The AMERICAN ACADEMY of HIV MEDICINE®

HIV SPECIALIST

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

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How Does It Fit?

ACA

STRIBILD is indicated as a complete single-tablet regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naïve.

Powerful performance in HIV[1]

STRIBILD is the first integrase inhibitor–based single-tablet regimen[2]

- **STRIBILD achieves strong efficacy with an overall rapid reduction in viral load[3,4]**
  - Noninferior efficacy at week 48
    - 90% of subjects taking STRIBILD reached undetectable viral loads compared to 87% of subjects taking ATV + RTV + FTC/TDF
    - 88% of subjects taking STRIBILD reached undetectable viral loads compared to 84% of subjects taking EFV/FTC/TDF
- **Convenient single-tablet regimen dosing**
  - 1 tablet taken once daily with food
  - Do not initiate in patients with eGFR <70 mL/min; discontinue in patients with eGFR <50 mL/min; not recommended in patients with severe hepatic impairment
- **Safety and tolerability profile through 48 weeks**
  - The most common adverse drug reactions (all severity grades) reported in ≥5% of subjects were nausea (16%), diarrhea (12%), abnormal dreams (9%), headache (7%), and fatigue (5%)
  - 3.7% of subjects taking STRIBILD discontinued therapy due to adverse events compared to 5.1% of subjects taking either ATV + RTV + FTC/TDF or EFV/FTC/TDF

BOXED WARNING

WARNING: 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 STRIBILD, in combination with other antiretrovirals.**
- **STRIBILD is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of STRIBILD 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 human immunodeficiency virus-1 (HIV-1) and have discontinued EMTRIVA or VIREAD, which are components of STRIBILD. 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 STRIBILD. If appropriate, initiation of anti-hepatitis B therapy may be warranted.**

Please see additional Important Safety Information on the next page.

Study designs: STRIBILD was assessed in 2 randomized, double-blind, active-controlled, phase 3, noninferiority clinical trials in treatment-naïve, HIV-1–infected subjects with baseline estimated creatinine clearance >70 mL/min. Study 103 compared STRIBILD (n = 353) to ATV + RTV + FTC/TDF (n = 355); Study 102 compared STRIBILD (n = 348) to a single-tablet regimen consisting of EFV/FTC/TDF (n = 352). The primary endpoint of both studies was the proportion of subjects with viral suppression (<50 copies/mL) at week 48 according to FDA snapshot analysis.

Baseline characteristics: Viral load: In Studies 103 and 102, respectively, 41% and 33% of subjects had baseline viral loads >100,000 copies/mL. **CD4 count:** Mean baseline CD4+ cell count was 370 cells/mm^3 (range 5 to 1132) in Study 103, and 386 cells/mm^3 (range 3 to 1348) in Study 102; 13% of subjects in both studies had CD4+ cell counts <200 cells/mm^3.

Abbreviations: ATV, atazanavir; EFV, efavirenz; eGFR, estimated glomerular filtration rate; FTC, emtricitabine; RTV, ritonavir; TDF, tenofovir disoproxil fumarate.

Important Safety Information (*continued*)

Contraindications

- **Coadministration:** Do not use with drugs highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events. Do not use with drugs that strongly induce CYP3A as this may lead to a loss of virologic response and possible resistance to STRIBILD. Use with the following drugs is contraindicated: alfuzosin, rifampin, dihydroergotamine, ergotamine, methylergonovine, cisapride, lovastatin, simvastatin, pimozide, sildenafil for pulmonary arterial hypertension, triazolam, oral midazolam, and St. John's wort.

Warnings and precautions

- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir DF and STRIBILD. Monitor estimated creatinine clearance (CrCl), urine glucose, and urine protein in all patients prior to initiating and during therapy; additionally monitor serum phosphorus in patients with or at risk for renal impairment. Cobicistat may cause modest increases in serum creatinine and modest declines in CrCl without affecting renal glomerular function; patients with an increase in serum creatinine >0.4 mg/dL from baseline should be closely monitored for renal safety. Do not initiate STRIBILD in patients with CrCl below 70 mL/min. Discontinue STRIBILD if CrCl declines below 50 mL/min. Avoid concurrent or recent use with a nephrotoxic agent.
- **Use with other antiretroviral products:** STRIBILD is a complete regimen for the treatment of HIV-1 infection. Do not coadminister with other antiretroviral products, including products containing any of the same active components; products containing lamivudine; products containing ritonavir; or with adefovir dipivoxil.
- **Decreases in bone mineral density (BMD)** and cases of osteomalacia have been seen in patients treated with tenofovir DF. Consider monitoring BMD in patients with a history of pathologic fracture or risk factors for bone loss.
- **Fat redistribution** and accumulation have been observed in patients receiving antiretroviral therapy.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

Adverse reactions

- **Common adverse drug reactions** in clinical studies (incidence ≥5%; all grades) were nausea (16%), diarrhea (12%), abnormal dreams (9%), headache (7%), and fatigue (5%).

Drug interactions

- **CYP3A substrates:** STRIBILD can alter the concentration of drugs metabolized by CYP3A or CYP2D6. Do not use with drugs highly dependent on these factors for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening adverse events.
- **CYP3A inducers:** Drugs that induce CYP3A can decrease the concentrations of components of STRIBILD. Do not use with drugs that strongly induce CYP3A as this may lead to loss of virologic response and possible resistance to STRIBILD.
- **Antacids:** Separate STRIBILD and antacid administration by at least 2 hours.
- **Prescribing information:** Consult the full prescribing information for STRIBILD for more information on potentially significant drug interactions, including clinical comments.

Dosage and administration

- **Adult dosage:** One tablet taken orally once daily with food.
- **Renal impairment:** Do not initiate in patients with CrCl below 70 mL/min. Discontinue in patients with CrCl below 50 mL/min.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.

Pregnancy and breastfeeding

- **Pregnancy Category B:** There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk. An Antiretroviral Pregnancy Registry has been established.
- **Breastfeeding:** Emtricitabine and tenofovir have been detected 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.

Please see Brief Summary of full Prescribing Information, including **BOXED WARNING,** on the following pages.

References: 1. STRIBILD [package insert]. Foster City, CA: Gilead Sciences, Inc; 2012. **2.** US Food and Drug Administration. Antiretroviral drugs used in the treatment of HIV infection. http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/hivandaidsactivities/ucm118915.htm. Accessed May 7, 2013. **3.** DeJesus E, Rockstroh JK, Henry K, et al; for the GS-236-0103 Study Team. Co-formulated elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate versus ritonavir-boosted atazanavir plus co-formulated emtricitabine and tenofovir disoproxil fumarate for initial treatment of HIV-1 infection: a randomised, double-blind, phase 3, non-inferiority trial. *Lancet.* 2012;379(9835):2429-2438. **4.** Sax P, DeJesus E, Mills A, et al; for the GS-US-236-0102 Study Team. Co-formulated elvitegravir, cobicistat, emtricitabine, and tenofovir versus co-formulated efavirenz, emtricitabine, and tenofovir for initial treatment of HIV-1 infection: a randomised, double-blind, phase 3 trial, analysis of results after 48 weeks. *Lancet.* 2012;379(9835):2439-2448.

STRIBILD™

elvitegravir 150mg/ cobicistat 150mg/ emtricitabine 200mg/ tenofovir disoproxil fumarate 300mg tablets

Performance by design

Learn more at www.**STRIBILD**.com/hcp

STRIBILD™ (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) tablets, for oral use

Brief summary of full Prescribing Information. See full Prescribing Information. Rx only.

WARNING: 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 (tenofovir DF), a component of STRIBILD, in combination with other antiretrovirals *[See Warnings and Precautions]*.

STRIBILD is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of STRIBILD 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 human immunodeficiency virus-1 (HIV-1) and have discontinued EMTRIVA or VIREAD, which are components of STRIBILD. 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 STRIBILD. If appropriate, initiation of anti-hepatitis B therapy may be warranted *[See Warnings and Precautions]*.

INDICATIONS AND USAGE:
STRIBILD is indicated as a complete regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naive.

DOSAGE AND ADMINISTRATION:
The recommended dose is one tablet taken orally once daily with food.

Renal Impairment: Do not initiate in patients with estimated creatinine clearance (CrCl) below 70 mL/min. Discontinue if CrCl declines below 50 mL/min during treatment *[See Warnings and Precautions, Adverse Reactions, Use in Specific Populations]*.

Hepatic Impairment: No dose adjustment is required in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. No pharmacokinetic or safety data are available regarding use in patients with severe hepatic impairment (Child-Pugh Class C). STRIBILD is not recommended for use in patients with severe hepatic impairment *[See Use in Specific Populations]*.

CONTRAINDICATIONS:
Coadministration: Do not use with drugs highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening adverse events, or with drugs that strongly induce CYP3A as this may decrease STRIBILD plasma concentrations leading to a loss of virologic response and possible resistance *[See Drug Interactions]*:

- Alpha 1-adrenoreceptor antagonists: alfuzosin. Potential for hypotension.
- Antimycobacterial: rifampin. May lead to a loss of virologic response and possible resistance to STRIBILD.
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine. Potential for acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues.
- GI motility agents: cisapride. Potential for cardiac arrhythmias.
- Herbal products: St. John's wort (*Hypericum perforatum*). May lead to a loss of virologic response and possible resistance to STRIBILD.
- HMG CoA reductase inhibitors: lovastatin, simvastatin. Potential for myopathy, including rhabdomyolysis.
- Neuroleptics: pimozide. Potential for cardiac arrhythmias.
- PDE-5 inhibitors: sildenafil when dosed as REVATIO for the treatment of pulmonary arterial hypertension. A safe and effective dose has not been established; the potential for sildenafil-associated adverse events (visual disturbances, hypotension, priapism, and syncope) is increased.
- Sedative/hypnotics: orally administered midazolam, triazolam. Potential for prolonged or increased sedation or respiratory depression.

WARNINGS AND PRECAUTIONS:
Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with nucleoside analogs, including tenofovir DF, a component of STRIBILD, 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 STRIBILD 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 HBV before initiating antiretroviral therapy. STRIBILD is not approved for the treatment of chronic HBV infection and the safety and efficacy of STRIBILD 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 DF, two of the components of STRIBILD. 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 STRIBILD. 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 tenofovir DF and with STRIBILD *[See Adverse Reactions]*. In clinical trials of STRIBILD over 48 weeks (N=701), 8 (1.1%) subjects in the STRIBILD group and 1 (0.1%) subject in the combined comparator groups discontinued study drug due to a renal adverse event. Four (0.6%) of the subjects who received STRIBILD developed laboratory findings consistent with proximal renal tubular dysfunction leading to discontinuation of STRIBILD compared to none in the comparator groups. Two of these 4 subjects had renal impairment (CrCl less than 70 mL/min) at baseline. The laboratory findings in these 4 subjects improved but did not completely resolve in all subjects upon discontinuation. Renal replacement therapy was not required. STRIBILD should be avoided with concurrent or recent use of a nephrotoxic agent. ***Monitoring:*** CrCl, urine glucose and urine protein should be documented in all patients prior to initiating therapy. STRIBILD should not be initiated in patients with CrCl below 70 mL/min. Routine monitoring of CrCl, urine glucose, and urine protein should be performed during STRIBILD therapy in all patients. Additionally, serum phosphorus should be measured in patients at risk for renal impairment. Although cobicistat may cause modest increases in serum creatinine and modest declines in CrCl without affecting renal glomerular function *[See Adverse Reactions]*, patients who experience a confirmed increase in serum creatinine of greater than 0.4 mg/dL from baseline should be closely monitored for renal safety. STRIBILD should be discontinued if CrCl declines below 50 mL/min.

Use with Other Antiretroviral Products: STRIBILD is a complete regimen for the treatment of HIV-1 infection and should not be coadministered with other antiretroviral products. STRIBILD should not be coadministered with products containing any of the same active components (ATRIPLA, COMPLERA, EMTRIVA, TRUVADA, VIREAD); or with products containing lamivudine (COMBIVIR, EPIVIR, EPIVIR-HBV, EPZICOM, TRIZIVIR). STRIBILD should not be administered with adefovir dipivoxil (HEPSERA).

Decreases in Bone Mineral Density (BMD): In previous clinical trials, tenofovir DF has been associated with decreases in BMD and 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 VIREAD. The effects of tenofovir DF-associated changes in BMD on 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 tenofovir DF *[See Adverse Reactions]*. In Study 103, BMD was assessed by DEXA in a non-random subset of 120 subjects. Mean percentage decreases in BMD from baseline to Week 48 in the STRIBILD group (N=54) were comparable to the atazanavir + ritonavir + emtricitabine/tenofovir DF group (N=66) at the lumbar spine (-2.6% versus -3.3%, respectively) and at the hip (-3.1% versus -3.9%, respectively). In Studies 102 and 103, bone fractures occurred in 9 subjects (1.3%) in the STRIBILD group, 6 subjects (1.7%) in the efavirenz/emtricitabine/tenofovir DF group, and 6 subjects (1.7%) in the atazanavir + ritonavir + emtricitabine/tenofovir DF group. These findings were consistent with data from an earlier 144-week trial of treatment-naive subjects receiving tenofovir DF + lamivudine + efavirenz. Assessment of BMD should be considered for patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Although the effect of supplementation with calcium and vitamin D was not studied, such supplementation may be beneficial in all patients. If bone abnormalities are suspected appropriate consultation should be obtained.

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 currently unknown. A causal relationship has not been established.

Immune Reconstitution Syndrome (IRS): IRS has been reported in patients treated with combination antiretroviral therapy, including STRIBILD. 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. Autoimmune disorders (such as Graves' disease, polymyositis, and Guillain-Barre syndrome) have been reported to occur in the setting of immune reconstitution, however, the time to onset is more variable, and can occur many months after initiation of treatment.

ADVERSE REACTIONS:
*See **BOXED WARNINGS** and **WARNINGS AND PRECAUTIONS** sections for additional serious adverse reactions.*

Adverse Reactions from Clinical Trials Experience: The safety assessment of STRIBILD is based on pooled data from 1408 subjects in two Phase 3 trials, Study 102 and Study 103, in antiretroviral treatment-naive HIV-1 infected adult subjects. A total of 701 subjects received STRIBILD once daily for at least 48 weeks. The proportion of subjects who discontinued treatment with STRIBILD due to adverse events, regardless of severity, was 3.7%.

Treatment Emergent Adverse Drug Reactions: Treatment emergent adverse drug reactions (all grades) reported in ≥5% of subjects receiving STRIBILD (N=701) in Studies 102 and 103 (Week 48 analysis) were: nausea (16%); diarrhea (12%); abnormal dreams (9%); headache (7%); and fatigue (5%). Frequencies of adverse reactions are based on all treatment emergent adverse events, attributed to study drugs. See ***WARNINGS AND PRECAUTIONS*** for a discussion of renal adverse events from clinical trials experience with STRIBILD.

Laboratory Abnormalities: Treatment emergent laboratory abnormalities (Grades 3-4) occurring in ≥2% of subjects receiving STRIBILD (N=701) in Studies 102 and 103 (Week 48 analysis) were: creatine kinase (≥10.0 x ULN), 5%; urine RBC (hematuria) (>75 RBC/HPF), 3%; AST (>5.0 x ULN), 2%; and amylase (>2.0 x ULN), 2%. For subjects with serum amylase >1.5 x ULN, lipase test was also performed. The frequency of increased lipase (Grades 3-4) occurring in STRIBILD (N=58) was 12%. Proteinuria (all grades) occurred in 39% of subjects receiving STRIBILD. Cobicistat has been shown to decrease CrCl due to inhibition of tubular secretion of creatinine without affecting renal glomerular function. In Studies 102 and 103, decreases in CrCl occurred early in treatment with STRIBILD, after which they stabilized. Mean ± SD changes after 48 weeks of treatment were 0.14 ± 0.13 mg/dL for serum creatinine and -13.9 ± 14.9 mL/min for estimated glomerular filtration rate (eGFR) by Cockcroft-Gault method. Elevation in serum creatinine (all grades) occurred in 7% of subjects.

Serum Lipids: In the clinical trials of STRIBILD, 11% of subjects were on lipid lowering agents at baseline. While receiving study drug through Week 48, an additional 4% of subjects were started on lipid lowering agents. Through 48 weeks, 1% or fewer subjects in any treatment arm experienced Grades 3-4 elevations in fasting cholesterol (greater than 300 mg/dL) or fasting triglycerides (greater than 750 mg/dL). Mean changes from baseline in total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides reported in subjects receiving STRIBILD (N=701) in Studies 102 and 103 (Week 48 analysis) were: total cholesterol (fasted): baseline 166 mg/dL (N=675), week 48 change +11 (N=606); HDL-cholesterol (fasted): baseline 43 mg/dL (N=675), week 48 change +6 (N=605); LDL-cholesterol (fasted): baseline 100 mg/dL (N=675), week 48 change +10 (N=606); triglycerides (fasted): baseline 122 mg/dL (N=675), week 48 change +13 (N=606). The change from baseline is the mean of within-patient changes from baseline for patients with both baseline and Week 48 values.

Emtricitabine and Tenofovir DF: ***Adverse drug reactions:*** In addition to the adverse drug reactions observed with STRIBILD, the following adverse drug reactions occurred in at least 5% of treatment-experienced or treatment-naive subjects receiving emtricitabine or tenofovir DF with other antiretroviral agents in other clinical trials: depression, 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 rhinitis. 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:*** In addition to the laboratory abnormalities observed with STRIBILD, the following laboratory abnormalities have been previously reported in subjects treated with emtricitabine or tenofovir DF with other antiretroviral agents in other clinical trials: Grades 3-4 laboratory abnormalities of ALT (M: greater than 215 U/L; F: greater than 170 U/L), alkaline phosphatase (greater than 550 U/L), bilirubin (greater than 2.5 x ULN), serum glucose (less than 40 or greater than 250 mg/dL), glycosuria (greater than or equal to 3+), neutrophils (less than 750/mm^3), fasting cholesterol (greater than 240 mg/dL), and fasting triglycerides (greater than 750 mg/dL). ***Postmarketing Events:*** The following adverse reactions have been identified during post approval use of tenofovir DF: allergic reaction (including angioedema), lactic acidosis, hypokalemia, hypophosphatemia, dyspnea, pancreatitis, increased amylase, abdominal pain, hepatic steatosis, hepatitis, increased liver enzymes (most commonly AST, ALT gamma GT), rash, rhabdomyolysis, osteomalacia (manifested as bone pain and which may contribute to fractures), muscular weakness, myopathy, 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, and asthenia. The following adverse reactions listed above may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia, hypokalemia, muscular weakness, myopathy, and hypophosphatemia.

DRUG INTERACTIONS:
See ***CONTRAINDICATIONS*** *for additional serious adverse reactions.*

STRIBILD is a complete regimen for the treatment of HIV-1 infection. STRIBILD should not be administered with other antiretroviral medications for treatment of HIV-1 infection. Complete information regarding potential drug-drug interactions with other antiretroviral medications is not provided.

STRIBILD should not be used in conjunction with protease inhibitors or non-nucleoside reverse transcriptase inhibitors due to potential drug interactions including altered and/or suboptimal pharmacokinetics of cobicistat, elvitegravir, and/or the coadministered antiretroviral products. STRIBILD should not be administered concurrently with products containing ritonavir or regimens containing ritonavir due to similar effects of cobicistat and ritonavir on CYP3A.

Potential for STRIBILD to Affect Other Drugs: Cobicistat is an inhibitor of CYP3A and CYP2D6. The transporters that cobicistat inhibits include p-glycoprotein (P-gp), BCRP, OATP1B1 and OATP1B3. Coadministration of STRIBILD with drugs that are primarily metabolized by CYP3A or CYP2D6, or are substrates of P-gp, BCRP, OATP1B1 or OATP1B3 may result in increased plasma concentrations of such drugs. Elvitegravir is a modest inducer of CYP2C9 and may decrease the plasma concentrations of CYP2C9 substrates.

Potential for Other Drugs to Affect One or More Components of STRIBILD: Elvitegravir and cobicistat are metabolized by CYP3A. Cobicistat is also metabolized, to a minor extent, by CYP2D6. Drugs that induce CYP3A activity are expected to increase the clearance of elvitegravir and cobicistat, resulting in decreased plasma concentration of cobicistat and elvitegravir, which may lead to loss of therapeutic effect of STRIBILD and development of resistance. Coadministration of STRIBILD with other drugs that inhibit CYP3A may decrease the clearance and increase the plasma concentration of cobicistat.

Drugs Affecting Renal Function: Because emtricitabine and tenofovir are primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion, coadministration of STRIBILD with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of emtricitabine, tenofovir, and other renally eliminated drugs.

Established and Other Potentially Significant Interactions: The drug interactions described are based on studies conducted with either STRIBILD, the components of STRIBILD as individual agents and/or in combination, or are predicted drug interactions that may occur with STRIBILD. The list includes potentially significant interactions but is not all inclusive. **An alteration in dose or regimen may be recommended for the following drugs when coadministered with STRIBILD:**

- Acid Reducing Agents: antacids. Separate STRIBILD and antacid administration by at least 2 hours.
- Antiarrhythmics: amiodarone, bepridil, digoxin, disopyramide, flecainide, systemic lidocaine mexiletine, propafenone, quinidine. Caution warranted and therapeutic concentration monitoring recommended.
- Antibacterials: clarithromycin, telithromycin. Clarithromycin: no dose adjustment required for patients with CrCl ≥60 ml/min; the dose should be reduced by 50% for patients with CrCl between 50 and 60 mL/min. Telithromycin: concentrations of telithromycin and/or cobicistat may be increased.
- Anticoagulants: warfarin. International normalized ratio (INR) monitoring recommended.
- Anticonvulsants: carbamazepine, oxcarbazepine phenobarbital, phenytoin, clonazepam, ethosuximide. Phenobarbital, phenytoin, carbamazepine, and oxcarbazepine: may lead to loss of virologic response and possible resistance to STRIBILD. Alternative anticonvulsants should be considered. Clonazepam and ethosuximide: clinical monitoring recommended.
- Antidepressants: Selective Serotonin Reuptake Inhibitors (SSRIs), Tricyclic Antidepressants (TCAs), trazodone. Dose titration of the antidepressant and monitoring for antidepressant response recommended.
- Antifungals: itraconazole, ketoconazole, voriconazole. Ketoconazole and itraconazole: the maximum daily dose should not exceed 200 mg/day. Voriconazole: an assessment of benefit/risk ratio is recommended to justify use.
- Anti-gout: colchicine. Do not coadminister in patients with renal or hepatic impairment. For other patients, modify the dose and/or regimen as described in the full PI for STRIBILD.
- Antimycobacterials: rifabutin, rifapentine. May lead to loss of virologic response and possible resistance to STRIBILD. Coadministration not recommended.
- Beta-Blockers: metoprolol, timolol. Clinical monitoring recommended and a dose decrease of the beta blocker may be necessary.
- Calcium Channel Blockers: amlodipine, diltiazem, felodipine, nicardipine, nifedipine, verapamil. Caution warranted and clinical monitoring recommended.
- Corticosteroids (Systemic): dexamethasone. May lead to loss of virologic response and possible resistance to STRIBILD.
- Corticosteroids (Inhaled/Nasal): fluticasone. Alternative corticosteroids should be considered, particularly for long term use.
- Endothelin Receptor Antagonists: bosentan. Discontinue bosentan at least 36 hours prior to initiating STRIBILD. For patients taking STRIBILD for at least 10 days, start or resume bosentan at 62.5 mg once daily or every other day based on individual tolerability.
- HMG CoA Reductase Inhibitors: atorvastatin. Initiate with the lowest starting dose and titrate carefully while monitoring for safety.
- Hormonal Contraceptives: norgestimate/ethinyl estradiol. Coadministration with STRIBILD resulted in decreased plasma concentrations of ethinyl estradiol and an increase in norgestimate. The effects of increased progesterone exposure are not fully known. The potential risks and benefits of coadministration should be considered, particularly in women who have risk factors for progesterone exposure. Alternative (non hormonal) methods of contraception can be considered.
- Immunosuppressants: cyclosporine, rapamycin, sirolimus, tacrolimus. Therapeutic monitoring recommended.
- Inhaled Beta Agonist: salmeterol. Coadministration not recommended due to the increased risk of salmeterol cardiovascular adverse events, including QT prolongation, palpitations, and sinus tachycardia.
- Neuroleptics: perphenazine, risperidone, thioridazine. Decrease in dose of the neuroleptic may be needed.
- Phosphodiesterase-5 (PDE5) Inhibitors: sildenafil, tadalafil, vardenafil. *Dosage for erectile dysfunction:* sildenafil, a single dose not exceeding 25 mg in 48 hours; vardenafil, a single dose not exceeding 2.5 mg in 72 hours; tadalafil, a single dose not exceeding 10 mg in 72 hours; increase monitoring for PDE-5 associated adverse events. *Dosage for pulmonary arterial hypertension (PAH):* tadalafil: stop tadalafil at least 24 hours prior to initiating STRIBILD; start or resume at 20 mg once daily in patients receiving STRIBILD for at least 1 week and increase to 40 mg once daily based on individual tolerability.
- Sedative/hypnotics: Benzodiazepines. Parenteral midazolam: coadministration should be done in a setting ensuring close clinical monitoring and appropriate medical management in case of respiratory depression and/or prolonged sedation; dose reduction should be considered, especially if more than a single dose is administered. Other sedative/hypnotics: dose reduction may be necessary and clinical monitoring recommended.

Consult the full PI prior to and during treatment with STRIBILD for potential drug interactions; this list is not all inclusive.

USE IN SPECIFIC POPULATIONS:
Pregnancy: STRIBILD is Pregnancy Category B; however, there are no adequate and well-controlled studies in pregnant women. STRIBILD 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 STRIBILD, 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 elvitegravir, cobicistat, and tenofovir are secreted in milk. Emtricitabine and tenofovir have been detected in human milk; it is not known if elvitegravir or cobicistat is secreted in human milk. Because of both the potential for HIV transmission and the potential for serious adverse reactions and/or drug resistance in nursing infants, **mothers should be instructed not to breastfeed if they are receiving STRIBILD.**

Pediatric Use: Safety and effectiveness in children less than 18 years of age have not been established.

Geriatric Use: Clinical studies of STRIBILD did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Renal Impairment: STRIBILD should not be initiated in patients with CrCl below 70 mL/min. STRIBILD should be discontinued if CrCl declines below 50 mL/min during treatment with STRIBILD. *[See Warnings and Precautions, Adverse Reactions].*

Hepatic Impairment: No dose adjustment is required in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. STRIBILD is not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C) as no pharmacokinetic or safety data are available in these patients *[See Dosage and Administration].*

OVERDOSAGE:
If overdose occurs the patient must be monitored for evidence of toxicity. Treatment consists of general supportive measures including monitoring of vital signs as well as observation of the clinical status of the patient.

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BY JAMES M. FRIEDMAN, MHA, EXECUTIVE DIRECTOR, AAHIVM

The New HIV Math

The Opportunities of Health Reform Plus the Ryan White Program

THE ACADEMY HAS long been an advocate for the widespread availability of high quality, comprehensive HIV care. That is really the reason we exist in the first place. To be sure, the increase in this kind of care over the past 30 years is one of the reasons we have seen such a reduction in the HIV/AIDS death rates in the U.S. The Ryan White Program has been a major part of this story. Now there is an expectation that the implementation of health reform will improve access to additional care options and further reduce the impact of HIV in the U.S. But how will the Ryan White Program and healthcare reform work together in the coming years?

In a presentation given this past November, Robert Greenwald, the director of the Center for Health Law and Policy Innovation at Harvard Law School, provided data that gives a factual basis for answering this question. Greenwald conducted a careful analysis of healthcare in the State of Massachusetts to provide insights of how state healthcare reform and a refocused Ryan White Program combined to meet National HIV/AIDS Strategy goals.

Let's examine what Massachusetts did:

- In 2001, the State expanded Medicaid to pre-disabled people living with HIV with an income level up to 200 percent of the Federal Poverty Level (FPL).
- In 2006, Massachusetts enacted private health insurance reform and a subsidized health insurance plan for those with incomes up to 300 percent of the FPL. This is what we now call "Romney Care".
- The state then modified the Ryan White Program by implementing the following changes:
  - –ADAP funding spent on insurance, not pharmaceuticals
  - –Waiver of the 75/25 rule to allow greater support for dental, vision, and behavioral care, as well as case management, transportation, food and nutrition services
  - –Maintained an unrestricted formulary and 500 percent of FPL.

Greenwald cited a substantial impact on a number of critical HIV health indicators:

- The percentage of Massachusetts HIV patients in medical care taking HIV medications and virally suppressed was more than twice the percentage in each category for the nation.
- Between 2006 and 2009, new HIV diagnoses rates fell in Massachusetts by 25 percent compared to a 2 percent national increase. As of 2012, the Massachusetts rate has fallen by 46 percent.
- Between 2002 and 2008, the Massachusetts AIDS mortality rates decreased by 44 percent compared to 33 percent nationally.
- The Massachusetts Department of Public Health estimates that reforms reduced HIV healthcare expenditures by approximately $1.5 billion in the past 10 years.

James M. Friedman

Some may argue that Massachusetts may be a special case. Certainly every state's healthcare reform program and demographics differ from one another and from Massachusetts. And as the article "Health Care Reform: California's Lessons Learned" in the June 2012 issue of *HIV Specialist* points out, California's implementation of its 1115 waiver program can be full of potholes.

In this issue, former ONAP head Jeff Crowley attempts to forecast what the future of the Ryan White Program might look like post-healthcare reform, and how the program might change or adapt to continue serving HIV patients in the long-term future.

In addition to these articles, I would like to suggest a few of my own thoughts about the program's future. First, we know that even after full implementation, healthcare reform will not provide health insurance for everyone. Further, there will be individuals for whom the new systems are not sufficient. The Ryan White Program will need to act as a safety net to provide medical services for these individuals.

Secondly, numerous HIV workforce studies, including the Academy's 2008 workforce study, show that there is a continuing and growing shortage of HIV experienced healthcare providers. The HRSA HIV Workforce study due out later this year will likely show the same. Hopefully, its findings will point the way for more Ryan White programmatic workforce efforts in this area.

While increased coverage by private insurance will lessen the financial burden of paying for HIV treatment for some patients, it does not represent a panacea. Private insurance and state programs will continue to search for cost-saving and cost-sharing mechanisms for high-priced medications that will affect patients. The need for the ADAP program to assist in paying for co-pays and deductibles or to fill in for insufficient formularies will likely be as important as ever to HIV patients.

Nearly two-thirds of all Americans infected with HIV are not retained in continuous care. The Special Projects of National Significance (Part F of the current Ryan White Program) should conduct pilot programs designed to substantially reduce this number.

The opportunities for the Ryan White Program to continue to serve as a vital resource are abundant. A careful implementation of healthcare reform, coupled with substantial flexibility in the Ryan White Program, could lead to real benefits to HIV patients. HIV

NIH Discontinues Immunizations in HIV Vaccine Study

THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) has announced it will stop administering injections in its HVTN 505 clinical trial of an investigational HIV vaccine regimen.

NIAID said an independent data and safety monitoring board (DSMB) found during an interim review that the vaccine regimen did not prevent HIV infection nor reduce viral load among vaccine recipients who became infected with HIV.

The HVTN 505 study began in 2009 and was testing an investigational prime-boost vaccine regimen developed by NIAID's Vaccine Research Center. The Phase IIb study, conducted by the NIAID-funded HIV Vaccine Trials Network (HVTN), was designed to determine whether the vaccine regimen could prevent HIV infection and/or reduce the amount of virus in the blood of vaccine recipients who became infected with HIV.

The investigational HIV vaccine regimen involved a series of three immunizations over the course of eight weeks, beginning with a DNA-based vaccine designed to prime the immune system. The DNA priming vaccine contained genetic material expressing antigens representing proteins from both the surface and internal structures of HIV.

Immunizations with the priming vaccine were followed by a single injection at week 24 with a recombinant vaccine (the booster vaccine) based on a weakened adenovirus type 5 (Ad 5). The adenovirus was used as a vector of genetic material expressing a matching set of HIV antigens. Structures from all three major HIV clades, or subtypes, were included. Adenoviruses are a common cold virus, but the Ad5 virus used in the study's vaccine regimen was disabled so it could not cause a cold or other respiratory illness. The two investigational vaccines tested in HVTN 505 cannot cause HIV infection because neither contains live or weakened versions of HIV.

The HVTN 505 study enrolled 2,504 volunteers at 21 sites in 19 U.S. cities. Included were men who have sex with men and transgender people who have sex with men.

In its April 22 interim review, the DSMB examined the information gathered from 1,250 volunteers who received the investigational vaccine regimen and 1,244 volunteers who received the placebo vaccine.

The primary analysis looked at volunteers who were diagnosed with HIV infection after having been in the study a minimum of 28 weeks. This was done to enable enough time for the vaccine regimen to be given and stimulate an immune response.

In this analysis, 27 HIV infections occurred among the vaccine recipients, and 21 HIV infections occurred among the placebo vaccine recipients. Among volunteers who became HIV-infected during the first 28 weeks of the study, 14 cases of HIV infection occurred among those who received the investigational vaccine regimen, and nine HIV infections occurred among the placebo vaccine recipients.

Overall in the study from the day of enrollment through the month 24 study visit, a total of 41 cases of HIV infection occurred in the volunteers who received the investigational vaccine regimen and 30 cases of HIV infection occurred among the placebo vaccine recipients.

The DSMB also found that the vaccine failed to reduce viral load among volunteers who acquired HIV infection at least 28 weeks after entering the study and who had been followed for at least 20 weeks after diagnosis. There were 30 participants with measurable viral load (15 vaccine recipients; 15 placebo recipients).

Based on these findings, the DSMB recommended that no further vaccinations with the investigational vaccine regimen be administered. As the trial's sponsor, NIAID concurred with the DSMB's recommendation and said it has instructed all HVTN 505 study sites to immediately cease administering injections but continue follow-up with study participants to further evaluate the trial data.

"It should be noted that there was a non-statistically significant increase in HIV acquisition among volunteers in the investigational vaccine group compared to those in the placebo group," a statement from NIAID said. "It is not clear why this occurred and further analysis is needed to draw any firm conclusions."

Based on the finding, the DSMB recommended closer follow-up of participants beyond their month 24 study visit. NIAID said it concurred, and will, in concert with the study investigators, amend the study protocol to allow for closer, extended follow up of the vaccine recipients.

As with all NIAID-sponsored HIV prevention trials, the HVTN 505 participants were offered extensive counseling on how to reduce their risk of becoming HIV-infected and provided free condoms.

As an added precaution, study participants were required at time of enrollment to be circumcised and free of antibodies to Ad5. These precautions were taken in light of an HIV vaccine clinical trial, known as the Step Study, which found in 2007 an increased number of HIV infections among vaccine recipients, particularly those who were not circumcised and/or had Ad5 antibodies.

"NIAID and the HVTN 505 study team are working to thoroughly analyze the study data to better understand why the vaccine did not work and to guide future vaccine development efforts. Detailed scientific findings will be made publicly available as soon as possible," the NIAID statement said.

Study investigators at each of the 21 clinical trial sites have been informed of the decision to stop immunizations in the HVTN 505 study and are contacting study volunteers to inform them of the developments. The study investigators will continue following all study participants for five years from the time of enrollment.

NIAID said it "remains committed to the pursuit of a highly effective, preventive HIV vaccine as part of a multifaceted HIV prevention research program." HIV

SHUTTERSTOCK

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IN THE NEWS

Study

Peer Referral Programs Can Boost HIV-Testing In Hospital EDs

Including a peer-referral program for HIV testing in hospital emergency departments can reach new groups of high-risk patients and bring more patients in for testing, according to researchers at the University of Cincinnati (UC).

Co-author and assistant professor of emergency medicine Michael Lyons, MD, said public health officials study multiple approaches to increasing early diagnosis of HIV -- including expanding testing in health care centers, particularly emergency departments (EDs) that treat disadvantaged, at-risk populations.

"There's another high-yield way to identify people, which is to take those who are at risk of infection or who are HIV-positive and have them refer their social contacts or partners for testing," he said. "This 'social network testing' is typically used in public health departments to efficiently identify high-risk populations by targeting the social network of those high-risk or HIV-positive individuals."

In their prospective observational study, Lyons and fellow researchers implemented a social network and partner testing program from May to September 2011 in an urban academic health center ED. They recruited high-risk or HIV-positive individuals to participate in a paid coupon program, in which individuals receive coupons for HIV testing to give to their friends or partners. If an individual recruited a friend to come to the ED for HIV testing, that friend could also participate in the coupon program.

During the process, researchers reviewed hospital records to determine whether people tested by the peer-referral program also had study-site ED visits or HIV tests within the previous five years.

At the end of the study, the program had diagnosed four new cases of HIV. Of the participating individuals, 34 percent had no prior visits to the ED and 69 percent had never been tested by the ED HIV testing program.

According to Lyons, the results show that social network programs can be implemented in health care settings, providing valuable access into high-risk, uninsured populations with minimal difficulty.

"We were able to use an existing ED-based program to reach out into the community beyond what the ED would otherwise able to do. This suggests the two HIV-testing approaches may be complementary rather than fully redundant, illustrating the ways in which health centers can feed social network and partner testing programs," he said.

The team presented their abstract, "*Can a Social Network HIV Testing Program Expand HIV Testing Beyond the Usual Emergency Department Population?*" at the Society for Academic Emergency Medicine annual meeting in Atlanta.

CO-AUTHORS WERE: **Robbie Paulsen**, **Andrew Ruffner**, **Christopher Lindsell**, **Kimberly Hart**, **Christopher Barczak**, **Alexander T. Trott, Carl J. Fichtenbaum** and **Michael Lyons**. The project was supported by the National Institute of Allergy and Infectious Diseases at the National Institutes of Health.

New Tool Can Identify HIV Antibodies, Could Speed HIV Vaccine Research

Medical News Today **reported May 13 that a team of NIH scientists has developed a new tool to identify broadly neutralizing antibodies (bNAbs) capable of preventing infection by the majority of HIV strains found around the globe, an advance that could help speed HIV vaccine research.**

Scientists have long studied HIV-infected individuals whose blood shows powerful neutralization activity because understanding how HIV bNAbs develop and attack the virus can yield clues for HIV vaccine design. But until now, available methods for analyzing blood samples did not easily yield specific information about the HIV bNAbs present or the parts of the virus they targeted.

In addition, the report noted, determining where and how HIV bNAbs bind to the virus has been a laborious process involving several complicated techniques and relatively large quantities of blood from individual donors.

The new tool lets scientists determine precisely the HIV bNAbs present in a particular blood sample by analyzing the neutralized HIV strains there. Called "neutralization fingerprinting," the tool is a mathematical algorithm that exploits the large body of data on HIV bNAbs generated in recent years. The neutralization fingerprint of an HIV antibody is a measurement of which virus strains it can block and with what intensity. Antibodies that target the same portion of the virus tend to have similar fingerprints.

Since blood samples contain mixtures of antibodies, the new algorithm calculates the specific types of HIV bNAbs present and the proportion of each by comparing the blood's neutralization data with the fingerprints of known HIV bNAbs.

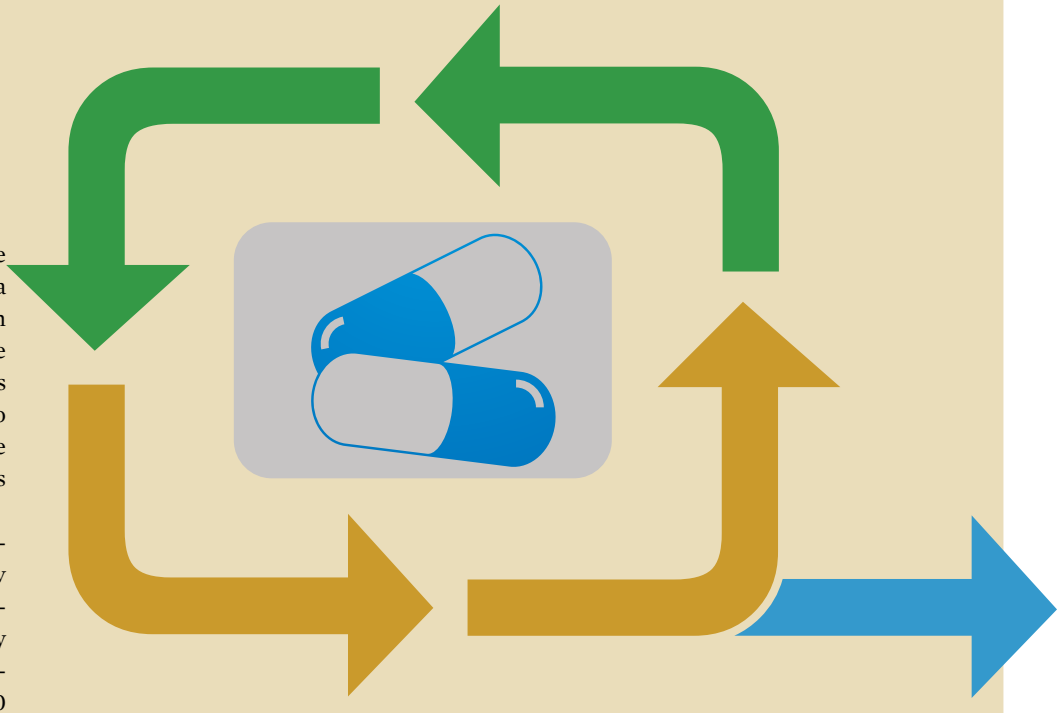
"This approach is particularly useful when other methods of determining bNAbs targets in a blood sample are not feasible, such as when just a small amount of blood is available," the report said. "Neutralization fingerprinting also is significantly faster than older analytic methods."

According to the researchers who developed the assay, the underlying approach could be applied to the study of human responses to other pathogens, such as influenza and hepatitis C viruses, for which scientists have much information about neutralizing antibodies.

Research

HIV Patients Can Omit NRTIs When Switching to New Regimen

Editor's Note: The following is a condensed version of an article by Liz Highleyman originally published by HIVandHepatitis.com *and is published with the author's permission.*



Omitting nucleoside reverse transcriptase inhibitors (NRTIs) when changing from a non-suppressive regimen to a new regimen with at least two active agents can reduce the number of pills required as well as side effects without decreasing effectiveness, according to a study reported in March at the Conference on Retroviruses and Opportunistic Infections (CROI 2013) in Atlanta.

The study findings were reported by Karen Tashima of Brown University and fellow investigators who enrolled 360 study participants between February 2008 and May 2011 who were on a failing protease inhibitor regimen with viral load of at least 1,000 copies/mL and had experience using, or showed evidence of resistance to, NRTIs and non-nucleoside reverse transcriptase inhibitors (NNRTIs).

Three-quarters of participants were men, about 40 percent were black, and one-quarter were Hispanic. The median age was 46 years and they had been on antiretroviral therapy for 12 years on average. Entering the study, they had a low median CD4 T-cell count of approximately 200 cells/mm3 and viral load of 4.2 log. Half had exclusively CCR5-tropic virus, making then eligible to use maraviroc (Selzentry).

Investigators helped participants create new regimens, guided by resistance and tropism testing, selecting from 20 potential three or four drug combinations including ritonavir-boosted darunavir (Prezista), enfuvirtide (Fuzeon), etravirine (Intelence), maraviroc, raltegravir (Isentress) or boosted tipranavir (Aptivus).

Fifty-six percent of participants selected a regimen that consisted of raltegravir, boosted darunavir, and etravirine, which combined an integrase inhibitor, a modern protease inhibitor, and a second-generation NNRTI. Patients and their clinicians then selected NRTIs -- with tenofovir plus emtricitabine (the drugs in Truvada) or lamivudine (Epivir) selected by at 82 percent.

After one year, results showed that omitting NRTIs was not inferior to adding NRTIs to an otherwise optimized regimen. Overall regimen failure occurred in 30 percent of those who omitted NRTIs and 26 percent of those who added them. Virological failure occurred in 25 percent of the participants in both groups. Meanwhile, similar proportions in both groups achieved undetectable plasma viral load (<50 copies/mL), while CD4 cell gains were also statistically similar.

With respect to tolerability, 11 people who omitted NRTIs withdrew from the study prematurely, as did five who added them. The researchers said there was "no statistically significant difference in primary safety when considering both symptoms and labs."

However, six NRTI users in the study group died during follow-up, compared with none who did not use NRTIs -- a significant difference. Causes of death included heart, kidney, and liver failure, bacterial meningitis, sepsis, and progressive multifocal leukoencephalopathy. Investigators could not rule out that study drugs may have been a contributing factor in some of those cases.

"In this population, NRTIs can be safely omitted without compromising regimen failure," the researchers concluded. "Potential benefits of omitting NRTIs include reduced pill burden and cost."

Andrew Zolopa, professor of medicine and infectious diseases at Stanford University called the study "a game changer."

"You don't need to include NRTIs when new active agents are onboard," Tashima said during a press conference. "We don't need to hang onto this old class. We've become quite comfortable with them, but they add to pill burden and toxicity." HIV

Reference: K Tashima, L Smeaton, A Andrade, et al. Omitting NRTI from ARV Regimens Is Not Inferior to Adding NRTI in Treatment-experienced HIV+ Subjects Failing a Protease Inhibitor Regimen: The ACTG OPTIONS Study. 20th Conference on Retroviruses and Opportunistic Infections. Atlanta, March 3-6, 2013. Abstract 153LB.

SHUTTERSTOCK

IN THE NEWS

Research

HIV/HCV Coinfected at Risk for Liver Decompensation

A research report presented at the EASL International Liver Congress (EASL2013) in Amsterdam cautions that HIV positive people coinfected with hepatitis C may experience liver decompensation with advanced fibrosis before progressing to cirrhosis and may benefit from earlier antiviral treatment.

While many patients and providers are awaiting all-oral DAA regimens without interferon, many patients suffering from advanced liver disease cannot wait for treatment. Since the disease progresses more rapidly in HIV/HCV coinfected than those with HCV alone, they may be candidates for earlier therapy, the researchers said.

Juan Macias from Hospital Universitario de Valme in Seville and colleagues assessed the risk of hepatic decompensation among HIV positive people with chronic hepatitis C coinfection who had advanced fibrosis or cirrhosis.

The researchers presented findings from two retrospective cohorts of coinfected patients, one with liver disease stage determined by traditional biopsies, the other estimated using liver stiffness measurements

FDA OKs Use of SUSTIVA® in HIV-1 Infected Pediatric Patients

Bristol-Myers Squibb Company has announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) for SUSTIVA® (efavirenz), including dosing recommendations for HIV-1 infected pediatric patients three months to three years old and weighing at least 3.5 kg.

This approval offers a once-daily option as part of a regimen for this population and includes a "capsule sprinkle" administration method for patients who cannot swallow capsules or tablets, the company said.

SUSTIVA is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that was originally approved in the U.S. in 1998 to treat HIV-1 infected children three years of age or older and weighing at least 10 kg. SUSTIVA is not to be taken by patients who are allergic to efavirenz, or to any of its ingredients.

Bristol-Myers Squibb said it continues to pursue the development of treatment options for children and adults with HIV. Studies are ongoing for new treatments, including an NRTI (BMS-986001), an attachment inhibitor (BMS-663068) and a maturation inhibitor, the company said, adding that it is also developing a fixed-dose combination of atazanavir sulfate and Gilead's investigational drug cobicistat.

UN Report: 7.1 Million People Now Receive HIV Treatment in Africa

THE NUMBER OF PEOPLE IN AFRICA receiving antiretroviral treatment increased from less than 1 million to 7.1 million over seven years, according to a United Nations report released in May.

The report said nearly 1 million were added in the last year alone, as AIDS-related deaths declined by 32 percent from 2005 to 2011.

The UNAIDS *Update* on Africa attributes the success to strong leadership and shared responsibility in Africa and among the global community. It urges sustained commitment to ensure Africa eliminates new HIV infections and AIDS-related deaths.

According to the report, 16 African countries now ensure that more than three-quarters of pregnant women living with HIV receive antiretroviral medicine to prevent transmission to their child.

Nevertheless, Africa accounts for 69 percent of people living with HIV globally. In 2011, there were still 1.8 million new HIV infections across the continent, and 1.2 million people died of AIDS-related illnesses. **HIV**

THINKSTOCK

Mobile App for Teens, Telemedicine for Prisons

BY BOB GATTY

Recognized as the 2013 Technology Award Winners

An HIV telemedicine clinic providing care to over 500 inmates and a mobile application geared towards raising adherence for adolescents with HIV have won the second annual AAHIVM/Institute for Technology in Health Care HIV Practice Award.

Dr. Melissa Badowski of the University of Illinois Medical Center and Dr. Nadia Dowshen of the Children's Hospital of Philadelphia and the University of Pennsylvania School of Medicine are the winners of the two $10,000 awards recognizing innovative use of technology in the HIV care setting.

"We had an excellent pool of candidates this year," said Richard Prokesch, MD, AAHIVS, who chaired the selection panel that considered the applications. "These two winners epitomize the unique approach to care for specific populations through cutting-edge technology."

This is the second year AAHIVM has teamed with the Institute for Technology in Health Care on the awards, which were created to help foster best practices in technological developments for the benefit of HIV care providers and patients alike.

Providing Care in the Correctional Setting: Dr. Melissa Badowski

Dr. Badowski and her team at the University of Illinois Medical Center (UIMC), using an HIV telemedicine clinic, provide direct patient care to some 500 inmates in 28 correctional facilities in Illinois. Utilizing a secure connection with audio and video technologies, inmate patients receive care from an interdisciplinary team that includes an infectious diseases physician, HIV pharmacist, and HIV case manager.

Dr. Melissa Badowski

UIMC implemented the HIV telemedicine clinic to provide specialized, multidisciplinary HIV services to those incarcerated in each facility within the Illinois Department of Corrections (IDOC). Patients are now able to receive specialty care within their individual corrections facility.

"Basically, we have a virtual visit," explained Dr. Jeremy Young, medical director of telehealth at UIMC. "We're here in Chicago, but are able to communicate face to face with inmates all over the state. Each of the prison infirmaries has a telemedicine suite and we are able to have a live encrypted video chat. We can see and hear the patient and they can see and hear us, and we can perform focused medical exams."

The HIV positive prisoner has access to a physician who conducts a physical exam facilitated by a nurse at the facility. An electronic exam camera and stethoscope provide live images and heart/

lung sounds in real time. The HIV clinical pharmacist provides medication education and adherence counseling.

Together, the clinical pharmacist, patient and physician construct an optimal ART regimen tailored to the individual, taking into account, lifestyle, side effects, medical and treatment history, and drug-drug interactions. The case manager provides information and appointments for follow-up to ensure continuity of HIV care once patients are discharged from corrections.

"The ability to provide virtual care is important because there are 28 prison facilities in the state of Illinois and most of them, by design, are in rural areas. Typically, inmates have a lack of access to HIV specialty care in these rural settings because specialists tend to congregate in cities," Dr. Young explained.

Dr. Badowski pointed out that the technology for HIV care need not be limited to the prison setting, but may be useful in rural settings where the nearest medical center may be hundreds of miles away.

Not only does the system provide for improved care for far more patients than would otherwise be the case, it does so much more efficiently. Dr. Badowski noted that this model saves staff travel time, allows for standardized services at all facilities, eliminates the need to transport prisoners, reduces security costs – all while providing care within the HIV setting, improving immunologic status and achieving virologic suppression.

Dr. Badowski said her team intends to use the award funds to provide education for nurses at each facility. "We hope to increase their knowledge of HIV," she said, adding that while their knowledge has dramatically increased since the program was launched, there are areas where improvement is needed. She also intends to use the funds to travel to conferences to present findings and explain the technology that is involved.

Telemedicine, she explained, is an efficient way to cover the miles between facilities and provide a multi-disciplinary approach. "It can be modeled into cardiology, nephrology – it's not only limited to HIV."

That multidisciplinary approach is what sets the UIMC program apart from others, Dr. Badowski said. "We have a clinical pharmacist, a physician and a case manager all working together to improve outcomes in the correctional facility, and once patients are released, we can provide a continuity of care for them at one of our seven university clinics."

The program was launched more than two and a half years ago, and Dr. Badowski said benefits clearly are being achieved.

"We are able to see a lot of patients become virologically suppressed, where their viral load is undetectable. We've been able to identify and manage side effects. We're also educating the prisoners about managing their HIV, and how they can prevent transmission."

Dr. Nadia Dowshen

Adherence at Your Fingertips: Dr. Nadia Dowshen

"New technology has changed the way we provide care for our patients living with HIV in a major way," said Dr. Dowshen, who with her team developed a prototype of a smart phone-based application to improve adherence among youth living with HIV/AIDS. "Technology has changed the way that we care for our patients by allowing us to access information more quickly, by allowing us to communicate in ways that we couldn't before, and by allowing us to be connected with each other."

Dr. Dowshen believes that some of the most compelling and innovative technologies for HIV care are

related to mobile technology, which allows providers to connect effectively with patients. This belief was the motivation for the development of her award-winning mobile application, geared to an audience accustomed to relying on this type of technology as their main source of information, entertainment and social connection.

"When taking care of young people living with HIV, one of the things that has always struck me is how, often times, when I'm trying to get through to them, they are busy on their phones texting or talking or Facebooking. I concluded that teens are the ones teens are the ones who adopt these technologies first, and they're using them all the time, so we should use it to help them improve their health."

The "app" includes time-based personalized text message reminders that are responsive to previous behavior and prompt patient-provider interaction when poor adherence is identified.

The "app" includes time-based personalized text message reminders that are responsive to previous behavior and prompt patient-provider interaction when poor adherence is identified. The interactive app also includes visual depiction of adherence rates and outcomes, and features gaming incentives for reinforcement of positive behaviors.

Besides receiving the standard reminder message for medications, they have different options for recording how they took their medication, when they took it, or if they are not ready to take it because something else is happening and there is a privacy issue. "Then they can press a snooze button and be reminded later, or they can simply say 'I didn't take it.' Depending on which one of those options they choose, they will receive feedback – positive and encouraging feedback."

Dr. Downshen said the gaming feature is designed to encourage compliance with medications. When the young person logs in, they will see that they have, for example, taken their medication for five days in a row, which will generate points that may result in their ability to obtain prizes for their avatar that they select on the application's home screen. "We are really trying to build this in ways that will keep the youth engaged and give them feedback on a regular basis, as opposed to just when they come in for their clinic appointments," she said.

In fact, if the patient fails to respond for a specific period of time, they will receive a prompt – as will the provider – asking if there is a problem and if they need to talk. "That will allow people to get help in the time when they really need it instead of waiting until the next clinic appointment," Dr. Downshen said.

Dr. Dowshen's next steps for the app include optimizing the user experience on the front end for behavior change and the back end for data collection, which will include obtaining key feedback from youth who make up the target population on the design/esthetics, privacy concerns, and features they would like to see added or removed.

"We believe that this application has the potential to improve individual health outcomes related to adherence for youth living with HIV," said Dr. Dowshen. "If successful, the app will also have important implications for preventing secondary transmission by bolstering the current strategy of 'treatment as prevention,' ensuring that those individuals who are in care are on ART and virally suppressed." HIV

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The Ryan White Program at a Crossroads

How does it fit into the Affordable Care Act?

BY HOLLY KILNESS PACKETT, MA

The Ryan White Program is reaching a crossroads in its history. Ryan White providers are feeling the urgency of a fast-approaching deadline that has been four years in the making. Most, if they are honest, will admit to feeling unprepared.

The word of the day seems to be "soon." Changes are coming soon. Determinations will be settled soon. Details will be made public soon. Policies will be put into place soon. Requirements will be enacted, soon. Worst of all is the assurance that providers will see huge changes soon—and they need to be prepared to meet them even sooner.

It all seems a bit surreal considering that the last three years since the Patient Protection and Affordable Care Act (ACA) was signed into law have passed with what seemed like very little change. The ACA was passed in 2010 and a deluge of information followed in the months after, foretelling the drastic changes that would come out of the law. Though some of the law's provisions went into effect immediately, most were set for a date that seemed far into the future.

For those in the policy-making and advocacy field, the last three years have been remarkably busy. Dozens of proposed regulations were issued, panels were established to consider important implementation topics, congressional battles to overturn or defend the law were waged, and a legal challenge was issued—the eventual ruling of which caused a massive reassessment of one of the law's most significant provisions. Throughout this time, HIV advocacy organizations and stakeholders worked to ensure that HIV-related issues were considered and the needs of the HIV constituency met.

However, for medical providers in the field treating patients day-in and day-out, the last three years have been remarkably quiet – many would say ominously so. They have been waiting for a foretold tidal wave of change. They have been told repeatedly that they would need to prepare, but no one could give specifics on how to do so.

Now we are entering the final six months before the ACA wave hits (or rather, before the policies are implemented and take effect). The implementation date for the two biggest changes—the creation of individual and small group insurance exchanges (or marketplaces) in every state, and the expansion of Medicaid in the states that have chosen to opt in—is January 1, 2014, just six months from now. However, the processes that will bring them to fruition are already in full motion. Many aspects of the changes are beginning this summer, and many more will get underway this fall, either in trial version, or in full start mode.

Providers Taking Stock

In light of the changes that are coming "soon," stakeholders in the Ryan White Program, and its Part C providers, are taking stock. The program's future, as well as the future of the providers who participate in it and the patients who depend on it, are inextricably linked. All will be affected in the coming years.

There is reason to believe the ultimate effect will be positive, but the issues facing participants and stakeholders in the program are vast.

There is the matter of educating Ryan White providers on how to connect to the new systems. If Ryan White pro-

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viders are not successfully integrated into the new systems, they will lose access to many of their current patients who are transitioning into new care settings.

There is also the question of what will happen to Ryan White patients. Upwards of 30 million uninsured patients in the U.S. will become eligible for new forms of coverage. But how will they learn about their options, and become enrolled in these new systems?

There is also the issue of both the short-term and long-term future of the Ryan White program as a whole. In the short term, the program was created by a law that is due to be re-authorized in September of this year. Yet with so many uncertainties about the health care system over the coming years, it is difficult to predict how the Ryan White Program will fit into it. However, Congressional and Administration support for continuance of the program is strong.

Making the Case

All of these questions lead to the final and perhaps ultimate question of the Ryan White Program: why should it exist? Why should there be a government program and dedicated funding stream for this one disease? No other disease or condition has its own program within the federal government focused on the prevention of that disease, and the care and treatment of those affected with it; not cancer, not obesity, not Alzheimer's.

Perhaps the answer is this – HIV is unlike any other disease. It is a communicable virus, and also a long-term progressing disease, that can be controlled into the state of a chronic condition. It is a permanent infection, and also a treatable one. It is a disease that revolves around social behavior, and has roots in human sexuality and identity, and impacts entire communities of people. It is completely preventable, but one of the most prolific epidemics in the world today. It is costly to treat, and even more costly not to, but treatment efforts also yield prevention efforts against the disease's spread. It impacts public health, health care systems, and the economy.

If we can design a healthcare system that works for HIV, that system will work for any disease or condition. If the healthcare system is adequate for the coverage, care and treatment needs of those infected with HIV, it will also work for the patients of any disease. If the health prevention efforts are adequate to address those at risk for HIV, they will also present a multitude of opportunities to prevent or stymie many other negative health conditions. Ultimately, good HIV medicine is just good medicine. The Ryan White program has made significant strides in responding to the largest epidemic of the last 30 years. It has provided a model for other parts of the health care system to emulate. How the program moves forward over the next ten years will speak volumes about whether healthcare reform is truly able to incorporate and build upon the successes already achieved. HIV

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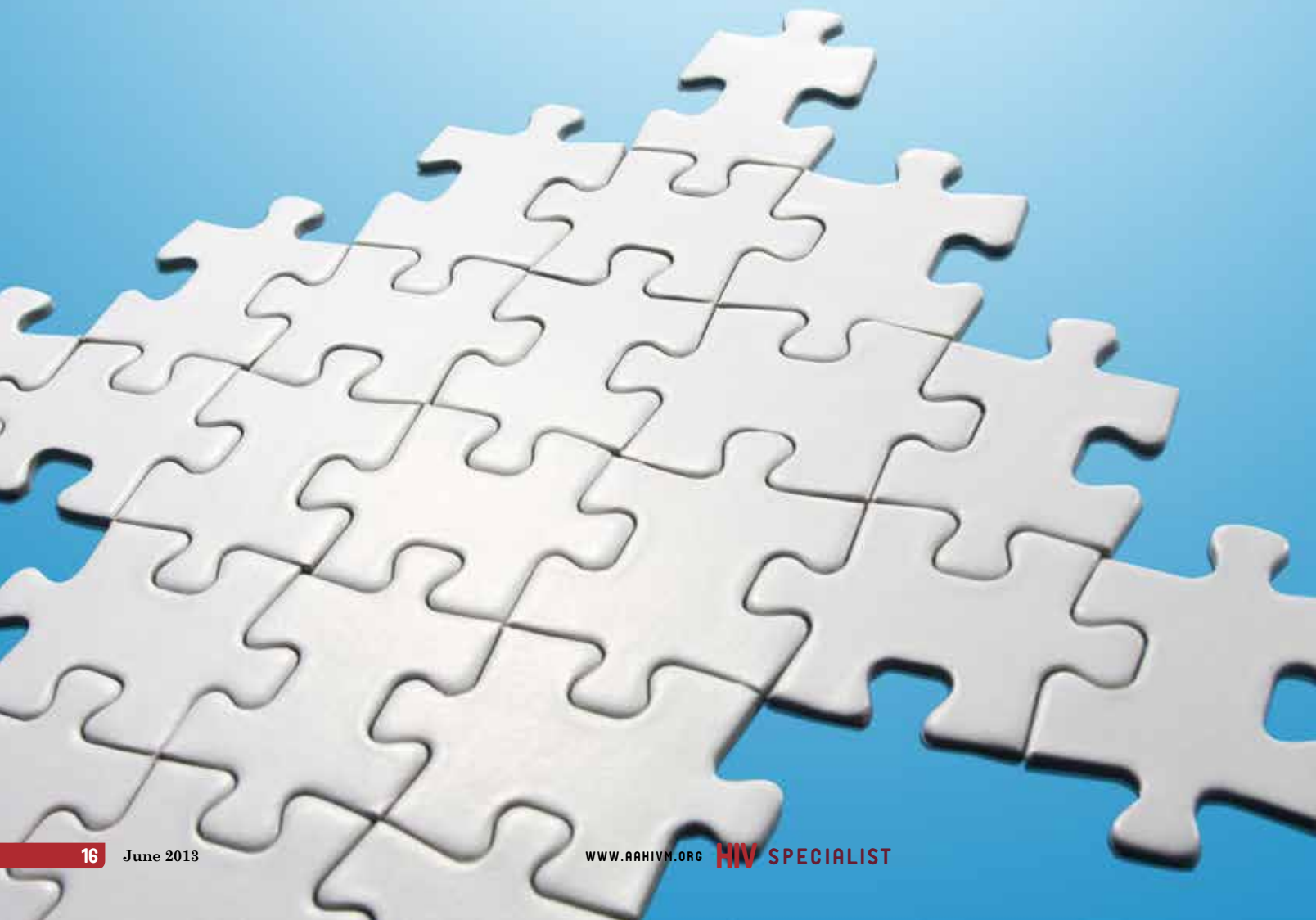
The Future Direction of the Ryan White HIV/AIDS Program

A critical time for the Part C network to lead the way



BY JEFFREY S. CROWLEY

As the nation prepares for the pending expansion in access to health insurance coverage next year resulting from the Patient Protection and Affordable Care Act (ACA), many within the HIV community have begun to worry about the future role of the Ryan White HIV/AIDS Program and others have questioned whether it will still be needed.

The Ryan White program, however, will continue to be a central part of the care response to the domestic HIV epidemic, but it will need to change. Navigating these changes—for people with HIV and the medical and support providers that serve them—demands an all-hands-on-deck approach.

Part C medical clinics and HIV medical providers have a significant opportunity to make the case for continued support for the Ryan White Program and provide leadership in charting a new course to ensure that the program is optimally targeted at improving outcomes and constructively supporting the most seamless integration with the broader health care system.

From its beginnings, the Ryan White Program has come a long way. First enacted in 1990 just a few months after the death of its namesake, the program has transformed from an emergency response into a cornerstone of the HIV care system in the United States, providing services to more than 500,000 people living with and affected by HIV.

Funded at $2.4 billion in FY 2012, the program is the third largest source of federal financing for HIV after Medicaid and Medicare. A component of Ryan White, the Part C program provides support to roughly 367 grantees, including approximately 270 medical clinics that support outpatient HIV early intervention services and ambulatory care.

While Medicaid and Medicare provide comprehensive HIV care to tens of thousands of people with HIV/AIDS, the Ryan White Program is not simply an added source of financing. Rather, it plays a distinct role in complimenting private insurance, Medicaid, and Medicare to enable our health system to work for people with HIV.

It does this by supplementing insurance coverage for the roughly 70 percent of Ryan White clients who have insurance, yet who turn to Ryan White for assistance with case management, support services, and help with cost-sharing—all of which are critical to supporting continued engagement in care.

In addition, Ryan White serves as the primary source of medical care and support services for uninsured people with HIV, including some immigrant populations who will remain ineligible for insurance coverage under the ACA.

Moreover, a core function of the Ryan White Program is to invest in community infrastructure, through Part C and other aspects of the program, to ensure that support service and health care capacity exists to meet the needs of people with HIV throughout the United States, including within underserved geographic areas and among marginalized populations that bear a heavy burden of HIV. These investments must continue if people with HIV in all parts of the country are to have a place to take their newly minted insurance cards in order to receive high quality HIV care and to keep providing critical care and services to those who remain uninsured.

These investments must continue if people with HIV in all parts of the country are to have a place to take their newly minted insurance cards in order to receive high quality HIV care...

Responding to Change

In the 20-plus year history of the Ryan White Program, HIV care has changed, as have the demographics and the distribution of the epidemic across the country. In turn, the program has also changed.

At the end of September, the program's current authorization expires, which is adding to questions about the program's future. The Obama Administration has continually expressed strong support for the Ryan White Program. Indeed, in speaking about the role of the program in relation to the ACA, the National HIV/AIDS Strategy says, "the implementation of health insurance reform presents the Nation with an opportunity to re-think what will be needed from the Ryan White HIV/AIDS Program in order to bring people with HIV into care and retain them in care once more people have insurance coverage," and explicitly states that Ryan White will continue to be necessary after the ACA is implemented.

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It is important to be clear that the program can continue once the authorization has expired.

Further, the congressional justification for the President's FY 2014 budget, issued in April 2013, states, "the FY 2014 request reflects our continued support of the Ryan White program while assessing the preliminary impact of and adapting to the changes that the Affordable Care Act [will bring]...It is anticipated, however, that, on average, coverage will not be adequate for the care and treatment of people living with HIV/AIDS (PLWH) due to plan limitations on the scope of coverage...Other Ryan White services that may not be covered include oral health care, medical case management, treatment adherence counseling, psychosocial support services, outreach and a host of other support services that in many cases are critical to identifying, linking and maintaining people living with HIV and AIDS in care."

For the short-term, it is important to be clear that the program can continue once the authorization has expired. In fact, many federal programs currently operate with lapsed authorizations. Given the current challenges associated with enacting any significant legislation in Washington, uncertainty created by the unresolved fiscal showdown, and lack of clarity as to how to update the Ryan White program in advance of the ACA's implementation, there appears to be a broad consensus among HIV stakeholders and congressional supporters to seek continued support for the program through the appropriations process, and defer major legislative updates until after we have transitioned people with HIV to new ACA coverage and can apply lessons from this experience.

Recently, the Kaiser Family Foundation released *"Updating the Ryan White HIV/AIDS Program for a New Era: Key Issues and Questions for the Future,"* a paper that I co-authored with Jennifer Kates, vice president and director of global health and HIV policy at the Kaiser Family Foundation.

This paper seeks to frame the changing context faced by the program in light of scientific advances, implementation of the ACA, and efforts to achieve the goals of the National HIV/AIDS Strategy. It discusses a range of issues and potential program improvements organized around four intersecting areas: 1) supporting people with HIV at each stage of the treatment cascade, from diagnosis to viral suppression, 2) building HIV care networks in underserved communities, 3) integrating HIV care expertise into the mainstream health care system, and 4) effectively and fairly allocating Ryan White resources. The paper can be accessed at http://kff.org/hivaids/.

Meeting a Growing Need

Whereas the largest funding lines within Ryan White are grants to heavily impacted metropolitan areas through Part A, and states and territories through Part B (including the AIDS Drug Assistance program, ADAP, which is the single largest component of Ryan White), direct funding for medical clinics through Parts C and D is an essential aspect of the Ryan White program.

Over time, the number of clients receiving services from Part C institutions has grown significantly faster than program funding – indicating that we may be reaching the limits of capacity at these clinics at a moment when only one in three people with HIV in the U.S. is retained in care and only one in four is virally supressed. Clearly, these facts place greater emphasis on the need to increase engagement in care.

At moments like these, we can respond to challenges and change by expressing pessimism, or we can see opportunities. I believe we are poised to make very real and sustained progress at working toward the goals of the National HIV/AIDS Strategy, in part, by effectively implementing the ACA.

Nonetheless, future progress likely turns on retaining a vibrant HIV care system supported by Ryan White that works alongside the ACA and other sources of public and private insurance coverage. HIV medical providers and the Part C network have an important opportunity to demonstrate leadership over the coming years. I believe a focus is needed in three areas: collaboration, accountability, and innovation.

Improving Collaboration

A common and easy critique of the U.S. health care system is that there are too many silos, and they do exist within Ryan White.

At moments like these, we can respond to challenges and change by expressing pessimism, or we can see opportunities. I believe we are poised to make very real and sustained progress at working toward the goals of the National HIV/AIDS Strategy, in part, by effectively implementing the ACA.

One important opportunity for improving HIV care is to form new partnerships between medical and support providers to better support their clients. Too frequently, support providers believe their role is devalued and that medical providers do little more than give lip service to the benefits of social supports.

Conversely, medical providers often feel that support services are not adequately coordinated with medical care, and, therefore, are not contributing effectively to achieving the improved health outcomes that we are all seeking. Or, medical providers may feel that they are doing their best to serve a community, but they are surrounded by community critics that limit the capacity for honest dialogue.

Can't we have a new conversation about how HIV medical providers are meeting with their partners who provide support services to provide mutual support instead of talking past each other?

In many cases, there are real inequities between partners. Part C clinics may feel stretched to the limit, but they actually may be the most well resourced entity within the community.

What is needed to support Part C providers to engage in a community dialogue without dominating the conversation? Now is a unique moment to have honest dialogues that can lead to more efficiency in how care is delivered, better monitoring of patient outcomes, and more targeted efforts to reach people not being engaged in care in order to narrow health disparities and improve HIV viral suppression.

Increasing Accountability

A constant focus of health care programs must always be to find more effective ways to provide better care. Another goal is to ensure that as many people as possible get the maximum benefit from the investments we make in health care services.

Ryan White has benefited from its flexible nature as it has allowed a lot of experimentation and it has enabled the program to fill a variety of diverse needs. When we consider the treatment cascade, the program already funds a variety of services to keep people engaged in care and support people at each step of the care continuum.

Does the program, however, hold anyone accountable when two-thirds of people with HIV are not in care and three in four people are not virally suppressed? How do we ensure that every person with HIV in this country receives care of the same quality as we have seen in some of our finest institutions?

As we think about how Ryan White should be updated, HIV medical providers must fully engage in a conversation about building in pay-for-performance or other mechanisms to ensure that we reward quality care and limit funding for low-quality care.

Fostering Innovation

Despite any policy decisions that are made in Washington or state capitals, the HIV epidemic will continue to evolve.

A benefit of the Ryan White Program in the past has been that it has served as a source of innovation in HIV care delivery. The Special Projects of National Significance (SPNS) program, and other programs within Ryan White have supported some remarkable efforts that have moved the field of HIV care forward.

At present, however, a challenge is to accelerate this level of innovation and become more systematic at evaluating models of care that are both more efficient and produce better results. The collective wisdom of the Part C network and its HIV medical providers has a lot to contribute to this conversation.

When I travel across the country meeting with various HIV community stakeholders, I often hear about their fears for the future. Medical clinics and community-based organizations are closing. Funding is tight. Policy makers and others seem to want to move on from supporting HIV/AIDS. These issues are valid and real.

But, I sometimes ask people when exactly was this golden time in our past when we had adequate resources for responding to the epidemic, when broader communities were fully supportive, and when our jobs were easy? We may be a ways away from ending the HIV epidemic in the United States, but this is clearly a seminal moment in our history.

Ensuring that the Ryan White program remains a vital and strong cornerstone of the HIV care system seems a worthy community priority, as it is likely to remain central to our future success at caring for all people living with HIV in the United States. HIV medical providers must provide leadership—not just in their clinics with their patients, but also in their communities as they work with partners and policymakers alike. HIV

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Reauthorization and the Legislative Battles Ahead

BY WILLIAM D. MCCOLL

The Ryan White Program, which provides HIV treatment and care to more than 500,000 people each year, has long been the HIV community's most visible domestic legislative achievement.

At $2.2 billion, it is the largest source of treatment and care solely directed towards HIV and the third largest supplier of treatment after Medicaid and Medicare. As such, many in the HIV community have looked to the health of the Ryan White Program as an indicator of the strength of its advocacy abilities and whether or not Congress is hearing its messages.

The current authorization of the Ryan White Program ends on September 30, 2013. As that date has crept closer, many national and local HIV community members and advocates have begun to assess how best to produce a successful reauthorization. In particular, working through the Ryan White Work Group of the Federal AIDS Policy Partnership, of which I am the co-chair, the HIV community has hosted two meetings with national experts and Congressional staff working on the Ryan White Program.

One immediate result of these meetings is that most people working on the issue have concluded that it is unlikely that reauthorization can be accomplished prior to the end of 2013. Fortunately, there is no "sunset provision" (a provision which specifies that a law that reaches the end of its authorization is specifically repealed) governing the Ryan White Program. As a result, the law will mostly remain intact, allowing Congress to provide funding.

There are several policy reasons to wait to reauthorize the Act, including that members of authorizing committees and of the HIV community want to better understand how the Ryan White Program will complement the Patient Protection and Affordable Care Act (ACA).

Moreover there are more than 100 new members of Congress since the last reauthorization, so the community needs time to educate new members about the Ryan White Program's purpose and that it has always been supported as a bipartisan program. On a more logistical note, Congress is so deadlocked right now it has been very hard to move any any legislation whatsoever.

Funding at Risk

This points us to a second and more significant issue.

In fact, our most important battle in Congress right now is that HIV funding remains at great risk of being sharply cut due to the ongoing efforts to reduce the deficit. As a result, the community simply must focus more of its time and attention on the budget and appropriations process to ensure that Congress understands the damage severe cuts could do to not only HIV treatment and care, but prevention and research as well.

Ultimately, with a reauthorization, we will seek legislative action based on a strong understanding and agreement among the Administration, Congress and the community on how to move forward. Right now it is clear that the Obama Administration and most Members of Congress continue to support the Ryan White Program.

The Ryan White Work Group will continue to meet and work to educate Members of Congress about the important role of the Ryan White Program as the Affordable Care Act is implemented. The Group also will help provide the HIV advocacy community's perspective on how to move the program forward in the future. We will look for the right opportunity to accomplish a reauthorization, as well.

However, we are clear that our most important task is to ensure that Congress understands the ongoing need for the Ryan White Program in ultimately ending the HIV epidemic. With the budget as the principle focus, advocacy from the entire HIV/AIDS community is needed to make certain that funding is not reduced and that the Ryan White Program remains strong. HIV

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HRSA Insight on The Ryan White Program

What HIV Providers Need to Know

BY YOLONDA CAMPBELL, J.D., M.P.H. AND LAURA CHEEVER, M.D., SCM

Prior to the Affordable Care Act, people living with HIV/AIDS (PLWH) had limited access to health insurance coverage. Many people with HIV were effectively shut out of the individual market either because HIV was considered an uninsurable pre-existing condition by insurers or, if available, private insurance was often unaffordable.

Additionally, to be eligible for Medicaid, an individual needed to meet the income criteria set by their state and belong to a "categorically eligible" group, such as children, parents with dependent children, pregnant women, and individuals with disabilities. Non-disabled adults without dependent children were categorically excluded from Medicaid unless a state obtained a waiver or used state-only dollars to cover them. Furthermore, in order to qualify for Medicaid, many people living with HIV were required to have a diagnosis of AIDS. Due to limited access to health coverage and services, many PLWH have relied on the Ryan White HIV/AIDS Program to provide them with their HIV care needs.

The Affordable Care Act makes a number of important changes to improve access to health insurance coverage for PLWH. However, as implementation of the new law moves forward, the Ryan White HIV/AIDS Program will continue to play a vital role in the lives of many uninsured and underinsured PLWH.

New Coverage Opportunities for People Living With HIV/AIDS

The Affordable Care Act increases access to health insurance coverage and health services for PLWH through a number of private market reforms, an expansion of Medicaid eligibility, and the establishment of a Health Insurance Marketplace (also referred to as an Affordable Insurance Exchange) in every state. Under the Affordable Care Act, PLWH will no longer be denied from purchasing health insurance due to HIV/AIDS as a pre-existing condition.[1] Starting October 1, 2013 every state will have a Health Insurance Marketplace[2] where individuals can apply for Medicaid/CHIP or purchase private health insurance. Some low-income individuals also may be eligible for financial assistance (e.g., premium tax credits and/or cost-sharing reductions) to help them lower their out-of-pocket costs for private plans offered in the Marketplace.

The Affordable Care Act also establishes a new Medicaid eligibility category for low-income adults between 19-64 years of age with income at or below 133 percent of the Federal Poverty Level (FPL). In states that implement Medicaid expansion, low-income people living with HIV who meet the new eligibility criteria will no longer have to wait for an AIDS diagnosis to qualify for Medicaid.

As more PLWH gain access to health care coverage, it is important to remember that the Ryan White HIV/AIDS Program will continue to be the payer of last resort. Although many PLWH will likely gain health coverage under the new law, some PLWH may remain uninsured and underinsured and will continue to rely on the Ryan White HIV/AIDS Program for their HIV care.

Ryan White HIV/AIDS providers should understand the new health coverage options and the types of financial assistance that may be available to their patients under the Affordable Care Act. Many patients who stand to benefit from the law are unaware of their new coverage options.[3] Providers are a key source of information for patients. Through mechanisms within their clinics or through partnerships, providers can educate their patients about Medicaid and the Marketplace and assist patients with applying for and enrolling in these new

programs. Patients may rely on providers to help them understand their new coverage options and how health insurance works.

It is important for patients to evaluate health plans based on out-of-pocket cost (e.g., premiums, co-payments, and deductibles), prescription drug and other benefits coverage, and whether their provider is part of a health plan's network.

Ryan White HIV/AIDS providers are encouraged to proactively work towards identifying and contracting with qualified health plans and Medicaid managed care plans that will be offered in their state.

Ryan White HIV/AIDS Program Part C Providers' Role in Ensuring Continuity of Care

HIV providers have an important role in ensuring continuity of care for their patients during the implementation of the Affordable Care Act. Providers should be aware that many states are moving their Medicaid populations into Medicaid managed care. In addition, private health insurance plans offered through the Marketplace—known as Qualified Health Plans (QHPs)— are required to include a sufficient number of "Essential Community Providers" in their networks. These are providers who serve predominately low-income medically underserved individuals, such as health care providers defined in the 340B program.[4] This definition includes Ryan White HIV/AIDS Providers.

In states with a Federally-Facilitated or State-Partnership Marketplace, CMS will use a tiered approach in determining whether a qualified health plan has a sufficient number of ECPs. For 2014, QHPs can meet a safe harbor standard if they demonstrate that at least 20 percent of available ECPs in the plan's service area participate in the issuer's provider network(s).[5] In addition, the QHP issuer must agree to offer contracts to one ECP per type[6] per county (where available) and all available Indian providers. QHP issuers may also meet a minimum expectation standard in which at least 10 percent of available ECPs in the plan's service area participate in the issuer's provider network(s). In addition, the issuer must submit a narrative justification describing how its provider network delivers an adequate level of service for low-income and medically underserved enrollees.

Consequently, neither QHPs nor Medicaid managed care plans are necessarily required to include all Ryan White HIV/AIDS providers in their networks. Ryan White HIV/AIDS providers are encouraged to proactively work towards identifying and contracting with qualified health plans and Medicaid managed care plans that will be offered in their state.

It is important for providers to become familiar with the individual and small group health insurance markets in their state. It may be helpful for providers to contact their State Department of Insurance and State Medicaid Agency to determine which plans will be participating in the Marketplace or Medicaid.

Providers should also assess their capacity to bill third parties in this rapidly evolving health care marketplace. Providers may need to refine their billing systems to meet the new demands and should seek technical assistance from the Health Resources and Service Administration HIV/AIDS Bureau as necessary.

Future of the Ryan White HIV/AIDS Program

The Ryan White HIV/AIDS Program will evolve with the implementation of the Affordable Care Act. As more Ryan White clients gain insurance coverage, more Ryan White funding may be allocated towards HIV/AIDS medical and support services that may have traditionally not been as comprehensively covered, such as oral health care, adherence counseling, and risk reduction counseling. Ryan White funds may also be allocated towards premium and cost-sharing assistance to help clients purchase and maintain health coverage. It is important to recognize that despite the increased access to health coverage and services, the Ryan White HIV/AIDS Program will continue to play a vital role in providing services that are not covered, or limited in scope, by health plans to ensure coverage completion of necessary HIV/AIDS services. HIV

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Yolonda Campbell, JD, MPH, is a public health analyst in the Health Resources and Services Administration's Office of Planning, Analysis, and Evaluation. Her current areas of expertise include private health insurance market reforms, rural health, and the Ryan White HIV/AIDS Program.

References

1 This provision of the Affordable Care Act becomes effective January 1, 2014. To learn more about other private market reforms that benefit PLWH, please visit http://hab.hrsa.gov/affordablecareact/keyprovisions.pdf.

2 To learn more about the Health Insurance Marketplace, visit: http://www.healthcare.gov/marketplace/index.html.

3 A recent study by Enroll America found that among uninsured Americans who are likely to qualify for help paying for coverage through the Marketplace, only 22 percent were aware of the financial assistance available to them through the Affordable Care Act. In addition, among uninsured Americans likely to qualify for Medicaid under the expansion, only 17 percent were aware of this possibility. See http://files.www.enrollamerica.org/best-practices-institute/public-education-resources/Enroll_America_Survey_Final_Report.pdf

4 See 45 C.F.R. § 156.235.

5 QHP issuers may use CMS/CCIIO's ECP database to identify ECPs in their service area. See https://data.cms.gov/dataset/Non-Exhaustive-List-of-Essential-Community-Provide/ibqy-mswq. Issuers may also write in ECPs that are not included in the CMS/CCIIO ECP database. See http://cciio.cms.gov/programs/Files/ecp-listing-cover-sheet-03262013.pdf.

6 The six types of ECPs are Federally Qualified Health Centers; Ryan White HIV/AIDS providers; family planning providers; Indian providers; hospitals; and other providers, such as STD clinics, TB clinics, and hemophilia treatment centers. See Letter to Issuers on Federally-Facilitated and State Partnership Exchanges, Table 1.1, (April 5, 2013), http://cciio.cms.gov/resources/regulations/Files/2014_Letter_to_Issuers_04052013.pdf.

Navigating ACA Coverage Options

BY ANDREA WEDDLE

Similar to the role that navigators on ships play in getting passengers to the final destination, beginning in October 2014 Patient Protection and Affordable Care Act (ACA) "Navigators" will guide people to the health care coverage that best meets their medical needs. Not to be confused with "patient navigators" who play a key role on many HIV care teams helping patients access health and social service needs, the ACA navigators will specifically help patients determine which insurance option will provide the best coverage to ensure affordable medical coverage and continuity of care.

For people with HIV currently receiving care through Ryan White Programs, becoming enrolled in the right plan is critical to avoid disruptions in care and treatment. The right health plan will include the patient's medical providers, cover required medications and be affordable taking into account premiums, deductibles and cost sharing for services and prescriptions drugs. Similar to Medicare Part D, patients will have many options, and the plan they choose will make a difference.

Who Are the Navigators?

Under the ACA, at least two organizations will be funded in every state to provide assistance with enrolling in the ACA's new coverage options to uninsured and underinsured individuals and families and small businesses. At least one of the organizations must be a non-profit. The Navigators will perform the following functions:

- Conduct public education activities to raise awareness of the availability of Qualified Health Plans (QHPs);
- Distribute fair and impartial information concerning enrollment in QHPS and the availability of premium tax credits and cost-sharing reductions in accordance with federal laws;
- Facilitate enrollment into QHPs;
- Provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman or any other appropriate state agency or agencies, of any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan of coverage; and
- Provide information in a manner that is culturally and linguistically appropriate to meet the needs of the population being served by the Marketplace/Exchange.

The funding available to support Navigators and how the Navigators are selected depends on whether the state's Marketplace/Exchange is run by the federal government, the state or as a partnership between the federal government and the state. Note that applications to serve as ACA navigators were due by June 7.

In some states, Ryan White AIDS Service Organizations (ASOs) may receive funds to officially serve as ACA navigators. However, in most states, larger organizations are likely to receive navigator funding.

The Health Resources and Services Administrations' HIV/AIDS Bureau (HAB) issued a number of guidance notices related to the ACA, including information on how Ryan White funds may be used from Parts A to D to conduct ACA-related outreach and enrollment activities. Check out the *Outreach, Enrollment and Benefits Counseling* guidance along with other guidance notices, including how Ryan White can complete Medicaid coverage, at http://hab.hrsa.gov/affordablecareact.

More Assistance with Navigating the New System

Recognizing the tall-order Navigators have in providing enrollment assistance, states with federal-state partnership and some state-run Marketplaces will offer additional funding to support "In-Person Assisters," which may be a better option for Ryan White programs.

Like the Navigators, In-Person Assisters will play the same role in helping individuals select and enroll in a health plan. However, they are funded through a different mechanism (Navigators will be funded from the Exchange/Marketplace's operating fund). Given an anticipated high demand for enrollment assistance, states running their own Exchanges can use federal funding to establish in-person assistance programs to also provide education and outreach through September 2015.

PROVIDERS: It's Time to Get on Board

Ryan White Providers are facing a sea of change in the next six months, year, and years to come. Now is the time to start preparing to ensure your patients can continue to see you and to not be left out of larger system changes.

Learn whether your state has decided to expand Medicaid next year and if your state will be running the Health Insurance Exchange/Marketplace alone with the federal government or if they are leaving it to the federal government.

In states that expand Medicaid, many HIV patients currently receiving Ryan White-funded services will become eligible for Medicaid coverage. Ryan White providers should take steps to become integrated with Medicaid program and their state's Medicaid managed care plans. In most states, that means becoming certified to bill Medicaid. Providers who are not already enrolled should contact the state Medicaid office for details about specific requirements, and additional information.

Ryan White providers should educate themselves about what type of marketplace is being established in your state. Will your marketplace be state-run, federally-run, or federal-state partnership? What policies are in place to ensure access to HIV medical providers and to monitor the quality of HIV care provided?

Then providers should learn what health plans will be available through the Marketplace/Exchange. Contact the plans and initiate the contracting process to become a part of their provider networks so your patients can continue to see you when they gain new health coverage.

Ryan White Providers are considered "Essential Community Providers" and health plans in the marketplaces are required to contract with some Essential Community Providers who care for medically underserved populations like people with HIV. If you receive Ryan White funding, when you contact health plans let them know you are an Essential Community Provider and would like to be included in their network. As a Ryan White provider, it is vital that you also become integrated with these new health plans in order for your patients to continue to see you for their HIV care. More details are available in an HIVMA Essential Community Provider fact sheet available at. http://www.hivma.org/Health_Care_Reform_Implementation/.

According to Families USA, "states that run their own exchanges can *opt* to establish an assister program that is separate from its navigator program. States that partner with the federally facilitated exchange to provide consumer assistance *must* establish in-person assister programs that are separate from navigator programs. In states that are neither running their own exchange nor partnering to provide consumer assistance, the federal government will establish consumer assistance resources, including the exchange website, call center, and navigator programs."

Case Managers

ASOs and case managers will still play a critical role in helping uninsured and underinsured people with HIV select plans that best meets their medical needs. Case managers and other Ryan White providers also can help patients determine their health care coverage options by becoming "Certified Application Counselors (CACs)." While CACs do not receive special funding, they complete training that prepares them to help patients enroll in Medicaid or Marketplace plans and become certified to help with the enrollment process. They also will be charged with providing fair and impartial information to enrollees. Staff affiliated with medical providers or clinics who become CACs will have a responsibility to provide patients with information on all of their plan options and will need to be cautious to not "steer" patients towards a plan with which their clinic may have an affiliation. Details on the training have not been released yet, but visit the Enroll America website at www.enrollamerica.org or the Department of Health and Human Services Partnerships at www.hhs.gov/partnerships/ to learn the latest.

The ACA ship that is setting sail will offer a historic opportunity to revolutionize access to HIV prevention, care and treatment in the U.S. Assistance from Ryan White providers in navigating the enrollment process and assisting with plan selection will be a key factor in determining how quickly and effectively people with HIV arrive at the health care coverage that best meets their medical and financial needs. HIV

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ACA Enrollment: How Ryan White Providers Can Get Ready

- Learn Who Is Running Your State's Marketplace/Exchange
- Contact the Plans Available in Your Marketplace to Join their Networks as an Essential Community Provider
- Connect with the Organizations Running Your State's Navigator Programs
- Educate your Clinic Staff on the New Health Coverage Options
- Encourage Case Managers to Become Certified Application Counselors
- Stay Informed by regularly visiting the following websites:
  - www.hivma.org
  - www.aahivm.org
  - www.hivhealthreform.org
  - http://hab.hrsa.gov/

BY ANNE DONNELLY

BEST PRACTICES

Learning from the San Francisco HIV Health Care Reform Task Force

Recognizing the need to address changes in the San Francisco model of HIV care, the San Francisco HIV Health Care Reform Task Force was formed in 2012 to plan for the secure and safe transition of approximately 7,000 HIV+ individuals who currently rely primarily on the Ryan White system into broader systems of care in 2014. The task force members include representation from the SF Department of Public Health, SF HIV service providers and HIV planning council members.

This collaborative planning process has had the great benefit of beginning serious discussion and planning among HIV providers, as well as sharing strategies for sustainability. The Task Force believes this is a viable model for jurisdictions and/or regions and states to begin the health care reform planning process.

Thus far, the Task Force has produced several pieces of information, including provider planning considerations and client health care reform templates to help providers in their discussions with client about upcoming changes. Although the documents that have been produced are specific to San Francisco, they can be easily adapted to another locality. Here is a portion of the Provider Planning Considerations document:

For organizations that provide services reimbursable through medical insurance, consider the following as you prepare for ACA transition:

- **Conduct a basic analysis of your payer mix.** Consider what your payer mix is now and how that might change after full implementation of the ACA.
- **Explore how to receive reimbursement once clients shift to different payers.** In anticipation of clients shifting to different payers (i.e., from Ryan White to Medicare Managed Care or private insurance), determine if you are able to receive reimbursement from these payers.
- **Consider future availability of Ryan White funds.** As clients shift to other payers besides Ryan White, paricularly for primary medical care, consider what portion of your current Ryan White funds may be available to address continued unmet needs for your client population.
- **Ensure Data Management Systems can support pay-for-performance in the future.** Continue to develop and standardize your quantitative and qualitative data collection/evaluation systems to report regularly on outcomes (quarterly for most measures).
- **Look into strategic diversification. In order to sustain your financial viability and a full scope of multi-disciplinary services, consider strategic diversification.** This may mean expanding your HIV program(s) to serve patients with other complex conditions, or partnering with other community organizations to integrate services while reducing overhead costs and increasing ease of access for clients.

For organizations that provide services not reimbursable through medical insurance, consider the following questions as you prepare for ACA transition:

- **How do your services promote linkage and engagement in testing, risk-reduction, and primary care for persons who are HIV positive or at high risk for HIV?** Community providers can re-enforce their relevance and vital contributions by showing the essential services they provide for engaging community members in primary care.
- **How do you/will you document the outcomes of your services?** Documenting outcomes will continue to be very important, particularly for primary prevention, community outreach, and testing. HIV Service Organizations will need to demonstrate if and how their intervention leads to reaching at-risk groups.
- **Are there services for which you can bill Medicare or other payers, such as mental health and/or substance abuse services?** You may need to consider the licensing/credentials of the staff providing such services, since only certain types of providers can bill for insurance for their services.
- **Have you explored options for diversification of services?** You know the communities you serve best and have the ability to reach those most in need. Consider how you could expand your scope of work to address other health issues beyond HIV.
- **Have you considered strategic partnerships?** In a resource-limited setting, consider actively pursuing partnerships, including co-location with other service providers in order to continue to offer essential non-medical services in a streamlined and integrated way.

In addition, the Task Force is in the process of completing a series of key informant interviews that are expected to lead to the formulation of some best practices regarding transition and integration which will also inform future education efforts. Information and events are also being planned for clients to begin to educate themselves on upcoming changes.

To view the Planning Considerations Document for Providers of HIV Services in its entirety and a sample FAQ for PLWH who receive their care through Ryan White, visit the Task Force webpage at www.sfhiv.org/community-planning/hiv-healthcare-reform-task-force/. A customizable version of the FAQs can be found at www.hivhealthreform.org. HIV

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How to Make the First Visit Count

BY VICTORIA A. CARGILL, MD, MSCE

Editor's Note: *With the upcoming implementation of the Affordable Care Act (ACA), an estimated 30 million newly insured Americans will flood our healthcare system. Inevitably, HIV care providers will begin to see new patients in their offices, many seeking treatment for the first time. With only 50 percent of those diagnosed with HIV in the U.S. currently in care, there has never been a better opportunity to get more HIV infected individuals into a consistent care setting.*

With the potential influx of new HIV patients coming, the following refresher by Dr. Victoria A. Cargill might help maximize a first-time patient visit and ensure a long-term care relationship:

Without retention in care, effective HIV treatment and patient management are impossible. Patients retained in care benefit in a number of ways: 1) greater chance of a suppressed viral load; 2) increased survival; 3) less risk of opportunistic infection; and 4) reduced risk of transmission.1 Patients who are not engaged in care or fall out of care not only experience increased HIV-associated morbidity and mortality, but also are increasingly likely to transmit HIV infection to others. Patients who miss visits in the first year after initiating HIV treatment have more than twice the rate of long-term mortality compared with those who keep all appointments.[1]

As you know, when patients first present for HIV care, they are already upset, vulnerable, frightened and aware that they have an illness that is highly stigmatizing. Being sensitive to their situation, while also acknowledging a patient's cultural context, will enhance his/her comfort and encourage retention.

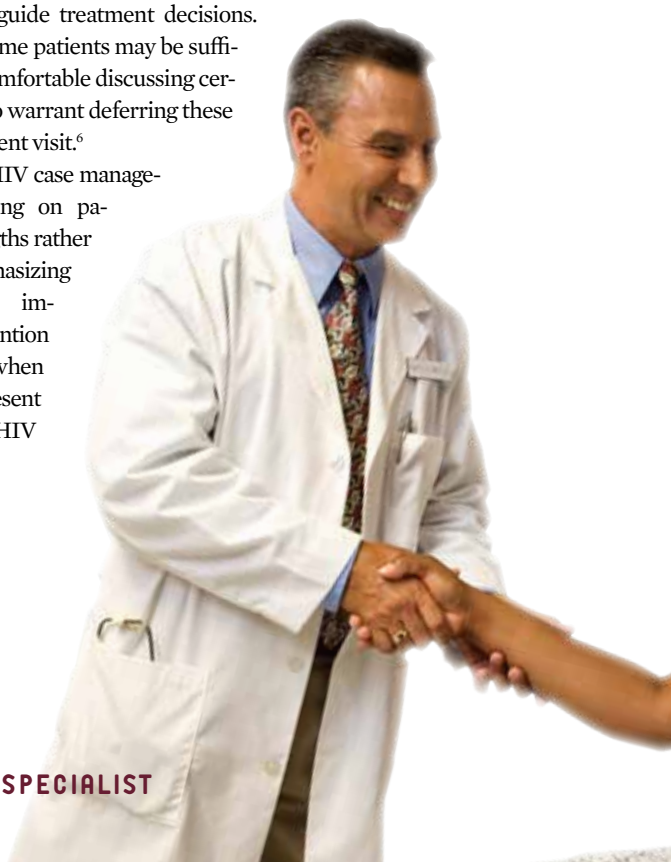
We know that retention in care and care engagement are associated with providers who: 1) treated the patient with dignity and respect; 2) answered questions in an open fashion and in a way that was easy to understand; 3) demonstrated genuine interest in the patient and his/her entire context; and 4) took the time to hear his/her concerns. For specific patient populations such as African Americans, trust is the single most important component of the care relationship upon which retention and engagement in care are heavily based.2,3 Retention in care can also be reinforced by simple messages in posters, cards, brochures, and flyers, which provide small but significant retention benefits.[4]

What can providers do at the first visit to improve retention in care?

The first visit is crucial as it sets the tone for subsequent visits, and, appropriately, providers spend more time with patients at the first visit than at any subsequent visit. It is the visit during which preliminary assessments are made regarding sexual risk behaviors, including number of sexual partners and drug risk behavior, home environment, social support, prior travel and infections (including sexual), and any prior or current abuse or violence. Initiating the visit by asking patients how they wish to be addressed is associated with better communication.[5] While establishing eye contact will convey engagement and can strengthen trust, the patient's ability to engage in eye contact in return may vary by race/ethnicity, with some using a downward gaze as a sign of deference or respect.

Asking personal questions at the first visit may make follow-up questions at subsequent visits easier; however, it is important to explain why certain questions are being asked. This is especially true when asking questions about potentially sensitive subjects such as sexual behavior, sexual partners, sexually transmitted infections, and drug use. Given the discomfort associated with such questions, it is important for the provider to stress the need for honest answers, which will guide treatment decisions. However, some patients may be sufficiently uncomfortable discussing certain topics to warrant deferring these to a subsequent visit.[6]

Finally, HIV case management focusing on patients' strengths rather than emphasizing deficiencies improves retention in care when persons present with a new HIV diagnosis.[7]



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What else can providers do to improve retention in care?

Providers should examine the care environment from a patient perspective to determine what potential barriers to care exist. Office staff trained to reinforce the importance of retention in care is a key component. Peer navigators can be useful for teaching patients the skills to traverse the medical system and to coordinate care.[8,9] Language continues to remain a barrier to HIV care; HIV education and appointment information in language that reflects the patient populations served are helpful.[10] Patients who feel that the provider and staff are interested in their overall well being and not just focused on HIV are more satisfied with their care and more likely to be retained in care.

Other strategies that can improve retention in care include active outreach, appointment coordination, and co-location of primary care and social services.[10]

Finally, a staff trained to recognize the signs of impending loss to care, including a retention specialist, can significantly improve retention in care, with one study reporting a 16.3% re-engagement rate attributable to the retention specialist alone.[11]

What individual patient factors impact retention in care?

Just as the provider plays a role in care engagement and retention, there are a number of individual factors that also affect patient engagement and retention in care. These include, but are not limited to, mental illness, fear, shame, stigma, active substance use, and lack of health insurance. Studies continue to demonstrate that younger patients, those with a higher baseline CD4 count, those who are black or of African descent, and those with active substance use are at highest risk for dropping out of care.[12]

For many patients, feeling well provides "proof" that they do not need care. In a New York City study of patients who had dropped out of care, over 40 percent did so because they felt well.[13] Thus it is important to emphasize to all patients, that despite feeling well, HIV care is required to prevent damage to the immune system and reduction of associated infectious and neoplastic complications. Providers cannot control individual patient factors, but they can improve the patient care environment.

Finally providers cannot solve every problem, but they can engage the patient, ask the appropriate questions, offer some next steps, and through the use of a team approach create an environment of trust and caring. HIV

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Quick Reminders for Making the Most of a New Patient Visit

- Review your office procedures from the perspective of a newly diagnosed or new-to-care HIV infected patient.
- Ensure that office reception and professional staffs are trained to be sensitive to patient comfort and that the office environment is friendly and not stigmatizing.
- Ask patients how they prefer to be addressed to improve communication at the first visit.
- When taking a history, explain to the patient why certain questions are being asked before asking them to encourage trust at the first visit. Patients who understand why a question is being asked are more likely to answer honestly.
- Frame questions in an open fashion to allow a range of responses, and ask questions in an open and nonjudgmental way, such as "Have you engaged in ....?" as opposed to "You don't do .... do you?"

ON THE FRONTLINES

BY JAMES M. SOSMAN, MD, FACP, AAHIVS

Challenges Facing Ryan White Part C Funded Programs

IN THE PAST YEAR, we have witnessed fundamental advances in our ability to control the HIV virus. Potent, durable and conveniently dosed antiretroviral medications have revolutionized the care and prognosis of our patients. We have also entered the era of biomedical HIV prevention. The roll out of test-and-treat strategies and efficacious pre-exposure prophylaxis (PREP) should significantly reduce transmission risk. In addition, cutting edge research is now focusing on the ultimate goal of HIV eradication.

It's difficult not to be an optimist with the steady stream in research advances. Yet, as impressive as these treatments appear, recent studies show that fewer than one in three Americans living with HIV are successfully engaged in care and achieve viral suppression. In fact, only 50 percent of those who have received an HIV diagnosis are in care.

For the past three years, I have observed the HIV treatment landscape through a sobered perspective as the medical director for a Wisconsin Ryan White Part C funded HIV care program. Our biomedical success in controlling HIV creates a false sense of security. Engaging and reengaging individuals in health care is not an easy pursuit. Ryan White Part C programs continue to allocate more resources to these efforts by implementing social service and case management practices, patient outreach, community contact and healthcare navigation. But, most individuals not engaged in care experience significant access barriers and are more likely to suffer mental health and addiction illness.

In Wisconsin, we are allocating a growing percent of our grant funds to support health care engagement efforts. In fact, almost all new grant support in the past two years has gone to support our new and expanded mental health, addiction medicine, case management and outreach navigation services. This has not been cheap. I expect a growing implementation challenge requiring additional funding for new skills, new commitments to staff training, and new ways of practice that traditional models of clinical care do not support.

Challenges

It can be a substantial challenge to pilot test HIV care innovations. Our Wisconsin Part C program does not exist in a vacuum, but is a part of a much larger hospital and medical school system within the University of Wisconsin. Although this provides some advantages for grant management and oversight, large and complex health care systems are not the most facile to respond to new or innovative clinical approaches. Even cost effective modifications in program practices must be discussed and agreed upon by a significant number of administrators and risk managers who are empowered with differing agendas.

Part C programs must prepare for the expected and unexpected new trends in HIV treatment and chronic care management. We have all read reports highlighting the potentially deleterious effects of chronic HIV infection over many years, even among virally controlled individuals. HIV infection contributes to a chronic inflammatory state, which has been hypothesized to be the catalyst to high rates of cardiovascular risk, malignancy, neurocognitive disease and metabolic bone disease as our patients age. Resources will have to be allocated to screen and treat these downstream co-morbid conditions.

These disease trends are difficult to prioritize. When should we start to allocate more of our finite program funds to screen for metabolic bone disease in our aging patients? How many neuropsychiatric tests or brain MRI scans should we allocate for the assessment of patients with mild neurocognitive concerns? Part C programs must adapt quickly to these evolving co-morbid concerns through clinician and staff education and training, and by aggressively pursuing additional funds to support these new services.

Federal health care reform poses some unexpected challenges for Part C programs. The Patient Protection and Affordable Care Act (ACA) will provide new opportunities for affordable healthcare for millions of Americans who are not currently covered. Under the ACA, Medicaid eligibility will be expanded to many more low-income individuals. This should allow coverage for a large number of the working and poor HIV-infected individuals who presently rely on services covered only by the Ryan White CARE Act. When Medicaid expansion goes into effect in 2014, it may allow these individuals to get into care and have access to a broader range of services than we can sometimes provide at a Part C funded clinic. However, there are many critical services that we do provide that are not part of most Medicaid programs, such as case management, care coordination and navigation services, onsite mental health and addiction services, dental care and transportation. These services are essential to achieve measurable progress towards raising the percent engaged in care and virally suppressed.

Likewise, 26 state governors and legis-

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latures including Wisconsin's have elected to opt out of Medicaid expansion. That will impact the ability of patients living in those states to access quality care. In addition, we may see people who now have other forms of coverage lose their ability to receive care at Ryan White-funded clinics. Finally, there is fear that Ryan White programs may not be as well-funded going forward. There is lots of uncertainty out there, which makes methodical Part C program planning difficult.

Action Needed

I propose a few options to address these challenges.

First, we must continue to focus on providing the best clinical care for our HIV patients. Today, that means adapting to the latest epidemiologic and clinical trends outlined above. It also means investing in clinician and staff training to ensure state of the art care. This may seem like an obvious goal, but with so many challenges competing for our attention, we must not lose sight of this most important role.

Second, we must inform others of what our Part C programs do well. Although this may already be measured to some degree through Part C program outcome reports, many local and regional stakeholders and opinion leaders, who should value the good work we provide and the challenges we address, need to receive clearly presented information on our programs' critical role and accomplishments.

Much of the health care reform will roll out at the local level under the oversight of local administrative and political leaders. This creates an accessible opportunity for our voice to be heard.

Finally, we need sustained patient and programmatic advocacy to ensure that ACA implementation provides synergy with our Part C program goals. Much of the health care reform will roll out at the local level under the oversight of local administrative and political leaders. This creates an accessible opportunity for our voice to be heard. Fortunately, AAHIVM maintains current policy and advocacy information regarding individual states, which is updated several times per week. Wisconsin HIV clinicians are planning to partner with AAHIVM and the regional AETC to provide an update on the effects of the ACA on HIV care in our state. We plan to establish an advocacy agenda and train clinicians to make their voices heard.

Obviously, there is much to be done. I am confident that together we can continue to improve access to high quality care for our patients, and advocate for the necessary support to continue the critical work provided by our Part C funded programs. HIV

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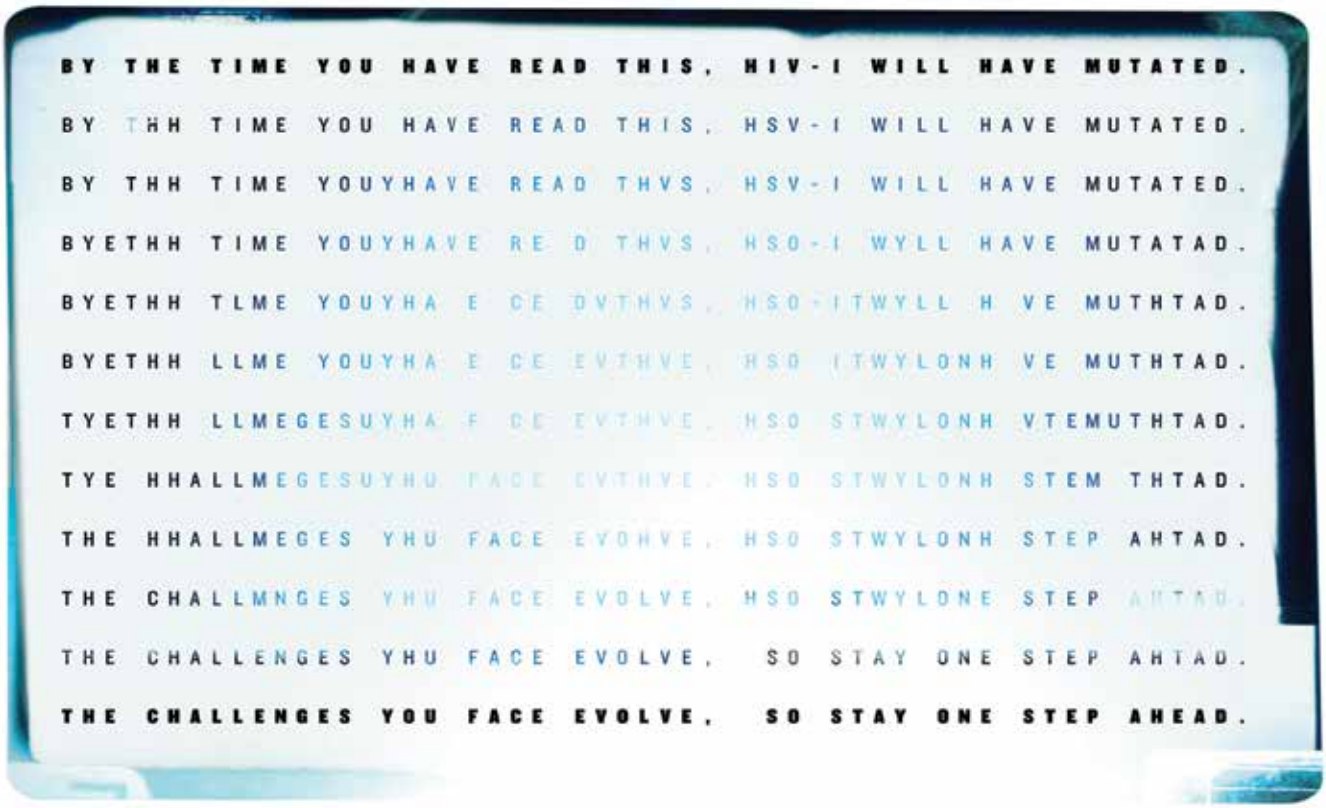

Rapidly mutating HIV-1 virus can continue to evade quantification with a single target viral load assay. The innovative Dual Target HIV-1 assay from Roche Molecular Diagnostics measures two unique regions of the HIV-1 genome, which are not subject to selective drug pressure. Therefore, drug-induced mutations should not impact the assay's ability to detect and quantify the virus accurately. In turn, more accurate results drive better decisions for a positive impact on patients' lives.

Visit us at **http://molecular.roche.com** and ask for more information about the COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 Test, v2.0.

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