The AMERICAN ACADEMY of HIV MEDICINE®

HIV SPECIALIST

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

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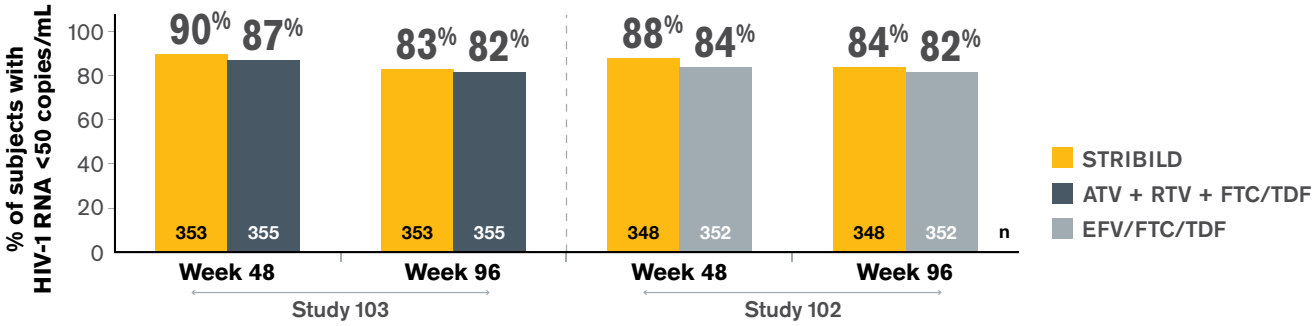
HIV/AIDS in the South

Individual patients, different journeys, one goal

STRIBILD is the first integrase inhibitor–based single-tablet regimen for treatment-naïve adults with HIV-1[1,2]

Noninferior efficacy at weeks 48 and 96[3,4]



Important Safety Information

BOXED 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.**
- **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 HIV-1 and have discontinued emtricitabine or tenofovir DF, 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.**

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 loss of efficacy 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. In all patients, monitor estimated creatinine clearance (CrCl), urine glucose, and urine protein prior to initiating and during therapy. In patients with or at risk for renal impairment, additionally monitor serum phosphorus. Do not initiate STRIBILD in patients with CrCl <70 mL/min. Discontinue STRIBILD if CrCl declines to <50 mL/min. 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. Avoid concurrent or recent use with a nephrotoxic agent. Cases of acute renal failure, some requiring hospitalization and renal replacement therapy, have been reported after initiation of high dose or multiple NSAIDs in patients with risk factors for renal dysfunction; consider alternatives to NSAIDs in these patients. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function.

Important Safety Information (*continued*)

Warnings and precautions (*continued*)

- **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.
- **Bone effects:** Decreases in bone mineral density (BMD) and mineralization defects, including 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. In patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms, hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered.
- **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%), and headache (7%).

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 efficacy and possible resistance to STRIBILD.
- **Drugs affecting renal function:** Coadministration of STRIBILD with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of emtricitabine and tenofovir and the risk of adverse reactions.
- **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.
- **Testing prior to initiation:** Test patients for HBV infection and document baseline CrCl, urine glucose, and urine protein.

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.

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; the FDA snapshot analysis at week 96 was a secondary endpoint.

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; FTC, emtricitabine; RTV, ritonavir; TDF, tenofovir disoproxil fumarate.

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

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 emtricitabine or tenofovir DF, 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:
See ***Warnings and Precautions***, ***Adverse Reactions***, and ***Use in Specific Populations*** for additional information.

Adult Dosage: One tablet taken orally once daily with food.

Renal Impairment: Do not initiate in patients with estimated creatinine clearance (CrCl) <70 mL/min. Discontinue if CrCl declines to <50 mL/min during treatment.

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

Testing Prior to Initiation: Test patients for HBV infection and document CrCl, urine glucose, and urine protein.

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 efficacy and possible resistance to STRIBILD *[See Drug Interactions]*:

- Alpha 1-adrenoreceptor antagonist: alfuzosin. Potential for hypotension.
- Antimycobacterial: rifampin. May lead to a loss of efficacy and possible resistance.
- 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. May lead to a loss of efficacy and possible resistance.
- 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. Increased potential for sildenafil-associated adverse events (visual disturbances, hypotension, priapism, and syncope).
- 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: All patients with HIV-1 should be tested for chronic HBV infection 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 emtricitabine, 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 acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with tenofovir DF and with STRIBILD. In clinical trials through 96 weeks, 10 (1.4%) subjects in the STRIBILD group (N=701) and 2 (0.3%) subjects in the combined comparator groups (N=707) discontinued study drug due to a renal adverse reaction. Four (0.6%) subjects who received STRIBILD developed laboratory findings consistent with proximal renal tubular dysfunction leading to discontinuation of STRIBILD compared to 0 in the comparator groups. Two of these 4 subjects had renal impairment (CrCl <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 (e.g., high-dose or multiple NSAIDs) *[see Drug Interactions]*. Cases of acute renal failure after initiation of high dose or multiple NSAIDs have been reported in HIV-infected patients with risk factors for renal dysfunction who appeared stable on tenofovir DF. Some patients required hospitalization and renal replacement therapy. Alternatives to NSAIDs should be considered in patients at risk for renal dysfunction. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function. ***Monitoring:*** CrCl, urine glucose and urine protein should be documented in all patients prior to initiating therapy. Do not initiate in patients with CrCl <70 mL/min. Routinely monitor CrCl, urine glucose, and urine protein during therapy in all patients. Additionally monitor serum phosphorus 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 with a confirmed increase in serum creatinine of >0.4 mg/dL from baseline should be closely monitored for renal safety. Discontinue STRIBILD if CrCl declines to <50 mL/min.

Use with Other Antiretroviral Products: STRIBILD is a complete regimen for the treatment of HIV-1 infection and coadministration with other antiretroviral products is not recommended. Do not coadminister with products containing any of the same active components; with products containing lamivudine; with products containing ritonavir; or with adefovir dipivoxil.

Bone Effects of tenofovir DF: ***Bone Mineral Density (BMD):*** In clinical trials in HIV-1 infected adults, tenofovir DF was associated with decreases in BMD and increases in biochemical markers of bone metabolism, suggesting increased bone turnover relative to comparators. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher in subjects receiving tenofovir DF. For additional information, consult the VIREAD (tenofovir DF) full Prescribing Information. The effects of tenofovir DF-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. Consider assessing BMD in patients with 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. If bone abnormalities are suspected appropriate consultation should be obtained. ***Mineralization Defects:*** Cases of osteomalacia associated with proximal renal tubulopathy, manifested as bone pain or pain in extremities and which may contribute to fractures, have been reported in association with the use of tenofovir DF. Arthralgias and muscle pain or weakness have also been reported in cases of proximal renal tubulopathy. Hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms while receiving products containing tenofovir DF. *[See Adverse Reactions]*

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 (e.g., *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jirovecii* pneumonia [PCP], or tuberculosis), which may necessitate further evaluation and treatment. Autoimmune disorders (e.g., 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 WARNING** and **Warnings and Precautions** for additional serious adverse reactions.* The safety assessment of STRIBILD is based on pooled data from two Phase 3 trials in antiretroviral treatment-naive HIV-1 infected adults. A total of 701 subjects received STRIBILD once daily for at least 96 weeks. 4.6% of subjects discontinued STRIBILD due to adverse events, regardless of severity.

Adverse Reactions: Treatment emergent adverse reactions (all grades) reported in ≥5% of subjects receiving STRIBILD (N=701) through week 96 were: nausea (16%), diarrhea (12%), abnormal dreams (9%), and headache (7%). Frequencies are based on all treatment emergent adverse reactions attributed to study drugs. See *Warnings and Precautions* for more information on renal adverse reactions.

Laboratory Abnormalities: Treatment emergent laboratory abnormalities (Grades 3-4) occurring in ≥2% of subjects receiving STRIBILD (N=701) through 96 weeks were: creatine kinase ≥10.0x ULN (7%); urine RBC (hematuria) >75 RBC/HPF (3%); amylase >2.0x ULN (3%); and AST >5.0x ULN (2%). For subjects with serum amylase >1.5x ULN, lipase test was performed; increased lipase (Grades 3-4) occurring in STRIBILD (N=61) was 15%. Proteinuria (all grades) occurred in 46% of subjects receiving STRIBILD. Cobicistat has been shown to decrease CrCl due to inhibition of tubular secretion of creatinine without affecting renal glomerular function; decreases in CrCl occurred early in treatment with STRIBILD after which they stabilized. Mean ±SD changes after 96 weeks of treatment were: serum creatinine, 0.13 ±0.13 mg/dL; and eGFR by Cockcroft-Gault, -13.2 ±15.7 mL/min. Elevation in serum creatinine (all grades) occurred in 10% of subjects. BMD was assessed by DEXA in a non-random subset; mean decreases in BMD from baseline to Week 96 in the STRIBILD group (N=47) were comparable to the comparator group at the lumbar spine (-2.0%) and the hip (-3.2%). Bone fractures occurred in 14 subjects (2.0%) in the STRIBILD group.

Serum Lipids: In clinical trials, 11% of subjects receiving STRIBILD were on lipid lowering agents at baseline; through Week 96, an additional 8% of subjects were started on lipid lowering agents. Mean changes from baseline in fasting serum lipids in subjects receiving STRIBILD (N=701) through 96 weeks were: total cholesterol: week 96 change +12 (N=571; baseline 166 mg/dL); HDL-cholesterol: week 96 change +7 (N=571; baseline 43 mg/dL); LDL-cholesterol: week 96 change +12 (N=572; baseline 100 mg/dL); triglycerides: week 96 change +8 (N=571; baseline 122 mg/dL). The change from baseline is the mean of within-patient changes from baseline for patients with both baseline and Week 96 values.

Consult the respective full Prescribing Information for each available individual component of STRIBILD for additional information regarding adverse reactions, including laboratory abnormalities and postmarketing events.

DRUG INTERACTIONS:
*See **Contraindications** for additional serious drug interactions.*

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.

Potential for STRIBILD to Affect Other Drugs: Cobicistat is an inhibitor of CYP3A and CYP2D6 and the transporters 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 concentrations of such drugs. Elvitegravir is a modest inducer of CYP2C9 and may decrease the concentrations of CYP2C9 substrates.

Potential for Other Drugs to Affect 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 concentrations of cobicistat and elvitegravir, which may lead to loss of efficacy and development of resistance. Coadministration of STRIBILD with other drugs that inhibit CYP3A may decrease the clearance and increase the 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, which may increase the incidence of adverse reactions *[see Warnings and Precautions]*.

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 efficacy 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 efficacy 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 efficacy 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.
- Narcotic Analgesics: buprenorphine, naloxone. Closely monitor for sedation and cognitive effects.
- 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 reactions. *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. Caution should be exercised in the administration of STRIBILD in elderly patients.

Renal Impairment: STRIBILD should not be initiated in patients with CrCl <70 mL/min. STRIBILD should be discontinued if CrCl declines to <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.

203100-GS-002 October 2013

References: 1. STRIBILD [package insert]. Foster City, CA: Gilead Sciences, Inc; 2013. **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 January 3, 2014. **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. **5.** Panel on Antiretroviral Guidelines for Adults and Adolescents. Recommendation on integrase inhibitor use in antiretroviral treatment-naive HIV-infected individuals from the HHS panel on antiretroviral guidelines for adults and adolescents. AIDSInfo website. http://aidsinfo.nih.gov/news/1392/hhs-panel-on-antiretroviral-guidelines-for-adults-and-adolescents-updates-recommendations-on-insti-based-regimens-for-art-naive-individuals. Updated October 30, 2013. Accessed October 30, 2013.

GILEAD

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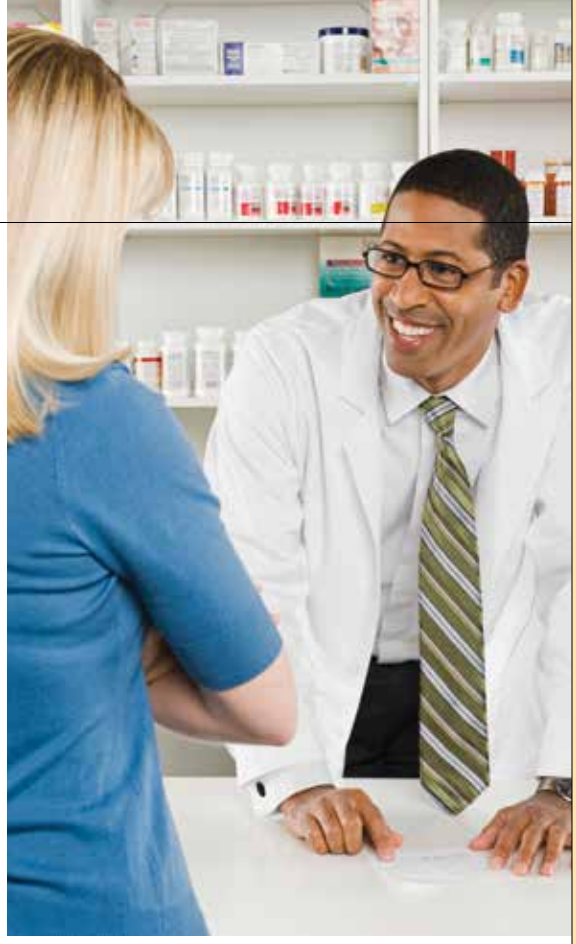

DEPARTMENTS

The AMERICAN ACADEMY of HIV MEDICINE
HIV SPECIALIST
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BY JAMES M. FRIEDMAN, MHA, EXECUTIVE DIRECTOR, AAHIVM

It Was a Different Time…Or Was it?

I JUST WAS READING this morning's edition of *Kaiser Health News*. The headlines included: *CBO Reports That Health Law Provision Called 'Bailout' By GOP Will Raise $8B; Poll: 51% Disapprove Of Obamacare; Health Care Law Projected To Cut The Labor Force; Health-Care Law Will Prompt Over 2 Million To Quit Jobs Or Cut Hours, A CBO Report Says; Web Site Woes Will Reduce Health Care Enrollment*. I am embarrassed and appalled.

James M. Friedman

My parents were first generation Americans. They grew up in working class families—my mother in Galesburg, Illinois and my father in Chicago. They were the first in their respective families to attend and graduate from college—this in spite of the Great Depression. They met and married in medical school and became physicians. My mother was a pediatrician who worked part time in a public health clinic and later part time for the state health department—all the while raising three sons. My father was a GP who set up a private practice in Decatur, Illinois after he left the Army Air Corps after World War II.

Why do I mention this? It was a different time. There was no Medicare, there was no Medicaid. My father, and some others like him, developed a sliding scale for payment (I don't think the term "reimbursement" existed at the time). Those who could afford it, paid full fare. Those who were less well off, paid as little as 2 dollars for an office visit. For those that found 2 dollars too expensive, they paid with a bag of tomatoes or sweet corn they had grown. But too many Americans had little or no access to medical care.

Then a couple of decades later, Medicare and Medicaid were created. At last there were programs that provided financial access for the elderly and the poor and disabled. Those programs helped tens of millions of Americans and reinforced what made America special—equal opportunity to achieve the dream of America, and the assurance that the poorest of the poor were cared for.

Now, almost 50 years later, almost 50 million Americans, one-sixth of our population, have fallen through the cracks of Medicare and Medicaid. They have fallen through the cracks of the American Dream.

Obamacare does not solve all of our problems; it does not fill all of those healthcare cracks, but it represents a big step in the right direction.

Though I must admit I cringe when I see those headlines. While they may be accurate to some extent, they also represent barriers to full implementation, to moving toward that dream of America. The drafting of our Constitution and achieving our independence was not easy. My parents becoming physicians and providing some care out of their own pockets was not easy. Implementing Obamacare is not easy. Sometimes being an American is hard. So let's get on with it.

I tell this story because I believe HIV practitioners are of the same ilk as my parents. So many of our patients are on Medicaid or have no health insurance. As you'll see from this issue of HIV Specialist, our colleagues in the South are especially struggling to provide the care and treatment their patients need and deserve. Yet we forge ahead always doing our best to find ways to provide quality HIV care to all who seek it. Sometimes we require silent auctions or bake sales to meet payroll. Sometimes being a HIV practitioner is hard. So let's get on with it. HIV

IN THE NEWS

President Obama Announces Douglas M. Brooks, MSW, as Director of the Office of National AIDS Policy


Brooks

President Obama on March 24 announced the appointment of Douglas M. Brooks, MSW, as the director of the White House Office of National AIDS Policy (ONAP).

A leading HIV/AIDS policy expert who lives with HIV, Brooks most recently served as senior vice president for community, health, and public policy at the Justice Resource Institute (JRI) based in Boston. As the Director of ONAP, he will lead the administration's work to reduce new HIV infections, improve health outcomes for people living with HIV, and eliminate HIV health disparities in the United States.

"Douglas's policy expertise combined with his extensive experience working in the community makes him uniquely suited to the task of helping to achieve the goal of an AIDS-free generation, which is within our reach," President Obama said. "I look forward to having him lead our efforts from the White House."

Brooks also served as executive director of the Sidney Borum Jr. Community Health Center at JRI, has managed programs in urban and rural environments and has served as a consultant to domestic and international governments and non-governmental organizations assisting in efforts to serve populations living with, and at greatest risk for, HIV/AIDS. Brooks was a Visiting Fellow at the McCormack School Center for Social Policy at the University of Massachusetts, Boston and chaired the Board of Trustees of AIDS United in Washington, DC.

In 2010, Brooks was appointed to the Presidential Advisory Council on HIV/AIDS (PACHA) and served as its liaison to the CDC/HRSA Advisory Committee, leading those bodies to achieve the tasks assigned to them in the National HIV/AIDS Strategy.

Brooks received a Master of Social Work degree from Boston University and is a licensed clinical social worker. HIV

White House Budget Expands Access to HIV Treatment, Care & Prevention

The White House Office of Management and Budget (OMB) says the President's 2015 federal budget proposal expands access to HIV/AIDS treatment, care, and prevention and supports housing assistance for people living with HIV/AIDS.

Here is the pertinent section of the OMB fact sheet:

Expanding Access to Health Coverage. The Affordable Care Act ensures that Americans have secure, stable, and affordable insurance. Insurance companies may no longer discriminate against consumers due to pre-existing conditions, and can no longer turn someone away just because he or she is lesbian, gay, bisexual, or transgender.

Addressing Health Care Disparities. The budget supports community effort to focus on prevention, and invests in expanding the health care workforce, especially in community health centers to provide primary care services. Continuing efforts to improve data collection on health disparities will help policymakers have the knowledge and tools needed to address the health needs and concerns of the LGBT community.

Civil Rights Enforcement and Hate Crime Prevention. The budget supports activities at the Department of Justice to ensure the protection of civil rights and provides additional resources for the Department of Justice Community Relations Service (CRS) to respond to alleged hate crimes based on race, color, national origin, gender, gender identity, sexual orientation, religion, or disability.

Improving Access to Services under the Violence Against Women Act (VAWA). The budget includes $423 million in Department of Justice Office on VAWA grants and assistance to support victims of violence, including LGBT victims of domestic violence.

Progress Toward Ending Homelessness. The budget provides $2.4 billion for the Department of Housing and Urban Development's Homeless Assistance Grants, $301 million above the 2014 enacted level. This funding supports new permanent supportive housing units and maintains over 330,000 HUD-funded beds that assist the homeless nationwide.

Expanding Access to HIV/AIDS Treatment, Care, and Prevention. The budget expands access to HIV/AIDS prevention and treatment activities and supports the goals of the National HIV/AIDS Strategy and HIV Care Continuum Initiative to reduce HIV incidence, increase access to care, and reduce HIV-related health disparities. It invests $2.3 billion in the Ryan White HIV/AIDS Program to provide treatment and care completion services, which includes $900 million for the AIDS Drug Assistance Program. It also invests $1.1 billion for CDC HIV/AIDS, Sexually Transmitted Diseases, Tuberculosis, and Viral Hepatitis activities, and aligns HIV funding with the epidemic by requiring public health departments to target resources where the epidemic is most concentrated.

Supporting Housing Assistance for People Living with HIV/AIDS. The budget provides $332 million for HUD's Housing Opportunities for Persons with AIDS (HOPWA) program to address housing needs among people living with HIV/AIDS and their families. HIV

AbbVie Presents PEARL-III Study in Patients with Chronic Hepatitis C at the 21st Conference on Retroviruses and Opportunistic Infections

The first detailed results from AbbVie's phase III study, PEARL-III, were presented March 4 at the 21st Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. PEARL-III evaluated the efficacy and safety of 12 weeks of treatment with AbbVie's investigational therapy with or without ribavirin (RBV) in non-cirrhotic, adult patients with chronic genotype 1b (GT1b) hepatitis C virus (HCV) infection who were new to treatment.

The PEARL-III study met its primary and secondary endpoints. In the 419-patient study, sustained virologic response rates 12 weeks post-treatment (SVR12) of 99.5 and 99.0 percent were achieved with the AbbVie regimen with and without RBV, respectively. There were no study drug discontinuations due to adverse events.

"Results from PEARL-III are encouraging, as they demonstrate AbbVie's regimen can achieve high rates of SVR, with and without ribavirin across several patient characteristics in those with genotype 1b chronic hepatitis C infection," said Peter Ferenci, M.D., professor of Gastroenterology and Hepatology, Medical University of Vienna.

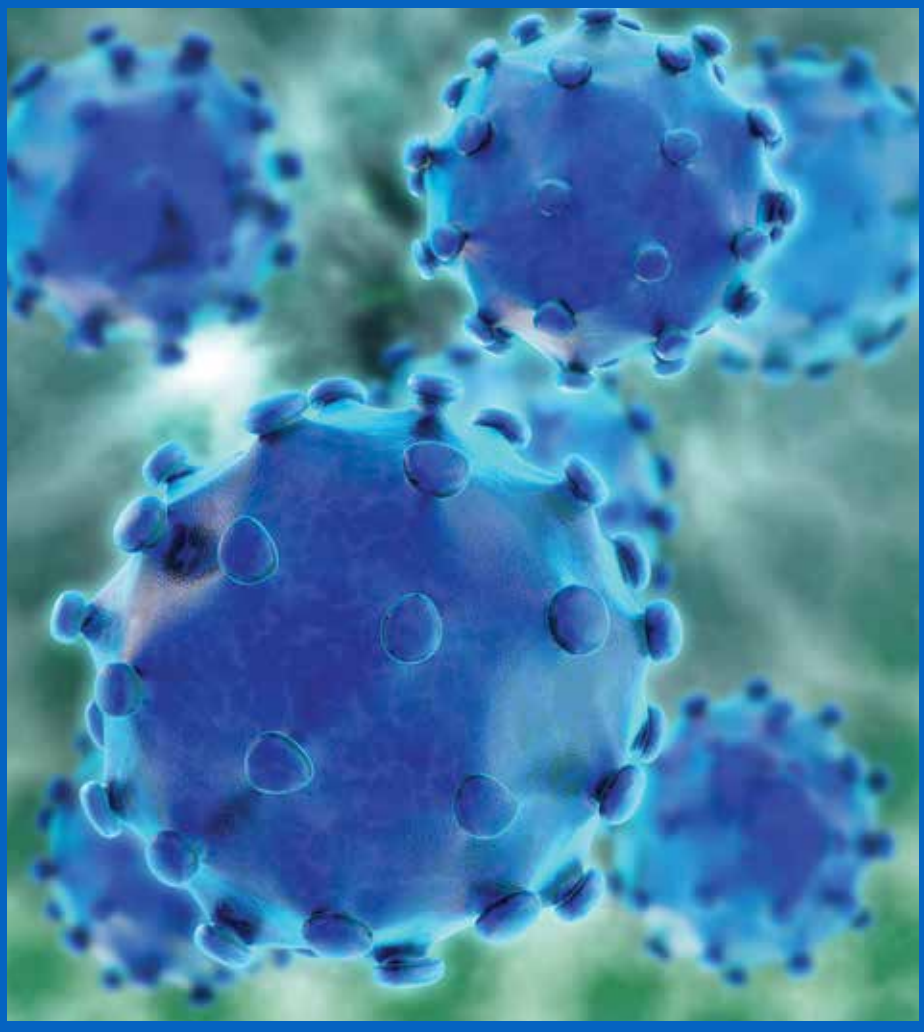
PEARL-III is a global, multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of 12 weeks of treatment with AbbVie's regimen with and without RBV in non-cirrhotic, GT1b HCV-infected, treatment-naïve adult patients.

The study population consisted of 419 GT1b treatment-naïve patients with no evidence of liver cirrhosis: 209 patients randomized to the regimen without RBV for 12 weeks, and 210 patients randomized to the regimen with RBV for 12 weeks. Following 12 weeks of treatment, 99.0 percent receiving the regimen without RBV (n=207/209) and 99.5 percent receiving the regimen with RBV (n=209/210) achieved SVR12. Patients in the treatment arm without RBV received placebo in substitution for RBV.

Across treatment arms in PEARL-III, there were no documented relapses within 12 weeks post-treatment. No on-treatment virologic failures occurred in the treatment arm without RBV and a single virologic failure occurred in the treatment arm with RBV. While all patients in the study completed therapy, two patients in the arm without RBV were lost to follow-up and therefore were considered treatment failures.

The most commonly reported adverse events (>10 percent for either arm) were headache, fatigue, pruritus, nausea and asthenia, with pruritus and nausea occurring at a statistically higher rate in the treatment arm with RBV compared to the arm without RBV. Anemia occurred more commonly among patients in the RBV-containing arm with clinically significant anemia requiring RBV dose reductions occurring in 9 percent of these patients.

Additional information about AbbVie's phase III studies can be found on www.clinicaltrials.gov. HIV



SHUTTERSTOCK

IN THE NEWS

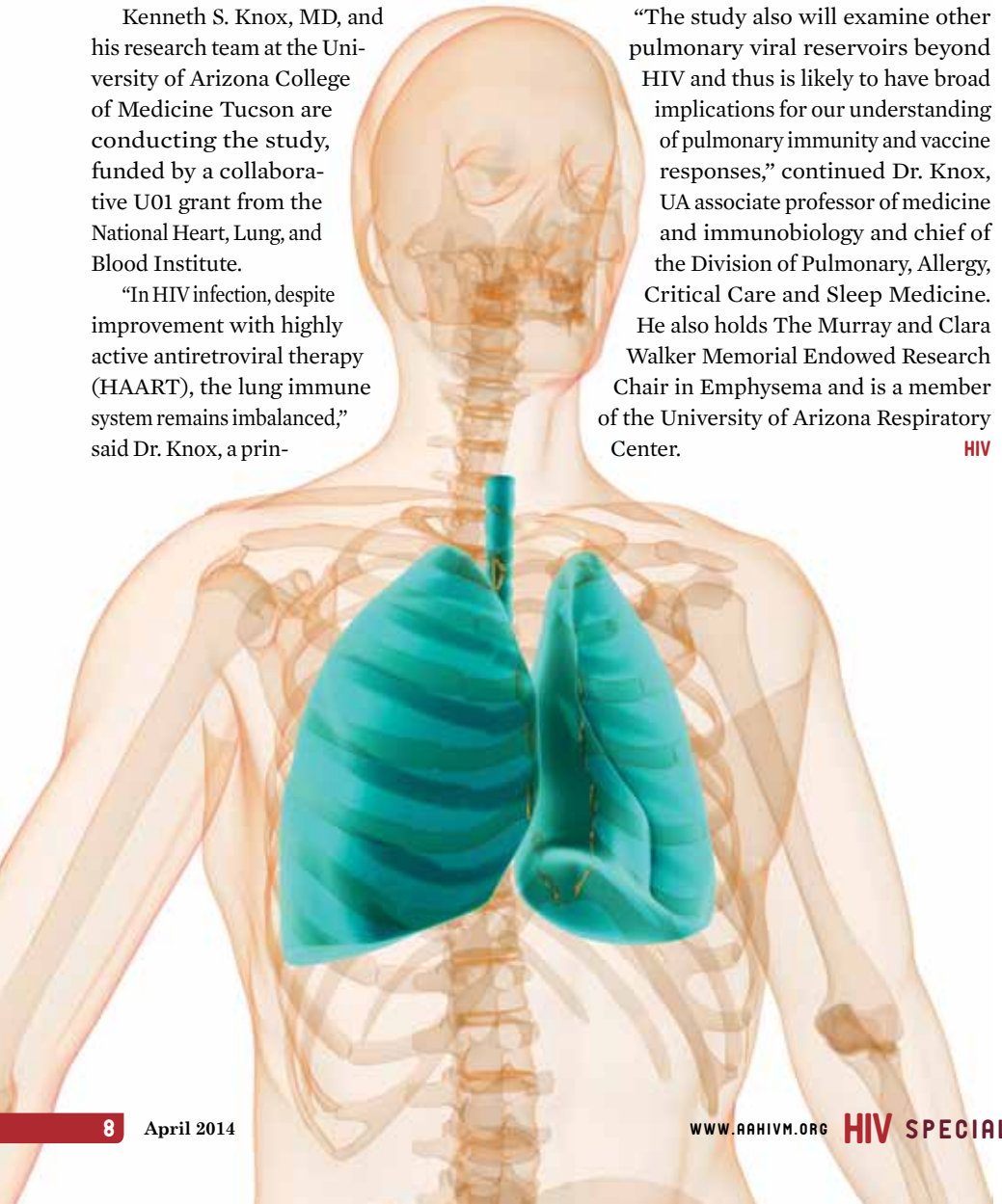
Research Studies Role of Pulmonary Inflammation in Development of HIV-Related Lung Disease

Because people infected with HIV commonly develop lung disease, including chronic obstructive pulmonary disease (COPD), pulmonary hypertension and immune reconstitution inflammatory syndrome (IRIS), new research is underway to determine the role pulmonary inflammation plays in the development of HIV-related lung disease.

Kenneth S. Knox, MD, and his research team at the University of Arizona College of Medicine Tucson are conducting the study, funded by a collaborative U01 grant from the National Heart, Lung, and Blood Institute.

"In HIV infection, despite improvement with highly active antiretroviral therapy (HAART), the lung immune system remains imbalanced," said Dr. Knox, a principal investigator on the multiple-PI study, which involves researchers at the University of Alabama, Indiana University and the Jackson Laboratory for Genomic Medicine. "The study's main hypothesis is that the presence of low-level HIV infection produces chronic inflammation in the lung, which drives the late pulmonary complications associated with HIV."

"The study also will examine other pulmonary viral reservoirs beyond HIV and thus is likely to have broad implications for our understanding of pulmonary immunity and vaccine responses," continued Dr. Knox, UA associate professor of medicine and immunobiology and chief of the Division of Pulmonary, Allergy, Critical Care and Sleep Medicine. He also holds The Murray and Clara Walker Memorial Endowed Research Chair in Emphysema and is a member of the University of Arizona Respiratory Center. HIV



THINKSTOCK

Study: Patients Co-Infected with HIV & HCV Susceptible to Liver Decompensation

Despite ART treatment, patients co-infected with HIV and hepatitis C virus (HCV) have higher rates of liver decompensation than patients with HCV alone, according to an article being published in *Annals of Internal Medicine.*

Up to 30 percent of patients with HIV also are often co-infected with HCV, and HCV-related liver complications are an important cause of morbidity in co-infected patients. While it has been suggested that ART slows HCV-associated liver fibrosis, it is unclear if rates of hepatic decompensation and other severe liver events in co-infected patients receiving ART are similar to those with HCV.

Veterans Affairs researchers compared health records for 4,280 patients co-infected with HIV and HCV who initiated ART with those of 6,079 veterans with HCV only to compare hepatic decompensation rates. Co-infected patients with HIV RNA levels less than 1,000 copies/ML had a lower rate of hepatic decompensation than those with a lesser degree of HIV suppression. However, the rate was still higher than that of patients with HCV alone. Higher rates of decompensation were seen in co-infected patients receiving ART who had baseline advanced liver fibrosis, severe anemia, diabetes, and were of nonblack race.

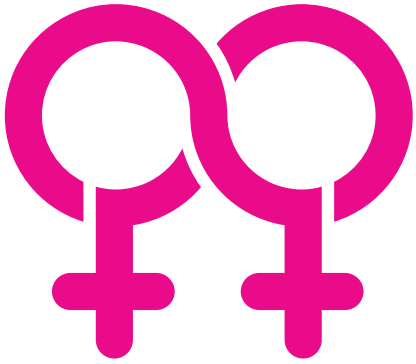
The article, "Hepatic Decompensation in Antiretroviral-Treated Patients Co-Infected With HIV and Hepatitis C Virus Compared With Hepatitis C Virus-Monoinfected Patients: A Cohort Study," is authored by M.J. Kallan, J.P. Tate, A.R. Localio, J.K. Lim, M.B. Goetz, M.B. Klein, D. Rimland, M.C. Rodriguez-Barradas, A.A. Butt, C.L. Gibert, S.T. Brown, L. Park, R. Dubrow, K.R. Reddy, J.R. Kostman, B.L. Strom, and A.C. Justice, and published March 17, 2014 in the *Annals of Internal Medicine.* HIV

US reports rare case of woman-to-woman HIV transmission

A rare case of suspected HIV transmission from one woman to another has been reported by US health authorities.

The 46-year-old woman "likely acquired" human immunodeficiency virus while in a monogamous relationship with an HIV-positive female partner in Texas, said the Centers for Disease Control and Prevention (CDC).

The woman, whose name was not released, had engaged in heterosexual relationships in the past, but not in the 10 years prior to her HIV infection. Her HIV-positive partner, a 43-year-old woman who first tested positive in 2008, was her only sexual partner in the six months leading up to the test that came back positive for HIV.



She did not report any other risk factors for acquiring HIV, such as injection drug use, organ transplant, tattoos, acupuncture or unprotected sex with multiple partners.

The strain of HIV with which she was infected was a 98 percent genetic match to her partner's, said the CDC. Authorities first learned of the case in August 2012 from the Houston Department of Health.

"They described their sexual contact as at times rough to the point of inducing bleeding in either woman," said the CDC report.

"They also reported having unprotected sexual contact during the menses of either partner."

The partner who was infected since 2008 had been prescribed antiretroviral drugs in 2009 but stopped taking them in November 2010, and was lost to follow up in January 2011. The CDC warned that although such cases are rare, "female-to-female transmission is possible because HIV can be found in vaginal fluid and menstrual blood." HIV

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Vaginal Gel May Prevent HIV Hours Following Exposure, Says Study

A new vaginal gel has the potential to protect women from HIV, even if it is applied several hours after sex, animal research suggests.

According to a CDC researcher, an antimicrobial gel protected five out of six monkeys from a hybrid simian/human AIDS virus when it was used three hours after exposure to the AIDS-causing virus.

The findings were reported by lead author Walid Heneine, a researcher in HIV/AIDS prevention for the U.S. Centers for Disease Control and Prevention.

The same gel also protected two out of three monkeys when applied a half-hour before HIV exposure, according to the study, published March 12 in *Science Translational Medicine*. Clinical trials are still needed, and Heneine said work is underway to improve the gel's effectiveness. Moreover, results of animal trials aren't necessarily replicated in humans.

The gel contains a 1-percent solution of the anti-HIV drug raltegravir (Isentress), and works by blocking the ability of the virus to integrate its DNA into the DNA of animal cells. Once the gel is applied, the HIV cannot transmit its DNA into cells, the researchers say.

Researchers first tested the gel's effectiveness pre-contact, by applying it to three monkeys who were exposed to HIV twice a week for seven weeks. By the end, two of the three remained HIV-free, compared with just one out of 10 monkeys in a group that received an inactive placebo gel.

The team then tested whether the gel could protect against HIV infection after exposure, using six monkeys exposed to HIV twice a week for two and a half months. By applying the gel three hours after exposure, researchers were able to protect five of the six monkeys from HIV infection. All four monkeys in the placebo group contracted HIV. HIV

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Immunizations for HIV-Infected Adults and Adolescents

PERSONS LIVING WITH HIV DISEASE require a series of immunizations that are generally the responsibility of the HIV provider who should be up-to-date on current guidelines. Accordingly, the Infectious Diseases Society of America (IDSA) recently updated its clinical practice guideline on vaccinations of individuals who are immunocompromised.[1] The Advisory Committee on Immunization Practices (ACIP) of Centers for Disease Control and Prevention (CDC) also recently released its annual recommendations.[2]

The ACIP adult vaccine schedule has been approved by the IDSA, American College of Physicians, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists.[3] Worth noting is that **not** all ACIP recommendations are consistent with U.S. Food and Drug Administration (FDA) licensing, although in most instances the IDSA guidelines are in agreement with CDC/ACIP recommendations, with a few exceptions.

There are several key points regarding immunizations in persons with HIV/AIDS diagnosis. First, HIV care providers must either assume or share responsibility with the primary care provider (if the patient has one) for ensuring that appropriate vaccinations are administered to all their patients. The IDSA guidelines also state that HIV specialists share responsibility with the primary care provider for recommending appropriate vaccinations for members of immunocompromised patients' households. With few exceptions, immunocompetent persons who reside in a household with an HIV-infected individual can safely receive recommended vaccines based on the ACIP/CDC vaccination schedules for children and adults[1,2]. These include: inactivated influenza vaccine (IIV) or live attenuated influenza vaccine, combined measles, mumps, and rubella (MMR), rotavirus vaccine and zoster vaccine. In addition, yellow fever vaccine and typhoid for travel can safely be given. However, oral polio vaccine (OPV) should not be given to household members.

Level of Immune Suppression

Both the IDSA guidelines and ACIP make recommendations based on a patient's CD4+ T lymphocyte count. The ACIP recommendations vary some based on a cut-off of < or > 200 cells/mm3. The IDSA guidelines consider "low-level immunosuppression" to include asymptomatic HIV-infected patients with CD4 T-lymphocyte counts of 200–499 cells/mm3 for adults and adolescents. Patients with "high-level immune suppression" include those with HIV infection and a CD4 T-lymphocyte count <200 cells/mm3 for adults.

SPECIFIC VACCINES

Haemophilus influenza type b Vaccination

Previous ACIP vaccine guidance recommended that giving Haemophilus influenza type b vaccine (Hib) to persons with HIV "be considered". The updated guidance **NO longer** recommends Hib vaccination of previously unvaccinated adults with HIV infection because the risk for this infection is very low.

Hepatitis A Vaccination

Hepatitis A vaccine is safe and highly immunogenic in HIV-infected patients. Specific indications include men who have sex with men, persons who use injection or non-injection illicit drugs, persons with chronic liver disease, and persons traveling to or working in countries with high or intermediate endemicity of Hepatitis A. The vaccine should be given as a two-dose series at 0 and then at six to 12 months. It can also be given as a three-dose series with hepatitis B vaccine (Twinrix) at zero, one, and six months. Worth noting is that seroreversion occurs in 10 percent of vaccinated persons within two years. Giving an additional booster dose of HepA vaccine if necessary is appropriate and will usually generate high antibody titers.

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BY JEFFREY T. KIRCHNER, DO, FAAFP, AAHIVS

The Advisory Committee on Immunization Practices (ACIP) of Centers for Disease Control and Prevention (CDC) also recently released its annual recommendations.

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Hepatitis B Vaccination

Hepatitis B vaccine should be given to all HIV-infected patients as a three-dose series with the second dose at least one month after the first dose and the third dose at least four months after the first dose. The vaccine can also be given as a three-dose series with hepatitis A vaccine (Twinrix). Immunogenicity is low in this population with only 18-72 percent of patients developing protective level of antibody following the three-dose series. One to two months after completion of the three-dose series patients should be tested for anti-HBS. If the antibody titer is < 10 mIU/mL, a second three-dose series should be given with either standard or high-dose (40g). The IDSA guidelines note as an alternative, one high-dose of HepB vaccine can be given after which anti-HBS should be tested. An additional recommendation is given for patients who are anti-HBC positive (antibody to core antigen) to also receive a 3-dose HBV series if the they are negative for HBV DNA.

Human Papillomavirus Vaccination

Human papillomavirus vaccine (HPV) is recommended for HIV-infected persons, both males and females through the age of 26 years if they did not receive the vaccine when they were younger. A complete series consists of three doses with the second dose given four to eight weeks after the first dose. The third dose should be given 24 weeks after the first dose and 16 weeks after the second dose. The four-

valent vaccine is recommended over the bivalent vaccine because HPV4 prevents genital warts. However, there are no data on differences between bivalent vaccine (HPV2) and HPV4 for preventing cervical dysplasia in HIV-infected women.

Both the IDSA guidelines and ACIP makes recommendations based on a patient's CD4+ T lymphocyte count.

Influenza Vaccination (IIV)

Inactivated influenza vaccine (IIV) should be given annually to all adults with HIV. Antibody responses are diminished in persons with low CD4+ counts, particularly if they are not receiving treatment for HIV. The efficacy and clinical effectiveness ranges from 27 percent to 78 percent. In contrast to earlier reports, administration of influenza vaccine does not appear to impact HIV-RNA levels.

The IDSA and the ACIP do not express a preference for standard dose over high-dose vaccine for persons who are immunocompromised and/or aged 65 years or older. However, a recent study of 190 HIV- infected persons found that high-dose trivalent vaccine produced higher levels of influenza antibody if compared to standard-dose.[4] Another recent randomized trial including 32,000 adults age under 65 years found that the high-dose influenza vaccine was 24 percent more effective than standard flu vaccine in preventing influenza.[5] It is not clear whether these newer data will change future adult influenza immunization recommendations.

Meningococcal Vaccine

HIV-positive adults should not be routinely vaccinated with the meningococcal vaccine. Those who are eligible should receive two doses of meningococcal quadrivalent conjugate (MCV4) at least two months apart. This includes adults of all ages with functional asplenia or persistent complement deficiencies.

Revaccination every five years is recommended for adults previously vaccinated who remain at increased risk for infection. No mention is made by the IDSA or ACIP regarding vaccinating men who have sex with men. However, in a recent publication in the *Annals of Internal Medicine*, officials from the New York City Department of Health urged all men who have sex with men, especially those attending the city's Gay Pride events, to be vaccinated against meningitis.[6]

Pneumococcal Vaccines

The 13-valent pneumococcal conjugate vaccine (PCV13) should be administered to all HIV-infected adults. The 23-valent pneumococcal polysaccharide vaccine (PPSV23) should be given > eight weeks after PCV13 and ideally to patients with a CD4 T-lymphocyte count of > 200 cells/mm3. For persons with a CD4 T-lymphocyte count < 200, the IDSA guideline states the vaccine may be given but lists this as a "weak" recommendation. Revaccination should be offered to these patients once antiretroviral therapy has resulted in a CD4 count > 200. A second dose of PPSV23 should be given five years after the initial dose. Some clinicians elect to continue giving the 23-valent vaccine at 5-year intervals although there is no evidence to support this practice.

Tetanus, Diphtheria, acellular Pertussis Vaccination

All HIV-infected adults should receive one dose of Tdap vaccine after the age of 11 if they have not received a prior dose or if prior vaccine status is unknown. The Tdap can be given regardless of the time interval since the last tetanus or diphtheria-toxoid containing vaccine. A tetanus and diphtheria toxoids (Td) should then be given every 10 years. One dose of Tdap vaccine should be given to pregnant women during each pregnancy at 27 to 36 weeks gestation regardless of the interval since the prior Td or Tdap vaccination.

Varicella Vaccination

The ACIP recommends this vaccination for varicella non-immune (IgG negative) HIV-positive persons > 14 years and who have a CD4 T-cell lymphocyte count of > 200 cells/mm3. Two doses of the vaccine are recommended, separated by > three months. Although there is efficacy and safety data for HIV-positive children with varicella vaccine there is no comparable data for HIV-infected adults.

Zoster Vaccination

The IDSA guideline states this vaccine is **contraindicated** for persons with HIV disease regardless of whether they have high or low-level immunosuppression. The ACIP state the vaccine is **contraindicated** in HIV-infection with a CD4+ T lymphocyte count of < 200 cells/mm3 and make no recommendation for patients with a count > 200. An ACTG study presented in 2012 found two doses of zoster vaccine to be safe and efficacious

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(based on VZV antibody titers) in almost 400 HIV-positive adults [7] For non-HIV adults, Zoster vaccine is recommended by the ACPP for adults aged 60 years or older regardless of whether they had a prior episode of herpes zoster. The vaccine has FDA approval for healthy persons age 50 year or older.

Future directions and gaps in knowledge regarding vaccinations in HIV-infected persons

The IDSA guidelines note several key clinical areas where data from clinical studies is needed. These include:

- When is the optimal time to initiate vaccinations after starting cART for HIV infection?
- What are the indications for and effect of revaccination of patients who were vaccinated before starting cART?
- What is the efficacy and safety of HBV vaccination for persons who are anti-HBs negative but anti-HBc positive?
- What is the efficacy and safety of Zoster vaccination? HIV

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Hi-Tech, Hi-Care

AAHIVM/Institute for Technology in Health Care HIV Practice Awards

BY BOB GATTY

IN SAN FRANCISCO, Dr. Joanna Eveland, MS, MD and her multidisciplinary HIV team at the Clinica Esperanza Mission Neighborhood Health Center use technology's power to keep track of patients, even those living on the street, and get those in need into care.

"What it is doing is letting us work as a much more efficient team. Our clients want to stay virally suppressed and stay in care, but sometimes they need extra help to do so. There is always someone on our team who knows where to find them, even if they're living under a bridge. These are people who otherwise would slip quietly out of care."

The tool Dr. Eveland and her team is using is the i2iTracks Population Health Management software (www.i2isys.com), implemented in 2011, with usage expanded over the past three years to facilitate linkage and retention, as well as treatment adherence for a high-risk population.

As a result of that effort, Dr. Eveland was selected as one of two winners of the 2014 AAHIVM/Institute for Technology in Health Care HIV Practice Award and was given a $10,000 award.

McCrosky

In the Arizona desert, Steve McCrosky, MSN, FNP, AAHIVS, has implemented multiple telehealth technologies to improve and expand direct clinical care services that help him serve some 200 patients who live in a vast area that takes some seven hours to travel from the eastern-most clinic to the western-most. He also is a $10,000 AAHIVM Technology Award winner.

McCrosky, who sees patients through North Country HealthCare (NCHC), Flagstaff, is spread thin.

"People living with HIV in northern Arizona face multiple barriers to accessing HIV specialty care," he explained. "The few certified HIV specialists and infectious disease physicians in the region are located only in larger cities and geographical distances make travel by patients and providers expensive and time consuming. Small HIV panel sizes, ranging from one patient to 30 patients per city, make it challenging for a community to offer a local provider certified and experienced in HIV specialty care."

Because of this time and distance problem, McCrosky normally would be able to see patients face-to-face from once a month to once every six months, depending upon the number of patients attending the clinic. But through the telemedicine system, meant to augment, not replace, existing services, he can see them as often as twice weekly.

"If you are in a small town with HIV, you can connect with me even though I won't be there in person for the next several months," he explained.

So through the creative and effective use of technology, Dr. Eveland and McCrosky are able to treat patients in need, regardless of whether they live under a San Francisco bridge or in a tiny desert community in Arizona. The bottom line is that technology is enabling this care, which otherwise might not be—most probably would not be—provided to patients who are desperately in need.

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Improved Outcomes

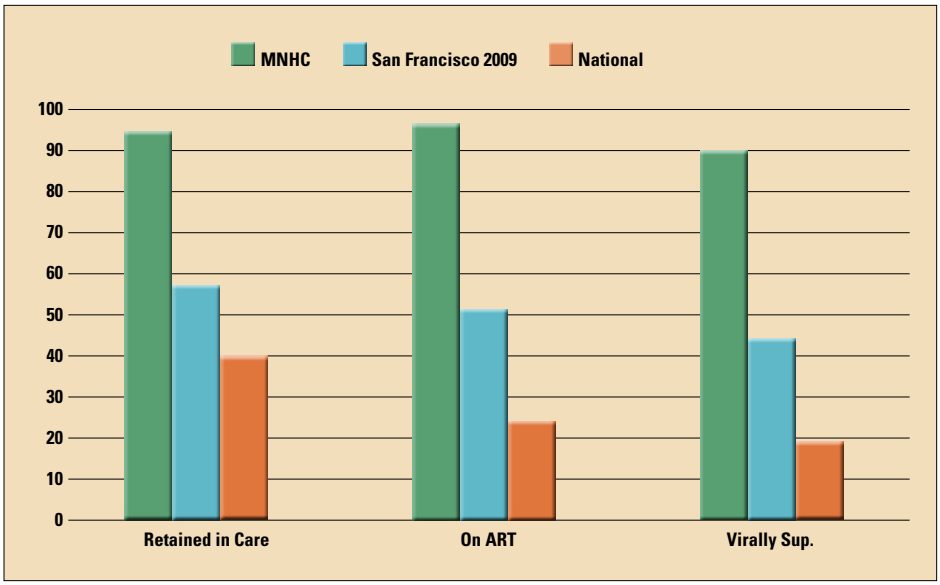
While Dr. Eveland stressed that the service at Clinica Esperanza, which serves about about 400 HIV+ patients annually, "was very strong" before the i2i Tracks software was implemented, she said it has consistently improved outcomes over time and has made a big difference. "Now, people have an understanding how their work with individual clients fits in with the outcomes for the whole population," she said. "We have shown some critical improvements, going from excellent to really outstanding."

She explained that the software has allowed the clinic to shift from a system based on annual audits to real time population management. I2i stands for "interface-to-interface," and the program inputs data from the Electronic Health Record, practice management system, laboratory, and manually entered data to populate an easily searchable database that can be accessed by any staff member.

"While we are not the first HIV clinic to use i2iTracks, our incorporation of this technology into the workflow of every member of our multidisciplinary staff has transformed a strong team into an outstanding team, with clinical outcomes that stand in stark contrast to national data," she said. "Our commitment to training staff on the use of this technology helps guide interventions and QI processes at all levels in our HIV practice."

Dr. Joanna Eveland (front row, center) says her team at Clinica Esperanza (Clinic of Hope) was already outstanding, but that implementation of i2i has even improved upon that level of service.

Before i2iTracks was implemented, Dr. Eveland said the clinic's focus primarily was on individual patients rather than the whole patient population. "We saw most of our patients doing fairly well, but knew that some vulnerable individuals stopped medicines or fell out of care. Now, we can rapidly generate a list of all patients with an elevated viral load who are overdue for follow up, make a plan to reengage them, and evaluate the effectiveness of that plan."



Implementation of i2iTracks Population Health Management software has helped Clinica Esperanza/Mission Neighborhood Health Center dramatically exceed the rates in San Francisco and nationally for patients retained in care, on ART, and those who are virally suppressed.

The technology is now fully in place for tracking HIV core indicators, added Dr. Eveland. "We continue to expand its use to improve management of other chronic diseases which affect our HIV positive patients, including Hepatitis C co-infection and Diabetes, to track vulnerable subpopulations, such as transgender patients and smokers, and to improve health care maintenance."

She pointed out that recently there were clients who did not have phone access or housing, so it was difficult to find them. "When we reviewed the list of those out of care at our weekly team meeting, a peer advocate noted that these missing clients were actually attending support groups at our HIV prevention center down the street. We were able to reach out through this group and reengage them in care."

Extending Care

Meanwhile, at NCHC in Flagstaff, AZ, the video network used by McCrosky provides a two-way secure video feed within a local area network that covers the main facility Flagstaff and satellite clinics throughout the region. The service is augmented by a variety of telehealth services, including telenutrition, behavioral health counseling, teledermatology, a network-enabled stethoscope, and continuing education teleconferences.

Equipment includes a camera that can be moved around the room as needed, peripheral devices for dermatology consults, the Bluetooth-enabled stethoscope and software that connects to McCrosky's laptop computer. The medical assistant in the local clinic places the scope over the heart of the patient, and McCrosky can listen to the signal as though he were actually there.

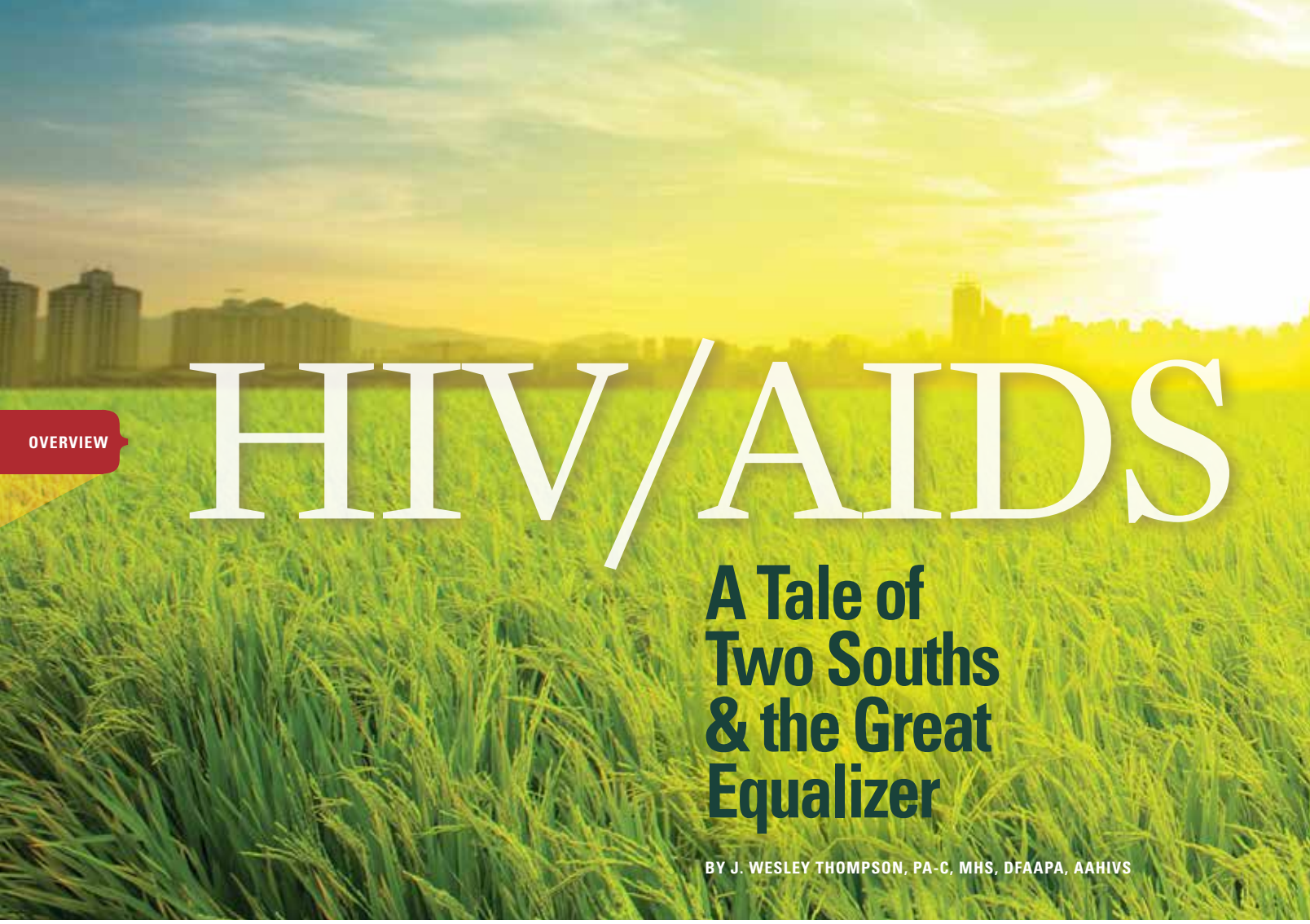
"I use it every day in my practice," he said. "It is really remarkable."

Video telemedicine, he added, allows for more frequent "check-ins" for patients with medication adherence issues, mental health and substance abuse problems. Video appointments also can be created immediately for evaluation of post-exposure prophylaxis candidates.

Behavioral health appointments, said McCrosky, allow access to mental health services in communities where access to this care is often limited. "Improved behavioral health leads to better health outcomes for people living with HIV and reduced community viral load," he said.

"All of these services combined can lead to improved quality of life for people living with HIV/AIDS, encouraging others to engage in appropriate care," he added. "By providing greater access to care and allowing people with HIV to enter a care system more quickly, a rural program can reduce its community viral load more quickly, thereby reducing the risk of transmission to others."

All of this is precisely why AAHIVM and the Institute for Technology in Health Care launched the annual HIV Practice Award in 2012. The point is to demonstrate effective and practical uses of technology in improving patient care for those living with HIV. HIV



OVERVIEW

HIV/AIDS

A Tale of Two Souths & the Great Equalizer

BY J. WESLEY THOMPSON, PA-C, MHS, DFAAPA, AAHIVS

GONE WITH THE WIND are the Antebellum days of Scarlet O'Hara's Old South. Since the Civil War (AKA the War of Northern Aggression), the New South has experienced unprecedented economic growth. However, it seems A Tale of Two Cities is a more accurate literary representation.

As the first chapter opens: "It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness, it was the epoch of belief, it was the epoch of incredulity, it was the season of Light, it was the season of Darkness, it was the spring of hope, it was the winter of despair, we had everything before us, we had nothing before us, we were all going direct to Heaven, we were all going direct the other way..."

And so it seems when one observes the disparity in prosperity between our southern metropolitan areas and our southern rural areas.

Except for HIV/AIDS. The great equalizer of the South.

When we compare the rural South to the metropolitan areas of the South, there is little difference in the HIV/AIDS epidemic. In 2011, the Southern states of Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Texas made up 37 percent of the US population, yet accounted for 49 percent of all new HIV/AIDS cases.

These targeted states had the highest new HIV diagnoses rates, as well as the highest AIDS mortality rates. Seven of the 10 metropolitan areas with populations of at least 500,000 with the highest HIV diagnoses rates were in these targeted Southern states and they also have the highest number of individuals living with HIV, death rates greater than the US average, and the highest STI rates.

HIV/AIDS disproportionately affects Blacks, Latinos, the poor, and the disenfranchised in both the rural South and in the Southern metropolitan areas. And while these two Souths may look very different, the unmet needs of these groups are very similar. Access to healthcare, transportation, food security, housing security, childcare, consistent telephone service, for example, are challenges for both South lands.

In addition to unmet needs, there is stigma and discrimination to the vulnerable sub-populations, such as men who have sex with men (MSM), transgender/transidentified individuals, and sex workers. The stigma and discrimination occurs both from within and from outside of these groups.

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in the South

Religious persecution in the Bible Belt states is rampant. The dichotomy between love and judgment within our houses of worship, particularly, impact these vulnerable groups.

Healthcare and Other Concerns

While access to healthcare is being addressed through the implementation of the Affordable Care Act (ACA), the targeted states region is unlikely to benefit from the ACA because none of those states have elected to implement Medicaid expansion yet. They are likely to experience a greater disparity in the resources available to individuals living with HIV/AIDS.

Many of the unmet needs our patients experience in the rural South, as well as in the metropolitan areas, are due to poverty. Poverty reaches 50 percent or more in many areas. A collaborative partnering at the local, state, and federal level is required to address the unmet needs tied to poverty.

The stigma and discrimination from without and within the vulnerable groups are more complex. What our patients espouse in the office is often not what is espoused in the barber shops and beauty salons.

Distrust, misinformation, and suspicion must be dispelled calmly, with patience and forgiveness. The medical community has proffered much harm to our patients, including The Tuskegee Syphilis Trials between 1932 & 1972, the pseudoscience of reparative/conversion therapy, the outcasting/second classing of transidentifying patients, and the marginalizing of sex workers.

The Southern medical community's knowledge base must be improved, as well as the patient knowledge base. There is a misconception in both communities that HIV is a death sentence.

The Multicenter AIDS Cohort Study (MACS) of 1984 stated a patient diagnosed with HIV at that time had approximately 18 months to live. With the advent of highly active antiretroviral therapy (HAART) in 1995, the paradigm of palliative care shifted to one of longer life. Indeed in 1997, the MACS reassessed the data and decided a patient had approximately 10 years to live. In 2010, the MACS reassessed the life span to 20 years. And in 2012, the data revealed that with proper adherence to medications coupled with diet and lifestyle modification, HIV would not appreciatively shorten the lives of patients.

As I travel the Southern US lecturing on HIV/AIDS, I am continually amazed at medical professionals and patients who are unaware of this data.

The medical community is woefully undereducated on post exposure prophylaxis (PEP). Emergency Departments (ED's) in many hospitals have refused to test and start PEP, despite state guidelines being amended to match the CDC recommendations.

Pre-exposure prophylaxis (PrEP) with Truvada is understood even less. Despite the literature citing 96 percent efficacy with daily use, matching condom efficacy, the medical community has been slow to discuss and prescribe PrEP because of a general concern that prescribing PrEP will promote sex without a condom.

As a medical provider in the daily trenches of HIV/AIDS care, I can confirm we have already lost the battle in condom use. Condom fatigue and sero-sorting have won out.

A Team Effort

President Obama, in his World AIDS Day address December 2, 2013, referenced the three goals of the National HIV/AIDS Strategy (NHAS): 1) reducing HIV incidence, 2) increasing access to care and optimizing health outcomes, and 3) reducing HIV-related health disparities. He said the success we have experienced in the field of HIV care has not been achieved by a single government or foundation or corporation working alone. It is the result of countless people.

In our clinic, the healthcare team includes the receptionist, the nursing staff, the phlebotomist, the billing clerk, medical records, the patient advocates, the physician assistant, the physician, and yes, the cleaning crew. From the clean rooms we use, to the medications we prescribe, each of us contributes to the care of our patients.

HIV/AIDS IN THE SOUTH

Seeking Resources to Fight the Epidemic

Southern HIV/AIDS Strategy Initiative

BY CAROLYN MCALLASTER

With funding from the Ford Foundation, the Southern HIV/AIDS Strategy Initiative (SASI) was launched by the Duke AIDS Legal Project in 2011. That year, The Centers for Disease Control (CDC) revealed 2009 surveillance data showing that half of new HIV diagnoses in the US were in the South.[1]

Just the year before, in 2010, President Obama announced the first ever National HIV/AIDS Strategy (NHAS)[2] providing a road map for the goals of reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV and reducing HIV-related health disparities. The NHAS identified the South as a "geographic hot spot," and acknowledged that the South is "disproportionately impacted by HIV."[3]

SASI was formed with the goal of ensuring that NHAS implementation included a federal commitment for coordinated resources focused on the South, which was and remains, at the epicenter of the current HIV epidemic in the United States. SASI is led by a Steering Committee of HIV advocates from 9 Southeastern states[4] that works closely with a research team based at the Duke Center for Health Policy and Inequalities Research to develop evidence-based policy and strategy recommendations. SASI works in coalition with close allies, including the Southern AIDS Coalition, the Harvard Center for Health Law and Policy Innovation, and AIDS United.

SASI's research reports have documented that for a subset of nine deep south states, Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee and Texas, the CDC HIV surveillance data is particularly striking. This region has the highest rate of new HIV and AIDS infections and the highest HIV case fatality rates.[5]

SASI reports have highlighted the disproportionate impact of HIV on African Americans and Latinos in the South with African Americans accounting for 56 percent of new HIV diagnoses in the South between 2005 and 2008 and half of the new HIV diagnoses among Latinos occurring in the South.[6] Fifty percent of men and 71 percent of women diagnosed with HIV in the South between 2005 and 2008 were African American.[7] African American women represent the largest recent disparity, with the majority of new HIV diagnoses (71 percent).[8]

Young MSM (men who have sex with men) are particularly impacted by HIV. MSM accounted for 49 percent of HIV transmissions in the nine deep south states in 2009, followed by heterosexual contact (27 percent).[9]

SASI's research-based advocacy with the White House Office of National AIDS Policy (ONAP), Health and Human Services (HHS) and the Centers for Disease Control (CDC), among other federal agencies, has not only served to highlight the burgeoning HIV epidemic in the South, but also has produced direct tangible results.

- In 2012, HHS announced $44 million in funding for Care and Prevention in the United States (CAPUS) Demonstration Project. CAPUS funds are designed to reduce HIV-related morbidity, mortality, and related health disparities among racial and ethnic minorities. Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases at HHS, specifically credited SASI's advocacy along with that of the 30 for 30 campaign and the Presidential Advisory Council on HIV/AIDS (PACHA) for the CAPUS funding. Six of the eight states funded were southern states.[10]
- CDC recently released a new Request for Proposals (RFP) to enhance HIV prevention and care and 4 of the 9 states eligible to apply are deep south states.[11]
- SASI's advocacy with ONAP resulted in a May 2013 announcement by then ONAP

In Charlotte and surrounding communities, our HIV care team includes the community based organizations (CBO's), AIDS Service Organizations (ASO's), local pharmacists and their adherence counseling, philanthropists small and large, houses of worship, civil society, activists, and most of all, our patients who have stood up and demanded care with dignity and respect.

So where do we go from here?

The Southern HIV/AIDS Strategy Initiative (SASI) report, *HIV/AIDS in the Southern US: Trends from 2008–2011 Show a Consistent Disproportionate Epidemic,* has identified the need for a "holistic approach that includes local, state, and federal partnerships and has addressed the multiple factors that contribute to the disproportionate epidemic in the South, such as lack of resources and regional resource inequities, as well as stigma and high STI rates, are needed to adequately address HIV in the region."

Only through partnership and collaboration can we address the epidemic of HIV in the South. Communities, states, patients, and the entire healthcare teams must work together to define the need, identify the resources and opportunities, and enact change.

Maybe then we will have the new New South. HIV

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director, Dr. Grant Colfax, that the White House and the Department of Health and Human Services would co-host a White House Meeting on HIV in the South. The initially scheduled meeting was postponed because of the government shut down in October, 2013, but the White House has committed to conducting the meeting in 2014.

- In 2012 and 2013, SASI worked in coalition with AIDS United, the Southern AIDS Coalition and the Treatment Access Expansion Project to bring southern HIV advocates to Washington DC for AIDSWatch. Advocates have met each year with members of Congress and with policy makers at HHS and ONAP to provide them with SASI's research reports on the southern HIV epidemic and to request resources for our region.

What's Ahead

In 2014, with the continued support of the Ford Foundation and new funding from the Elton John AIDS Foundation, SASI will refine its research agenda to look closely at three-to-five-year survival rates and HIV case fatality rates in the deep south and to examine whether there are differences in survival rates by race, gender, or transmission category.

The team will also look at whether other factors predict survival after HIV diagnosis. A close review of the demographics, the HIV-related prevention and care infrastructure, and community characteristics of some of the southern "hot spots" is also on the SASI agenda.

The research team will update the original SASI report, *HIV/AIDS Epidemic in the South Reaches Crisis Proportions in the Past Decade* (originally released in 2012) and will look closely at our hardest hit populations: MSM, particularly African American MSM, African American women, and Latinos. Finally we will examine the widening resource gap between the states that have expanded Medicaid under the Affordable Care Act and those that have not.

SASI will continue to work with regional partners to inform its research and advocacy goals, to share state and regional based research, and to strengthen grassroots strategies in the southern region.

Some of SASI's policy goals for 2014 include advocacy in support of continued funding for the Ryan White Care Act, support of Congressional action to make federal housing funds through Housing Opportunities for Persons with AIDS (HOPWA) more equitable,[12] monitoring the implementation of the CAPUS grants in six southern states, and continuing to work with the White House and HHS on the White House Meeting on HIV in the South.

To get on SASI's list serve, please e-mail sasi@law.duke.edu. Like us on Facebook: http://goo.gl/jhezjR or follow us on Twitter @SASICoalition. HIV

ABOUT THE AUTHOR:
Carolyn McAllaster is a Clinical Professor of Law and the Director of the Duke Legal Project in Durham, NC.

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10 http://southernaidsstrategy.org/capus/

11 Center for Disease Control and Prevention. Secretarys Minority AIDS Initiative Funding to Increase HIV Prevention and Care Service Delivery among Health Centers Serving High HIV Prevalence Jurisdictions.: Centers for Disease Control; 2014. Eligible deep south states are Alabama, Florida, South Carolina and Texas. Additional eligible states: California, Maryland, Massachusetts, Michigan, and New York

12 See http://southernaidsstrategy.org/research/ for SASI's research report analyzing HOPWA's grant funding formula.

HIV/AIDS in the South; Frankly, No One Gives A Damn

CALL 911!! There is an emergency and no one has answered our call.

AS A MEDICAL PROVIDER for people living with HIV/AIDS in rural North Carolina, I feel compelled to address the distinctive epidemics of HIV/AIDS and sexually transmitted infections (STIs) and their disparate impact on people living in rural, isolated impoverished communities in the south, particularly in North Carolina.

Located just south of the Virginia border in rural north central North Carolina (NC), the Warren-Vance Community Health Center's (WVCHC) target population is drawn from a six-county area with a high percentage of at-risk minorities living in poverty. The service area, which includes Warren, Vance, Granville, Franklin, Person and Halifax counties, is designated as a Medically Underserved Area (MUA) and a Health Professional Shortage Area (HPSA). Poverty is at 50 percent and public transportation is nonexistent. Alarming rates of teen pregnancy and preventable, chronic diseases such as HIV/AIDS and syphilis consistently contribute to sky-high morbidity and mortality rates among the African-American and Hispanic populations, which continue to increase. *WVCHC is the only HIV Specialty clinic with Infectious Disease trained, HIV certified providers and in-house case management services in a 2,079 square mile region.*

Transportation problems and lack of telephone service and complete plumbing and kitchen facilities are far too common issues for our patients. A few years ago, we had an HIV infected patient who, after repeated visits with our doctor and medical case manager, was still having low CD 4 cell counts and a very small decrease in the viral load. After conducting a home visit, we found that the patient did not own a refrigerator and lived in a community where the only store was a gas station convenience store. The patient was taking ritonavir gel capsules which required refrigeration. The unrefrigerated capsules melted together so he wasn't taking them with the Protease Inhibitor (PI) to give the boosted effect. As a result, the PI was ineffective. Unfortunately, this is typical of the obstacles our patients face living in isolated rural communities. With unreliable transportation and no kitchen facilities, the patient explained to our case manager that he could only buy non-perishable food from the gas station and this made it difficult for him to have food to eat with his medication. He was not intentionally non-adherent to his treatment plan; his life circumstances and socioeconomic condition prevented him from being able to keep his HIV in control. Examples such as these scream out the need for additional resources for basic daily needs.

The median household income in our service area ranks in the lower 10 percent of all NC counties with the unemployment rate at 11.1 percent for the service area compared to the state rate of 8.5 percent (North Carolina Employment Security Commission, June 2013). Perhaps the most shocking and disturbing statistic of the service area population is the percentage of children and elderly living in poverty. According to the recent U.S. Census, in Halifax County 33 percent of the children and 22.4 percent of the elderly live in poverty; in Vance County 27.7 percent of the children and 19.3 percent of the elderly live in poverty; and in Warren County 24.9 percent of the children and 20.8 percent of the elderly live in poverty. Compared to the state poverty rates (child: 15.7 percent and elderly 13.2 percent), our service area is a distressed community with the brunt of the economic impact felt by the most vulnerable: our children and our elders. This sense of economic despair ultimately leads adolescents and young adults to poor choices often involving prostitution and/or drug use.

As the HIV/AIDS epidemic continues to increase in the south, state governments refuse to find or use federal / state dollars for disease prevention interventions, support or treatment of people living with HIV/AIDS and/or STIs[1]. Of the nine targeted states in the south, eight have flat out refused to expand Medicaid under the provisions of the Affordable Care Act. The median family income for a person living with HIV/AIDS in Vance County is $15,000, qualifying many of them for Medicaid. In North Carolina, however, Medicaid is available only to the disabled poor. With exceptions, such as pregnant women, individuals over 18 years of age living in poverty but without a Social Security Administration disability determination are not eligible for Medicaid. NC legislatures voted to refuse expansion of Medicaid. As a result, about 30 percent of our patients who would have qualified for Medicaid

Clinic Bridge Counselor, Rita Cozart with Sharon Burwell, clinic RN.

BY DR. MICHELLE COLLINS-OGLE

will continue to be uninsured and require Ryan White funded services. More importantly, these patients do not have enough money to afford insurance even with the federal subsidies. NC legislatures voted to NOT allow state based marketplace insurance exchange. The result is only two insurance companies with marketplace plans. These plans are expensive and are not options for our uninsured patients with such low incomes. These so called "legislators" do not care about the HIV epidemic and how it negatively impacts the citizens in the south who are also their constituents.

This epidemic will continue to increasingly and disparately claim the lives of poor and disenfranchised populations, particularly in the rural south. If we are really serious about meeting the goals of the National HIV/AIDS Strategy (NHAS), then we must insist on a rural HIV/AIDS strategy which will sustain the lives of folks currently living with HIV/AIDS and STIs.

The NHAS 12 Cities Project, serves as a proving ground to establish how the broad range of Federally-supported HIV prevention, care, and treatment activities can work more effectively across organizational and program boundaries[2]. Interestingly, this effort purports to result in better identification of and response to service gaps and unmet needs. The Rural South continues to experience unmet needs, inadequate funding to serve vulnerable sub-populations and lack a uniform approach to the treatment of HIV/AIDS and STIs in these resource poor settings. In fact, there is no place with more unmet needs than the Rural South, yet our communities were not considered in this federal initiative. Of the 12 cities, only four are located in the Deep South and they are all major metropolitan cities (Dallas /Houston TX, Miami FL and Atlanta GA)[2].

It is unquestionable that what works in Atlanta will not meet the needs of resource deficient areas in rural NC, SC, LA, MS, GA or AL. If our state and federal government agencies are serious about an "AIDS Free Generation" I would advocate for a robust, standardized and coordinated delivery system in the rural communities in the southern states. I propose a Rural HIV/AIDS Treatment Strategy (RHATS). If we are committed to eliminating disparities in HIV/AIDS and STIs, we must provide a standardized and synchronized healthcare infrastructure in the rural south which would encompass a comprehensive range of services for individuals / families with HIV/AIDS and STIs to meet their "unmet" needs. This initiative requires consideration to the distinct cultural norms of the South.

Lastly, we must also address the stigma and discrimination of vulnerable HIV infected sub-populations such as men who have sex with men (MSM) and transgender individuals. MSM, especially African American MSM in rural areas continue to be at risk for HIV and Syphilis[3]. The "Moral" hypocrisy of the Bible Belt State conservatives is astonishing to say the least. These same Christians prohibit our southern residents from speaking openly about sexual topics, including birth control and condom use. The public school systems are reluctant to distribute accurate, age appropriate prevention messages to our youth. The Bible is used to spout bigotry and "correctness" which contributes to the discrimination and high risk behavior by isolating minority MSM and condemning their way of life. This is also true for our transgender community. The net effect of this hypocrisy is the inability of these individuals to gain employment, housing and access to care. We must speak to the unique culture of the Rural South and the various sub-populations existing within the southern culture. This would positively impact our ability to provide a comprehensive range of services for individuals with HIV/AIDS and STIs to meet their health care and psychosocial needs throughout their illness. In addition, we must provide prevention and interventions tailored to the needs of the southern states. This is germane to a successful RHATS and NHAS. HIV

ABOUT THE AUTHOR

Dr. Michelle Collins-Ogle is the Medical Director of The Warren-Vance Community Health Center, Inc. in Henderson, NC. Dr. Ogle received her undergraduate degree at the University of Michigan Ann Arbor, Michigan and her medical degree from Wayne State University, Detroit. She trained in Pediatrics and Infectious Diseases at Children's Hospital of Michigan. She currently serves on the Steering Committee for the Ryan White Medical Provider's Coalition. She is a member of HIVMA, AAHIVM and Pediatric Infectious Disease Society.

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Clinical Pharmacist Interventions

Impact of an Intensive HIV Adherence Counseling Program at a Ryan White Part D Clinic in South Alabama

BY SOMER L. SMITH, PHARM.D., AAHIVP; HAIDEE CUSTODIO, M.D.; JOHN VANDEWAA, PhD,D.O.

VIRAL LOAD (VL) suppression is a significant indicator of medication adherence, client health, and quality of care.[1] A VL less than 200 copies/mL suggests good medication compliance and viral suppression, which in turn affects disease progression.

Additionally, the highest level of antiretroviral therapy (ART) adherence possible for a given patient helps to minimize viral mutations and keep therapy options available for the longest time possible. Studies have shown that poor treatment adherence is a strong predictor of HIV progression to AIDS. An added benefit of suppressed viral loads is decreasing transmission, both perinatal and sexual. [2-3]

Both retention in care along with adherence to treatment are closely associated with optimal health outcomes and cost effectiveness. Most published reports reveal typical adherence rates to ART in the 50 to 75 percent range and are a universal challenge to care. 2 Predictors of poor adherence are concurrent psychiatric illnesses (especially depression), drug and/or alcohol use, history of non-adherence, side effects (metabolic and morphologic), and lack of education about treatments. Adherence versus compliance demonstrates collaboration between the patient and the provider, as patients become actively involved in their health and developing medication plans. An established relationship of trust between patient and provider is essential to patient participation in medication adherence and is achieved through retention in care.[1-3]

While, newer ART treatments have reduced the pill burden of these complex regimens and yield far less intolerable side effects, barriers to treatment adherence still exist in achieving successful life-long therapy.

The University of South Alabama Family Specialty Clinic (USAFSC), located in Mobile, has been the sole referral clinic for Ryan White Part D services spanning from Mississippi to the Florida panhandle since 2001. In an effort to improve adherence to ART, retention in care, and viral load suppression, USAFSC proposed to start a program for intensive medication adherence counseling and intervention for fiscal year 2013 (FY2013).

Methodology

As a proactive response to this challenge, a pharmacist certified with American Academy of HIV Medicine's Credentialing Program was hired to spearhead the intensive medication adherence program. The objective was to assess outcomes by measuring and monitoring viral load suppression rates and CD4 T-cell counts of patients on ART and retained in care. USAFSC set a goal of at least 80 percent of clients on ART to have viral loads less than 200 copies/mL and 85 percent of clients on ART to have a CD4 T-cell count greater than 350 copies/µL.

The pharmacist provided initial counseling and education on adherence and baseline assessment of labs (VL, CD4) for approximately 200 total patients on ART, initiating ART, or with each change in ART. Adherence assessments were provided at each three-month follow-up appointment. The pharmacist made phone follow-ups for missed appointments, medication refills, and medication pick-up.

A uniform adherence counseling document was utilized with each clinic visit that included an evaluation of each client's medication profile, CD4 T-cell and VL trends, changes

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USAFSC Clinical Outcomes	Baseline August 2011–July 2012	FY 2013 (August 2012–August 2013)	P-value
CD4 Counts > 350 cells (for clients on ART)			
Total Patients with CD4 > 350 on ART	103	161	
Total Patients with CD4 ≤ 350 on ART	27	29	
Performance	79.00%	85.00%	0.2316
Viral Load (VL) Suppression < 200 copies (for clients on ART)			
Total Patients with VL < 200 copies on ART	90	152	
Total Patients with VL ≥ 200 copies on ART	40	38	
Performance	69.00%	80.00%	0.0338

in medications, patient knowledge of medication, number of missed doses in the past month, and barriers to adherence. This document was generated in the patient's electronic medical chart. The pharmacist reviewed with the patient about his/her perception of health goals, HIV disease and purpose of ART, role of adherence and consequence of non-adherence.

The pharmacist worked with the providers to identify barriers to non-adherence, focusing on prior and current causes of non-adherence so that subsequent new regimens were not likely to fail due to uncorrected problems. The pharmacist provided less complex regimens by changing all or parts of patient's ART to facilitate a better match of acceptable side effects, pill burden, dosing and timing. Many times the pharmacist was able to identify and resolved these problems in one follow-up appointment or phone call, as well as identify psychosocial issues earlier during phone follow-ups before the patient's regularly scheduled appointment.

Literacy barriers were identified and addressed as early as the initial visit and tools were created (color coding labels, medication pictures, unit dosing) to help the patient understand medication directions. Medication adherence tools and devices, such as pillboxes, reminder watches, alarms, supported computerized devices and applications were suggested for patient use and provided if the clinic had them available.

The pharmacist also works with the patients to problem-solve and develop strategies on how to take medications in places where they might have to hide to take their medicines, such as work, public places or in the presence of family members who are unaware of the HIV status.

Data Analysis

Outcomes data were collected utilizing electronic medical record systems CAREWare and NEXTGEN. Each indicator was measured against target benchmarks to determine: how our program compared to national benchmarks (HIVQUAL); whether or not our objective was met or exceeded for the indicator; and whether health outcomes for our clients have improved, declined, or remained the same.

Subjective and objective data collection were utilized to measure patient adherence and included pill counts, electronic monitoring, patient self-report, and pharmacy refill records. Statistical analysis included Fischer's exact test with two-tailed

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Patient Demographics at USAFSC	%
Patient Ages	
0-12 years old	5%
13-24 years old	17%
Females and Males ≥ 25 years old	78%
Race/Ethnicity	
African American	87%
Caucasian	11%
> 1 Race	2%
Hispanic	0%
Gender	
Female	89%
Male	11%
Clients by Exposure Category	
Perinatal Transmission	19%
Heterosexual Contact	81%

P values. Each month, the pharmacist collected data outlining performances on specific clinical indicators (VL, CD4). The findings were presented at quarterly quality meetings.

Results

Active clients were defined as patients with at least one primary care visit to USAFSC within the data collection period. Viral load suppression was defined as a VL < 200 copies/mL and retention in care was measured as patients with at least two primary care visits at least three months apart within each data collection period. Baseline data was retrospectively collected for August 2011-August 2012 and compared to monthly outcomes from August 2012-August 2013.

Approximately, 211 patients were active clients in care at the start of the FY2013 and 148 for the baseline year. Of the 148 active clients during the baseline year, 130 (88 percent) were retained in care and of these, 90 (69 percent) patients were on ART and achieved viral load suppression and 103 (79 percent) with a CD4 count of greater than 350 copies/µL. Of the 211 active clients during FY2013, 190(90 percent) were retained in care and of these, 152 (80 percent) patients were on ART and achieved viral load suppression and 161 (85 percent) with a CD4 count of greater than 350 copies/µL.

Discussion

After implementation of the pharmacist-driven intensive medication adherence program, the primary outcomes of achieving 80 percent viral load suppression and 85 percent CD4 counts greater than 350 copies/µL for retained patients on ART were both accomplished.

Retention and care and adherence to ART are both necessary for optimal health outcomes for patients living with HIV/AIDs as well as cost effectiveness of interventions. Implementing an adherence program was the beginning of resolving both issues of retention in care and adherence to medications at USAFSC. Identifying barriers to medication adherence prior to initiation of ART, during therapy, as well as frequent follow-up by the pharmacist helped to facilitate patient retention in care and effective outcomes of therapy.

Although this study is of short duration, the pharmacist interventions and outcomes continue to be collected and reported each month. Limitations of potential confounders such as literacy level, disclosure of status, depression, socioeconomic issues, stigma and substance abuse were taken into account and screened for at each initial and follow-up appointment. HIV

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BEST PRACTICES

BY BRIAN R. WOOD, MD AND KENTON T. UNRUH, PhD

Building Mentorship Networks for Providers in Rural and Underserved Areas

The NW AETC ECHO Program

CLINICIANS IN UNDERSERVED AND RURAL AREAS are critical to the fight against HIV. However, providers in these settings, who are often primary care practitioners, may not have access to the latest in evidence-based HIV medicine or may lack the infrastructure for specialized psychosocial support of HIV-infected patients. Comprehensive support of these community providers is necessary to increase HIV care quality and effectiveness.

To address this need, the Northwest AIDS Education and Training Center (NW AETC) and University of Washington in 2012 developed a collaborative, real-time, video-based mentorship and consultation program called NW AETC ECHO (Extension for Community Health Outcomes).

Modeled after Dr. Sanjeev Arora's of the University of New Mexico's seminal Project ECHO concept, the program connects HIV providers in rural and underserved areas to an interdisciplinary panel of specialists (infectious disease, psychiatry, pharmacy, nursing, and social work) for weekly mentorship through didactics, clinical case consultation, and discussion of best practices.

The program connects HIV providers in rural and underserved areas to an interdisciplinary panel of specialists.

Participating clinicians (spanning five states in the Pacific Northwest, including Alaska) attend simultaneously via live interactive video and present their clinical cases to the interdisciplinary panel for real-time discussion. All participants listen to each case and ask questions or offer advice based on their experience in similar settings.

Preliminary program assessment indicates that, over time, participants' HIV knowledge increases, as does their confidence in caring for individuals with HIV in their practice setting. The impact is broadened because participants report sharing new knowledge with their local clinical staff.

Moreover, participants who otherwise felt isolated begin to develop a network of professional support, and qualitative feedback indicates that feelings of professional isolation decrease. In this way, NW AETC ECHO moves beyond the classic one-to-one consultation model to provide longitudinal mentoring for HIV providers with the main objectives of: stimulating knowledge sharing, facilitating a learning community, and building capacity.

For example, a provider in a rural area of Montana was challenged by a complicated case of a pregnant patient with HIV who had a long history of poor adherence to antiretroviral therapy as well as multiple medical comorbidities.

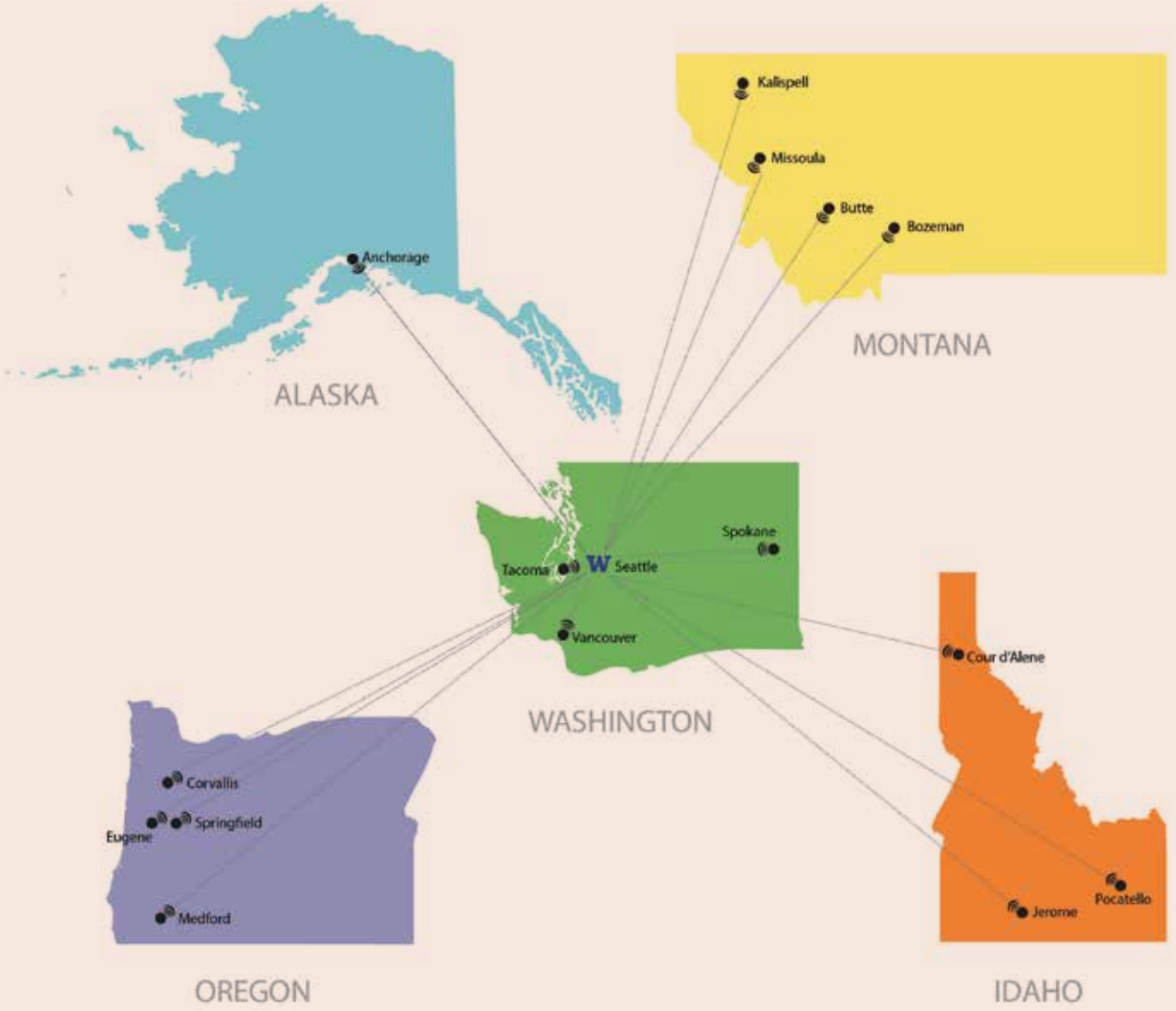
This provider presented the case to the ECHO network regularly throughout the pregnancy, receiving advice from the expert panel and additional input from participating providers around the Northwest. With this support, the provider was able to help the patient achieve the lowest viral load she had in years. Despite an early and precipitous delivery, staff involved were prepared and the baby remains HIV-uninfected.

Now, as other participants care for pregnant patients with HIV, the provider shares her knowledge and experience via the ECHO network, distributing the birth plan she created to help guide others and offers advice based on her experience. In this way, the ECHO program amplifies learning and fosters mutual support amongst providers who share similar practice settings but remain geographically disparate.

The NW AETC ECHO program is just over two years old and recently celebrated its 100th weekly session. To date, the program has provided 310 real-time consultations via the ECHO video network to providers at 15 sites around the Northwest.

SHUTTERSTOCK

NW AETC ECHO sites



The weekly didactic talks, posted online and made freely available, have been viewed over 6,000 times in 77 countries and on six continents. We believe ECHO is a model and a program that can improve care quality by facilitating support amongst providers and by providing longitudinal mentorship to those without specialty training.

In the changing landscape of healthcare in the United States, we believe it is a model that can be cost-effective and should be explored in areas where there remains a need for specialty support and continuing education for providers. For more information: http://depts.washington.edu/nwaetc/echo/. HIV

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HIV-Age.org Launched by AAHIVM

AAHIVM STAFF have been working in the field of HIV and LGBT aging issues for several years. Basic knowledge of the demographics of the baby boomer generation itself presents a challenge to all working in the field of HIV.

Given the experience of the early days of the epidemic, it was inconceivable then to be thinking about HIV and Medicare, or HIV and senior citizens, or "retiring with HIV" in the same sentence; not to mention the possibility of an HIV patient dying of old age and not an opportunistic infection. Since the introduction of the "HIV cocktail" in the 90s, all this has changed dramatically.

In 2006, the AIDS Community Research Initiative of America (ACRIA) published its historic and outstanding research called the ROAH Study (Research on Older Adults with HIV). Its participating 1,000 older adults with HIV disease resulted in remarkable data that is still being analyzed and used by clinicians and researchers around the world.

In November 2008, Stephen Karpiak, PhD, director of research for ACRIA, was asked to come to the AAHIVM offices and present on the results of the study to our staff. The eye opening presentation compelled the Academy to respond. The need for the world of HIV medicine and the world of Geriatric medicine to become collaborating, knowledgeable partners in the new reality of HIV and aging also became obvious.

Academy staff spent the next several months seeking funding for what would be called "*The HIV and Aging Consensus Project*," which was subsequently supported by Janssen Pharmaceuticals, Inc., ViiV Healthcare, Strativa Pharmaceuticals, and the Campbell Foundation. The two-year project was designed to bring together in an expert panel, both HIV specialists and Geriatric specialists.

The two Co-PIs of the project were both HIV and Geriatric specialists; Jonathan Appelbaum, MD, FACP, AAHIVS from Florida State University, College of Medicine and long time AAHIVM board member, and Wayne C. McCormick, MD, of the University of Washington, Department of Medicine, Division of Gerontology and Geriatric Medicine, Harborview Medical Center, and board member of the American Geriatrics Society.

The project required a partnership with two key national organizations with expertise in this field so the American Geriatrics Society and AIDS Community Research Initiative of America joined in on the project.

Key to the outcome of this effort was the selection of the expert panel to research and write the chapters of the document which was published by the Academy in November of 2011 entitled: *The HIV and Aging Consensus Project: Recommended Treatment Strategies for Clinicians Managing Older Patients with HIV.*

The Need for an HIV & Aging Clinical Online Community

If there is one constant in the field of HIV medicine, it is that of constant change. The science of HIV is an ever changing landscape of new research findings, new medications with new targets and also new side effects. In addition to new populations affected by the epidemic, such as the elderly, there is the ever demanding goal of seeking an actual cure for HIV disease.

Because of this constant change, every study, recommendation for treatment, and area of study within the field of HIV medicine is in need of constant updating to keep abreast of the changes. The authors of the *HIV & Aging Recommendations* were acutely aware of this fact. In the brief time from the publishing of the document in 2011 until now, there are many additions, updating of information and re-writes to be completed to keep the document vibrant and relevant.

In anticipation of this reality both the planning committee and expert panel suggested that the recommendations be

kept as a "living document" and that an **HIV & Aging Online Clinical Community** be established where a healthy, vibrant dialogue among practitioners, and others could be held. Suggestions for changes to the *HIV & Aging Recommendations* document would come from those practitioners currently treating elderly HIV patients. And each of the chapters originally published in 2011 will be updated by it author to reflect changes since then within their particular topic.

And as the entire field of HIV & Aging continues to grow, there is a need for a "go to" place for information and resources to assist providers, researchers, journalists, clients and the general public to find resources like; relevant journal articles, case histories, up and coming HIV & Aging Conferences, and links to other HIV organizations who include aging programs. In addition, the site contains editorials from experts in the field on emerging topics and trends, and spotlights on "hot topics." Most sections of the site provide the reader with the ability to comment to keep the dialogue on HIV & Aging alive and dynamic for the good of all interested in this field of HIV/Geriatric medicine.

Funding for HIV-Age.org

None of this important work can be accomplished without a sizable amount of dedicated funding. After several months of research and proposals sent to various sources, the Archstone Foundation, a private foundation formed in 1985, and headquartered in San Diego, CA, responded with a generous grant to the Academy to see the HIV-Age.org site become a reality.

Prior to the Academy's relationship with the Foundation, its board of directors determined that it should target its focus exclusively on issues of aging. Archstone also has taken a leadership role in the field of aging. After two decades of operation, and over 800 grants, the Foundation's grantmaking commitment has surpassed the initial endowment with over $86 million in grants awarded.

The mission of the Archstone Foundation is to contribute toward the preparation of society in meeting the needs of an aging population. The funding of HIV-Age.org is the foundations' first support of an HIV related program.

The success of any site on the internet is the way in which it encourages participation from its readers. The Academy staff and planning team urge you to see the blog in action by becoming a participant; go to HIV-Age.org and add your voice to this "living document." HIV

ABOUT THE AUTHOR:
Ken South is the director of credentialing programs at AAHIVM. He is also the manager of the HIV & Aging initiative.

Who We Are

This HIV & Aging Clinical Online Community is is presented by the American Academy of HIV Medicine, (AAHIVM), and its partners, ACRIA, (the AIDS Community Research Initiative of America) and the American Geriatrics Society, (AGS)

It is supported by a generous grant from the Archstone Foundation.

The Managing Committee for the site includes:

Medical Director:

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Laurie L. Dozier Jr., M.D.,
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Tallahassee, FL

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Fellow, Division of Geriatrics

Amber McCracken
Marketing & Communications Director
American Academy of HIV Medicine

AMERICAN CONFERENCE FOR THE TREATMENT OF HIV (ACTHIV)

May 8 - 10, 2014
Sheraton Downtown Hotel
Denver, Colorado

DON'T MISS the upcoming American Conference for the Treatment of HIV (ACTHIV), to be held May 8 - 10, 2014 in the beautiful Mile High City of Denver, Colorado. The 2014 conference will feature a wide variety of relevant topics, an exhibit hall, poster sessions and great networking opportunities.

ACTHIV is a state-of-the-science conference specifically targeted toward US frontline providers of care to persons at risk of, or with HIV infection. Physicians, physician's assistants, nurses, pharmacists, medical case managers, social workers, psychologists, mental health and substance abuse workers, treatment advocates, educators, and other healthcare professionals involved in caring for those infected with HIV are encouraged to attend.

SESSION HIGHLIGHT

Thursday, May 8th , 1:00 pm–2:00 pm

"Paperless Records & HIV Clinical Care With a Laptop!"

PRESENTING:

Joanna Eveland, MS, MD, AAHIVS
Clinica Esperanza
Mission Neighborhood Health Center
San Francisco, CA

Steve McCrosky, FNP, AAHIVS
North Country HealthCare
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