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Crystal methamphetamine use poses sexual health risks in women and men

Study finds male heterosexual drug users engage in risky sex

Call it "crystal," "tina," or "crank," use of crystal methamphetamine is cutting across all socioeconomic and sexual boundaries. How does that affect your family planning facility? A new report reveals that risky sexual behavior under the influence of the drug, which has been reported in men who have sex with men (MSM), also is turning up among heterosexual men.[1]

Researchers in five California counties found that heterosexual men who reported recent methamphetamine use were much more likely to have casual or anonymous sex, anal sex, and sex for money or drugs with female partners than those who did not use the addictive stimulant.[1]

Long reported as a predominant drug problem in the Western United States, methamphetamine abuse now has become a substantial drug problem in other areas of the country as well, according to the National Institute on Drug Abuse (NIDA) in Bethesda, MD.[2] Once associated with white, male blue-collar workers, methamphetamine now is being used by more diverse population groups that change over time and

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A new report reveals that risky sexual behavior under the influence of crystal methamphetamine, which has been reported in men who have sex with men, also is turning up among heterosexual men.

- Researchers in five California counties found that heterosexual men who reported recent methamphetamine use were much more likely to have casual or anonymous sex, anal sex, and sex for money or drugs with female partners than those who did not use the addictive stimulant.
- Methamphetamine use makes many users feel hypersexual and uninhibited. This loss of inhibition puts users at risk for sexually transmitted diseases and, in the case of heterosexual women, unplanned pregnancies.

differ by geographic area.[2] Case in point: Crystal meth use has been noted among patients attending Planned Parenthood of Central and Northern Arizona in Phoenix, says agency spokeswoman **Melissa Fink**.

Methamphetamine use makes many users feel hypersexual and uninhibited.[3] This loss of inhibition puts users at risk for sexually transmitted diseases (STDs) and, in the case of heterosexual women, unplanned pregnancies.[4] For many women, the drug often is seen as the answer to the conflicting demands that come with the role of "super mom" — work, child care, cooking, cleaning, and companionship.[4]

Public health officials are concerned about the relationship between crystal meth use and new HIV infections. Researchers at the Centers for Disease Control and Prevention, the University of California San Francisco, and the San Francisco Department of Public Health showed that crystal meth users were three times more likely to get HIV-infected than nonusers.[5] Among those who reported crystal meth use during sex, the likelihood was nearly four times as high, investigators found.[5]

To combat the problem in San Francisco, Mayor Gavin Newsom and Supervisor Bevan Dufty appointed a citywide Crystal Meth Task Force in 2005. Responses from the task force should be forthcoming, says **Jeffrey Klausner**, MD, MPH, director of the STD Prevention and Control Services at the San Francisco Department of Public Health.

The task force already has considered the use of meth broadly, that is, in groups outside of gay men and other men who have sex with men including transgender people, women, youth, and vulnerable groups, such as the homeless and mentally ill, reports Klausner. The task force's upcoming recommendations will be aimed at the breadth of the using and at-risk population but remain prioritized among those populations most affected, he notes.

"That response should emphasize prevention and treatment over criminalization and enhanced enforcement," states Klausner. "It is a public health problem, not one of public safety; thus, it requires a response framed in public health."

Understand the problem

According to NIDA, amphetamines are the most potent of the stimulant drugs in increasing dopamine levels, more than three times that of cocaine.[2] Since crystal methamphetamine can be synthesized from over-the-counter ingredients, the drug has been easy to access. Law enforcement officials have battled the rise of home-based methamphetamine labs as well as illicit drug importation from Mexico.[3]

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NIDA reports show indicators of methamphetamine abuse have persisted at high levels in the Western United States, including Honolulu, Seattle, San Francisco, Los Angeles, and San Diego, and have increased in several areas through 2003-2004, including Colorado, Phoenix, Atlanta, and Minneapolis/St. Paul.[2] In Minneapolis/St. Paul, primary treatment admissions for methamphetamine as a percent of illicit drug treatment admissions increased from 10.6% to 18.7% from 2001 to 2004; while in Atlanta, primary methamphetamine admissions represented nearly 11% of the illicit drug treatment admissions in the first half of 2004, compared to 6.7% and 6.9% in 2002 and 2003.[2]

Meet the challenge

How can reproductive health providers address the crystal methamphetamine crisis? AIDS Project Los Angeles (APLA) has instituted a Crystal CLEAR support program for friends and family members concerned for a loved one in their life who is using the drug.

APLA began its crystal methamphetamine program to address the increasing evidence that users of the drug may be at a higher risk for STDs and HIV, explains **Justin Burke**, APLA communications manager. The program creates and coordinates free community forums and two sets of training: one for crystal users, and one for their friends and sexual partners.

The program is designed to meet the needs of users and their social affiliates, because the drug too often leads to social isolation, he notes. The affiliates' support group provides education and prevention through facilitated group discussion and expert presentations, as well as through role play and similar group activities, says Burke. One of the primary techniques explored in the group is motivational interviewing, which is a nonconfrontational and supportive approach to communication.

Members of the affiliates' group meet for four two-hour sessions over the course of a month. APLA also offers a monthly follow-up meeting for affiliates who have completed all four sessions and have received the Social Affiliate Certificate issued by APLA. The follow-up meeting provides an opportunity for the group to share feedback and best practices based on their experiences in applying motivational interviewing techniques with the user in their life, says Burke.

"Our affiliates' support group is based on a harm reduction model; in other words, we acknowledge use of the drug and provide information and tips that help the user's loved ones identify problematic behaviors that the user may want to change," he states. "We teach them skills that will help promote the physical, sexual, and mental health of the user until the user is ready to access treatment."

Launched in last August, the affiliates support group has been positively received by clients, reports Burke. Although the group is open to anyone, male or female, HIV-positive or negative, the target population remains gay and bisexual men, so there have been some growing pains as APLA attempts to reach people from all backgrounds, he states.

"We have had several success stories, as well as growth in participation, as we come together to deal with the devastation caused by crystal meth," says Burke.

In San Francisco, major efforts at integrating substance use services and STD/HIV prevention have been made over the past year and a half, reports Klausner. Progress has been made, not as quickly as most would like, but the direction is clear, he states.

"Trainings have occurred for both types of providers: STD/HIV training for substance use providers, and substance use training — in particular meth — for STD/HIV care providers," says Klausner. "They have all been very well received, extremely well attended, and clearly met an important gap in provider capacity."

References

1. Centers for Disease Control and Prevention (CDC). Methamphetamine use and HIV risk behaviors among heterosexual men — preliminary results from five northern California counties, December 2001-November 2003. *MMWR* 2006; 55:273-277.

2. National Institute on Drug Abuse. Medications Development Research for Treatment of Amphetamine and Methamphetamine Addiction — Report to Congress, August 2005. Accessed at: www.drugabuse.gov/about/Legislation/MethReport/Index.html.

3. Jefferson DJ. America's most dangerous drug. *Newsweek* Aug. 8, 2005. Accessed at: www.msnbc.msn.com/id/8770112/site/newsweek/.

4. Sullivan S. Women and crystal meth. *Choice!* March 20, 2006. Accessed at: www.plannedparenthood.org/pp2/portal/files/portal/webzine/sexualityhealth/feas-060320-meth-women.xml.

5. Buchacz K, McFarland W, Kellogg TA, et al. Amphetamine use is associated with increased HIV incidence among men who have sex with men in San Francisco. *AIDS* 2005; 19:1,423-1,424. ■

AIDS drugs may hold HIV prevention promise

Early research in rhesus monkeys indicates that a combination of two AIDS treatment drugs, tenofovir (TDF, Viread, Gilead; Foster City, CA) and emtricitabine (FTC, Emtriva; Gilead), may be effective in HIV prevention.[1] Led by researchers from the Centers for Disease Control and Prevention (CDC), the findings may be the strongest animal data yet to suggest that the antiretroviral combination given before HIV exposure may prevent sexual HIV transmission.

Research of the drug combination is just one approach scientists are examining to stem the AIDS epidemic. The need for effective prevention tools is great: More than 5 million people worldwide are infected with the HIV virus each year; an estimated 40,000 Americans become infected on an annual basis, according to the CDC.[2]

There are currently three CDC trials designed to answer important questions about the safety and efficacy of pre-exposure prophylaxis (PREP) among populations at high risk for HIV infection, according to **Terry Butler**, CDC spokeswoman.

CDC has two studies of tenofovir PREP well under way, including a safety and efficacy trial among injection drug users in Thailand and an extended safety trial among men who have sex with men (MSM) in the United States, reports Butler. These studies will provide the first answers to whether with tenofovir alone is safe and effective in reducing HIV infection, she says.

The Thailand trial likely will produce the first data on the efficacy of PREP in humans, says Butler. Results may be available as soon as 12-18 months, she notes. Results from the U.S. trial will follow and provide data on the acceptability and behavioral safety of a daily PREP regimen in general, as well as the clinical safety of tenofovir among uninfected individuals.

Family Health International (FHI) of Research Triangle Park, NC, also is looking at the use of tenofovir in HIV prevention. Supported by a grant from the Bill & Melinda Gates Foundation of Seattle, researchers are looking at the drug's safety and effectiveness in preventing HIV infection in women from the West African country of Ghana who are at high risk of HIV infection.

The data analysis for the Ghana site was scheduled to be completed in mid-May, says **Beth Robinson**, deputy director for research dissemination at FHI. FHI is planning to share study findings in August at the Toronto International AIDS Conference, she reports.

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- The Centers for Disease Control and Prevention has planned three trials to look at the safety and efficacy of pre-exposure prophylaxis of tenofovir among populations at high risk for HIV infection.
- Family Health International also is looking at the use of tenofovir in HIV prevention.

Why test existing drugs?

Why look at existing AIDS drugs for HIV prevention? Research suggests that an antiretroviral drug, taken on a regular basis, may prove effective in reducing a person's risk for infection:

- A single dose of nevirapine (Viramune, Boerhinger Ingelheim, Ingelheim, Germany) to HIV-infected women during labor and to their newborns immediately after birth has been shown to almost halve the risk for mother-to-child transmission of HIV.[3]
- Zidovudine (Retrovir, GlaxoSmithKline, Research Triangle Park, NC), taken soon after exposure and continued for several weeks, has been associated with an 80% reduction in the risk of HIV infection among health care workers after needlesticks or other accidental exposures.[4]
- Animal studies have shown that tenofovir, administered before and immediately after a single retroviral exposure, can prevent the transmission of a virus similar to HIV in monkeys.[5]

Combination eyed

Why is the CDC looking at a tenofovir-plus regimen using the TDF/FTC combination?

"There are now significant data suggesting the promise of both of these regimens [TDF alone, and TDF plus FTC] for different types of exposure," says Butler. "Because we don't yet know for sure how the animal data will correlate to human protection, we believe it is essential to move forward

as quickly as possible to evaluate both of these extremely promising interventions."

The CDC is retooling plans for a Botswana, Africa trial designed to examine heterosexual HIV transmission to evaluate a tenofovir plus FTC regimen, says Butler. CDC researchers also are planning a safety study of the tenofovir plus FTC regimen in the United States. Study details have not yet been finalized, says Butler.

While the promise of PREP is enticing, public health officials do not see it as the only tool in the war against AIDS. The impact of PREP, if proven safe and effective, will be determined by how effectively it is combined with other strategies to provide the greatest protection. The CDC would not recommend it as a first-line defense against HIV, as no biomedical strategy is likely to be 100% effective, says Butler.

"PREP would need to be combined with reduction in sexual partners, HIV counseling and testing, consistent and correct condom use, and other prevention measures," Butler observes. "Even a high level of efficacy could be offset by increases in other risk behaviors, so it will be critical to guard against the abandonment of other, highly effective strategies."

References

1. Garcia-Lerma J, Otten R, Qari S, et al. Prevention of Rectal SHIV Transmission in Macaques by Tenofovir/FTC Combination. Presented at the 13th Conference on Retroviruses and Opportunistic Infections. Denver; February 2006.
2. Centers for Disease Control and Prevention. *CDC's Clinical Studies of Daily Oral Tenofovir for HIV Prevention*. Fact sheet. June 2005.
3. Guay LA, Musoke P, Fleming T, et al. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999; 354:795-802.
4. Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *N Engl J Med* 1997; 337:1,485-1,490.
5. Otten RA, Smith DK, Adams DR, et al. Efficacy of post-exposure prophylaxis after intravaginal exposure of pig-tailed macaques to a human-derived retrovirus (human immunodeficiency virus type 2). *J Virol* 2000; 74:9,771-9,775. ■

At-risk teens? Help them to 'get teSTeD'

When it comes to sexually transmitted diseases (STDs), new data released by the American Social Health Association (ASHA) in Research Triangle Park, NC, shows that the average age of people who are tested for chlamydia is 28.9 for women and 30.5 for men.[1] Yet the Centers for Disease Control and Prevention (CDC) reports 79% of new chlamydial infections occur in people between ages 15 and 24.[2] How can providers get the STD prevention message to those most at risk: sexually active adolescents?

Urge teens to "Get teSTeD," a new campaign developed by ASHA. The initiative, developed in time for the April 2006 observance of National STD Awareness Month, encourages those who are sexually active to get tested in an effort to reduce the spread of STDs. As part of the campaign, ASHA has developed a new brochure, *STDs, The Real Deal*, which provides advice to teens who might feel uncomfortable talking about sex and STDs with their provider. It lists information about STDs, testing sites, and how teens can protect themselves through the use of condoms. **(See the resource box on p. 66 for access and order information.)**

ASHA has developed two web sites, **www.iwannaknow.org** and **www.quierosaber.org** (a Spanish-language counterpart), both which have been written for and tested by teens, says **James Allen**, MD, MPH, ASHA president and chief executive officer. These web sites get more than 250,000 annual visitors as young people gather the information they need to make healthy decisions, he notes. ASHA also answers thousands of e-mails each year from adolescents who are searching for

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The American Social Health Association (ASHA) has developed a new initiative, "Get teSTeD," to encourage teens who are sexually active to get tested in an effort to reduce the spread of sexually transmitted diseases (STDs).

- ASHA has developed a brochure, *STDs, The Real Deal*, which provides advice to teens who might feel uncomfortable talking about sex and STDs with their provider. It lists information about STDs, testing sites, and how teens can protect themselves with condoms.
- In talking with teens, emphasize that everyone who is sexually active, including those engaging in oral, anal, and vaginal sex, should get tested for STDs. Many teens do not believe that oral sex is a risk factor for STD transmission.

RESOURCE

To download a free copy of the American Social Health Association brochure, ***STDs, The Real Deal*,** visit the organization's web site, www.asha std.org. Click on the "Get TeSTeD" logo; the brochure is available in English and Spanish. Printed brochures are $17.50 (for 50), plus shipping and handling; for 1,000 or more, discounts begin at 15%. Call (800) 783-9877 for a direct quote on quantity discounts. Shipping and handling charges are $0-59, $5; $60-$499, 9%; more than $500, 7%. For orders outside the United States and Canada, add 20%. Orders may be mailed to ASHA Customer Service, P.O. Box 13827, Research Triangle Park, NC 27709, or faxed to (919) 361-8430, Attention: Customer Service.

information that is complete and nonjudgmental, yet accurate, says Allen.

Focus in on chlamydia

When it comes to STDs in adolescents, chlamydial infection is of particular concern. Like other common STDs, chlamydia typically has mild symptoms such as an abnormal vaginal discharge or a burning sensation when urinating, or none at all.[3] If left untreated, up to 40% of women with chlamydia develop pelvic inflammatory disease, which can result in infertility.[4]

In the first nationally representative study of chlamydia prevalence in the general adult population (ages 14-39), CDC researchers found nearly one in 20 women between the ages of 14-19 (4.6%) were infected — the highest proportion of any age group.[5] Among men, 20- to 29-year-olds were most heavily affected, with a prevalence of 3.2%.[5] The findings were based on responses from participants in the National Health and Nutrition Examination Survey from 1999 to 2002.

What's 'the real deal'?

When talking with adolescents about STD prevention, health care providers should emphasize that everyone who is sexually active, including those engaging in oral, anal, and vaginal sex, should get tested for STDs, says **Peter Leone**, MD, medical director of the HIV/STD Prevention and Control Branch of North Carolina's Department of Health and Human Services in Raleigh. Most sexually transmitted infections are associated with little to no symptoms, yet can lead to future complications and disease, says Leone.

"Adolescents often do not realize that they can get and spread STDs through oral sex," notes Leone. "Many do not consider oral sex to be 'sex'; however, this behavior is becoming increasingly common in this age group."

Recent information from the National Survey of Family Growth underlines Leone's concern. Its data reveals that about one in four teens ages 15 to 19 who have not had sexual intercourse report oral sex with an opposite sex partner.[2] **(See the December 2005 *Contraceptive Technology Update* article, "New national data in: Oral sex gaining ground among adolescents," p. 137, for a review of the statistics.)** As a result, adolescents must know what tests to ask for, identify testing sites in their area, and learn how to protect themselves through the use of condoms, says Leone.

References

1. American Social Health Association. New Data Indicate Few Young Americans Tested for Common STD. Press release. March 28, 2006.
2. Mosher WD, Chandra A, Jones J. Sexual behavior and selected health measures: Men and women 15-44 years of age, United States, 2002. *Adv Data* 2005; 362:1-55.
3. Weinstock H, Berman S, Cates W. Sexually transmitted diseases among American youth: Incidence and prevalence estimates, 2000. *Perspect Sex Reprod Health* 2004; 36:6-10.
4. Rein D, Kassler W, Irwin K, et al. Direct medical cost of pelvic inflammatory disease and its sequelae: Decreasing, but still substantial. *Obstet Gynecol* 2000; 95:397-402.
5. Datta SD, Sternberg M, Johnson R, et al. Prevalence of chlamydia and gonorrhea in the United States among persons aged 14-39 years, 1999-2002. Presented at the 16th biennial meeting of the International Society for Sexually Transmitted Diseases Research. Amsterdam, the Netherlands; July 2005. ■

Where does your state stand on EC in the ED?

A new patient tells you that she is a recent victim of sexual assault. What care was she provided when she underwent treatment at your local hospital's emergency department (ED)?

There is a good chance she was not offered emergency contraception (EC). According to results from a 2005 national telephone survey of 615 non-Catholic hospitals and 587 Catholic hospitals, ED staff answering the telephone at 42% of the non-Catholic hospitals and 55% of Catholic hospitals

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Sexual assault groups, legislative officials, medical groups, women's health advocates, and civil liberties groups throughout the country have launched statewide campaigns to urge governors and other state officials to adopt protocols for treating sexual assault survivors that ensure access to emergency contraception.

- According to results from a 2005 national telephone survey of 615 non-Catholic hospitals and 587 Catholic hospitals, emergency department (ED) staff answering the telephone at 42% of the non-Catholic hospitals and 55% of Catholic hospitals said their department does not dispense emergency contraception under any circumstance.
- Twelve states have introduced bills this year in an effort to get emergency contraception in EDs.

said their department does not dispense emergency contraception under any circumstance. The survey was conducted by Ibis Reproductive Health, a Cambridge, MA-based women's reproductive health research and advocacy organization.[1]

In 2004, the Department of Justice published the first-ever national medical guidelines for sexual assault treatment; however, no mention of EC was included in the document.[2] ***(Contraceptive Technology Update* reported on the omission in the May 2005 article, "EC in the ED: What is your state's policy?" p. 59.)** According to the American Civil Liberties Union (ACLU) Reproductive Freedom Project, based in New York City, the Department of Justice ignored requests filed in 2005 by advocates and members of Congress to amend the publication's protocol to include information about EC and pregnancy prevention. In August 2005, the ACLU sent a Freedom of Information Act request to the federal government on behalf of a broad coalition asking for documents that explain the omission of information about EC from the protocol; however, the government failed to provide responsive materials, according to the ACLU.[2]

Sexual assault groups, legislative officials, medical groups, women's health advocates, and civil liberties groups throughout the country have launched statewide campaigns to urge governors and other state officials to adopt protocols for treating sexual assault survivors that ensure access to emergency contraception.

Advocates are looking to states to get EC in the ED: 12 states have introduced bills this year, according to **Jennifer McAllister-Nevins**, state strategies attorney for the ACLU Reproductive Freedom Project. The states are Arizona, Connecticut, Florida, Hawaii, Illinois, Minnesota, Missouri, Pennsylvania, South Dakota, Tennessee, Wisconsin, and West Virginia. "We don't know if any of these are moving, but we expect that state legislatures will recognize the importance of providing appropriate care to rape victims," she says.

In addition, advocates in Alaska, Colorado, Idaho, New Hampshire, Oklahoma, Pennsylvania, and Wyoming have issued letters asking their governors and other state officials to "act where the federal government has failed to, making certain that [their state] protocol recommends victims of sexual assault be offered emergency contraception on-site in their initial exam."[3] The letters also ask for officials to advocate for increased funding in their state for medical staff that specialize in treating sexual assault patients.[3]

Through this project, reproductive rights advocates around the country have joined forces with sexual assault victims' advocates to ensure rape victims receive appropriate care in the ED, explains McAllister-Nevins. The states that participated in the letter-writing campaign did so because they believe that writing letters to state official to include emergency contraception in their state sexual assault protocols is an effective way to ensure rape victims receive the care they need, she notes.

Reproductive rights advocates and sexual assault victims' advocates are continuing to work together to increase access to EC for rape victims, including efforts in states that did not participate in the original letter-writing campaign, says McAllister-Nevins.

Use the toolkit

Nine states now require hospital EDs to provide EC-related services to sexual assault victims, according to the Alan Guttmacher Institute in New York City.[4] Eight states — California, Illinois, Massachusetts, New Jersey, New Mexico, New York, Texas, and Washington — require EDs to provide information about EC. Seven states — California, Massachusetts, New Jersey, New Mexico, New York, South Carolina, and Washington — require EDs to dispense EC on request to assault victims. While Ohio and Oregon have EC in the ED policies, neither have an enforcement mechanism in place.[4]

While progress has been made on the state front, there still is room for improvement, says **Carol Petraitis**, director of the Clara Bell Duvall

RESOURCE

To access the publication "Preventing Pregnancy from Sexual Assault: Four Action Strategies to Improve Hospital Policies on Provision of Emergency Contraception," go to the Clara Bell Duvall Reproductive Freedom Project web site, www.aclupa.org/duvall. Click on "Duval Project Publications," then "EC toolkit," to download the publication.

Reproductive Freedom Project at the Philadelphia-based American Civil Liberties Union of Pennsylvania. According to a just-released survey conducted by Ibis Reproductive Health for the Washington, DC-based Catholics for a Free Choice, staff at 35% of Catholic hospitals in New York, California, South Carolina, and Washington state — three states with EC in the ED legislation on the books — refused to provide emergency contraception to women who requested it.[5]

If your state does not have EC legislation, take a look at "Preventing Pregnancy from Sexual Assault: Four Action Strategies to Improve Hospital Policies on Provision of Emergency Contraception," a joint publication of the National Sexual Violence Resource Center Education in Enola, PA, the Education Fund of the Albany, NY-based Family Planning Advocates of New York State, and the Clara Bell Duvall Reproductive Freedom Project. **(See the resource box, this page, to learn how to access the publication.)** It offers information on how to assess the need for EC in your state's EDs, as well as how to build coalitions among reproductive health advocates and sexual assault victim organizations.

About 25,000 American women become pregnant each year following an act of sexual violence; as many as 22,000 of these pregnancies could be prevented through the prompt use of emergency contraception.[6] Know that the number of women who visit an ED following a sexual assault represent only a "tiny fraction" of the number who have been assaulted, says Petraitis. Increasing access to emergency contraception through legislation, pharmacy access, and other efforts is important to help reach these women, she adds.

References

1. Harrison T. Availability of emergency contraception: A survey of hospital emergency department staff. *Ann Emerg Med* 2005; 46:105-110.

2. U.S. Department of Justice. Office of Violence Against Women. *National Protocol for Sexual Assault Medical Forensic Examinations. Adults/Adolescents*. Washington, DC; September 2004.

3. American Civil Liberties Union Reproductive Freedom Project. Advocates throughout the Country Urge States to Ensure Access to Emergency Contraception for Rape Victims. Press release. Jan. 19, 2006. Accessed at: www.aclu.org/reproductiverights/contraception/23543prs20060119.html.

4. Alan Guttmacher Institute. *State Policies in Brief. Emergency Contraception*. April 1, 2006. Accessed at: www.guttmacher.org/statecenter/spibs/spib_EC.pdf.

5. Ibis Reproductive Health for Catholics for a Free Choice. Complying with the Law? How Catholic Hospitals Respond to State Laws Mandating The Provision of Emergency Contraception to Sexual Assault Patients. Washington, DC. January 2006.

6. Stewart FH, Trussell J. Prevention of pregnancy resulting from rape: A neglected preventive health measure. *Am J Prev Med* 2000; 19:228-229. ■

Mifepristone ruled out in one of two deaths

The Food and Drug Administration (FDA) has ruled out mifepristone (Mifeprex, Danco Laboratories, New York City) as the cause in one of two recent deaths of women who had taken the drug. The agency is continuing to investigate the other death.[1]

The FDA issued a March 17 public health advisory in light of the two reported deaths. The advisory comes after reports of four previous U.S. deaths from serious bacterial infection and sepsis following use of the medication abortion regimen. According to a 2005 report, the four earlier

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- Four earlier deaths have been linked to toxic shock caused by the bacterium *Clostridium sordellii*. The FDA has tested batches of Mifeprex and misoprostol and has not found any contamination with the type of bacteria involved in the four cases.
- Results from a May public workshop on emerging clostridial disease sponsored by three federal agencies may provide possible answers to the health issues surrounding the deaths.

deaths were linked to toxic shock caused by the bacterium *Clostridium sordellii*.[2] The FDA has tested batches of Mifeprex and misoprostol and has not found any contamination with the type of bacteria involved in the four cases.

Health officials are looking to results from a May 2006 public workshop on emerging clostridial disease sponsored by the FDA, National Institute of Allergy and Infectious Diseases, and the Centers for Disease Control and Prevention (CDC) to provide possible answers to the health issues surrounding the deaths.

The workshop is intended to develop a draft research agenda to better understand the virulence, pathogenesis, host factors, and nonantimicrobial risk factors contributing to reports of morbidity and mortality associated with *Clostridium sordellii* and *Clostridium difficile*, says **Pam Long**, Danco Laboratories spokeswoman. Representatives from Danco are scheduled to attend the meeting, she adds.

About 575,000 women in the United States have used Mifeprex since the FDA approved the drug in 2000. Reports of fatal sepsis in women undergoing medical abortion are very rare: about one in 100,000, according to the agency. Danco Laboratories is working closely with the FDA, CDC, health care providers, and other medical experts to understand the circumstances surrounding these events, says Long.

Changes in protocol?

In issuing the March 2006 advisory, the FDA reiterated the approved Mifeprex regimen for a medical abortion through 49 days' pregnancy:

- **Day One: Mifeprex Administration:** Three tablets of 200 mg Mifeprex orally at once.
- **Day Three: Misoprostol Administration:** Two tablets of 200 mcg misoprostol orally at once.
- **Day 14: Post-Treatment:** The patient must return to confirm that a complete termination has occurred. If not, surgical termination is recommended to manage medication abortion treatment failures.[3]

Many medication abortion providers have used vaginal administration of misoprostol in "off-label" practice following research indicating effectiveness of the delivery method.[4-7] Following the FDA public health advisory, the Planned Parenthood Federation of America (PPFA) said it would no longer offer vaginal administration of misoprostol in its medication abortion procedures.

"Patients will now receive misoprostol orally or buccally [where the pill is placed between the cheek and gum and dissolves]," says **Vanessa Cullins**, MD, MPH, PPFA vice president for medical affairs. "This change in protocol is effective immediately."

The National Abortion Federation has updated its protocol for use of mifepristone/misoprostol in early abortion.[8] The organization continues to support a variety of regimens, including vaginal administration of misoprostol.[9]

Be alert for symptoms

All providers of medical abortion and emergency department health care providers should be alert for the possibility of sepsis in patients who are undergoing medical abortion and present with nausea, vomiting, or diarrhea and weakness with or without abdominal pain, and without fever or other signs of infection more than 24 hours after taking misoprostol, according to the FDA. Strong consideration should be given to obtaining a complete blood count to help identify patients with hidden infections, the FDA advises.

If patients do present with the described symptoms, the FDA recommends that providers consider immediate initiation of antibiotic treatment that includes coverage of anaerobic bacteria such as *Clostridium sordellii*.

When it comes to use of prophylactic antibiotics, the FDA says it does not have sufficient information to recommend the use of drug treatment. Prophylactic antibiotic use can be dangerous: Some patients may have severe or fatal allergic drug reactions, and high use of antibiotics can lead to bacterial resistant to such drugs, notes the FDA.

References

1. Bridges A. RU-486 Ruled Out in 1 of 2 Recent Deaths. *Washington Post*; April 10, 2006. Accessed at: www.washingtonpost.com/wp-dyn/content/article/2006/04/10/AR2006041000829.html.
2. Fischer M, Bhatnagar J, Guarner J, et al. Fatal toxic shock syndrome associated with *Clostridium sordellii* after medical abortion. *N Engl J Med* 2005; 353:2,352-2,360.
3. Food and Drug Administration. FDA Public Health Advisory. Sepsis and Medical Abortion Update. Accessed at: www.fda.gov/cder/drug/advisory/mifeprex200603.htm.
4. Schaff EA, Eisinger SH, Stadalius LS, et al. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. *Contraception* 1999; 59:1-6.
5. Schaff EA, Fielding SL, Eisenger SH, et al. Low-dose mifepristone followed by vaginal misoprostol at 48 hours for abortion up to 63 days. *Contraception* 2000; 61:41-46.
6. Schaff EA, Fielding SL, Westhoff C. Randomized trial of oral vs. vaginal misoprostol at one day after mifepristone

or early medical abortion. *Contraception* 2001; 64:81-85.

7. Schaff EA, Fielding SL, Westhoff C, et al. Vaginal misoprostol administered 1, 2, or 3 days after mifepristone for early medical abortion: A randomized trial. *JAMA* 2000; 284:1,984-1,953.

8. National Abortion Federation. *NAF Protocol for Mifepristone/Misoprostol in Early Abortion*. Revised March 2006. Accessed at: www.prochoice.org/pubs_research/publications/downloads/professional_education/medical_abortion/protocol_mife_miso.pdf.

9. National Abortion Federation. Medical abortion update. Clinicians for Choice 2006; accessed at: www.prochoice.org/cfc/newsletter.html#5. ■

Check your approach to vaginal symptoms

EXECUTIVE SUMMARY

Women's health providers are taught to use the classic approach in evaluating vaginal symptoms, examining discharge characteristics as well as performing pH tests, whiff test, and microscopy with both normal saline and potassium hydroxide (KOH).

- Research indicates that providers often do not employ all of the steps and rely on symptoms alone to diagnose and treat women.
- Self-care of vaginal symptoms is employed by many women. A new noninvasive diagnostic test, Fem-V, has been developed to assist women in diagnosing vaginal infections at home. Test results will help women determine if an over-the-counter treatment may be considered or if they should seek professional care.

Check the chart of your next patient. She says she has vaginal itching and irritation, odor, and vaginal discharge. What is your next step?

Vaginal complaints are the most common reason for gynecological consultation, accounting for about 10 million office visits each year.[1] When it comes to managing vaginal symptoms, women's health providers are taught to use the classic approach in evaluating vaginal symptoms, examining discharge characteristics as well as performing pH tests, whiff test, and microscopy with both normal saline and potassium hydroxide (KOH).[2] But how often do providers follow all of the steps, and how effective are they in diagnosis of vaginal symptoms?

According to an Internet survey of 556 nurse practitioners and 608 physicians, while most providers conduct a physical examination before treatment, performance of a wet mount, whiff test, and pH are done less commonly.[2] While about 60% of providers said they always or often test for gonorrhea and chlamydia, only about one-third did a culture for *Candida albicans*, which accounts for about 20%-25% of all cases of vaginitis.[1]

Basing diagnoses simply on vaginal symptoms can pose problems in effective treatment.[3] Telephone consultations for vaginitis often result in misdiagnosis.[4] Evidence suggests that telephone diagnosis and management of vaginitis/vaginosis symptoms is often not accurate. In a study of 253 patients, investigators found that providers' diagnostic accuracy was poor; telephone diagnosis for trichomonas, bacterial vaginosis, and yeast was inaccurate most of the time when compared with microscopic findings.[5]

The time is ripe for new approaches to diagnosing and treating vaginal symptoms, says **Matthew Anderson**, MD, assistant professor in the department of family and social medicine at the Albert Einstein College of Medicine of Yeshiva University in New York City.

"Most doctors do not follow the [diagnostic] algorithm, so the real question is, is the diagnostic algorithm relevant?" he says.

Anderson is preparing to do a randomized pilot study, where one arm of the study will have women who receive the entire algorithm: wet mount, pH test, and whiff test. In the other arm, women will be treated empirically, says Anderson. Women will be rechecked for symptoms after two weeks.

Anderson and fellow researchers performed a structured literature review for information on sensitivity and specificity for symptoms, signs, and office laboratory procedures using the terms *diagnosis with vaginitis*, *vaginal discharge*, *candidiasis*, *bacterial vaginosis*, and *trichomoniasis*.[6] They found that while the cause of vaginal complaints

COMING IN FUTURE MONTHS

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may be easily diagnosed when typical findings appear in microscopy, the poor performance of individual symptoms, signs, and office laboratory tests often makes it problematic to identify the cause of vaginal symptoms.

"Vaginal symptoms may be the most common gynecological complaint in primary care, but much remains to be learned about their clinical diagnosis," the researchers state.[6]

Self-care eyed

In 2002, women in the United States spent more than a half-billion dollars on medications to treat vulvovaginal candidiasis; about half of this amount was spent on over-the-counter preparations.[7]

Can women determine for themselves the appropriate care for vaginal symptoms? Researchers surveyed 552 women ages 16 and older on the classical signs of pelvic inflammatory disease, bacterial vaginosis, acute cystitis, vaginal trichomoniasis, and vulvovaginal candidiasis (VVC). Of the 552 surveyed, 365 of the women reported a prior VVC diagnosis. However, only 34.5% of them could correctly identify VVC symptoms in the survey.[8]

Synova Healthcare of Media, PA, is launching a new at-home test called Fem-V, a noninvasive diagnostic test developed to assist women in diagnosing vaginal infections at home. The test uses a detection strip attached to a panty liner to test the pH and dilution of vaginal discharge. Test results will help women determine if an over-the-counter treatment may be considered or if they should seek treatment from a health care professional, according to the company.

The product, to be sold in retail pharmacies, was scheduled for a May 2006 launch as of *CTU* press time. The over-the-counter test carries a retail price of $7.99, according to **Patty Bowman**, Synova's vice president of marketing.

References

1. Kent HL. Epidemiology of vaginitis. *Obstet Gynecol* 1996; 165:1,168-1,176.

2. Anderson MR, Karasz A. How do clinicians manage vaginal complaints? An Internet survey. *MedGenMed* 2005; 7:61.

3. Allen-Davis, JT. Why we can't diagnose based on symptoms alone. In: *Optimal Diagnosis of Vaginitis*. *OBG Management* 1998; November:1S-5S.

4. MacNeil JS. Diagnose vaginitis by exam, not by phone. *OBG Management* 2005; 40:26.

5. Allen-Davis JT, Beck A, Parker R, et al. Assessment of vulvovaginal complaints: Accuracy of telephone triage and in-office diagnosis. *Obstet Gynecol* 2002; 99:18-22.

6. Anderson MR, Klink K, Cohrssen A. Evaluation of vaginal complaints. *JAMA* 2004; 291:1,368-1,379.

7. Ferris DG, Dedle C, Litaker MS. Women's use of over-the-counter anti-fungal pharmaceutical products for gynecologic symptoms. *J Fam Pract* 1996; 42:595-600.

8. Marrazzo J. Vulvovaginal candidiasis. *Br Med J* 2003; 326:993-994. ■

CTU remembers Felicia Stewart, MD

Felicia Hance Stewart, MD, co-author of *Contraceptive Technology* and member of the *Contraceptive Technology Update* Editorial Board, died April 12 of lung cancer at her home in San Carlos, CA.

At the time of her death, Stewart was an adjunct professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California San Francisco (UCSF) and co-director of the Center for Reproductive Health Research & Policy. She was the former director of the reproductive health program at the Henry J. Kaiser Family Foundation in Menlo Park, CA, where she was responsible for grant making in the field of reproductive health and in supporting the foundation's work with media and public education. She also served as deputy assistant secretary for population affairs for the U.S. Department of Health and Human Services, where she helped formulate and implement domestic and international policies on family planning and population issues. Prior to her federal appointment, Stewart was in gynecological practice as a member of the Sutter Medical Group, a large multispecialty medical group in Sacramento,

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. **The semester ends with this 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. ■

CA. Throughout her career, she was a tireless advocate for reproductive rights issues, including emergency contraception and abortion.

"Felicia will be remembered for so many things: her wit and wisdom, her remarkable sense of humor, her political savvy, her relentless quest for the truth, and her unwillingness to be overly influenced by the contraceptive fad of the day," says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta and head of the *CTU* Editorial Board.

A May 20 memorial in San Francisco was planned. Details will be posted on the Washington, DC-based Association of Reproductive Health Professionals' (ARHP) web site at www.arhp.org; click on "Remembering Dr. Stewart." Tributes also may be posted on-line at the ARHP web site. ■

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.
- **Describe** how those issues affect service delivery and the benefits or problems created in patient care in the participant's practice area.
- **Integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

21. Crystal methamphetamine increases levels of:
A. dopamine.
B. aspartate.
C. acetylcholine.
D. glycine.

22. Which of the following is NOT a typical symptom of chlamydia?
A. Abnormal vaginal discharge
B. Burning sensation when urinating
C. Granulomatous heaped ulcers
D. Lower abdominal pain

23. Which of the following is NOT one of the steps in the classic approach of evaluating vaginal symptoms?
A. pH test
B. Whiff test
C. Microscopy with both normal saline and potassium hydroxide (KOH)
D. Colposcopy

24. Buccal administration of misoprostol calls for the drug to be:
A. Placed under the tongue, where it dissolves.
B. Placed between the cheek and gum, where it dissolves.
C. Crushed, then injected under the skin.
D. Placed in the vagina.

Answers: 21. A; 22. C; 23. D; 24. B.

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.*