

Avoid Common Pitfalls of EHR Implementation

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BOSTON — To successfully implement an electronic health record system, set clear and specific goals and involve your clinical and administrative staff in all of the planning, Jerome H. Carter, M.D., said at a congress sponsored by the American Medical Informatics Association. “You have to plan,” said Dr. Carter, chief executive officer of NT&M Infor-

matics, Inc., Atlanta, and the editor of “Electronic Medical Records: A Guide for Clinicians and Administrators,” published by the American College of Physicians. As many as half of complex software implementations fail, Dr. Carter said, and usually for the same reasons: vague objectives, bad planning and estimation, poor project management, insufficient involvement by senior staff, and poor vendor performance.

“This is not the time to experiment with the latest gadgets,” he said. Implementation doesn’t start when the organization purchases the EHR products, but, rather, as soon as the group accepts the idea of moving from paper to an electronic system, Dr. Carter said.

The first step is to understand the current problems within the practice, to figure out how the practice should function, and identify what keeps the practice and its current system from working in an ideal way.

Potential EHR buyers should spend at least 3-4 weeks canvassing everyone in the practice to find out the problems and goals and to create a statement to capture those ideas, he said.

The next step is a systems and process analysis to be conducted by clinicians and executive management. This is a chance to figure out if an EHR will help to solve current problems, he said.

The executive management should also

assess everyone’s job functions. Adding an EHR to a practice will change job functions, and it’s important to make sure that all the important duties are still covered, Dr. Carter said.

Once this backgrounding has been done, a request for proposals based on practice needs can be created.

During product review, it’s important to have a designated project manager whose only job is to shepherd the project through each stage. In addition, senior executive support—both administrative and clinical—is key since that group will make the final decision on a system.

And staff input is essential since these are the people who really know what goes on in your practice, Dr. Carter said.

Spend time figuring out what resources will be needed in terms of new personnel, technical support, security, and equipment.

“Without that level of estimation and planning, it’s very likely you’ll be in a situation where you need a critical person and that person is not there,” he said.

Consider hardware issues. For example, it’s important to consider the types of input devices that will be used, such as tablets, desktop computers, or personal

digital assistants (PDAs). Tablet computers are popular but people also tend to drop them and spill coffee on them, he said.

Don’t forget to factor in security issues, Dr. Carter advised. For example, practices should be sure that any system they buy is compatible with the Health Insurance Portability and Accountability Act of 1996.

When the time comes, there are a variety of ways to roll out a system, Dr.

Carter said. For example, a practice can test all the features at once through a pilot at one site in the practice. Another option is to phase in implementation of the most important features first across the

entire organization.

Or a practice could opt to try a “big bang” rollout where all features are implemented across the organization at once. This approach is generally more successful in smaller practices with only two sites and fewer than 10 physicians, Dr. Carter said.

Regardless of the type of rollout, ongoing staff training is critical. It is not a one-time event. Staff will need training on the workflow change and planning aspects and the actual EHR system. Physicians will need additional training on physician-specific issues related to implementation, he said.

Ezetimibe: The pharmacokinetics of ezetimibe in adolescents (10 to 18 years) have been shown to be similar to that in adults. Treatment experience with ezetimibe in the pediatric population is limited to 4 patients (9 to 17 years) with homozygous sitosterolemia and 5 patients (11 to 17 years) with HoFH. Treatment with ezetimibe in children (<10 years) is not recommended.

Simvastatin: Safety and effectiveness of simvastatin in patients 10-17 years of age with heterozygous familial hypercholesterolemia have been evaluated in a controlled clinical trial in adolescent boys and in girls who were at least 1 year post-menarche. Patients treated with simvastatin had an adverse experience profile generally similar to that of patients treated with placebo. **Doses >40 mg have not been studied in this population.** In this limited controlled study, there was no detectable effect on growth or sexual maturation in the adolescent boys or girls, or any effect on menstrual cycle length in girls. Adolescent females should be counseled on appropriate contraceptive methods while on therapy with simvastatin (see CONTRAINDICATIONS and PRECAUTIONS, *Pregnancy*). Simvastatin has not been studied in patients younger than 10 years of age, nor in pre-menarchal girls.

Geriatric Use
Of the patients who received VYTORIN[®] (ezetimibe/simvastatin) in clinical studies, 792 were 65 and older (this included 176 who were 75 and older). The safety of VYTORIN was similar between these patients and younger patients. Greater sensitivity of some older individuals cannot be ruled out. (See CLINICAL PHARMACOLOGY, *Special Populations and ADVERSE REACTIONS*.)

ADVERSE REACTIONS
VYTORIN has been evaluated for safety in more than 3800 patients in clinical trials. VYTORIN was generally well tolerated. Table 1 summarizes the frequency of clinical adverse experiences reported in ≥2% of patients treated with VYTORIN (n=1236) and at an incidence greater than placebo regardless of causality assessment from 3 similarly designed, placebo-controlled trials.

Table 1*
Clinical Adverse Events Occurring in ≥2% of Patients Treated with VYTORIN and at an Incidence Greater than Placebo, Regardless of Causality

Body System/ Organ Class Adverse Event	Placebo (%) n=311	Ezetimibe 10 mg (%) n=302	Simvastatin** (%) n=1234	VYTORIN** (%) n=1236
Body as a whole – general disorders				
Headache	6.4	6.0	5.9	6.8
Infection and infestations				
Influenza	1.0	1.0	1.9	2.6
Upper respiratory tract infection	2.6	5.0	5.0	3.9
Musculoskeletal and connective tissue disorders				
Myalgia	2.9	2.3	2.6	3.5
Pain in extremity	1.3	3.0	2.0	2.3

* Includes 2 placebo-controlled combination studies in which the active ingredients equivalent to VYTORIN were coadministered and 1 placebo-controlled study in which VYTORIN was administered.
** All doses.

Ezetimibe: Other adverse experiences reported with ezetimibe in placebo-controlled studies, regardless of causality assessment: *Body as a whole – general disorders:* fatigue; *Gastrointestinal system disorders:* abdominal pain, diarrhea; *Infection and infestations:* infection viral, pharyngitis, sinusitis; *Musculoskeletal system disorders:* arthralgia, back pain; *Respiratory system disorders:* coughing.

Post-marketing Experience
The following adverse reactions have been reported in post-marketing experience, regardless of causality assessment:
Hypersensitivity reactions, including angioedema and rash; increased CPK; elevations in liver transaminases; hepatitis; thrombocytopenia; pancreatitis; nausea; cholelithiasis; cholecystitis; and, very rarely in patients taking an HMG-CoA reductase inhibitor with ezetimibe, rhabdomyolysis (see WARNINGS, *Myopathy/Rhabdomyolysis*).

Simvastatin: Other adverse experiences reported with simvastatin in placebo-controlled clinical studies, regardless of causality assessment: *Body as a whole – general disorders:* asthenia; *Eye disorders:* cataract; *Gastrointestinal system disorders:* abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea; *Skin and subcutaneous tissue disorders:* eczema, pruritus, rash. The following effects have been reported with other HMG-CoA reductase inhibitors. Not all the effects listed below have necessarily been associated with simvastatin therapy. *Musculoskeletal system disorders:* muscle cramps, myalgia, myopathy, rhabdomyolysis, arthralgias. *Nervous system disorders:* dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, dizziness, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy, psychic disturbances. *Ear and labyrinth disorders:* vertigo. *Psychiatric disorders:* anxiety, insomnia, depression, loss of libido. *Hypersensitivity Reactions:* An apparent hypersensitivity syndrome has been reported rarely which has included 1 or more of the following features: anaphylaxis, angioedema, lupus erythematosus-like syndrome, polymyalgia rheumatica, dermatomyositis, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, eosinophilia, arthritis, arthralgia, urticaria, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome. *Gastrointestinal system disorders:* pancreatitis, vomiting. *Hepatobiliary disorders:* hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma. *Metabolism and nutrition disorders:* anorexia. *Skin and subcutaneous tissue disorders:* alopecia, pruritus. A variety of skin changes (eg, nodules, discoloration, dryness of skin/mucous membranes, changes to hair/nails) have been reported. *Reproductive system and breast disorders:* gynecomastia, erectile dysfunction. *Eye disorders:* progression of cataracts (lens opacities), ophthalmoplegia. *Laboratory Abnormalities:* elevated transaminases, alkaline phosphatase, γ -glutamyl transpeptidase, and bilirubin; thyroid function abnormalities.

Laboratory Tests
Marked persistent increases of serum transaminases have been noted (see WARNINGS, *Liver Enzymes*). About 5% of patients taking simvastatin had elevations of CK levels of 3 or more times the normal value on 1 or more occasions. This was attributable to the noncardiac fraction of CK. Muscle pain or dysfunction usually was not reported (see WARNINGS, *Myopathy/Rhabdomyolysis*).

Concomitant Lipid-Lowering Therapy
In controlled clinical studies in which simvastatin was administered concomitantly with cholestyramine, no adverse reactions peculiar to this concomitant treatment were observed. The adverse reactions that occurred were limited to those reported previously with simvastatin or cholestyramine.

Adolescent Patients (ages 10-17 years)
In a 48-week controlled study in adolescent boys and girls who were at least 1 year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia (n=175), the safety and tolerability profile of the group treated with simvastatin (10-40 mg daily) was generally similar to that of the group treated with placebo, with the most common adverse experiences observed in both groups being upper respiratory infection, headache, abdominal pain, and nausea (see CLINICAL PHARMACOLOGY, *Special Populations and PRECAUTIONS, Pediatric Use*).

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Coalition to Begin Certifying Electronic Health Record Software in the Fall

BOSTON — A coalition of private sector informatics groups plans to launch a process for certifying electronic health record products late this year.

Certification will bring some predictability into the market for physicians, vendors, and payers, Mark Leavitt, M.D., chair of the Certification Commission for Healthcare Information Technology, said at a congress sponsored by the American Medical Informatics Association.

The commission’s initial scope is to certify electronic health record (EHR) products for physician offices and other ambulatory settings. They plan to begin beta testing products as part of a pilot project in September.

By the end of the year, the commission is slated to publish certification requirements and to outline a roadmap for vendors for requirements for the next 1-2 years, Dr. Leavitt said.

The roadmap is a key part of the commission’s work because the cycle for getting new features, interfaces, and interoperability functions into a product can be 6-18 months or more. “We need to signal to the industry as to where we are going next, so it has time to respond,” he said.

The commission was founded last year by the American Health Informa-

tion Management Association, the Healthcare Information and Management Systems Society (HIMSS), and the National Alliance for Health Information Technology.

The three groups have provided seed funding and have loaned staff members to the effort. As the process moves forward, the commission will charge fees to the vendors to cover the cost of testing the products. They also plan to seek sustaining grants from other organizations to maintain their operations, said Dr. Leavitt, who is also the medical director at HIMSS.

Under the voluntary certification process, products will either be certified or not certified. “We are not trying to create a competitive rating system,” Dr. Leavitt said.

The idea is that the commission will be setting a baseline standard, leaving space for competition and innovation above that standard. And the standard needs to be based on reality, he said, to get participation from vendors.

In the first year of certification, the members of the commission want to be sure that they don’t create requirements that will shut down the marketplace. However, Dr. Leavitt said he expects that as the standards become more rigorous in the years to come, the market-

place will evolve to follow the certification process.

Currently, adoption is progressing slowly because the market lacks order and predictability. For example, physicians won’t buy EHR systems until costs are lower, their own risk is lower, and the incentives are higher. However, it’s hard for vendors to bring down prices when the sales volumes are so low and the sales cycle is so costly.

Payers have expressed interest in offering incentives for the use of EHRs, but many are concerned that if they start to offer incentives, an industry of minimal systems will spring up to capture that money, Dr. Leavitt said.

Certification is a way to take some of the risk out of the process for all the players, Dr. Leavitt said.

Another challenge is to make sure that there isn’t a wave of adoption of products that aren’t interoperable.

“We want to ensure that these products that get adopted will be interoperable in this emerging infrastructure,” according to Dr. Leavitt. “The challenge is the infrastructure isn’t there yet, it’s emerging.”

—Mary Ellen Schneider

For more information on the certification timeline, visit www.cchit.org.