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Win-Win: Health care reform law will help HIV patients and providers

More access to providers and drugs

HIV/AIDS providers and others say the Patient Protection and Affordable Care Act (H.R. 3590), which was signed by President Barack Obama on March 23, 2010, contains mostly good news for the HIV/AIDS community.

It will expand access for HIV patients who currently do not qualify for Medicaid, Medicare, or private insurance. It will make it easier for HIV patients to obtain new private health insurance coverage, and it eliminates the life-time caps on how much an insurer will pay for expensive medical issues, including HIV/AIDS.

The expansion of the private insurance pool and the prohibition against denying coverage for pre-existing conditions will make it easier for HIV patients who are healthy enough to work to find jobs that provide insurance coverage, says **William E. Arnold**, director of Title II CANN — Community Access National Network, founder of the ADAP Working Group, in Washington, DC.

"That will put more HIV patients into the mainstream system, as opposed to the Medicaid system," Arnold says.

Plus the new legislation will create a wellness/prevention fund with $7 billion in funding over 10 years, and some of this money could go toward HIV/AIDS projects, says **Michael Ochs**, a government relations associate with the Infectious Diseases Society of America in Arlington, VA.

This funding will be distributed through the U.S. Department of Health and Human Services as a discretionary fund, and it will start with $500 million. It's designated to be used for prevention and wellness, Ochs explains.

The health care reform bill will increase access to affordable health care for all Americans, including people living with HIV/AIDS, says **Ronald Johnson**, deputy executive director of AIDS Action in Washington, DC.

"We are confident this bill could improve health outcomes as having more dependable care is critical to their health," Johnson adds.

The bill's clause that prevents insurers from denying health care coverage to adults because of pre-existing conditions is a very important part of what was passed, but it doesn't go into effect until 2014, Johnson notes.

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Everyone in the pool

"In the interim, the bill calls for the establishment of a temporary, high-risk pool, and through that high-risk pool people living with HIV/AIDS can get access to health care coverage within 90 days," he adds.

Another feature that will increase access is the part that raises the Medicaid eligibility to 133% of the federal poverty level.

"This is a very important provision, particularly for people living with AIDS, and it goes into effect in 2014," Johnson says.

Also, the bill's provision to increase Medicaid payments to primary care providers to 100% of Medicare rates is an important feature that hopefully will result in HIV patients who have Medicaid coverage being able to find physicians who will provide them with care, he adds.

"When you're expanding Medicaid coverage, it's important that you don't lose any Medicaid providers," he says.

From the perspective of the AIDS Drug Assistance Program (ADAP), the Medicaid expansion is the single most important benefit, Arnold says.

"The vast majority of ADAP clients are poor," Arnold says. "This will pick up some people who are not picked up right now."

As more HIV patients receive Medicaid coverage, the ADAP roles likely will ease a little, although the help will be none too soon, Arnold notes.

"We have immediate trouble because of states pulling out a lot of their ADAP money and the federal ADAP appropriations being flat for too long," he says. "The Medicaid expansion will definitely be a help, but the issue is how fast it will be phased in."

ADAPs now have 800 people on waiting lists to receive antiretroviral medications, and it's possible this number will double or triple in the next few years, he says.

Plus, some of the states with the highest number of HIV/AIDS patients also have high numbers of undocumented workers who have no insurance coverage and who are not eligible for Medicaid, Arnold notes.

"They still receive help from ADAP," he says.

The bill's Medicare Part D "donut hole" fix also could benefit ADAPs. It's a long-term fix, although this year Medicare beneficiaries who reach the Part D coverage gap will receive a $250 rebate. Gradually, this gap will be eliminated by 2020.

Also, the bill allows ADAP drug payments to

count toward patients' out-of-pocket costs when they are in the coverage gap of Medicare Part D, says **Kristina E. Lunner**, vice president of government affairs for the American Pharmacists Association in Washington, DC.

"Previously, Medicare Part D prescription drug benefit did not count drugs provided through ADAP programs, and this law would change it so they do count," Lunner says. "Before, even if ADAPs had helped people it didn't go toward the patient's out-of-pocket costs, although different states have assistance programs, and those payments counted toward it, but ADAPs didn't."

Now the ADAP funds will count and help patients bridge the Medicare Part D doughnut hole gap.

"If more money goes to cover the doughnut hole, then potentially ADAPs will keep more money to cover their clients," Arnold says.

But it will take some time before anyone can predict how the Medicare Part D changes might benefit ADAPs financially, Arnold says.

"It's clearly good news down the road and will clearly help when you look at the national picture, but you'll have to see how it is played out in the states," he adds.

One part of the health care reform bill that AIDS advocates don't like is a provision inserted by Orrin Hatch (R-Utah) to provide more than $250 million for Title V abstinence-only-until-marriage programs.

AIDS advocates had pressed the Obama administration to eliminate funding for abstinence-only education which had been one of the only HIV prevention funding areas to be increased over the Bush administration's eight years. The research that came out of those years of funding clearly did not show any public health benefits to abstinence-only education.

"We will continue to speak out against abstinence-only funding, and it's unfortunate that money was stuck in the bill," Johnson says. ■

HIV clinic gets ART to toughest cases

Patients with 10-plus meds targeted

For HIV providers who continually see a certain cohort of patients return to the hospital and fail on their antiretroviral therapy (ART) regimens, there's a new model for medication support that might prove helpful.

The outpatient Comprehensive Care Center HIV clinic in Nashville, TN, launched a program in January, 2009, that identifies HIV patients most at risk for health and medication-related problems and provides them with medication therapy support.

The program includes a full-time nurse case manager, a nurse practitioner, and a part-time pharmacist who handle all referrals for medication adherence and other issues.

More than 2,200 HIV patients visit the clinic, and about 450 of them have prescriptions for 10 or more medications, says **Kimberly S. Lippard**, RN, MSN, case manager of clinical pharmacy services at Comprehensive Care Center.

ART adherence is a huge issue at the clinic, but it's particularly problematic for the people who have comorbidities and high numbers of medications, she notes.

The clinic formed the interdisciplinary team to improve outcomes and to give physicians assistance in achieving optimal medication therapy adherence.

"Our chief medical officer was astute to admit that when it came to medication reconciliation and screening for drug events and interactions, he and the other providers didn't have time to do all that needed to be done," Lippard says.

The team is dynamic with different backgrounds and strengths, she says.

"I look at a patient's issue and see if it's something I can handle or if the nurse practitioner or pharmacist needs to handle it," she says.

For instance, some patients have ongoing substance abuse problems, and the nurse practitioner has a great deal of experience in working with these patients, Lippard explains.

"And some patients are on 20-plus medications, and our pharmacist can quickly and easily look at their medication list, screen for drug-drug interactions, and see which medications they might not need to be taking," she says.

Patient trackers

The team members' clinical pharmacy services time is covered by Ryan White funding, which gives them flexibility in how they pursue solutions.

For instance, Lippard or the nurse practitioner might go to great lengths to track down a patient who, perhaps for substance abuse reasons, has

stopped coming to the clinic.

"We will go out looking for the patient, calling family members, or checking certain drug hotspots," Lippard says.

The team's pharmacist also provides smoking cessation sessions, which is a big issue for some patients, she adds.

The team also has collected some useful data about the clinic's patients. For instance, they found that only 6% of the HIV patients brought their medications with them to the clinic on a regular basis, Lippard says.

"There was this huge gap in being able to accurately assess these patients and provide medication reconciliation, and so that's where we've tried to target our efforts," she says. "We've had some improvement in this."

Team members also track their total number of patient contacts and drug events, finding that from January, 2009, to October, 2009, they had 651 patient contacts and discovered 220 adverse drug events and 446 potential adverse drug events, she adds.

"Our ultimate goal is for every patient who comes to the clinic to have a medication reconciliation done, but that's not a reality right now," Lippard says.

The team initially tackled all 456 cases of patients taking 10 or more medications, meeting with these patients when they visited the clinic to conduct medication reconciliation.

"In some cases we'd have to call the patient's pharmacy to do the medication reconciliation," Lippard says. "So we slowly tackled the list."

Also, soon after the program began, the clinic's medical and psychiatric providers and social workers began to refer patients with actual or anticipated adherence problems and other issues.

"We'd receive notes from providers stating that patients had issues going on in their lives that could cause problems with medication adherence, and so we'd target those patients first," Lippard says.

Other referrals arrive from outside organizations that work closely with the clinic's patients.

The team approach to medication reconciliation might have begun as a way to take some of the burden off of providers' shoulders, but it has also been a boon to patients.

Team members develop trust with patients and take a long view, with follow-up care.

"I handle a lot of issues with patients being unable to afford their medications or co-pays," Lippard says.

She looks for programs that could assist them with obtaining medications, and she also might help patients receive home health services or hospice care when these are needed.

"I work with the inpatient case manager, ensuring our patients have had a medication reconciliation to see if any of their drugs have changed," Lippard says.

The medication reconciliation team also is involved in the clinic's twice-weekly ART conferences.

Providers attend one of these Tuesday or Friday morning conferences to discuss all patients starting new therapy or changing their medication regimen because of side effects or treatment failure.

"The conferences give everyone a chance to discuss patients and what's going in their lives, including whether a patient is homeless or is being turned down for coverage by a medical insurer," Lippard says. "There might be a psychiatric issue or other things going on."

Through the conference, new patients are automatically referred to the team, which meets with new patients for 40 minutes to an hour to discuss HIV, its pathology, how HIV affects the body, general medication information, and the patient's specific medication.

"We screen patients' backgrounds to find out what support systems they have and where they live," Lippard says.

The program is too new to show concrete outcomes, but anecdotal evidence suggests that it is making a big difference in patients' lives.

For example, Lippard had one 51-year-old female patient who had been admitted to Vanderbilt Medical Center repeatedly for hospitalizations due to her poor medication adherence and renal disease.

"She came to our clinic to see one of our providers, and he referred her to our team, saying, 'She has a huge bag of medications, and I don't have time to go through all of them,'" Lippard recalls.

"I sat down with the woman and found out she was taking old HIV medications that had been discontinued months ago, along with new HIV medications," she adds. "So she was double-dosing with medication."

Med woes, substance abuse

Plus the woman was taking multiple doses of Lactulose, a diarrhea medication. She had a prescription under one generic name and a second prescription under a different generic name, and she didn't know they were the same thing.

"And she was taking old hypertension medications that had been discontinued months ago," Lippard says.

Since the woman had most recently been admitted to the hospital for hypotension and acute renal failure, her continuing the old medication was particularly alarming.

And despite her double-dosing of ART, her HIV disease was not well controlled because of her inconsistent medication habits when she was home, Lippard says.

On top of everything else, the woman had long-standing substance abuse issues.

The team addressed all of her problems by eliminating the duplicate and unnecessary medications and helped her become adherent to her ART.

"I met with her several times, and I am still following-up with her today," Lippard says. "She has been managing her HIV disease very well, but because of her substance abuse issues, her renal disease and the decline of her mental status, she's now in hospice care."

When team members meet with patients like this woman, they go over all of the patients medications, discussing why the patient needs to take certain drugs and why others should be discontinued.

'We talk about what the side effects are and help them understand their medications better," Lippard says.

"We work with setting up weekly pill boxes that are delivered in bubble packets once a month," she adds.

These show patients which pills to take at which times.

"We provide an education sheet that shows a picture of the pill, its brand name and generic name, and it provides information on how to take the medication, when to take it and what the side effects are," Lippard says. "They can hang this information from their refrigerator and it serves as a guide." ■

TB rates rise among HIV+ Latinos in Southern Cal

Study sounds alarm about trend

The overall public health picture looks good with tuberculosis (TB) rates continuing to decline in both HIV-infected and general United States populations. But these facts mask a disturbing trend that researchers found in Southern California.

Hispanics from Mexico increasingly are co-infected with HIV and TB, a new study finds.[1]

"The reason we started this work is because in San Diego, we've found that HIV/TB co-infection is pretty consistent and did not seem to be going down even though there was an overall decline in TB rates," says **Timothy C. Rodwell**, MD, PhD, MPH, an assistant professor in the division of global public health in the school of medicine at the University of California - San Diego in La Jolla, CA.

"We wanted to see what was going on," Rodwell says. "Was there something on the surface or something deeper underneath?"

Examining HIV/TB co-infection rates over time in different demographic groups, the researchers found that a disease that affected all groups in the 1990s now is almost exclusively Hispanic, he says.

"HIV/TB co-infection has been improving in the other two groups, but it's failing to improve in Hispanics," Rodwell says.

The study found that of 5,172 TB cases from 1993 through 2007 in San Diego County, CA, 8.8% were also infected with HIV.

Over this same period, the proportion of cases among Hispanics increased significantly. Cases of HIV/TB co-infection among non-Hispanic Whites and Blacks decreased.

Test HIV patients for TB

"The majority of cases that are Hispanic are people born in Mexico, and there's a lot of binational movement between Mexico and the United States — some 60 million border crossings a year in this area," he adds. "So it means the relationship is complicated."

HIV clinicians should test all patients with HIV for tuberculosis, and infectious diseases clinicians should test all TB patients for HIV, he says.

The study identified the scale and scope of the HIV/TB co-infection phenomenon, as well as identifying risk factors of people with co-infection.

"We found that young, male injection drug users (IDUs) were much more likely to have HIV/TB co-infection," Rodwell says. "This is a hard group to find and a hard group to treat, as well."

The study specifically found that co-infection rates were higher among this cohort of men in the 30 to 49 years age range.[1]

Both diseases require time and resources for proper treatment, and the fact that many of the male IDUs with co-infection also are Hispanic makes it even more challenging.

"This is one of the toughest groups to find and treat, and we don't know what proportion of this group is undocumented," Rodwell says. "All we know is whether they're born in Mexico or the

United States, and the majority of HIV/TB cases are born in Mexico."

These patients typically are diagnosed late in their disease.

"They show up severely ill with both HIV and TB, so we never had a chance to work preventatively with this population," Rodwell says. "If we can identify them early, we can get them into treatment and treat the latent disease before it becomes active."

About 70% of all TB cases in San Diego are among foreign-born residents, and 80% of TB/HIV cases are among Hispanics, he says.

"San Diego's TB incidence is double that of the rest of the United States, so even though we're improving, we're not improving at the same speed as the rest of the nation," he adds.

There is a possibility that San Diego's HIV/TB co-infection rate is the result of people contracting tuberculosis in Mexico, where TB is more common, and then moving to the United States where they then contract HIV, Rodwell explains.

"People might be contracting HIV here quite quickly because of social disruption," he says.

Although the new study looks at HIV/TB co-infection in Southern California, its implications should inform all practice decisions made by all American clinicians.

"Everybody with HIV absolutely should be tested for TB," Rodwell says. "If a patient is in a risk group — young, male, IDU — then there's no question this person should be tested for HIV and quite regularly."

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To protect patients, test viral load of infected HCWs

SHEA guidelines for HCWs

Do some health care workers infected with HIV or hepatitis B or C pose a risk to their patients? Should they be restricted from performing exposure-prone procedures? A new guideline from the Society for Healthcare Epidemiology of America (SHEA) seeks to answer these longstanding and controversial questions by specifically targeting health care workers with a high viral load of circulating virus.

The SHEA guideline identifies the most exposure-prone procedures and specifies how and why some health care workers should face restrictions.

The precautions range from double-gloving and other safety measures to an outright restriction on performing certain exposure-prone procedures if they have a high viral load — defined as equal to or greater than 104 genome equivalents per milliliter of blood for HBV and HCV and equal to or greater than 5x102 genome equivalents per milliliter of blood for HIV.

In a precedent-setting position, the SHEA guideline also suggests that health care workers infected with hepatitis B or C or HIV should be tested at least every six months to determine their viral load. All infected health care workers would consult an Expert Review Panel, comply with infection control precautions, and follow up regularly with occupational medicine staff or public health clinicians, the guideline states.

However, in what some say is a glaring omission, the guideline does not address routine testing of surgeons and other OR personnel, except to say that testing should not be mandatory and that health care workers performing invasive, exposure-prone procedures are "ethically obligated" to know their status.

The guideline represents an update of the 1997 SHEA guideline, "Management of Healthcare Workers Infected with Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus and Other Bloodborne Pathogens."

The Centers for Disease Control and Prevention guideline dates from 1991 and covers only HBV and HIV. However, the scientific understanding and treatment of HIV and hepatitis B and C have advanced considerably in the past two decades.

"We felt the science had progressed to the point where we really could define [these] issues — define the points where there was minimal risk to the patient while still allowing infected providers to pursue their livelihood," says **Neil Fishman**, MD, director of health care epidemiology, infection prevention and control at the University of Pennsylvania Health System in Philadelphia, an author of the guideline and president of SHEA. "The primary viewpoint was [the dictum of patient safety], 'Above all, do no harm.'"

In that regard, SHEA urges healthcare provid-

SHEA identifies invasive, exposure-prone procedures

New guidelines for the Society for Healthcare Epidemiology of America (SHEA) for health care workers infected with bloodborne viruses include the following procedures at greatest risk of transmission to patients.
Category III: Procedures for which there is definite risk of bloodborne virus transmission or that have been classified previously as "exposure-prone"
• General surgery, including nephrectomy, small bowel resection, cholecystectomy, subtotal thyroidectomy other elective open abdominal surgery
• General oral surgery, including surgical extractions, hard and soft tissue biopsy (if more extensive and/or having difficult access for suturing), apicoectomy, root
amputation, gingivectomy, periodontal curettage, mucogingival and osseous surgery, alveoplasty or alveoectomy, and endosseous implant surgery guideline on HCWs infected with HBV, HCV, and/or HIV
• Cardiothoracic surgery, including valve replacement, coronary artery bypass grafting, other bypass surgery, heart transplantation, repair of congenital heart defects, thymectomy, and open-lung biopsy
• Open extensive head and neck surgery involving bones, including oncological procedures
• Neurosurgery, including craniotomy, other intracranial procedures, and open-spine surgery
• Non-elective procedures performed in the emergency department, including open resuscitation efforts, deep suturing to arrest hemorrhage, and internal cardiac massage
• Obstetrical/gynecological surgery, including cesarean delivery, hysterectomy, forceps delivery, episiotomy, cone biopsy, and ovarian cyst removal, and other transvaginal obstetrical and gynecological procedures involving hand-guided sharps
• Orthopedic procedures, including total knee arthroplasty, total hip arthroplasty, major joint replacement surgery, open spine surgery, and open pelvic surgery
• Extensive plastic surgery, including extensive cosmetic procedures (eg, abdominoplasty and thoracoplasty)
• Transplantation surgery (except skin and corneal transplantation)
• Trauma surgery, including open head injuries, facial and jaw fracture reductions, extensive soft-tissue trauma, and ophthalmic trauma
• Interactions with patients in situations during which the risk of the patient biting the physician is significant; for example, interactions with violent patients or
patients experiencing an epileptic seizure
• Any open surgical procedure with a duration of more than 3 hours, probably necessitating glove change.

Reference

1. Henderson DK, Dembry L, Fishman NO, et al. SHEA guideline for management of health care workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol* 2010; 31:203-232.

ers to comply with institutional policies and procedures designed to protect patients. Healthcare providers have an ethical responsibility to promote their own health and well-being, and a responsibility to remove themselves from care situations if it is clear that there is a significant risk to patients despite appropriate preventive measures, the guideline states.

However, infection with a bloodborne pathogen does not itself justify restriction on the practice of an otherwise competent healthcare provider, SHEA notes in the guideline. Healthcare providers infected with bloodborne pathogens should seek ongoing care and treatment. Restrictions may be justifiably imposed when a healthcare provider has a physical or mental impairment that affects his or her judgment and/or jeopardizes patient safety. Examples might include exudative lesions or weeping dermatitis; a history of poor infection-control technique or adherence to proper technique; mental confusion; or a prior incident of transmitting a bloodborne pathogen to a patient, the guideline states.

Janine Jagger, PhD, MPH, director of the International Health Care Worker Safety Center at the University of Virginia in Charlottesville, affirms that it is not necessary to sacrifice patient health and safety to spare healthcare workers' practice rights. With advances in the treatment and prophylaxis of HBV, HCV and HIV, there are new opportunities for policies that protect both patient and healthcare worker, she notes. It is essential for surgeons to be fully engaged with the policy process, she says.

"Today, it is no longer in the interest of surgeons not to know their bloodborne pathogen sta-

tus – although some may still need to be convinced of that," she says.

HCV viral levels 'arbitrary'

The guideline drew criticism both for what it contains and what it does not. Its authors readily acknowledge that it does not follow the usual rigorous standards of scientific evidence. In fact, the authors note that the cut-off levels of viral load are "arbitrary." HCV research and experience, in particular, provides little basis for a specific value, they say: "This level was chosen in the absence of data that definitively associate a given level with either a clear risk for transmission or, more importantly, an absence of risk."

"There will never be a randomized control study of the risk of transmission of hepatitis B, hepatitis C or HIV. For ethical reasons, that could never happen," explains Fishman, who is also associate professor of medicine in the Division of Infectious Diseases at the University of Pennsylvania. However, there is evidence of a relationship between greater "circulating viral burden" and a higher risk of transmission, the guideline states.

In the United States, HBV transmission has been associated with e antigen-positive status. However, the SHEA guideline notes a report from the United Kingdom in which health care providers were infected with a "pre-core" mutant of HBV that caused them to be e antigen negative but to have a high viral load.

The authors note that the restrictions in Europe are greater for HBV and HIV than those recommended in the SHEA guideline. (The European Consortium could not reach consensus on HCV infected providers.) The United Kingdom guideline states that HCV-infected providers with circulating RNA should not conduct exposure-prone procedures.

In contrast, the current CDC guideline states that health care workers who are HIV-positive or HBV-positive with the e antigen (Hear) "should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures." It does not cite specific procedures as exposure-prone or recommend any specific action on the part of the expert review panels.

"We did review all of the European guidelines. But we felt that the evidence that was available did not support the European recommendations, that they were a little out of date," Fishman says.

Yet without data to support a cut-off level – in which transmission occurs more frequently above the cutoff than below it — the recommendation for viral load status for hepatitis C is problematic, says **Miriam J. Alter**, PhD, an HCV expert and director of the Infectious Disease Epidemiology Program at the Institute for Human Infections and Immunity at the University of Texas Medical Branch at Galveston.

"It's very hard to defend a policy in which the data are so lacking unless you're choosing zero risk, and this is not what this [guideline] is choosing," says Alter, who is also the Robert E. Shope Professor in Infectious Disease Epidemiology.

Most cases of HCV transmission in the United States have been linked to contamination of multidose vials, reuse of syringes, or medication abuse (and needle-sharing) on the part of the health care worker. In one case, a Long Island, NY, surgeon infected 14 of 937 patients over a 10-year period. Investigations of five HCV-infected providers in the United Kingdom found 15 probable cases of transmission to patients among 5,868 patients tested, or a transmission rate of about .26%.

Transmission risk is higher from HBV-positive individuals who are also e-antigen positive — which corresponds to a higher viral load. Alter cautions that the viral load can vary, and that facilities need to consistently use the same test for viral load because of possible variations among those of different manufacturers.

And what about patients? Should they be informed of their surgeon's HBV, HCV or HIV status? SHEA states that infected health care workers should not be required to inform patients of their infection status. Fishman notes that the SHEA panel included an ethicist. "We did consider the ethics of the recommendations and situations," he says. The guideline also was reviewed by representatives of the American College of Surgeons and the American College of Occupational and Environmental Medicine, he says.

No mandate for HCW testing?

The guideline relies on health care workers to report their status. Yet if health care workers don't know their HIV, HBV or HCV status, there is no opportunity to consider restrictions. The guideline states that health care providers performing the most exposure-prone procedures are "ethically obligated" to know their status,

and that any provider who inadvertently exposes a patient to his or her blood or body fluid should notify the patient and undergo testing.

Still, in the absence of specific recommendations for testing — either at hire or periodically — the health care provider may avoid the issue altogether. Both SHEA and CDC recommend against mandatory testing of health care providers. This position hasn't changed, although in 2006, CDC recommended that all HIV testing should be routine for patients "in all health care settings."

The guideline advocates strict adherence to infection control practices. Yet there has been relatively low compliance with sharps safety practices and devices in U.S. operating rooms, says **Jane Perry**, MA, associate director of the International Healthcare Worker Safety Center at the University of Virginia. According to 2007 data from the EPINet (Exposure Prevention Information Network) surveillance, more sharps injuries occur in the OR than any other hospital locale and 24% of all injuries are from suture needles.

Perry also notes that surgeons have the highest under-reporting rate of sharps injuries and blood exposures in most studies. Promoting safe practices and encouraging reporting of bloodborne pathogen exposures is important for institutions and all health care workers involved in exposure-prone procedures, says Fishman. "It's critical that the various institutions have mechanisms in place to survey adherence to safe practices by all providers," he says.

Jagger favors a proactive approach: "It all hinges on accurate reporting of percutaneous injuries during surgical procedures. Institutions need to develop mandatory reporting policies specifically for the OR with rigorous administrative checks. Only then will patients benefit from the same post-exposure protocol that is offered by law to blood-exposed healthcare workers."

(The SHEA guideline is available at: www.shea-online.org/Assets/files/guidelines/BBPathogen_GL.pdf)

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Overcoming cancer screening barriers in HIV infected women

Due to their impaired immune function, HIV-positive women have a much higher risk of developing cervical and uterine cancers than do women without the disease.[1] However, many women with HIV do not receive necessary cancer screening due to a reluctance to seek care or other barriers such as psychosocial factors.

One program has stepped up its care by integrating gynecologic care into overall HIV management. The Christiana Care Health Services HIV Program, based in Wilmington, DE, has implemented a weekly women's clinic, where HIV-infected patients can receive necessary screening, such as Pap tests, as well as pregnancy management and contraceptive/reproductive counseling in a comfortable setting.

Numbers for the women's clinic have risen from 178 in 2008 to 380 in 2009, according to **Arlene Bincsik**, RN, MS, CCRC, ACRN, program director. To meet the increased demand, the clinic has been expanded to include two days per month at one of the program's southern satellite clinics in Smyrna and has added an additional half day per week at the program's main site in Wilmington.

The program has increased cervical cancer screening rates, which in turn has led to the identification and treatment of many cervical cancer cases. More than half of HIV program patients receiving a Pap test in the first 10 months of the women's clinic had abnormal results; of these patients, 60% have received colposcopy and follow-up care at the Christiana Care Women's Health Clinic.

Before the implementation of the women's clinic, 90% of the women seen in the Christiana Care

HIV Clinic were referred annually for routine Pap tests, yet less than 10% actually followed through with the screening. Many women, especially working, single mothers, found it difficult to make the time for appointments, as well as arrange transportation, clinic officials say. Others might have been reluctant to reveal their HIV-positive status to outside gynecologic providers, they note.

To operate the women's clinic, officials have allocated funding for an obstetrician/gynecologist who works one-half day per week, as well as a full-time nurse practitioner and nurse, who devote 50% of their time to direct gynecologic patient care and the other 50% to the HIV primary care clinic. Program expenses include labor; equipment such as a colposcope, ultrasound machine, and associated tools; and disposable gynecologic care supplies. The equipment cost about $45,000.

"We have all seen women who have developed cervical cancer, so we are all very committed to prevention," says Bincsik. "This is particularly true of my nurse practitioners, who are very willing to do pelvic exams and Pap [tests] during routine clinical visits."

Two of the program's nurse practitioners have become certified to do on-site colposcopies to follow up on abnormal results, says Bincsik. She also notes the leadership provided by clinic medical director **Lisa Phillips**, MD, who has demonstrated commitment to quality patient care and is involved in the program's implementation and evaluation.

How does it work?

To schedule clinic visits, HIV program nurses review patients' medical records before each physician visit to determine whether certain components of preventive gynecologic care are needed, including annual cervical cancer screening. If a screening has not been done in the past year, the nurse asks the patient if she has obtained screening elsewhere or if she would like an appointment at the weekly clinic. If the patient desires an appointment, the front office staff schedules the next HIV appointment for a Friday morning so that HIV care can be provided in conjunction with a gynecological exam. Patients receive a reminder call from a peer educator one or two days in advance of the appointment.

Women who attend the clinic are provided with a routine gynecology exam, including a pelvic exam and Pap test; an evaluation for sexually transmitted diseases; education on breast health, mammography, and breast self-exam; and family planning services, including birth control and education on reproductive health and safe sexual practices including condom use, based on a standardized treatment protocol. Women who attend gynecology appointments also receive a 'goodie' bag with small soaps, shower gels, and other products.

Other health professionals are involved in the weekly clinic. A clinical social worker is available to address patients' psychosocial needs, while a female peer educator is available in the waiting room to provide comfort and support. Transportation to the clinic is provided, if needed.

To provide follow-up care for those with abnormal findings, the gynecology nurse telephones patients with abnormal Pap smear results to schedule an on-site colposcopy. If results suggest the need for more comprehensive follow-up care, patients are referred to Christiana Care's Women's Health Center, where the women's clinic physician is on staff and can provide or coordinate necessary care.

The Christiana Care HIV Program, as a Ryan White Part D grantee, supports the provision of family-centered care to HIV-infected women who are pregnant, abusing drugs, have advanced HIV disease, or have mental illness. The women's clinic program was developed in response to research indicating that many women referred for cervical cancer screening did not obtain that screening. The on-site clinic now allows women to easily and sensitively access needed services.

"We are very pleased with the clinical outcomes associated with this program and feel that it truly meets the needs of our patient community," says Bincsik.

REFERENCE

1. Oster A, Sullivan P, Blair J. Prevalence of cervical cancer screening among HIV+ women in the United States, 2000 to 2004. Presented at the 16th Conference on Retroviruses and Opportunistic Infections. Montréal, Canada; February 2009. ■

FDA NOTIFICATIONS

FDA meeting in May scheduled

The U.S. Food and Drug Administration (FDA) will hold a public meeting of its Endocrinologic and Metabolic Drugs Advisory Committee to discuss the safety and efficacy of

new drug application (NDA) 22–505, tesamorelin acetate (EGRIFTA®) sterile lyophilized powder for injection, by Theratechnologies, Inc. EGRIFTA is an analogue (a chemical compound that resembles another compound in structure) of growth hormone releasing hormone (GHRH). The proposed indication (use) for EGRIFTA in this application is to induce and maintain a reduction of excess visceral abdominal fat in human immunodeficiency virus (HIV)-infected patients with lipodystrophy (a condition in which abnormal deposits of fat are seen partly as a result of using certain drugs to treat HIV disease).

The meeting will take place on May 27, 2010, from 8 a.m. to 5 p.m. at The Inn and Conference Center, University of Maryland University College (UMUC), 3501 University Blvd. East, Adelphi, MD. You can contact the hotel directly at 301–985– 7300 for directions or to arrange accommodations.

The meeting will be open to the public, and no registration is required.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Written submissions may be made to Paul Tran, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301– 827–6776, e-mail: paul.tran@fda.hhs.gov on or before May 13, 2010. ■

Etravirine label updated by FDA

The U.S. Food and Drug Administration (FDA) recently updated the label for etravirine (Intelence®) to include drug-drug interaction infor-

COMING IN FUTURE MONTHS

- New TB vaccine helps HIV patients
- Clinicians can use acne drug to prevent HIV breakout
- Clinic-based prevention efforts prove effective
- Individualize HIV disease management
- HIV patients at higher risk of MRSA infection

CNE/CME QUESTIONS

1. The Patient Protection and Affordable Care Act (H.R. 3590), which was signed by President Barack Obama in March, 2010, likely will benefit HIV patients and providers. Which of the following is a provision that will help the HIV/AIDS community?
   A. The bill has a clause that prevents insurers from denying health care coverage to adults because of pre-existing conditions
   B. The bill will raise Medicaid eligibility to 133% of the federal poverty level
   C. The bill will increase Medicaid payments to primary care providers to 100% of Medicare rates
   D. All of the above

2. The outpatient Comprehensive Care Center HIV clinic in Nashville, TN, has a program that identifies HIV patients most at risk for health and medication-related problems and provides them with medication therapy support. How does this work?
   A. The program refers HIV patients to an inpatient service to stabilize their disease before having them meet with a case manager-led team to identify their psychosocial obstacles to adherence and develop strategies for overcoming these obstacles
   B. The program has a team of physicians and pharmacists work with patients to find an antiretroviral regimen that will work best for that patient
   C. The program has a team consisting of a full-time nurse case manager, a nurse practitioner, and a part-time pharmacist who meet with patients referred for medication adherence and other issues. They identify their adherence obstacles and help overcome these.
   D. None of the above

3. A new study of HIV/TB co-infection rates in Southern California has found that which of the following demographic groups is most at risk for co-infection?
   A. Hispanics who were born in Mexico
   B. Men, ages 30 to 49
   C. Injection drug users
   D. All of the above

Answers: 1. D; 2. C; 3. D.

mation between etravirine and fluconazole, voriconazole, lopinavir/ritonavir tablets and clopidogrel. The major changes to Section 7 Drug Interactions are summarized below.

In addition the magnitude of the interaction for etravirine in the presence of fluconazole, voriconazole and lopinavir/ritonavir tablets can be found in section 12.3 Pharmacokinetics.

Please also refer to http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022187s003lbl.pdf to view the complete updated label.

Etravirine - fluconazole and voriconazole: Co-administration of etravirine and fluconazole or voriconazole significantly increased etravirine exposures. The amount of safety data at these increased etravirine exposures is limited; therefore, etravirine and fluconazole or voriconazole should be co-administered with caution. No dose adjustments of Intelence, fluconazole or voriconazole is needed.

Etravirine - lopinavir/ritonavir tablets: Intelence and Kaletra (lopinavir/ritonavir) tablets can be coadministered without dose adjustment.

Etravirine - clopidogrel: Activation of clopidogrel to its active metabolite may be decreased when clopidogrel is co-administered with Intelence. Alternative to clopidogrel should be considered. ■

CNE/CME OBJECTIVES

The CE/CME objectives for AIDS Alert, are to help physicians and nurses be able to:

- Identify the particular clinical, legal, or scientific issues related to AIDS patient care;
- Describe how those issues affect nurses, physicians, hospitals, and clinics;
- Cite practical solutions to the problems associated with those issues.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any question answered incorrectly, please consult the source material.

After competing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.