

The AMERICAN ACADEMY of HIV MEDICINE®

HIV SPECIALIST

PATIENT CARE, PRACTICE MANAGEMENT & PROFESSIONAL
DEVELOPMENT INFORMATION for HIV CARE PROVIDERS

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A Single Tablet Regimen That Reaches Many Treatment-Naïve Adults¹



Indication¹

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 Information¹

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 coinfecting with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting 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 coinfecting with HIV-1 and HBV and discontinue COMPLERA. If appropriate, initiation of anti-hepatitis B therapy may be warranted

Please see additional Important Safety Information for COMPLERA on following pages.

Patient models. Pill shown is not actual size.



References: 1. COMPLERA Prescribing Information. Gilead Sciences, Inc; August 2011. 2. Molina J-M, Cahn P, Grinsztejn B, et al; for ECHO Study Group. Rilpivirine versus efavirenz with tenofovir and emtricitabine in treatment-naïve adults infected with HIV-1 (ECHO): a phase 3 randomised double-blind active-controlled trial. *Lancet*. 2011;378(9787):238-246. 3. Cohen CJ, Andrade-Villanueva J, Clotet B, et al; for THRIVE Study Group. Rilpivirine versus efavirenz with two background nucleoside or nucleotide reverse transcriptase inhibitors in treatment-naïve adults infected with HIV-1 (THRIVE): a phase 3, randomised, non-inferiority trial. *Lancet*. 2011;378(9787):229-237.

Put These Benefits Within Reach for Your Patients

Proven viral suppression through 48 weeks (HIV-1 RNA <50 copies/mL)^{1-3*}

- 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)¹⁻³
- Incidence of virologic failure: 13% with rilpivirine + emtricitabine/tenofovir disoproxil fumarate (N=550) versus 8% with efavirenz + emtricitabine/tenofovir disoproxil fumarate (N=546)¹
- 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 therapy¹
- 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 efavirenz¹
- More subjects treated with rilpivirine developed lamivudine/emtricitabine associated resistance compared to efavirenz¹

Demonstrated safety through 48 weeks¹

- The most common adverse drug reactions (Grades 2-4, ≥2%) were insomnia and headache¹
- 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 50 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=678), 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).¹ The primary endpoint was non-inferior viral suppression to efavirenz through 48 weeks (HIV-1 RNA <50 copies/mL).^{2,3}

BR=background regimen; NNRTI=non-nucleoside reverse transcriptase inhibitor; NRTI=nucleoside reverse transcriptase inhibitor.



COMPLERA[®]

emtricitabine 200mg/rilpivirine 25mg/
tenofovir disoproxil fumarate 300mg tablets

ONE COMPLETE SINGLE TABLET

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 insomnia and headache
- The most common adverse drug reactions to emtricitabine and tenofovir disoproxil fumarate (incidence ≥10%) 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. Coadministration 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. Coadministration of rilpivirine and drugs that inhibit CYP3A may result in increased plasma concentrations of rilpivirine
- **Drugs increasing gastric pH:** Coadministration 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, coadministration of COMPLERA with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of emtricitabine, tenofovir, and/or other renally eliminated drugs. Some examples include, but are not limited to, acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valganciclovir, 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.**



COMPLERA®

emtricitabine 200mg/rilpivirine 25mg/
tenofovir disoproxil fumarate 300mg tablets

COMPLERA® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) tablets Brief Summary of full prescribing information. See full prescribing information. Rx Only.

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 [See 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 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 or VIREAD, 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 [See Warnings and Precautions].

INDICATIONS AND USAGE

COMPLERA (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) 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 [See Clinical Studies in Full Prescribing Information].

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 [See Clinical Studies in Full Prescribing Information].
- 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 [See Microbiology in Full Prescribing Information].
- More subjects treated with rilpivirine developed lamivudine/emtricitabine associated resistance compared to efavirenz [See Microbiology in Full Prescribing Information].

COMPLERA is not recommended for patients less than 18 years of age [See Use in Specific Populations].

DOSEAGE AND ADMINISTRATION

Adults: The recommended dose of COMPLERA is one tablet taken orally once daily with a meal [See Clinical Pharmacology in Full Prescribing Information].

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).

DOSEAGE FORMS AND STRENGTHS

COMPLERA is available as tablets. Each tablet contains 200 mg of emtricitabine (FTC), 27.5 mg of rilpivirine hydrochloride (equivalent to 25 mg of rilpivirine) and 300 mg of tenofovir disoproxil fumarate (TDF, equivalent to 245 mg of tenofovir disoproxil).

The tablets are purplish-pink, capsule-shaped, film-coated, debossed with "GSI" on one side and plain-faced on the other side.

CONTRAINDICATIONS

COMPLERA should not be coadministered with the following drugs, as significant decreases in rilpivirine plasma concentrations may occur due to CYP3A4 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 [See Drug Interactions and Clinical Pharmacology in Full Prescribing Information]:

- 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

Lactic Acidosis/Severe Hepatomegaly with Steatosis: 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. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogs to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with COMPLERA should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

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 virus before initiating antiretroviral therapy. COMPLERA is not approved for the treatment of chronic 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 emtricitabine or tenofovir disoproxil fumarate, two of the components of COMPLERA. In some patients infected with HBV and treated with EMTRIVA, the exacerbations of hepatitis B were associated with liver decompensation and liver failure. Patients who are coinfected with HIV-1 and HBV should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment with COMPLERA. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

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 [See Adverse Reactions].

It is recommended that creatinine clearance be calculated in all patients prior to initiating therapy and as clinically appropriate during therapy with COMPLERA. Routine monitoring of calculated creatinine clearance and serum phosphorus should be performed in patients at risk for renal impairment, including patients who have previously experienced renal events while receiving HEPSEARA.

COMPLERA should be avoided with concurrent or recent use of a nephrotoxic agent.

Emtricitabine and tenofovir are principally eliminated by the kidney; however, rilpivirine is not. Since COMPLERA is a combination product and the dose of the individual components cannot be altered, patients with creatinine clearance below 50 mL per minute should not receive COMPLERA.

Drug Interactions: Caution should be given to prescribing COMPLERA with drugs that may reduce the exposure of rilpivirine [See Contraindications, Drug Interactions, and Clinical Pharmacology in Full Prescribing Information].

In 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 [See Drug Interactions and Clinical Pharmacology in Full Prescribing Information]. 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 HIV-1 infected patients who have a history of pathologic bone fracture or are at risk for osteopenia. Although the effect of supplementation with calcium and Vitamin D was not studied, such supplementation may be beneficial for all patients. If bone abnormalities are suspected then appropriate consultation should be obtained.

Tenofovir Disoproxil Fumarate: In a 144 week study of HIV-1 infected treatment-naïve adult subjects treated with tenofovir disoproxil fumarate (Study 903), decreases in BMD were seen at the lumbar spine and hip in both arms of the study. At Week 144, there was a significantly greater mean percentage decrease from baseline in BMD at the lumbar spine in subjects receiving tenofovir disoproxil fumarate + lamivudine + efavirenz (-2.2% ± 3.9) compared with subjects receiving stavudine + lamivudine + efavirenz (-1.0% ± 4.6). Changes in BMD at the hip were similar between the two treatment groups (-2.8% ± 3.5 in the tenofovir disoproxil fumarate group vs. -2.4% ± 4.5 in the stavudine group). In both groups, the majority of the reduction in BMD occurred in the first 24–48 weeks of the study and this reduction was sustained through 144 weeks. Twenty-eight percent of tenofovir disoproxil fumarate treated subjects vs. 21% of the comparator subjects lost at least 5% of BMD at the spine or 7% of BMD at the hip. Clinically relevant fractures (excluding fingers and toes) were reported in 4 subjects in the tenofovir disoproxil fumarate group and 6 subjects in the comparator group. Tenofovir disoproxil fumarate was associated with significant increases in biochemical markers of bone metabolism (serum bone-specific alkaline phosphatase, serum osteocalcin, serum C telopeptide, and urinary N telopeptide), suggesting increased bone turnover. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher in subjects receiving tenofovir disoproxil fumarate.

The effects of tenofovir disoproxil fumarate-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. For additional information, please consult the VIREAD prescribing information.

Cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures) have been reported in association with the use of VIREAD [See Adverse Reactions].

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, EDURANT, VIREAD, TRUVADA, ATRIPLA), with medicinal products containing lamivudine (EPVIR, EPVIR-HBV, EPZICOM, COMBIVIR, TRIZIVIR), or with didanosine (VDD, VDD-HBV, VDD-HIV) (HEPSERA).

Fat Redistribution: Redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and "cushingoid appearance" have been observed in patients receiving antiretroviral therapy. The mechanism and long-term consequences of these events are unknown. A causal relationship has not been established.

Immune Reconstitution Syndrome: Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including the components of COMPLERA. During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections (such as *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jirovecii* pneumonia (PCP), or tuberculosis), which may necessitate further evaluation and treatment.

ADVERSE REACTIONS

The following adverse drug reactions are discussed in other sections of the labeling:

- Lactic Acidosis/Severe Hepatomegaly with Steatosis [See *Banned Warnings and Precautions*].
- Severe Acute Exacerbations of Hepatitis B [See *Banned Warnings and Precautions*].
- New Onset or Worsening Renal Impairment [See *Warnings and Precautions*].
- Depressive Disorders [See *Warnings and Precautions*].
- Decreases in Bone Mineral Density [See *Warnings and Precautions*].
- Immune Reconstitution Syndrome [See *Warnings and Precautions*].

Adverse Reactions from Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. **Studies C209 and C215 – Treatment-Emergent Adverse Drug Reactions:** The safety assessment of rilpivirine, used in combination with other antiretroviral drugs, is based on pooled data from 1368 patients in the Phase 3 trials TMC278-C209 (ECHO) and TMC278-C215 (THRIVE) in antiretroviral treatment-naïve HIV-1 infected adult patients. A total of 686 patients received rilpivirine in combination with other antiretroviral drugs as background regimen; most (N=550) received emtricitabine + tenofovir disoproxil fumarate as background regimen. The number of subjects randomized to the control arm efavirenz was 682, of which 546 received emtricitabine + tenofovir disoproxil fumarate as background regimen [See Clinical Studies in Full Prescribing Information]. The median duration of exposure for subjects in either treatment arm was 56 weeks.

Adverse drug reactions (ADR) observed in patients who received rilpivirine or efavirenz plus emtricitabine + tenofovir disoproxil fumarate as background regimen are shown in Table 1. The adverse drug reactions observed in this subset of patients were generally consistent with those seen for the overall patient population participating in these studies (refer to the prescribing information for EDURANT).

The proportion of subjects who discontinued treatment with rilpivirine or efavirenz + emtricitabine/tenofovir disoproxil fumarate due to ADR, regardless of severity, was 2% and 5%, respectively. The most common ADRs leading to discontinuation were psychiatric disorders: 8 (1.5%) subjects in the rilpivirine + emtricitabine/tenofovir disoproxil fumarate arm and 12 (2.2%) subjects in the efavirenz + emtricitabine/tenofovir disoproxil fumarate arm. Rash led to discontinuation in 1 (0.2%) subjects in the rilpivirine + emtricitabine/tenofovir disoproxil fumarate arm and 10 (1.8%) subjects in the efavirenz + emtricitabine/tenofovir disoproxil fumarate arm.

Common Adverse Drug Reactions

Clinical ADRs to rilpivirine or efavirenz of at least moderate intensity (≥ Grade 2) reported in at least 2% of adult subjects are shown in Table 1.

Table 1 Selected Treatment-Emergent Adverse Reactions* (Grades 2–4) Reported in ≥2% of Subjects Receiving Rilpivirine or Efavirenz in Combination with Emtricitabine/Tenofovir Disoproxil Fumarate in Studies C209 and C215 (Week 48 analysis)

	Rilpivirine + FTC/TDF N=550	Efavirenz + FTC/TDF N=546
Gastrointestinal Disorder		
Nausea	1%	2%
Nervous System Disorders		
Headache	2%	2%
Dizziness	1%	7%
Psychiatric Disorders		
Depressive disorders ^a	1%	2%
Insomnia	2%	2%
Abnormal dreams	1%	3%
Skin and Subcutaneous Tissue Disorders		
Rash	1%	5%

a. Frequencies of adverse reactions are based on all treatment-emergent adverse events, assessed to be related to study drug.

b. Includes adverse drug reactions reported as depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, suicide ideation.

Rilpivirine: 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=686) in clinical studies C209 and C215 include (grouped by Body System): vomiting, diarrhea, abdominal discomfort, abdominal pain, fatigue, cholelithiasis, cholelithiasis, decreased appetite, somnolence, sleep disorders, anxiety, glomerulonephritis membranous and glomerulonephritis mesangiolipofoliar.

Emtricitabine and Tenofovir Disoproxil Fumarate: The following adverse reactions were observed in clinical trials of emtricitabine or tenofovir disoproxil fumarate in combination with other antiretroviral agents:

The most common adverse drug reactions occurred in at least 10% of treatment-naïve subjects in a phase 3 clinical trial of emtricitabine and tenofovir disoproxil fumarate in combination with another antiretroviral agent are diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams, and rash. In addition, adverse drug reactions that occurred in at least 5% of treatment-experienced or treatment-naïve subjects receiving emtricitabine or tenofovir disoproxil fumarate with other antiretroviral agents in clinical trials include abdominal pain, dyspepsia, vomiting, fever, pain, nasopharyngitis, pneumonia, sinusitis, upper respiratory tract infection, arthralgia, back pain, myalgia, paresthesia, peripheral neuropathy (including peripheral neuritis and neuropathy), anxiety, increased cough, and thrush.

Skin discoloration has been reported with higher frequency among emtricitabine-treated subjects; it was manifested by hyperpigmentation on the palms and/or soles and was generally mild and asymptomatic. The mechanism and clinical significance are unknown.

Laboratory Abnormalities: The percentage of subjects treated with rilpivirine + emtricitabine/tenofovir disoproxil fumarate or efavirenz + emtricitabine/tenofovir disoproxil fumarate in studies C209 and C215 with selected treatment-emergent laboratory abnormalities (Grade 1 to 4), representing worst grade toxicity are presented in Table 2.

Table 2 Selected Laboratory Abnormalities (Grades 1-4) Reported in Subjects Who Received Rilpivirine or Efavirenz in Combination with Emtricitabine/Tenofovir Disoproxil Fumarate in Studies C209 and C215 (Week 48 Analysis)

Laboratory Parameter Abnormality (%)	DAIDS Toxicity Range	Rilpivirine + FTC/TDF N=550	Efavirenz + FTC/TDF N=546
BIOCHEMISTRY			
Increased Creatinine			
Grade 1	≥1.1-≤1.3 x ULN ^a	5%	<1%
Grade 2	>1.3-≤1.8 x ULN	<1%	1%
Increased AST			
Grade 1	≥1.25-≤2.5 x ULN	13%	16%
Grade 2	>2.5-≤5.0 x ULN	3%	7%
Grade 3	>5.0-≤10.0 x ULN	2%	2%
Grade 4	>10.0 x ULN	<1%	1%
Increased ALT			
Grade 1	≥1.25-≤2.5 x ULN	16%	19%
Grade 2	>2.5-≤5.0 x ULN	4%	6%
Grade 3	>5.0-≤10.0 x ULN	1%	2%
Grade 4	>10.0 x ULN	1%	1%
Increased Total Bilirubin			
Grade 1	≥1.1-≤1.5 x ULN	2%	<1%
Grade 2	>1.5-≤2.5 x ULN	5%	<1%
Grade 3	>2.5-≤5.0 x ULN	<1%	<1%
Increased Total Cholesterol (fasted)			
Grade 1	5.18-6.19 mmol/L 200-239 mg/dL	13%	29%
Grade 2	6.20-7.77 mmol/L 240-300 mg/dL	4%	15%
Grade 3	>7.77 mmol/L >300 mg/dL	<1%	2%
Increased LDL Cholesterol (fasted)			
Grade 1	3.37-4.12 mmol/L 130-159 mg/dL	11%	25%
Grade 2	4.13-4.90 mmol/L 160-190 mg/dL	5%	11%
Grade 3	>4.91 mmol/L >191 mg/dL	1%	2%
Increased Triglycerides (fasted)			
Grade 2	5.65-8.48 mmol/L 500-750 mg/dL	1%	1%
Grade 3	8.49-13.56 mmol/L 751-1,200 mg/dL	<1%	1%

N = number of subjects per treatment group

a. ULN = Upper limit of normal value.

Note: Percentages were calculated versus the number of subjects in ITT population with emtricitabine + tenofovir disoproxil fumarate as background regimen.

Emtricitabine or Tenofovir Disoproxil Fumarate: The following laboratory abnormalities have been previously reported in subjects treated with emtricitabine or tenofovir disoproxil fumarate with other antiretroviral agents in other clinical trials: Grade 3 or 4 laboratory abnormalities of increased pancreatic amylase (>2.0 x ULN), increased serum amylase (>175 U/L), increased lipase (>3.0 x ULN), increased alkaline phosphatase (>550 U/L), increased or decreased serum glucose (<40 or >250 mg/dL), increased glycursia (>3+), increased creatine kinase (MC >990 U/L; F >845 U/L), decreased neutrophils (<750/mm³) and increased hematuria (>75 RBC/HPC) occurred.

Adrenal Function: In the pooled Phase 3 trials of C209 and C215, in subjects treated with rilpivirine plus any of the allowed background regimen (N=686), at Week 48, the overall mean change from baseline in basal cortisol showed a decrease of -13.1 nmol/L in the rilpivirine group, and an increase of +9.0 nmol/L in the efavirenz group. At Week 48, the mean change from baseline in ACTH-stimulated cortisol levels was lower in the rilpivirine group (+16.5 ± 6.14 nmol/L) than in the efavirenz group (+58.1 ± 6.66 nmol/L). Mean values for both basal and ACTH-stimulated cortisol values at Week 48 were within the normal range. Overall, there were no serious adverse events, deaths, or treatment discontinuations that could clearly be attributed to adrenal insufficiency. Effects on adrenal function were comparable by background N(0)RTs.

Serum Creatinine: In the pooled Phase 3 trials of C209 and C215 in subjects treated with rilpivirine plus any of the allowed background regimen (N=686), increases in serum creatinine occurred within the first four weeks of treatment and remained stable through 48 weeks. A mean change of 0.09 mg/dL (range: -0.20 mg/dL to 0.62 mg/dL) was observed after 48 weeks of treatment. In subjects who entered the trial with mild or moderate renal impairment, the serum creatinine increase observed was similar to that seen in subjects with normal renal function. These changes are not considered to be clinically relevant and no subject discontinued treatment due to increases in serum creatinine. Creatinine increases were comparable by background N(0)RTs.

Serum Lipids: Changes from baseline in total cholesterol, LDL-cholesterol and triglycerides are presented in Table 3.

Table 3 Lipid Values Reported in Subjects Receiving Rilpivirine or Efavirenz in Combination with Emtricitabine/ Tenofovir Disoproxil Fumarate in Studies C209 and C215*

Mean	N	Pooled Data from the C209 and C215 Trials						
		Rilpivirine + FTC/TDF			Efavirenz + FTC/TDF			
		N=550			N=546			
		Baseline Mean (mg/dL)	Week 48 Mean (mg/dL)	Mean Change ^b (mg/dL)	Baseline Mean (mg/dL)	Week 48 Mean (mg/dL)	Mean Change ^b (mg/dL)	
Total Cholesterol (fasted)	460	162	162	0	438	160	185	25
HDL-cholesterol (fasted)	459	42	45	3	437	40	49	9
LDL-cholesterol (fasted)	457	97	95	-2	436	95	109	13
Triglycerides (fasted)	460	122	111	-11	438	129	138	8

N = number of subjects per treatment group

a. Excludes subjects who received lipid lowering agents during the treatment period.

b. The change from baseline is the mean of within-patient changes from baseline for patients with both baseline and Week 48 values.

Subjects Concocted with Hepatitis B and/or Hepatitis C Virus: In patients concocted with hepatitis B or C virus receiving rilpivirine in studies C209 and C215, the incidence of hepatic enzyme elevation was higher than in subjects receiving rilpivirine who were not concocted. The same increase was also observed in the efavirenz arm. The pharmacokinetic exposure of rilpivirine in concocted subjects was comparable to that in subjects without concoction.

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 their frequency or establish a causal relationship to drug exposure.

Emtricitabine: No postmarketing adverse reactions have been identified for inclusion in this section.

Tenofovir Disoproxil Fumarate:

Immune System Disorders: allergic reaction, including angioedema

Metabolism and Nutrition Disorders: lactic acidosis, hypokalemia, hypophosphatemia

Respiratory, Thoracic, and Mediastinal Disorders: dyspnea

Gastrointestinal Disorders: pancreatitis, increased amylase, abdominal pain

Hepatobiliary Disorders: hepatic steatosis, hepatitis, increased liver enzymes (most commonly AST, ALT gamma GT)

Skin and Subcutaneous Tissue Disorders: rash

Musculoskeletal and Connective Tissue Disorders: rhabdomyolysis, osteomalacia (manifested as bone pain and which may contribute to fractures), muscular weakness, myopathy

Renal and Urinary Disorders: acute renal failure, renal failure, acute tubular necrosis, Fanconi syndrome, proximal renal tubulopathy, interstitial nephritis (including acute cases), nephrogenic diabetes insipidus, renal insufficiency, increased creatinine, proteinuria, polyuria

General Disorders and Administration Site Conditions: asthenia

The following adverse reactions, listed under the body system headings above, may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia, hypokalemia, muscular weakness, myopathy, hypophosphatemia.

DRUG INTERACTIONS

COMPLERA is a complete regimen for the treatment of HIV-1 infection; therefore, COMPLERA should not be administered with other antiretroviral medications. Information regarding potential drug-drug interactions with other antiretroviral medications is not provided. Please refer to the EDURANT, VIREAD and EMTRIVA prescribing information as needed.

There were no drug-drug interaction trials conducted with the fixed-dose combination tablet. Drug interaction studies were conducted with emtricitabine, rilpivirine, or tenofovir disoproxil fumarate, the components of COMPLERA. This section describes clinically relevant drug interactions with COMPLERA. [See *Contraindications and Clinical Pharmacology in Full Prescribing Information*].

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 [See *Clinical Pharmacology in Full Prescribing Information, Contraindications*]. Coadministration 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. Coadministration of rilpivirine and drugs that inhibit CYP3A may result in increased plasma concentrations of rilpivirine.

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.

Drugs Increasing Gastric pH

Coadministration 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 [See *Table 4*].

Drugs Affecting Renal Function

Because emtricitabine and tenofovir are primarily eliminated by the kidneys through a combination of glomerular filtration and active tubular secretion, coadministration of COMPLERA with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of emtricitabine, tenofovir, and/or other renally eliminated drugs. Some examples of drugs that are eliminated by active tubular secretion include, but are not limited to, acyclovir, adefovir dipivoxil, didanosine, 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 [See *Clinical Pharmacology in Full Prescribing Information*]. COMPLERA should be used with caution when coadministered with a drug with a known risk of torsade de Pointes.

Established and Other Potentially Significant Drug Interactions

Important drug interaction information for COMPLERA is summarized in Table 4. The drug interactions described are based on studies conducted with emtricitabine, rilpivirine, or tenofovir disoproxil fumarate as individual medications that may occur with COMPLERA or are potential drug interactions; no drug interaction studies have been conducted using COMPLERA [for pharmacokinetic data see *Clinical Pharmacology*, tables 6-7 in *Full Prescribing Information*]. The tables include potentially significant interactions, but are not all inclusive.

Table 4 Established and Other Potentially Significant* Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction

Concomitant Drug Class: Drug Name	Effect on Concentration ^a	Clinical Comment
Antacids: antacids (e.g., aluminum, magnesium hydroxide, or calcium carbonate)	↔ rilpivirine (antacids taken at least 2 hours before or at least 4 hours after rilpivirine) ↓ rilpivirine (concomitant intake)	The combination of COMPLERA and antacids should be used with caution as coadministration may cause significant decreases in rilpivirine plasma concentrations (increase in gastric pH). Antacids should only be administered either at least 2 hours before or at least 4 hours after COMPLERA.
Azole Antifungal Agents: fluconazole itraconazole ketoconazole posaconazole voriconazole	↑ rilpivirine ^d ↓ ketoconazole ^d	Concomitant use of COMPLERA with azole antifungal agents may cause an increase in the plasma concentrations of rilpivirine (inhibition of CYP3A enzymes). No dose adjustment is required when COMPLERA is coadministered with azole antifungal agents. Clinically monitor for breakthrough fungal infections when azole antifungals are coadministered with COMPLERA.
H₂-Receptor Antagonists: cimetidine famotidine nizatidine ranitidine	↔ rilpivirine ^d (famotidine taken 12 hours before rilpivirine or 4 hours after rilpivirine) ↓ rilpivirine ^d (famotidine taken 2 hours before rilpivirine)	The combination of COMPLERA and H ₂ -receptor antagonists should be used with caution as coadministration may cause significant decreases in rilpivirine plasma concentrations (increase in gastric pH). H ₂ -receptor antagonists should only be administered at least 12 hours before or at least 4 hours after COMPLERA.
Macrolide antibiotics: clarithromycin erythromycin troleandomycin	↑ rilpivirine ↔ clarithromycin ↔ erythromycin ↔ 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.
Narcotic Analgesics: methadone	↓ R(-) methadone ↓ S(+) methadone ↔ rilpivirine ↔ methadone (when used with tenofovir)	No dose adjustments are required when initiating coadministration of methadone with COMPLERA. However, clinical monitoring is recommended as methadone maintenance therapy may need to be adjusted in some patients.

a. This table is not all inclusive.

b. Increase = ↑; Decrease = ↓; No Effect = ↔

c. The interaction was evaluated in a clinical study. All other drug-drug interactions shown are predicted.

d. This interaction study has been performed with a dose higher than the recommended dose for rilpivirine. The dosing recommendation is applicable to the recommended dose of rilpivirine 25 mg once daily.

Drugs with No Observed or Predicted Interactions with COMPLERA

No clinically significant drug interactions have been observed between emtricitabine and famciclovir or tenofovir disoproxil fumarate. Similarly, no clinically significant drug interactions have been observed between tenofovir disoproxil fumarate and entecavir, methadone, oral contraceptives, ribavirin, or zalcitabine in studies conducted in healthy subjects.

No clinically significant drug interactions have been observed between rilpivirine and acetaminophen, atazanavir, chlorzoxazone, ethinylloestradiol, norethindrone, sildenafil, and tenofovir disoproxil fumarate. No clinically relevant drug-drug interaction is expected when rilpivirine is coadministered with ribavirin.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

Emtricitabine: The incidence of fetal variations and malformations was not increased in embryofetal toxicity studies performed with emtricitabine in mice at exposures (AUC) approximately 60 times higher and in rabbits at approximately 120 times higher than human exposures at the recommended daily dose. **Rilpivirine:** Studies in animals have shown no evidence of embryonic or fetal toxicity or an effect on reproductive function. In offspring from rat and rabbit dams treated with rilpivirine during pregnancy and lactation, there were no toxicologically significant effects on developmental endpoints. The exposures at the embryo-fetal No Observed Adverse Effects Levels in rats and rabbits were respectively 15 and 70 times higher than the exposure in humans at the recommended dose of 25 mg once daily.

Tenofovir Disoproxil Fumarate: Reproduction studies have been performed in rats and rabbits at doses up to 14 and 19 times the human dose based on body surface area comparisons and revealed no evidence of impaired fertility or harm to the fetus due to tenofovir.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, COMPLERA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Antiretroviral Pregnancy Registry: To monitor fetal outcomes of pregnant women exposed to COMPLERA, an Antiretroviral Pregnancy Registry has been established. Healthcare providers are encouraged to register patients by calling 1-800-258-4263.

Nursing Mothers

The Centers for Disease Control and Prevention recommend that HIV infected mothers not breastfeed their infants to avoid risking postnatal transmission of HIV. Studies in rats have demonstrated that tenofovir is secreted in milk. Studies in lactating rats and their offspring indicate that rilpivirine was present in rat milk. It is not known whether emtricitabine, rilpivirine, or tenofovir is excreted in human milk. Because of both the potential for HIV transmission and the potential for serious adverse reactions in nursing infants, **mothers should be instructed not to breastfeed if they are receiving COMPLERA.**

Pediatric Use

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*].

Geriatric Use

Clinical studies of emtricitabine, rilpivirine, or tenofovir disoproxil fumarate did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for the elderly patients should be cautious, keeping in mind the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy [See *Clinical Pharmacology in Full Prescribing Information*].

Renal Impairment

Because COMPLERA is a fixed-dose combination, it should not be prescribed for patients requiring dosage adjustment such as those with moderate, severe or end stage renal impairment (creatinine clearance below 50 mL per minute) or that require dialysis [See *Warnings and Precautions, 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 has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) [See *Clinical Pharmacology in Full Prescribing Information*].

OVERDOSAGE

If overdose occurs the patient must be monitored for evidence of toxicity. Treatment of overdose with COMPLERA consists of general supportive measures including monitoring of vital signs and ECG (QT interval) as well as observation of the clinical status of the patient.

Emtricitabine: Limited clinical experience is available at doses higher than the therapeutic dose of EMTRIVA. In one clinical pharmacology study, single doses of emtricitabine 1200 mg were administered to 11 subjects. No severe adverse reactions were reported. The effects of higher doses are not known. Hemodialysis treatment removes approximately 30% of the emtricitabine dose over a 3-hour dialysis period starting within 1.5 hours of emtricitabine dosing (blood flow rate of 400 mL per minute and a dialysate flow rate of 600 mL per minute). It is not known whether emtricitabine can be removed by peritoneal dialysis.

Rilpivirine: There is no specific antidote for overdose with rilpivirine. Human experience of overdose with rilpivirine is limited. Since rilpivirine is highly bound to plasma protein, dialysis is unlikely to result in significant removal of rilpivirine.

If indicated, elimination of unabsorbed active substance may be achieved by gastric lavage. Administration of activated charcoal may also be used to aid in removal of unabsorbed active substance.

Tenofovir Disoproxil Fumarate: Limited clinical experience at doses higher than the therapeutic dose of VIREAD 300 mg is available. In one study, 600 mg tenofovir disoproxil fumarate was administered to 8 subjects orally for 28 days, and no severe adverse reactions were reported. The effects of higher doses are not known.

Tenofovir is efficiently removed by hemodialysis with an extraction coefficient of approximately 54%. Following a single 300 mg dose of VIREAD, a four-hour hemodialysis session removed approximately 10% of the administered tenofovir dose.

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information)

A statement to patients and healthcare providers is included on the product's bottle label: **ALERT: Find out about medicines that should NOT be taken with COMPLERA from your healthcare provider.** A Patient Package Insert for COMPLERA is available for patient information.

Information for Patients

Patients should be advised that:

- Patients should remain under the care of a healthcare provider when using COMPLERA.
- 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 decrease HIV-related illnesses. Patients should be told that sustained decreases in plasma HIV RNA have been associated with a reduced risk of progression to AIDS and death.
- Patients should be advised to continue to practice safer sex and to use latex or polyurethane condoms to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions or blood. Patients should be advised never to reuse or share needles.
- It is important to take COMPLERA on a regular dosing schedule with a meal and to avoid missing doses. A protein drink does not constitute a meal. If the patient misses a dose of COMPLERA within 12 hours of the time it is usually taken, the patient should take COMPLERA with a meal as soon as possible and then take the next dose of COMPLERA at the regularly scheduled time. If a patient misses a dose of COMPLERA by more than 12 hours, the patient should not take the missed dose, but resume the usual dosing schedule. Inform the patient that he or she should not take more or less than the prescribed dose of COMPLERA at any one time.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Treatment with COMPLERA should be suspended in any patients who develop clinical symptoms suggestive of lactic acidosis or pronounced hepatotoxicity (including nausea, vomiting, unusual or unexpected stomach discomfort, and weakness) [See *Warnings and Precautions*].
- Patients with HIV-1 should be tested for hepatitis B virus (HBV) before initiating antiretroviral therapy. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued EMTRIVA or VIREAD [See *Warnings and Precautions*]. COMPLERA should not be discontinued without first informing their healthcare provider.
- Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported in association with the use of VIREAD. COMPLERA should be avoided with concurrent or recent use of a nephrotoxic agent [See *Warnings and Precautions*].
- COMPLERA may interact with many drugs; therefore, patients should be advised to report to their healthcare provider the use of any other prescription or nonprescription medication or herbal products, including St. John's wort [See *Warnings and Precautions*].
- 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 antifungals carbamazepine, oxcarbazepine, phenobarbital, phenytoin; the antismycobacterials rifabutin, rifampin, rifapentine; proton pump inhibitors, such as esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole; the glucocorticoid systemic dexamethasone (more than a single dose); or St. John's wort (*Hypericum perforatum*) [See *Contraindications*].
- Patients should be informed that depressive disorders (depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, suicidal ideation) have been reported with COMPLERA. If they experience depressive symptoms, they should seek immediate medical evaluation [See *Warnings and Precautions*].
- Decreases in bone mineral density have been observed with the use of VIREAD. Bone monitoring should be considered in patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss [See *Warnings and Precautions*].
- COMPLERA should not be coadministered with ATRILA, TRUVADA, EMTRIVA, VIREAD or EDURANT, or with drugs containing lamivudine, including COMBIVIR, EPVIR or EPVIR-HBV, EPZICOM, or TRIZIVIR, or with HEPSERA [See *Warnings and Precautions*].
- Redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy and that the cause and long-term health effects of these conditions are not known [See *Warnings and Precautions*].
- In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. Patients should be advised to inform their healthcare provider immediately of any symptoms of infection [See *Warnings and Precautions*].



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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 M. Fox
1967-2012

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.

HIV

James M. Friedman

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 (Victrelis) 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 Victrelis 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 Victrelis 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>.



THINKSTOCK

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 rapid decline in 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.



THINKSTOCK

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 McAllister, 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.



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 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 T-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.
- The estimated median time to progression for the stable normal CD4 group was 6.2 years, compared to the 4.0 years for patients with stable below-normal counts ($P < 0.001$).
- Among the 1,204 long-term positive, ART-naïve 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-naïve asymptomatic patients had unstable or declining CD4 counts, of whom 95 (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-naïve 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-1," 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 T-cell counts compared to those with unstable CD4 T-cell counts."

Reference

S Mandalia, SJ Westrop, EJ Beck, et al. Are Long-Term Non-Progressors Very Slow Progressors? Insights from the Chelsea and Westminster HIV Cohort, 1988-2010. PLoS ONE 7(2):e29844. February 20, 2012.





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-naïve patients infected with CCR5-tropic HIV-1.

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.

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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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 non-practicing clinicians. The HIV Pharmacist™ (AAHIVP) certification, new this year, is available to eligible HIV-specialized pharmacists. To be eligible to apply for the exam applicants must demonstrate the following:

- **EXPERIENCE:** the applicant must be a licensed provider in his or her state of practice, and must declare when applying that they are actively treating a specified number of HIV patients in an environment appropriate



to their profession (non-practicing frontline 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 quali-

fication (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.

HIV



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.”

— excerpt from www.WhiteHouse.gov

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. **HIV**



ABOUT THE AUTHOR:

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Prepping for PrEP

There have been major developments in pre-exposure prophylaxis (PrEP) research the past two 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 mini-

mum 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.

HIV



ABOUT THE AUTHOR:

Dr. Jeffrey Schouten, Attorney at Law, is the director of the Office of HIV/AIDS Network Coordination (HANC) and a Member and

immediate past-chair of the AAHIVM Board of Directors. HANC facilitates coordination and collaboration between the NIH's Division of AIDS six HIV/AIDS Clinical Trials Networks. He has been involved in HIV clinical research and HIV primary care for more than a decade. He is also a clinical investigator at the University of Washington AIDS Clinical Trials Unit and an attorney with a strong interest in HIV public policy.



HIV & Technology

Electronic health records, telemedicine, other applications
are being used to improve care

BY BOB GATTY

According to the U.S. Department of Health & Human Services (HHS), over one-third of Primary Care Providers have adopted the practice of using Electronic Health Records (EHRs). This commitment represents a major step toward broad and meaningful use of technology in the health care community.

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.

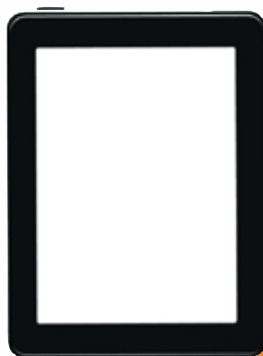
"Nowadays most of my patients come in and have researched everything from opportunistic infections, CD4 counts, medications and have a great deal of knowledge, and it didn't use to be like that," he explained. "Technology is huge when it comes to managing HIV patients. They tweet each other about their 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

"When doctors and hospitals use health IT, patients get better care and we save money."

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."



"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."

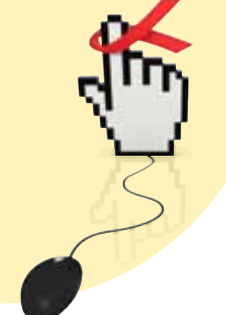
"They can keep up with their numbers in real time, rather than waiting for the care provider to call them, they can actually get access electronically."

"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."



Over one-third of Primary Care Providers have adopted the practice of using Electronic Health Records (EHRs).

THINKSTOCK, BONOTOM STUDIO



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 tech-

nology 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...”



proved health outcomes. Stage 3 also will focus on decision support for national high priority conditions, patient access to self-management tools, access to comprehensive patient data through robust, patient-centered health information exchange and improving population health.

Also released last November was a new Centers for Disease Control and Prevention (CDC) survey showing that 52 percent of office-based physicians in the US intend to take advantage of the incentive payments for doctors and hospitals through the Medicare and Medicaid EHR incentive programs. Those payments can total as much as \$44,000 under the Medicare program and \$63,700 under the Medicaid program.

Meanwhile, to meet the demand for workers with health IT experience and training, the Obama administration launched four workforce development programs to help train these employees. 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.

"You can jump through those (meaningful use) hoops and you can get some reimbursement," Dr. Prokesch said, "but soon they will start holding back money if you don't comply." So, it makes sense, he stressed, to get on board.

Prescription Accuracy

The use of EHR also helps to reduce mistakes, including in the transmission of prescriptions from physician to pharmacy.

"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," said Dr. Prokesch. "That's another part of the governmental mandate, but I think it's a good one."

Jim Scott, PharmD, ME, AAHIVE, associate dean of experiential and professional affairs and associate professor of pharmacy practice and administration at Western University of Health Sciences, College of Pharmacy, Pomona, CA., understands that first hand.

Dr. Scott, who served on the technology awards panel with Dr. Prokesch and four other tech savvy AAHIVM Members, pointed out that today's systems now allow pharmacists to

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.

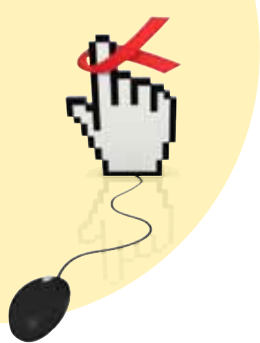
"Communication breakdowns are frequently a factor in patient safety events," said Dr. Michael McKenna, chief medical officer at Advocate Lutheran General Hospital. "PerfectServe makes it extremely easy for our medical staff to find physicians and offers a better way to streamline the flow of information."

"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.

... and they get into financial issues, as well. It really makes a big difference in HIV care."





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

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. Lando-vitz 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.” **HIV**

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.

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,



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Editor of HIV Specialist, Bob Gatty is a Washington, DC-area health policy

writer and publications professional. He is founder of G-Net Strategic Communications and can be reached at bob@gattyedits.com.

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

THE JOHNS HOPKINS UNIVERSITY SCHOOL 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 ReferralLink 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.



The 2011 Tech Awards

Telemedicine, social media initiatives takes honors in the first annual AAHIVM/Institute for Technology in Health Care HIV Practice Awards

BY BOB GATTY

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 develop-

ments 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."

Following are profiles of the 2011 AAHIVM/Institute of Technology in Health Care HIV Practice Awards:

Social Media & HIV

Raphael J. Landovitz, MD, MSc

Dr. Landovitz and his colleagues used the GPS-based social networking application GRINDR to recruit young MSMs to a sexual risk behavior survey designed to demonstrate that these individuals could be effectively reached through social media.

"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 in-

fections 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 individuals. 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

"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

piece, depending on what we think is the best combination of prevention 'puzzle pieces'."

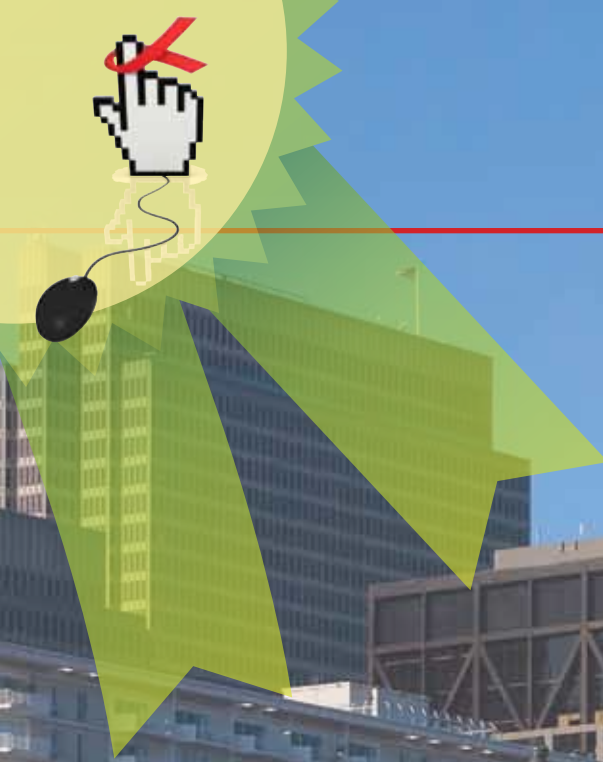
"Prevention efforts which need to reach YMSM can easily access the GRINDR platform, and without pretense, rapidly access a well characterized population," he contended. "This technology has boundless possibilities, including prevention messaging, education (in the moment, as well as later extracurricular 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."





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.

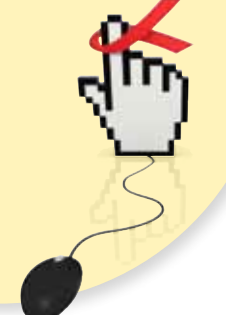
The Center is obtaining new equipment that will make it easier for such consultations, including high definition camera equipment that will allow physicians, for example, to clearly see a patient’s skin lesions for the purpose of diagnoses and treatment.

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.

HIV

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.





Social Media +

AIDS.GOV using new media applications to connect people with testing and care

BY BOB GATTY

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.



Miguel Gomez

“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/deve;p\[omg-a-new-media-plan/](http://www.aids.gov/using-new-media/getting-started/deve;p[omg-a-new-media-plan/). **HIV**







Health IT Improvements Recommended

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 pay-

ment 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.

THINKSTOCK

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 agreement 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



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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.



Janet Marchibroda

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Sen. Bill Frist

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HIV



HIV Testing Innovations Contribute to NHAS Goal

BY RONALD VALDISERRI, MD, MPH

WITH AN ESTIMATED 20 PERCENT OF PEOPLE LIVING WITH HIV in the United States unaware of their status, strengthening our HIV testing efforts will be key to achieving the goals of the *National HIV/AIDS Strategy* (NHAS). Fortunately, many innovative HIV testing efforts are underway in communities across the country.

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 per-

centage 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,



DMV

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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. **HIV**



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EDITOR'S
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HIV Adult and Adolescent Treatment Guidelines

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.

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.

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

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

Non-NRTI + 2 NRTIs	Efavirenz / emtricitabine / tenofovir
Boosted-PI + 2 NRTIs	Atazanavir + ritonavir + emtricitabine / tenofovir Darunavir + ritonavir + emtricitabine / tenofovir
INSTI + 2 NRTIs	Raltegravir + emtricitabine / tenofovir
Pregnancy	Lopinavir / ritonavir bid + zidovudine / lamivudine

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

Non-NRTI based	■ Efavirenz + Abacavir / Epivir ■ Rilpivirine + Abacavir / Epivir ■ Rilpivirine + Tenofovir / Emtricitabine
Protease Inhibitor-based	■ Atazanavir/r + Abacavir / Epivir ■ Darunavir/r + Abacavir / Epivir ■ Fosamprenavir/r + Abacavir / Epivir ■ Fosamprenavir + Tenofovir / FTC ■ Lopinavir/r + Abacavir / Epivir ■ Lopinavir/r + Tenofovir / FTC
ISI based	■ Raltegravir + Abacavir / Epivir

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 data 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 viro-

logic failure on unboosted fosamprenavir.

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. **HIV**

Reference:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. October 14, 2011; 1-167.

Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>.



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TABLE 3

DHHS Guidelines for Initial Therapy: Dual-NRTI Pairs

Preferred TDF/FTC	■ Once-daily dosing ■ High virologic efficacy ■ Active against HBV ■ Potential for renal and bone toxicity
Alternative ABC/3TC	■ Once-daily dosing ■ Risk of hypersensitivity reaction if positive for HLA-B*5701 ■ Possible risk of cardiovascular events; caution in patients with CV risk factors ■ Possible inferior efficacy if baseline HIV RNA >100,000 copies/mL
Acceptable ZDV/3TC	■ Twice-daily dosing ■ Preferred dual NRTI for pregnant women ■ More toxicities than TDF/FTC or ABC/3TC

TABLE 4

ARVs Not Recommended in Initial Treatment

High rate of early virologic failure	■ ddI + TDF
Inferior virologic efficacy	■ ABC + 3TC + ZDV as 3-NRTI regimen ■ ABC + 3TC + ZDV + TDF (as 4-NRTI regimen) ■ PddI + (3TC or FTC) ■ FPV (unboosted) ■ DLV ■ NFV ■ SQV as single PI (unboosted) ■ TPV/r
High incidence of toxicities	■ d4T + 3TC ■ ddI + TDF ■ IDV/r ■ RTV as single PI

'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 strength, so now our counseling sessions focus on diet, exercise and healthy living habits.

That is what I do at Walgreens as the Lead HIV/AIDS clinical pharmacist, and that is the type of service we are working to provide in our stores across the country. I have been involved in the care of HIV-infected patients since 1996 and have witnessed the remarkable changes in therapy and disease management that have occurred. With HIV patients living longer, we



commonly see the comorbidities of aging, 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**

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