

CONTRACEPTIVE TECHNOLOGY

U P D A T E[®]

A Monthly Newsletter for Health Professionals

View previous issues at www.contraceptiveupdate.com

THOMSON
AMERICAN HEALTH
CONSULTANTS

IN THIS ISSUE

- **Drawing in men:** Agencies share tips 4
- **Methods for men?** Scientists investigate options 6
- **Vasectomy:** Check your technique 7
- **Emergency contraception:** Update your practice 9
- **CTUpdates:**
— *Contraceptive Technology* conference 11

- **Enclosed in this issue:**
— Men's health web sites

JANUARY 2004

VOL. 25, NO. 1 • (pages 1-12)

Meeting the health needs of men: Ensure that your facility stacks up!

Survey shows there is room for improvement in reaching young males

Review the number of services offered at your family planning agency, then check off the number that address the reproductive health needs of men. If your agency is like most of the facilities participating in a recently published survey, you may be serving some male patients, but doing very little to recruit more.¹

By the late 1990s, 87% of agencies providing publicly funded family planning services in the United States served at least some male patients, primarily through condom provision, contraceptive counseling, and testing and treatment for sexually transmitted diseases (STDs).¹ Most of the facilities surveyed expressed interest in serving more men in the future; however, only one in five conducted activities to recruit more men, according to a report of the survey's results.

"It appears that many men are unaware that family planning clinic services are available to them, or they may have the perception that clinics are the domain of women only," states **Lawrence Finer**, PhD, the report's lead author and associate director for domestic research at the New York City-based Alan Guttmacher Institute (AGI). "In addition, agencies report inadequate funds to deliver services to men."

Special focus: Male reproductive health services

Men and women play equal roles in reproduction. While there has been an increased focus on men in recent years, their care still needs improvement, some family planning experts maintain. This issue of *Contraceptive Technology Update* offers a special focus on male reproductive health services. We highlight programs that are addressing young men and review promising research in the field of male contraception. We also have enclosed a list of selected web links to information on male health issues.

Don't miss reading this special issue of *CTU*!

NOW AVAILABLE ON-LINE! www.ahcpub.com/online.html
Call (800) 688-2421 for details.

Contraceptive Technology Update® (ISSN 0274-726X), including **STD Quarterly**™, is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Contraceptive Technology Update**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcpub.com). **Hours of operation:** 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

Subscription rates: U.S.A., one year (12 issues), \$449. Approximately 18 nursing contact hours or Category 1 CME credits, \$499; Outside U.S., add \$30 per year, total prepaid in U.S. funds. Two to nine additional copies, \$359 per year; 10 to 20 additional copies, \$269 per year; for more than 20, call (800) 688-2421. **Back issues**, when available, are \$75 each. (GST registration number R128870672.)

Photocopying: No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact Thomson American Health Consultants. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. World Wide Web: <http://www.ahcpub.com>.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Rebecca Bowers**.

Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@thomson.com).

Editorial Group Head: **Valerie Loner**, (404) 262-5475, (valerie.loner@thomson.com).

Senior Managing Editor: **Joy Daughtery Dickinson**, (229) 551-9195, (joy.dickinson@thomson.com).

Production Editor: **Nancy McCreary**.

Editorial Questions

Questions or comments?
Call **Joy Daughtery Dickinson**
(229) 551-9195.

Copyright © 2004 by Thomson American Health Consultants. **Contraceptive Technology Update**® and **STD Quarterly**™ are trademarks of Thomson American Health Consultants. The trademarks **Contraceptive Technology Update**® and **STD Quarterly**™ are used herein under license. All rights reserved.

Statement of financial disclosure: **Dr. Hatcher** (editorial board chairman and peer reviewer) discloses that he is a consultant for Pharmacia/Upjohn, performs research for Ortho, and is on the speaker's bureau for Ortho, Wyeth, Organon, Berlex, and Pharmacia-Upjohn. **Dr. Kaunitz** (board member) discloses that he does continuing medical education presentations and publications for Aventis, Organon, Ortho-McNeil, Pharmacia, and Wyeth-Ayerst, is a consultant for Aventis, Barr Laboratories, Berlex, Johnson & Johnson, Lilly, and Pharmacia, and is a stockholder in Aventis and Johnson & Johnson, and performs research for Barr Laboratories, Berlex, Galen, Lilly, Merck, National Institutes of Health, Organon, Parke Davis, Pfizer, Pharmacia, R.W. Johnson Pharmaceutical Research Institute, and Solvay. **Ms. Dominguez** (board member) discloses that she is on the speaker's bureau for Ortho, Pfizer, Roche, and Organon. **Ms. Wysocki** (board member) discloses that she is on the speaker's bureau for Ortho-McNeil, Wyeth Ayerst Pharmaceuticals, Berlex, Organon, Pharmacia, Pfizer, and Bristol Myers Squibb. **Dr. Nelson** (board member) serves on the speaker's bureau for Berlex Laboratories, Gynetics, Eli Lilly & Co., 3M Pharmaceuticals, Ortho-McNeill, Organon, Parke-Davis, Pfizer, Pharmacia & Upjohn Co., and Wyeth Ayerst; she conducts research for Ortho-McNeil and Pharmacia & Upjohn. **Dr. Rosenfield** (board member) is a stockholder and board member of Biotechnology General Corp., a consultant for Organon; serves on the speaker's bureau for Organon, Wyeth-Ayerst, and Parke-Davis; and conducts research for Organon, Wyeth-Ayerst, Ortho-McNeil, and Parke-Davis.

THOMSON
★
AMERICAN HEALTH CONSULTANTS

EXECUTIVE SUMMARY

Most U.S. agencies providing publicly funded family planning services are serving some males but could bulk up their care with the addition of male programs.

- While most of the facilities surveyed expressed interest in serving more men, only one in five conducted activities to recruit them.
- Men need sexual health services: Reported rates of chlamydia and gonorrhea reach 500-600 per 100,000 men in their early 20s. Men in their 20s account for about half of births and half of abortions in the United States each year.

According to previous AGI research, men do not seek preventive services to the extent that women do, he points out. The fact that most men who do go to clinics are the partners of female clients means that those who are at greater risk, such as those whose partners are not receiving family planning and STD services, are exactly the ones who aren't being served, Finer observes.

Men are at risk

Why it is so important to offer reproductive health services for men?

"The first reason for involving young men is that they have significant needs, and they have rights and needs that are not being addressed thoroughly as it relates to their own health," says **Bruce Armstrong**, DSW, director of the Young Men's Clinic and associate clinical professor in the Heilbrunn Department of Population and Family Health, Mailman School of Public Health at Columbia University in New York City. "As it relates to women's health, it is really just common sense that involving men in sexual and reproductive health care can enhance the health of women."

The Young Men's Clinic is one of the first community-based programs for men, founded in 1987 in New York City. It provides medical, social work, mental health, and health education services to men ages 13-30, and it has been successful in reaching its target population.² (*Contraceptive Technology Update* reported on the facility in its June 2002 article, "Bring in the men: One clinic's tale," p. 68.)

Many young men may receive some form of services during their high school years at school-based health clinics; however, when they reach

Identify the needs, barriers to men's care

- From adolescence on, most men need information and counseling about sexual and reproductive matters, and they need somewhere reliable to go for related education and health care.
- There is no commonly agreed upon definition of sexual and reproductive health care for men, and many barriers impede the provision of such care.
- Obstacles to care include the tendency of many men not to seek regular, routine checkups; the fact that health insurance often does not cover the services men need; and the high proportions of men — particularly poor men — who do not have health insurance.
- Few health professionals are specifically trained to provide men with sexual and reproductive health education and services.
- The older men get, the more likely they are to need medical sexual and reproductive health services rather than information.
- At all ages, sexually active men, particularly those who do not use a condom and have multiple partners, need regular screening for sexually transmitted diseases.

Source: Alan Guttmacher Institute. *In Their Own Right: Addressing the Sexual And Reproductive Health Needs of American Men*, New York City; 2002.

their 20s, they may become “missing men” in the health care picture, says Armstrong. The absence of men at this point in time is troubling, he adds. Reported rates of chlamydia and gonorrhea reach 500-600 per 100,000 men in their early 20s, levels that are much higher than those of men in their 30s or older.³ Men in their 20s account for about half of births and half of abortions in the United States each year.³

There are opportunities to extend recent improvements found in adolescent male sexual behaviors if young men are better served, Armstrong points out. Recent surveys show a decrease in the proportion of adolescent males ever having sexual intercourse and an increase in the use of condoms among male teens.⁴ **(Read more about this trend in the June 2000 article, “Teens waiting longer, using better protection,” p. 133.)**

“Can you imagine the further change in terms of outcomes that could be achieved if we didn’t neglect the 20-24 age male so much?” asks Armstrong. “It would be amazing, I think.”

Results from the AGI survey show that many

publicly funded agencies that run family planning clinics are offering some form of services used by men. Almost all (95%) of the surveyed facilities say they provide condoms and STD counseling, contraceptive counseling (93%), and STD treatment (90%) and testing (89%).¹

The number of male patients had increased at 53% of agencies, and four out of five agencies said they were interested in serving more men in the future, according to the survey. The most commonly reported barriers to serving men were their unawareness that services were available (58%) and inadequate agency funding (55%).

One way to promote male services is to talk with your existing female patients. At the Young Men’s Clinic, the male social worker talks with women in the family planning clinic waiting area, says Armstrong.

“It is a very obvious way to get the women thinking that maybe the men need to be involved, and they can be the linkage point,” he explains. “Women can make an appointment for their boyfriend, husband, or brother, and he will be taken care of, because of their efforts.”

The Young Men’s Clinic has developed a video that depicts the clinic and shows the providers in action. Former male patients are portrayed, with testimonials given about the care received at the facility. By seeing the video, some of the hesitation in visiting the facility is minimized, says Armstrong. The video is shown in school-based clinics and community organizations to help raise awareness of the facility’s services.

Break down the barriers

Since 1997, the Office of Population Affairs/Office of Family Planning (OPA/OFP) has funded programs that address family planning and reproductive health information and services for males, and it recently has made males a priority population.⁵ However, men still represent a small proportion of all family planning clinic patients: They comprise just 4% all patients at Title X-funded clinics in 2002.⁶

Armstrong praises OPA’s efforts in supporting access to male health services; however, the hunt for funding continues for the clinic, as it does for other agencies.

“It appears that agencies, their clinics, and the public health community as a whole need to develop new strategies for informing men about services and making them feel welcome; in addition, we need more research into which of these

strategies are the most cost-effective," says Finer. "Finally, advocates need to make the case for increased funding for services in this area."

References

1. Finer LB, Darroch JE, Frost JJ. Services for men at publicly funded family planning agencies, 1998–1999. *Perspect Sex Reprod Health* 2003; 35:202–207.
2. Armstrong B. The Young Men's Clinic: Addressing men's reproductive health and responsibilities. *Perspect Sex Reprod Health* 2003; 35:220–225.
3. Alan Guttmacher Institute. *In Their Own Right: Addressing the Sexual And Reproductive Health Needs of American Men*. New York; 2002.
4. Santelli JS, Lindberg LD, Abma J, et al. Adolescent sexual behavior: Estimates and trends from four nationally representative surveys. *Fam Plann Perspect* 2000; 32:156–165, 194.
5. Office of Population Affairs. *Male Involvement Projects: Prevention Services*. Washington, DC: U.S. Government Printing Office; 2000.
6. Alan Guttmacher Institute. *Family Planning Annual Report, 2002*. New York City; 2003. ■

Reach out to young men: Add strength in services

Will adding male programs to existing family planning services subtract from existing care? Not according to the experience of one California center, which nearly tripled its number of adolescent male patients, more than doubled its number of adult male patients, and increased its female patient load by 10% within the first year of adding a male clinic.

Addition of male services at New Generation Health Center, a publicly funded affiliate clinic of the University of California, San Francisco (UCSF), did not impact use of the center by women: Female patients who came to the center completed questionnaires to assess their satisfaction with services and attitudes toward men being served by the center. Most of the women surveyed, both before and after the male clinic opened, expressed satisfaction with their care.¹

The opportunity to serve men, particularly adolescents, is wide open to family planning clinics: While 69% of the more than 7,000 publicly funded U.S. family planning clinics have at least one program devoted to outreach, education, or services for teens, just 39% routinely serve young men.² See if one of the following approaches used by two family planning agencies can help move

EXECUTIVE SUMMARY

Two family planning agencies are making strides in reaching young men.

- Programs for men can be incorporated into an existing family planning program without negatively impacting existing services, suggest findings from a study of male services added to the New Generation Health Center in San Francisco.
- Man2Man, a program targeting at-risk young men in Philadelphia, uses the collaborative efforts of several community groups to reach its target population.

your agency toward increased services for young men.^{1,3}

Reasons to seek men

Why did the New Generation Health Center decide to expand its services to include young men?

"In an effort to fulfill our mission to help adolescents and young adults avoid unintended pregnancies and sexually transmitted infections, we believe we need to address the male component of the equation, i.e., women do not become pregnant or get sexually transmitted infections in a vacuum," says **Tina Raine**, MD, an associate clinical professor at UCSF's Department of Obstetrics/Gynecology and Reproductive Health Sciences. "There are relatively fewer providers of reproductive health services for men, and we felt we were aptly prepared to address the reproductive health needs of men."

To prepare for the clinic's opening in July 2001, staff members performed several tasks. First, they completed a staff survey asking about whether they thought males should be served in the center, their concerns or reservations, their experiences serving male clients, and their suggestions for ways of preparing the clinic and its staff. In addition, clinic staff participated in a half-day workshop on providing services to young men led by **Arik Marcell**, MD, MPH, an assistant professor of pediatrics and medical director of the Adolescent & Young Adult Center at the Baltimore-based University of Maryland School of Medicine. It included presentations from providers from the community with more experience dealing with males and covered areas including sports physicals. (See the resource box on p. 5 to obtain contact information for training leaders.)

Male peer educators evaluated the clinic for its “malefriendliness” prior to the opening, says Raine.

“In addition to providing staff orientation and training on serving male clients, we went to special effort to place male gender-specific art in the public areas and rest rooms, and we expanded our patient literature to include male-specific educational materials,” she states.

Before opening the clinic, male involvement program staff took inventory of other primary care resources available to young men, contacted other primary care doctors and clinics serving males in the area to inform them about the new clinic, and developed a list of primary care providers for referrals for the staff’s clinicians and male patients.

Male clinic sessions are held one-half day each week and are staffed by four rotating adolescent medicine fellows (two male, two female) and a female family nurse practitioner. A clinic assistant assembles client charts, shows patients to examination rooms, measures vital signs, and obtains blood samples. Male and female health educators are available to conduct risk assessments and individualized counseling.

Services provided during the male clinic sessions include STD screening, counseling and treatment; diagnosis of and treatment for genitourinary conditions; HIV counseling and testing; and sports physicals. In addition, female partners of male patients can obtain family planning services.

There are challenges in providing male services, Raine acknowledges. Finding ways to appeal to male clients is one hurdle, she says. Having clinicians who are trained and experienced in dealing with male reproductive health and primary care concerns also presents a challenge, Raine states.

For the Philadelphia-based Family Planning Council (FPC), working with other community organizations has been the key to addressing the sexual and reproductive health needs of area at-risk young men.

The organization, the Title X grantee for southeastern Pennsylvania, is working with three Philadelphia organizations — the Drexel University School of Public Health, St. Christopher’s Hospital for Children, and NorthEast Treatment Centers (NET), a local agency providing mental health, substance abuse treatment and social services — in offering Man2Man. The program targets young men in an economically disadvantaged section of Philadelphia with high teen pregnancy and STD rates. Funding for the project has been provided through demonstration and research grants from the Atlanta-based Centers for Disease Control and

SOURCES/RESOURCES

More information on the training material used in preparation of the New Generation Health Center is available by contacting:

- **Arik Marcell**, MD, MPH, University of Maryland School of Medicine, 120 Penn St., Baltimore, MD 21201. E-mail: amarcell@peds.umaryland.edu.
- **Erica Monasterio**, RN, MN, NP, Associate Clinical Professor of Pediatrics and Nursing, University of California, San Francisco, 400 Parnassus, ACC Second Floor, San Francisco, CA 94143. E-mail: ericam@itsa.ucsf.edu.
- **Barbara Long**, MD, Assistant Clinical Professor of Pediatrics, University of California, San Francisco, 3333 California Ave., Suite 245, San Francisco, CA 94118. E-mail: blong@itsa.ucsf.edu.

Marcell’s workshop used materials developed by The Center for Health Training. The center offers a free download of its program, “Blueprint for Male Involvement.” Click on “Materials and Resources” at the home page, then the program title. The material is available in Adobe Portable Document Format. For more information, contact:

- **The Center for Health Training**, 614 Grand Ave., Suite 400, Oakland CA 94610-3523. Telephone: (510) 835-3700. Fax: (510) 625-9307. E-mail: oakland@jba-cht.com. Web: www.centerforhealthtraining.org.

The charge for the three-day Fatherhood Development training workshop (including all materials) is \$600. Check the web site below for 2004 scheduled workshops, with dates to be posted soon. Cost for an on-site workshop is \$15,000. Up to 25 people may attend. For more information, contact:

- **National Partnership for Community Leadership**, 2000 L St. N.W., Suite 815, Washington, DC 20036. Telephone: (202) 822-6725. Fax: (202) 822-569. E-mail: info@npcl.org. Web: www.npcl.org.

Prevention and the Washington, DC-based Department of Health and Human Services (HHS), Office of Population Affairs, through a HHS Region III special initiative grant.

Man2Man uses adult male role models to provide young men with information and support regarding sexual health, disease prevention, child development, relationships with women, and

fathering skills. The program has adapted an existing curriculum, "Fatherhood Development: A Curriculum for Young Fathers," developed by Public Private Ventures and distributed by the National Center for Strategic Non-Profit Planning and Community Leadership (now the National Partnership for Community Leadership), to use as the foundation for the Man2Man program. (See resource box on p. 5 for program information.)

The Man2Man program consists of 15 weekly, two-hour sessions delivered to groups of 10-12 adolescents by a adult male facilitator. Sessions work toward developing personal definitions of manhood, discussing myths and misperceptions about male sexuality, and exploring differences in men's and women's health. Two high schools serve as sites for the program, as well as NET, which serves adjudicated young men through one of its behavioral health programs.

Traditional recruitment strategies, such as announcements over the public address systems and fliers displayed on school bulletin boards, have been used at the high school sites to recruit young men, says **Genevieve Sherrow**, FPC research

associate. At the community-based center, adult male facilitators have distributed informational materials and given formal presentations to probation officers and judges to increase their awareness of the program. Once informed of the program, judges and probation officers can refer young men to Man2Man.

The Man2Man program has just completed its fourth year. Its next goal is to not only enhance its services, but expand its boundaries to other disadvantaged neighborhoods in Philadelphia and other surrounding communities, says Sherrow.

References

1. Raine T, Marcell AV, Rocca CH, et al. The other half of the equation: Serving young men in a young women's reproductive health clinic. *Perspect Sex Reprod Health* 2003; 35:208-214.
2. Frost J, Bolzan M. The provision of public-sector services by family planning agencies in 1995. *Fam Plann Perspect* 1997; 29:6-14.
3. Sherrow G, Ruby T, Braverman PK, et al. Man2Man: A promising approach to addressing the sexual and reproductive health needs of young men. *Perspect Sex Reprod Health* 2003; 35:215-219. ■

Male contraceptives: Research examines options

When you review birth control options with your female patients, you tick off several items: a shot, a patch, an intravaginal ring, intra-uterine devices, barrier methods, and several types of pills. But when it comes to meeting men's reproductive health needs, your list is considerably shorter.

Male contraceptive methods account for almost one-third of all current contraception in the United States, despite having just two effective options: condoms and vasectomy.¹

"Increasing the number of male contraceptive options available will help make men equal partners in family planning, provide additional options for women who are unable to use birth control, and provide more options for population control in a hazardously growing global population," says **John Amory**, MD, assistant professor of medicine at the University of Washington in Seattle. Amory recently presented an update on the status of male contraceptives at the annual meeting of the Washington, DC-based Association of Reproductive Health Professionals, held in La Jolla, CA.²

While researchers have explored several

avenues of contraception for men, moving closer to an actual product has been difficult with no backing from a major pharmaceutical company, he observes.

This scenario is set to change, however; Organon International of Oss, the Netherlands, and Schering AG of Berlin, Germany, are co-sponsoring a Phase III clinical trial of 250 men at 14 sites: the University of Washington; the University of California, Los Angeles; and 12 European sites. The study will look at the use of an etonogestrel implant used with injections of testosterone undecanoate, says Amory.

EXECUTIVE SUMMARY

Male contraceptive methods account for almost one-third of all current contraception in the United States, despite having just two effective options: condoms and vasectomy.

- A Phase III multisite clinical trial is examining the use of a etonogestrel implant used with injections of testosterone undecanoate.
- The Population Council is looking at analogs of lonidamine, an anti-cancer drug, in a potential pill form for male contraception. The council also continues to examine use of its trademarked synthetic androgen, 7alpha-methyl-19-nortestosterone (MENT).

The etonogestrel implant is designed to suppress sperm production in the testes; however, its use can lead to a drop in testosterone concentrations in the blood. To prevent side effects such as loss of libido, researchers have looked at giving testosterone injections. Previously available testosterone preparations required frequent administration; with the long-acting formulation of testosterone undecanoate, researchers may be able to see steady-state drug levels in the bloodstream and a user-friendlier rate of administration.³

The study's design calls for seven different treatment groups, with the injection intervals ranging from six to 12 weeks, with the average injection interval at two months, says Amory. If the results prove promising, research may yield a product in three to four years, he states.

Where's a male pill?

A 2000 survey designed to gauge perceptions of proposed hormonal methods indicate that men are most interested in a contraceptive pill.⁴ The Population Council, a New York City-based research organization, is looking at analogs of lonidamine, an anti-cancer drug.⁵

Researchers have noted one side effect of lonidamine is a temporary, profound disruption of spermatogenesis; however, due to other toxic side effects, lonidamine cannot be used as a contraceptive.⁴ Scientists have since developed two analogs of lonidamine that may help disrupt the process that is essential to the formation and development of sperm.⁶

"We are testing both of those compounds in animals at the moment," says **Regine Sitruk-Ware**, MD, the council's executive director of contraceptive development. "It is very effective and reversible. It is effective when given once a week, so it could also be a more convenient way of administration."

Researchers must complete a full toxicology program before starting any clinical study of the compounds, she notes.

MENT for men?

The Population Council continues to research the potential male contraceptive use of its trademarked synthetic androgen, 7alpha-methyl-19-nortestosterone (MENT). Scientists are studying use of the androgen since it suppresses gonadotropin secretion, which leads to suppression of testosterone and sperm production in the testes. (*Contraceptive*

Technology Update reviewed MENT research in its February 2003 article, "Male contraception: Search is on for options," p. 18.)

Research suggests that MENT acetate implants are a promising method for long-term androgen administration in male contraception.^{7,8} Sitruk-Ware says MENT has an advantage over other testosterone derivatives in that it does not impact the prostate. Further tests are needed to prove its safety and efficacy as a contraceptive.

"It is very well accepted," she notes. "The men who have participated in the studies were very keen to continue the method."

References

1. Alan Guttmacher Institute. *Facts In Brief. Contraceptive Use*. New York City; accessed at www.agi-usa.org/pubs/fb_contr_use.html.
2. Amory JK. Male contraception: Update 2003. Presented at the 40th annual clinical conference of the Association of Reproductive Health Professionals. La Jolla, CA; September 2003.
3. Schwartz JL, Gabelnick HL. Current contraceptive research. *Perspect Sex Reprod Health* 2002; 34:310-316.
4. Martin CW, Anderson RA, Cheng L, et al. Potential impact of hormonal male contraception: Cross-cultural implications for development of novel preparations. *Hum Reprod* 2000; 15:637-645.
5. No author listed. Altering cell bonds in testis may yield contraceptive. *Pop Briefs* 2002; 8:4.
6. Cheng CY, Mo M, Grima J, et al. Indazole carboxylic acids in male contraception. *Contraception* 2002; 65:265-268.
7. Suvisaari J, Moo-Young A, Juhakoski A, et al. Pharmacokinetics of 7 alpha-methyl-19-nortestosterone (MENT) delivery using subdermal implants in healthy men. *Contraception* 1999; 60:299-303.
8. Von Eckardstein S, Noe G, Brache V, et al. A clinical trial of 7alpha-methyl-19-nortestosterone implants for possible use as a long-acting contraceptive for men. *J Clin Endocrinol Metab* 2003; 88:5,232-5,239. ■

Vasectomy research eyes enhancement of method

New developments are arising on the vasectomy front, with researchers taking a look at the effectiveness of different methods of vas deferens occlusion and identifying chemical candidates to help speed up time to vasectomy success.

Vasectomy represents an important contraceptive option in the United States; nearly one in five white U.S. men married to women of childbearing age has undergone the procedure.¹ It is safe and effective: *Contraceptive Technology* estimates

EXECUTIVE SUMMARY

Research is ongoing for vasectomy. Nearly one in five white U.S. men married to women of childbearing age has undergone the procedure.

- Findings suggest that fascial interposition, which calls for the sheath covering the vas to be pulled over one severed end and sewn shut to create a natural tissue barrier, significantly improves the outcomes of vasectomies done with ligation and excision.
- Typical recommendations on how long men should wait before relying on vasectomy using ligation and excision may need to be revised in light of recent findings.
- Scientists are looking at two compounds, diltiazem and methylene blue, as potential vas irrigants to decrease the time between vasectomy and sterility.

the method has about a 0.1% probability of pregnancy in the first year.²

Family Health International (FHI), a Research Triangle Park, NC-based research organization, and EngenderHealth, a New York City-based reproductive health organization, recently have completed a series of studies addressing the effectiveness of different methods of vas occlusion, reports **David Sokal**, MD, FHI associate medical director. In these studies, scientists have looked at sperm counts, rather than pregnancies, to define outcomes.

In a randomized controlled trial, findings suggest that fascial interposition, which calls for the sheath covering the vas to be pulled over one severed end and sewn shut to create a natural tissue barrier, significantly improves the outcomes of vasectomies done with ligation and excision, says Sokal. Partial results have been published,³ with the manuscript reporting the full results of the trial now submitted for publication. (*Contraceptive Technology Update* reported on the initial work in the February 2002 article, "Consider additional vasectomy technique," p. 17.)

Ligation and excision calls for a short segment of the vas (the tube which carries sperm from the testicles to the penis) to be cut and removed, and the remaining two ends tied. It is the most common method of vas occlusion used in developing countries. Recanalization is a spontaneous reconnection of the two ends of the vas that can occur following a vasectomy; data suggest that the risk of recanalization appears to be related to the

surgical technique used for vas occlusion.⁴ The use of more effective surgical techniques, such as fascial interposition and cautery, can reduce this risk, scientists note.

U.S. clinicians are more familiar with cautery, which calls for burning the inside of the ends of the vas, and/or metal clips, often with fascial interposition, says **Amy Pollack**, MD, MPH, EngenderHealth president.

In 1995, about 71% total of the U.S. providers surveyed by EngenderHealth (then known as AVSC International) were using cautery only, or cautery with another technique, she states.⁵ EngenderHealth is performing another survey to obtain an updated view of what techniques are now in use, Pollack says.

Check waiting period

Typical recommendations on how long men should wait before relying on vasectomy using ligation and excision may need to be revised, according to a new study.⁶ Men in developing countries who have had a vasectomy usually are counseled to use a backup method of contraception either for 12 weeks following the vasectomy or until they have ejaculated 20 times.

Researchers in the new study examined 217 men who received ligation and excision vasectomies at three public health clinics in Mexico City. They found that the number of men who reached azoospermia was nearly 20% higher by 12 weeks than by 20 ejaculations.

The researchers also estimated that for every 100 men who undergo a vasectomy by ligation and excision, about 60 will reach azoospermia by 12 weeks, while only about 28 will reach azoospermia by 20 ejaculations. Results from the new study suggest that after use of the ligation and excision method of vasectomy, 12 weeks is a more reliable waiting period than 20 ejaculations. However, neither guideline is ideal, the study reports.⁶ Sokal adds that men should always be counseled that a vasectomy is not 100% effective. Pregnancies do occur after vasectomy procedures, especially among men who do not get a semen analysis to confirm that the procedure was successful, he states.

Contraceptive Technology reinforces this stance, reminding clinicians to counsel men that they are not sterile immediately, and that for many men, sperm will not be cleared from the vas tube until after about 20 ejaculations.¹ The best way for men to determine whether they are sterile is to have a

semen analysis after 20 ejaculations, states the book.¹

Early research suggests that two chemicals now used in the medical field also may inhibit sperm function, which could lead to possible use in washing away residual sperm after a vasectomy.⁷ Use of the chemicals, diltiazem and methylene blue, as vas irrigants could decrease the time between vasectomy and sterility.

Researchers from FHI and the CONRAD program at the Eastern Virginia Medical School in Norfolk looked at five chemical compounds, and examined sperm from human volunteers to determine each chemical's effects on sperm motility, viability, and ability to penetrate cervical mucus. Diltiazem, a calcium-channel blocker used to treat high blood pressure and chest pain, and methylene blue, a compound used to dye the vas during other surgical and diagnostic procedures, were identified as the most promising candidates for vas irrigants.⁷

More research will have to be performed to test the safety and efficacy of these compounds as vas irrigants, say Sokal and Pollack. Even if the compounds are found effective, some clinicians may continue to recommend a three-month waiting period before confirming vasectomy success due to the chance of recanalization, notes Sokal.

References

1. Abma J, Chandra A, Mosher WD, et al. Fertility, family planning, and women's health: New data from the 1995 National Survey of Family Growth. *Vital Health Stat* 1997; 23:62-63.

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

3. Chen-Mok M, Bangdiwala SI, Dominik R, et al. Termination of a randomized controlled trial of two vasectomy techniques. *Control Clin Trials* 2003; 24:78-84.

4. Sokal DC, Irsula B, Chen-Mok M, et al. A comparison of vas occlusion techniques: Cautery vs. ligation and excision with fascial interposition. Presented at the annual meeting of the Association of Reproductive Health Professionals. La Jolla, CA; September 2003.

5. Haws JM, Morgan GT, Pollack AE, et al. Clinical aspects of vasectomies performed in the United States in 1995. *Urology* 1998; 52:685-691.

6. Barone MA, Nazerali H, Cortez M, et al. A prospective study of time and number of ejaculations to azoospermia after vasectomy by ligation and excision. *J Urology* 2003; 170:892-896.

7. Wood BL, Doncel GF, Reddy PR, et al. Effect of diltiazem and methylene blue on human sperm motility, viability and cervical mucus penetration: Potential use as vas irrigants at the time of vasectomy. *Contraception* 2003; 67:241-245. ■

Clinicians change practice when it comes to EC

Your next patient is a young woman who has pressed for an appointment Monday morning after her boyfriend's condom broke on Sunday night. Your formulary calls for use of progestin-only emergency contraception pills (ECPs). What is your next step?

Clinicians who prescribe progestin-only EC are moving to administering a single dose (1.5 mg) of the drug following research conducted by the Geneva-based World Health Organization (WHO) that indicates a single dose of levonorgestrel to be as effective in reducing the risk of pregnancy as two 0.75 mg doses taken 12 hours apart.¹ A Nigerian study corroborated the finding that a single 1.5 mg dose of levonorgestrel is effective and safe.² (*Contraceptive Technology Update* reported on the WHO data in its March 2003 article, "Research eyes options in emergency contraception," p. 30.)

"There is a huge advantage in not having to take a second dose 12 hours later, simply because the regimen is simplified," says James Trussell, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University. He reviewed EC protocols during the recent *Contraceptive Technology* conference in Atlanta.³

The New York City-based Planned Parenthood Federation of America (PPFA) has now revised its medical standards and guidelines to include the new dosing option, according to Vanessa Cullins, MD, MPH, vice president of medical affairs.

EXECUTIVE SUMMARY

Clinicians who prescribe progestin-only emergency contraception (EC) are moving to administering a single dose (1.5 mg) of the drug following research conducted by the World Health Organization that indicates a single dose of levonorgestrel to be as effective in reducing the risk of pregnancy as two 0.75 mg doses taken 12 hours apart.

- Labeling changes already have occurred in Europe for one product, Norlevo, with similar changes scheduled for another drug, Levonelle.
- Research also indicates that EC can prevent pregnancy up to five days (120 hours) after unprotected intercourse in both levonorgestrel and Yuzpe regimens.

"We give our clients a choice about which dosing option they want to use, and we point out the fact that new medical evidence shows that it is just as effective as the two-dosing option and has no more side effects than the other option," she says.

U.S. clinicians have one dedicated progestin-only product, Plan B. The drug is packaged with two 0.75 mg doses, and its package insert calls for the second dose to be taken 12 hours after the first dose. PPEA clinicians point out that the FDA labeling calls for the two doses when counseling on use of Plan B, says Cullins.

Barr Laboratories of Pomona, NY, has entered an agreement with the drug's manufacturer, Washington, DC-based Women's Capital Corp. (WCC), to acquire Plan B, and Barr officials says they will continue to seek regulatory approval to take Plan B over the counter (OTC). **(CTU reported on Barr's move in its December 2003 article, "Barr to acquire Plan B: EC access to expand?" p. 138.)**

"As far as I know the focus now is entirely on Plan B OTC, not on any other label changes," says Trussell.

Labeling changes already have occurred in Europe. HRA Pharma of Paris has received regulatory approval to change its label to simplify the dosage and administration of its Norlevo EC product (levonorgestrel 0.75 mg tablet) from two 0.75 mg doses (one taken as soon as possible after unprotected intercourse and the other 12-24 hours later) to a single two-tablet intake of 1.5 mg.⁴ This change applies to the European Concerned Member States where the drug currently is marketed: as a behind-the-counter/over-the-counter product in France, Belgium, Luxembourg, Switzerland, Portugal, Sweden, Finland, Denmark, Norway; and as a prescription-only product in Spain, Italy, Greece, Netherlands, Germany (where it is marketed as Duofem), and Austria (where it is marketed as Vikela).

Further regulatory procedures soon will extend the label change to the more than 50 countries where Norlevo is available.⁴

"The application for the label change — single intake of the 2 x 0.75-mg tablet — has been filed in all the countries where Norlevo is on the market,

RESOURCE

Review the International Consortium for Emergency Contraception's policy statement on regimen update at its web site, www.cecinfo.org. Click on "Policy Statements" and "Regimen Update: Dosage and Timing;" the document is available in Adobe Portable Document Format.

and it is likely that the change will be approved in all the countries by early 2004," reports **André Ulmann**, MD, PhD, HRA Pharma spokesman.

A similar product, Levonelle, marketed by Schering AG, a Berlin-based pharmaceutical company, is scheduled to have its label revised this month to reflect the new single dosing, reports Trussell. Levonelle is marketed in Australia, Ireland, Italy, New Zealand, Portugal, Spain, and the United Kingdom.⁵

What is your approach when deciding when to administer EC? Research now indicates that ECPs (both levonorgestrel and Yuzpe regimen, marketed in the United States as Preven [Gynetics of Belle Mead, NJ]), can prevent pregnancy up to five days (120 hours) after unprotected intercourse.^{1,6,7} **(Review the latest research findings in the August 2003 article, "Research eyes EC regimens, timing issues," p. 88.)**

Results from the WHO study showed a significant trend toward lower efficacy the longer the delay between treatment and unprotected intercourse, and earlier WHO trials have indicated that pregnancy risk increases over time with delay of treatment,^{1,8} according to information provided by the International Consortium for Emergency Contraception, a 31-member global EC advocacy organization based in Washington, DC.

"These results underscore the importance of providing ECPs to women who seek treatment beyond 72 hours," according to the consortium.⁹ "To maximize the effectiveness of the method, however, women should be encouraged to take ECPs as soon as possible after unprotected intercourse." **(See the resource listing, above, to access the consortium's policy statement on regimen update.)**

COMING IN FUTURE MONTHS

■ Contraceptive effectiveness: How to discuss it

■ Check new approaches to partner management

■ Emergency contraception: Focus on collaborative practice

■ Bacterial vaginosis: Treatment tips

■ Is the contraceptive patch cost-effective?

References

1. Von Hertzen H, Piaggio G, Ding J, et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: A WHO multicentre randomized trial. *Lancet* 2002; 360:1,803-1,810.
2. Arowojolu AO, Okewole IA, Adekunle AO. Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians. *Contraception* 2002; 66:269-273.
3. Trussell J. Emergency contraception: A cost-effective approach to preventing unintended pregnancy. Presented at the Contraceptive Technology: Quest for Excellence conference. Atlanta; October 2003.
4. Norlevo label evolves to reflect simpler, single-intake administration. *Emergency Contraception Newsletter* 2003. Accessed at www.cecinfo.org/files/Newsletter.
5. American Society for Emergency Contraception. *Dedicated ECPs Worldwide*. Updated Sept. 12, 2003. Accessed at www.emergencycontraception.org/asec/ecpillsworldwide.html.
6. Ellertson C, Evans M, Ferden S, et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. *Obstet Gynecol* 2003; 101:1,168-1,171.
7. Rodrigues I, Grou F, Joly J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. *Am J Obstet Gynecol* 2001; 184:531-537.
8. Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998; 352:428-433.
9. International Consortium for Emergency Contraception. Policy Statement. Regimen Update. July 2003. Accessed at: www.cecinfo.org/. ■

CTU UPDATES

News ■ Resources ■ Events

Conferences on tap for *Contraceptive Technology*

Update your knowledge on current issues in reproductive health at the annual *Contraceptive Technology* conference. The Washington, DC, session is scheduled for Feb. 29-March 3, with the San Francisco session set for March 24-27.

Sessions will cover such topics as future methods of contraception, long-term methods of birth control, breast cancer screening, management of abnormal Pap smears, and advances in sexually

transmitted disease testing.

Four preconferences also are scheduled: "Practical GYN Endocrinology," "The Fundamentals of Colposcopy," "Back to Basics: The Fundamentals of Hormonal Contraception," and "Advances in Intrauterine Contraception: IUD Insertion Training." All preconferences will be offered on Feb. 29 in Washington, DC, and March 24 in San Francisco.

"Early-bird" registration deadline is Jan. 19 for the Washington, DC, conference, with Feb. 11 set for the San Francisco conference. Early/regular fees are \$475/\$525 for MD/DOs; \$375/\$525 for nurses, pharmacists, physician assistants, residents, and other health professionals; and \$285 for students.

Registration may be made on-line at www.cforums.com or by calling (800) 377-7707, ext. 3, Monday-Friday, 8 a.m.-5 p.m. (Pacific Time); faxing (800) 329-9923, or mailing to Contemporary Forums, Attention: Registrar, 11900 Silvergate Drive, Dublin, CA 94568. ■

Newsletter binder full?
Call **1-800-688-2421**
for a complimentary
replacement.



CE/CME instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, 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 and 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 with the **June 2004** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

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 “Male contraceptives: Research examines options.”)
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant’s practice area. (See “Meeting the health needs of men: Ensure that your facility stacks up!”)
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See “Vasectomy research eyes enhancement of method,” and “Clinicians change practice when it comes to EC.”)

1. Men in their 20s account for about what percentage of births and abortions in the United States each year?
 - A. 25%
 - B. 35%
 - C. 50%
 - D. 75%
2. What form of testosterone is scheduled to be tested in an upcoming Phase III clinical trial of an etonogestrel implant and testosterone injection?
 - A. Testosterone undecanoate
 - B. Testosterone enanthate
 - C. Testosterone buciclate
 - D. 7 alpha-methyl-19-nortestosterone
3. What are the two compounds identified for further study as potential vas irrigants following vasectomy?
 - A. Lidocaine and methylene blue
 - B. Diltiazem and methylene blue
 - C. Nicardipine and methylene blue
 - D. Diltiazem and nicardipine
4. What is a chief finding of von Hertzen H, et al., Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: A WHO multicentre randomized trial. *Lancet* 2002; 360:1,803-1,810?
 - A. Study results indicate that a single dose of 1.5 mg levonorgestrel can substitute for two 0.75 mg doses 12 hours apart for emergency contraception.
 - B. Study results indicate that a single dose of 1.5 mg levonorgestrel cannot substitute for two 0.75 mg doses 12 hours apart for emergency contraception.
 - C. Study results indicate that a single dose of 1.5 mg desogestrel can substitute for two 0.75 mg doses 12 hours apart for emergency contraception.
 - D. Study results indicate that a single dose of 1.5 mg gestodene can substitute for two 0.75 mg doses 12 hours apart for emergency contraception.

Answers: 1. C; 2. A; 3. B; 4. A.

EDITORIAL ADVISORY BOARD

Chairman:

Robert A. Hatcher, MD, MPH
Senior Author, *Contraceptive Technology*
Professor of Gynecology and Obstetrics
Emory University School of Medicine, Atlanta

David F. Archer, MD
Professor of OB/GYN
The Jones Institute for
Reproductive Medicine
The Eastern Virginia Medical School
Norfolk

Kay Ball, RN, MSA, CNOR, FAAN
Perioperative Consultant/Educator
K&D Medical
Lewis Center, OH

Linda Dominguez, RNC, OGNP
Assistant Medical Director
Planned Parenthood
of New Mexico
Albuquerque

Andrew M. Kaunitz, MD
Professor and Assistant Chair
Department of OB/GYN
University of Florida
Health Sciences Center
Jacksonville

Anita L. Nelson, MD
Medical Director,
Women’s Health Care Clinic
Harbor-UCLA Medical Center
Torrance, CA

Amy E. Pollack, MD, MPH
President, EngenderHealth
New York City

Michael Rosenberg, MD, MPH
Clinical Professor of OB/GYN
and Epidemiology
University of North Carolina
President, Health Decisions
Chapel Hill

Allan Rosenfield, MD
Dean, School of Public Health
Columbia University
New York City

Sharon B. Schnare
RN, FNP, CNM, MSN
Clinician
South Kitsap Family Care Clinic
Port Orchard, WA

Wayne Shields
President & CEO, Association of
Reproductive Health Professionals
Washington, DC

Felicia H. Stewart, MD
Adjunct Professor
Department of Obstetrics,
Gynecology, and Reproductive
Sciences, Co-Director,
Center for Reproductive Health
Research and Policy,
University of California
San Francisco

James Trussell, PhD
Professor of Economics
and Public Affairs
Director, Office of
Population Research
Associate Dean, Woodrow Wilson
School of Public and
International Affairs
Princeton University
Princeton, NJ

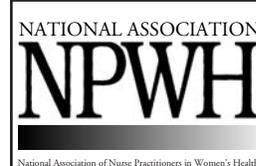
Susan Wysocki, RNC, BSN, NP
President
National Association of Nurse
Practitioners in Women’s Health
Washington, DC

This continuing education offering is sponsored by Thomson American Health Consultants (AHC), which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center’s Commission on Accreditation. Thomson American Health Consultants is an approved provider by the California Board of Registered Nursing for approximately 18 contact hours (provider #CEP10864).

Thomson American Health Consultants (AHC) designates this educational activity for a maximum of 18 hours in Category 1 credit toward the AMA Physician’s Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Thomson American Health Consultants is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. This CME activity was planned and produced in accordance with the ACCME Essentials.

Contraceptive Technology Update is endorsed by the National Association of Nurse Practitioners in Women’s Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.



Web Sites Target Male Information

Searching for male-centered information to boost your facility's services to men? Take a look at the following sites:

1. Men's Health Week. Web: www.menshealthweek.org.

If your facility is trying to build awareness of its male services, you may want to observe Men's Health Week, scheduled this year for June 14-20.

The purpose of Men's Health Week is to heighten the awareness of preventable health problems and encourage early detection and treatment of disease among men and boys.

Men's Health Network, a nonprofit educational organization in Washington, DC, coordinates the annual event, which is now in its 12th year.

2. The Nemours Foundation's KidsHealth. Web: www.kidshealth.org.

Click on "Enter Teens," then "Sexual Health," to see the list of topics addressed for adolescent males. Of particular interest is "Why Do I Need Testicular Exams?" and "A Guy's Guide to Testicular injuries."

The site is operated by the Wilmington, DE-based Nemours Center for Children's Health Media. Its material is copyrighted.

3. National Women's Health Information Center. Web: www.4woman.gov.

Click on "Men's Health" to access a wide range of resources on various male health issues, including reproductive health, fitness and nutrition, prostate health, and HIV/AIDS.

Click on "Screening Tests for Men" to view a chart listing recommended screenings and immunizations for men at average risk for most diseases. Resources marked with an American flag are government property and are freely reproducible.

4. New York Online Access to Health (NOAH). Web: www.noah-health.org.

NOAH, formed by New York City library organizations, provides access to consumer health information in English and Spanish. Click on "Health Topics," then "Men's Health" to see a links to information on many male medical conditions, including penile cancer, testicular cancer, and impotence/erectile dysfunction.

5. National Library of Medicine's MEDLINEplus. Web: medlineplus.gov.

Click on "Health Topics" then "Men's Health Issues" to gather health information from the National Library of Medicine, the world's largest medical library. Under "Male Genital Disorders," surf links on physiology, clinical trials, diagnosis/symptoms, and specific conditions.

6. National Kidney and Urologic Diseases Information Clearinghouse. Web: kidney.niddk.nih.gov.

Click on "Kidney and Urologic Diseases," then "Erectile Dysfunction" to view a freely reproducible publication on the subject. The publication also is available in Spanish. ■