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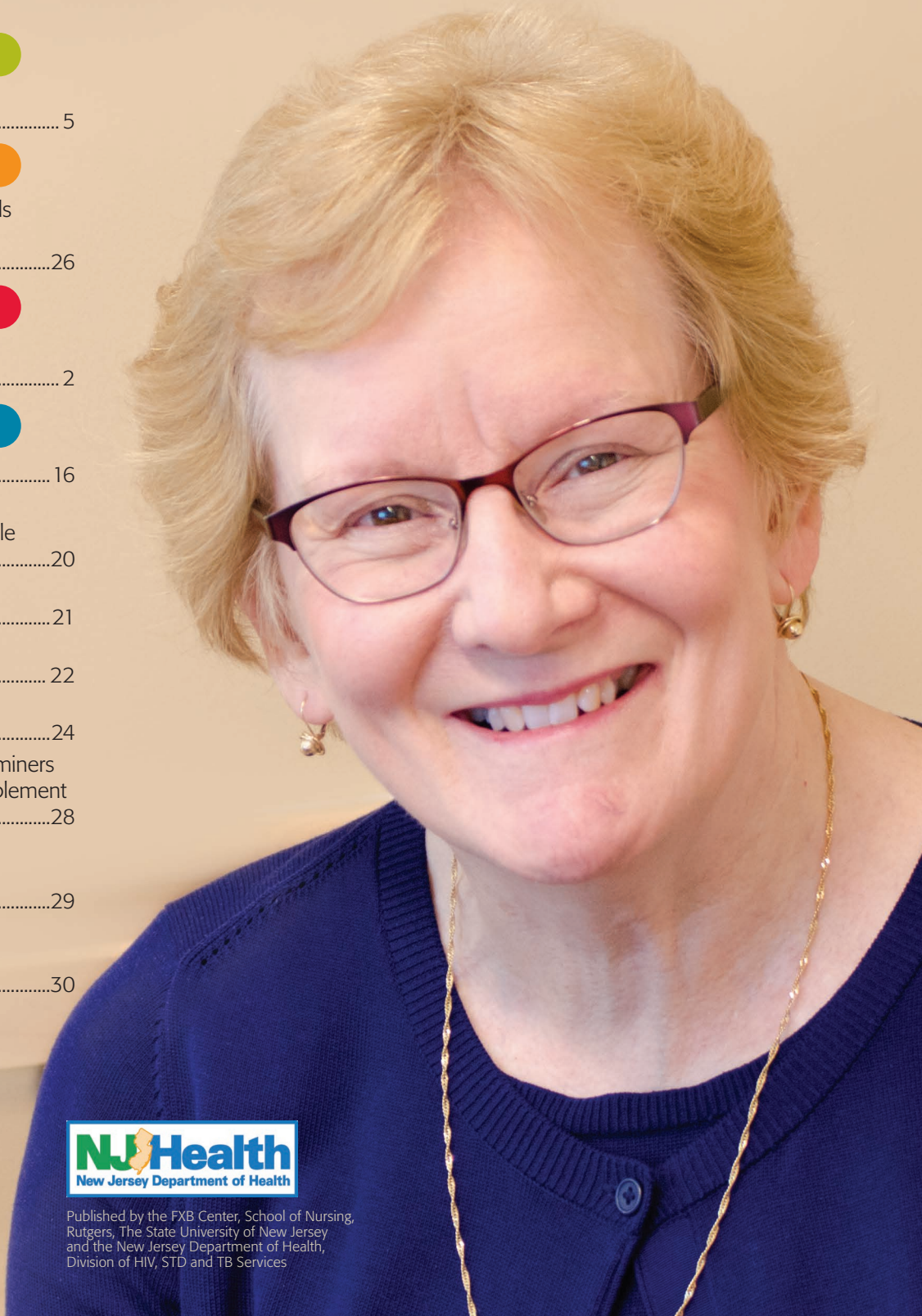
HIV, TB and STD news and information for health professionals



CME/CE Article #1

Spotlight

Special Feature

News

RUTGERS
François-Xavier Bagnoud Center
SCHOOL OF NURSING

NJ Health
New Jersey Department of Health

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Carolyn Burr: Tribute to a Career Fighting Perinatal HIV Infection

In July 2012 Carolyn Burr and I both attended the International AIDS Society conference in Washington, D.C. I was already in the cavernous conference meeting hall for the opening ceremony plenary when she came in. Spotting her in the distance, I was pleased to see a familiar face amongst a crowd of more than 23,000 people from 183 countries, at least 10,000 of whom were packed into the same meeting space where I was sitting. From my seat I waved to her in the distance, inviting her to sit in the empty chair next to me, assuming she'd welcome a familiar face as much as I would. It must have taken her about 20 minutes to travel — by that time she was using her scooter to move around — to where I was seated. She was stopped, like a celebrity, every 10 or 20 feet by someone she knew, someone who greeted her with a hug and kind words, pleased to see her after many months or years.

Dr. Burr knew not only attendees, but also speakers: at a plenary session later in the week, a globally renowned motivational speaker, a woman gifted in sharing her personal journey with AIDS, personally thanked Carolyn Burr from the podium for inspiring her when she was at her lowest, giving her the strength and courage to do the advocacy work that she does today. Dr. Burr's renown was obvious: it got to the point where the colleague sitting next to me asked, "How does she know so many people?" In awe myself, I just responded that she spent many years travelling across the state of New Jersey, the United States, and the world educating healthcare providers about pediatric and maternal HIV care and prevention.

Burr, a native of Indiana, came to work with the Children's Hospital AIDS Program in Newark—which later became known as the François-Xavier Bagnoud (FXB) Center—in 1987. At that point in time she already had 16 years of nursing under her belt. During her 27 years at the FXB Center, she was promoted from Pediatric Nurse Practitioner to Nurse Educator, Associate Director (by which time she has completed her EdD in Adult Education from Teachers College at Columbia University), and eventually Deputy Executive Director. Her work in prevention of mother-to-child transmission of HIV (PMTCT), the work for which she became so widely known, started with the early 1994 announcement that the Pediatric AIDS Clinical Trials Group (PACTG) 076 study would be unblinded and zidovudine offered to mothers in the placebo group. PACTG 076 is the landmark PMTCT study that demonstrated that the zidovudine regimen reduced mother-to-infant transmission by approximately two-thirds (from 25.5% to 8.3%), with minimal short-term toxic effects.

Burr says that she remembers the day in 1994 when the Data and Safety Monitoring Board recommended halting enrollment of women into PACTG 076 — the way those of us who were alive at the time remember precisely where we were when we found out that John F. Kennedy was assassinated. Dr. Edward Connor, co-chair of the PACTG 076 protocol and associate professor of pediatrics at the University of Medicine and Dentistry of New Jersey (now Rutgers University), relayed the news via a phone call that she took from an extension in the makeshift offices in an old hospital ward. At that time HIV was the fifth leading cause of death in US children younger than 15 years of age (it is now the 39th) and the FXB Ambulatory Care Center had lost 33 children to HIV in the previous year. At that moment, Burr knew that PACTG 076 was the long awaited "light on the horizon".

The encouraging results of PACTG 076 led to the CDC recommendation that HIV testing be offered to all pregnant women. In 2007, the state of New Jersey passed a measure that would include HIV testing in routine prenatal tests, unless the pregnant woman has explicitly declined the test. The FXB Center was funded to work collaboratively

with the state's Maternal Child Health (MCH) Consortia to develop a training-of-trainers curriculum to support healthcare professionals to provide rapid HIV testing of women in labor and delivery if they were not tested during pregnancy. The FXB Center systematically trained personnel from all hospitals where deliveries took place.

Cover photo and inset photo: Carolyn Burr. Background photo: Carolyn Burr (far right) with some of the other men and women responsible for reducing New Jersey's perinatal HIV transmission rates, 2013 Perinatal Conference and Ryan White Part D HIV Case Study Day. November 18, 2013. Photo credit: Karen A. Forgash

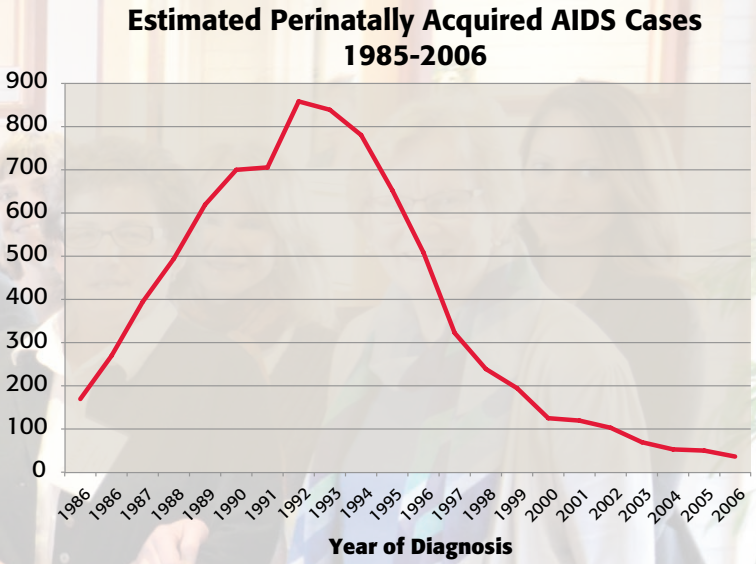
Carolyn Burr: Tribute to a Career Fighting Perinatal HIV Infection

The training of healthcare professionals in New Jersey led to a federally-funded (CDC) grant that supported the FXB Center to expand its work across the US. Once the curriculum was revised for a national audience, Burr led the team that took the FXB Center's materials on the road. They conducted 22 workshops across the country, from Los Angeles to Miami and Boston, targeting healthcare professionals working in labor and delivery units and emergency departments. Workshop participants attended in interdisciplinary teams that included clinicians and administrators who used the training to undertake a SWOT analysis to assist with the develop of a strategic plan; they were provided with model policies and procedures for local adaptation. The follow-up evaluation showed that nearly 90% of the teams with whom she worked had operationalized routine testing in labor and delivery (the percentage for emergency departments was somewhat lower — about two-thirds). In reference to her work with CDC, Margaret Lampe, MPH, RN, Health Education Specialist CDC stated "I learned early on in the 14 years that I have worked with Carolyn, that she is a colleague on whom I could depend. She consistently developed and implemented work with a solid basis in science."

Between 1992 and 2004 the number of perinatally-acquired AIDS cases had dropped by 95%, so by 2007, what remained was the challenge of continuing the public health interventions that enabled such progress (testing during pregnancy and antiretroviral therapy) and trying to eliminate the last 5% of perinatally-acquired HIV. This marked a transition in thinking from PMTCT to EMTCT, i.e., from the prevention to the elimination of mother-to-child transmission of HIV. Dr. Burr continued to remain involved in national and state-wide efforts when the FXB Center became an HIV/Fetal-Infant Mortality Review (FIMR) site. The FIMR/HIV Prevention Methodology is a community-based, case review approach to identify and address system issues contributing to perinatal HIV transmission.

In 2008 Dr. Burr was invited to CDC's seminal meeting to discuss EMTCT. She was one of only two nurses in attendance amongst the 50 nationally-renowned stakeholders. This was the meeting from which the EMTCT framework, currently used by CDC, was developed. In defense of eliminating the last few cases of perinatal HIV, Burr argues that as long as there are women living with HIV, there is a risk that children will be born with HIV. These children and mothers deserve to have every opportunity to take advantage of the services that will interrupt transmission to infants and keep mothers healthy. Getting these services to the remaining women at risk is challenging. The FIMR/HIV data has provided much direction on the strategy that will be needed to reach these women, who are mostly from traditionally marginalized groups, perhaps they use drugs, fear the healthcare system or fear deportation should they enter care.

When asked about her most poignant memories of her 27 year career with the FXB Center, Dr. Burr reflects on working with specific clients: examining babies routinely brought back to the HIV screening clinic for HIV antibody testing until they were 18 months old (remember the days before infant viral testing was available?), reassuring anxious parents who needed answers, counselling a teenager who acquired HIV as an infant when she had a blood transfusion during cardiac surgery, listening to an 11 year old who was diagnosed with perinatally-acquired HIV. She also spoke of how much she learned from her first International AIDS Society Conference in 1991 in Florence, Italy. The international meetings have a way of re-defining the HIV epidemic from a local one to a global one. The presentations and discussions highlight our interdependence and the importance of working together to solve the problems that we all share, not the least of which has been perinatal HIV. Dr. Burr was inspired at the Florence meeting; by the Washington, DC meeting 21 years later, it was obvious that many people across New Jersey and the US had been inspired by Carolyn's work and wanted to thank her for it.



Source: Fenton K. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. March 25, 2008. HIV/AIDS in the United States: An Update. Available at: http://aids.gov/federal-resources/pacha/meetings/march-2008/hiv-aids-update-in-us.pdf

In March 2014 Dr. Burr went on long term medical leave. It has been 16 years since she was diagnosed with MS. She had decided that it was time for her to focus on her own health, rather than that of others. In her retirement, Dr. Burr said that she is "looking forward to slowing down, but not too slow!" ❖

—Virginia Allread

CE Continuing Education

TREATMENT UPDATE

Hepatitis C Infection

Release Date: June 1, 2014 ▪ Expiration Date: May 31, 2016 ▪ Course Code: 16HH04
Nursing credit for this activity will be provided through May 31, 2016

SPONSOR

Sponsored by François-Xavier Bagnoud Center, School of Nursing, Rutgers, The State University of New Jersey and the Center for Continuing and Outreach Education at Rutgers Biomedical and Health Sciences.

FUNDING

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STATEMENT OF NEED

Given the relatively high prevalence of chronic hepatitis C (HCV) in the US (about 1% or 2.7 million infections) and the high risk of developing chronic infection (75–85%), chronic liver disease (60–70%), cirrhosis (5–20%), or dying due to chronic infection (1–5%), treatment of chronic HCV is important. Until 2011, the only treatment for chronic HCV was pegylated interferon with ribavirin, a regimen with low success rates (often ranging as low as 11-37%) and a significant degree of anemia that complicated therapy.

In 2011 the US Food and Drug Administration (FDA) approved the first two direct-acting antivirals (DAAs): boceprevir and telaprevir. In late 2013 the FDA approved two additional DAAs to treat adults with chronic HCV: simeprevir in November and sofosbuvir in December. Given the effectiveness, once daily dosing, shorter treatment course, and tolerability of simeprevir and sofobuvir, these two drugs have made boceprevir and telaprevir as well as all pre-2013 treatment guidelines obsolete. By late 2013, HCV treatment guidelines (including the CDC regimens outlined in the STD Treatment Guidelines, 2010) were considered out of date. Instead, healthcare professionals should turn to the Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD) web-based process for current evidence-based, expert-developed recommendations for HCV management.

This pace of change in the HCV field is likely to continue as there are a number of drugs in Phase 3 testing that are likely to be FDA-approved in 2014 or 2015. These drugs are expected to be at least as effective as simeprevir and sofobuvir, and in some cases more effective or preferable for specific patient populations such as those with documented early fibrosis.

TARGET AUDIENCE

This activity is designed for physicians, nurses, health educators, and other health care professionals in New Jersey who are involved in the care of people co-infected with HIV and Hepatitis C.

METHOD OF PARTICIPATION

Participants should read the learning objectives, review the activity in its entirety, and then complete the self-assessment test, which consists of a series of multiple-choice questions. Upon completing this activity as designed and achieving a passing score of 70% or more on the self-assessment test, participants will receive a letter of credit and the test answer key four (4) weeks after receipt of the self-assessment test, registration, and evaluation materials. This activity may also be completed online at *http://ccoe.rbhs.rutgers.edu/catalog/*.

Estimated time to complete this activity as designed is 1.00 hour for nurses, and 0.75 hour for physicians.

LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

1. Incorporate current HCV treatment recommendations by the American Association for the Study of Liver Diseases (AASLD) in daily practice.
2. Evaluate the efficacy and safety of current and emerging therapeutic strategies for the treatment of HCV.

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CE Continuing Education

New Jersey AIDSLine Summer 2014
HIV, TB and STD news and information for health professionals

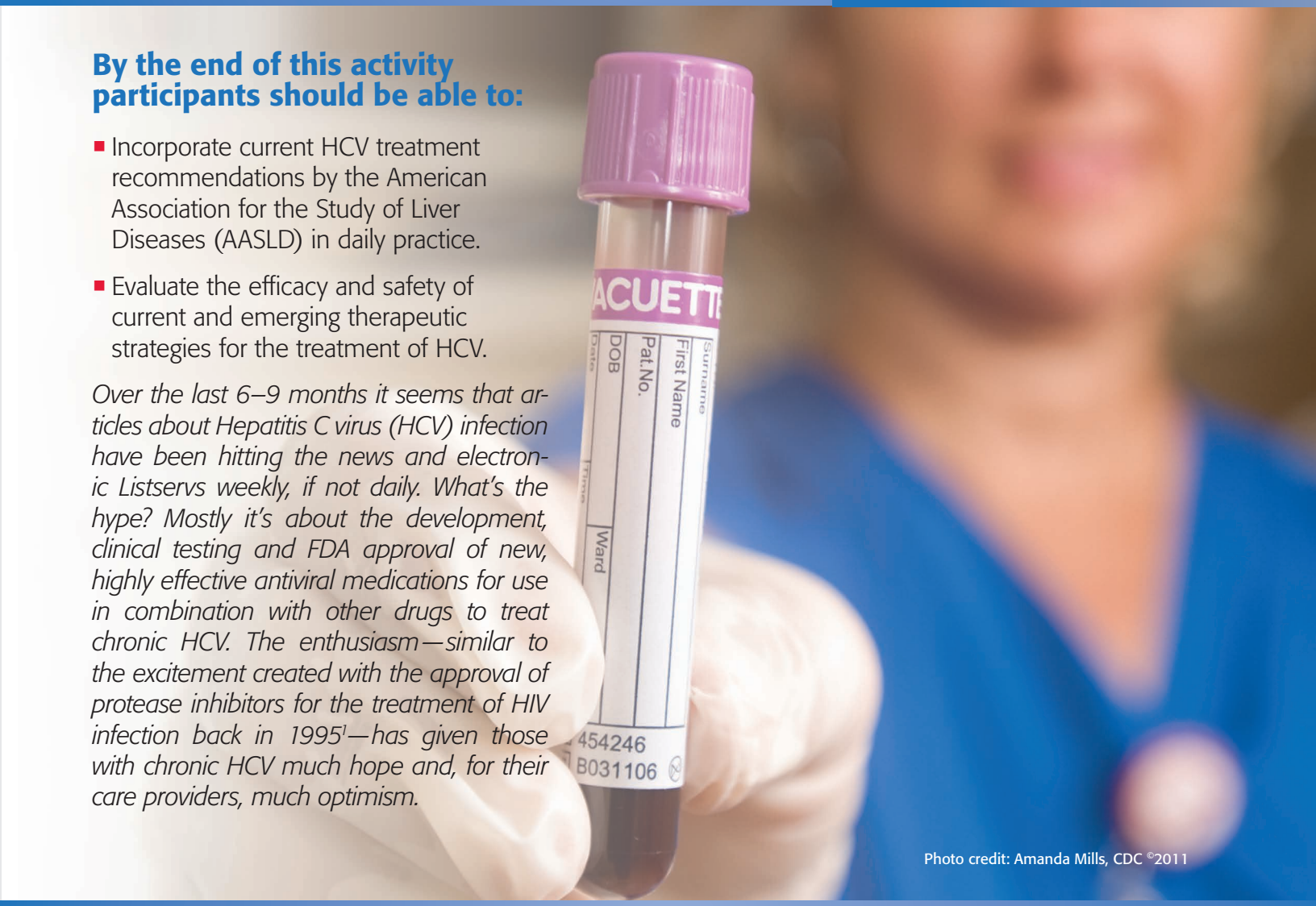
TREATMENT UPDATE
Hepatitis C Infection

Virginia Allread, MPH

By the end of this activity participants should be able to:

- Incorporate current HCV treatment recommendations by the American Association for the Study of Liver Diseases (AASLD) in daily practice.
- Evaluate the efficacy and safety of current and emerging therapeutic strategies for the treatment of HCV.

Over the last 6–9 months it seems that articles about Hepatitis C virus (HCV) infection have been hitting the news and electronic Listservs weekly, if not daily. What's the hype? Mostly it's about the development, clinical testing and FDA approval of new, highly effective antiviral medications for use in combination with other drugs to treat chronic HCV. The enthusiasm—similar to the excitement created with the approval of protease inhibitors for the treatment of HIV infection back in 1995[1]—has given those with chronic HCV much hope and, for their care providers, much optimism.



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Release Date: June 1, 2014 ▪ Expiration Date: May 31, 2016 ▪ Course Code: 16HH04 ▪ Nursing credit for this activity will be provided through May 31, 2016

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NJ Health New Jersey Department of Health

Rutgers François-Xavier Bagnoud Center SCHOOL OF NURSING

Overview

Chronic HCV infection continues to be one of the most common blood-borne infections, accounting for approximately 40% of all chronic liver disease.[2] Chronic HCV infection is the leading cause of liver-related death and the most common reason for liver transplantation in the US. HCV recently eclipsed HIV infection as a cause of death.[3] According to the Centers for Disease Control and Prevention (CDC), of every 100 persons infected with HCV, approximately

- 75–85 will go on to develop chronic infection
- 60–70 will go on to develop chronic liver disease
- 5–20 will go on to develop cirrhosis over a period of 20–30 years
- 1–5 will die from the consequences of chronic infection (liver cancer or cirrhosis)[4]

The estimated US prevalence of HCV infection is 1.0%, corresponding to 2.7 million chronically infected persons.[5] In 2007, the annual incidence—after adjusting for asymptomatic infection and underreporting—was approximately 17,000 cases per year with 15,000 annual deaths.[4]

Since the discovery of the virus in 1989, attention has focused on treating the chronic form of the infection as acute hepatitis C is a self-limiting process. Liver cancer and cirrhosis can be prevented by early treatment—treatment regimens that have improved exponentially over the past year, offering the potential of a cure to more patients than has been previously possible.[6]

HCV epidemiology

In the US, people with HCV are more likely to be aged 40 to 59 years, male, and non-Hispanic Black; they tend to have less education and lower family income. Factors significantly associated with chronic HCV infection are illicit drug use (including injection drugs) and receipt of a blood transfusion before 1992, but 49% of persons with HCV infection did not report either risk factor.[5]

HCV recently eclipsed HIV infection as a cause of death.

HCV genotype

HCV genotypes influence response to therapy, and recently approved direct-acting antivirals (DAAs) are genotype-specific. HCV genotype distributions were studied in a diverse cross-section of patients in the Northern California Kaiser Permanente health plan. Of the 10,256 patients studied, 70% were genotype 1, 16% genotype 2, 12% genotype 3, 1% genotype 4, <1% genotype 5, and 1% genotype 6. Within specific groups[7]:

- Blacks and Asians were more likely to have genotype 1 than 2 or 3 (in comparison with non-Hispanic Whites)
- Women were less likely to have genotype 1 (versus genotype 2 or 3) than did men
- Hispanics and Native Americans were more likely to have genotype 1a than 1b
- Patients age ≥65 years were less likely to have genotype 1a than 1b (in comparison to those age 45-64)

These figures are similar to those from the NHANES III study, which found that nearly 74% of HCV was genotype 1.[8]

Newly approved drugs

The treatment of HCV infection evolved substantially with the US Food and Drug Administration (FDA) approval of the first two HCV protease inhibitor therapies in 2011: boceprevir (Victrelis) and telaprevir (Incivek).[9] In late 2013 the FDA approved two additional DAAs to treat adults with chronic HCV: Janssen Therapeutics' simeprevir (Olysio) in November 2013 and Gilead Sciences' sofosbuvir (Sovaldi) in December 2013. For all practical purposes, the approval of simeprevir and sofobuvir has made boceprevir and telaprevir obsolete (see "What happened to boceprevir and telaprevir?" later in this article).

Simeprevir and sofobuvir are both used in combination with other drugs (see "Current treatment recommendations" below), most often ribavirin (RBV) and peginterferon alfa (PEG). Neither is recommended as monotherapy. Both may be used in the treatment of HCV-infected adults who are treatment naïve or were previously unsuccessfully treated. Use of simeprevir is not recommended in patients with moderate to severe hepatic impairment[6] and sofosbuvir is not recommended in patients with severe renal impairment (estimated glomerular filtration rate (eGFR) <30 mL/min) or with end stage renal disease[10]. Both drugs—when used in combination with RBV or PEG/RBV—are contraindicated in pregnant women and in men whose female partners are pregnant.[11,12] Both drugs have the advantage of shortening duration of treatment: which depends on specific viral genotype, patient population and regimen. Sofosbuvir is listed as recommended or alternate in the treatment of HCV genotype 1, 2, 3, 4, 5 and 6; whereas simeprevir is recommended or alternate for genotypes 1 and 4.[6]

Sofosbuvir: Sofosbuvir is a prodrug (i.e. a medication that is administered in an inactive or less than fully active form, which becomes converted to its active form through a normal metabolic process) of a nucleotide analogue inhibitor of the HCV NS5B RNA-dependent RNA polymerase. Sofosbuvir is available as a 400 mg tablet, taken once daily. It may be taken with or without food, but should be taken at the same time each day.

Sofosbuvir's effectiveness was evaluated in six clinical trials that included 1,947 participants who were treatment-naïve or treatment-experienced. Sofosbuvir demonstrated efficacy in a wide range of participants, including those who could not tolerate or take an interferon (IFN)-based treatment regimen and in participants with liver cancer awaiting liver transplantation. The overall cure rate was higher than 80% (and more like 90% in treatment-naïve patients), but depended on the HCV genotype.

The safety profile in HCV/HIV coinfected patients is similar to that in HCV monoinfected persons. Elevated total bilirubin (grade 3 or 4) was observed in 30/32 (94%) subjects receiving atazanavir as part of the antiretroviral regimen. Among subjects not taking atazanavir, grade 3 or 4 elevated total bilirubin similar to the rate observed with monoinfected patients.[13]

Most common (≥20%, all grades) adverse reactions include the following:

- Sofosbuvir + PEG/RBV combination therapy: fatigue, headache, nausea, insomnia, and anemia
- Sofosbuvir + RBV combination therapy: fatigue and headache

Drug interactions

- In addition to rifampin and St. John's wort, coadministration of sofosbuvir is not recommended with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. Such coadministration is expected to decrease the concentration of sofosbuvir, reducing its therapeutic effect.

Simeprevir: Simeprevir is an HCV NS3/4A protease inhibitor used in combination with PEG/RBV in the treatment of chronic HCV. Simeprevir is available as 150 mg capsule taken once daily with food. Studies of simeprevir in HCV/HIV coinfected patients is limited at this time; despite the absence of data, simeprevir may be considered in the treatment or re-treatment of HCV in this population as current data suggest that it is likely to be highly effective.[6] Given this recommendation, it is important to note that simeprevir is metabolized primarily by cytochrome P450 3A4 (CYP3A4) and therefore is susceptible to drug interactions with inhibitors and inducers of the enzyme. Drug interaction studies with antiretroviral drugs in non-infected volunteers suggested no substantial interactions with tenofovir, rilpivirine, or raltegravir; however, simeprevir concentrations were substantially decreased when dosed with efavirenz and substantially increased when dosed with darunavir/ritonavir.[6]

Simeprevir's safety and efficacy data is based on the more than 2,000 patients enrolled in five placebo-controlled clinical trials with treatment-naïve and relapsed patients or those for whom earlier PEG treatment had failed. The participants received PEG/RBV and simeprevir; or placebo. In the trials, a higher percentage of patients treated with simeprevir achieved sustained virologic response compared with the control group (80% versus 50%).

A reduction in simeprevir's effectiveness was observed in participants infected with HCV genotype 1a with an NS3 Q80K polymorphism, a strain of the HCV commonly found in the United States. Simeprevir's drug label includes a recommendation to screen for the presence of the strain prior to beginning therapy and to consider alternative therapy if the strain is detected.[14]

Most common adverse reactions (all grades, at least 3% higher frequency) when taken in combination with PEG/RBV—in comparison to PEG/RBV—include the following:

- Rash (including photosensitivity) (28% vs. 20%),
- Pruritus (22% vs. 15%)
- Nausea (22% vs. 18%)
- Myalgia (16% vs. 13%)
- Dyspnea (12% vs. 8%) [15]

The IDSA and AASLD in collaboration with the IAS-USA, host a web-based process for the rapid dissemination of evidence-based, expert-developed recommendations for HCV management. Note that the CDC HCV treatment regimens from as recent as 2010 are no longer considered current. Even guidance from as recently as 2013 should be considered outdated.

Treatment cost

Neither simeprevir nor sofosbuvir is cheap; both Janssen and Gilead Sciences have been criticized for their drug's price tag. Sofosbuvir sells for about $1,000 for a single one day dose and simeprevir for $948. Without insurance, the cost of a 12 week course of simeprevir is more than $79,000 and sofosbuvir $84,000. Private insurers are considering how to pay for the new drugs. Gilead has agreements with US government health plans to discount the price by 23%, with an additional discount for Veterans Administration and Department of Defense patients. Together, the Veterans Administration and Medicaid patients account for approximately 20–30% of the HCV-infected people in the US.[16]

continued on page next page

Strategies under consideration to deal with the high cost of these drugs (which is high, even when discounted) include requiring prior authorization or limiting use of the new drugs to the sickest patients. Some Medicaid insurers were seeking additional funding from states.[17] Both pharmaceutical companies have established assistance programs for patients with or without insurance who need the drugs and qualify for assistance.

Current treatment recommendations for HCV/HIV coinfection Initial treatment and relapsers

Recent clinical trials have shown that the combination approach to treating chronic HCV is capable of producing sustained virologic response rates exceeding 90%, with or without the use of PEG (note that the interferon-free combinations are all-oral).[3]

As per the AASLD guidelines, the regimen and regimen duration for the treatment or re-treatment of chronic HCV depends on viral genotype and whether the patient is eligible to receive IFN.

HIV/HCV coinfection results in increased liver-related morbidity and mortality, non-hepatic organ dysfunction, and overall mortality. Even in the era of highly-effective antiretroviral therapies, HIV infection remains independently associated with advanced liver fibrosis and cirrhosis in patients with HCV coinfection.[6] The following is a summary of the *initial treatment* and treatment for *relapsers* with HIV who have genotype 1 or 2. Readers are referred to the AASLD guidelines for the treatment of patients with genotypes 3, 4, 5 and 6, those with compensated and decompensated cirrhosis (moderate or severe hepatic impairment), post-liver transplant HCV, and those with severe renal impairment or end-stage renal disease (ESRD).

Initial treatment refers to the treatment of patients with chronic HCV who are treatment naïve. **Relapsers** refers to patients who achieved an undetectable level of virus during a prior treatment course of PEG/RBV and relapsed. The re-treatment of PEG/RBV relapsers is currently the same as for those being treated for the first time.

In general, the treatment recommendations for those coinfected with HIV/HCV are very similar, if not the same, to those who are HCV monoinfected. In the recommendations for those who are treatment-naïve, the regimen with simeprevir was moved down (in terms of priority for recommendation) due to interactions with antiretroviral medications. In general, response is similar in coinfected as well as monoinfected populations or there is insufficient data at this point in time to make a separate recommendation for those who are coinfected.

HCV genotype 1: Recommended regimens for HIV-infected treatment-naïve patients

Patients eligible to receive IFN
▪ Daily sofosbuvir (400 mg) **and** ▪ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg]) **plus** ▪ Weekly PEG **Duration: 12 weeks (regardless of subtype)**
Patients NOT eligible to receive IFN[18]
▪ Sofosbuvir (400 mg once daily) **and** ▪ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg] daily) **Duration: 24 weeks** **OR** ▪ Daily sofosbuvir (400 mg) **plus** ▪ Simeprevir** (150 mg) **with or without** ▪ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg]) **Duration: 12 weeks**
Alternative regimen for patients eligible to receive IFN
▪ Daily simeprevir** (150 mg) for 12 weeks **and** ▪ Daily weight-based RBV* (1000 mg [<75 kg to 1200 mg [>75 kg]) for 24 weeks **plus** ▪ Weekly PEG for 24 weeks **This regimen is acceptable in persons with either:** ▪ HCV genotype 1b **or** ▪ HCV genotype 1a infection in whom the Q80K polymorphism is not detected prior to treatment If the HCV RNA at week 4 of treatment is less than 25 IU/mL, continue therapy as above. If HCV RNA is greater than 25 IU/mL at treatment week 4 or thereafter, the regimen should be discontinued.
Alternative regimen for patients NOT eligible to receive IFN
▪ None

* RBV has the potential for dangerous drug interactions with **didanosine** (resulting in mitochondrial toxicity with hepatomegaly/steatosis, pancreatitis, and lactic acidosis), as such the concomitant administration of these 2 drugs is contraindicated. In addition, the combined use of RBV and **zidovudine** has been reported to increase the rates of anemia and the need for RBV dose reduction, and is therefore not recommended.

** Simeprevir should only be used with antiretroviral drugs with which it does not have significant interactions: raltegravir, rilpivirine, maraviroc, enfuvirtide, tenofovir, emtricitabine, lamivudine, and abacavir.

Use of simeprevir and PEG/RBV are not recommended in patients with moderate to severe hepatic impairment.

Sofosbuvir may be used with all HIV drugs except didanosine, zidovudine and tipranavir.

Recommendation ratings are available at: http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection-patients-starting-treatment and http://www.hcvguidelines.org/full-report/unique-patient-populations

AASLD. 2014. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/

HCV genotype 2: Recommended regimens for HIV-infected treatment-naive patients

Patients regardless of IFN eligibility
▪ Daily sofosbuvir (400 mg) and ▪ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg]) **Duration: 12 weeks**
Alternative regimens
▪ None

* RBV has the potential for dangerous drug interactions with **didanosine** (resulting in mitochondrial toxicity with hepatomegaly/steatosis, pancreatitis, and lactic acidosis), as such the concomitant administration of these 2 drugs is contraindicated. In addition, the combined use of RBV and **zidovudine** has been reported to increase the rates of anemia and the need for RBV dose reduction, and is therefore not recommended.

Sofosbuvir may be used with all HIV drugs except didanosine, zidovudine and tipranavir.

Recommendation ratings are available at: http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection-patients-starting-treatment

AASLD. 2014. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/

Given the number of new treatments for chronic HCV (see "Drugs in the pipeline" below) for some patients, including those with documented early fibrosis stage (F 0–2), it may be advisable to delay treatment to 2015 to await approval of some of the highly effective IFN-free regimens. It is important to note that PEG is poorly tolerated by the majority of people with hepatitis C, especially those with advanced liver disease. People lacking a favorable genetic profile (the IL28B 'CC' gene) have a poorer response to IFN-based treatment. The majority of patients taking RBV develop anemia during treatment, and some have to discontinue treatment as a result.[19]

Patients receiving HCV antiviral therapy require careful pretreatment assessment for co-morbidities that may influence treatment response. All patients should have careful monitoring during treatment, particularly for anemia if RBV is included in the regimen. Treatment of HIV/HCV-coinfected patients requires awareness and attention to the complex drug interactions that can occur between DAA and antiretroviral therapy.

Current treatment recommendations for HCV/HIV coinfection
Retreatment of persons in whom prior therapy has failed

Treatment responses are generally lower in prior non-responders, which includes null responders (those in whom serum HCV RNA levels declined less than 2 log10 IU/mL by week 12 during a prior treatment course) and partial responders (those with a > 2 log10 IU/mL response whose virus remained detectable up to 24 weeks or the end of treatment).

As with the treatment of chronic HCV genotype 1, in many instances it may be advisable to delay treatment to await approval of the IFN-free regimens. The treatment of non-responders is the same regardless of HIV infection status.

HCV genotype 1: Recommended regimens for HIV-infected nonresponder patients

Patients regardless of IFN eligibility (without an HCV protease inhibitor)
▪ Daily sofosbuvir (400 mg) **plus** ▪ Simeprevir** (150 mg) **with or without** ▪ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg]) **Duration: 12 weeks**
Patients eligible to receive IFN
▪ Daily sofosbuvir (400 mg) for 12 weeks **plus** ▪ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg]) for 12 to 24 weeks **and** ▪ Weekly PEG for 12 to 24 weeks
Alternative regimen for patients NOT eligible to receive IFN
▪ Daily sofosbuvir (400 mg) **and** ▪ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg]) **Duration: 24 weeks**

* RBV has the potential for dangerous drug interactions with **didanosine** (resulting in mitochondrial toxicity with hepatomegaly/steatosis, pancreatitis, and lactic acidosis), as such the concomitant administration of these 2 drugs is contraindicated. In addition, the combined use of RBV and **zidovudine** has been reported to increase the rates of anemia and the need for RBV dose reduction, and is therefore not recommended.

** Simeprevir should only be used with antiretroviral drugs with which it does not have significant interactions: raltegravir, rilpivirine, maraviroc, enfuvirtide, tenofovir, emtricitabine, lamivudine, and abacavir.

Use of simeprevir and PEG/RBV are not recommended in patients with moderate to severe hepatic impairment.

Sofosbuvir may be used with all HIV drugs except didanosine, zidovudine and tipranavir.

Recommendation ratings are available at: http://www.hcvguidelines.org/full-report/retreatment-persons-whom-prior-therapy-has-failed and http://www.hcvguidelines.org/full-report/unique-patient-populations

AASLD. 2014. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/

continued on page next page

HCV genotype 2: Recommended regimens for HIV-infected nonresponder patients

Patients regardless of IFN eligibility
■ Daily sofosbuvir (400 mg) **and**
■ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg])
Duration: 12 weeks
■ Patients with cirrhosis may benefit by extension of treatment to 16 weeks.
Alternative regimens for patients eligible to receive IFN
■ Daily sofosbuvir (400 mg) **and**
■ Daily weight-based RBV* (1000 mg [<75 kg] to 1200 mg [>75 kg]) **plus**
■ Weekly PEG
Duration: 12 weeks
Alternative regimen for patients NOT eligible to receive IFN
■ None

* RBV has the potential for dangerous drug interactions with **didanosine** (resulting in mitochondrial toxicity with hepatomegaly/steatosis, pancreatitis, and lactic acidosis), as such the concomitant administration of these 2 drugs is contraindicated. In addition, the combined use of RBV and **zidovudine** has been reported to increase the rates of anemia and the need for RBV dose reduction, and is therefore not recommended.

Use of PEG/RBV is not recommended in patients with moderate to severe hepatic impairment.

Sofosbuvir may be used with all HIV drugs except didanosine, zidovudine and tipranavir.

Recommendation ratings are available at: http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection-patients-starting-treatment and http://www.hcvguidelines.org/full-report/unique-patient-populations

AASLD. 2014. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/

Timely guidance on HCV therapies for healthcare professionals

The Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD) in collaboration with the International Antiviral Society-USA (IAS-USA), host a web-based process for the rapid dissemination of evidence-based, expert-developed recommendations for HCV management.

The AASLD/IDSA guidelines include specific considerations of persons with HIV/HCV coinfection, compensated and decompensated cirrhosis, post-liver transplant HCV, and those with severe renal impairment or ESRD. Refer to these guidelines for up-to-date genotype-specific treatment regimens, pre-treatment testing, and monitoring.

http://www.hcvguidelines.org/

Outdated recommendations

It is important to note that the CDC HCV treatment regimens from as recent as 2010 (see the STD Treatment Guidelines, 2010 at http://www.cdc.gov/std/treatment/2010/hepC.htm) are no longer considered current. Even guidance from as recently as 2013 should be considered outdated, as an example, boceprevir and telaprevir (referred to above, as the first two DAAs approved in 2011) have been, for the most part, replaced by the newer DAA drugs.

What happened to boceprevir and telaprevir?

Although boceprevir and telaprevir improved response rates and treatment durations for many patients with genotype 1 disease (whether HIV infected or not), clinical trials demonstrated that many patients still do not achieve sustained virologic response with these drugs. In addition, substantial drug interactions with antiretroviral and other drugs limit use, the high pill burden and prolonged treatment course makes compliance difficult, resistance and side effects are still threats. As such these agents are no longer recommended for HIV/HCV coinfected patients.

Drugs in the pipeline

There were more than 25 HCV drugs in development in 2013[20], the pace of change in HCV treatment options is expected to continue as new drugs with different mechanisms of action are likely to become available over the next few years. At least three of these drugs have been awarded "Breakthrough Therapy designation" by the FDA. The Breakthrough Therapy designation, signed into law in July 2012, is intended to expedite the development and review process of drugs for serious or life-threatening conditions. These drugs are put on a fast-track approval program and given intensive guidance from the FDA.

A summary of some of the most important new HCV drugs, not yet FDA-approved but worth watching include:

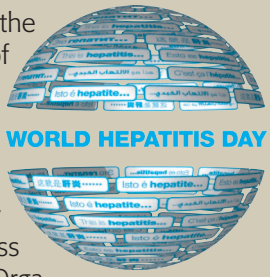
- **Daclatasvir (DCV) combined with asunaprevir (ASV):** DCV is an investigational NS5A replication complex inhibitor; ASV is an investigational NS3 protease inhibitor. Both drugs are manufactured by Bristol-Myers Squibb. The DCV Dual Regimen is taken orally without RBV or PEG and is used to treat HCV genotype 1b. This Dual Regimen was given Breakthrough Therapy designation based on ongoing Phase 3 trials of the drug combination. Daclatasvir has also been combined with simeprevir; this combination led to sustained response in 85 to 95% of people with hepatitis C genotype 1b.[21] Along with Gilead's sofosbuvir/ledipasvir combination (below), the new BMS combination of DCV/ASV is the first hepatitis C regimen for genotype 1b that omits both RBV and PEG.
- **DCV, ASV, and BMS-791325:** This Bristol-Myers Squibb three-drug combination showed high rates of sustained virologic response of up to 94% in treatment naïve, genotype 1 chronic HCV patients at time points ranging from 4 to 36 weeks post-treatment. This combination, which is in Phase 3 studies, has also been designated a Breakthrough Therapy.[22]

- **Ledipasvir:** Manufactured by Gilead and used in combination with sofosbuvir or sofosbuvir and RBV. Ledipasvir has completed Phase 3 trials and was submitted in February 2014 for FDA approval. Among the 440 patients, rates of sustained virologic response were 94% in the group that received 12 weeks of ledipasvir/sofosbuvir; 96% in the group that received 12 weeks of ledipasvir/sofosbuvir + RBV; 99% in the group that received 24 weeks of ledipasvir/sofosbuvir; and 99% in the group that received 24 weeks of ledipasvir/sofosbuvir + RBV. No patient discontinued treatment owing to an adverse event. The most common adverse events were fatigue, headache, and nausea.[23] Ledipasvir attacks the NS5A protein, which plays a key role in replicating the HCV.[24] Gilead has also submitted to the FDA a New Drug Application (NDA) for a once-daily fixed-dose combination of ledipasvir 90 mg and sofosbuvir 400 mg. Ledipasvir/sofosbuvir has also been assigned Breakthrough Therapy designation.
- **Faldaprevir:** Manufactured by Boehringer Ingelheim, faldaprevir is a potent selective inhibitor of HCV NS3/4A protease, and has antiviral activity against genotypes 1 (response is better to genotype 1b than 1a), 2, 4, 5, and 6. It is administered orally once a day. In Phase 3 trials where it was evaluated in combination with PEG/RBV, 88% of patients achieved undetectable virus by week 8 and at least 86% (86% in the low-dose group and 89% in the high-dose group) of them had a sustained virologic response at 24 weeks.[25]
- **RNA-interference drugs, such as miravirsen:** Miravirsen is Santaris Pharma's host-targeted, pan-HCV genotype anti-viral agent and the first microRNA-targeted drug to enter clinical trials for the treatment of HCV. Miravirsen is an inhibitor of miR-122, a liver-specific microRNA required by the HCV for replication. Miravirsen is designed to recognize and sequester miR-122, making it unavailable to the HCV. As a result, the replication of the virus is inhibited. In a Phase 2a study, five weekly injectable doses of miravirsen monotherapy given over 29 days provided robust dose-dependent antiviral activity.[26] For some of the patients, though, the response was temporary.
- **DCV combined with sofosbuvir, with or without RBV:** This drug combination was associated with high rates of sustained virologic response in treatment-naïve patients infected with genotype 1, 2, or 3 and in patients with genotype 1 infection in whom previous treatment with protease inhibitors had failed and who had no current treatment options. Overall, 98% of patients with genotype 1 infection and 91% of the patients infected with genotype 2 or 3 had a sustained virologic response 12 weeks after treatment.[27]
- **Multi-drug PEG-free combinations of ABT-450/r** (a protease inhibitor with ritonavir), **ABT-267** (also called ombitasvir, an NS5A inhibitor), **ABT-333** (also called dasabuvir, a nonnucleoside polymerase inhibitor), and RBV: were associated with superior rates of sustained virologic response ranging from 95.3–98% in patients who were treatment-naïve with HCV genotype 1 infection and no cirrhosis. The rate of discontinuation due to adverse events during the 12 week period was 0.6%.[28]

A second Phase 3 trial, also reported in the New England Journal of Medicine, evaluated the efficacy and safety of the same multi-drug combination (ABT-450/r + ABT-267 + ABT-333 + RBV) but for retreatment of HCV in patients who were previously treated with PEG/RBV. In this study, 95.3% of patients with a prior relapse, 95.2% of patient with a prior null response, and 100% of patients with a prior partial response experienced a sustained virologic response at post-treatment week 12. One percent of patients discontinued the study drugs owing to adverse events.[29] A third trial of the same drug combination in another Phase 3 trial, but for 12 or 24 weeks and in patients with HCV infection and cirrhosis in whom PEG/RBV treatment had failed, repeated the findings of the other two studies. All patients in the third trial experienced high rates (91.8–95.9%) of sustained virologic response, but significantly more patients in the 12-week group than in the 24-week group had a relapse: 5.9% versus 0.6%. Overall, 2.1% of patients in this trial discontinued treatment owing to adverse events.[30]

These three recently reported studies show that the all-oral combination regimen of ABT-450/r + ABT-267 + ABT-333 + RBV results in rates of sustained virologic response at post-treatment week 12 of more than 95%, regardless of HCV genotype (1a or 1b) and with low rates of treatment discontinuation, in both treatment-naïve and previously treated patients. Rates of sustained virologic response is nearly as successful (at least 91.8%) in patients with compensated cirrhosis.[29, 30]

28 July



World Hepatitis Day takes place on the 28 July every year, in recognition of the birthday of Professor Baruch Blumberg, a New Yorker and NIH investigator, who won the Nobel Prize for discovering the hepatitis B virus. World Hepatitis Day is one of only four official world disease awareness days endorsed by the World Health Organization (WHO) and its 194 member states.

Conclusion

These are exciting times for the treatment of chronic HCV infection. With the approval of two antiviral medications in 2013 and more on the way, it soon may be possible to cure HCV in nearly all infected patients with fewer drug-related side effects and with shorter durations of treatment. These truly ground-breaking advances combined with the substantial number of HCV-infected persons unaware of their infection give further evidence to CDC's recent recommendation that all adults at risk for HCV infection as well any adult born between 1945–1965 (regardless of HCV risk) should receive one-time testing for HCV and referral for care if found to have chronic HCV.

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18. IFN-ineligible is defined as one or more of the following:
    - Intolerance to IFN
    - Autoimmune hepatitis and other autoimmune disorders
    - Hypersensitivity to PEG or any of its components
    - Decompensated hepatic disease
    - History of depression, or clinical features consistent with depression
    - A baseline neutrophil count below 1500/µL, a baseline platelet count below 90,000/µL or baseline hemoglobin below 10 g/dL
    - A history of preexisting cardiac disease
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TREATMENT UPDATE

Hepatitis C Infection

POST TEST — Page 1 of 1

CE Continuing Education

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1. What percentage of all chronic liver disease is due to chronic HCV infection?
   - A. 20%
   - B. 30%
   - C. 40%
   - D. 50%

2. What is the estimated US prevalence of HCV infection?
   - A. 1.0%
   - B. 5.0%
   - C. 6.0%
   - D. 7.0%

3. HCV genotype 1 accounts for approximately what percentage of HCV in the US?
   - A. 40–44%
   - B. 50–54%
   - C. 60–64%
   - D. 70–74%

4. In 2013 the FDA approved which of the following direct-acting antivirals?
   - A. Boceprevir and telaprevir
   - B. Simeprevir and sofosbuvir
   - C. Boceprevir and simeprevir
   - D. Sofosbuvir and daclatasvir

5. Which of the following is true?
   - A. Use of simeprevir is not recommended in patients with severe renal impairment
   - B. Use of simeprevir is not recommended in patients with moderate to severe hepatic impairment
   - C. Use of sofosbuvir is not recommended in patients with severe renal impairment
   - D. Both B and C are correct

6. The currently **recommended** regimen for the treatment-naïve HIV-infected patient with chronic HCV genotype 1 is:
   - A. Sofosbuvir + RBV for 24 weeks
   - B. Sofosbuvir + RBV + weekly PEG for 12 weeks
   - C. Sofosbuvir + RBV for 12 weeks
   - D. Telaprevir + RBV + weekly PEG for 24 weeks

7. For the patient with chronic HCV and documented early fibrosis stage (F 0–2), it may be advisable to:
   - A. Delay treatment to 2015 to await approval of some of the highly effective IFN-free regimens
   - B. Treat as soon as possible, but avoid use of PEG/RBV
   - C. Treat as soon as possible and extend treatment to 16 weeks
   - D. Treat as soon as possible, but avoid use of simeprevir

8. The currently **recommended** treatment for the HIV-infected patient with chronic HCV genotype 1 in whom prior therapy has failed is:
   - A. Sofosbuvir + RBV + weekly PEG for 12–24 weeks
   - B. Sofosbuvir + simeprevir +/- RBV 12 weeks
   - C. Simeprevir + RBV + weekly PEG for 48 weeks
   - D. Boceprevir + RBV + weekly PEG for 24 weeks

9. In the treatment or re-treatment of HCV genotype 1, boceprevir and telaprevir:
   - A. Are used as alternative therapies
   - B. Are not recommended because many patients do not achieve sustained virologic response with these drugs
   - C. Are not recommended because drug–drug interactions limit use
   - D. Both B and C are correct

10. Which of the following drug/drug combinations has **NOT** been given Breakthrough Therapy designation by the FDA?
    - A. Daclatasvir + asunaprevir
    - B. Faldaprevir
    - C. Daclatasvir + asunaprevir + BMS-791325
    - D. Ledipasvir + sofosbuvir

CE Continuing Education

TREATMENT UPDATE

Hepatitis C Infection

REGISTRATION FORM

RUTGERS

In order to obtain continuing education credit, participants are required to:

(1) Read the learning objectives, review the activity, and complete the post-test.

(2) Complete this registration form and the activity evaluation form on the next page. Record your test answers below.

(3) Send the registration and evaluation forms to: Rutgers Center for Continuing & Outreach Education ▪ VIA MAIL: PO Box 1709, Newark, NJ 07101-1709 ▪ VIA FAX: (973) 972-7128

(4) Retain a copy of your test answers. Your answer sheet will be graded and if you achieve a passing score of 70% or more, a credit letter and the test answer key will be mailed to you within four (4) weeks. Individuals who fail to attain a passing score will be notified and offered the opportunity to complete the activity again.

Online option: This activity will be posted at **http://ccoe.rbhs.rutgers.edu/catalog/** where you may obtain a credit letter upon successful completion of the online post-test and evaluation. ***Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.***

SELF-ASSESSMENT TEST *Circle the best answer for each question.*				
1. A B C D	**2.** A B C D	**3.** A B C D	**4.** A B C D	**5.** A B C D
6. A B C D	**7.** A B C D	**8.** A B C D	**9.** A B C D	**10.** A B C D

– PLEASE PRINT –

First Name M.I. Last Name Degree

Profession Specialty

Company/Affiliation

Preferred Mailing Address: ☐ Home ☐ Business

Address

City State Zip Code Country

Phone Email

Indicate the type of continuing education credit you wish to obtain as a result of your participation in this activity.

☐ **Nurses:** 1.0 CNE Contact Hour. Contact Hours Claimed: _____

☐ **Physicians:** 0.75 *AMA PRA Category 1 Credit*™ : Credits Claimed: _____

☐ **General:** Continuing Education Units (CEUs) (up to 0.1) Claimed: _____

One credit/contact hour for each hour of participation. Continuing Education Units: one unit per ten hours of participation.

I attest that I have completed this activity as designed. I will report the number of credits/contact hours claimed during my filing of continuing education credit with professional organizations, licensing boards, or other agencies.

Signature Date

Release date: June 1, 2014 ▪ Expiration date: Credit for this activity will be provided through May 31, 2016.
A CE credit letter will be mailed to you in approximately 4 weeks.

Rutgers Center for Continuing & Outreach Education
PO Box 1709 ▪ Newark, New Jersey 07101-1709 ▪ Phone: 973-972-4267 or 1-800-227-4852 ▪ Fax: 973-972-7128

CE Activity Code: 16HH04 — This form may be photocopied.

TREATMENT UPDATE

Hepatitis C Infection

EVALUATION FORM

CE Continuing Education

RUTGERS

The planning and execution of useful and educationally sound continuing education activities are guided in large part by input from participants. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few moments to complete this evaluation form. Your response will help ensure that future programs are informative and meet the educational needs of all participants.

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

PROGRAM OBJECTIVES: Having completed this activity, are you better able to:

	Strongly Agree				Strongly Disagree
Objective 1: Incorporate current HCV treatment recommendations by the American Association for the Study of Liver Diseases (AASLD) in daily practice.	5	4	3	2	1
Objective 2: Evaluate the efficacy and safety of current and emerging therapeutic strategies for the treatment of HCV.	5	4	3	2	1

OVERALL EVALUATION:	Strongly Agree				Strongly Disagree
The information presented increased my awareness/understanding of the subject.	5	4	3	2	1
The information presented will influence how I practice.	5	4	3	2	1
The information presented will help me improve patient care.	5	4	3	2	1
The author demonstrated current knowledge of the subject.	5	4	3	2	1
The program was educationally sound and scientifically balanced.	5	4	3	2	1
The program avoided commercial bias or influence.	5	4	3	2	1
The self-assessment was appropriate and helpful.	5	4	3	2	1
Overall, the program met my expectations.	5	4	3	2	1
I would recommend this program to my colleagues.	5	4	3	2	1

Based on the content of the activity, what will you do differently in the care of your patients? (check one)

☐ Implement a change in my practice.

☐ Seek additional information on this topic.

☐ Do nothing differently. Current practice reflects activity recommendations.

☐ Not applicable. I do not see patients in my current position.

☐ Do nothing differently as the content was not convincing.

☐ Do nothing differently. System barriers prevent change.

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

May we contact you in two months to see how you are progressing on the changes indicated above?

☐ **Yes. Please provide your email address.**
email:

☐ **No. I do not wish to participate in the follow-up assessment.**

If you are not able to effectively implement what you learned at this activity, please tell us what the system barriers are (e.g., reimbursement issues, managed care rules, formulary decisions, countervailing practice guidelines, etc).

Please list any topics that you would like addressed in future educational activities.

CE Activity Code: 16HH04 — This form may be photocopied.

Perinatal Guidelines Update

Carolyn K. Burr, EdD, RN
Deborah Storm, MSN, PhD

On March 28, 2014, the HHS Panel on Treatment of HIV-Infected Pregnant Woman and Prevention of Perinatal Transmission issued an updated version of the "Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women and Interventions to Reduce Perinatal HIV Transmission in the United States.", which are also referred to as the Perinatal Guidelines. Last updated in July 2012, the Guidelines reflect the management of an individual mother-child pair and are organized across the continuum from preconception care to management during the antepartum, intrapartum and postpartum periods, including the care of HIV-exposed infants. The Panel carefully considers available scientific evidence and expert opinion when making recommendations for practice. To facilitate access to information, every section begins with a bulleted list of the Panel's recommendations for that topic area with their rating for the strength of each recommendation and the quality of evidence to support it (see Table1). Reference tables summarize and add to information discussed in the text. The complete document, with all changes highlighted in yellow, is available in PDF format on the AIDSInfo website at aidsinfo.nih.gov. The boxed, bulleted recommendations and the reference tables are also available as separate PDF documents. This article summarizes some of the key changes in the revised Recommendations described in the "What's New in the Guidelines" section (http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/224/whats-new-in-the-guidelines). Some text is taken directly from this document. Readers are urged to consult the guidelines online for more details on the changes and to review comprehensive recommendations for the care of HIV-infected pregnant women and their infants.

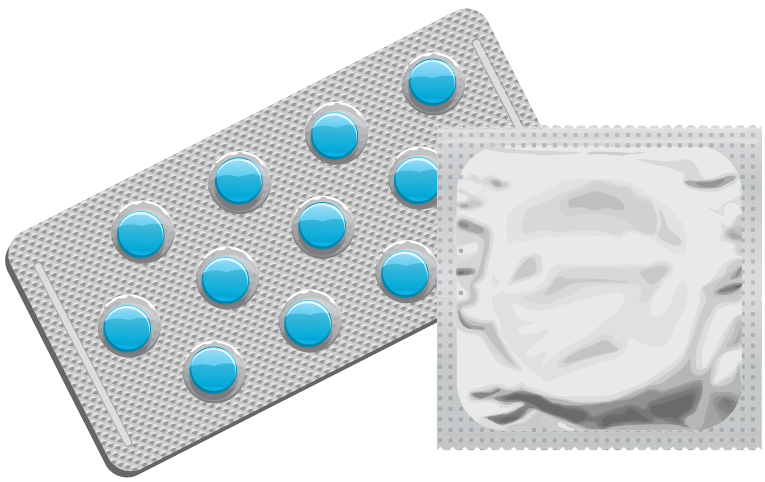
Rating Scheme for Recommendations

Strength of Recommendation	Quality of Evidence for Recommendation
A. Strong recommendation for the statement B. Moderate recommendation for the statement C. Optional recommendation for the statement	I. One or more rendomized trials with clinical outcomes and/or validated laboratory endpoints II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes III. Expert opinion

Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf. Accessed (May 1, 2014) [Table 2, p A-3]

The revised Perinatal Guidelines include new data and publications in the text, appendices, and references. Some content, including tables, has been reorganized and revised to make the document easier to use. An interesting and significant change in the revision is not a clinical or public policy recommendation, but rather a change in language. Beginning with this revision, the guidelines consistently use the terms "perinatal transmission" and "prevention of perinatal transmission" rather than "mother-to-child transmission" and "prevention of mother-to-child transmission." With leadership from the consumer representatives on the Panel, the group decided to adopt the change in language to lessen the risk of inadvertently perpetuating stigma of women living with HIV infection.

In the section on "Preconception Counseling and Care for HIV-infected Women of Childbearing Age," the Panel strongly recommends that all HIV-infected women contemplating pregnancy should be on a maximally suppressive antiretroviral (ARV) regimen (AII). The recommendation highlights again the importance of HIV clinicians bringing up pre-conception and sexual health issues with their patients at every visit. For women



Perinatal Guidelines Update

who do not wish to become pregnant, the Panel recommends offering effective and appropriate contraceptive measures which include all available contraceptive methods. They note that includes hormonal contraception and emergency contraception, as appropriate. Table 3 "Drug Interactions between Antiretroviral Agents and Hormonal Contraceptives (CIII)" has been revised and updated. It includes details about the effects of individual ARV drugs on contraceptive levels with dosing recommendations and clinical comments about the need for alternative or additional contraceptive methods when indicated.

The Panel reorganized the section on "Reproductive Options for HIV–Concordant and Sero-discordant Couples" to provide recommendations for HIV-concordant and sero-discordant couples generally and specifically when the male or the female partner has HIV infection. The Panel recommends that the HIV-infected partner or partners in both discordant and concordant couples planning pregnancy attain maximum viral suppression before attempting conception (AIII). Table 4 has been added on "Clinical Trials of Pre-Exposure Prophylaxis" to support the panel's CIII recommendation that periconception administration of antiretroviral pre-exposure prophylaxis (PreP) "may offer an additional tool to reduce the risk of sexual transmission." They note that the use of PreP when the infected partner is on combination antiretroviral therapy (cART) and is fully virally suppressed has not been studied. Guidelines also point out that pregnancy is not a contraindication to using PreP.

The section on "Recommendations for the Use of Antiretroviral Drugs during Pregnancy" strongly recommends that "multiple factors must be considered when choosing a regimen for a pregnant woman including comorbidities, convenience, adverse effects, drug interactions, resistance testing results, pharmacokinetics (PK), and experience with use in pregnancy (AIII)". A new table assists in this process by detailing combination antiretroviral therapy (cART) choices for women who have never received ART, "Table 6. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women." More information is included in "Table 7. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy" which summarizes information on formulation, dosing, and recommendations for individual drugs. This Table underwent a major revision and has been updated as well as streamlined and redesigned to make it more user-friendly. Additional, more detailed information can be found in "Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy."

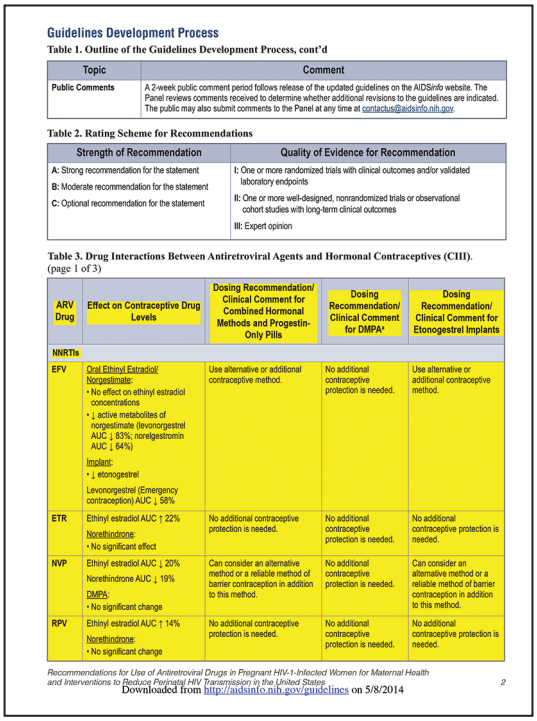
Table 6 classifies regimens and specific drugs as Preferred, Alternative, Insufficient Data in Pregnancy to Recommend Routine Use, and Not Recommended. The Panel made a number of changes in recommendations regarding Preferred and Alternative antiretroviral drugs and drug regimens as well as discussing drugs for which there are insufficient data to make a recommendation or that are not recommended. Clinicians should carefully review Tables 6 and 7 and update themselves on those new recommendations as they reflect the panel's review of the most current clinical trial data.

The panel discusses the use of Raltegravir in women with a high viral load in late pregnancy but because the safety and efficacy of this approach has only been reported in anecdotal reports the Panel does not make a recommendation.

Because of the complexity of management of Hepatitis C and HIV co-infection the Panel strongly recommends consultation with an expert in hepatitis C and HIV. Data are lacking on the newly available anti-hepatitis C drugs in pregnancy and earlier drugs are not recommended or should not be used in pregnancy.

The difficulty in diagnosing HIV -2 infections is discussed. Newer rapid HIV tests

continued on page next page



Guidelines Development Process

Table 1. Outline of the Guidelines Development Process, cont'd

Topic	Comment
Public Comments	A 2-week public comment period follows release of the updated guidelines on the AIDSinfo website. The Panel reviews comments received to determine whether additional revisions to the guidelines are indicated. The public may also submit comments to the Panel at any time at contactus@aidsinfo.nih.gov.

Table 2. Rating Scheme for Recommendations

Strength of Recommendation	Quality of Evidence for Recommendation
A: Strong recommendation for the statement	I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
B: Moderate recommendation for the statement	II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes
C: Optional recommendation for the statement	III: Expert opinion

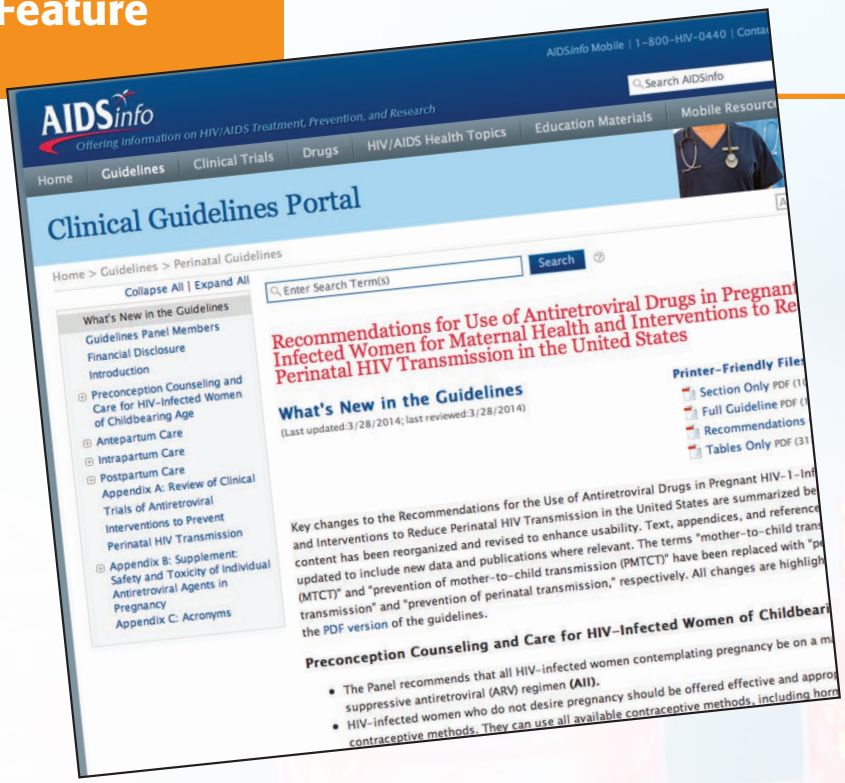
Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraceptives (CIII). (page 1 of 3)

ARV Drug	Effect on Contraceptive Drug Levels	Dosing Recommendation/ Clinical Comment for Combined Hormonal Methods and Progestin-Only Pills	Dosing Recommendation/ Clinical Comment for DMPA[a]	Dosing Recommendation/ Clinical Comment for Etonogestrel Implants
NNRTIs				
EFV	Oral Ethinyl Estradiol/ Norgestimate: • No effect on ethinyl estradiol concentrations • ↓ active metabolites of norgestimate (levonorgestrel AUC ↓ 83%; norelgestromin AUC ↓ 64%) Implant: • ↓ etonogestrel Levonorgestrel (Emergency contraception) AUC ↓ 58%	Use alternative or additional contraceptive method.	No additional contraceptive protection is needed.	Use alternative or additional contraceptive method.
ETR	Ethinyl estradiol AUC ↑ 22% Norethindrone: • No significant effect	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.
NVP	Ethinyl estradiol AUC ↓ 20% Norethindrone AUC ↓ 19% DMPA: • No significant change	Can consider an alternative method or a reliable method of barrier contraception in addition to this method.	No additional contraceptive protection is needed.	Can consider an alternative method or a reliable method of barrier contraception in addition to this method.
RPV	Ethinyl estradiol AUC ↑ 14% Norethindrone: • No significant change	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.

Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States 2

Downloaded from http://aidsinfo.nih.gov/guidelines on 5/8/2014

An interesting and significant change in the revision is not a clinical or public policy recommendation, but rather a change in language. Beginning with this revision, the guidelines consistently use the terms "perinatal transmission" and "prevention of perinatal transmission" rather than "mother-to-child transmission" and "prevention of mother-to-child transmission." With leadership from the consumer representatives on the Panel, the group decided to adopt the change in language to lessen the risk of inadvertently perpetuating stigma of women living with HIV infection.



Readers are urged to consult the guidelines online for more details on the changes and to review comprehensive recommendations for the care of HIV-infected pregnant women and their infants. Go to: http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/224/whats-new-in-the-guidelines

can differentiate HIV-1 and HIV-2 on screening but are not diagnostic. Suspected HIV-2 cases should be reported to state health department surveillance programs who can arrange confirmatory testing through CDC.

In the section on "Monitoring of the Woman and Fetus During Pregnancy," CD4 T-lymphocyte cell counts continue to be recommended at the initial visit and generally every 3 months. However, for patients with consistently suppressed viral load whose CD4 cell count is well above the threshold for the risk of opportunistic infection, that interval can be increased to every six months.

In the section on "Intrapartum Care", the recommendation on the administration of intravenous (IV) zidovudine (ZDV) has been modified to be consistent with the recommendation for scheduled cesarean section based on additional data. IV zidovudine should be administered to HIV-infected women with an HIV RNA >1000 copies/mL (or unknown HIV RNA) near delivery (A1). IV ZDV is not required for women receiving cART whose HIV RNA is <1000 copies/mL consistently during pregnancy and near delivery and for whom there are no concerns about adherence to the regimen.

In the "Postpartum Follow-up" section, the Panel expanded their discussion of the importance of coordination of care particularly regarding cART between the antepartum and the postpartum periods. They strongly recommend

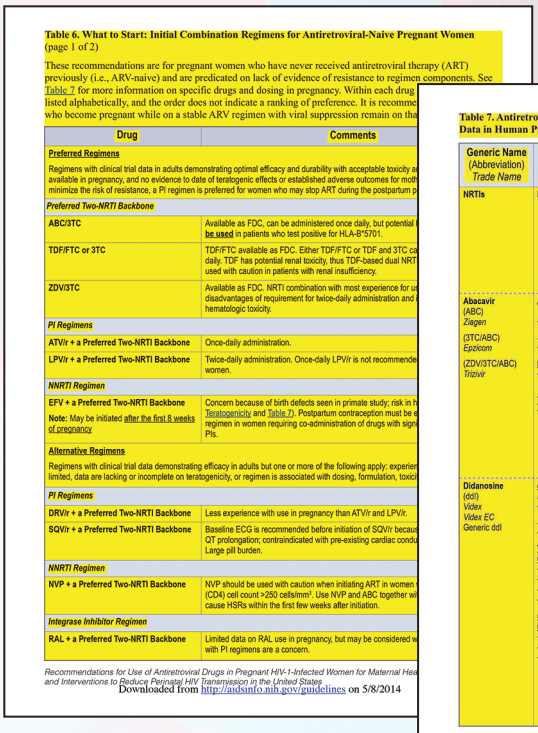


Table 6. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women (page 1 of 2)

These recommendations are for pregnant women who have never received antiretroviral therapy (ART) previously (i.e., ARV-naive) and are predicated on lack of evidence of resistance to regimen components. See Table 7 for more information on specific drugs and dosing in pregnancy. Within each drug listed alphabetically, and the order does not indicate a ranking of preference. It is recommended who become pregnant while on a stable ARV regimen with viral suppression remain on the

Drug	Comments
Preferred Regimens	
Regimens with clinical trial data in adults demonstrating optimal efficacy and durability with acceptable toxicity available in pregnancy, and no evidence to date of teratogenic effects or established adverse outcomes for moth minimize the risk of resistance, a PI regimen is preferred for women who may stop ART during the postpartum p	
Preferred Two-NRTI Backbone	
ABC/3TC	Available as FDC, can be administered once daily, but potential **be used** in patients who test positive for HLA-B*5701.
TDF/FTC or 3TC	TDF/FTC available as FDC. Either TDF/FTC or TDF and 3TC ca daily. TDF has potential renal toxicity, thus TDF-based dual NRT used with caution in patients with renal insufficiency.
ZDV/3TC	Available as FDC. NRTI combination with most experience for u disadvantages of requirement for twice-daily administration and hematologic toxicity.
PI Regimens	
ATV/r + a Preferred Two-NRTI Backbone	Once-daily administration.
LPV/r + a Preferred Two-NRTI Backbone	Twice-daily administration. Once-daily LPV/r is not recommende women.
NNRTI Regimen	
EFV + a Preferred Two-NRTI Backbone **Note:** May be initiated after the first 8 weeks of pregnancy	Concern because of birth defects seen in primate study; risk in h Teratogenicity and Table 7). Postpartum contraception must be e regimen in women requiring co-administration of drugs with signi PIs.
Alternative Regimens	
Regimens with clinical trial data demonstrating efficacy in adults but one or more of the following apply: experien limited, data are lacking or incomplete on teratogenicity, or regimen is associated with dosing, formulation, toxici	
PI Regimens	
DRV/r + a Preferred Two-NRTI Backbone	Less experience with use in pregnancy than ATV/r and LPV/r.
SQV/r + a Preferred Two-NRTI Backbone	Baseline ECG is recommended before initiation of SQV/r becau QT prolongation; contraindicated with pre-existing cardiac condu Large pill burden.
NNRTI Regimen	
NVP + a Preferred Two-NRTI Backbone	NVP should be used with caution when initiating ART in women (CD4) cell count >250 cells/mm³. Use NVP and ABC together wi cause HSRs within the first few weeks after initiation.
Integrase Inhibitor Regimen	
RAL + a Preferred Two-NRTI Backbone	Limited data on RAL use in pregnancy, but may be considered w with PI regimens are a concern.

Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Hea and Interventions to Reduce Perinatal HIV Transmission in the United States

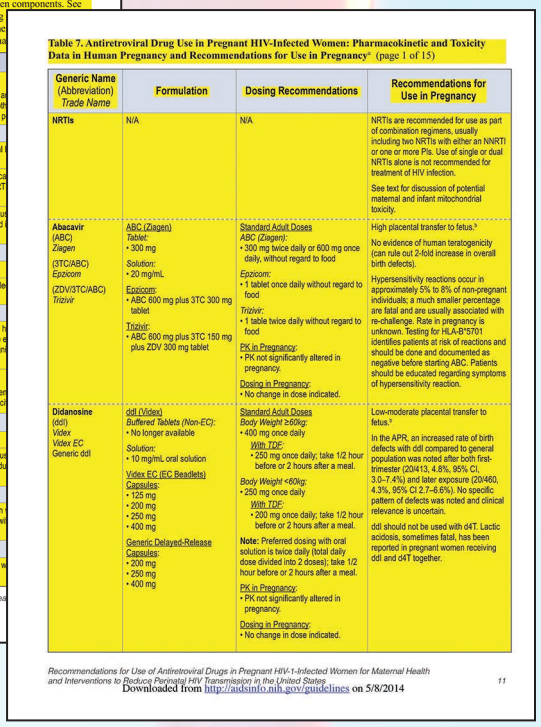


Table 7. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 1 of 15)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Recommendations for Use in Pregnancy
NRTIs	N/A	N/A	NRTIs are recommended for use as part of combination regimens, usually including two NRTIs with either an NNRTI or one or more PIs. Use of single or dual NRTIs alone is not recommended for treatment of HIV infection. See text for discussion of potential maternal and infant mitochondrial toxicity.
Abacavir (ABC) *Ziagen* (3TC/ABC) *Epzicom* (ZDV/3TC/ABC) *Trizivir*	ABC (Ziagen) *Tablet:* • 300 mg *Solution:* • 20 mg/mL Epzicom: • ABC 600 mg plus 3TC 300 mg tablet Trizivir: • ABC 600 mg plus 3TC 150 mg plus ZDV 300 mg tablet	Standard Adult Doses *ABC (Ziagen)* • 300 mg twice daily or 600 mg once daily, without regard to food *Epzicom:* • 1 tablet once daily without regard to food *Trizivir:* • 1 table twice daily without regard to food PK in Pregnancy: • PK not significantly altered in pregnancy. Dosing in Pregnancy: • No change in dose indicated.	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects). Hypersensitivity reactions occur in approximately 5% to 8% of non-pregnant individuals; a much smaller percentage are fatal and are usually associated with re-challenge. Rate in pregnancy is unknown. Testing for HLA-B*5701 identifies patients at risk of reactions and should be done and documented as negative before starting ABC. Patients should be educated regarding symptoms of hypersensitivity reaction.
Didanosine (ddI) *Videx* *Videx EC* Generic ddI	ddI (Videx) *Buffered Tablets (Non-EC):* • No longer available *Solution:* • 10 mg/mL oral solution Videx EC (EC Beadlets) Capsules: • 125 mg • 200 mg • 250 mg • 400 mg Generic Delayed-Release Capsules: • 200 mg • 250 mg • 400 mg	Standard Adult Doses *Body Weight ≥60kg:* • 400 mg once daily *With TDF:* • 250 mg once daily; take 1/2 hour before or 2 hours after a meal. *Body Weight <60kg:* • 250 mg once daily *With TDF:* • 200 mg once daily; take 1/2 hour before or 2 hours after a meal. **Note:** Preferred dosing with oral solution is twice daily (total daily dose divided into 2 doses); take 1/2 hour before or 2 hours after a meal. PK in Pregnancy: • PK not significantly altered in pregnancy. Dosing in Pregnancy: • No change in dose indicated.	Low-moderate placental transfer to fetus.[b] In the APR, an increased rate of birth defects with ddI compared to general population was noted after both first-trimester (20/413, 4.8%, 95% CI, 3.0–7.4%) and later exposure (20/460, 4.3%, 95% CI 2.7–6.6%). No specific pattern of defects was noted and clinical relevance is uncertain. ddI should not be used with d4T. Lactic acidosis, sometimes fatal, has been reported in pregnant women receiving ddI and d4T together.

Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States 11

(AIII [A3]) that decisions about cART be made in consultation with the woman and her HIV provider preferably before delivery. cART is currently recommended by the Panel on Antiretroviral Guidelines for Adults and Adolescents for all HIV-infected persons both to reduce the risk of disease progression and to prevent HIV sexual transmission, although the strength of the recommendations vary by pretreatment CD4 count.

In the "Infant Antiretroviral Prophylaxis" section, a six week course of neonatal zidovudine chemoprophylaxis continues to be generally recommended. However, the Panel now recommends that a 4-week course of zidovudine (ZDV) can be considered if the mother has received and been adherent to a standard cART during pregnancy with consistent viral suppression. The Guidelines discuss the case of "functional cure" reported in the "Mississippi baby." Further investigation is ongoing and clinical trials are planned to assess whether administration of a three-drug therapeutic-dose regimen could alter the establishment and persistence of HIV infection. Also under investigation with planned clinical trials are issues around the safety of such an approach especially in pre-term infants where pharmacokinetic data is often lacking. For infants born to women who received no ARV during pregnancy or received only intrapartum ARV, the Panel continues to strongly recommend (AI) a two-drug prophylaxis regimen of 6 weeks of ZDV plus 3 doses of nevirapine in the first week of life ((i.e., at birth, 48 hours later, and 96 hours after the second dose), begun as soon after birth as possible. The Guidelines recommend expedited (rapid) HIV testing of infants born to women of unknown HIV status, with ARV prophylaxis initiated immediately if the test is positive (AII [A2]). Medication can be discontinued if supplemental testing is negative.

The March 2014 Perinatal Guidelines represent over a year's work by the Panel, made up of approximately 30 clinicians, researchers, community representatives, and government agency staff, with expertise in management of HIV in pregnant women and exposed infants and prevention of perinatal transmission. The Panel is a working group of the Office of AIDS Research Advisory Council (OARAC) and meets regularly by conference call. Details of the methodology the Panel uses to develop the Guidelines are outlined in the "Guidelines Development Process" at the beginning of the document. Dr. Storm and Dr. Burr from the François-Xavier Bagnoud Center, Rutgers School of Nursing serve as staff and nonvoting observers of the Panel and have had the privilege over many years of observing the dedication and hard work of this committed group of professions who care deeply about the women and children for whom they write these thoughtful and scientifically sound guidelines. ❖

1. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf. Accessed (May 1, 2014)

New assay for chlamydia testing

New test is reliable and applicable to point-of-care settings

Priyana R. Oza

Researchers have developed a new assay to detect *Chlamydia trachomatis*, commonly known as Chlamydia. Chlamydia is the most frequently reported STD in the United States, with 1.3 million cases reported in 2010[1]; it is particularly prevalent among young adults, under 25 years of age. Chlamydia affects both men and women; rates are 2.5 times higher in women. It causes a number of reproductive tract infections in women, including cervicitis, pelvic inflammatory disease (PID), and chronic pelvic pain.[2,3] Chlamydia infection increases the risk of ectopic pregnancies and is the leading cause of infertility worldwide. It can cause epididymitis, prostatitis, urethritis, and reactive arthritis in men and neonatal pneumonia and conjunctivitis in newborns.[4]

According to the *Reproductive Health Module*, published by Columbia University Mailman School of Public Health, it is recommended that sexually active women under 25 years of age are screened annually for chlamydia.[5] Annual screening is particularly important because chlamydia is often asymptomatic—two-thirds of infections in women are asymptomatic. The ideal test to detect chlamydia would be not only accurate, but also provide a result while the client waited, so that treatment can be started at initial visit. Rapid tests are important because studies show that 50% of patients who are tested for Chlamydia never return to get diagnostic results or required treatment[6]. Currently, polymerase chain reaction (PCR) tests are widely used to test for chlamydia. Although highly sensitive and specific, PCR tests require trained personnel, costly automated equipment,[7] and results are not typically available on the same day. There are a number of point-of-care (POC) chlamydia tests that provide a result at time of initial patient visit. These POC tests have 96–99% specificity, but poor sensitivity (10–60%), limiting their wider use.[8]

A study published in the *Journal of Molecular Diagnostics*, by researchers in Estonia, reported that a new chlamydia assay uses recombinase polymerase amplification (RPA), a nucleic acid amplification technique to detect *C. trachomatis* directly from urine samples.[9] The assay does not require purification of DNA from urine samples, eliminating the need for costly specialized equipment, making it less laborious and less time-consuming. Urine-based screening is preferred to traditional chlamydia tests and it is a less invasive.[10] Traditional chlamydia tests involve methods such as pelvic examinations for women and the insertion of a probe in the male urethra.[11] Instead the amplification is a one-step procedure that takes 10 minutes at 38°C, uses lateral flow detection strips that provide a result in 15–20 minutes, making it applicable to POC settings.[12] Initial clinical evaluation of the RPA suggests that it has a specificity of 100% (95% CI, 92%–100%) and a sensitivity of 83% (95% CI, 51%–97%),[13] making it significantly more sensitive than the currently available POC tests. In comparison to PCR testing, the RPA is cost-efficient, and offers a POC screening option that is both sensitive and specific. ❖

References

1 Stoner, Bradley; Rother, D. 2012. *Current Epidemiology of Selected STDs.* Available at: http://www.cdc.gov/std/training/std101/presentations-2012/STD-Epidemiology.pdf

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Expedited Partner Therapy (EPT) in New Jersey

What is EPT?

Expedited partner therapy (EPT) is when a healthcare provider gives the patient with an STD an antibiotic or a written prescription for the patient's sexual partner(s) to take. In effect EPT is the practice of treating a patient's sex partner(s) without first examining the partner(s).

EPT is allowable by New Jersey State Administrative Code (N.J.A.C. 13:35-7.1)[1] which states that healthcare providers may give medications or prescriptions without a medical examination when denying such timely care has a reasonable possibility of "placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part."

EPT Recommendations

The Centers for Disease Control and Prevention (CDC) recommended EPT for heterosexual partners of patients diagnosed with chlamydia or gonorrhea when it is ***unlikely*** that these partners will seek medical care. Treatment involving an injection is not possible with EPT. Therefore, EPT cannot be used in the treatment of syphilis and has implications for the treatment of gonorrhea.

The following is summarized from CDC's Guidance on expedited partner therapy[2] (additional information can be found at www.cdc.gov/std/ept):

- **Gonorrhea and chlamydial infection in women (who have sex with men) and men (who have sex with women):** EPT can be used to treat partners when other strategies are unfeasible or unsuccessful. Female partners utilizing EPT should be strongly encouraged to seek medical care, especially those with symptoms that suggest acute PID, such as abdominal or pelvic pain. Symptomatic male partners should also be encouraged to seek medical attention in addition to accepting therapy through EPT.
  - In accordance with updated CDC guidelines for the treatment of gonorrhea, EPT with cefixime and azithromycin, which are administered orally, should still be considered when partners are not likely to access healthcare since the potential harm in not treating gonorrhea is much higher than with EPT. Instructions for partners should include recommendations and resources for seeking a test-of-cure approximately one-week after finishing medication.
- **Gonorrhea and chlamydial infection in men who have sex with men:** Insufficient data regarding the efficacy of EPT in this population as well as high risks of co-infection in partners, especially HIV, suggest that EPT should not be used as a routine partner management strategy with this population and should only be used selectively and with caution.
- **Syphilis:** Because syphilis requires injection therapy with benzathine penicillin G, EPT is not recommended for routine use in the management of syphilis. ❖

EPT is not applicable to sexually transmitted infections, such as HIV and Hepatitis, that require diagnosis, evaluation, counseling and long-term treatment. ❖

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United States and New Jersey STD trends

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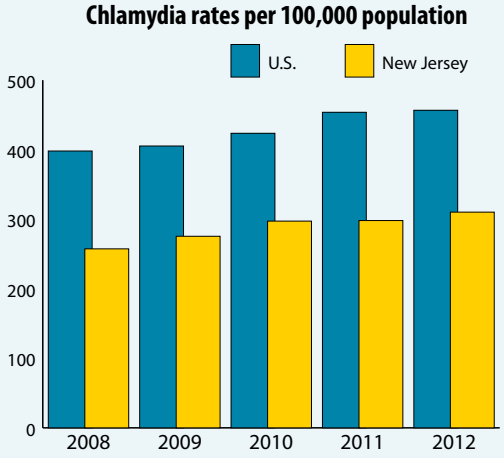
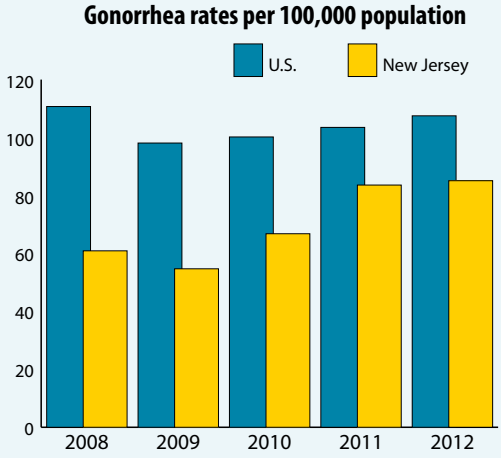
In January the Centers for Disease Control and Prevention (CDC) released its 2012 report of sexually transmitted disease (STD) surveillance data,[1] which shows that the rates of STDs throughout the United States continue to increase. The report showed that New Jersey STD rates mirror the national trends, though with some markedly sharper increases.

Chlamydia: the most commonly reported STD

Nationwide, the 1.4 million cases of chlamydia reported in 2012 was the largest number of cases for any condition ever reported to the CDC. In addition, almost



335,000 cases of gonorrhea and nearly 50,000 cases of syphilis were reported to the CDC in 2012. Similarly in New Jersey, the 27,269 cases of chlamydia reported in 2012 was the largest number of cases of any reportable disease ever reported in New Jersey. New Jersey also reported over 7,000 cases of gonorrhea and over 880 cases of syphilis.



Five-year trends

National five-year trends show remarkable overall rises in STD rates, including an increase of 14.7% in **chlamydia** rates. This increase was sharper in New Jersey with an increase of 20.5% between 2008 and 2012.

Nationwide, a drop in **gonorrhea** rates was reported from 2008 to 2009, however rates have increased by 9.7% since 2009. New Jersey gonorrhea rates mirrored national rates as a dip was seen between 2008 to 2009, however rates increased by a staggering 55.6% between 2009 and 2012. These increases continue to fuel concern about possible cases of resistant gonorrhea (see "The Growing Threat of Multidrug-Resistant Gonorrhea" in the June 2013 edition of AIDSLine, http://www.fxbcenter.org/downloads/AIDSLINE/AIDSLine_June2013_FINAL.pdf).

Since 2008, national rates in primary and secondary syphilis cases increased by 13.6%, and by 14.6% in early latent syphilis. By contrast, New Jersey primary and secondary as well as early latent syphilis rates did not change significantly between 2008 and 2012. However, preliminary data from 2013 suggests a possible 25.5% uptake in early latent syphilis cases between 2012 and 2013.

Disparities

While STDs are a significant health issue facing the United States as a whole, some populations carry a disproportionate share of the burden, particularly youth and men who have sex with men (MSM). Nationwide, half of new STD cases each year occur among 15–24 year-olds. The highest rates of gonorrhea in 2012 were seen in women aged 15–19 and 20–24. In addition, an estimated 75% of primary and secondary syphilis cases reported to the CDC are among MSM.

Not surprisingly, these disparities are also seen in New Jersey. Seventy percent of all STD cases reported from 2008 to 2012 occurred in young people age 24 and under. MSM account for 61% of primary and secondary syphilis cases reported in this time frame.

In the United States, race and ethnicity correlate with many determinants of health status, including STD infection.[2] CDC surveillance data shows higher STD rates among some ethnic and racial minorities when compared to White populations. In 2012:

- Chlamydia rates among Blacks were almost seven times higher than rates among Whites, and rates among Hispanics were 3.2 times higher than those for Whites.
- Gonorrhea rates among Blacks were 15 times higher compared to rates among Whites, and rates among Hispanics were 1.9 times higher.
- This trend was seen to a lesser extreme in rates of primary and secondary syphilis with rates in Black populations six times those for Whites, and rates in Hispanic populations over two times those for Whites.

Minority populations also shoulder a larger share of the STD burden in this state. In 2012, Blacks in New Jersey accounted for 62% of cases in which a racial category was identified. Hispanics accounted for 20.4% and Whites for just 16.1%

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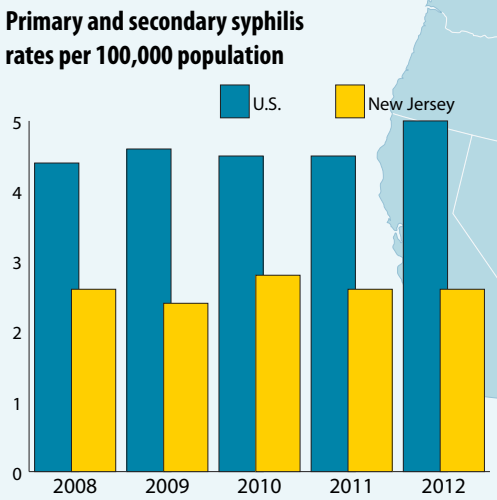
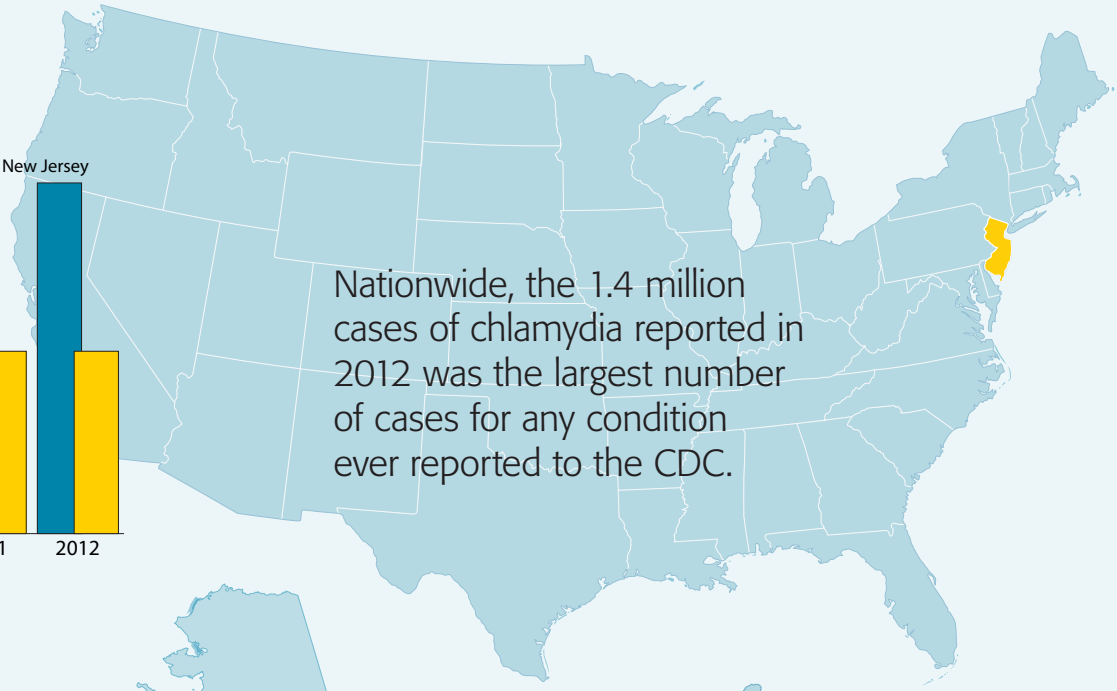
United States and New Jersey STD trends





of such cases. Also in 2012, 46.4% of reported cases of STD-HIV co-infection were reported in Blacks, 80.6% of which were in Black males.

Geography also plays a factor in STD burden in New Jersey. In 2012, the highest percentage of reported chlamydia and gonorrhea cases occurred in Essex County (20.8%), and Camden County (11.6%). Five-year trends show an increase in each of these counties of 36.4% and 31.5% respectively. Essex and Hudson Counties consistently exceed other counties in cases of primary and secondary syphilis with 24% of all cases reported in 2012 in Hudson and 21.4% in Essex. Five year trends show a 9% increase in cases of primary and secondary syphilis in Hudson County and a decrease of 12.5% in Essex. Cases of latent and late syphilis, on the other hand, remained consistent in Essex County but increased by 13.2% in Hudson.

Conclusion

STDs continue to place a substantial economic burden on the healthcare system. CDC estimates that the cost of treating eight of the most common STDs over a lifetime is at least $15.6 billion.[3] While there is no estimate of the monetary costs of STDs in New Jersey, there is no doubt that it is substantial. A 2013 CDC analysis of prevalence and incidence data suggests that there are about 20 million new STD infections in the United States each year, and that about 110 million Americans are infected with an STD, including HIV and hepatitis, at any given time.[4] This high prevalence among the population as a whole indicates that many Americans, including New Jersians, are at a significant risk of exposure to STDs and, in turn, the serious health complications that can result from such infections. Given the overwhelming financial and health-related burden of STDs and HIV, the need for prevention as well as early screening and treatment is clear, and primary healthcare providers play an important role in this. As CDC states, "Healthcare providers have a unique opportunity to provide education and counseling to their patients. As part of the clinical interview, healthcare providers should routinely and regularly obtain sexual histories from their patients and address management of risk reduction".[5] Only through such comprehensive interventions with patients can we begin to make an impact on the often devastating effects of STDs in our communities. ❖

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Getting to the CORE of Quality HIV Care:
H4C in New Jersey

Dan Sendzik, Quality Coach, National Quality Center

If we could do just two things that would improve the lives and health of people with HIV, what would we do?

Two key activities are central to clients' positive health outcomes:

1. Engaging HIV-positive clients in care and
2. Supporting them to reach a suppressed viral load level.

Of the 37,272 people with HIV in New Jersey, 54% are in care. Of those who are in care, 72% have a suppressed viral load.

The Core Measures

Core Measures created by the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration aim to improve retention and viral suppression. This is also the purpose of New Jersey's participation in HAB's new H4C initiative. The five Core Measures, as issued by HAB in 2013, are:

- Viral suppression
- Gap in care
- Frequency of care
- Antiretroviral therapy prescribed
- PCP prophylaxis

H4C

H4C, or the HIV Care Cross-Part Continuum Collaborative, was initiated by HAB earlier this year. It is led by the National Quality Center and focuses on the first four Core Measures (above). H4C takes a systematic approach to improving the quality of HIV health care. As participants in the H4C initiative, providers will test and measure improvement strategies and then share their experiences to accelerate learning and spread successful strategies throughout the network of Ryan White-funded grantees. H4C is engaging grantees in New Jersey, Arkansas, Mississippi, Missouri, and Ohio.

The 23-member H4C state team for New Jersey includes representatives of Parts A, B, C, D, and the AETC, along with a consumer. John Marcinkiewicz, the consumer member of the team, says: "Getting started with HIV care, keeping appointments, and taking medications may not sound that difficult. But it is. Many people have a hard time accepting their HIV diagnosis. Some are afraid of being identified as a person with HIV. Some don't have insurance and therefore don't think they can get care. (They can!) Taking medication is a challenge for anyone, but taking pills every day, sometimes more than once a day, forever — that's tough. I believe H4C can help people get the care they need, and take care of themselves."

Through their participation in the H4C initiative, all Ryan White-funded HIV healthcare providers in the state will be asked to measure their performance on four measures every two months. Based upon what the data tell them — where their performance is strong, where it needs improvement—they will test out changes to their HIV care delivery systems. By re-measuring performance every two months, they can tell if the strategy they have chosen is working, or if they need to consider revising it. There will be a series of trainings for providers and consumers, as well as statewide and national conference calls and webinars.

"NJDOH is excited to take part in H4C. New Jersey has excellent HIV medical providers," says Sindy Paul, MD, MPH, FACPM, formerly Medical Director of New Jersey's Ryan White Part B Program, "but there is still much to do to bring the benefits of care to all HIV-positive people in the state. H4C can help us move closer to that goal."

Ellen Dufficy, RN, is the Nurse Consultant for New Jersey's Ryan White Part D Program and chairs the state's H4C team. She notes: "HIV care providers in New Jersey have a rich history of working together. This is the third HAB collaborative in which the state has been invited to participate. HIV program staff and consumers enjoy and value being part of these initiatives. And they make a difference. Over the past nine years, the number of HIV-positive [people] in care has risen from 50% to 54% in this state."

How can HIV healthcare providers in New Jersey take part in H4C?

- If you are not already participating, get involved! Contact Ms. Dufficy for details: Ellen.Dufficy@doh.state.nj.us
- Review the H4C measures with your clinic's care team. Understand the definitions and expectations for clinical care, which you can find at http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html. Include all your staff; everyone has a role in patient retention, from clerks to case managers to nurses to medical providers!
- Incorporate the Core Measures into your quality management process and apply quality improvement (QI) techniques to improve performance. To do this:
  - Follow a clear QI methodology, such as Plan-Do-Study-Act (PDSA), when launching QI projects. Establish your baseline data (starting point), analyze your process, choose one strategy, test it out, re-measure every two months, and, if it is working, make the change permanent.
  - Stay in close touch with the NJ statewide H4C initiative as you are working to improve your performance on the Core Measures. They can give you support, guidance and ideas, and they want to hear about your experiences — the challenges and the successes. In this way you can learn from others, and they can learn from you. ❖

Starting HIV care and staying in HIV care.

GETTING THE VIRUS UNDER CONTROL.

The highest priorities for people with HIV.

Let's **learn from one another.**

For more information about the H4C measures, go to:
http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html

Federation of State Medical Boards (FSMB) Guidelines on Opioid Prescribing

Sindy M. Paul, MD, MPH, FACPM, Medical Director, New Jersey Board of Medical Examiners

In 1997, in order to better educate physicians and aid in proper diagnosis and treatment of pain, the FSMB developed guidelines to encourage state medical boards to adopt policies encouraging safe and effective use of opioids, the document is entitled Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (and referred to as simply the Model Guidelines). The FSMB updated its guidelines in 2013, with emphasis on inadequate treatment and the inappropriate use of opioids. The Model Policy emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate.[1] Many aspects of the most recent FSMB Model Policy are included in the current New Jersey Board of Medical Examiners regulations.

Under-treatment of pain is recognized as a serious public health problem. Physician's lack of knowledge, conflicting clinical guidelines, concerns of scrutiny by regulatory authorities and fear of causing addiction or being deceived by a patient who seeks drugs for purposes of misuse all contribute to the difficulty of chronic pain management.

Patients share with physicians a responsibility for appropriate use of their pain medication. This responsibility includes providing the physician with true information and complying with the medical instructions and contract guidelines. The Model Policy provides the state medical boards with guidelines for physicians to follow so that they can adhere to the accepted best clinical practices.

Physicians are held liable to determine if opioids are clinically indicated and to discuss possible risks and benefits of therapy. The decision to begin opioids should be a shared decision between the physician and patient after such a discussion. Given the possibility of addiction, the physician must monitor for signs of potential abuse, and when appropriate, make dose reductions or wean off the opioid. The dose should be as low as possible and continue only if beneficial effects and pain relief are achieved. The New Jersey Prescription Monitoring Program (NJPMP, see below) should be checked in advance of prescribing opioids and should be monitored throughout the course of management.

The FSMB in its Model Policy defines the usual course of professional medical practice. A legitimate physician patient relationship must exist. The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and non-pharmacologic modalities, including the use of opioid analgesics and non-opioid therapies. Prescribing needs to be based on careful assessment of the patient and their pain through a history, physical examination, and diagnostic work-up. Medication prescribing or administration should be appropriate for the diagnosis, and should include careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed. This and appropriate referral should be documented as necessary. The choice of treatment modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk of potential abuse or misuse.

New Jersey Prescription Monitoring Program (NJPMP)

New Jersey has taken many proactive steps to protect the public from improper controlled dangerous substance (CDS) prescribing and to prevent public access to CDS medications. This includes implementation of a prescription monitoring program. Nationally, prescription monitoring programs were created through funding from Congress via the Fiscal Year 2002 United States, Department of Justice Appropriations Act (Public Law 107-77). Their purpose is to help prevent and detect the diversion and abuse of pharmaceutical controlled substances by enhancing the ability of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. Prescription monitoring programs focus on the retail level where the prescribed medications are purchased.

The NJPMP is one of New Jerseys' initiatives to halt the abuse and diversion of prescription drugs. Established by New Jersey law (N.J.S.A. 45:1-45 et. seq.), the NJPMP is a statewide database that collects prescription data on CDS and Human Growth Hormone (HGH) dispensed in outpatient settings in New Jer-

sey, and by out-of-state pharmacies dispensing into New Jersey. Pharmacies are required to submit this data weekly.[2] Physician participation is voluntary.

NJPMP access is granted to prescribers and pharmacists who are licensed by the state of New Jersey and in good standing with their respective licensing boards. Prior to prescribing or dispensing a medication, qualified prescribers and pharmacists registered to use the NJPMP are able to access the website and request a CDS and HGH prescription history of the patient. The users must certify that they are seeking information for a specific, current patient.

Prescribers and pharmacists authorized to access the NJPMP, must certify before each search that they are seeking data solely for the purpose of providing healthcare to current patients. Authorized users agree that they will not provide access to the NJPMP to any other individuals, including members of their staff. The patient information is strictly confidential, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules.

NJPMP has penalties for prescribers or pharmacists who access or discloses NJPMP information for any purpose other than to provide healthcare to a current patient or to verify the record of prescriptions issued by the prescriber, or who allow any other individuals to access the NJPMP using the prescriber's or pharmacist's own access code. Violations are subject to civil penalties of up to $10,000 for each offense and disciplinary action by the prescriber's or pharmacist's professional licensing board.

As with all prescription monitoring programs, patient information in the NJPMP is intended to supplement an evaluation of a patient, confirm a patient's prescription history, or document compliance with a therapeutic regimen. When prescribers or pharmacists identify a patient as potentially having an issue of concern regarding drug use, they are encouraged to help the patient locate assistance and take any other action the prescriber or pharmacist deems appropriate.[3]

Although prescription monitoring programs, such as NJPMP, are state-based, information sharing among states is a national priority. The Bureau of Justice Assistance has developed policy and technology to enable interstate sharing of the information in the prescription monitoring program.

Other steps taken by the state of New Jersey to protect the public from improper CDS prescribing and to prevent public access to CDS medications were described in the cover article of the December 2013 issue of AIDSLine, available at: http://www.fxbcenter.org/education/index.html

Conclusion

Pain can cause considerable disability and discomfort in HIV-infected individuals. Treatment should be based on the same principles applied to the management of cancer-related pain. A combination of modalities should be used as part of a pain management plan for all causes of pain in HIV-infected individuals, including opioids, non-opioids, NSAIDS, physical therapy and holistic measures.

Common causes of pain in HIV-infected clients include herpes simplex and herpes zoster infections, painful peripheral neuropathy, back pain and arthralgias. But AVN is also an important cause of pain in those with HIV. Healthcare professionals treating patients with HIV should have a high index of suspicion for AVN in patients with pain in one or more joints. The same principles of management for AVN in HIV-uninfected patients should be followed.

Although it is important to manage pain symptoms, prescription drug abuse and misuse is an increasing public health problem. The BME has established standards for prescribing, dispensing and administering CDS. The FSMB has guidelines that have been adopted in New Jersey emphasizing the professional and ethical responsibility of physicians to assess and manage patients' pain and relative level of risk for misuse and addiction. In New Jersey, the prescription monitoring program is used to aid prescribers and pharmacists in detecting the abuse of controlled substances. By educating and making healthcare professionals aware of this novel approach, New Jersey hopes to decrease the misuse of prescription drugs and also allow providers to monitor patient compliance with their pain regimens. ❖

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New Jersey Board of Medical Examiners (BME) Certificate of Waiver to Implement the Overdose Prevention Act

also known as the Good Samaritan Act (P.L. 2013, c. 46)

Sindy M. Paul, MD, MPH, FACPM
New Jersey Board of Medical Examiners

Governor Chris Christie is joined by musician Jon Bon Jovi as he signs the bipartisan Overdose Protection Act (S2082) into law at Turning Point in Paterson, N.J. on Thursday, May 2, 2013. (Governor's Office/Tim Larsen)

Prescription drug abuse is considered the fastest growing drug problem in the United States. The major increase is in unintentional drug overdose from opioid analgesics, which has caused more overdose-related deaths since 2003 than cocaine and heroin combined.[1]

In New Jersey, the number of drug treatment admissions for opioid pill addictions tripled from 2006 to 2011, with more than 8,600 admissions in 2011. Nearly half of these patients were age 25 or younger. Prescription drug abuse related mortality increased by 51% in New Jersey from 6.5/100,000 population in 1999 to 9.8/100,000 population in 2010.[2] The epidemic of prescription drug abuse triggered a resurgence in heroin abuse by young people. Heroin is a less expensive analogue of prescription pain killers that delivers a stronger high and is currently more readily available than ever in areas with suburban and rural zip codes.[3]

On May 2, 2013, Governor Christie signed into law the Overdose Prevention Act (P.L. 2013, c. 46, N.J.S.A. 24:6J-1 et seq.), also referred to as the Good Samaritan Law. The broad purpose of the Act is to encourage witnesses and victims of drug overdoses to seek medical assistance without fear of criminal or civil liability, in an effort to decrease overdose-related fatalities. In addition, the statute has expressly recognized that greater availability and accessibility of the drug Naloxone, an opioid antidote, would "reduce the number of opioid overdose deaths and be in the best interests of the citizens of this State." N.J.S.A. 24:6J-2. The legislation specifically endorses distribution of Naloxone to those who themselves are at-risk for an opioid overdose and to "members of their families or peers and persons "in a position to assist". With the enactment of this legislation, New Jersey became the 12th state to have a Good Samaritan law.[4]

The Act, under certain circumstances, provides immunity from civil and criminal liability for non-health care professionals who administer naloxone hydrochloride (Narcan) or any similar acting Food and Drug Administration approved medication, to someone whom they believe is having an opioid overdose. The Good Samaritan Act also provides civil, criminal, and professional disciplinary immunity for health care professionals and pharmacists involved in prescribing or dispensing the opioid antidote in accordance with this Act.[5]

In March the New Jersey Board of Medical Examiners (BME) approved a rule proposal to ensure that physicians will understand that they are relieved of certain obligations when prescribing Naloxone to first responders or to the family and friends of a person at-risk. Under the Act, the prescription may be issued in the name of a person who is not the intended end-user of the medication. Accordingly, there is no need for an examination before or following the issuance of the prescription, as existing Board rules, N.J.A.C. 13:35-7.1A and 7.2 require. In addition, while awaiting the adoption of this rule relaxation, on April 9, 2014, the BME issued a Certificate of Waiver to all physicians licensed by the BME, waiving enforcement of these rules as to prescriptions to those not intended to be the end-user of the medication, in order to facilitate the implementation of the Overdose Prevention Act.[5] Thus physicians are presently authorized to write opioid antidote prescription in the name and address of the person to whom the prescription is issued, rather than in the name of the person to whom the opioid antidote will ultimately be administered, without examination or follow-up.[5] The Certificate of Waiver expires on April 9, 2015 or upon adoption of revised BME regulations (N.J.A.C. 13:35-7.1A and N.J.A.C. 13:35-7.2).[5] ❖

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Applying Molecular Epidemiology Techniques for Genotype Cluster Analysis and Investigation

Authors: Erick Cortes, MPH: New Jersey Department of Health; Barry Kreiswirth, PhD, Natalia Kurepina, PhD and Elena Shashkina, PhD: The Public Health Research Institute, Rutgers University; Reynard McDonald, MD: The Rutgers Global Tuberculosis Institute, Rutgers New Jersey Medical School.

BACKGROUND: The New Jersey Department of Health continues its partnership with the Public Health Research Institute (PHRI) to provide *IS6110* Restriction Fragment Length Polymorphism (RFLP) on all culture positive M.tb samples, as part of its universal genotyping project. In 2009, two *M.tb* cultures were DNA matched on *IS6110* RFLP. Both samples were submitted to the national genotyping laboratory for full genotyping sequencing. In 2013, two samples submitted for *IS6110* RFLP and full genotype sequencing returned DNA fingerprints and genotype sequences that matched the 2009 cluster.

METHODS: For 2009 and 2013, LJ slant cultures were submitted to PHRI, for strain genotyping using standard *IS6110* methods. The RFLP patterns were compared against the archived PHRI image database (over 10,000 images, 31,000 *M.tb* isolates) for strain identification. The analyzed DNA was then sent to the national genotyping laboratory for sequencing and comparison against the archived national *M.tb* genotyping database.

RESULTS: Both the 2009 and 2013 clusters generated matching *IS6110* RFLP patterns labeled CH60 (12 bands) and all samples returned with matching spoligotypes. However, two samples had differing MIRU-24 patterns; MIRU-12 (locus 4) for *sample 2* in the 2009 cluster and MIRU-24 (LOCI 3 and 17) for sample 1 in the 2013 cluster. Thus, the resulting PCR types differed between two of the four RFLP matched cases.

CONCLUSIONS: The 2009 cluster investigation identified a direct epidemiological link, via a previously shared home address, between the two case-patients. The follow-up investigation for the 2009 RFLP cluster revealed that two case-patients now acknowledge close contact with each other. The 2013 RFLP cluster investigation found that both cases were epidemiologically linked as father and child. Further epidemiological investigation revealed the case-patient/*sample 1* in the 2013 RFLP cluster, identified case-patient *sample 1* from 2009 as a close contact. Although the PCR types differed between these two cases, the investigation placed these individuals in the same place at the same time during the infectious period of the 2009 RFLP cluster. The timely availability of *IS6110* RFLP in New Jersey verifies the need for, and the importance of epidemiological investigations in TB prevention control. ❖

25th Annual HIV Medical Update: Celebrating a Milestone in HIV Education

On December 10, 2014, Garden State Infectious Disease Associates, the Rutgers School of Nursing, Francois-Xavier Bagnoud (FXB) Center and the Rutgers Biomedical and Health Sciences Center for Continuing and Outreach Education will host the 25th Annual HIV Medical Update conference at the Crowne Plaza Hotel in Cherry Hill, New Jersey. This is the state's largest and longest running HIV/AIDS continuing medical education conference and continues to draw over 200 physicians, physician assistants, advanced practice nurses, nurses, pharmacists, dentists, social workers and other interested health care professionals.

The history of the US AIDS epidemic began in illness, fear and death. We are now hopeful for a cure and an AIDS–free generation. This year's conference will spotlight some of New Jersey's best and most knowledgeable, dedicated clinicians from around New Jersey.

HIV infection remains a complex, challenging illness and an area of very active research and discovery. The knowledge base in HIV medicine is evolving rapidly, as is HIV clinical practice. Efforts to educate healthcare providers who care for patients with HIV has needed to keep pace. This is underscored by the complexities of working with 32 approved antiretroviral agents with more on the way, issues of worldwide stigma, and the hope for an effective vaccine. In addition, the National HIV/AIDS Strategy emphasizes that the pursuit of a concerted national effort to get and keep people living with HIV in care by establishing a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV is a priority.

The History of the Medical Update

The Medical Update conference coincides with the beginning of the HIV epidemic. In 1989, very little was known about the treatment and prevention of HIV/AIDS. Early clinical trials presented limited opportunities for effective treatment strategies. Opportunistic infections such as *pneumocystis carinii* pneumonia (PCP) was a major cause of illness and death for people living with the disease and HIV counseling and testing was just being implemented. There was widespread concern by the medical community in New Jersey, and nationally, that HIV/AIDS was becoming so devastating that many hundreds of people would become infected. A lack of general knowledge, in and outside, the medical community was fueling fear which was contributing to poor care and further stigma. In Voorhees, New Jersey several early pioneers, Dr. David Condoluci, an infectious disease specialist and the Medical Director of Garden State Infectious Disease Associates along with Karen Wallenobrien, MSW, and Judy Comito, RN, wanted to do something about this. They assessed a critical need for education and training of NJ primary care providers about HIV/AIDS. This was the genesis of the HIV Medical Update.

The very first conference was held in December, 1989 at the Mansion in Voorhees. There were about 100 medical providers from throughout the state in attendance. The agenda of the conference focused on available treatment and prevention of transmission. Early treatment was limited to zidovudine (AZT) monotherapy and prevention and treatment of opportunistic infections such as *pneumocystis carinii* pneumonia (PCP), mycobacterium avium complex (MAC) and others. In addition, national spokespeople began to relate their illness and advocate for treatment and involvement in their care creating new models of patient-provider engagement and care delivery for people living with HIV/AIDS. True patient-centered care became a priority early on. To highlight this in 2004 Dr. Condoluci presented the first Teddy DePrince Award named after a young man, who, along with his mother Elaine, fought for the New Jersey Hemophilia Justice Act of 1996. Mrs. DePrince went on to write ***Cry Bloody Murder: A Tale of Tainted Blood*** in 1997, after losing two of her sons to HIV/AIDS. There was much to be learned from these experiences. The tradition of awarding this honor to an outstanding member of the southern New Jersey HIV service pro-

Above right: Lisa O'Neill of Spirit of the Holidays was the recipient of the 2013 Teddy DePrince Award. Photo credit: Karen A. Forgash

vider community and recognizing him or her at the conference continues today. In 2013 Lisa O'Neill of Spirit of the Holidays was the recipient. In 1997 Lisa's brother Kevin Todd lost his hard fought battle with HIV/AIDS. Lisa promised her brother they would find ways to always remember him. After his death the family started a scholarship in his memory at Lenape High School, his alma mater. In 1999 they started Spirit of the Holiday to help families during the holiday season. To read more about the Spirit of the Holidays and the services they provide, please visit their website at http://www.spiritoftheholidays.org.

HIV in 2014: Spotlight on New Jersey's Best

The history of the US AIDS epidemic began in illness, fear and death. We are now hopeful for a cure and an AIDS–free generation. This year's conference will spotlight some of New Jersey's best and most knowledgeable, dedicated clinicians from around the state. An exciting day is planned with topics including an overview of the 25 year history of HIV in New Jersey, strategies for reducing HIV-related stigma, a hope for a cure highlighting the "Mississippi infant" functionally cured of HIV, hepatitis C treatment updates, papanicolaou screening and anal carcinoma, tuberculosis and HIV, cardiovascular and metabolic disorders, pre-exposure prophylaxis (PrEP) and post prophylaxis exposure (PEP).

The HIV Medical Update conference, an educational staple for southern New Jersey's healthcare provider population, ensures that attendees receive state-of-the-science information and a link to additional educational resources such as the NY/NJ AIDS Education and Training Center. Both the Garden State Infectious Disease Associates and Rutgers School of Nursing, François-Xavier Bagnoud (FXB) Center are Local Performance Sites of the NY/NJ AIDS Education and Training Center and offer ongoing individual HIV training and consultation. ❖

– Michelle Thomson, Program Manager, Rutgers School of Nursing, FXB Center
– Andrea Norberg, MS, RN, Executive Director, Rutgers School of Nursing, FXB Center, Contributing Author

Speakers at the 24th Annual HIV Medical Update in December 2013

Pictured below clockwise: Donna Futterman, MD, Director, Adolescent AIDS Program, Children's Hospital at Montifiore, Bronx, NY; David Condoluci, DO, FACOI, Medical Director, Garden State Infectious Disease Associates, Voorhees, NJ and Co-founder of the HIV Medical Update; Mohamed G. Atta, MD, Associate Professor of Medicine, John Hopkins University, Baltimore, MD; and James Dwyer, DO, Medical Director, Northpoint Health Care Center-AIDS Healthcare Foundation, Fort Lauderdale, FL
Photo credit: Karen A. Forgash

New Jersey AIDSLine Summer 2014
HIV, TB and STD news and information for health professionals

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25th Annual HIV Medical Update: Wednesday, December 10th Crowne Plaza, Cherry Hill
For more information contact: Michelle Thompson at ccthomps@sn.rutgers.edu or (973) 972-1293.

NJDOH-DHSTS The New Jersey AIDS Drug Distribution Program (ADDP) and Social Media for Agencies, Centers and Academic Institutions http://hpcpsdi.rutgers.edu/training/main.php

NY/NJ AETC Cervical Pap Test Training Program for Clinical Providers
http://www.nynjaetc.org/on-demand/cervicalpapprogram.html or (212) 304-5530

NY/NJ AETC Online training and education for healthcare professionals providing care and services for people living with HIV, the first online learning module is Hepatitis C Medications and Special Considerations for People Living with HIV.
https://learn.nynjaetc.org/accounts/login/?next=/

The NY/NJ AETC disseminates clinical support tools developed by our faculty experts. These products are designed to provide quick and easy references for providers. Our newest tools include Timelines for Expected Hormonal Changes in Trans Women & Trans Men, HIV and HCV Drug Interactions: A Quick Guide for Clinicians and The role of Integrase Strand Transfer Inhibitors in HIV Care. Our website offers continuing education accredited videos and monographs. Courses are available for physicians, physician assistants, nurse practitioners, nurses, pharmacists, and oral health providers. All activities are free of charge. Please visit www.nynjaetc.org today.

HIV/AIDS Training & Information Resources

New Jersey Department of Health–Division of HIV, STD, and TB Services (NJDOH-DHSTS) (609) 984-5874 ▪ www.state.nj.us/health/aids
- NJ HIV/AIDS statistical reports, regulations, forms, and links to HIV care, prevention programs, and training
- New Jersey rapid testing site: www.state.nj.us/health/aids/rapidtesting
- New Jersey AIDS/STD Hotline: (800) 624-2377

François-Xavier Bagnoud (FXB) Center, School of Nursing, Rutgers, The State University of New Jersey (973) 972-5644 ▪ Fax: (973) 972-0397 ▪ http://www.fxbcenter.org/about.html
- HIV/AIDS conferences, training
- Free online continuing education (CE) credits for healthcare professionals
- HIV/AIDS MEDICAL UPDATE SERIES: with funding from NJDHSS
- Free on-site HIV medical education for healthcare sites. **Contact** Michelle Thompson at (973) 972-1293 or ccthomps@sn.rutgers.edu

AIDS Education and Training Centers (AETC) National Resource Center: www.aidsetc.org
- NY/NJ AETC: www.nynjaetc.org

AIDSinfo: a service of the U.S. Department of Health and Human Services, offers access to the latest, federally approved HIV/AIDS medical practice guidelines, HIV treatment and prevention clinical trials, and other research information. http://www.aidsinfo.nih.gov/

AIDS InfoNet: HIV treatment fact sheets in English and 10 other languages. www.aidsinfonet.org

ClinicalTrials.gov: a registry and results database of publicly and privately supported clinical studies conducted around the world. http://clinicaltrials.gov

Centers for Disease Control and Prevention (CDC): http://www.cdc.gov/hiv/default.html

Health Resources and Services Administration (HRSA): http://www.hrsa.gov

FDA MedWatch: (800) FDA-1088; Subscribe to **e-bulletin:** www.fda.gov/medwatch/elist.htm

HealthHIV: Advances effective prevention, care and support for people living with, or at risk for, HIV by providing education, capacity building, health services research, and advocacy. http://www.healthhiv.org/index.php

National HIV/AIDS Clinicians' Consultation Center: http://www.nccc.ucsf.edu/
- Warmline: (800) 933-3413
- Post-Exposure Prophylaxis Hotline/PEPline: (888) 448-4911
- Perinatal HIV Hotline: (888) 448-8765

National Quality Center: no-cost, technical assistance for Ryan White funded grantees to improve the quality of HIV care nationwide. www.nationalqualitycenter.org

TARGET Center: technical assistance and training resources for the Ryan White community. www.careacttarget.org

Going Green

AIDSLine is Going Green! This is the last printed issue.
If you would like to be added to our electronic mailing list, confirm your email address, or be deleted from the mailing list, please contact FXBCenter@sn.rutgers.edu or call (973) 972-5644. You will receive an e-mail when AIDSLine is posted on the website.