

Health

FDA issues hold on Avandia study

Federal health officials are barring new patients from enrolling in a safety study of GlaxoSmithKline's controversial diabetes pill Avandia, a week after a panel of experts ruled that the drug increases heart risks.

The Food and Drug Administration said it issued a "partial clinical hold" on the study to update researchers on the latest concerns about Avandia, which has been under scrutiny since 2007.

Last week a panel of experts voted that the drug appears to increase heart risks, but a majority ultimately voted to leave the drug on the market because the evidence was not definitive.

The FDA is currently reviewing the panel's opinions and deciding what action to take.

GlaxoSmithKline said in a statement it would halt recruitment for the so-called TIDE trial and update the study's chief investigators on last week's meeting. Patients already in the study will be permitted to continue participating.

The London-based drugmaker agreed to conduct the trial in 2007, after safety questions about Avandia were first publicized.

The TIDE study is designed to give a definitive assessment of whether Avandia's heart risks are greater than its chief competitor Actos.

Last week, the FDA's panel of outside advisers voted 20-10 that the trial should continue if Avandia stays on the market.

However, Avandia's critics have argued that the trial is unethical since current evidence already shows

Avandia is riskier than Actos, which is made by Japan-based Takeda Pharmaceuticals.

Dr. Steven Nissen, chairman of cardiovascular medicine at the Cleveland Clinic, said halting enrollment in the trial was "the ethically correct thing to do."

Nissen first drew attention to Avandia's risks in a 2007 medical journal article estimating that patients taking Avandia were 43 percent more likely to experience heart attack than those taking other diabetes drugs or no diabetes medication. He noted that the FDA's advisory panel specifically voted last week that Avandia increased risk of heart attacks more than Actos.

"I still think there's a very good chance that the FDA will decide to remove Avandia from the market," Nissen said.

The TIDE study is supposed to enroll 16,000 patients, though safety concerns surrounding Avandia have slowed recruitment. Researchers reported last week that just 1,100 patients have volunteered for the study.

Dr. Robert Califf of Duke University, a researcher who is leading three major industry-funded diabetes studies, said there is still "tremendous uncertainty" about Avandia's balance of risk and benefit, and that not completing the study could leave a big hole in the information needed by patients and doctors.

Califf said the FDA's move is "a reasonable and rational step while the company gets its information together" but cautioned that it could push some

current study participants to drop out.

The FDA said TIDE's researchers should update the informed consent forms used to describe the risks of the study to potential recruits.

But Yale University cardiologist Dr. Harlan Krumholz questioned how doctors could get patients to give truly informed consent to participate in a study "where the best-case scenario is that they are not harmed by the drug."

"I just wonder if patients in this trial really understand that the entire point is to determine if those randomized to the arm with Avandia are at higher risk," said Krumholz, who is also a professor at Yale.

Public Citizen's Dr. Sidney Wolfe said the FDA's move is an "important half-step," but said it would not help patients who are already enrolled in TIDE.

"It doesn't really speak to the health risks of the people staying in the trial," said Wolfe, who has petitioned the FDA to withdraw Avandia. "My guess is most, if not all the people in that study would drop out if they were given information about how much more dangerous Avandia is compared with Actos."

The American Diabetes Association said in a statement that the FDA's announcement only pertains to the TIDE trial and urged doctors "not to over-generalize this announcement to the use of Avandia in clinical care."

The FDA first approved Avandia in 1999 and it quickly became the top-selling diabetes pill in the world. However, U.S. sales have plummeted from \$2.2 billion in 2006 to \$520 million last year as safety concerns swirled around the drug.

The drug works by increasing the body's sensitivity to insulin, a key protein needed for digestion that diabetics don't adequately produce.

The FDA added a black box warning to the drug in 2007. New studies on the drug's safety combined with pressure from safety advocates has prompted the agency to take another look at the drug.

The FDA is expected to make a decision on whether to keep the drug on the market in coming months.

Guidelines to reduce repeated C-sections studied

Most women who've had a C-section, and many who've had two, should be allowed to try labor with their next baby, say new guidelines - a step toward reversing the "once a cesarean, always a cesarean" policies taking root in many hospitals.

Wednesday's announcement by the American College of Obstetricians and Gynecologists eases restrictions on who might avoid a repeat C-section, rewriting an old policy that critics have said is partly to blame for many pregnant women being denied the chance.

Fifteen years ago, nearly 3 in 10 women who'd had a prior C-section gave birth vaginally the next time. Today, fewer than 1 in 10 do.

Last spring, a National Institutes of Health panel strongly urged steps to reverse that trend, saying a third of hospitals and half of doctors ban women from attempting what's called VBAC, for "vaginal birth after cesarean."

The new guidelines declare VBAC a safe and appropriate option for most women - now including those carrying twins or who've had two C-sections - and urge that they be given an unbiased look at the pros and cons so they can decide whether to try.

Women's choice is "what we want to come through loud and clear," said Dr. William Grobman of Northwestern University, co-author of the guidelines. "There are few times where there

is an absolute wrong or an absolute right, but there is the importance of shared decision-making."

Overall, nearly a third of U.S. births are by cesarean, an all-time high. Cesareans can be lifesaving but they come with certain risks - and the more C-sections a woman has, the greater the risk in a next pregnancy of problems, some of them life-threatening, like placenta abnormalities or hemorrhage.

The main debate with VBAC: That the rigors of labor could cause the scar from the earlier surgery to rupture. There's less than a 1 percent chance of that happening, the ACOG guidelines say. Also, with most recently performed C-sections, that scar is located on a lower part of the uterus that's less stressed by contractions.

Of those who attempt VBAC, between 60 percent and 80 percent will deliver vaginally, the guidelines note. The rest will need a C-section after all, because of stalled labor or other factors. Success if more likely in women who go into labor naturally - although induction doesn't rule out an attempt - and less likely in women who are obese or are carrying large babies, they say.

Thus the balancing act that women and their doctors weigh: A successful VBAC is safer than a planned repeat C-section, especially for women who want additional children - but an emergency C-section can be riskier than a planned one.

Because of those rare uterine ruptures, the obstetricians' group has long recommended that only hospitals equipped for immediate emergency C-sections attempt VBACs. Many smaller or rural hospitals can't do that, and that recommendation plus high-dollar lawsuits have been blamed for some hospital VBAC bans.

"Restricting access was not the intention," the new guidelines say. They say hospitals ill-equipped for immediate surgery should help women find care elsewhere, have a plan to manage uterine ruptures anyway, and not coerce a woman into a repeat C-section.

Educating women about their options early enough in pregnancy for them to make an informed choice is key, said Dr. F. Gary Cunningham of the University of Texas Southwestern Medical Center, who chaired the NIH panel on repeat C-sections.

It requires a fair portrayal of risks and benefits that can differ by patient, added Dr. Howard Minkoff of Maimonides Medical Center in Brooklyn, N.Y., which has women sign a special VBAC consent after counseling yet has a higher-than-average VBAC rate of 30 percent.

"There's no doubt that how things get framed influences how people act," he said.

While the guidelines cannot force hospital policy changes, some women's groups welcomed them.

"I feel like ACOG has really listened to how their previous policies have impacted women," said Barbara Stratton of the International Cesarean Awareness Network's Baltimore chapter, adding that she'll advise women seeking a VBAC to hand a copy of the guidelines to caregivers who balk.

But she called for reducing overuse of first-time C-sections, too, so that repeats become less of an issue.

microbicide and the others, a dummy gel. Women were told to use it 12 hours before sex and as soon as possible within 12 hours afterward.

At the study's end, there were 38 HIV infections among the microbicide group versus 60 in the others.

Can deciphering your doctor's notes improve care?

Don't be offended if your doctor writes that you're SOB, or that an exam detected BS.

The aim is to help, not insult: A project is beginning to test if patients fare better when given fast electronic access to more of their medical chart - the detailed notes that doctors record about you during and after every visit. You just might have to look up some of the technical jargon, like those abbreviations for "shortness of breath" and "bowel sounds."

Didn't know about those notes? Researchers involved in the "OpenNotes" project say they are surprised at how many patients don't.

"You really have to be a partner with your doctor to do well," says Dr. Tom Delbanco of Harvard and Beth Israel Deaconess Medical Center, who heads the study and thinks better use of those notes will help.

"It's your body. It's your record. It's your illness. You should have ready

access to everything about it."

Yes, your clinic may have an electronic records system that lets you log in to make an appointment, check your cholesterol test or review your medications. But Delbanco and nursing colleague Jan Walker have found few include those doctor notes that provide details about a patient's health.

They can stretch two or three pages, as doctors mull alternate diagnoses they may not have mentioned, like a test ordered to rule out cancer.

Or doctors may jot reminders about personal issues that could complicate care - maybe the patient ignores medical advice, or is in denial, or has financial difficulties.

Doctors may detail problems in more blunt terms than they'd used face-to-face.

Hence easier access is debated. Say the doctor carefully avoids the "O" word while urging you to lose 20 pounds, only to write that "Joe is obese." Will you get mad, or be more likely to follow the advice?

To find out, three large health centers - Beth Israel, the Geisinger Health System in Pennsylvania and Seattle's Harborview Medical Center - are enrolling 115 doctors and up to 25,000 patients in the OpenNotes study.

For a year, participants will get an e-mail after each office visit saying their doctor's note is available through a secure online portal. Researchers will track if patients read it and find errors, and how they use it. Doctors' habits are being tracked, too - if they censor themselves or write more patient-friendly notes.

It's not just for the Web-savvy and well-off. Among the Seattle participants are homeless patients who can log in at such places as the public library.

Harborview's Dr. Joann Elmore sees the potential value: She has a patient who e-mails health questions from remote Alaskan fishing camps where he travels seasonally to find work. But she also wonders if patients with low literacy, especially, can use the notes. After all, they're intended mostly to jog the doctor's memory, communicate with other physicians and justify

insurance billing.

Indeed, in Monday's Annals of Internal Medicine, Delbanco and Walker describe doctors' fears of time lost editing their words or calming patients upset at reading of, say, an inconsequential heartbeat irregularity - while patients say they want the information but wonder if they'll misinterpret something. To further check interest, the journal is posting a survey for doctors and the general public alike at <http://www.annals.org>.

By federal law, you can get a copy of everything in your medical chart, visit notes included, by filing a formal request, but it can be difficult. Clinics may take two or three weeks to respond, and Delbanco says copying fees can run as high as 75 cents a page. Seattle's Elmore last week saw a woman who'd succeeded in getting records from just one of four care sites; her office intervened to help get the rest.

Given the hurdles, patients rarely seek copies of their medical records unless they're facing a big illness, says Stephen Downs of the Robert Wood Johnson Foundation, which is funding the \$1.4 million OpenNotes study.

With growing use of electronic records making easier access possible, the question becomes whether doctors will write easier-to-understand notes to help engage patients in their care, he says.

"The way I view my relationship with the doctor is, I'm the CEO of me and he works for me," says Ed Leonard, an engineer in Acton, Mass. He'd never seen a doctor's note until a recent visit to Delbanco, but he welcomed the change.

Another patient stopped an error by telling a doctor that her note didn't mention the tests she'd promised to order, Walker says.

And in New Hampshire, where the Dartmouth-Hitchcock Medical Center provides routine electronic access to doctor's notes, Dr. Mary Merkel inadvertently shamed a diabetic into better health. Three months after she wrote that he was "noncompliant," he returned 30 pounds lighter, saying he'd felt bad at her disappointment in him.

"I don't want to hurt my patients' feelings," says Merkel, admitting she'd had a hard time telling the man how badly he was doing. "Who knew this could be such a powerful tool?"

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AIDS breakthrough: Gel helps prevent infection

For the first time, a vaginal gel has proved capable of blocking the AIDS virus: It cut in half a woman's chances of getting HIV from an infected partner in a study in South Africa. Scientists called it a breakthrough in the long quest for a tool to help women whose partners won't use condoms.

The results need to be confirmed in another study, and that level of protection is probably not enough to win approval of the microbicide gel in countries like the United States, researchers say. But they are optimistic it can be improved.

"We are giving hope to women," who account for most new HIV infections, said Michel Sidibe in a statement. He is executive director of the World Health Organization's UNAIDS program. A gel could "help us break the trajectory of the AIDS epidemic," he said.

And Dr. Anthony Fauci of the U.S. National Institutes of Health said, "It's the first time we've ever seen any microbicide give a positive result" that scientists agree is true evidence of protection.

The gel, spiked with the AIDS drug tenofovir, cut the risk of HIV infection by 50 percent after one year of use and 39 percent after 2 1/2 years, compared to a gel that contained no medicine.

To be licensed in the U.S., a gel or cream to prevent HIV infection may need to be at least 80 percent effective, Fauci said. That might be achieved by adding more tenofovir or getting women to use it more consistently. In the study, women used the gel only 60 percent of the time; those who used it more often had higher rates of protection.

The gel also cut in half the chances of getting HSV-2, the virus that causes genital herpes. That's important because other sexually spread diseases raise the risk of catching HIV.

Even partial protection is a huge victory that could be a boon not just in poor countries but for couples anywhere when one partner has HIV and the other does not, said Dr. Salim Abdool Karim, the South African researcher who led the study. In the U.S., nearly a third of new infections each year are among heterosexuals, he noted.

Countries may come to different decisions about whether a gel that offers this amount of protection should be licensed. In South Africa, where one in three girls is infected with HIV by age 20, this gel could prevent 1.3 million infections and 826,000 deaths over the next two decades, he calculated.

He will present results of the study Tuesday at the International AIDS Conference in Vienna. The research was published online Monday by the journal Science.

"We now have a product that potentially can alter the epidemic trends ... and save millions of lives," said Dr. Quarraisha Abdool Karim, the lead researcher's wife and associate director of the South African program that led the testing.

It's the second big advance in less than a year on the prevention front. Last fall, scientists reported that an experimental vaccine cut the risk of HIV infection by about 30 percent. Research is under way to try to improve it.

If further study shows the gel to be safe and effective, WHO will work to speed access to it, said its director-general, Dr. Margaret Chan.

The gel is in limited supply; it's not a commercial product, and was made for this and another ongoing study from drug donated by California-based Gilead Sciences Inc., which sells tenofovir in pill form as Viread. If further study proves the gel effective, a full-scale production system would need to be geared up to make it.

The study tested the gel in 889 heterosexual women in and near Durban, South Africa. Researchers had no information on the women's partners, but the women were heterosexual and, in general, not in a high-risk group, such as

prostitutes.

Half of the women were given the

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