

iPLEDGE Registry Back On Track Despite Delays

Patients not registered and activated in the system by March 1 will not be able to be prescribed isotretinoin.

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NEW YORK — Despite bugs in the system that have delayed implementation of the iPLEDGE isotretinoin registry and physicians' dismay at the increased red tape and monitoring they are facing, the program is moving forward—and ultimately may be beneficial for clinicians, Dr. Hilary Baldwin said.

"The biggest asset of this system is that, in the case of a horrible event, with pregnancy and fetal malformations, it's no longer her word against yours in a court of law," Dr. Baldwin said at a meeting on medical and surgical dermatology sponsored by Mount Sinai School of Medicine in New York.

"Patients are assuming more responsibility, and there is less liability on our shoulders," she said.

Because the voluntary SMART program failed to decrease the number of pregnancies among women taking isotretinoin, women of childbearing potential now must not only have monthly pregnancy tests, physician visits, and counseling, but must also attest that they have done so by filling out the required forms on the iPLEDGE Web site.

"If she gets pregnant and a year later wants to sue you because of birth defects, she can't claim that you didn't tell her she needed to use two forms of birth control, because she has attested to this not once, but monthly," said Dr. Baldwin of the State University of New York Health Science Center at Brooklyn.

The patient also will be responsible for contacting iPLEDGE if she is given a "red light" at the pharmacy.

The pharmacist will not know the reason—whether she failed to interact with the system, or the two forms of birth control entered by the patient and physician did not match, or if she did not have a pregnancy test—and it will be up to her to contact the system.

The iPLEDGE card she is given when she is registered will have the registry phone number and her password.

Because of delays and difficulties in getting the program up and running, the compliance date for physicians and patients was pushed back to March 1, 2006 (FAMILY PRACTICE NEWS, Dec. 15, 2005, p. 32).

A total of 17,000 prescribers have registered for the program, and about 5,000 have been activated.

At the meeting, though, a number of attendees complained that they still had not received the materials they needed to register and activate their registrations, while

others said they had not been given the requisite passwords. (Physicians and other prescribers such as nurse practitioners, physician assistants, and residents can call the program at 866-495-0654 or visit www.ipleddgeprogram.com for information and materials.)

Women of non-childbearing potential and men also must register with iPLEDGE, though they do not need to interact with the system monthly as do women of childbearing potential. They still must be seen and counseled each month, however, on the risk of fetal malformations should they share the drug with a woman of childbearing potential, and reminded not to do so and also not to donate blood.

Physicians who have in the past treated men with low-dose isotretinoin face a particular obstacle: Each prescription must be for a 1-month supply, so writing a prescription for 30 pills for a man who intends to take two pills a week for several months without being seen by his physician will not be a prudent option.

"If you do this, it's your risk, and you have to remember to document in the system every month that you have seen and counseled him. You will have to

keep that lie going, which I think is a very bad idea," Dr. Baldwin said, adding "Big brother is watching."

It also will not be possible to use alternating 40- and 80-mg pills to achieve a 60-mg dose, because that regimen involves 45 pills, and the pharmacist can't cut up a foil of 10.

One area in which the Food and Drug Administration has relented is in permitting abstinence to count as both forms of birth control. Originally, the FDA wanted abstinence to count only once, but for patients such as minors, nuns, or lesbians it may count as both forms.

"You may not be willing to do that, though. If I have a 16-year-old who claims abstinence/abstinence, I don't feel real comfortable with that. You can still require them to be on birth control. Just because the system doesn't require it doesn't mean you can't do what you feel comfortable with," she said.

Don't delay in registering patients, because those who are not registered and activated by March 1 will not be prescribed the drug, Dr. Baldwin advised.

"The time for arguing is gone. Every time I give one of these talks there's a lot of argument as to why it shouldn't happen and how silly it is and how angry we are. You might very well be angry, but it's too late. It's time now to accept it or not accept it and move on because it's mandatory and it's done," she said. ■

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DERM Dx

A 26-year-old law student presented with an asymptomatic, reticulated, hyperpigmented rash on her right thigh that had been increasing in size. Some degree of erythema also was present. She was otherwise healthy, was not taking any medications, and had no relevant family history. What's your diagnosis?



When asked to demonstrate her typical use of a laptop computer, she held it directly on her bare thighs.

"We then turned her computer on for 30 minutes and then tested the surface heat of its underside with an infrared thermometer," said Dr. Kimberly Scott of Eastern Virginia Medical School, Norfolk, Va.

The area that corresponded to her right thigh, where the computer's central processing unit was located, measured 125° F, while the area that corresponded to her left thigh was only 95° F.

The diagnosis was erythema ab igne, a condition that is caused by repeated nonburning exposure to infrared radiation. It is characterized by transient erythema that evolves into reticulated hyperpigmentation and possibly telangiectasia.

The exact pathogenesis of erythema ab igne is not known, but it is thought that cutaneous hyperthermia involving temperatures of 43°-47° C (109°-117° F) can result in changes similar to those that occur with exposure to ultraviolet radiation.

Traditionally, the condition was seen among women who sat in front of wood-burning stoves, but since the advent of central heating, most

cases involve occupational exposures among patients such as bakers and glassblowers who are exposed to heat for prolonged periods.

Patients with chronic pain also can develop the condition from using heating pads or hot-water bottles excessively. In one novel case, a patient heated a bag of popcorn just to the brink of popping in a microwave oven and applied the bag to her wrist for relief of arthritis pain (J. Dermatol. 2002;29:172-3).

Typical histologic findings include hyperkeratosis of the epidermis, with atypia of the epithelial cells. In the dermis, there may be collagen degeneration that appears similar to solar elastosis.

The course is usually benign if the heat source is removed promptly, but there have been cases of malignant transformation resulting in squamous cell or Merkel cell carcinoma, so follow-up is advisable.

If hyperpigmentation persists, tretinoin or hydroquinone or one of the combination products can be useful, Dr. Scott said at the annual meeting of the National Medical Association.

"And advise patients to not take the term 'laptop' literally," she said.

—Nancy Walsh

