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Should surgery be an option for obese adolescents?

Expert opinions differ about permanent procedure for weight loss

With a significant percentage of the U.S. population deemed overweight, surgical treatments for obesity have become much more widespread.

The most common, and most successful, is a surgical procedure known as the gastric bypass. Developed in the late 1960s, the operation involves surgically isolating a small pouch at the top of the stomach and reattaching the small intestine to this pouch in order to bypass the lower stomach.

According to the American Society of Bariatric Surgery (ASBS), more than 100,000 procedures will be performed this year.

Long used as a last resort in adults for whom other weight-loss options have failed and who have significant weight-related health problems, the procedure is becoming more common in people younger than 18.

"This is a controversial hot topic in medicine and in society," notes **Atul K. Madan**, MD, a bariatric surgeon with the University of Tennessee Medical Group in Memphis. "There are no established guidelines for pediatric patients, those below the age of 18, although some are currently being developed."

Although the surgery poses significant risks for patients, including death, serious nutritional deficiencies, and tissue damage, severely obese patients — including adolescents — often have life-threatening medical conditions that may outweigh such risks, he says.

With the number of overweight children and teens increasing at an alarming rate, these procedures will continue to be a needed option for some young patients, Madan says.

"We see 18-year-olds who are diabetic, who have congestive heart failure, illnesses that you would expect to see in patients who are 30-40 years older," he says. "These are problems that cannot be ignored. The best treatment for morbid obesity is prevention, but that is very difficult in our society right now."

Bariatric surgery — surgical techniques to treat obesity — evolved

after surgeons noticed that certain gastrointestinal procedures used to treat cancer or severe ulcers resulted in significant long-term weight loss in patients who underwent them.

These initial procedures involved removal of large portions of the stomach or small intestine.

The first procedure widely used for severe obesity was the intestinal bypass, first used 40 years ago, which produced weight loss by preventing the body from absorbing too many calories. However, this procedure caused many patients to suffer loss of essential nutrients. Side effects were often unpredictable and sometimes fatal. The original procedure is no longer performed.

The modern version, gastric bypass, also is a "malabsorption" procedure, which works primarily by reducing the amount of food a person can hold in the stomach and by preventing the absorption of most of the calories in the food.

The surgery is recommended only for patients who have at least one of the following:

- a body mass index (BMI) of more than 40 (higher than 30 is considered clinically obese);
- a life-threatening obesity-related health problem, such as diabetes, severe sleep apnea, or heart disease and a BMI greater than 35;
- obesity-related physical problems that interfere with employment, walking, or family function.

Most surgeons also say the procedure should only be considered in patients (adults and adolescents) who have tried other weight-loss options unsuccessfully.

"The patient should have failed to lose weight following more conservative measures such as structured diet, increased physical activity, and behavior changes," says **Michele Bachhuber**, MD, internal medicine specialist with the Marshfield (WI) Clinic. "They also need to be fully informed about the side effects of this procedure."

Once the surgery, a permanent procedure, is performed, the patient's stomach can hold only approximately four ounces of food at one time. Eating more than this amount can result in nausea, a blockage, or extreme gastrointestinal distress. Normally, a person can consume only three-quarters to one cup of food at a time without discomfort. And heavy, hard-to-digest foods cannot be consumed at all.

Vomiting also is a common side effect because the smaller stomach can be stressed by food particles that are not chewed well.

There also is a significant risk of nutritional deficiency with this procedure because it bypasses the duodenum and jejunum, where the body absorbs the most calcium and iron. Menstruating women may develop anemia because not enough vitamin B_{12} and iron are absorbed. Decreased absorption of calcium also may bring on osteoporosis and metabolic bone disease. To have successful results, patients must comply with a strict diet, exercise, and vitamin regimen.

"This procedure is not a magic pill," Madan notes. "It does not — as many people think —

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automatically make you lose weight."

The procedure gives patients physiological feedback that makes them feel full after consuming about four ounces of food, but the surgery itself will not resolve the complex emotional and social reasons why people overeat.

"Patients can still not lose the weight if they don't adhere to the dietary restrictions," Madan continues. "And they can cheat. You can't sit down and eat a 12-ounce steak, because your body physically can't take that. But some patients can still tolerate forbidden foods and they can cheat."

The procedure still has an overall failure rate approaching 20% — sometimes due to technical issues with the surgery, but often due to patient noncompliance.

Appropriate for teens?

Because the surgery carries high risks and is permanently life-altering, some physicians feel its use in minors should be restricted.

"Gastric bypass is more accepted for adult patients than adolescents," says Bachhuber. "There are still some questions regarding long-term side effects, and it is more controversial for the adolescent population. The procedure is considered an accepted treatment for adults, but only for a select group of adults."

She would be hesitant to recommend the procedure for adolescents because they may not have reached their adult height, and nutritional deficiencies could be much more problematic in individuals who are still growing.

"With adolescents, there are also more variables — you have a parent or school personnel responsible for preparing food, and they are dependent on others for so many things," she says. "There are many more people that need to be involved in coordinating care to make the surgery successful, and a younger person's ability to understand all issues surrounding the surgery and lifestyle changes after surgery could be problematic."

However, Madan contends it is more important to carefully select patients and consider many individual factors besides the patient's age.

"A lot of the concerns we think of in adolescent patients can also be true of adult patients," he notes. "The real fact is that you can get a 35-year-old patient or a 15-year-old patient and, if you don't choose them carefully, they won't do well. You have to be very strict and have a low threshold for holding off on doing the operation if you don't think they are psychologically ready."

A specific concern in pediatric patients, however, is that they may not want the procedure.

"You need to carefully watch the interaction between the patient and family," he notes. "If it seems like the family is pushing it on [the patient] — and that is why you should do a psychological evaluation of both the patient and the family — you should not do it. Although the parents are the ones to give legal consent, I absolutely think you must get the consent of the patient as well, even if they are not the ones to legally consent. They must be told of the potential risks and benefits and take the responsibility of the surgery."

Not all patients who are good candidates for the procedure should have the surgery, Madan says. "I have had other physicians see patients that I have operated on, and they see that they have lost their diabetes, lost the sleep apnea, or they're only on half the hypertension medication they were on before, and they say, 'This is great,'" he relates. "Then, they send over all of their obese patients. You talk to the patients and find out they don't even want the surgery. It's something that physicians and hospitals considering this must understand — not every obese patient is a candidate or even desires the procedure."

Research examines results

Researchers are beginning to study the impact that gastric bypass procedures have on pediatric patients.

A study performed at Alvarado Hospital Medical Center in San Diego tracked 37 teens ages 14-18 who underwent laparoscopic bypass surgery.[1] Investigator **Alan Wittgrove**, MD, the medical director of the center's bariatric program, found they lost an average of 82 pounds of excess body weight within a year of surgery, with no poor outcomes.

He recommended the procedure be performed only in adolescents who have reached their full height and sexual maturity, are extremely overweight, and have a family environment that is supportive of the new dietary restrictions and weight loss.

Madan also recommends a full psychological evaluation of the patient and the patient's immediate family.

"Eating habits are, a lot of times, determined by where you live," he says. "If someone is under 18, they don't buy the food. So, you have to feel assured that they will be able to support the person's new lifestyle."

SOURCES

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- **Michele Bachhuber**, MD, Marshfield Clinic, 1000 N. Oak Drive, Marshfield, WI 54449.

He also makes all patients take a true-false quiz before they can be considered for the procedure. The quiz covers information about the potential side effects and risks of the surgery and is designed to help ensure patients understand what they are agreeing to do.

"They take it once, and if they get any answers wrong, we talk about it, and then they can take the test again," he says. "If they can't get the answers right the second time, they are definitely not appropriate candidates for surgery."

The patient takes the test alone in a room, so it better evaluates his or her level of knowledge, he adds. "They aren't sitting in front of you, trying to tell you what you want to hear."

Bariatric programs also should have a multifaceted support and counseling program in place to help patients adopt a healthy lifestyle post-surgery, Bachhuber says.

"Social support is very important for the patient to have no matter what measures they use to lose weight," she says.

Both Bachhuber and Madan say the surgical procedures are an example of extreme measures needed to cope with society's problem with obesity.

According to statistics published by the Centers for Disease Control and Prevention, approximately 61% of the population is overweight or obese, defined as having a BMI of 25 or more.

Among U.S. adults ages 20-74 years, the prevalence of overweight persons has increased an estimated 2% since 1980, increasing from 33% of the population to 35% in 1999. In the same population, obesity has nearly doubled from approximately 15% of the population in 1980 to an estimated 27% by 1999.

Of particular concern, however, are the rates of obese and overweight children.

According to the same study, the percentage of children and adolescents who are defined as overweight has more than doubled since the 1970s. Approximately 15% of U.S. children and adolescents are now overweight.

Halting and reversing the obesity epidemic will require a comprehensive effort by all segments of society, says Madan.

"The medical community can only do so much," he notes. "The best way to address obesity is certainly not this. The best solution would be prevention. But there comes a point for some individuals where it is almost impossible to reverse the weight gain. If someone is 100-200 pounds overweight — and these are the patients we are talking about — it is very difficult for them to exercise, and the motivation is not there because they won't see significant results if they can't alter their eating habits."

Society needs to focus efforts on prevention and make it easier for people to adopt healthy lifestyles, Bachhuber adds.

"As health care providers, we need to increase awareness of rising rates of obesity and the importance of lifestyle changes," she says. "We as individuals need to take the lead in making these lifestyle changes so that our society can reduce the rates of obesity."

Reference

1. Hellmich N. Obese teenagers seen as candidates for gastric bypass. *USA Today,* July 6, 2003.

For More Information

- Weight-Control Information Network (WIN), One WIN Way, Bethesda, MD, 20892-3665. Telephone (202) 828-1025, fax (202) 828-1028. www.niddk.nih.gov/health/nutrit/nutrit.htm.
- American Society for Bariatric Surgery, 140 N.W. 75th Drive, Suite C, Gainesville, FL 32607. www.asbs.org.
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Is BESST the best method for measuring IVF success?

Twins' gestation is a complication, researcher says

Fertility programs worldwide need to change their methods for calculating successful birth rates to emphasize births of single babies at term as the desired outcome of assisted reproductive technologies, rather than the birth of twins or

triplets, an Australian researcher argues.

As high-risk pregnancies, twin gestations should be considered complications of assisted reproductive technology (ART) treatment and not counted as successes, states **David Healy**, FRANZCOG, CREI, chair of the department of obstetrics and gynecology at Monash University and head of the reproductive biology unit at Monash Medical Centre in Victoria, Australia.

"Since the birth of the first IVF [in vitro fertilization] baby in 1978, the treatment of subfertility has significantly advanced," Healy notes. "We no longer practice in an area where assisted reproductive technology is experimental and pregnancy alone, without consideration of obstetric and neonatal outcomes, is the objective."

Multiple pregnancies are the most frequent and most serious complication of ART, and it is universally recognized that multiple pregnancies and related premature births are associated with increased morbidity and mortality, both for mothers and fetuses.

To encourage better outcomes, Healy and colleagues published a report in the January issue of *Human Reproduction and Biology,*[1] the journal of the European Society of Human Reproduction, calling for programs worldwide to adopt the Birth Emphasizing a Successful Singleton at Term (BESST) method for measuring outcomes.

The BESST method would count only the births of healthy, term, single babies as successful outcomes, calculating the births of twins and other multiples as complications of treatment. The key strategy to achieving success in this fashion would be to limit the number of embryos transferred during any single cycle to one.

Currently, programs in Australia, the United States, and Europe do not report the birth rates of full-term, single, healthy babies per assisted cycle; normally they report the total number of live births per assisted cycle, a number that includes any multiple births and premature births.

"Assisted reproductive technology techniques are now older than some of our patients," Healy says. "The objective of treatment and reporting of endpoints must parallel this mature science."

U.S. focuses on higher-order multiples

Fertility specialists worldwide recognize that multiple gestations are a problem with ART that needs to be addressed, says **Owen Davis**, MD, FACOG, president of the Birmingham, AL-based Society for Assisted Reproductive Technology (SART), associate director of the in vitro fertilization program at the Center for Reproductive Medicine and Infertility at Presbyterian Medical Center in New York City, and chief of the division of gynecology at Weill Medical College at Cornell University.

However, experts in this country primarily have focused on reducing the number of triplets and higher-order multiples, rather than twins.

"IVF is responsible for a lot of twins and, to a certain extent, triplets," he explains. "But the average gestational age at which most twins deliver is term, and most twins do fine. The average gestational age that triplets deliver is premature and, although there are other risks of multiples, besides prematurity, that is the most significant. So we have focused our efforts on trying to reduce the number of triplets and higher births."

That said, the gestation of twins is never the goal of an ART procedure, he emphasizes.

"I would acknowledge, as most people would, that the most desired outcome is a singleton," he states. "Often, it is a hard sell, if you can imagine talking to patients who have been trying for eight years to get pregnant. The couple may be in their 40s, and this is their last chance to have children and they often say, 'Can you make sure we have twins?' My response is always, 'No, that's not what we want to do.'"

But the proposal for only transferring a single embryo back to the uterus in all cases is too simplistic, Davis and others argue.

Not all embryos will develop into fetuses, he notes. There are several reasons for this. Sometimes, embryos have genetic flaws that prevent them from developing. In some cases, fertility factors on the part of the mother play a role. Older mothers tend to have lower "implantation rates" — rates at which fertilized embryos implant in the uterus to grow — and they often have older eggs that may not function as well.

Overall, only about 40% of patients seeking IVF treatments will be able to conceive successfully, and even then, most patients must pursue more than one treatment.

However, because of the concern about higher-order multiples, most programs have adopted guidelines developed by SART and the American Society of Reproductive Medicine (ASRM) that call for limiting the number of embryos transferred based on the patient's age and other factors.

"The guidelines are pretty clear cut," Davis says. "In a young age group, patients under age 34 or 35, if the eggs look to be of good quality,

probably you should not transfer more than two. But if you are talking about people who are older, probably not more than three. In patients who are in their 40s, where implantation rates and fertility really falls off precipitously, it may be reasonable to put back more than two — maybe even three and four."

Even then, the incidence of twins still is low, he emphasizes. Many patients who have two or three embryos transferred back will not conceive at all.

With a patient older than 40, particularly one with a history of infertility, deciding to transfer one embryo is almost like deciding to be unsuccessful.

"With this method, it is as if they are equating the occurrence of twins with never conceiving at all," Davis says. "They are saying having twins is just as bad as having no baby at all — and I am not convinced that is true, and I don't think most of my patients would feel that is true."

That being said, programs in the United States are beginning to report the number of singleton births as a separate figure from the overall birth rate, Davis says.

Each year, the Centers for Disease Control and Prevention (CDC) publishes individual clinic data collected by SART and ASRM. This year, for the first time, an additional category, indicating the number of singleton births, has been added.

"The table lists clinic-specific data and includes the live birth rates per cycle initiated, per embryos transferred, per egg retrieval, etc." he explains. "Those numbers include multiples. Now, there is a line that reports the singleton rate per mother's age group. And it also spells out the overall live birth rate and how it breaks down — singleton vs. twin vs. triplet."

There still is some question about whether such statistics are a good measure of the quality of a particular program, Davis says.

"What if two different clinics both put back two embryos only in everybody — which is considered conservative by our guidelines — and let's say that Clinic A has a 50% live birth rate, but they are all twins, and Clinic B has a 15% live birth rate, but they are all singletons. Is the first clinic really not as good a program as the second one?"

Using the BESST method, in fact, the first clinic would have to report a zero successful birth rate because all of its births were twins, and the second clinic would report a 15% birth rate.

The CDC data provide a more complete picture of each program and allow potential patients to judge for themselves, he adds.

And in most cases, decisions about how many embryos to transfer — within acceptable limits — should be made by the individual patients themselves, with assistance from their physician, Davis notes.

"It may be different in Europe, where, because they have a single-payer health system that absorbs the costs of the medical care, and, ultimately, the lifelong health care of its citizens, that they see this as more of a societal concern," he states. "In this country, I think we look at it more of an individual decision."

Research needed to improve rates

However, even specialists opposed to rigid limits on the numbers of embryos that can be transferred do feel that more can be done to reduce the incidence of twins and triplets among patients undergoing IVF.

"We should focus on reducing the number of twins and in performing research that will help us determine how to do this," says **David Adamson**, MD, FRCSC, FACOG, FACS, director of Fertility Physicians of Northern California and clinical professor at Stanford University School of Medicine.

Fertility specialists in this country must take concerns about multiples seriously, Adamson argues. It is a point he will emphasize in an upcoming editorial in the journal *Fertility and Sterility*, he notes.

Improved diagnostic techniques could help physicians determine patients in whom single-embryo transfer would be appropriate, and improved embryo selection techniques could help clinicians transfer fewer embryos in patients with poorer prognoses, thereby cutting the risks of multiples even further.

"This is an important issue, and there are things we should be doing," Adamson says. "And there are respected people in the field who have differing

SOURCES

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- **Owen Davis**, MD, Society of Assisted Reproductive Tech-nology, 1209 Montgomery Highway, Birmingham, AL 35216.
- **David Healy**, FRANZCOG. CREI, Monash University, Faculty of Medicine, Nursing and Health Sciences, Building 64, Clayton Campus, Wellington Road, Victoria 3800, Australia.

opinions about how this problem should be addressed. I happen to think that proposing only single-embryo transfer in all cases is too simple a solution to a very complex problem."

Reference

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ASRM issues guidance on gamete donation

Providers should consider potential consequences

A woman seeking help conceiving through assisted reproduction inquires about the possibility of using her sister as an egg donor because previous attempts using her own have failed. Would your program allow it?

Another patient wants to use donor eggs from her adult daughter to conceive a child with her second husband, the potential donor's stepfather. Would your program allow this? Why or why not?

Assisted reproduction technologies (ART) present the possibility of family relationships that would never before have been possible. A woman could gestate the genetic child of her daughter or her sister.

It also may allow the formation of genetic relationships that are socially or physiological unacceptable, such as a man providing donor sperm for an in vitro procedure for his sister and her husband, or a father for his daughter.

It may be surprising to some, but such requests are not unheard of in ART circles, says **Lori A. Marshall**, MD, fertility specialist with the Center for Fertility and Reproductive Endocrinology at Virginia Mason Medical Center in Seattle, and author of a recent ethics committee report from the American Society of Reproductive Medicine (ASRM).[1]

"Sometimes, it comes up as a serious request — certainly sister-to-sister egg donation is a pretty common request — but some of the other requests are uncommon, but do happen," she says. "My feeling is that much of the time, it is exploratory — 'My brother said he would give me sperm for my egg donor procedure' — but they haven't thought it through."

The ethics committee developed its report to help providers decide what requests are appropriate and inappropriate, she says.

The document evaluates the different ethical and physiological issues raised by different types of intergenerational and intragenerational gamete donation and surrogacy arrangements.

For example, it examines potential brother-to-sister sperm donation (never considered acceptable), a traditional surrogacy arrangement for a mother by her daughter (acceptable only if issues of potential coercion and undue pressure are addressed); and sister-to-sister ovum donation (generally accepted).

Not all of the situations addressed are known to have occurred — or even to have been proposed — Marshall notes, but they are important to address in a methodical and reasoned way, she says.

Marshall first became interested in the issue after a woman seeking treatment at her facility asked to use donor eggs from her daughter, who lived with the patient and her new husband.

"Without giving it too much thought, the team said, 'No way,'" she relates.

However, several months later, other team members decided to accept the request of another woman to use donor eggs from her niece.

"I said, 'Wait a minute, why did we say yes to one and no to the other?'" Marshall says. "In all fairness, it really was the specific circumstances of the case — the mother was an extremely manipulative individual and the daughter lived in the same home at the time. Those things raised so many red flags that no one would even consider involving themselves. With the other situation, the woman had the respect of the team, the niece did not live nearby, and it was a situation where the niece was a medical student and volunteered to donate rather than being asked."

However, their reasons were not well articulated prior to both decisions, so Marshall felt it was important to independently evaluate the different ethical issues involved in order to ensure that such decisions are made fairly and not based on a transient feeling or emotion.

"The whole point of the paper is to encourage providers to step back a minute, spend some time on this, and think about the issues," she says.

First, the committee recommends that clinics not allow any procedure that would involve the combination of consanguinous gametes (those from first-degree relatives), such as brother to sister, woman to sister-in-law, father to daughter,

daughter to father, etc.

Such procedures obviously would produce a child that would be genetically the same as a child conceived through an incestuous relationship.

For clarification, Marshall notes that "incest" is defined as a sexual relationship between two closely related persons, but consanguinity refers to marriage and/or reproduction between close relatives.

Providers also should be cautious, however, about procedures that would not actually involve mixing of consanguinous genes but still might give the appearance of incest.

As an example, Marshall cites the well-publicized case of a French woman and her brother who traveled to the United States to undergo ART. "The woman was about 50 or so, and they posed as husband and wife, and she had egg donation and used his sperm," she recalls. "There ended up being a huge outcry when they returned home that this was awful, that it was incestuous, etc. In truth, it wasn't, because there was no sexual relationship and no combination of consanguinous gametes."

The team at her facility probably would have had the biggest problem with the couple's deception, but might have been willing to agree to the procedure provided they were comfortable that the couple were prepared for the consequences of their decision, Marshall notes. "In a sense, gestational surrogacy (in which the woman carrying the pregnancy is not genetically related to the child) presents the least problems, but they may give the appearance of incest. Certainly, when a woman is pregnant, that appearance is very public and not something that is confined to family and friends."

Donors or surrogates who are related to the prospective parents also are vulnerable to coercion, and these issues should be investigated before any procedures are initiated, she adds.

A woman agreeing to donate eggs to her mother, with whom she lives and is financially dependent upon, may not feel able to refuse a request and may have difficulty weighing the risks and benefits involved in the process.

The life partners of potential donors or surrogates also should be questioned to determine whether they understand the consequences of the procedure and whether they are supportive of the process, she adds.

In one survey of sperm donors that included family donors, 25% of the respondents said the donation process led to a deterioration of the relationship between the infertile couple and the donor; and, the deterioration was always related to the attitude of the donor's partner, who had not been involved in the decision to donate sperm.

"We cite that study to highlight the need to counsel and involve as many people as possible in these relationships, so they can assess how they feel about the donation or the surrogacy relationships and make absolutely sure they buy into it, and you don't just look at the donor or surrogate as an isolated individual," Marshall says.

It's important that ART providers have policies in place that ensure that decisions about familial donation and surrogacy are handled fairly and consistently and are not made in an arbitrary fashion, she continues.

The ethics committee report is designed to give them a framework for evaluating all of the issues involved in different situations. Specific policies should reflect the mores and ethics of the providers at that program.

"You should be able to look through the cases that have come through your facility and feel that you have been fair to all the individuals who presented to you for care," she said.

The committee also wants to emphasize to providers that they have a responsibility to their patients beyond just providing a safe, effective ART procedure.

Patients who ask to use family members as surrogates and donors, as well as the potential surrogates and donors and any other family members, should undergo counseling and education to explore the possible ramifications the proposed procedure would have.

"The other point we tried to make in the paper is that if you don't have the ability to investigate these relationships further, then you should not involve yourself in these relationships," Marshall says. "If you are saying, 'You know, I really cannot tell whether this daughter is being coerced or not and I don't have the ability or resources to investigate this further,' then you should not do the procedure."

SOURCE

- **Lori Marshall**, Center for Fertility and Reproductive Endocrinology, Virginia Mason Medical Center, 1100 Ninth Ave., Seattle, WA 98101.

Reference

1. American Society of Reproductive Medicine. Ethics committee report: Family members as gamete donors and surrogates. *Fertil Steril* 2003; 80:1,124-1,130. ■

What's the best approach to HPV prevention?

Lawmakers and health advocates clash

A U.S. congressman caused a stir in public health and sexually transmitted disease (STD) prevention circles in December by accusing federal health officials of failing to comply with federal law and asking them to testify at a special hearing.

In a Dec. 22, 2003, press release titled "CDC Violates HPV Report Law," U.S. Rep. **Mark Souder** (R-IN), chair of the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources, accused the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) of failing to comply with requirements in a 2000 federal law aimed at improving treatments for and public education about breast and cervical cancer.

Public Law 106-554, also known as the Breast and Cervical Cancer Treatment Act, was signed into law by President Clinton in 2000. Among the law's provisions was a requirement that the CDC prepare and release a report by Dec. 21, 2003, detailing the best strategies for prevention of the spread of human papilloma virus (HPV), the most common sexually transmitted disease in the United States. Certain strains of HPV are strongly linked to the development of cervical cancer.

The law also required the FDA to re-examine condom labels to determine whether they are "medically accurate."

Both agencies failed to comply with these mandates, Souder alleged. "The CDC and FDA are today in violation of federal law, and the health of thousands of women is at risk as a result," he stated in the press release. "We are deeply concerned whenever a federal agency fails to abide by the law, but especially so when the public's health is threatened."

To address the issue, Souder asked leaders in both agencies to testify before the subcommittee at a Jan. 28 hearing.

The hearing was later postponed after CDC officials announced they intended to release a report in January, noted **Martin Green**, a spokesman for the congressman.

The called hearing is an attempt by Souder to ensure that cervical cancer prevention and treatment continues to get the attention it deserves and will be rescheduled once the report is reviewed and the different witnesses can be available to give testimony, he said.

"At this point, the representative is pleased with what he has seen in the [CDC] report and the issues addressed," Green added.

However, some public health advocates feel the congressman may be pushing the hearings in order to forward a political — not health — agenda.

"We were concerned by the title of the press release for the hearing, 'CDC Violates HPV Report Law,'" says **Deborah Arrindell**, senior director of health policy at the American Social Health Association (ASHA). "It makes it difficult to feel confident that the hearing will focus on positive prevention efforts. The real focus should be on preventing cervical cancer."

Instead, health officials say, the true focus of the hearings and the requirements in the law is to garner support for funding of abstinence-only STD prevention and education programs by attacking public health messages advocating condom use.

In 1999, then-Rep. **Tom Coburn** (R-OK), a physician and proponent of federal funding for abstinence-only family planning and sex education programs, successfully attached an amendment to the House version of the Breast and Cervical Cancer Treatment Act requiring condom packages to carry a warning label indicating they offered "little or no protection" against HPV.

SOURCES

- **Martin Green**, Office of Rep. Mark Souder, U.S. House of Representatives, 1227 Longworth House Office Building, Washington, DC 20515.
- **Deborah Arrindell**, American Social Health Association, P.O. Box 13827, Research Triangle Park, NC 27709.

The final version of the bill altered this directive to require only that the FDA study the labeling issue and that the CDC issue a report.

In fact, Souder cites a 2001 report from the National Institute of Allergy and Infectious Diseases concluding that condom use could not be shown to reduce the risk of HPV infection.

While it's true that the full effectiveness of condoms in preventing HPV still is unknown, there is evidence that condoms may reduce the risk of developing cervical cancer in people exposed to HPV, Arindell says. And condoms have been shown to significantly reduce the risk of contracting other sexually transmitted diseases, particularly HIV and hepatitis B and C.

"We know, if only anecdotally, that people get confused by [use of the terms] HPV, HIV, and HSV — all sexually transmitted," she continues. "Simple messages work the bet. Any label on condoms should encourage people to use them. It's the FDA's job to determine the most appropriate labeling on condoms and other medical devices — not the members of Congress."

The report published by the CDC advocates several strategies to prevent HPV transmission and cervical cancer, Arindell says.

It mentions abstinence from sexual intercourse, monogamy, and the use of condoms as preventive measures. In addition, it recommends more research into current provider knowledge and practices, and the concerns of women diagnosed with HPV in order to develop new prevention messages and strategies.

Studies indicate that HPV can be spread through intimate skin-to-skin contact, not just in bodily fluids, so abstinence may be the best way to avoid contacting the infection, she notes. But, most people will not remain abstinent and they will be at risk of contracting other STDs if they do not use condoms.

"Seventy-five to 80% of sexually active Americans will be infected with HPV at some point in their lives," she says. "Pretty much anyone who has ever had sexual relations has a high chance of being exposed. Abstinence is a public health message that ASHA supports, but we don't think it can be the only message."

Surveys indicate that more than 90% of Americans have sex before marriage, and public health messages must reflect the real world, not a particular ideology, she says.

"Decreasing condom use among sexually active individuals will not reduce the prevalence of HPV," she adds. "However, it will put sexually active individuals at risk of life-threatening STDs such as HIV. For people who are sexually active, the regular and correct use of condoms remains the best protection against the transmission of STDs." ■

FDA issues guidance on drug company advertising

Survey reveals physicians' perspective

Stung by criticism that it is not doing enough to enforce its own regulations governing direct-to-consumer advertising by pharmaceutical companies and medical device manufacturers, the U.S. Food and Drug Administration (FDA) announced the publication of three new guidance documents designed to improve communications the public sees about new drugs and devices.

"We intend to do all that we can under the law to make sure that the information conveyed by prescription drug promotion is as useful as possible," FDA commissioner **Mark B. McClellan**, MD, said in a Feb. 4 statement announcing the new guidelines. "Our new regulatory guidance provides new direction to sponsors on how to provide higher-quality health information to the public, based on recent evidence on what works and what doesn't in drug promotion."

The guidance documents were largely the result of a September 2003 open meeting on direct-to-consumer advertising held by the FDA.

Such advertising has long been a concern of health care providers and public health advocates because of the potential to influence consumers to seek treatments they may not need or that may not be appropriate.

A 1999 survey by the American Medical Association (AMA) found that half of all consumers believe the FDA preapproves drug ads and 43% incorrectly believe that only risk-free drugs are advertised.

"The AMA supports patients' increased access to drug information, but questions whether direct-to-consumer drug advertising, designed to sell a product, provides the objective and accurate information that patients need," **Nancy H. Nielsen**, MD, PhD, said in a July 2003 testimony before the Senate Special Committee on Aging.

The AMA recommended to Congress that the pharmaceutical industry be required to use AMA guidelines for ads to improve their educational value; that independent research on the ads is needed to determine their impact on the physician-patient relationship and on health outcomes and costs; and that more funding be allocated to FDA efforts to oversee direct-to-consumer advertising.

However, the FDA reported that a nationwide survey of physicians indicated that most felt that drug advertising aided the physician-patient relationship by encouraging patients to seek screening for conditions that might otherwise go unnoticed and discuss their health concerns with their physicians.

"The evidence shows that promotions directed to consumers can play an especially important role in helping patients start a discussion with their health care practitioner about conditions that are often unrecognized and therefore undertreated, such as diabetes, high blood pressure, high cholesterol, and depression," McClellan said.

According to the survey, a majority of physicians felt that direct-to-consumer advertising increased patient awareness and involvement and improved compliance. The study also showed that the advertising-stimulated visits to a physician could help identify a previously undiagnosed condition.

Of patients who visited their physicians because of an ad they saw and who asked about that prescription drug by brand name, 87% actually had the condition the drug treated.

The FDA issued three different guidance documents covering key areas of potential confusion for consumers viewing advertising and information about new drugs and devices:

• **"Brief summaries" of risk information in print advertisements.** The first guidance covers information contained in print advertisements that is intended to disclose information about the potential risks of taking the advertised drug. The FDA requires a brief summary of the product's risks and most companies fulfill this requirement by reprinting, verbatim, the complete risk-related sections of the FDA-approved professional labeling. The information typically is located in a box at the bottom of the ad in very small type.

However, says McClellan, the labeling information often contains complex clinical and technical language that does not effectively convey key information to patients.

In the FDA survey, 56% of people who saw a consumer-directed print advertisement stated that they did not read the summary statement and, in a follow-up study, that number jumped to 73%.

The draft guidance is designed to help manufacturers create more user-friendly brief summaries to include in the ads.

The FDA now wants manufacturers to present key risk information in a more consumer-friendly fashion by using clearer, less-cluttered formats, focusing the disclosures on the most important and most common risks, and using language that can easily be understood by the average consumer.

• **"Help-seeking" communications vs. advertisements.** The second document covers the "help-seeking" or "disease awareness" communications that some manufacturers produce that provide general information about recognizing signs and symptoms of a particular condition, but that do not advertise a specific product or treatment for it.

Advertisements are subject to FDA regulation as advertising or promotional labeling, but true "help-seeking" communications are not. The second document provides clarification to companies about the distinction between disease awareness communications and advertising.

SOURCE

- **U.S. Food and Drug Administration**, 5600 Fishers Lane, Rockville MD 20857-0001.

COMING IN FUTURE MONTHS

- Public health approaches to substance abuse in pregnant women
- New donor organ allocation policies
- Hostile health care work environments
- Research on patients at the end of life

• **Broadcast advertising of restricted devices.** Some manufacturers of restricted devices also have begun advertising their products directly to consumers through the broadcast media, McClellan notes.

The third document provides explicit guidance to industry on how its regulations for risk disclosure apply to broadcast advertising, and to help assure that the ads are accurate and not misleading.

A manufacturer of a restricted device may satisfy the statutory requirement for risk information disclosure by presenting a major statement of product risks and by identifying alternative sources of the complete risk information.

"Clear, evidence-based regulatory guidance will help the FDA use its limited resources to police the marketplace as effectively as possible," McClellan said. "FDA will take action against sponsors whose ads violate the law by presenting false or misleading information to the public."

The guidance documents are available on the FDA web site at www.fda.gov. ■

CME Questions

9. A potential complication of gastric bypass surgery is:
A. Death
B. Tissue injury
C. Nutritional deficiency
D. All of the above

10. Australian fertility specialist recommends what strategy for ensuring that IVF programs aim to produce singleton healthy babies delivered at term?
A. Selective reduction of multiple pregnancies
B. Improved selection of IVF candidates
C. Improve diagnostic criteria
D. Single-embryo transfer per cycle

11. U.S. Rep. Mark Souder accused what federal agency of failing to comply with federal law regarding labeling of condoms?
A. NIH
B. CDC
C. FDA
D. None of the above

12. The FDA recently issued guidance to industry about:
A. Direct-to-consumer advertising
B. Vaccine injury compensation
C. Safe use of vaccines in the workplace
D. None of the above

Answers: 9-D; 10-D; 11-C; 12-A.

CME instructions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided at the end of each semester and return it in the reply envelope provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■