr said. Mistakes can be made in the rush to enter data. Sponsors also would be delayed in knowing important information about the study until it had been entered into the system.

With the integration, components are almost always up-to-date, he said. "You could actually speed up the study and give sponsors better information so they could make faster decisions." In addition, the data is more valid because it comes from the original record.

Another important benefit comes outside the scope of a clinical trial, Barr said. "Doctors, sites, sponsors, regulatory entities and even the drug companies all benefit by having better post-marketing reporting related to drug interactions, device issues and, in general, all adverse events." Currently, a MedWatch form must be filled out for an adverse event. This form can take a doctor a significant amount of time, more than that spent with a patient. With integration using pre-population of data directly from the

Practicing physician adoption of EHR systems



Source: DesRoches, C. et al. New England Journal of Medicine, 2008 (July 3)

EHR, he said, the form can be filled out in minutes.

"Many events do not get reported if they are not seen as serious or relevant," said Barr. "Having this system in place would allow doctors or clinicians to fill out the required forms and submit these events on a regular basis, giving us a much better cross-section of data that could show patterns and issues that may have been missed in the past."

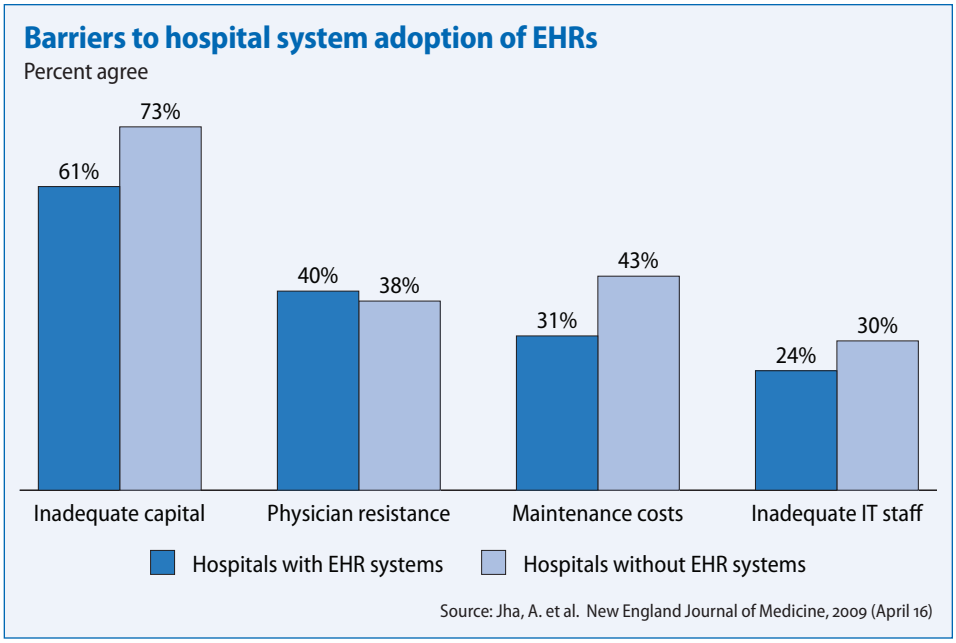
There's a real need to track adverse events, as well as to document items in clinical records information that happen to a patient outside a trial, Nolte said. This patient documentation could include an acknowledgement of what is going on with the patient through the course of the clinical trial, including any outside visits to another clinician or admissions to an emergency room.

"The tracking of that today is pretty spotty," he said, adding that the ability to see this information through the EHR would add context around patient care.

Updated EHRs also offer a wealth of data for researchers. Nextrials recently conducted a retrospective study with Greenway Medical Technologies, a clinical systems provider based in Carrollton, Ga. With the appropriate approvals in place, forms can collect the data straight out of the EHRs and finish an entire study fairly quickly, Barr said.

"We found that with the EDC/EHR integration [in the study], the time it took to bring sites online, get data entered and complete the study was greatly reduced," he said. The NextGreen Pilot Project used smaller sites that were research naïve, meaning they that had not participated in a clinical trial in the past, partly because of the cost and burden to smaller sites to become trained and up to speed on clinical research systems. Nextrials provided EDC through its Prism product, but allowed the sites to enter their data into Prism through Greenways PrimeSUITE EHR products interface.

"The burden on the site was greatly reduced, and the trial was able to start with a fraction of the training and effort that goes on today to bring a new site online," Barr said. "This will allow a much greater number of sites the option of participating in clinical trials, giving us a greater pool of patients and better data. This will also reduce costs not only at the site but for the sponsor as well. In the end, the life of the study is shortened, more efficient and potentially the outcome provided might yield better data."



"This will allow a much greater number of sites the option of participating in clinical trials, giving us a greater pool of patients and better data. This will also reduce costs not only at the site but for the sponsor as well. In the end, the life of the study is shortened, more efficient and potentially the outcome provided might yield better data."

—Robert Barr, chief technology office, Nextrials

DIY integration

Some sites see the importance of integrating clinical research into the electronic health record—and tackle the project themselves.

When Roswell Park Cancer Institute (RPCI), a National Cancer Institute-designated comprehensive cancer center, decided to go live with an EMR, the initial implementation plan focused on orders. Prior to the EMR, requests to radiology for specific tumor measurements took place by oral or email communication, said Debi Kinsey, nurse analyst. Now the request goes through the EMR with a list of the tumors the radiologist had identified on the last scan, unless it is the baseline measurement.

"The EMR requests have improved communication between the clinical research coordinator and the radiology team and have

improved protocol compliance," she said. In addition, the request becomes part of the patient record, allowing someone else to see that the tumor measurements had been requested.

These initiatives are a few of at least 50 that integrate EMRs with clinical research at RPCI, said Linda Schmieder, director of study implementation. "Customizing the electronic health record to clinical research is important to a research institute," she said. "It has improved how we function across the whole spectrum."

FDA observing the process

Not everyone shares the optimism for EHR/EDC integration or the opinion as to the best way to approach it. For example, some feel the reliance on EHR data is impractical for most clinical research focused on investigational new drugs and that the integration doesn't address budget issues such as site management. Still others see EHR completely replacing EDC, absorbing all of the EDC and clinical trial management system functionality into the EHR.

CDISC acknowledges the other views, but it chooses to focus on both the EHR and EDC—retaining their unique value and interoperating to achieve the best of both, Bain said. CDISC now is working to identify a regulated phase III study to implement Healthcare Link, a study the FDA would observe.

An FDA representative attended the first Interoperability Showcase sponsored by CDISC and IHE at the Drug Information Association (DIA) annual meeting in Chicago in June. The representative said it was "nice" that the demonstrated process used the CCD, which is required for EHRs for certification for meaningful use, wrote Rebecca Kush, CEO and president of CDISC, in her blog about the showcase. "He stated that the FDA neither prohibits nor does it require the use of EHRs for research; hence the work demonstrated in the showcase is voluntary. EHR compliance will not be assessed by FDA."

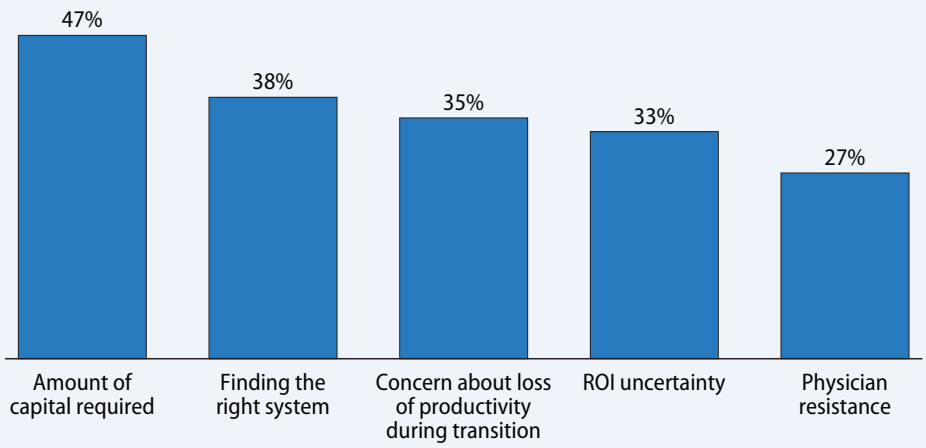
"We want to make sure that FDA is comfortable with this data capture approach and the electronic source archiving approach," Bain said. "We are involving them all along the way. They want to see the change, but they want to see it and observe it from their perspective."

Drug developers worry that billions of dollars of investment spent to get a drug to market could be washed away with one misstep with a federal regulator, Bain said. For this reason, he said, sites will be nervous about the regulatory impact of EHR integration until FDA approves the process. "[Approval] is the final piece that will push this into widespread adoption. I like to think that in 2012 we will start to see that."

Sue Coons has been a freelance journalist for 15 years. Her work has appeared in national magazines and healthcare industry publications. She holds a master's degree from the University of North Carolina at Chapel Hill.

Top barriers to practicing physician adoption of EHRs

Percent agree



Source: DesRoches, C. et al. New England Journal of Medicine, 2008 (July 3)