

# Expert Advice on Preparing for EHR

BY MARY ELLEN SCHNEIDER

In less than 6 months, doctors can begin to qualify for tens of thousands of dollars in incentive payments from the federal government for using electronic health record technology. Many physicians are asking: How do I get ready?

The first step, experts agree, is to prepare your practice. Implementing an electronic health record (EHR) effectively is

only partially about the technology, said Mary Griskewicz, senior director for ambulatory information systems at Healthcare Information and Management Systems Society (HIMSS), a nonprofit organization.

Most of the work is about reengineering the practice, assessing and changing processes and workflows. "This is not a small task, in particular for small practices," she said.

And before practices jump into an implementation, Dr. Steven Waldren, director of the Center for Health IT at the American Academy of Family Physicians, suggests that they examine their motivation for using an EHR. He cautioned physicians not to do it just to take advantage of the new federal incentives.

Physicians who qualify as "meaningful users" of EHR technology through the Medicare program can receive up to

\$44,000 over 5 years, and those who qualify through the Medicaid program can earn about \$64,000. But that may not cover the costs of a new system, Dr. Waldren said, so physicians should have other reasons for making the switch.

"They shouldn't be doing this for the \$44,000," Dr. Waldren said. "They should be doing it because they believe it's the right thing to do for them, their practice, and their patients. Without that, you don't have the commitment to make it actually happen."

Once a practice has decided to purchase an EHR and laid the groundwork with the staff, there are still a number of

## ParaGard<sup>®</sup> T 380A<sup>®</sup> intrauterine copper contraceptive

Brief Summary

(See package brochure for full prescribing information)

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

ParaGard<sup>®</sup> T 380A Intrauterine Copper Contraceptive should be placed and removed only by healthcare professionals who are experienced with these procedures.

### INDICATIONS AND USAGE

ParaGard<sup>®</sup> is indicated for intrauterine contraception for up to 10 years. The pregnancy rate in clinical studies has been less than 1 pregnancy per 100 women each year.

### CONTRAINDICATIONS

ParaGard<sup>®</sup> should not be placed when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy
2. Abnormalities of the uterus resulting in distortion of the uterine cavity
3. Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
4. Postpartum endometritis or postabortal endometritis in the past 3 months
5. Known or suspected uterine or cervical malignancy
6. Genital bleeding of unknown etiology
7. Mucopurulent cervicitis
8. Wilson's disease
9. Allergy to any component of ParaGard<sup>®</sup>
10. A previously placed IUD that has not been removed

### WARNINGS

#### 1. Intrauterine Pregnancy

If intrauterine pregnancy occurs with ParaGard<sup>®</sup> in place and the string is visible, ParaGard<sup>®</sup> should be removed because of the risk of spontaneous abortion, premature delivery, sepsis, septic shock, and, rarely, death. Removal may be followed by pregnancy loss.

If the string is not visible, and the woman decides to continue her pregnancy, check if the ParaGard<sup>®</sup> is in her uterus (for example, by ultrasound). If ParaGard<sup>®</sup> is in her uterus, warn her that there is an increased risk of spontaneous abortion and sepsis, septic shock, and rarely, death. In addition, the risk of premature labor and delivery is increased.

Human data about risk of birth defects from copper exposure are limited. However, studies have not detected a pattern of abnormalities, and published reports do not suggest a risk that is higher than the baseline risk for birth defects.

#### 2. Ectopic Pregnancy

Women who become pregnant while using ParaGard<sup>®</sup> should be evaluated for ectopic pregnancy. A pregnancy that occurs with ParaGard<sup>®</sup> in place is more likely to be ectopic than a pregnancy in the general population. However, because ParaGard<sup>®</sup> prevents most pregnancies, women who use ParaGard<sup>®</sup> have a lower risk of an ectopic pregnancy than sexually active women who do not use any contraception.

#### 3. Pelvic Infection

Although pelvic inflammatory disease (PID) in women using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days following insertion. Therefore, the visit following the first post-insertion menstrual period is an opportunity to assess the patient for infection, as well as to check that the IUD is in place. Since pelvic infection is most frequently associated with sexually transmitted organisms, IUDs are not recommended for women at high risk for sexual infection. Prophylactic antibiotics at the time of insertion do not appear to lower the incidence of PID.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID.

Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at [www.cdc.gov](http://www.cdc.gov) or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomyces-like organisms on Papanicolaou smear in an asymptomatic IUD-user is unknown, and so this finding alone does not always require IUD removal and treatment. However, because pelvic actinomyces is a serious infection, a woman who has symptoms of pelvic infection possibly due to actinomyces should be treated and have her IUD removed.

#### 4. Immunocompromise

Women with AIDS should not have IUDs inserted unless they are clinically stable on antiretroviral therapy. Limited data suggest that asymptomatic women infected with human immunodeficiency virus may use intrauterine devices. Little is known about the use of IUDs in women who have illnesses causing serious immunocompromise. Therefore these women should be carefully monitored for infection if they choose to use an IUD. The risk of pregnancy should be weighed against the theoretical risk of infection.

#### 5. Embedment

Partial penetration or embedment of ParaGard<sup>®</sup> in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

#### 6. Perforation

Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard<sup>®</sup> promptly, since the copper can lead to intraperitoneal adhesions. Intestinal perforation, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

#### 7. Expulsion

Expulsion can occur, usually during the menses and usually in the first few months after insertion. There is an increased risk of expulsion in the nulliparous patient. If unnoticed, an unintended pregnancy could occur.

#### 8. Wilson's Disease

Theoretically, ParaGard<sup>®</sup> can exacerbate Wilson's disease, a rare genetic disease affecting copper excretion.

### PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

#### 1. Information for patients

Before inserting ParaGard<sup>®</sup> discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard<sup>®</sup> as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

#### 2. Insertion precautions, continuing care, and removal.

(See Package Brochure for INSTRUCTIONS FOR USE.)

#### 3. Vaginal bleeding

In the 2 largest clinical trials with ParaGard<sup>®</sup> (see ADVERSE REACTIONS, Table 2), menstrual changes were the most common medical reason for discontinuation of ParaGard<sup>®</sup>. Discontinuation rates for pain and bleeding combined are highest in the first year of use and diminish thereafter. The percentage of women who discontinued ParaGard<sup>®</sup> because of bleeding problems or pain during these studies ranged from 11.9% in the first year to 2.2% in year 9. Women complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue ParaGard<sup>®</sup>. (See ADVERSE REACTIONS.)

#### 4. Vasovagal reactions, including fainting

Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when getting up.

#### 5. Expulsion following placement after a birth or abortion

ParaGard<sup>®</sup> has been placed immediately after delivery, although risk of expulsion may be higher than when ParaGard<sup>®</sup> is placed at times unrelated to delivery. However, unless done immediately postpartum, insertion should be delayed to the second postpartum month because insertion during the first postpartum month (except for immediately after delivery) has been associated with increased risk of perforation.

ParaGard<sup>®</sup> can be placed immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after the first trimester abortion.

#### 6. Magnetic resonance imaging (MRI)

Limited data suggest that MRI at the level of 1.5 Tesla is acceptable in women using ParaGard<sup>®</sup>. One study examined the effect of MRI on the CU-7<sup>®</sup> Intrauterine Copper Contraceptive and Lippos Loop<sup>™</sup> intrauterine devices. Neither device moved under the influence of the magnetic field or heated during the spin-echo sequences usually employed for pelvic imaging. An in vitro study did not detect movement or temperature change when ParaGard<sup>®</sup> was subjected to MRI.

#### 7. Medical diathermy

Theoretically, medical (non-surgical) diathermy (short-wave and microwave heat therapy) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. However, a small study of eight women did not detect a significant elevation of intrauterine temperature when diathermy was performed in the presence of a copper IUD.

#### 8. Pregnancy

ParaGard<sup>®</sup> is contraindicated during pregnancy. (See CONTRAINDICATIONS and WARNINGS.)

#### 9. Nursing mothers

Nursing mothers may use ParaGard<sup>®</sup>. No difference has been detected in concentration of copper in human milk before and after insertion of copper IUDs. The literature is conflicting, but limited data suggest that there may be an increased risk of perforation and expulsion if a woman is lactating.

#### 10. Pediatric use

ParaGard<sup>®</sup> is not indicated before menarche. Safety and efficacy have been established in women over 16 years old.

### ADVERSE REACTIONS

The most serious adverse events associated with intrauterine contraception are discussed in WARNINGS and PRECAUTIONS. These include:

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

Table 2 shows discontinuation rates from two clinical studies by adverse event and year.

Table 2. Summary of Rates (No. per 100 Subjects) by Year for Adverse Events Causing Discontinuation

Adverse Event	Year									
	1	2	3	4	5	6	7	8	9	10
Pregnancy	0.7	0.3	0.6	0.2	0.3	0.2	0.0	0.4	0.0	0.0
Expulsion	5.7	2.5	1.6	1.2	0.3	0.0	0.6	1.7	0.2	0.4
Bleeding/Pain	11.9	9.8	7.0	3.5	3.7	2.7	3.0	2.5	2.2	3.7
Other Medical Event	2.5	2.1	1.6	1.7	0.1	0.3	1.0	0.4	0.7	0.3
No. of Women at Start of Year	4932	3149	2018	1121	872	621	563	483	423	325

\*Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the Population Council (3,536 subjects) and the World Health Organization (1,396 subjects) trials.

The following adverse events have also been observed. These are listed alphabetically and not by order of frequency or severity.

Anemia	Menstrual flow, prolonged
Backache	Menstrual spotting
Dysmenorrhea	Pain and cramping
Dyspareunia	Urticarial allergic skin reaction
Expulsion, complete or partial	Vaginitis
Leukorrhea	

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TEVA WOMEN'S HEALTH

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## Don't Wait, but Don't Rush

Dr. David Blumenthal, the national coordinator for health information technology, has been making the rounds, getting the word out to physicians about the new meaningful use requirements and how to qualify for incentive payments for using EHRs.

During recent Webinars offered by professional medical societies, Dr. Blumenthal told physicians that they should get started on EHR implementation, but that they don't have to rush to be using the system by Jan. 1, when the new incentive program begins. At that point, physicians can begin to apply to the Centers for Medicare and Medicaid Services to become meaningful users.

Those who qualify could begin receiving incentive payments as early as May 2011, according to Dr. Blumenthal. However, under the Medicare program, physicians can take advantage of the full amount of incentive payments, just at a later date, as long as they can become meaningful users by Oct. 1, 2012.

"You have time to learn to be a meaningful user," Dr. Blumenthal said during a Webinar sponsored by the Medical Group Management Association.

For physicians who need assistance selecting or implementing EHR technology, Dr. Blumenthal recommended that they contact their local regional extension centers. The Office of the National Coordinator for Health Information Technology has awarded grant money to set up 60 of these centers around the country. The centers are focused on assisting primary care physicians in small practices and in underserved areas, but no practices will be turned away, Dr. Blumenthal said. For more information about the regional extension program, go to [healthit.hhs.gov/extensionprogram](http://healthit.hhs.gov/extensionprogram).

challenges. For example, under the HITECH Act, which established the EHR incentive program, physicians can qualify only if they are meaningful users of certified EHR technology. While the government has released regulations defining meaningful use requirements, as well as requirements for certification, there are currently no certified products on the market. The first products are expected to gain certification sometime this fall, according to the Office of the National Coordinator for Health Information Technology, which is shepherding this effort.

But the current lack of certified products shouldn't keep physicians from shopping for a system now, experts said. One way to deal with it is to build a guarantee of certification into the contract with the vendor. Physicians just need to be sure to get any assurances in writing, said Dr. Waldren. And they need to be clear on the terms of the guarantee. For example, will the guarantee allow you to get your money back if the vendor fails to become certified or does it allow you to withhold payments until the vendor becomes certified?

Physicians also should look to include service level agreements in their contracts with vendors, Dr. Waldren said. This ensures that the practice will get specific levels of support within certain time frames. If the company fails to deliver on the promised level of service, the practice may be able to make reduced payments or hold payments until that service level is met. These agreements could become important, Dr. Waldren said, since vendors are likely to be very busy as more practices adopt EHRs over the next few years.

When choosing an EHR product, there are several factors to consider, Ms. Griskewicz said, such as whether the software will fit in with the workflow of the practice and whether it is usable by everyone in the office.

One way to answer some of those questions is to talk to clinicians at other practices who have already implemented the product. It's best to try to find practices that are similar to your own, Ms. Griskewicz said. And ask about integration issues such as how the system will work with existing billing software or how it can help the practice to handle future regulatory changes such as the switch from ICD-9 to ICD-10, she said.

Physicians should consider future meaningful use requirements when choosing a product, Dr. Waldren advised. Right now, physicians have to meet stage 1 criteria for meaningful use, but the requirements will get more difficult in stages 2 and 3 and require different functionality from the EHR technology, he said.

For now, physicians may be able to meet many of the early requirements through the implementation of e-prescribing and registry programs. Since the law does not require that physicians implement a full EHR system to qualify for incentive payments, physicians who are buying an EHR product for the first time may want to consider purchasing individual EHR modules, Dr. Waldren said.

The modules are significantly less expensive than traditional full systems. However, physicians who are considering a modular approach need to find out how the vendor would support stages 2 and 3

of meaningful use. And they would need a plan for how to move their data if they decided to switch to a different system later, he said.

For those practices that have already implemented an EHR system, the work is not over. They now have to ensure that they can meet the meaningful use requirements and that their system will be certified under the new federal rules. Many vendors will be offering upgrades to meet the certification requirements at varying costs.

If you're satisfied with your current system, it makes sense to stay with that

vendor even if certification requirements can't be met right away, Dr. Waldren said. Although physicians can begin to qualify for meaningful use on Jan. 1, 2011, they can start submitting information to the government as late as October 2012 and still be eligible for the full incentive payments under Medicare.

Physicians who are not satisfied with their current system and who want to switch to a new product should consider that it may take some time to migrate the data from one product to another, Dr. Waldren added. Since vendors will be focused on trying to add as many new

users as possible, getting the support and service for data migration may be challenging, he said.

As physicians consider their options, the key is to get educated, Ms. Griskewicz said. She recommends that physicians seek out trusted sources such as the Centers for Medicare and Medicaid Services and their medical professional societies, many of which are offering free Webinars and other online information. "The big thing right now is that they educate themselves as to what are the requirements" and what they need to do and what is the best fit for their practice, she said. ■

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**References:** 1. VEREGEN® Ointment, 15% [Prescribing Information, 2008]. Melville, NY: PharmaDerm, a division of Nycomed US Inc. 2. Data on file, PharmaDerm. Please see adjacent page for Brief Summary of full Prescribing Information.

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