Prepping for PrEP

HIV & Technology

2011 Tech Awards

HHS Treatment Guidelines
A Single Tablet Regimen That Reaches Many Treatment-Naïve Adults

Indication

COMPLERA is indicated for use as a complete regimen for the treatment of HIV-1 infection in antiretroviral treatment-naïve adults. This indication is based on Week 48 safety and efficacy analyses from 2 randomized, double-blind, active controlled, Phase 3 trials in treatment-naïve subjects comparing rilpivirine to efavirenz. The following points should be considered when initiating therapy with COMPLERA:

- More rilpivirine-treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure compared to subjects with HIV-1 RNA less than 100,000 copies/mL at the start of therapy.
- The observed virologic failure rate in rilpivirine-treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz.
- More subjects treated with rilpivirine developed lamivudine/emtricitabine associated resistance compared to efavirenz.

COMPLERA is not recommended for patients less than 18 years of age.

Important Safety Information

BOXED WARNINGS: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate, a component of COMPLERA, in combination with other antiretrovirals.
- COMPLERA is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of COMPLERA have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued EMTRIVA® (emtricitabine) or VIREAD® (tenofovir disoproxil fumarate), which are components of COMPLERA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue COMPLERA. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

References:
1. COMPLERA Prescribing Information. Gilead Sciences, Inc; August 2011.

Additional information:

- COMPLERA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- There are no adequate and well-controlled studies in pregnant women.
- To monitor fetal outcomes of pregnant women exposed to COMPLERA, an Antiretroviral Pregnancy Registry has been established and healthcare providers are encouraged to register patients by calling 1-800-258-4263.
- Please see additional Important Safety Information for COMPLERA on following pages.

Patient models. Pill shown is not actual size.
Put These Benefits Within Reach for Your Patients

Proven viral suppression through 48 weeks (HIV-1 RNA <50 copies/mL)1-2
- Proven non-inferior viral suppression to efavirenz: 83% with rilpivirine + emtricitabine/tenofovir disoproxil fumarate (N=550) versus 81% with efavirenz + emtricitabine/tenofovir disoproxil fumarate (N=546)1,4
- Incidence of virologic failure: 13% with rilpivirine + emtricitabine/tenofovir disoproxil fumarate (N=550) versus 8% with efavirenz + emtricitabine/tenofovir disoproxil fumarate (N=546)4
- More rilpivirine-treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure compared to subjects with HIV-1 RNA less than 100,000 copies/mL at the start of therapy6
- The observed virologic failure rate in rilpivirine-treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz2
- More subjects treated with rilpivirine developed lamivudine/emtricitabine associated resistance compared to efavirenz2

Demonstrated safety through 48 weeks1
- The most common adverse drug reactions (Grades 2-4, ≥2%) were insomnia and headache3
- Low rate of discontinuation due to adverse reactions (2% with rilpivirine + emtricitabine/tenofovir disoproxil fumarate versus 5% with efavirenz + emtricitabine/tenofovir disoproxil fumarate)1
- Smaller mean changes in fasting lipid levels (rilpivirine + emtricitabine/tenofovir disoproxil fumarate versus efavirenz + emtricitabine/tenofovir disoproxil fumarate)1
  - Total cholesterol (0 mg/dL versus 25 mg/dL), HDL cholesterol (3 mg/dL versus 9 mg/dL), LDL cholesterol (~2 mg/dL versus 13 mg/dL), triglycerides (~11 mg/dL versus 8 mg/dL)1

Additional information: Pregnancy Category B1
- There are no adequate and well-controlled studies in pregnant women1
- COMPLERA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus1
- To monitor fetal outcomes of pregnant women exposed to COMPLERA, an Antiretroviral Pregnancy Registry has been established and healthcare providers are encouraged to register patients by calling 1-800-258-42631

A complete once-daily, single tablet regimen1
- The recommended dose of COMPLERA is one tablet taken orally once daily with a meal1
- Because COMPLERA is a fixed-dose combination, it should not be prescribed for patients requiring dose adjustment such as those with moderate or severe renal impairment (creatinine clearance below 30 mL/min)1

For more information, please visit

www.complera.com

Safety and efficacy have not been established in patients less than 18 years old.1

*Study designs: The efficacy of COMPLERA is based on the analyses of 48-week data from 2 randomized, double-blind, controlled studies C209 (ECHO) and C215 (THRIVE) in treatment-naïve, HIV-1–infected subjects (N=1368). The studies were identical in design with the exception of the BR. Subjects were randomized in a 1:1 ratio to receive either rilpivirine 25 mg (N=686) once daily or efavirenz 600 mg (N=682) once daily in addition to a BR. In the ECHO study (N=690), the BR was emtricitabine/tenofovir disoproxil fumarate. In the THRIVE study (N=682), the BR consisted of 2 NRTIs: emtricitabine/tenofovir disoproxil fumarate 60% (n=406), lamivudine/zidovudine (30%, n=204), or abacavir + lamivudine (10%, n=68). The median baseline plasma HIV-1 RNA was 5 log10 copies/mL (range 2-7). The primary endpoint was non-inferior viral suppression to efavirenz through 48 weeks (HIV-1 RNA <50 copies/mL).1-3

BR=background regimen; NRTI=non-nucleoside reverse transcriptase inhibitor; NNRTI=non-nucleoside reverse transcriptase inhibitor.
Important Safety Information for COMPLERA (cont)

Please see previous page for Boxed WARNINGS about lactic acidosis, severe hepatomegaly with steatosis, and exacerbations of hepatitis B upon discontinuation of therapy.

CONTRAINDICATIONS

COMPLERA should not be coadministered with the following drugs, as significant decreases in rilpivirine plasma concentrations may occur due to CYP3A enzyme induction or gastric pH increase, which may result in loss of virologic response and possible resistance to COMPLERA or to the class of NNRTIs:

- the anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- the antimycobacterials rifabutin, rifampin, rifapentine
- proton pump inhibitors, such as esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole
- the glucocorticoid systemic dexamethasone (more than a single dose)
- St. John’s wort (Hypericum perforatum)

WARNINGS AND PRECAUTIONS

New onset or worsening renal impairment

- Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of tenofovir disoproxil fumarate. Assess creatinine clearance (CrCl) before initiating treatment with COMPLERA. Monitor CrCl and serum phosphorus in patients at risk for renal impairment, including patients who have previously experienced renal events while receiving HEPSERA® (adefovir dipivoxil). Avoid administering COMPLERA with concurrent or recent use of nephrotoxic drugs. Patients with CrCl below 50 mL per minute should not receive COMPLERA

Drug interactions

- COMPLERA should be used with caution when given with drugs that may reduce the exposure of rilpivirine
- COMPLERA should be used with caution when coadministered with a drug with a known risk of Torsade de Pointes

Depressive disorders

- The adverse reaction depressive disorders (depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, suicidal ideation) has been reported with rilpivirine. During the Phase 3 trials (N=1368), the incidence of depressive disorders (regardless of causality, severity) reported among rilpivirine (N=686) or efavirenz (N=682) was 8% and 6%, respectively. Most events were mild or moderate in severity. The incidence of Grade 3 and 4 depressive disorders (regardless of causality) was 1% for both rilpivirine and efavirenz. The incidence of discontinuation due to depressive disorders among rilpivirine or efavirenz was 1% in each arm. Suicide attempt was reported in 2 subjects in the rilpivirine arm while suicide ideation was reported in 1 subject in the rilpivirine arm and in 3 subjects in the efavirenz arm. Patients with severe depressive symptoms should seek immediate medical evaluation to assess the possibility that the symptoms are related to COMPLERA, and if so, to determine whether the risks of continued therapy outweigh the benefits

Decreases in bone mineral density

- Bone mineral density (BMD) monitoring should be considered for patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures) have been reported in association with the use of VIREAD® (tenofovir disoproxil fumarate).

Coadministration with other products

- COMPLERA should not be administered concurrently with other medicinal products containing any of the same active components, emtricitabine, rilpivirine, or tenofovir disoproxil fumarate (EMTRIVA® [emtricitabine], EDURANT® [rilpivirine], VIREAD, TRUVADA® [emtricitabine/tenofovir disoproxil fumarate], ATRIPLA® [efavirenz/emtricitabine/tenofovir disoproxil fumarate]), with medicinal products containing lamivudine (EPIVIR® or EPIVIR-HBV® [lamivudine], EPZICOM® [abacavir sulfate/lamivudine], COMBIVIR® [zidovudine/lamivudine], TRIZIVIR® [abacavir sulfate/lamivudine/zidovudine]), or with adefovir dipivoxil (HEPSERA®)

Fat redistribution

- Redistribution/accumulation of body fat has been observed in patients receiving antiretroviral therapy

Immune reconstitution syndrome

- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including the components of COMPLERA. Further evaluation and treatment may be necessary

ADVERSE REACTIONS

- The most common adverse drug reactions to rilpivirine (incidence greater than or equal to 2%, Grades 2–4) were diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams, and rash

DRUG INTERACTIONS

- COMPLERA should not be used with drugs where significant decreases in rilpivirine plasma concentrations may occur (See CONTRAINDICATIONS)
- COMPLERA is a complete regimen for the treatment of HIV-1 infection, therefore, COMPLERA should not be administered with other antiretroviral medications
- Drugs inducing or inhibiting CYP3A enzymes: Rilpivirine is primarily metabolized by cytochrome P450 (CYP) 3A, and drugs that induce or inhibit CYP3A may thus affect the clearance of rilpivirine. Co-administration of rilpivirine and drugs that induce CYP3A may result in decreased plasma concentrations of rilpivirine and loss of virologic response and possible resistance to rilpivirine or to the class of NNRTIs. Co-administration of rilpivirine and drugs that inhibit CYP3A may result in increased plasma concentrations of rilpivirine
- Drugs increasing gastric pH: Co-administration of rilpivirine with drugs that increase gastric pH may decrease plasma concentrations of rilpivirine and loss of virologic response and possible resistance to rilpivirine or to the class of NNRTIs
- Drugs affecting renal function: Because emtricitabine and tenofovir are primarily eliminated by the kidneys, co-administration of COMPLERA with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of emtricitabine, tenofovir, and/or other renal eliminated drugs. Some examples include, but are not limited to, acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, and valganciclovir
- QT prolonging drugs: There is limited information available on the potential for a pharmacodynamic interaction between rilpivirine and drugs that prolong the QTc interval of the electrocardiogram. In a study of healthy subjects, supratherapeutic doses of rilpivirine (75 mg once daily and 300 mg once daily) have been shown to prolong the QTc interval of the electrocardiogram. COMPLERA should be used with caution when coadministered with a drug with a known risk of Torsade de Pointes

DOSAGE AND ADMINISTRATION

Adults: The recommended dose of COMPLERA is one tablet taken orally once daily with a meal.

Renal Impairment: Because COMPLERA is a fixed-dose combination, it should not be prescribed for patients requiring dose adjustment such as those with moderate or severe renal impairment (creatinine clearance below 50 mL per minute).

Please see brief summary of Full Prescribing Information for COMPLERA on following pages, including Boxed WARNINGS about lactic acidosis, severe hepatomegaly with steatosis, and exacerbations of hepatitis B upon discontinuation of therapy.
The following adverse drug reactions are discussed in other sections of the labeling:

**ADVERSE REACTIONS**

Infection, wasting, facial wasting, breast enlargement, and “cushingoid appearance” have been observed in patients receiving antiretroviral therapy. The disorders (regardless of causality, severity) reported among rilpivirine (N = 686) or efavirenz (N = 682) was 8% and 6%, respectively. Most events

In addition, adverse drug reactions that occurred in at least 5% of treatment-emerged at treatment-emerged adverse drug reactions in combination with other antiretroviral agents are:

- **Skin and Subcutaneous Tissue Disorders**
- **Psychiatric Disorders**
- **Nausea**
- **Abnormal dreams**
- **Alcohol withdrawal**
- **Increased**
- **Abnormalities**
- **Skin discoloration**
- **Increased**
- **Nausea**
- **Abnormal dreams**
- **Alcohol withdrawal**
- **Increased**
- **Abnormalities**
- **Skin discoloration**

**WARRNINGS AND PRECAUTIONS**

**Lactic Acidosis/Severe Hepatomegaly with Steatosis:** Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been associated with the use of nucleoside analogues, including tenofovir disoproxil fumarate, component of COMPLERA and other antiretrovirals. A definite causal relationship to treatment with tenofovir disoproxil fumarate cannot be ruled out. In clinical trials of rilpivirine plus the allowed background regimen, plasma concentrations of lactic acid were within normal limits in 97.5% of patients treated at the end of the 48-week period. In phase 3 clinical trials, tenofovir disoproxil fumarate and rilpivirine were used in patients with and without known risk factors. Treatment with COMPLERA should be considered in any patient who develops clinical and laboratory findings suggestive of lactic acidosis or hepatomegaly with steatosis (see Table 1). In the absence of a causal relationship to continued treatment with tenofovir disoproxil fumarate.

**Patients Coinfected with HIV-1 and HBV:** It is recommended that all patients with HIV-1 be tested for the presence of chronic hepatitis B infection and the safety of efavirenz have not been evaluated in patients with chronic hepatitis B infection. Chronic hepatitis B infection is defined as plasma HBV DNA levels >10^5 copies/mL (N = 148). Exposure of patients with known risk factors. Treatment with COMPLERA should be considered in any patient who develops clinical and laboratory findings suggestive of lactic acidosis or hepatomegaly with steatosis (see Table 1). In the absence of a causal relationship to continued treatment with tenofovir disoproxil fumarate.

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**Increased AST**

Grade 2  >2.5 – ≤5.0 x uLN  4% 15%

Grade 3  >5.0 – ≤10.0 x uLN  1%  2%

Grade 4  >10.0 x uLN  1%  2%

**Increased ALT**

Grade 2  >2.5 – ≤5.0 x uLN  4% 15%

Grade 3  >5.0 – ≤10.0 x uLN  1%  2%

Grade 4  >10.0 x uLN  1%  2%

**Increased Bilirubin**

Grade 2  >1.2 – 3.0 x uLN  1%  3%

Grade 3  >3.0 – ≤10.0 x uLN  1%  2%

Grade 4  >10.0 x uLN  1%  2%

**Increased Total Cholesterol**

Grade 2  >200 – 240 mg/dL  1%  1%

Grade 3  >240 – 270 mg/dL  <1% 1%

Grade 4  >270 mg/dL  <1% 1%

**Increased LDL Cholesterol**

Grade 2  >130 – 159 mg/dL  1% 1%

Grade 3  >159 – 189 mg/dL  1% 1%

Grade 4  >189 mg/dL  <1% 1%

**Increased Triglycerides**

Grade 2  150 – 199 mg/dL  1% 1%

Grade 3  >199 mg/dL  <1% 1%

**t-statistic from Student’s t-test**

**Increased AST**

Grade 2  >2.5 – ≤5.0 x uLN  4% 15%

Grade 3  >5.0 – ≤10.0 x uLN  1%  2%

Grade 4  >10.0 x uLN  1%  2%

**Increased ALT**

Grade 2  >2.5 – ≤5.0 x uLN  4% 15%

Grade 3  >5.0 – ≤10.0 x uLN  1%  2%

Grade 4  >10.0 x uLN  1%  2%

**Increased Bilirubin**

Grade 2  >1.2 – 3.0 x uLN  1%  3%

Grade 3  >3.0 – ≤10.0 x uLN  1%  2%

Grade 4  >10.0 x uLN  1%  2%

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Grade 2  >200 – 240 mg/dL  1%  1%

Grade 3  >240 – 270 mg/dL  <1% 1%

Grade 4  >270 mg/dL  <1% 1%

**Increased LDL Cholesterol**

Grade 2  >130 – 159 mg/dL  1% 1%

Grade 3  >159 – 189 mg/dL  1% 1%

Grade 4  >189 mg/dL  <1% 1%

**Increased Triglycerides**

Grade 2  150 – 199 mg/dL  1% 1%

Grade 3  >199 mg/dL  <1% 1%

**Grade 1**

**Grade 2**

**Grade 3**

**Grade 4**

**No patient was treated with rilpivirine who developed lamivudine/emtricitabine associated resistance compared to efavirenz** [See Adverse Reactions].

Caution should be given to prescribing COMPLERA with drugs that may reduce the exposure of rilpivirine [See Contraindications, Warnings and Precautions].

COMPLERA is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of COMPLERA have not been established in patients infected with HBV and treated with EMTRIVA, the exacerbations of hepatitis B were associated with liver decompensation and liver failure.

If appropriate, treatment-emergent adverse drug reactions of at least moderate intensity (≥ Grade 2) that occurred in less than 2% of subjects treated with rilpivirine plus any of the allowed background regimen N = number of subjects per treatment group

**Emtricitabine and Tenofovir Disoproxil Fumarate:**

• the antimycobacterials rifabutin, rifampin, rifapentine

• the anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, phenytoin

• the protease inhibitors nelfinavir, saquinavir, indinavir, ritonavir, lopinavir, atazanavir

Combination therapy with antiretroviral drugs is generally the same as that seen with other antiretroviral drugs.本品に含まれる薬物成分の用量や薬効が変化することなく、薬物相互作用のリスクを最小限に抑えることが可能な薬物を指す。
Triglycerides
nizatidine
famotidine
voriconazole
H2-Receptor Antagonists:
magnesium hydroxide, or
Antacids:
Drug interaction studies have been conducted using COMPLERA [for pharmacokinetic data see
Important drug interaction information for COMPLERA is summarized in Table 4. The drug interactions described are based on studies conducted with
QT Prolonging Drugs
limited to, acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, and valganciclovir.
emtricitabine, tenofovir, and/or other renally eliminated drugs. Some examples of drugs that are eliminated by active tubular secretion include, but are not
[see Table 4].
Rilpivirine at a dose of 25 mg once daily is not likely to have a clinically relevant effect on the exposure of drugs metabolized by CYP enzymes.
Of rilpivirine and drugs that inhibit CYP3A may result in increased plasma concentrations of rilpivirine.
Rilpivirine is primarily metabolized by cytochrome P450 (CYP) 3A, and drugs that induce or inhibit CYP3A may thus affect the clearance of rilpivirine
•  Patients with HIV-1 should be tested for hepatitis B virus (HBV) before initiating antiretroviral therapy. Severe acute exacerbations of hepatitis B have
•  Patients should be informed that COMPLERA is not a cure for HIV infection. Patients should stay on continuous HIV therapy to control HIV infection and
Mean Changeb
Mean (mg/dL)
Mean Changeb
Mean (mg/dL)
Total Cholesterol
260 ± 50
220 ± 40
40 ± 10
15 ± 5
Triglycerides
150 ± 100
100 ± 80
50 ± 40
25 ± 20
LDL-Cholesterol
260 ± 50
220 ± 40
30 ± 20
15 ± 5
High Density Lipoprotein
260 ± 50
220 ± 40
40 ± 10
15 ± 5
Narcotic Analgesics:
clarithromycin
erthyromycin
troleandomycin
Concomitant use of COMPLERA with clarithromycin, erythromycin
and troleandomycin may cause an increase in the plasma
concentrations of rilpivirine (inhibition of CYP3A enzymes). Where
possible, alternatives such as azithromycin should be considered.
Rilpivirine may need to be adjusted in some patients.
COMPLERA is not recommended for patients less than 18 years of age because not all the individual components of the COMPLERA have safety,
efficacy and dosing recommendations available for all pediatric age groups. [See Clinical Pharmacology in Full Prescribing Information]
Hepatic Impairment
No dose adjustment of COMPLERA is required in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment.
COMPLERA is not recommended for patients with severe hepatic impairment (Child-Pugh Class C).
[See Clinical Pharmacology in Full Prescribing Information]
Ovarian Dysgenesis
There is no specific ovulation for ovulation by ovulation.
HIV-1 proteins were identified at doses ranging from 20 to 200 mcg/kg/day.
Administration of an needed ovulation may also be needed to the administration.
N = number of subjects per treatment group. a. Includes subjects who were lossed during the treatment period. b. The design change from baseline to treatment period was computed for patients with both baseline and Week 48 values.
Subjects Conflated with HbV and/or HCV: If patients with conflated with hepatitis B or C are receiving studies in C209 and C215 were not
not randomized to the same center. The common baseline was also
observed in the same arm. The pharmacokinetic exposure of emtricitabine in subjects not conflated was subject to what influences that were not
Postmarketing Experience
The following adverse reactions have been identified during postapproval use of emtricitabine or tenofovir disoproxil fumarate. Because postmarketing
reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate frequency or establish a causal
relationship. Emtricitabine: No postmarketing adverse reactions have been identified for this section.
Respiratory, Thoracic, and Mediastinal Disorders:
dyspnea
Metabolism and Nutrition Disorders:
lactic acidosis, hypokalemia, hypophosphatemia
Antihypertensive:
Non-steroidal Anti-Inflammatory Drugs:
steroid and other anti-inflammatory drugs, including aspirin and other NSAIDs, may increase
the risk of GI bleeding, peptic ulceration, and related adverse events for these patients.
Concomitant use of COMPLERA with acetaminophen, atorvastatin, chlorzoxazone, ethinylestradiol, norethindrone,
or tacrolimus in studies conducted in healthy subjects.
No clinically significant drug interactions have been observed between emtricitabine and fosamprenavir or tenofovir disoproxil fumarate. Similarly, no
clinically significant drug interaction have been observed between tenofovir disoproxil fumarate and rifampin, methadone, carbamazepine, diclofenac,
diazepam, or fosamprenavir. Tenofovir disoproxil fumarate has not been studied in interaction studies.
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Metabolism and Nutrition Disorders:
lactic acidosis, hypokalemia, hypophosphatemia
Antihypertensive:
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the risk of GI bleeding, peptic ulceration, and related adverse events for these patients.
Concomitant use of COMPLERA with acetaminophen, atorvastatin, chlorzoxazone, ethinylestradiol, norethindrone,
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Metabolism and Nutrition Disorders:
lactic acidosis, hypokalemia, hypophosphatemia
Antihypertensive:
Non-steroidal Anti-Inflammatory Drugs:
steroid and other anti-inflammatory drugs, including aspirin and other NSAIDs, may increase
the risk of GI bleeding, peptic ulceration, and related adverse events for these patients.
Concomitant use of COMPLERA with acetaminophen, atorvastatin, chlorzoxazone, ethinylestradiol, norethindrone,
or tacrolimus in studies conducted in healthy subjects.
No clinically significant drug interactions have been observed between emtricitabine and fosamprenavir or tenofovir disoproxil fumarate. Similarly, no
clinically significant drug interaction have been observed between tenofovir disoproxil fumarate and rifampin, methadone, carbamazepine, diclofenac,
diazepam, or fosamprenavir. Tenofovir disoproxil fumarate has not been studied in interaction studies.
Saying Goodbye

AAHIVM experienced a great loss on January 2, 2012. Our beloved friend and colleague, Peter Fox, passed away after a short, yet brave fight against CNS lymphoma.

Peter was an amazing individual who lived a dozen lives in his too short 45 years. He was a cross country trucker operating out of Buffalo. He was an Emergency Medical Tech in Pittsburgh. He was an avid motorcyclist who rode with friends throughout the US and Europe, eventually starting a small business focused on planned motorcycle tours specifically directed at LGBT riders called ‘RideOut Adventures.’ He was a professional singer who performed at President Obama’s Inauguration Celebration, at the Kennedy Center, at Nationals Park and many times over with his beloved Gay Men’s Choir of DC. And like everything else he did, he was passionate and committed about each and every one of these endeavors. And like everything else he did, he did them unimaginably well.

At the Academy, Peter ran the Credentialing Program from 2005 until the present. But to say he ran it is selling him short. He owned it, nurtured it, he kept it safe, he helped—no he made it grow. And grow it did. He planned and executed the Low Volume Option, where practitioners with fewer HIV patients, with the help of a mentor, could still become credentialed—so that those patients, too, could receive high quality, up-to-date care. He created, planned and executed all aspects of the credential for HIV-specializing Pharmacists—because they are so important to the HIV care team. He believed, as do all of us, that the credential identified highly qualified HIV practitioners to the new HIV patient. Today the Academy credentials over 2000 practitioners—more than twice the number when he took over in 2005. Peter did that. Peter made that happen. His legacy will live on in many ways, including through thousands of HIV patients who are receiving the best care possible.

Peter was a perfectionist and he was persistent—oh, was he persistent. He willed us to upgrade and improve our internal data and technology systems. He was the ad-hoc techie in the office, so he became the point person for our contractor. And through the year-long process of these improvements, he often complained about the extra work. But he sure wasn’t going to let anyone else take over. He wanted it to be perfect. And, it is.

To honor his leadership and dedication to the Credentialing Program, we have created the Peter M. Fox Excellence in AAHIVM Credentialing Award to be bestowed annually to those HIV practices where all of the HIV practitioners are currently credentialed.

And of course, the HIV Credentialing Program will continue to thrive—but now under the experienced hand of Ken South—formerly our director of membership. You will find an overview of the AAHIVM Credentialing Program written by Ken that appears elsewhere in this edition.

But as important as all of his personal and professional accomplishments are, Peter was our friend. He cared for us and we cared for him. His overwhelming positivity and strong spirit are indelible, unmistakable memories to all of us who knew him. We still think of his charming smile and infectious laugh and his measured and yet brilliantly creative approach to work and life. He loved life and the people in his as much as anyone could.

We miss him every day.
FDA Issues Alert on HCV and HIV Drug Interaction

The Food and Drug Administration (FDA) has notified healthcare professionals and patients that drug interactions between the hepatitis C virus (HCV) protease inhibitor Victrelis (boceprevir) and certain ritonavir-boosted human immunodeficiency virus (HIV) protease inhibitors (atazanavir, lopinavir, darunavir) can potentially reduce the effectiveness of these medicines when they are used together.

A drug interaction study showed that taking boceprevir (Vicrelis) with ritonavir (Norvir) in combination with atazanavir (Reyataz) or darunavir (Prezista), or with Kaletra (lopinavir/ritonavir) reduced the blood levels of the HIV medicines and boceprevir in the body. FDA will update the Vicrelis drug label to include information about these drug interactions.

FDA advised that healthcare professionals who have started patients infected with both chronic HCV and HIV on Vicrelis and antiretroviral therapy containing a ritonavir-boosted protease inhibitor should closely monitor patients for HCV treatment response and for potential HCV and HIV virologic rebound.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA’s MedWatch Safety Information and Adverse Event Reporting Program by visiting https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm.

Study Links Tenofovir with Kidney Damage Risk

Tenofovir, one of the most effective and commonly prescribed antiretroviral medications for HIV/AIDS, is associated with a significant risk of kidney damage and chronic kidney disease that increases over time, according to a study of more than 10,000 patients led by researchers at the San Francisco VA Medical Center and the University of California, San Francisco (UCSF).

The researchers called for increased screening for kidney damage in patients taking the drug, especially those with other risk factors for kidney disease.

In their analysis of comprehensive VA electronic health records, the study authors found that for each year of exposure to tenofovir, risk of protein in urine, a marker of kidney damage, rose 34 percent, risk of rapidly declining kidney function rose 11 percent and risk of developing chronic kidney disease (CKD) rose 33 percent. The risks remained after the researchers controlled for other kidney disease risk factors such as age, race, diabetes, hypertension, smoking and HIV-related factors.

For individual patients, the differences in risk between users and non-users of tenofovir for each year of use were 13 percent vs. 8 percent for protein in urine, 9 percent vs. 5 percent for rapidly declining kidney function and 2 percent vs. 1 percent for CKD.

The numbers are based on the average risks in the study population, and patients with more risk factors for kidney disease would be at proportionately higher risk, said principal investigator Michael G. Shlipak, MD, MPH, chief of general internal medicine at SFVAMC and professor of medicine and epidemiology and biostatistics at UCSF.

Patients were tracked for an average of 1.2 years after they stopped taking tenofovir. They remained at elevated risk for at least six months to one year compared with those who never took the drug, suggesting that the damage is not quickly reversible, said Dr. Shlipak. “We do not know the long-term prognosis for these patients who stop tenofovir after developing kidney disease,” he cautioned.

The implications for patients already on or starting antiretroviral therapy are “mixed,” Dr. Shlipak said. “The best strategy right now is to work with your health care provider to continually monitor for kidney damage. Early detection is the best way to determine when the risks of tenofovir begin to outweigh the benefits.”

Dr. Shlipak noted that HIV itself, increases the risk of kidney damage, while modern antiretroviral treatments reduce that overall risk. “For an otherwise healthy patient, the benefits of tenofovir are likely to exceed the risks,” he said, “but for a patient with a combination of risk factors for kidney disease, tenofovir may not be the right medication.”

Co-authors of the study were Michelle Estrella, MD, of Johns Hopkins School of Medicine; the late Andy I. Choi, MD, MAS, of SFVAMC and UCSF; Steven G. Deeks, MD, of San Francisco General Hospital; and Carl Grunfeld, MD, PhD, of SFVAMC and UCSF.

The study was supported by funds from the National Institutes of Health, the National Center for Research Resources, the American Heart Association and the Department of Veterans Affairs, some of which were administered by the Northern California Institute for Research and Education.

The study was published electronically Feb. 9, 2012 in the journal AIDS.
Increased Fed HIV Support Sought for Southern US

The Southeastern United States is experiencing the highest rate of new HIV/AIDS infections and the federal government should commit increased resources to combat the disease on those states, says a new research report, “HIV/AIDS Epidemic in the South Reaches Crisis Proportions in Last Decade,” released in January by the Southern HIV/AIDS Strategy Initiative (SASI).

The report analyzes nine southern states: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee and (East) Texas.

“We call on the President’s Office of National AIDS Policy to coordinate an enhanced federal response and focused federal resources on the southern states,” said Carolyn McAllaster, director of the Duke AIDS Legal Project and SASI project director. “The South faces an urgent need for resources to fight the epidemic as the South has the highest rates of both new HIV diagnoses and HIV-related deaths in the country, as well as poor social determinants of health and high poverty rates.”

According to the report, commissioned by SASI and compiled by the Duke Center for Health Policy and Inequalities Research, 35 percent of new HIV infections in 2009 were in the nine targeted southern states, which contain only 22 percent of the U.S. population. The targeted states also lead the nation in new AIDS diagnoses rates.

Nine of the ten states with the highest rates of death due to HIV in the country are in the South, and all nine states are among the 15 states with the highest HIV death rates. The report also says 99.5 percent of people on waiting lists for AIDS Drug Assistance Programs live in the South.

SASI representatives have shared the report findings with federal officials responsible for the government’s initiative against the disease.

SASI was launched earlier this year by the Duke AIDS Legal Project in collaboration with AIDS service providers, advocates and people living with HIV and AIDS throughout the South.

Feds Launch Grant Competition for HIV/AIDS Services for Women, Children

The HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration (HRSA) in January issued a Funding Opportunity Announcement (FOA) for the Ryan White HIV/AIDS Program Part D Grants for Coordinated HIV Services and Access to Research for Women, Infants, Children, and Youth (WICY). According to HRSA the entire $70 million Part D program is being re-competed through this FOA to respond to changing HIV epidemiology and better address the goals of the National HIV/AIDS Strategy (NHAS) by providing comprehensive health care services for the WICY populations in areas of greatest need for services.

HRSA pointed out that transmission of HIV from mother to infant has decreased substantially with universal prenatal HIV testing and ARV prophylaxis. Today, children comprise only 1 percent of the HIV epidemic in the United States, but women, especially women of color, now comprise 28 percent of all people in the U.S. living with HIV (PLWH).

Among persons aged 13-29 years, it is estimated that HIV incidence has increased 21% in recent years—driven largely by increased incidence in young men who have sex with men (MSM), especially young black MSM.

HRSA said Ryan White-funded services should ensure that newly identified PLWH, especially young African American MSM, are linked into healthcare, provided ARV medications, and retained in care.

The FOA solicits grant applications from organizations throughout the U.S. and its territories to provide family-centered primary medical care to women, infants, children, and youth living with HIV/AIDS when payments for such services are unavailable from other sources. Funding is intended to improve access to primary HIV medical care for HIV-infected women, infants, children, and youth through the provision of coordinated, comprehensive, culturally and linguistically competent services.

Grantees are expected to provide HIV primary care, specialty medical care, and support services to the clients they serve. The FOA requires that program activities should seek opportunities to increase collaboration, efficiency, and innovation in the development of program activities to ensure success of the NHAS.

HRSA estimates that approximately 200 awards will be made. Grant applicant technical assistance webinars are being provided. Visit http://careacttarget.org/ for more information.
IN THE NEWS

HIV+ Transgender Women of Color into Care is Target of New Grants

THE HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) is offering two new grant competitions to identify, evaluate, and promote successful strategies for getting HIV-positive transgender women of color into primary care and retaining them in care.

The first grant program is designed to improve the overall quality of HIV care for transgender women of color. Up to eight grantees will be eligible to receive up to $300,000 a year for five years to serve as demonstration sites that will design, implement, and evaluate innovative interventions to improve timely entry, engagement and retention in quality HIV care for transgender women of color living with HIV infection.

Applicants must be public or private non-profit entities including, state, county and city governments; institutions of higher education; community health centers receiving support under Section 330 of the PHS Act; federally qualified health centers; faith-based or community-based organizations; or Indian Tribes/Tribal organizations. For more information, please visit www.grants.gov. Search for Funding Opportunity Number “HRSA-12-099”.

The second grant opportunity will fund a related Evaluation and Technical Assistance Center that will coordinate a comprehensive array of capacity-building activities, provide technical assistance in clinical and cultural competencies, and oversee the dissemination of findings from the demonstration sites. For more information, please visit Visit www.grants.gov. Search for Funding Opportunity Number “HRSA-12-101”.

Both programs are funded under HRSA’s Ryan White HIV/AIDS Program, Special Projects of National Significance (SPNS), which provides grants to identify, evaluate and replicate innovative models of HIV/AIDS care and treatment for hard-to-reach and at-risk populations. Applications are due no later than April 16, 2012 at www.grants.gov.

HRSA is always looking for a diverse group of expert grant reviewers. Anyone interested in being a HRSA grant reviewer is encouraged to register at: http://www.hrsa.gov/grants/reviewers/index.html.

Study Indicates Non-Progressors May Be Slow Progressors

New research indicates HIV positive individuals traditionally classified as long-term non-progressors (LTNPs) or viral controllers actually may progress slowly over time and may benefit from antiretroviral therapy (ART).

The study, reported February 20, 2012 by the open-access journal PLoS ONE, was conducted by Researcher Sundhiya Mandalia and colleagues at the Department of Medicine, Imperial College London, Chelsea and Westminster Hospital, London and the London School of Hygiene and Tropical Medicine.

They analyzed medical records from patients with HIV-1 who were seen at Chelsea and Westminster Hospital between 1988 and 2010. LTNP were defined as patients who were HIV positive for more than seven years, ART-naïve, had no history of opportunistic illness, and a stable normal CD4 cell count.

The researchers compared those with a history of stable CD4 counts below normal (< 450 cells/mm3), or those whose level dropped below normal at least once to those whose levels always remained within the normal range. Within these groups, they identified individuals with HIV RNA consistently below the limit of detection.

A small proportion of people with HIV appear to be LTNPs who maintain a stable CD4-cell count and do not experience opportunistic illness even without ART. A smaller group, HIV controllers, maintain undetectable viral load without treatment.

• Of 14,227 patients, 5417 were diagnosed as HIV positive more than 7 years ago; 1,204 had never been prescribed ART. Of them, 239 (20 percent) had CD4 counts consistently within the normal range.

• Among the 1,204 long-term positive, ART-naive patients, 312 (26 percent) were consistently asymptomatic. Of them, 110 (35 percent) maintained CD4 counts within the normal range, and a median time to progression of 9.1 years, compared with 7.3 years for those whose CD4 count fell below normal at least once.

• 258 (83 percent) of the 312 ART-naive asymptomatic patients had unstable or declining CD4 counts, of whom 96 (37 percent) had counts consistently within the normal range; the estimated median time to progression for this group was 5.8 years — similar to the 4.6 years for the 163 patients (63 percent) with below-normal CD4 counts.

• 50 ART-naive patients had long-term stable CD4 cell counts. Of them, 13 were classified as LTNPs with CD4 counts consistently in the normal range, while the remaining 37 had at least 1 below-normal measurement.

• 1 of the 13 LTNPs (8 percent), and 3 of the 37 with at least 1 low CD4 count, met the viral load criteria to be classified as HIV controllers.

“This study suggests that by using varying selection criteria, disease progression is very likely in the majority of people living with HIV,” the researchers said. “The patients who had not progressed within the study period are likely to do so, as demonstrated in the analysis of individuals found to have long-term stable low CD4-cell counts compared to those with unstable CD4 T-cell counts.”

Reference

Siemens Forms New Diagnostics Partnerships

**SIEMENS HEALTHCARE DIAGNOSTICS** has announced new companion diagnostics partnerships with pharmaceutical companies Viiv Healthcare and Tocagen, marking a major step for Siemens into this fast-growing segment of the in vitro diagnostics (IVD) market.

Both partnerships intend to leverage the clinical trial and commercialization options within Siemens' CLIA laboratory, as well as Siemens' established IVD clinical and regulatory expertise, the company said.

Siemens' partnership with Viiv Healthcare will focus on clinical trials related to Celsentri/Selzentry® (maraviroc) Viiv Healthcare's novel CCR5 co-receptor antagonist for the treatment of CCR5-tropic HIV followed by potential commercialization of a diagnostics test to assist in patient selection prior to physician treatment decisions, subject to FDA approval.

The Siemens - Tocagen relationship will begin with diagnostic tests to support clinical trials related to Tocagen's unique viral gene therapy (Toca 511 & Toca FC) under investigation for the treatment of primary brain cancer, followed by potential commercialization of diagnostic tests for therapy monitoring, subject to FDA approval.

Viiv Healthcare previously announced the start of the Phase III MODERN Study [Maraviroc Once daily with Darunavir Enhanced by Ritonavir in a Novel regimen], also known as A4001095, comparing its CCR5-inhibitor, Celsentri/Selzentry® (maraviroc), to emtricitabine/tenofovir (Truvada®), both in combination with darunavir/ritonavir. The 96-week trial will evaluate a two-drug versus three-drug once-daily regimen for the treatment of antiretroviral-naive patients infected with CCR5-tropic HIV.

In addition, MODERN is the first large Phase III trial that will compare the performance of a genotypic test with a phenotypic test in identifying patients appropriate for use of Celsentri/Selzentry®. Patients will be randomised to undergo screening with either the genotypic or phenotypic test. Genotypic tropism testing in the MODERN study is provided by Siemens Healthcare Diagnostics as part of this partnership and phenotypic testing (Trofile®) by Monogram Biosciences. Subject to FDA approval, Siemens Healthcare Diagnostics may commercialize their genotypic tropism diagnostic test.

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**FDA OKs New Formulations of Viread® for Children With HIV**

**THE U.S. FOOD AND DRUG ADMINISTRATION** (FDA) has approved Viread® (tenofovir disoproxil fumarate) in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients ages 2-12.

The FDA approved a supplemental New Drug Application (sNDA) for three lower-strength once-daily tablets of Viread in doses of 150 mg, 200 mg and 250 mg for children ages 6-12. The agency also approved a New Drug Application (NDA) for an oral powder formulation of Viread for children ages 2-5. The active ingredient in Viread, tenofovir disoproxil fumarate, is currently the most-prescribed molecule for adults receiving HIV therapy in the United States.

Viread was originally approved by FDA in 2001 as a once-daily 300 mg tablet for individuals ages 18 and over for the treatment of HIV-1 infection in combination with other antiretrovirals. In March 2010, the 300 mg dose was approved for use in the United States among adolescents ages 12-17. In pediatric patients, the use of either the lower-strength tablets or the oral powder formulation of Viread is based on the patient’s age and weight. The safety and efficacy of Viread has not been established in children less than two years of age. In HIV-infected adult patients, the dose is one 300 mg Viread tablet once daily taken orally, without regard to food. For adults unable to swallow Viread tablets, the oral powder formulation equal to 300 mg may be used.

The pediatric regulatory applications for Viread were supported by clinical data from a Phase 3 safety and efficacy study of a Viread-containing antiretroviral regimen compared to an antiretroviral regimen containing zidovudine or stavudine in HIV-infected treatment-experienced children ages 2-12. The safety profile observed in the study was consistent with that observed in clinical trials in adults. The applications were submitted to the FDA on July 18, 2011.
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Winter 2012
www.aahivm.org
AAHIVM’s Credentialing Program
A Season of Change and Growth

There is no doubt that the sudden loss of the champion of the AAHIVM Credentialing Program, Peter Fox, has not only been a personal shock for Academy staff, but has meant that we have had to quickly fill in and catch up on the myriad of details that keeps this essential program moving forward.

Having worked at the Academy for over five years as director of membership, I had the opportunity to work in tandem with Peter on the credentialing program, often celebrating its growth, achievements and successes. Understanding the considerable responsibilities, I am honored to accept the challenge as the next director of the credentialing department. I look forward to not only maintaining its excellence, but seeing new aspects added as this program continues to grow in the future.

My colleague, Aaron Austin, has assumed my position as membership director, and I see that he is already doing a fantastic job.

As I settle into my new responsibilities, I wanted to take this opportunity to summarize the credentialing program...both where it’s been and where it’s going.

The Academy’s HIV-focused professional certifications are the first and only credentials offered domestically and internationally to physicians, nurse practitioners, physician assistants and pharmacists specializing in advanced level HIV care. The HIV Specialist™ (AAHIVS) credential is available to practicing frontline clinical providers, while the HIV Expert™ (AAHIVE) designation can be earned by clinicians working in research or industry are waived and earn the AAHIVE designation.

- EDUCATION: the applicant must be actively engaged in ongoing continuing medical education or related activities, and must declare and describe a minimum specified level of activity when applying. This aspect of the certification eligibility is critical as the earned credential in fact signifies (in part) that the HIV Specialist™ (AAHIVS), HIV Pharmacist™ (AAHIVP) or HIV Expert™ (AAHIVE) candidate is engaged in high level, ongoing learning and study in the field.

History of Credentialing at the Academy

In the late 1990’s, the late Scott Hitt, MD, of Los Angeles, former chairman of President Clinton’s Presidential Advisory Council on HIV/AIDS, and founder of the American Academy of HIV Medicine, became dismayed with the fact that there was little or no standardization or professional recognition for skilled providers working in HIV primary care. Nor was there any method to protect consumers of HIV-related healthcare services; consumers who would clearly be served by a public and recognizable minimum standard of HIV care quality.

At that time, and even now, the largest medical organizations had done little to create a measurable standard of care, or a means of professional recognition for providers in this challenging subspecialty. There was, in fact, no board certification, certificate of added qualification (CAQ) or other properly developed training or measurement mechanism that truly related to expert HIV primary care. These factors, among others, motivated Dr. Hitt and others at the Academy to begin the groundwork for the establishment of a valid and defensible provider credentialing program in HIV care.

The Program Today

The HIV Specialist™ exam is now in its tenth year and is a widely respected measurement program that has been carefully constructed and maintained over the years using expert guidance from the testing and certification industry, and has proved to be a highly defensible measurement mechanism.

This 1/1/2012-12/31/2013 cycle of credentialing was especially successful as enrollment in the program surpassed the last cycle. The numbers in this class of HIV Specialists™ (AAHIVS) are impressive: A total of 1,051 persons passed the exam. Of those, 687 are physicians, 160 are nurse practitioners and 68 are physician assistants. This was the first testing cycle to include the newly designed exam for HIV pharmacists and 136 of them took advantage of the opportunity and now carry the AAHIVP with their professional degrees. There are currently over 2,000 persons who are HIV Specialists™, HIV Pharmacists™ or HIV Experts™ representing both the 2011 and 2012 credentialing classes.

The next enrollment period for the credentialing cycle of January, 2013 to December 31st, 2014 will open in the spring of this year. Please consult the credentialing pages on the AAHIVM website at: www.aahivm.org for additional extensive information about the program.

About the Author: Ken South is Director of Credentialing at the American Academy of HIV Medicine.
What’s New in Your State?

“Most Americans have more daily contact with their state and local governments than with the federal government.”


This quote is true for private citizens, for patients, and also for providers. In all likelihood, more of your day as a health care provider is determined by your state executives and state legislature than you realize. The decisions of state lawmakers can affect health care, medical practice, and patient care and treatment.

The legislatures of 38 states began their 2012 legislative session in January. Another six state legislatures will assemble during the month of February, for a total of 44 state legislatures in session by Valentine’s Day. By the end of March, 10 of those states will have already adjourned the 2012 session of the legislature.

Many people do not realize that the state legislatures move very quickly through their legislative business. The four shortest state legislatures—those of Arkansas, New Mexico, Oregon, and Wyoming—are only in active session for about one month this year!

In fact, the majority of state legislatures will have convened, proposed, argued, amended and passed hundreds of bills, and adjourned business by early June.

At the state level, bills can go from introduction to enactment in a matter of days. Staying on top of such fast-paced developments can be very challenging. For those with specific concerns about areas of public law—such as HIV care and treatment—it can also be difficult to find reliable information on the bills that matter most to you.

Literally, hundreds of thousands of bills are introduced in the state legislatures across the country each year. While some of this legislation is obviously specific to HIV care and Treatment (such as the 1990 Pennsylvania legislation, the “Confidentiality of HIV-Related Information Act,” that dealt with HIV testing confidentiality provisions), much of it is more difficult to discover at first glance.

Last year, the New York State Assembly considered “Assembly Bill 5502—B.” The legislation, which ultimately became law, dealt with insurance plans that required patients to fill prescriptions by mail order. The bill had a number of implications for HIV patients, in terms of privacy, drug prices, and insurance coverage. It also had implications for HIV-specialized pharmacies and pharmacists. However, the bill would have been easy to miss, even by those who watch for news of such policy developments.

That is why AAHIVM has developed the AAHIVM State Legislation Tracker. This tool gives Members the ability to see the bills that are important to them, by generating a customized list of the bills that are most likely to impact the practice of HIV medical care.

It is available to all AAHIVM Members, and was set up to show you the bills in your state that will affect HIV medical care. You can access the State Legislative Tracking tool by visiting the Policy and Advocacy section of our website.

By Holly A. Kilness, MA

About the Author: Holly A. Kilness, MA is Director of Public Policy at the American Academy of HIV Medicine.
Prepping for PrEP

There have been major developments in pre-exposure prophylaxis (PrEP) research in recent years that are not all consistent.

Antiretroviral (ARV) prophylaxis has been the standard of care to reduce perinatal transmission of HIV since the landmark ACTG 076 study in 1996. The first study that showed efficacy of antiretroviral prophylaxis to reduce the sexual transmission of HIV was the CAPRISA 004 study conducted in South Africa. Tenofovir 1% gel, dosed peri-coitally, reduced the risk of HIV acquisition by 39 percent overall and by 54 percent in women with high gel adherence.

Subsequent results reported the effectiveness of oral tenofovir and emtricitabine (FTC)/tenofovir (TDF) (Truvada) in reducing sexual transmission of HIV.

The iPrEx study was conducted in 2,499 high-risk HIV-negative men who have sex with men (MSM) in the United States and countries in Africa, Asia and South America. The results, published in the New England Journal of Medicine in November 2010, showed that Truvada reduced the risk of HIV acquisition overall by 44 percent and by up to 73 percent among men who reported taking the drug consistently (at least 90 percent of days). Among men who had detectable drug in their blood, the risk was reduced by more than 90 percent.

The Partners PrEP study was conducted among 4,758 heterosexual serodiscordant couples in Kenya and Uganda. Results were presented at the 6th International AIDS Society Conference in July 2011. Oral Truvada reduced their risk of HIV acquisition by 73 percent, and oral tenofovir reduced HIV acquisition by 63% compared with placebo. Presented at the same conference were the preliminary results of the CDC-sponsored Botswana TDF2 trial in 1,200 HIV-negative heterosexual men and women. Oral Truvada for PrEP reduced HIV acquisition by 63 percent in this study.

However, there have been some notable disappointments in the PrEP research arena. The FEM-PrEP study was stopped in April 2011 based on a recommendation by the study’s Independent Data Monitoring Committee because the trial would not be able to establish the efficacy of Truvada among 1,951 HIV-negative women in sub-Saharan Africa.

The VOICE trial is a study conducted by the Microbicide Trials Network (MTN) in sub-Saharan Africa as well. This study had five arms, comparing vaginal and oral daily dosing of tenofovir 1 percent gel, oral tenofovir and oral Truvada to vaginal or oral placebo in 5,029 women at 15 trial sites in Uganda, South Africa and Zimbabwe. The Data and Safety Monitoring Board (DSMB) stopped the tenofovir gel and oral tenofovir arms due to a lack of efficacy in September and November 2011, respectively. The oral Truvada versus oral placebo arms are ongoing and the last study visits are scheduled for August 2012, with results expected in early 2013.

Based on the iPrEx trial results, in January 2011, the CDC issued interim guidance on the use of Truvada as PrEP among high-risk adult men who have sex with men. The CDC emphasized the need for HIV testing and clinical screening before initiation of PrEP to ensure that anyone starting PrEP is not already HIV infected. The CDC guidance also emphasized the importance of adherence, using other HIV prevention methods and regular testing for HIV infection while taking a PrEP regimen.

On December 15, 2011, Gilead Sciences submitted a supplemental New Drug Application to the FDA for the approval of Truvada for a new indication for PrEP. A review of that application is expected mid-year 2012. Final CDC guidance is pending the FDA review of Gilead’s application.

South Africa is conducting a confirmatory study of the CAPRISA 004 finding, the FACTS 001 study which began enrollment in October 2011. FACTS 001 is designed to test the safety and effectiveness of vaginal tenofovir gel used before and after sex to protect women against HIV infection and also against HSV-2. The study will enroll a minimum of 2,200 HIV-negative women. Also planned is FACTS 002, an adolescent safety study designed to test the safety and acceptability of tenofovir gel in 16 and 17-year-old South African young women. The MTN is planning phase II studies of tenofovir gel formulated for rectal use.

Studies will soon begin to investigate other ARVs for PrEP, including a vaginal dapivirine ring, and oral maraviroc. The MTN is planning a study to prevent HIV infection with a vaginal ring containing the ARV NNRTI drug dapivirine for extended use. The study will enroll approximately 3,475 women at several sites in Africa beginning mid-2012 and take approximately two years to conduct, with results anticipated late 2014 or early 2015.

The HIV Prevention Trials Network, in collaboration with the AIDS Clinical Trials Group, will soon initiate a safety and tolerability study in 400 MSM and 200 women in the U.S. comparing four PrEP regimens: maraviroc (MVC) 300 mg + FTC placebo + TDF placebo orally once daily; MVC 300 mg + FTC 200 mg + TDF placebo orally once daily; MVC 300 mg + FTC placebo + TDF 300 mg orally once daily; and MVC placebo + FTC 200 mg + TDF 300 mg orally once daily.

In all of the above studies no major safety concerns were noted with topical or systemic PrEP. The PrEP research field is very dynamic and the major studies noted above should clarify the conflicting efficacy data that has been observed to date.
However, this statistic only represents primary care physicians and does not include the thousands of specialists, including infectious disease physicians and other providers of HIV care, who have embraced the use of EHRs and other technology to make their practices more efficient, which in turn enables the patient to receive the best possible care.

HIV care providers are meeting the requirements of the Health Information Technology Economic and Clinical Health (HITECH) Act of 2009 and are transitioning from using paper records to implementing EHR. They are also implementing systems that improve communication with their patients, pharmacists and other health care providers and are opening up new and easier ways for patients to get updates and to track their own progress.

“It’s important to remember that the Internet itself has drastically changed the way we take care of HIV patients and how they interact with their providers,” observed Dr. Prokesch, MD AAHIVS, a private practice physician in Riverdale, GA, who chairs AAHIVM’s Georgia chapter and is a Member of the Academy's Board of Directors. He pointed out that many patients today are tech savvy and are much more knowledgeable about their conditions than those in the past because of what they learn online.

“Nowadays most of my patients come in and have researched everything from opportunistic infections, CD4 counts, medications and have a great deal of knowledge, and it didn’t use to be like that,” he explained. “Technology is huge when it comes to managing HIV patients. They tweet each other about their medication and non-traditional compounds and supplements they can take, and they get into financial issues, as well. It really makes a big difference in HIV care.”

With that in mind, many HIV providers are starting patient portals where patients can follow their CD4 counts and viral loads and graph them, explained Dr. Prokesch “When they can see that visually, it really helps in motivating patients and getting them to buy into their care.”

Through a secure log-in portal on such systems, the patient can access their laboratory information, including comments from the physician. “They can keep up with their numbers in real time,” Dr. Prokesch said. “Rather than waiting for the care provider to call them, they can actually get access electronically.”
Over one-third of Primary Care Providers have adopted the practice of using Electronic Health Records (EHRs).

“It’s important to remember that the Internet itself has drastically changed the way we take care of HIV patients and how they interact with their providers.”

“They can keep up with their numbers in real time, rather than waiting for the care provider to call them, they can actually get access electronically.”

“When I’m done with my patient, I can click on a prescription and it goes to the pharmacy electronically and nobody has to read my handwriting, and it is also documented.”
Other benefits of patient portals can include ways for patients to electronically schedule their own appointments or ask questions about medication side effects or other concerns. “It’s a new way to interact with the patient,” Dr. Prokesch said.

All of this, he added, not only benefits the patient, but it also helps the practice by cutting down on staff time that otherwise would be spent on phone calls.

Even the new patient intake process is made more efficient as new patients can obtain on the practice’s Website all of the forms needed, so they can be completed and brought to the office at the first visit—also a time saver.

Telemedicine Advances
Dr. Prokesch, who chaired AAHIVM’s selection committee for its new Technology in Health Care HIV Practice Awards (see story page 20), noted that one of the winning entries was for a telemedicine system established in San Francisco, CA and designed to reach underserved patient populations. That is a trend he expects to grow because of the ability to improve communication and care, particularly of patients in hard-to-reach locations.

“That also translates to other parts of care, in areas that have less access to HIV Specialists,” he said. “That is proliferating and it’s a whole new aspect of technology that will improve patient care. I think we will see more and more of that coming down the road.”

Electronic Health Records
It’s all about communication, stressed Dr. Prokesch. “If the primary care physician refers an HIV patient to me, when I sign off on my note in the EHR, that note is immediately faxed to the referring physician,” providing a near instantaneous response compared to the old system of sending the information through the mail. Eventually, he predicted, those documents will be transmitted directly via computer rather than being faxed, but the varied systems currently in use make that process difficult.

“There are some negatives with EHRs, but the positives that enhance care are really, really good,” Dr. Prokesch said, such as the immediate transmission of information from the lab that allows the physician to quickly change the HIV regimen if indicated.

EHR systems have become more affordable, he noted, and there has been some government assistance under the HITECH law for early adopters. “Some physicians object to the fact that this is being mandated by the government, but I think we need to capitalize on the positives,” he added.

In late November 2011, HHS released a report showing that doctors’ adoption of health information technology had doubled in two years, and at the same time announced new actions to speed use of health IT in doctors’ offices nationwide. One such action aims to make it easier for physicians and other health care professionals to receive incentive payments for adopting and meaningfully using health IT.

“When doctors and hospitals use health IT, patients get better care and we save money,” said HHS Secretary Kathleen Sebelius. “We’re making great progress, but we can’t wait to do more. Too many doctors and hospitals are still using the same record-keeping technology as Hippocrates.”

Under previous requirements, eligible doctors and hospitals that began participating in Medicare EHR incentive programs in 2011 would have to meet new standards for the program in 2013, and if they did not participate until this year, they could wait to meet the new standards until 2014 and still be eligible for incentive payments. To encourage faster adoption, HHS said it would allow providers to adopt health IT in 2011 without meeting the new standards until 2014, and the agency made it possible for fast-acting physicians to qualify for incentives in 2011 as well as 2012.

Stages of Meaningful Use
There are three stages for meaningful use standards under the health IT program, according to HHS:

- **STAGE 1 (2011 AND 2012)** sets the baseline for electronic data capture and information sharing.
- **STAGE 2 (EXPECTED TO BE IMPLEMENTED IN 2013)** will expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible. Exchange of information efforts can include the electronic transmission of orders entered using computerized provider order entry and the electronic transmission of diagnostic test results.
- **STAGE 3 (EXPECTED TO BE IMPLEMENTED IN 2015)** will focus on promoting improvements in quality, safety and efficiency leading to im-

“Technology is huge when it comes to managing HIV patients. They tweet each other about their medication and non-traditional compounds they can take and supplements...”
Communication Platform Connects Docs and Nurses

Clinical communications provider PerfectServe announced in February that it connects more than 20,000 physicians through its platform across 154 U.S. healthcare markets and 50 hospitals in health systems, including Advocate Health, Orlando Health, St. Joseph Health System and Dignity Health.

The platform is processing more than 35 million clinical communication transactions per year, enabling health systems to simplify and streamline nurse-to-physician and physician-to-physician communication while allowing doctors to selectively filter and control the communications they receive.

“Communication breakdowns are frequently a factor in patient safety events,” said Dr. Michael McKenna, chief medical officer at Advocate Lutheran General Hospital. “PerfectServe makes it extremely easy for our medical staff to find physicians and offers a better way to streamline the flow of information.”

“PerfectServe makes contacting colleagues much easier, and I especially like the functionality of the iPhone app,” said Dr. Daniel Wood, general surgeon at Advocate Good Shepherd Hospital. “It’s very reliable and cuts down on the time nurses have to spend tracking down physicians, which improves patient care.”

PerfectServe enables a single, standardized process to quickly connect clinicians across the continuum of care. This allows information to route faster, with great accuracy, reliability and safety resulting in fewer communication breakdowns and improved care coordination.
receive prescriptions by email. In addition, scanned prescriptions can easily be checked against the prescription that is on-line “if something doesn’t look right.”

“I think that helps to maintain safety and helps to maintain an appropriate income level for the pharmacy to make sure they can stay open and make sure their billing processes are taken care of,” he said. “That’s a good business model and a good health care model.”

Regarding the development of EHRs, Dr. Scott does not believe the impact on community pharmacies will be huge, other than having the ability to receive prescriptions electronically. However, for the clinical pharmacist working in concert with physicians in the same facility, the opportunities for communication are greatly expanded through the EHR system. “You have people looking at patient information at the same time, as opposed to always having to wait for the chart to become available,” he explained.

**Getting Social**

Both Dr. Scott and technology awards panel member Marjorie Golden, MD, AAHIVS, an infectious disease specialist at Hospital of Saint Raphael in New Haven, CT, were particularly impressed with the potential of using social networking within HIV care, as demonstrated in the study by Dr. Raphael J. Landovitz and his colleagues at the UCLA Center for Clinical AIDS Research & Education in Los Angeles.

“The practice where I see my HIV patients is a pretty poor inner city area, but the one thing that unites a lot of the patients is that no matter how poor and disenfranchised, they often have smart phones. Just for us to be able to get people into care, contact them when there is a problem, reminding them to take their medications and keep their appointments, and follow-up has tremendous potential,” she said.

Many patients, she said, have “chaotic” living situations and do not have access to landline phones. But, ironically, most have high-end smart phones email and texting capabilities, which opens up the potential of improving communication.

Dr. Golden said her facility is not using social networking as yet, but she is interested in the possibilities, although she expressed concern about meeting privacy requirements and protecting the privacy of the patients.

One of the big benefits of EHR, she said, is keeping track of medications, especially important for patients who are seeing multiple specialists.

“We don’t always get those records regarding what other medications patients are on, and what medications have been changed,” she explained. In terms of patient safety, that will be extremely important, as is the ability to electronically track what prescription narcotics patients are receiving.

Dr. Golden pointed out that as HIV patients are living longer, her practice is doing a considerable amount of primary care, so having easy access to accurate health history records is critical. That, she said, will be a benefit of EHR.

“As patients with HIV are living longer—our median age is around 56—we have a lot of patients with undetectable viral loads who are dealing with other health issues. So if we’re the only doctor that they’re seeing, we have to take care of all of those other medical issues. So that’s a good thing.”

That was the catalyst for the creation of the AAHIVM/Institute for Healthcare Technology awards. The awards are intended to help encourage creativity and progress in terms of using technology for the benefit of HIV care.

“I hope moving forward to see some more really innovative uses of technology,” Dr. Golden said. “I don’t know what that next application ought to be, but people are incredibly creative and I look forward to seeing what might be offered up down the road.”

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**The training is provided through 82 community colleges and nine universities nationwide. Currently, there are more than 10,000 students enrolled in the training programs and as of last November, universities had graduated 500 post-graduate and masters-level health IT professionals, with over 1,700 expected to graduate by July 2013.**

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**About the Author:**

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New App Facilitates HIV Screening, Counseling, and Linkage to Care

The University of Medicine, in collaboration with the Institute for Johns Hopkins Nursing, the American Academy of HIV Medicine (AAHIVM), and DKBmed, LLC has created SCALE HIV™ (Screening—Counseling—Linkage—Education - www.scalehiv.org).

The program is designed to address key practice and knowledge gaps in HIV screening, counseling, linkage to care, and adherence to clinical guidelines among clinicians. The program—launched in 2011—consists of a series of live symposia, webcasts and podcasts, and a Virtual Clinic where patients can be followed online.

To further support clinicians, a new application (app) brings select features of the SCALE HIV program to iPhone, iPad, and iPod Touch. The goal of the app is to enhance the ability of healthcare professionals to screen their patients with HIV infection and to link those with positive test results to appropriate counseling and treatment. A key component of the app is direct access to the AAHIVM Referral database.

Enormous strides have been made in streamlining the care of patients with HIV/AIDS, including the development of convenient medication regimens, which are helping people with the virus live longer than ever before. Yet clinical challenges remain: Who should be screened? How are HIV-positive individuals effectively counseled? And how do we link them to the care they need?

The U.S. Centers for Disease Control and Prevention recommends routine HIV testing for everyone between the ages of 13 and 64, but many healthcare professionals are not following these guidelines. Clinician inexperience or lack of training also means that many HIV-positive patients are not counseled effectively, if at all. Moreover, linkage to care for HIV-positive individuals is not optimal, especially among minorities and women.

“It is important to find effective and efficient ways to educate clinicians about HIV screening guidelines and to help them connect their patients to appropriate care,” said Gail Berkenblit, MD, Assistant Professor of Medicine at Johns Hopkins University School of Medicine. “Tools such as SCALE HIV go a long way to achieve those goals. The sooner we can start HIV treatment in the course of the infection, the better a patient’s outcome is likely to be.”

The Apple® platform was chosen based on the results of a 2011 study from Manhattan Research, which notes that 75 percent of U.S. physicians own some form of Apple device, such as an iPhone, iPad, or iPod. The free app is available in the Apple App Store.

The new SCALE HIV app provides the key information presented at the live seminars, current CDC recommendations, and guidance for counseling HIV-positive patients about what to do next, such as how to notify partners and how to access care. For the first time since the launch of the AAHIVM Referral Link, the database will be available on a mobile device for clinicians. This feature enables clinicians to find local HIV care providers who are convenient for the patient simply by inputting a zip code and other customizable fields, such as provider name, services, and payment types. (This search tool can also be viewed at aahivm.org.)

“ReferralLink connects healthcare professionals with credentialed HIV care providers all over the country,” said James M. Friedman, executive director of AAHIVM. “Making this feature available to more clinicians through a mobile iPhone/Pod/Pad-enabled app will make it even easier for them to connect their patients with high-quality care quickly and efficiently.”

SCALE HIV is supported by an educational grant from Bristol-Myers Squibb.
CREATIVE USE OF SOCIAL MEDIA TO REACH YOUNG MSM and the first urban-based HIV telemedicine program in the US were the first winners of the AAHIVM/Institute for Technology in Health Care (ITHC) HIV Practice Award, to be presented at the annual AAHIVM Membership Reception at the CROI Conference on March 6 in Seattle, WA.

Winners of the two $10,000 awards were Malcolm John, MD, MPH, associate clinical professor of medicine at the University of California San Francisco and director of 360: The Positive Care Center at UCSF; and Raphael J. Landovitz, MD, MSc, assistant professor of infectious diseases at the University of California at Los Angeles (UCLA) and an infectious disease specialist at the UCLA Center for Clinical AIDS Research & Education, Los Angeles.

“This is the first time that we had this opportunity to solicit submissions,” noted Richard Prokesch, MD, AAHIVS, AAHIVM national board member, who chaired the six-member selection panel that considered the applications. “In my mind, the winners were pretty clear cut. I hope this will be an ongoing award and that it will pick up momentum.”

With the growing use of electronic medical records (EMR) and the Internet as a platform for communication, the potential for increasing the effectiveness and efficiency of care through technology seems to be virtually boundless. The AAHIVM/ITHC awards are designed to help foster those developments for the benefit of HIV care providers and patients alike.

“Technologic advances will allow enhanced quality in patient care by improving communication between health care providers, as well as between health care providers and patients,” said Ken South, director of credentialing programs and staff coordinator of the Technology Awards. That, he said, will “speed the transmission of laboratory and radiologic data and even in direct patient care by allowing remote examination and monitoring of patients. Potential applications in HIV care are extensive and growing.”

“Everyone bemoans the fact that it’s difficult to engage YMSMs for interventions, and most larger prevention studies that have been done have recruited older populations,” Dr. Landovitz said. “But statistics show that the individuals most at risk and most impacted by HIV are MSMs ages 13 to 29. That is the population where HIV infections are going up most dramatically and consistently—particularly young Latino and African American men.”

Dr. Landovitz and other members of the Center for HIV Identification, Prevention and Treatment Services (CHIPTS) at UCLA decided to launch a study to determine if popular social networking sites could be used ef-
fectively to connect with these indi-

viduals. GRINDR, a popular all-male location-based networking tool used by many MSMs, was selected. The app works on iPhone, BlackBerry, and Android platforms.

GRINDR provides many of the contact features similar to those on Facebook, including text messaging, and through the GPS function allows members to contact others nearby. The service is believed to have more than 1.5 million users worldwide.

“We thought that because young guys are tech savvy, they are probably using it a lot—and using it to facilitate sexual partnering,” Dr. Landovitz said. “So we hypothesized that we could find young sexually active MSMs by using this.”

Two-person teams went to places in Los Angeles where YMSMs congregate late at night, turned on GRINDR and contacted prospective individuals asking if they would complete the survey in return for a $25 iTunes gift card. It took 4,500 individual contacts over five months to eventually obtain the 375 YMSMs ages 18-29 who successfully completed the 37-question iPAD survey that focused on beliefs about HIV risks and their own behavior.

“It was a fairly intensive endeavor,” Dr. Landovitz explained. “It was more challenging than I expected.” He pointed out that study staff arrived at the venues early, before they got busy, and stayed until people were beginning to leave when participants were more prone to take the time for the survey.

The research relied entirely on self-reporting and biological specimens were not collected, he said. “Our primary purpose was to prove we could recruit these young guys using this technology. We did. The mean age was 25.”

While the surveys, completed last March, demonstrated that YMSMs could be effectively reached through GRINDR, Landovitz believes the project also shows that the right social networking approach can be used to communicate with this vulnerable and difficult-to-reach population effectively for counseling and care.

“This could be a very powerful tool for finding young MSMs who are engaging in risky behavior, both positive and negative,” he said, adding that his group hopes to work directly with the GRINDR company to do that. “This is a very powerful strategy for reaching this population. We’re hoping to recruit people into a prevention study that would have a counseling piece and/or a biomedical piece, depending on what we think is the best combination of prevention ‘puzzle pieces’.”

“Prevention efforts which need to reach YMSM can easily access the GRINDR platform, and without pretense, rapidly access a well characterized population,” he contended. “This technology has boundless possibilities, including prevention messaging, education (in the moment, as well as later extracurricular opportunities), study recruitment, health literacy, and clinical service referral.”

He said an outcome of the proposed partnership with the site might be a widget that would allow a “chat with a health counselor/specialist,” providing a unique opportunity to establish confidential linkages to care and/or services.

Broad use of mainstream social networking sites to communicate with patients has its limitations, largely do to privacy concerns, said Dr. Landovitz. However, if sites could provide a way for patients to reach out to care, while preserving their privacy, that could be effective, he said.

“You have to provide some background and information to people via these social networking sites and then provide a mechanism by which they can get in touch with you,” Dr. Landovitz stressed. “Privacy is a huge concern.”

“Statistics show that the individuals most at risk and most impacted by HIV are MSMs ages 13 to 29. That is the population where HIV infections are going up most dramatically and consistently—particularly young Latino and African American men.”

— Raphael J. Landovitz, MD, MSc
Telemedicine & HIV
Malcolm John, MD, MPH
In San Francisco, clinics and community-based organizations can link to a telemedicine hub network to access HIV specialty services provided by 360: The Positive Care Center at the University of California at San Francisco (UCSF), ensuring their patients receive optimal, multidisciplinary services.

The telemedicine hub, launched in 2008, was the first urban-based HIV telemedicine program in the US, and now connects the Center with three neighborhood clinics, Haight Ashbury Free Clinic, South of Market Health Center, and Maxine Hall Health Center, and two community-based organizations, Black Coalition on AIDS and the San Francisco AIDS Foundation.

Dr. John said the plan this year is to further utilize telemedicine by promoting prevention services in at-risk youth populations, principally African American, in the underserved areas of San Francisco.

“The idea is to dial in and have private conversations with folks about sexual behavior and HIV,” he explained. “The idea is to give people the opportunity to talk to somebody without being labeled by going into a room or a clinic that says HIV.”

Dr. John pointed out that the remote sites that 360: The Positive Care Center at UCSF partners with save money because they no longer need to hire their own specialists, and participating specialists do
not need to travel between sites, saving time and energy. “Telemedicine is both time and cost-efficient,” he stressed.

“The front-line community clinic has allowed us to go from the ivory tower and have a presence in the community,” he said. Through telemedicine, that reach can be extended, allowing the clinics and community based organizations in San Francisco to provide patients with “optimal, multidisciplinary HIV services” simply by connecting to the hub.

All that is needed, Dr. John explained, is a one-time purchase of a telemedicine cart and broadband connection capabilities, adding that this model of care can easily be reproduced at other sites throughout the country with access to broadband technology and software.

For patients, the system improves utilization rates, their level of satisfaction with care and services provided, knowledge retention, adherence rates to medications and appointments, and results in improvement in CD4 counts and vital loads.

Other outcomes, he added, include provider/staff satisfaction and the ability to increase the range of service to underserved patients, noting that about one-third of patients reached through the service are uninsured who could not be seen at the clinic location.

“**The idea is to dial in and have private conversations with folks about sexual behavior and HIV. The idea is to give people the opportunity to talk to somebody without being labeled by going into a room or a clinic that says HIV.**”

— Malcolm John, MD, MPH

The system, he said, can be used both for one-on-one consultations with patients as well as group presentations, such as adherence sessions, for patients. In addition, Dr. John added that consultations and case conferences regarding patients who are being co-managed with other specialists and health care providers also can increase efficiency and improve patient care.

The Center is obtaining new equipment that will make it easier for such consultations, including high definition camera equipment that will allow physicians, for example, to clearly see a patient’s skin lesions for the purpose of diagnoses and treatment.

Dr. John said the plan is to do simulcast presentation to multiple sites on key issues, such as HIV and Aging. “It’s a way to be more efficient with time and travel, and hopefully we will see more connections with other partner organizations,” he added.

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**Editor’s Note:** This award was made possible by a generous grant to the American Academy of HIV Medicine by The Institute for Technology in Health Care, a Washington based foundation.
The federal government has thrown its weight behind a strategy of using social media and other “new media” applications to better communicate with young people who may be at risk, or who already may have been diagnosed with HIV.

Miguel Gomez, director of AIDS.GOV, part of the Office of HIV/AIDS Policy in the U.S. Department of Health and Human Services, stresses the importance of using communications tools that reach the younger audience. For 18-29 year olds, tools such as social media websites and mobile device applications are better for communicating key messages than other outlets.

“We know that the people we serve are using these tools, so it’s important for us to be where they are,” he told HIV Specialist in a recent interview. Gomez predicted that in less than five years more people will be using mobile devices, such as smart phones and tablets, than their laptops or desktop computers.

Understanding how to take advantage of new media tools, he said, is especially important because when people obtain health care information online, “they disproportionately believe the online information over the information they are getting face-to-face with a health care provider. They are using online information to make a health care decision about the management of their own personal health care.”

That fact, he stressed, makes it extremely important for health care providers to utilize the new media outlets that attract their patients, or potential patients, to provide useful information and to open a line of communication with them.

“Ten to 15 percent of young adults 18-29 years old are using apps to manage parts of their healthcare right now. For organizations like AAHIVM, those providers need to manage and watch how many people are coming to their website via mobile devices. It’s critically important. At AIDS.GOV, in the last six months we have seen a 50 percent increase in those patients coming to AIDS.GOV via their mobile device.”

That means the organization must be “mobile ready and design agnostic,” he said, explaining that regardless of the tool used to seek information, such as smart phone or tablet, the information must be accessible.

According to Gomez, it is critical to cultivate a better understanding of what tools and techniques young MSMs are using to seek out medical information in order to provide them with the best information available.

Facebook & Twitter
Pointing out that 800 million people are active users of Facebook and 50 percent of them check their account every day, Gomez said AIDS.GOV has launched a new Facebook app with its HIV/AIDS Prevention and Service Provider Locator. That service allows users to search for services without leaving Facebook.

The locator features HIV testing, housing assistance, health centers, Ryan White HIV care facilities, mental health clinics, substance abuse services, and family planning locations. Each of those services are plotted on a map, based either on the user’s location or the zip code or city/state provided in the search box. The Locator also links to Google Maps to provide directions. “By placing it directly on Facebook, it is our hope that more people will be able to find these important resources in their own communities,” Gomez explained.

In fact, Gomez encouraged health care providers who have a Facebook page to include a function to link individuals to HIV services. “It’s putting information where the users need it,” he said. “This is where people are making health care decisions and searching advice from others. If they land on your Facebook page or web page, they are looking to you as a reliable source, and you need to be ready to provide information.” Providers can add a widget to their website to connect users with the AIDS.GOV locator by connecting to this link: http://aids.gov/locator/.

In addition to utilizing Facebook, AIDS.GOV also makes use of Twitter to reach out to the HIV/AIDS Community. In one week, when the organization sent out a tweet about the locator program, 160 people re-tweeted that message, and 12,000 clicked on the link that was within the tweeted message. “We grow on Twitter by 1,000 to 1,500 people each week,” he said. “Our audience is continuing to move our message forward.”

“The world,” said Gomez, “has changed.”

AIDS.GOV includes on its website a tutorial on the use of new media in HIV. It includes a step-by-step approach to developing a new media plan, and is available at: http://www.aids.gov/using-new-media/getting-started/developing-a-new-media-plan/.
Policy Center says increased capabilities are needed to support patient-centered models of care.

**RECOGNIZING THAT HEALTH INFORMATION TECHNOLOGY (IT)** plays a critical role in improving the quality and cost-effectiveness of care, the Bipartisan Policy Center’s (BPC) Task Force on Delivery System Reform and Health IT has released a set of recommendations it says should be implemented to achieve improved health, better health care, and reductions in the cost of care.

The recommendations range from realigning incentives and payments to support higher quality, more cost-effective care to increasing the use of electronic health records (EHR) and health information exchange to enable doctors, hospitals, and patients to securely share health information when patients receive their care in multiple settings.

“There is strong bipartisan support for health IT, and for moving away from a payment model that largely focuses on volume — rewarding providers for doing more — rather than on quality outcomes or value,” said former Sen. Tom Daschle (D-SD), co-leader of BPC’s Health Project when the recommendations were released Jan. 27.

Health IT is seen as critical to supporting this shift in payment models, and as an essential improvement tool in a system where a patient’s records can be scattered throughout various health care offices and facilities.

“To deliver high-quality, cost-effective care, a physician or hospital needs good information,” said former Sen. Bill Frist (R-TN), who also co-leads the BPC Health Project. “Data about patients has to flow across primary care physicians, hospitals, labs, and anywhere that patients receive care.”

The Task Force noted that its recommendations come during a time of unprecedented public and private spending on health IT. A record investment of nearly $30 billion was triggered by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, spurring significant investments by the private sector.
Key Recommendations
A majority of the federal investment is in the form of incentive payments through the Medicare and Medicaid EHR Incentive Programs, informally known as “Meaningful Use.” The Task Force recommendations aim to channel these investments into health IT capabilities shown to be most effective at improving quality and reducing cost.

The Task Force recommends actions for aligning incentives and payment with higher quality, more cost-effective care, along with the health IT-enabled, coordinated, accountable, patient-centered delivery models that support such outcomes.

To further accelerate health information exchange, the Task Force recommended that the next phase of Meaningful Use and related standards and certification programs support the more robust exchange of standards-based data across multiple settings; public-private sector agreements on and execution of a common set of principles, policies and methods for exchange in the near-term; and the development and execution of a long-term strategy for the data standards and interoperability needs associated with delivering care, empowering patients, and improving population health.

Educating consumers about the benefits of electronic tools, and promoting their use, is an additional focus of the Task Force’s recommendations.

“We need a bold campaign to raise awareness among consumers about the benefits of using these tools,” said BPC Health Project State Co-Chair and former Ohio Gov. Ted Strickland. “We need to make it easier for consumers to navigate the health care system and take control of their health.”

The Task Force also recommended several actions to promote the use of electronic tools to improve patient-provider communication, coordinate care, expand access and empower individuals to manage their health and health care. They include expanding the current consumer awareness campaign; educating and supporting providers in the adoption of electronic tools to support patient engagement; and making tools widely available so patients can easily download health information from their provider’s EHR into their own personal health record.

The Task Force also said it is necessary to issue consistent, comprehensive and clear guidance on federal privacy and security laws covering personal health information and called for consistent protection of personal health information.

Additionally, the Task Force called for expansion of education and implementation assistance programs to help providers achieve Meaningful Use—with a particular focus on small physician practices and community hospitals and clinics that deliver care to rural and underserved populations.

Finally, the Task Force recommended further alignment of health IT requirements across federal health care programs so common health IT solutions can meet the multiple needs of programs supporting delivery system transformation, payment, public health, coverage and access, and administrative improvement. The Task Force urged coordination of quality measurement programs and alignment of measurement specifications with federally adopted data standards.

“Coordinated, accountable, patient-centered models of care—previously implemented by only a handful of high-performing organizations—are poised for more widespread adoption,” said Janet Marchibroda, Chair of BPC’s Health IT Initiative. “Health IT not only plays a critical role in the success of these organizations, it also enables the rapid spread of the very functions that have made these models successful, to the rest of the U.S. health care system.”

The Task Force included 24 nationally recognized and respected health system experts and leaders. Findings were based on a review of the literature and in-depth interviews with nearly 40 high-performing health care organizations.
HIV testing is integral to HIV prevention, treatment and care. Knowledge of one’s HIV status is important for preventing the spread of disease. Studies show that individuals who learn they are infected with HIV take active steps to reduce the likelihood of transmitting the virus to their partners. Early diagnosis of HIV helps to ensure that people living with the virus are linked into care and receive life-saving treatment. And recently we’ve learned that antiretroviral treatment can also help to prevent the further spread of HIV. Therefore, the NHAS aims to increase, by 2015, from 79 percent to 90 percent the percentage of people living with HIV who know their serostatus (from 948,000 to 1,080,000 people).

From Maine to California, health departments, community-based organizations, substance abuse and mental health programs, health care providers, hospitals and others are implementing novel and effective approaches to HIV testing to help contribute to this important outcome. Examples we’ve heard about recently include:

• HIV Screening Offered at the Department of Motor Vehicles—An innovative example of the Strategy’s call for greater collaboration among government service providers is underway in Washington, DC, where HIV testing has been offered at the Department of Motor Vehicles for the past year. While waiting to get a driver’s license,
temporary tags or other services, motorists visiting the Department of Motor Vehicles service center in the nation’s capital can get a free HIV test. This innovative collaboration between the DMV and the DC Department of Health (DOH) has tested more than 5,000 people since the program started in a single location in October 2010. According to Family and Medical Counseling Service Inc., the non-profit group that runs the program under a grant from DOH, between 25 and 35 people get tested every day, and anyone who is tested gets $7 off his or her DMV services. If someone tests positive, the nonprofit offers a ride to its office where staff can set up counseling and a doctor’s appointment. Building on the success of the DMV effort, officials expanded the program in late 2011 to offer testing at an office where Washington residents register for food stamps, Medicaid, and other government assistance. The same nonprofit will run the program there, offering as an incentive a $5 gift card to a local grocery store.

**Testing at Community Activities**—In Pine Ridge, South Dakota, the Oglala Sioux tribe partnered with its local Indian Health Service facility to increase the availability of HIV screening in nonclinical, community-based settings. An experienced and well-regarded public health nurse has taken HIV testing to events and venues where there may not normally be a health-related activity. Over the past year, this locally initiated program has offered confidential HIV testing at community potlucks, rodeos, basketball games and Pow Wows. Bringing HIV testing to nonclinical settings has allowed them to reach community members who may not be in regular health care, including young people, and provide them with HIV education and the opportunity for confidential HIV testing.

**Promoting the HIV-STD Link and Encouraging Screening**—Responding to a recent special surveillance report indicating a 23% increase in the number of primary and secondary syphilis cases in Chicago and a documented high rate of HIV-syphilis co-infection especially among MSM, the Chicago Department of Public Health recently launched the “Get Tested Chicago” campaign to encourage individuals to get tested for HIV and other Sexually Transmitted Infections (STI), including syphilis and, if diagnosed, to get into care. The public awareness campaign includes targeted billboards, radio public service announcements (PSAs), and bus advertisements aimed at early detection, testing and awareness. The campaign makes the link between syphilis, as well as other sexually transmitted infections, and HIV. It notes that studies have repeatedly demonstrated that people are more likely to become infected with HIV when other STDs are present. Moreover, it informs Chicagoans that if a person is HIV-positive, or if the immune system is weakened for any reason, syphilis (and other STIs) may progress faster and do more damage to the body.

**About the Author:**

Ronald Valdiserri, MD, MPH is Deputy Assistant Secretary for Health, Infectious Diseases, and Director, Office of HIV/AIDS Policy, U.S. Department of Health and Human Services.
IN OCTOBER 2011, the Department of Health and Human Services (DHHS) issued several key updates to the Adult and Adolescent Treatment Guidelines. Prior to this, the last updates occurred in January 2011 and much of the focus at that time was on the “when to start” antiviral therapy as opposed to which specific regimens were recommended.

The most recent updates did not seem to garner as much attention, but there were several key changes that should impact the way clinicians manage their HIV-infected patients.

Specifically in terms of initial antiretroviral therapy (ART) regimens, the guidelines note three separate categories. These include “Preferred” regimens for which randomized controlled trials show optimal efficacy and durability and which have favorable tolerability and toxicity profiles. The second tier of initial ART therapies is given the designation of “Alternative.” There is data supporting efficacy and tolerability, but each may have some individual disadvantages. However, they still could be the preferred regimens for select patients. Lastly, there is the designation of “Acceptable” for combinations of antiviral agents with less virologic efficacy, limited data, resistance concerns or greater risk of toxicity.

The four preferred first-line courses of therapy for treatment-naïve patients have not changed and include a non-nucleoside reverse transcriptase (NNRTI)-based, two protease-inhibitor (PI)-based, and one integrase strand inhibitor (INSTI)-based regimen. In addition, the “preferred” regimen for pregnant women with HIV specifically remains lopinavir/ritonavir plus zidovudine/lamivudine. (See table 1)

Regarding NNRTI-based regimens, rilpivirine was added as an “Alternative” option for initial therapy, but noted to be used with caution in patients with pretreatment HIV-RNA levels of > 100,000 copies/mL. In the ECHO and THRIVE studies there was a higher rate of rilpivirine failure in patients with viral loads above this threshold. This

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**TABLE 1**

**DHHS Guidelines: “Preferred” 3-Drug First Line Regimens**

<table>
<thead>
<tr>
<th>Category</th>
<th>Regimen Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-NRTI + 2 NRTIs</strong></td>
<td>Efavirenz / emtricitabine / tenofovir</td>
</tr>
<tr>
<td><strong>Boosted-PI + 2 NRTIs</strong></td>
<td>Atazanavir + ritonavir + emtricitabine / tenofovir</td>
</tr>
<tr>
<td></td>
<td>Darunavir + ritonavir + emtricitabine / tenofovir</td>
</tr>
<tr>
<td><strong>INSTI + 2 NRTIs</strong></td>
<td>Raltegravir + emtricitabine / tenofovir</td>
</tr>
<tr>
<td><strong>Pregnancy</strong></td>
<td>Lopinavir / ritonavir bid + zidovudine / lamivudine</td>
</tr>
</tbody>
</table>

**TABLE 2**

**DHHS Guidelines: “Alternative” 3-Drug First Line Regimens**

<table>
<thead>
<tr>
<th>Category</th>
<th>Regimen Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-NRTI based</strong></td>
<td>Efavirenz + Abacavir / Epivir</td>
</tr>
<tr>
<td></td>
<td>Rilpivirine + Abacavir / Epivir</td>
</tr>
<tr>
<td></td>
<td>Rilpivirine + Tenofovir / Emtricitabine</td>
</tr>
<tr>
<td><strong>Protease Inhibitor-based</strong></td>
<td>Atazanavir/r + Abacavir / Epivir</td>
</tr>
<tr>
<td></td>
<td>Darunavir/r + Abacavir / Epivir</td>
</tr>
<tr>
<td></td>
<td>Fosamprenavir/r + Abacavir / Epivir</td>
</tr>
<tr>
<td></td>
<td>Fosamprenavir + Tenofovir / FTC</td>
</tr>
<tr>
<td></td>
<td>Lopinavir/r + Abacavir / Epivir</td>
</tr>
<tr>
<td></td>
<td>Lopinavir/r + Tenofovir / FTC</td>
</tr>
<tr>
<td><strong>ISI based</strong></td>
<td>Raltegravir + Abacavir / Epivir</td>
</tr>
</tbody>
</table>
drug is available as a single agent or co-formulated with tenofovir and emtricitabine.

All nevirapine-based regimens have been reclassified as “Acceptable” options (indicated for females with pretreatment CD4 count of < 250, males with pretreatment CD4 count of < 400). Previously, nevirapine with zidovudine/lamivudine was classified as an “alternative” and nevirapine plus tenofovir/emtricitabine or with abacavir/lamivudine were recommended as “acceptable but should be used with caution.”

Regarding PI-based regimens, darunavir boosted with ritonavir plus abacavir/lamivudine has been reclassified as an “alternative” regimen. Previously this was listed as “acceptable but more definitive date needed.” In addition, unboosted fosamprenavir was completely removed as a PI option due to inferior potency. There is also potential to select for mutations conferring resistance to darunavir in patient who had virologic failure on unboosted fosamprnavir.

Raltegravir plus abacavir/lamivudine was reclassified as an “alternative” regimen. In the previous DHHS guidelines update, the combination of these three agents was classified as “acceptable but more definitive data are needed.”

Several key changes were made regarding the dual-nucleoside reverse transcriptase inhibitor (NRTI) options. (See Table 3) Zidovudine plus lamivudine was reclassified as “acceptable” from a previous “alternative” category because of greater toxicity relative to other options including tenofovir + emtricitabine or abacavir + lamivudine. Another disadvantage is that zidovudine + lamivudine must also be dosed twice daily. These two agents remain preferred dual NRTIs for women who are pregnant to prevent mother-to-child transmission of HIV. Lastly, the combination of didanosine + lamivudine was completely removed as a dual NRTI option due to a lack of clinical trial data and greater toxicity compared to other dual NRTI regimens.

The guidelines continue to note for clinicians specific older agents or combinations of agents that should no longer be used. (Table 4). These are for reasons of tolerability, toxicity, or inferiority compared to new agents.

**TABLE 3**

<table>
<thead>
<tr>
<th>DHHS Guidelines for Initial Therapy: Dual-NRTI Pairs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred</strong></td>
</tr>
<tr>
<td>TDF/FTC</td>
</tr>
<tr>
<td>■ High virologic efficacy</td>
</tr>
<tr>
<td>■ Active against HBV</td>
</tr>
<tr>
<td>■ Potential for renal and bone toxicity</td>
</tr>
<tr>
<td><strong>Alternative</strong></td>
</tr>
<tr>
<td>ABC/3TC</td>
</tr>
<tr>
<td>■ Risk of hypersensitivity reactino if positive for HLA-B*5701</td>
</tr>
<tr>
<td>■ Possible risk of cardiovascular events; caution in patients with CV risk factors</td>
</tr>
<tr>
<td>■ Possible inferior efficacy if baseline HIV RNA &gt;100,000 copies/mL</td>
</tr>
<tr>
<td><strong>Acceptable</strong></td>
</tr>
<tr>
<td>ZDV/3TC</td>
</tr>
<tr>
<td>■ Preferred dual NRTI for pregnant women</td>
</tr>
<tr>
<td>■ More toxicities than TDF/FTC or ABC/3TC</td>
</tr>
</tbody>
</table>

**TABLE 4**

<table>
<thead>
<tr>
<th>ARVs Not Recommended in Initial Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High rate of early virologic failure</strong></td>
</tr>
<tr>
<td>■ ddi + TDF</td>
</tr>
<tr>
<td><strong>Inferior virologic efficacy</strong></td>
</tr>
<tr>
<td>■ ABC + 3TC + ZDV as 3-NRTI regimen</td>
</tr>
<tr>
<td>■ ABC + 3TC + ZDV + TDF (as 4-NRTI regimen)</td>
</tr>
<tr>
<td>■ Pddl + (3TC or FTC)</td>
</tr>
<tr>
<td>■ FPV (unboosted)</td>
</tr>
<tr>
<td>■ DLV</td>
</tr>
<tr>
<td>■ NFV</td>
</tr>
<tr>
<td>■ SQV as single PI (unboosted)</td>
</tr>
<tr>
<td>■ TPV/r</td>
</tr>
<tr>
<td><strong>High incidence of toxicities</strong></td>
</tr>
<tr>
<td>■ d4T + 3TC</td>
</tr>
<tr>
<td>■ ddi + TDF</td>
</tr>
<tr>
<td>■ IDV/r</td>
</tr>
<tr>
<td>■ RTV as single PI</td>
</tr>
</tbody>
</table>

**Reference:**

**About the Author:** Jeffrey T. Kirchner, DO, FAAFP, AAHIVS is Medical Director at Comprehensive Care Medicine for HIV, Lancaster General Hospital, Lancaster, PA. He chairs the HIV Specialist Editorial Advisory Group.
ARTICLE: ‘This is Heaven-Sent’

The Changing Role of Pharmacist in a Community Setting

At 23, and already the mother of four children from multiple fathers, the patient was frail as she was wheeled into my office by her mother, having been referred to me by her HIV provider for adherence counseling.

Tearful and clearly overwhelmed from caring for her young daughter while trying to hold a full-time job, the mother presented several new prescriptions, including antiretrovirals and therapy for opportunistic infections prophylaxis. I held her hand and assured her that I would help, acknowledging the fact that her daughter has a history of non-adherence secondary to substance abuse, and her labs revealed CD4 cells of 35 and a viral Load of >75,000 copies/ml.

I organized a pill box, prepared a medication schedule, listed all active medications, removed discontinued and duplicate medications, and arranged home delivery. As we talked about the importance of adherence, I reviewed the goals of treatment and emphasized the risk of virologic failure and resistance secondary to non-adherence.

When we were finished, her mother, surprised that such service was being offered in a Walgreens pharmacy, raised her arms and shouted, “This is heaven-sent.” Now, two years later, the patient is virologically suppressed and immunologically stable at CD4 cells around 368. She has gained weight and is reviewed for treatment of comorbidities, such as diabetes, dyslipidemia and CVD. Walgreens was a leader in recognizing the need for a dedicated clinical pharmacist to manage the challenges of an HIV-infected person with multiple comorbidities.

In 2007, Walgreens initiated a new HIV clinical program and established multiple HIV Centers of Excellence (COEs), which are supported by the Lead HIV/AIDS Clinical Pharmacist. Each member of the COE is trained on HIV stigma and cultural competency. Pharmacists also are required to complete an HIV course provided by the University of Buffalo. By offering clinical pharmacy services, Walgreens has completed that missing link between patients, physician and pharmacist, and has bridged the gap between the clinical and community setting.

The pharmacist at a COE makes certain all HIV-infected patients are proactively receiving refill reminders, maintains a sufficient inventory of antiretrovirals, and reviews regimens for appropriateness (complete and correct), drug interactions and duplication of therapy. The patient’s profile is reviewed for treatment of comorbidities, and if an error is discovered, the physician and the patient are immediately contacted. Patients are offered free pill boxes, multivitamins and free home delivery.

The Lead HIV/AIDS Clinical pharmacist also offers consultation to multiple HIV and non-HIV specialist providers in managing their complex, highly treatment-experienced patients, while interpreting their resistance assays and designing a new regimen when indicated. The clinical pharmacist continues to improve care by completing applications for patient assistance programs provided by HIV manufacturers and refers patients to an AIDS service organization when medical case managers’ services are indicated.

Pharmacists and the staff in a COE are fully engaged and take personal responsibility in impacting the life of an HIV-infected person. Since HIV is a public health issue, we actively participate in out-reach efforts that promote early detection and prevention. Every Walgreens pharmacist now takes ownership of their HIV-infected patients because our goal is to make certain every patient feels welcomed without the risk of disclosure or stigma.

It is highly rewarding to know that by utilizing my expertise in a non-clinical setting, I am able to improve adherence, retention and outcomes. Although I am simply doing my job, when it results in a mother raising her hands and shouting “This is heaven-sent,” I realize this work is making a difference. HIV

About the Author: Sami Shafiq is Lead HIV/AIDS Clinical Pharmacist, Miami Dade County, Walgreens Pharmacy. She is also a mentor and preceptor for the PharmD candidates from Nova Southeastern University, Palm Beach Atlantic University and Howard University. She has been a member of the AAHIVM Steering Committee for the Florida Chapter since 2009.
The American Conference for the Treatment of HIV is uniquely designed for clinicians, physician assistants, nurse practitioners, nurses, pharmacists, and medical case managers providing HIV care for various population groups.

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SPEAKERS
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360: The Positive Care Center at UCSF

Raphael Landovitz, MD
MSC:UCLA Center for Clinical AIDS Research & Education

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