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INSIDE

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Revival of the Today sponge: Vaginal contraceptive returns

New pharmaceutical company aims for fall reintroduction

This fall, American women may see a familiar package on drugstore contraceptive shelves: the Today sponge. A New Jersey company has acquired the rights to manufacture and market the sponge, which was removed from the market five years ago by its former maker. The announcement by Allendale (NJ) Pharmaceuticals was met with enthusiasm by women's health advocates, who had decried New York City-based Whitehall-Robins Healthcare's 1995 decision to withdraw the sponge from the market. The company had determined it cost too much to correct manufacturing problems caused by water quality issues at the old factory where the sponge was made.

"ARHP advocates for the availability of as many safe, effective methods of contraception as possible, and we are pleased that another important option will be returning to American women," says **Felicia Stewart**, MD, director of reproductive health programs at Kaiser Family Foundation in Menlo Park, CA, and a member of the Washington, DC-based Association of Reproductive Health Professionals (ARHP).

The sponge was used by a group of women who wanted a disposable barrier device at a reasonable cost, says **David Archer**, MD, professor of

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The Today vaginal contraceptive sponge, once a popular over-the-counter contraceptive, is scheduled to return to the U.S. market this fall.

- Allendale (NJ) Pharmaceuticals has purchased rights to the sponge, which was withdrawn from the market in 1995 when its former owners determined it was too costly to correct manufacturing problems at the old factory where the contraceptive was made.
- The Today sponge has a New Drug Application with the Food and Drug Administration, so no further studies are needed to demonstrate its safety and efficacy. After regulatory requirements are met, the company will begin mass manufacturing the sponge, with possible delivery to drugstores and other vendors in the fall.

OB/GYN at the Eastern Virginia Medical School and Jones Institute of Reproductive Medicine in Norfolk, VA. The withdrawal of the Today sponge caused this group of women to use condoms or local spermicides instead.

"It is apparent that a physical barrier provides the consumer with a more secure feeling in terms of a product that has a spermicidal property," observes Archer, who has conducted research of various contraceptive methods.

New company, same sponge

Newly-formed Allendale Pharmaceuticals intends to move swiftly to get the Today sponge on the market, say its founders, **Gene Detroyer** and **Robert Staab**, PhD. The Today sponge is still recognized by the Food and Drug Administration (FDA) as a safe and effective product, notes Staab, the company's chairman and chief scientific officer. Its New Drug Application is still active, so no further clinical trials are required to prove the sponge's safety and efficacy.

The company is moving the manufacturing facilities to a plant in Mainland, PA, that has an established safety record with the FDA, says Staab. Once equipment is in place, Allendale will begin manufacturing a test product that will be examined by the FDA. If the product and facility pass the test, Allendale hopes to begin mass manufacturing, with possible delivery to drugstores and other vendors in the fall, he says.

In buying the Today sponge from American Home Products of Madison, NJ, Whitehall-Robins' parent company, Allendale Pharmaceuticals, acquired the worldwide rights to the Today name and packaging. Such built-in name recognition is a valuable plus for Allendale's first product, says Detroyer.

If acceptable to the FDA, Allendale plans only minor changes for the sponge's packaging. The result will be the reappearance of a product already familiar to many American women. To gauge consumer interest in the re-emergence of the Today sponge, Allendale posted questions on the Web site www.birthcontrol.com. **(Birthcontrol.com is one of several sites offering access to birth control products. For details on such sites, see *Contraceptive Technology Update,* September 1998, p. 120.)** More than 200 e-mails — all positive — have been received, reports Detroyer.

While the Today sponge offers convenient, accessible birth control, it is important to frame all family planning choices in light of their effectiveness. The sponge ranks behind both male and female condoms in typical- and perfect-use scenarios. **(See comparison of typical- and perfect-use rates for over-the-counter contraceptives, including the sponge, below.)**

Percentage of Women Experiencing an Unintended Pregnancy During First Year of Use

Method	Typical Use	Perfect Use
Spermicides	26	6
Sponge		
Parous women	40	20
Nulliparous women	20	9
Condom		
Female (Reality)	21	5
Male	14	3

Source: Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology.* 17th edition. New York City: Ardent Media; 1998.

How will the sponge affect women and their health care providers? asks **Anita Nelson**, MD, associate professor of obstetrics and gynecology at the University of California at Los Angeles (UCLA) and medical director of the Women's Health Care Clinic at the Harbor-UCLA Medical Center in Torrance, CA. "If women who are having unprotected intercourse now suddenly start using the sponge, it will have made an important contribution. If, however, women are wooed away from using oral contraceptives, depot medroxyprogesterone acetate, or Norplant on the basis that the sponge is 'more natural' or 'safer' than hormonal methods, we will have lost ground."

COMING IN FUTURE MONTHS

- Insurance coverage for contraception
- ECPs: Providers are informed, but are pharmacists?
- Raising awareness about HPV and cervical cancer
- Tracking Norplant satisfaction: One area's story
- Teens: What they know — and don't — about STDs

Allendale Pharmaceuticals plans to follow the sponge's re-emergence with other women's health care products. Staab, a board-certified toxicologist, holds patents to several products, including a vaginal film.

The sponge purchase also included the acquisition of a personal lubricant and a condom. While Allendale does not intend to move into the condom market, it does intend to examine the lubricant as a possible addition to its product line.

The Today sponge will maintain use of its original active spermicide, nonoxynol-9, but Allendale Pharmaceuticals will examine use of the sponge as a "carrier" for other ingredients, such as other spermicidal agents, Staab says. The company also may license the sponge design to other pharmaceutical companies for use in prescription-only applications, Detroyer adds.

Allendale Pharmaceuticals plans to set up a Web site, www.todaysponge.com, as well as a toll-free hotline, to answer consumer questions about the sponge. **Robert Hatcher**, MD, MPH, professor of OB/GYN at Emory University in Atlanta and chairman of the *CTU* editorial advisory board, says the hotline will be extremely helpful to women who may have difficulty removing the device, a fairly common problem in the past. ■

4-periods-a-year pill eyed for use in U.S.

For years, providers have counseled women who are about to go on vacation or a honeymoon that periods can be delayed by omitting the "pill-free" week and continuing their daily dose of OCs. While this idea is not new, it has not been patented — until now.

Barr Laboratories of Pomona, NY, has signed an exclusive rights agreement with Eastern Virginia Medical School of Norfolk to develop and market a four-periods-a-year pill as a unique oral contraceptive. Researchers at the school's Jones Institute for Reproductive Medicine, which patented the 84-day dosing regimen, will help devise the clinical trials necessary for Food and Drug Administration (FDA) approval of the product, now known as Seasonale.

Scientists are examining the actual hormonal components that will make up this monophasic pill, while others are organizing the summary of the clinical protocol that will be presented to the FDA, says **Bruce Downey**, Barr's chairman and chief executive officer. The goal is to begin patient recruitment and establish clinical trials before the end of the year, Downey says.

By sticking with estrogen and progestin components previously approved by the FDA, researchers will be working with known compounds having already-established safety and efficacy profiles. While a final decision has not yet been reached, ethinyl estradiol and levonorgestrel may compose the basis for the Seasonale pill, says **Gary Hodgen**, PhD, professor of OB/GYN at Eastern Virginia Medical School and chair of the Jones Institute of Reproductive Medicine. "There could be other progestins put in," he comments. "We may try this at different doses, so that we find which dose will give us the most satisfactory breakthrough bleeding profile."

In staying with an established estrogen and progestin, the product can move faster through the research pipeline. If the 84-day dosing regimen proves safe, effective, and acceptable, the product may be on U.S. pharmacy market shelves by late 2002 or 2003, Bar says.

Family planners may not be familiar with Barr Laboratories' name, but they already know one of its products. Barr manufactures the ethinyl estradiol/levonorgestrel pill used in the Preven Emergency Contraceptive Kit distributed by Gynétics of Somerville, NJ. The company also is collaborating with Gynétics to produce a progestin-only emergency contraceptive pill. **(For more information on Gynétics' initiation of advanced clinical trials on the progestin-only**

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Barr Laboratories of Pomona, NY, has signed an exclusive rights agreement with Eastern Virginia Medical School of Norfolk to develop and market a new oral contraceptive (OC), dubbed Seasonale. An application for approval from the Food and Drug Administration is being filed; clinical trials will begin as early as this year. If the OC proves safe and effective, it could see U.S. introduction in 2002.

- While the concept is not new, Eastern Virginia Medical School was the first to patent the 84-day dosing regimen. This course of pill-taking would result in four periods a year.
- Scientists are determining the hormonal combination for the OC, but they expect to see an already-accepted formula, such as one including ethinyl estradiol and levonorgestrel.

Indications for the tri-cycle regimen of OCs

British family planner **John Guillebaud**, MA, FRCSE, FRCOG, MFFP, medical director at the Margaret Pyke Family Planning Centre in London, has advocated tri-cycling — using three consecutive 21-day packs of monophasic OCs — for the following indications:

- headaches, including non-focal migraine, and other bothersome symptoms if they occur regularly in the withdrawal week;
- unacceptably heavy or painful withdrawal bleeds;
- epilepsy, which benefits from relatively more sustained levels of the administered hormones;
- endometriosis, where a progestin-dominant monophasic pill may be tricycled for maintenance treatment after primary therapy;
- suspicion of decreased efficacy.[1]

This regimen calls for 63 consecutive days of pill-taking, followed by seven days of no pills, then resuming the dose.

Reference

1. Guillebaud J. Tri-cycling, bi-cycling, late starts, and missed pills: Creative ways to manage OC problems. Presented at Contraceptive Technology conference. San Francisco and Washington, DC; March 1996. ■

ECP, see *Contraceptive Technology Update,* March 1999, p. 28.)

Barr's strength in the pharmaceutical business lies in its production of generic products. It markets generic versions of four hormonal agents used in women's health care: danazol, medroxyprogesterone acetate, estradiol, and estropipate. It also successfully challenged and won the right to produce the generic form of tamoxifen. Barr is now in court to challenge the patents protecting Ortho-Novum 7/7/7, produced by Ortho Pharmaceutical Corp. in Raritan, NJ.

Barr began some three years ago to broaden its generic base of women's health care drugs and establish its own proprietary products, says Downey. The collaboration with Gynétics in developing the Preven ECP kit represents the first of Barr's proprietary products. Through its partnership with East Virginia Medical School, Barr now looks to bring another new and innovative OC product to market as a proprietary drug.

Why seek approval of a regimen providers already use? As with the Preven Emergency Contraceptive Kit, Seasonale will give providers a dedicated product with established, approved labeling, says Downey. Patients will benefit from clear package instructions and a design that promotes ease of pill-taking. Without established labeling and packaging, the margin for error increases, Hodgen says.

"The consequences of being wrong are great," he observes. "A [poorly] timed pregnancy can be a significant problem."

Benefits, drawbacks

Breaking the barriers of the 21/7-day dosing regimen has been examined informally by many in the reproductive health field. **(For details, see box at left.)**

One benefit of an extended pill cycle is that it places the patient in a very low estrogenic state and prevents menstruation, notes **Rafael Haciski**, MD, FACOG, director of Gynecology & Infertility Associates in Baltimore. Suitable candidates for this type of regimen include patients with endometriosis who aren't ready to conceive but would benefit from suppression and can't take or afford gonadotropin hormone-releasing hormone analogue suppression therapy.

By maintaining a hypoestrogenic state, there would be little, if any, stimulation of the endometriotic sites, thus keeping the condition in check, Haciski says. With no menstruation, irritation at the sites of endometriotic tissue would be lessened, thus minimizing damage and scarring.

"With such low doses of estrogen, I doubt that there would be any build up of tissue — more atrophy than not," observes **Joseph Cutchin**, MD, FACOG, founder of Peninsula Obstetrics and Gynecology, PA in Salisbury, MD. "In a person later desiring pregnancy, the question is, how long can you suppress the ovary without permanent damage?"

Hodgen says, "I think the answer to that is that we have no idea how long, but we have no evidence that suppressing ovulation has any effect on the age of menopause." In addition, Hodgen says, OCs can prevent ovarian and endometrial cancer, decrease the risk of benign breast disease, prevent atherogenesis, and offer host of other health benefits.

"On that basis, I think there is no reason at all to have any fears for using OCs for years to control one's reproductive status," he notes. "There is no reason to suppose that it has any untoward effect on ovarian physiology." ■

Challenge for providers: Polycystic ovary syndrome

Weight gain. Excess hair growth. Infrequent periods. What's your initial diagnosis? Whether you write the term polycystic ovary syndrome (PCOS), Stein-Leventhal syndrome, or hyperandrogenic chronic anovulation in your patient's chart, you have just begun to touch on a condition estimated to affect 5% to 7% of women.

Diagnosing PCOS may prove challenging if the focus is on textbook characteristics: obesity, hirsutism, oligomenorrhea (where the interval between menses exceeds 35 days but is not long enough to be labeled amenorrhea), and subfertility.[1] In reality, many women with PCOS may not be heavy or exhibit excess hair growth. Even the appearance of polycystic ovaries does not mean an automatic diagnosis.

The lack of uniform diagnostic criteria has hampered effective diagnosis and treatment of polycystic ovary syndrome, says **Richard Legro**, MD, assistant professor of OB/GYN at Pennsylvania State University's College of Medicine at the Milton S. Hershey Medical Center in Hershey. Over the past 10 years, however, there has been a growing acceptance that the women who are most severely affected tend to have excess androgens and irregular periods due to chronic anovulation.

It is important to make a good diagnosis when anovulation is involved, stresses **Sarah Berga**, MD, associate professor of OB/GYN and reproductive sciences at the University of Pittsburgh School of Medicine at Magee-Womens Hospital. **(See how Berga approaches a diagnosis of polycystic ovary syndrome, p. 54.)** "Health consequences are very different, depending on the type of anovulation one has, and the therapies are radically different," she says.

The central problem in PCOS lies in aberrant gonadotropin-releasing hormones (GnRH) and gonadotropin response, which is associated with high serum levels of luteinizing hormone (LH).[1] LH stimulates ovarian androgen production. This testosterone adds to the amount of adrenally produced androgens and results in the classical symptoms of excess hair growth and acne. Also, the high androgen level suppresses pituitary production of follicle stimulating hormone (FSH), which affects ovarian cycling and luteal progesterone production. Endometrial proliferation continues, which results in irregular endometrial sloughing.

In dealing with polycystic ovary syndrome, some providers have focused on cosmetic symptoms of the condition or on infertility problems encountered by reproductive-age women. Providers also must consider long-term health consequences, says Legro. A risk of endometrial cancer exists due to infrequent endometrial sloughing. Many women with PCOS are obese and have abnormal lipid profiles, which may place them at risk of developing cardiovascular disease. Perhaps the most important health concern associated with PCOS is the risk of diabetes. In a recently published study, Legro and colleagues at New York City's Mount Sinai School of Medicine found that women with PCOS have a much higher chance of developing impaired glucose tolerance levels, a risk factor for diabetes.[2]

Treatment in research

According to Legro, the central problem in PCOS lies in insulin resistance. The condition leads to excess insulin, which stimulates the ovary to produce androgens. That line of reasoning is leading researchers to study the use of insulin sensitizers in women with polycystic ovary syndrome. Those drugs include metformin (Glucophage, Bristol-Myers Squibb, Princeton, NJ) and troglitazone (Rezulin, Parke-Davis, Morris Plains, NJ).

In one small study, almost 90% of women with polycystic ovary syndrome who took metformin for a month ovulated spontaneously or with help from the fertility drug clomiphene citrate.[3]

EXECUTIVE SUMMARY

Polycystic ovary syndrome (PCOS), also called Stein-Leventhal syndrome and hyperandrogenic chronic anovulation, is estimated to affect 5% to 7% of women.

- The textbook definition includes obesity, hirsutism, oligomenorrhea (or amenorrhea), and subfertility. However, there is a growing acceptance that women who are most severely affected by PCOS tend to have excess androgens and irregular periods due to chronic anovulation.
- While risks for endometrial cancer and cardiovascular disease have been associated with the condition, women with PCOS also face an increased risk of impaired glucose tolerance levels, which can lead to diabetes. Although the use of insulin sensitizers has been studied for those women, more studies are needed to determine safety and efficacy.

RESOURCE

- **Polycystic Ovarian Syndrome Association,** P.O. Box 7007, Rosemont IL 60018-7007. Telephone: (630) 585-3690. E-mail: info@pcosupport.org. Web: http://www.pcosupport.org. The organization's annual conference is scheduled for June 5-7, 1999, in Arlington Heights, IL. More information on the condition is on the Web: www.collmed.psu.edu/obgyn/pcos.htm.

Among those taking a placebo, only 12% ovulated even with clomiphene.

The role of insulin sensitizers in the long-term chronic management of PCOS is unknown, say Berga and Legro. More research must be conducted to determine their safety and efficacy in treating the condition.

Other research efforts are examining the use of androgen blockers such as flutamide. Because women with PCOS have high levels of androgens, scientists say flutamide may allow ovulation. A small European study showed that the drug restored ovulation in anovulatory PCOS patients.[4] Women with PCOS who have not responded to clomiphene citrate treatment for infertility are participating in a study sponsored by the National Institute of Child Health and Human Development in Bethesda, MD. Results from those and future studies may determine what role androgen blockers play in treatment.

Experts say treatment of PCOS varies, depending on which symptoms are present and which need to be controlled. A healthy diet, weight maintenance, and regular exercise can help improve the body's sensitivity to insulin and help diminish the chances of developing diabetes, heart attack, or stroke. Levels for LDL, HDL, and triglycerides should be monitored on a regular basis, with fasting glucose levels taken once a year for diabetes detection.

A low-dose oral contraceptive can help lower androgen levels, establish regular menstruation, and provide effective birth control for those who desire it.[1]

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PCOS: Diagnosis and contraceptive options

What tests are recommended to diagnose polycystic ovary syndrome (PCOS)? To determine chronic anovulation associated with polycystic ovary syndrome, **Sarah Berga**, MD, associate professor of OB/GYN and reproductive sciences at the University of Pittsburgh School of Medicine at Magee-Womens Hospital, uses the following diagnostic approach:

❑ Take a good patient history and perform a reasonable physical exam.

❑ Upon the initial findings, order these five tests from one blood sample: luteinizing hormone (LH), follicle stimulating hormone (FSH), thyroid stimulating hormone (TSH), prolactin, and an androstenedione level. Be sure the blood sample is timed not to follow the physical exam. If a physical exam, Pap smear, and breast exam are done prior to the blood sample, the patient's prolactin level is stimulated. If the sample is taken in a resting state, with a patient who has not just eaten, all the monitored levels should be normal.

❑ In the "first cut" for PCOS diagnosis, the LH/FSH ratio will be high, and the androstenedione will be high/normal or high, says Berga. At this point, the diagnosis is not confirmatory, but the provider will be able to exclude hyperprolactinemia, hypothyroidism, hyperthyroidism, and menopause.

❑ If the patient is believed to be ovulatory, but the provider is unsure, an estradiol/progesterone test can be performed to get a sense of the ovarian function. If the test confirms that the patient is ovulating, another condition outside of PCOS is most likely at play, she says. Because LH/FSH will vary when the patient is ovulating in an ovulatory cycle, Berga often adds the estradiol and progesterone tests to back up the LH/FSH tests. However, if the LH/FSH ratio is greater than 2.5 or 3, and the androstenedione is elevated, the vast majority of patients can be considered PCOS candidates.

❑ If PCOS is diagnosed, move forward to determine if the patient has glucose intolerance, impaired glucose tolerance, or frank diabetes. A two-hour post-glucose test should give an accurate depiction of those conditions.

Although women with PCOS can have unpredictable ovulatory cycles, they should not be considered protected against unintended pregnancy by their condition.[1] Low-dose oral contraceptives (OCs) provide birth control, lower free testosterone levels, relieve acne and hirsutism, and establish regular menses.

Because they restore regular cycles, prevent endometrial hyperplasia, and increase levels of sex hormone binding globulin, combination OCs are the contraceptive agent of choice in women with PCOS, says **Andrew Kaunitz**, MD, professor and assistant chair of the department of OB/GYN at the University of Florida Health Sciences Center in Jacksonville.

Use of a low-dose OC has shown reasonable suppression of the ovary, but with recovery occurring during the placebo phase.[2] For that reason, Berga suggests either using OCs on a continuous basis, or prescribing Mircette (Organon, West Orange, NJ) because it minimizes return of ovarian function.

There has been some debate about whether OCs worsen insulin sensitivity in women with PCOS, says **Richard Legro**, MD, assistant professor of OB/GYN at Pennsylvania State University's College of Medicine at the Milton S. Hershey Medical Center in Hershey, but he believes the benefits outweigh the risk.

What about the use of other contraceptives for birth control in women with PCOS? If depot medroxyprogesterone acetate (DMPA) is used, providers also may wish to add supplemental estrogen to increase levels of sex hormone-binding globulins and improve lipid profiles, Kaunitz says.

Legro questions the use of DMPA due to his concern that it may exacerbate already-irregular bleeding patterns. Intrauterine devices or barrier methods don't address the symptoms often encountered by women with PCOS, he adds.

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Be prepared for 1999 debut of mifepristone

Is your facility considering the use of mifepristone (RU-486) when it becomes available in the United States? If so, pencil in the end of this year as the target date for adding this form of medical abortion to your services and close the chapter on an announcement that has been some eight years in the making.

"We do expect to make mifepristone available by the end of the year in the U.S.," confirms **Heather O'Neill**, spokeswoman for the Danco Group in New York City. The firm was granted the U.S. manufacturing license from the Population Council, a nonprofit research group in New York City concerned with reproductive health.

Once the Food and Drug Administration (FDA) signs off on Danco's manufacturing plans, final approval will be issued, and the drug will be released on the U.S. market.

Danco is working with several women's health and provider groups in developing provider education, says O'Neill. The company also is garnering input from clinic administrators and counselors to cover all the bases of implementing the mifepristone/misoprostol regimen into current practice.

Mifepristone is an antiprogestin. When used in providing abortion services, it interrupts pregnancy in its early stages by blocking the action of the natural hormone, progesterone. Progesterone prepares the lining of the uterus for a fertilized egg, then maintains the pregnancy. Without the effect of progesterone, the lining of the uterus softens, breaks down, and bleeding begins. Misoprostol is a prostaglandin. When it is used in

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1999 is the year for U.S. introduction of mifepristone (RU-486), according to the company that holds the manufacturing license for the abortion drug. Food and Drug Administration approval is required before the drug is released.

- The company is working with women's health and provider groups to develop provider education for the drug's use.
- Because the mifepristone/misoprostol regimen represents a new form of medical abortion, providers may need to factor in more counseling time when the service is added.

abortion, the drug causes contractions of the uterus, helping to expel the embryo.[1]

The FDA has gathered safety and acceptability studies from the large-scale U.S. trial of the mifepristone / misoprostol regimen.[2,3] The studies, which included more than 2,000 women enrolled at 17 clinics in 15 states, found the method was safe, effective, and regarded as highly acceptable by patients. **(For more information on results of the safety study, see *Contraceptive Technology Update,* July 1998, p. 87. For more on the acceptability study, see *CTU*, September 1998, p. 113.)**

The U.S. trial called for three clinic visits, beginning with thorough counseling, physical examination, and determination of length of pregnancy. At the first treatment visit, women were instructed to swallow three 200 mg tablets of mifepristone and stay at the clinic 30 minutes for observation. At the second visit, women ingested two 200 mcg of misoprostol and remained at the clinic for four hours. The last visit, scheduled 12 days after the misoprostol visit, served as follow-up to make sure abortion was complete.

Study data suggest that an option of a less medically supervised regimen may be desirable. A study of 166 women who received mifepristone 600 mg orally, and subsequently self-administered 800 µg in the vagina at home two days later, found 90% agreed that home administration of misoprostol was acceptable.[4]

How can your facility prepare for implementing mifepristone / misoprostol services? Get as much information as possible, asserts **Beverly Winikoff**, MD, MPH, director of the Population Council's reproductive health programs. **(See box, below right, for the latest on medical abortion, presented at the recent *Contraceptive Technology* conference.)** "People need to understand it, not rely on fiction and mythology," notes Winikoff. "Think through the logistics, depending on how they want to provide the service. That is the critical thing in terms of service position."

With a new service such as mifepristone / misoprostol, time for additional counseling may need to be allotted, according to a survey of surgical abortion providers.[5] It is hard to access the amount of time needed for counseling, she says. Both providers and patients are inexperienced when it comes to mifepristone / misoprostol. Once providers integrate information into their practices and become comfortable with the regimen, they will be able to use that experience in talking with women about the method. Women have "street knowledge" when it comes to surgical abortion, but they aren't as familiar with medical abortion, Winikoff says. Over time, as the method grows, women will come to know more about it.

Before the FDA can give final approval of mifepristone, it must sign off on the manufacturing process and facilities that will be used to make the drug. Danco is working with the federal agency in meeting all requirements to obtain the final approval. Misoprostol already is approved for use in the United States as an ulcer medication.

The situation surrounding the approval of mifepristone is somewhat unique, Winikoff says. Other drugs often have patient demand driving approval, but those who would benefit from mifepristone can't delay decisions about pregnancy until it is approved. Providers have to be the spokespeople for consumer demand, she says. "If somebody has arthritis, they can say, 'I'm suffering so much I can't wait,' and it creates pressure on the system. It is hard to create pressure on the system with abortion clients because they get their problem solved one way or the other, then they are not waiting for it anymore, because they no longer need an abortion."

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RESOURCE

"Providing Medical Abortion Services" was the focus of a half-day preconference session at the recent *Contraceptive Technology* seminar in San Francisco and Washington, DC. For cassette recordings of the session, contact:

- **Audio Magic**, 4457 W. Lake Road, Mayville, NY 14757. Telephone: (800) 679-3646 or (716) 789-3170. The medical abortion services session (461-PC2) is $34.95 (four tapes), plus $7 shipping and handling.

Family planners gear up for Y2K challenge

When the clock strikes midnight on Dec. 31, 1999, administrators will hope they have everything in place to keep mission-critical computer programs running into Jan. 1, 2000. An informal survey by *Contraceptive Technology Update* shows that agencies are preparing for year 2000 (Y2K) computer problems. The extra funds to update computer hardware and software, plus the added expense of personnel time to track Y2K compliance issues, has put another burden on already-strained budgets, family planners report.

"It will be very costly, and we will get it done, but we might not be able to do some other things," says **Carol Mitchell**, ARNP, executive director of Southern Iowa Family Planning Clinic in Ottumwa. For example, Mitchell had planned for one of the independent not-for-profit agency's nurse practitioners to attend a training course in hopes of instituting colposcopy services. But faced with estimates of $4,000 to $6,000 to replace two noncompliant computers, Mitchell says such plans will have to wait.

Tapestry Health Care in Northampton, MA, is a not-for-profit organization providing comprehensive health services, education, outreach, and advocacy in five western Massachusetts counties. It is facing similar decisions, says **Alison Jones**, chief operations officer. "We will complete the project because we have to, but, as is usually the case, money that could have gone to direct services will be directed to this project."

Many computers use two digits to record the year. If no action is taken, these computers will recognize "00" as 1900 rather than 2000 when Jan. 1 arrives. A survey of 15,000 companies in 87 countries presented at a July 1998 U.S. Senate hearing shows the health care industry remains far behind others in efforts to handle the problems. Y2K woes can affect direct patient care in a variety of ways, from electronic chips embedded in medical devices to computerized programs recording prescription expiration dates. Computerized scheduling may be affected, as may claims processing for payment from Medicare, Medicaid, private insurance companies, and managed care organizations. Even the functioning capabilities of telephone systems, office security systems, electrical systems, and elevators could be affected by computer chips relying on two-digit date recording.

The Medical and Health Research Association of New York City, which works with more than 50 sites in the city's five boroughs, has a Y2K plan covering all program activities and the central office, says **Ellen Rautenberg**, president and chief executive officer. The plan involves testing hardware and software and getting assurances from vendors in accounting software, payroll processing company, and banks. Major problems are anticipated in the association's voicemail system (which is known to be noncompliant), "homegrown" software used in a variety of research projects, and physical plant problems in the buildings where space is rented, she says.

The Family Planning Council of Iowa in Des Moines has nine delegate agencies with 31 clinic sites. Physical plant problems are a "very real issue," says executive director **Jodi Tomlonovic**,

EXECUTIVE SUMMARY

- The Y2K problem stems from the fact that many computers use just two digits to record the year. If no action is taken, these computers will recognize "00" as 1900 rather than 2000 on Jan. 1.
- Y2K problems can affect direct patient care, from electronic chips embedded in medical devices to computerized programs recording prescription expiration dates. Computerized scheduling and claims payment processing are at risk, and telephone systems, office security systems, and electrical systems may be affected by computer chips relying on two-digit date recording.

RESOURCES

Members of the American College of Obstetricians and Gynecologists (ACOG) needing information on how Y2K may affect their practices may contact:

- **James Scroggs**, ACOG Department of Practice Management, 409 12th St. S.W., P.O. Box 96920, Washington, DC 20090-6920. Telephone: (202) 863-2447. Fax (202) 484-7480. E-mail: jscroggs@acog.org. Web: www.acog.org; click on "Practice Management," then "Year 2000 — Are You Ready?"

Helpful Web sites on the subject include these:

- **www.cdc.gov/y2k** — Centers for Disease Control and Prevention.
- **www.aha.org/y2k** — American Hospital Association; requires AHA password.
- **www.y2k.gov** — U.S. government site with links to government agencies and private organizations.
- **www.ama-assn.org/not-mo/y2k** — American Medical Association.

Health care Y2K reference available for our readers

With the year 2000 deadline fast approaching, hospitals, other health care providers, and the medical device industry are scrambling to complete a process that in many cases was started too late. What may have once been a logistical issue is burgeoning into an overwhelming problem, compounded by the scarcity of time, rising costs, and a lack of programming resources and expertise.

The health care industry has found itself under increased pressure as the realization dawns that it is behind the curve in preparing for Y2K. According to a recent *Modern Healthcare*/PriceWaterhouseCoopers survey, the biggest worry among 69% of health care providers is that patients will be "affected due to faulty monitoring gear," followed by concern over "inaccurate lab tests and pharmacy orders" (36%), problems with patient records (34%), and worries about billing and paychecks.

Crisis manual offers solutions

As the Y2K issue moves far beyond a mere "technological" issue, American Health Consultants, publisher of *Contraceptive Technology Update*, has compiled the *Hospital Manager's Y2K Crisis Manual*, a collection of resources for nontechnical managers. This 150-page reference manual includes information, in nontechnical language, on the problems your facility will face, the potential fixes, and the possible consequences, including:

- Will your computers and software work?
- What does Y2K mean for patient care?
- What will happen to your medical devices?
- How can you make sure your vendors are Y2K compliant?
- Are you at legal risk due to Y2K?
- Are you prepared if Y2K delays payments?

Jan. 1, 2000, is not a moving target. Either your computer systems, medical devices, and suppliers can handle the date change and maintain business as usual, or they can't — in which case your entire organization may face serious problems.

For additional information on the *Hospital Manager's Y2K Crisis Manual*, contact American Health Consultants customer service. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub.com. ■

MPA. The council is working on resolving such compliance issues.

Areas of concern for the California Family Health Council in Los Angeles include data, billing, point of service eligibility, and enrollment into the California Family Planning Program, says **Margie Fites Seigle**, council chief executive officer. The council, which administers federal and state monies for some 90 clinic sites in Los Angeles County, has devoted considerable resources to reconfigure its workstations for Y2K compliance.

A host of Internet Web sites offer insight on the Y2K issue in health care. **(See resources, p. 57. Also, see box at right.)** The American College of Obstetricians and Gynecologists (ACOG) also offers information and support, says **James Scroggs**, who is coordinating Y2K efforts for the society's department of practice management. Both he and Susanna Jones Esq., of ACOG's department of professional liability, are available to answer member physicians' Y2K questions.

The Health Care Financing Administration has made the Y2K initiative its No. 1 priority and is committed to making sure that its date-sensitive systems and those of its business partners are ready to verify eligibility, enrollment, coverage, and payments. The agency is posting updates on its Web site to keep providers informed. ■

Dealing with the age of conscience

By **Lisa Kaeser**, JD
Senior Public Policy Associate
Alan Guttmacher Institute
Washington, DC

As the ongoing — and fundamental — changes to the nation's health care system continue, the question of who will offer which services has become critical to anyone with a choice about health care coverage. The expansion of managed care, multiple mergers among health care organizations, and increasing government involvement in determining the package of

services to be offered to the insured have contributed to the new landscape of health care.

In the course of deciding what services to offer, individual health care providers and the administrators of health plans also are determining what services they will refuse to provide due to moral or religious objections.

Refusal to provide certain health care services because of conscientious objections has been sanctioned by the federal government for many years. In 1973, shortly after the Supreme Court's decision in *Roe v. Wade*, Congress passed an amendment to the Public Health Service Act that permits individual health care providers and medical facilities to refuse to provide abortion and sterilization services if they have moral or ethical objections. By the end of the 1970s, nearly all states followed suit, passing similar laws regarding the provision of so-called "sensitive" services.

Few would argue that individual health care providers should be forced to provide certain services if they have a legitimate objection to those services, as long as arrangements can be made for individuals seeking the services to obtain them without undue burden or cost.

Nonetheless, individuals seeking certain services may face even greater obstacles: In some instances, entire health care plans are invoking a broad "conscience clause" in refusing to cover certain services in their packages. In the private sector, employers are doing the same by offering one or more health care plans that do not cover services to which the employers object, even if their employees do not share those objections.

In response, federal and state governments have become increasingly involved in ensuring a full range of services is covered by insurance in the public sector, and they are looking at the private sector as well. At the heart of the issue is the tension between the right of individuals to obtain coverage for their health care and the right of providers or plans to exempt themselves from offering that coverage for adequate cause, such as religious beliefs or moral convictions.

This tension was especially apparent in last fall's debate in Congress about whether the health care plans offered by the federal government should be required to offer coverage for contraceptive services. In the end, equity won. Congress adopted a provision that requires health plans offered to federal employees to cover the full range of contraceptive services and supplies if those plans already offer coverage for other prescription drugs and devices. However, passage of the amendment was contingent on the addition of language that allowed plans that have objections based on bona fide "religious beliefs" (not moral) to opt out of covering contraceptive services.

In September 1998, the Health Care Financing Administration, which oversees the massive Medicaid program, published proposed regulations implementing another federal law that allows an entire Medicaid managed care plan, based on a religious or moral objection, to refuse to provide or reimburse for a service. This action was taken despite the fact that family planning is a covered service under Medicaid.

Moreover, providers would not even have to provide counseling about a given service if they had similar objections. The proposed rules would, however, require state Medicaid agencies to ensure access to all covered services. With more states moving their Medicaid clientele into managed care plans, these rules, which are

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expected to be finalized sometime this year, could have a major impact.

Meanwhile, many states also have considered this issue. So far, they generally have chosen to cover services and limit the religious exemption to employers rather than entire plans. Last year, Maryland was the only state to pass a law mandating contraceptive coverage; another was vetoed by the governor of California. A handful of other states have varying levels of regulatory requirements in place.

It may be some time before these issues can be sorted out, and the solutions likely will be varied. In Washington state, recent reports are that the Planned Parenthood affiliate and Catholic organizations have negotiated a religious exemption to a pending state bill in which an employee could purchase contraceptive coverage directly from her employer's insurer if her employer claimed to have a religious objection to providing that service directly. Clearly, continued access to these services — whether an individual is publicly or privately insured — will require ongoing vigilance and a familiarity with health insurance never before required. ■

CE objectives

[For details on Contraceptive Technology Update*'s continuing education program, contact: Customer Service, American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub. com. Web: http://www.ahcpub.com.]*

After reading *Contraceptive Technology Update,* the participant will be able to:

• Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. **(See "Four-periods-a-year oral contraceptive to be examined for use in U.S. market," p. 51, and "Be prepared for 1999 debut of mifepristone," p. 55.)**

• Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.

• Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "Challenge for providers: Polycystic ovary syndrome," p. 53.)** ■

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