Pharmacological Challenges

Aging Consensus Project Report

Older Patients Speak Out

Treatment Strategies

HIV & aging

Treatment Strategies for Clinicians Managing Older HIV Patients
A surge of evidence supports treating HIV earlier

- 2011 DHHS guidelines:
  - HAART is recommended for patients with a CD4 cell count of 350–500 cells/mm³
  - Half of the Panel favors initiating HAART for patients with a CD4 cell count >500 cells/mm³, while the remainder views HAART as an option
  - As part of the consideration for earlier initiation of HAART, the Panel cites both the benefits and potential limitations

- Significant improvement in patient survival
- Better long-term CD4 cell count
- Significant reduction in the probability of morbidity
- Lower probability of HIV transmission

▶ Talk to your patients and help them understand the potential of earlier initiation of HAART.

DHHS=Department of Health and Human Services.
*69% increase in relative risk of death when treatment was deferred until CD4 cell count was ≤350 cells/mm³ (versus initiating at 351–500 cells/mm³; P<0.0001) and 94% increase in relative risk of death when treatment was deferred until CD4 cell count was ≤500 cells/mm³ (versus initiating at >500 cells/mm³; P<0.0001), based on the NA-ACCORD analysis.
*After 6 years, patients with a baseline CD4 cell count >500 cells/mm³ achieved and maintained nearly normal CD4 levels with HAART (versus ≤350 cells/mm³) in an observational analysis.
*Earlier initiation (>350 cells/mm³) was associated with significantly reduced probability of opportunistic disease (OD), serious non-ADs events, and non-OD deaths in an analysis of the SMART study.
CDC Awards $55 million for HIV Prevention Among Youth of Color

The Centers for Disease Control and Prevention (CDC) has awarded $55 million over five years to 34 community-based organizations (CBOs) to expand HIV prevention services for young gay and bisexual men of color, transgender youth of color, and their partners. The awards expand upon a previous program with an increase of $10 million to fund additional community organizations. The average award for each organization is approximately $300,000 per year.

The new CDC awards are designed to enable CBOs with strong links to these populations to meet their specific HIV prevention needs. As part of these awards, each organization will be required to provide specific prevention services, including HIV testing and linking those who are HIV-infected to care and prevention services. CBOs will also carry out proven behavioral change HIV prevention programs and distribute condoms to young gay and bisexual men and transgender youth of color who are at high risk for HIV or are HIV-infected.

HHS Awards $1.89 Billion in Grants for HIV/AIDS Care and Medications

The U.S. Department of Health and Human Services (HHS) has announced the release of more than $1.89 billion in Ryan White funds to ensure that people living with HIV/AIDS continue to have access to health care and medications.

Approximately $1.21 billion will be sent to states and territories under Part B of the Ryan White Program. In FY 2011, $885 million was appropriated for the AIDS Drug Assistance Program (ADAP). Part B awards also include formula base grants that can be used for home and community-based services, insurance continuation, ADAP assistance, and other direct services.

Sixteen states will also receive Emerging Community grants based on the number of AIDS cases over the most recent 5-year period. A total of $8,386,340 in Part B Supplemental grants was awarded to 36 states and territories that demonstrated need based on the severity of the HIV/AIDS epidemic in the state/territory, including service needs of emerging populations, unmet need for core medical services, and unique service delivery challenges.

From the ADAP appropriation, 30 Part B States and Territories will receive $40 million Emergency Relief Funding to help eliminate or reduce ADAP waiting lists and/or supporting cost containment strategies to prevent implementation of a waiting list, HHS reported.

$645 million was awarded to 52 cities for core medical and support services for individuals living with HIV/AIDS under Part A of the Ryan White Program. These funds go to eligible metropolitan areas with the highest number of people living with HIV/AIDS and to areas experiencing increases in HIV/AIDS cases and emerging care needs.
Thirty Years in the Making:
Recommended Treatment Strategies for Clinicians Managing Older Patients with HIV

It has been thirty years since the first AIDS cases were reported in the United States. Defined typically as a young gay men's disease at the time, it was also considered a death sentence for most. Sure there were some that survived, and yes there were some older patients—but not many.

Effective treatment now greatly extends the lives of those with HIV such that by 2015, one-half of all persons with HIV in the US will be age 50 and older. That good news, however, is coupled with the reality that many older adults are developing conditions more commonly associated with advanced aging. The treatment of these co-morbidities, as well as HIV infection, presents new challenges for HIV practitioners—but without any real clinical guidance.

This issue of the HIV Specialist focuses on the development of “treatment strategies” for the clinician treating these older HIV patients. They are the result of a collaboration of American Academy of HIV Medicine (AAHIVM), the American Geriatrics Society (AGS) and the AIDS Community Research Initiative of America (ACRIA). This project started over two years ago when ACRIA gave a presentation to the AAHIVM staff on its seminal research study Research in Older Adults with HIV (ROAH) of nearly 1,000 New York City older adults living with HIV. We came to better understand how rapidly the HIV epidemic was now aging, largely as a function of the enormous improvements in HIV treatment over the past 30 years.

AAHIVM approached the AGS to consider partnering to develop a clinical guidance for practitioners who were already treating older patients. The AGS agreed and, after initial funding was secured, Dr. Wayne McCormick, a member of its board of directors, and Dr. Jon Appelbaum, from the AAHIVM board of directors, were selected as the Principal Investigators. Both Drs. Appelbaum and McCormick are practicing geriatricians as well as HIV specialists. Over the intervening eighteen months, a fourteen-member expert panel was convened. They authored this comprehensive report by contributing chapters from their respective fields of experience.

A summary of the treatment strategies and an interview with Appelbaum and McCormick appear in this issue. In addition, a PDF of the entire 90+ page report can be found on the Academy website (www.aahivm.org). We feel confident this report will contribute to the quality of care delivered to older patients living with HIV disease.

We acknowledge that there remain substantial gaps in our knowledge base. Therefore, it is our intention to keep this process open and to continually update this resource via an interactive website that will allow practitioners and researchers to report on their clinical experience with older HIV patients. This interactive blog that will encourage comments and updates from clinicians and researchers from across the globe (www.aahivm.org/hivandagingforum).

In addition to our thanks to Drs. Appelbaum and McCormick and all the panel members for their expertise and generosity, we acknowledge the enormous efforts of AAHIVM’s Ken South, Marianna Drootin of the American Geriatrics Society, and Stephen Karpia, PhD and Dr. Richard Havlik of ACRIA. Similarly, we thank Tibotec (now Janssen Pharmaceuticals), Strativa Pharmaceuticals, and the Campbell Foundation. Without their generous support, this undertaking would not have been possible.
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HIV does not discriminate. Seniors need counseling so they can protect themselves.

BY BOB GATTY, EDITOR, HIV SPECIALIST

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Dr. Robert James ‘Bob’ Fraschino

A life devoted to the fight against HIV

About the photos: The cover photo and the photos of Anna Fowlkes, Bill Rydewals, Ronald Johnson and Sue Saunders in “Patients Speak Out” are by photographer/writer Katja Heinemann. Working with writer/co-producer Naomi Schegloff, MPH, Ms. Heinemann created The Graying of AIDS, an ongoing multimedia documentary project and educational campaign that combines portrait photography with oral and video histories and health education materials to promote awareness, increase dialogue between older adults and their care providers, and advocate for improvements in the care of older adults at risk for or living with the virus. To learn more about The Graying of AIDS, please visit the project website at www.grayingofaids.org.
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Please see following pages for brief summary of the COMPLERA Full
Prescribing Information, including Boxed WARNINGS about lactic
acidosis, severe hepatomegaly with steatosis, and exacerbations
of hepatitis B upon discontinuation of therapy.
**COMPACT** (200 mg/rifampin 25 mg) once daily for 6 months was better tolerated than rifampin 300 mg/day once daily for the duration of 6 months.** ADVISORY** on the future of this drug is pending further trial results.

**INDICATIONS AND USAGE**

**COMPACT** (200 mg), previously labeled as rifapentine/ethambutol combination, is indicated for use as a complete regimen for the treatment of H.I. infections in combination with ethambutol.

**CONTRAINDICATIONS**

**COMPACT** (200 mg) is contraindicated in patients with known or suspected hypersensitivity to rifapentine or ethambutol.** ADVISORY** on the future of this drug is pending further trial results.

**WARNINGS**

**Acute Hepatitis**

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**INTERACTIONS**

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As our HIV-infected patients are living longer, they are living with multiple co-morbidities, including Non-AIDS-Defining Cancers (NADCs). We have seen this trend in many cohorts since the advent of HAART in 1996 and the data are clear that this trend is continuing in the post-HAART era.

One of the later recognized and ever-increasing NADCs is ano-rectal cancers. Earlier data analysis has shown that the rate of virtually all NADCs began to climb in the early post-HAART era. Current data shows us that “Although the rate of ADCs [AIDS-Defining Cancers] continues to fall, the rate of NADCs is rising and now accounts for the majority of cancers in HIV-infected persons.”

The development of NADCs is associated with increasing age among HIV patients. This data also observes that HAART use has been protective for ADCs, but has not shown a significant impact on NADCs.

Within the group of NADCs, anal cancer, although of relatively low prevalence compared with other cancers, has increased exponentially relative to both historic rates in the HIV-infected populations in the pre-HAART era and to the non-infected general population.

Prior to HAART, Bower M et al showed that the rate of anal cancer in HIV-positive MSM was 35 per 100,000 persons, and in the post-HAART era that number has tripled to 92 per 100,000 persons. Many other cohorts have also seen similar or still worsening trends in the HIV-infected community, and others more specifically in the MSM HIV-infected community.

Squamous cell carcinoma of the anal canal (SCCA) has been found to be etiologically linked to human papillomavirus (HPV), and its incidence is increased among the immunosuppressed. This is true for both women and men co-infected with HIV and HPV.

Although in the pre-HAART and early post-HAART eras we have seen more women developing SCCA than men, that gap may be narrowing. Palefsky, et al showed in one cohort of 357 MSM who underwent anal cytology HPV testing, and high-resolution anoscopy with biopsy for detection of AIN, that a full 81 percent had Anal Intraepithelial Neoplasia (AIN) of any grade and 52 percent had grades II and III. AIN II and III represent High Grade Anal Intraepithelial Neoplasia (HGAIN) lesions and are at a higher risk of developing SCCA.

As mentioned earlier, as with other studies, Palefsky’s data also “…indicate that HAART is not associated with a reduced prevalence of AIN and support measures to prevent anal cancer among HIV positive MSM whether or not they are using HAART.” Additional study cohorts also support this data.

Testing and prevention strategies have been recommended by multiple groups and proposed algorithms have been available to the HIV/AIDS treating community since at least 2001. In 2008, Scott, et al performed Routine Anal Cytology Screening for Anal Squamous Intraepithelial Lesions in an urban HIV clinic and found that “Routine anal cytology screening is a feasible tool to incorporate into HIV care for patients regardless of gender and HIV risk factors.” The group also noted the importance of further study on its impact on morbidity and mortality.

More recently at this year’s Conference on Retroviruses and Opportunistic Infections (CROI), Timothy Wilkins, MD, with Weill Cornell Medical College, presented updated compelling data on testing for, detection of, and treatment of HGAIN. He concluded that “HPV-associated anal cancer continues to be a significant issue for HIV-infected patients...and...Screening programs for AIN should be strongly considered.”

The data and information presented here See Best Practices on page 14
Post-marketing cases of liver injury, including some fatalities, have been reported. These have generally occurred in patients with advanced HIV-1 disease taking multiple concomitant medications, having co-morbidities including hepatitis B or C co-infection, and/or developing immune reconstitution syndrome. A causal relationship with PREZISTA/ritonavir therapy has not been established.

Appropriate laboratory testing should be conducted prior to initiating therapy with PREZISTA/ritonavir and patients should be monitored during treatment. Increased AST/ALT monitoring should be considered in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pre-treatment elevations of transaminases, especially during the first several months of PREZISTA/ritonavir treatment.

Evidence of new or worsening liver dysfunction (including clinically significant elevation of liver enzymes and/or symptoms such as fatigue, anorexia, nausea, jaundice, dark urine, liver tenderness, hepatomegaly) in patients on PREZISTA/ritonavir should prompt consideration of interruption or discontinuation of treatment.

Severe Skin Reactions
During the clinical development program (n=3063), severe skin reactions, accompanied by fever and/or elevations of transaminases in some cases, have been reported in 0.4% of subjects. Stevens-Johnson Syndrome was rarely (<0.1%) reported during the clinical development program. During post-marketing experience toxic epidermal necrolysis has been reported. Discontinue PREZISTA/ritonavir immediately if signs or symptoms of severe skin reaction are noted. These can include but are not limited to severe rash or rash accompanied with fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, hepatitis and/or esophagitis.

Rash (all grades, regardless of causality) occurred in 10.3% of subjects treated with PREZISTA/ritonavir [also see Adverse Reactions]. Rash was mostly mild to moderate, often occurring within the first four weeks of treatment and resolving with continued dosing. The discontinuation rate due to rash in subjects using PREZISTA/ritonavir was 0.5%.

Sulfa Allergy
Darunavir contains a sulfonamide moiety. PREZISTA should be used with caution in patients with a known sulfonamide allergy. In clinical studies with PREZISTA/ritonavir the incidence and severity of rash was similar in subjects with or without a history of sulfonamide allergy.

Drug Interactions
See Table 1 for a listing of drugs that are contraindicated for use with PREZISTA/ritonavir due to potential life-threatening adverse events, significant drug-drug interactions, or loss of therapeutic effect to PREZISTA [see Contraindications]. Please refer to Table 8 for established and other potentially significant drug-drug interactions [see Drug Interactions].

Diabetes Mellitus / Hyperglycemia
New onset diabetes mellitus, exacerbation of pre-existing diabetes mellitus, and hyperglycemia have been reported during postmarketing surveillance in HIV-infected patients receiving protease inhibitor (PI) therapy. Some patients may require initiation or dose adjustments of insulin or oral hypoglycemic agents for treatment of these events. In some cases, diabetic ketoacidosis has occurred. In those patients who discontinued PI therapy, hyperglycemia persisted in some cases. Because these events have been reported voluntarily during clinical practice, estimates of frequency cannot be made and causal relationships between PI therapy and these events have not been established.

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
During the initial phase of treatment, patients responding to antiretroviral therapy alone may develop an inflammatory response to indolent or residual opportunistic infections (such as Mycobacterium avium complex, cytomegalovirus, Pneumocystis jirovecii pneumonia, and tuberculosis), which may necessitate further evaluation and treatment.

Hemophilia
There have been reports of increased bleeding, including spontaneous skin hematomas and intrathoraxis in patients with hemophilia type A and B treated with PIs. In some patients, additional factor VIII was given. In more than half of the reported cases, treatment with PIs was continued or reintroduced if treatment had been discontinued. A causal relationship between PI therapy and these episodes has not been established.

Resistance/Cross-Resistance
Because the potential for HIV cross-resistance among PIs has not been fully explored in PREZISTA/ritonavir treated patients, the effect therapy with PREZISTA will have on the activity of subsequently administered PIs is unknown (see Microbiology (12.4) in Full Prescribing Information).

ADVERSE REACTIONS
The overall safety profile of PREZISTA/ritonavir 800/100 mg once daily and PREZISTA/ritonavir 800/200 mg twice daily is based on clinical trials and post-marketing data, and is consistent with the data presented in Table 3. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Due to the need for co-administration of PREZISTA with ritonavir, please refer to ritonavir prescribing information for ritonavir-associated adverse reactions.

Clinical Trials Experience: Treatment-Naive Adults
Study TMC114-C211
The safety assessment is based on all safety data from the Phase 3 trial TMC114-C211 comparing PREZISTA/ritonavir 800/100 mg once daily versus lopinavir/ritonavir 800/200 mg per day in 689 antiretroviral treatment-naive HIV-1 infected adult subjects. The total mean exposure for subjects in the PREZISTA/ritonavir 800/100 mg once daily arm and in the lopinavir/ritonavir 800/200 mg per day arm was 55.0 and 54.1 weeks, respectively.

The majority of the adverse drug reactions (ADRs) reported during treatment with PREZISTA/ritonavir 800/100 mg once daily were mild in severity. The most common clinical ADRs to PREZISTA/ritonavir 800/100 mg once daily (≥5%) of at least moderate intensity (≥ Grade 2) were diarrhea, headache, abdominal pain and rash. 2.3% of subjects in the PREZISTA/ritonavir arm discontinued treatment due to ADRs.

ADRs to PREZISTA/ritonavir 800/100 mg once daily of at least moderate intensity (≥ Grade 2) in antiretroviral treatment naive HIV-1-infected adult subjects are presented in Table 2 and subsequent text below the table.

Table 2: Selected Clinical Adverse Drug Reactions to PREZISTA/ritonavir 800/100 mg Once Daily* of At Least Moderate Intensity (≥ Grade 2) Occurring in ≥ 2% of Antiretroviral Treatment-Naive HIV-1-Infected Adult Subjects

<table>
<thead>
<tr>
<th>System Organ Class, Preferred Term, Systemic Organ Class, PREZISTA/ritonavir lopinavir/ritonavir</th>
<th>N=total number of subjects per treatment group</th>
<th>TDF/FTC</th>
<th>TDF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PreEX</td>
<td>PreEX</td>
<td>PreEX</td>
</tr>
<tr>
<td></td>
<td>N=258</td>
<td>N=295</td>
<td>N=342</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>800/100 mg once daily + TDF/FTC</td>
<td>800/200 mg per day + TDF/FTC</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>5%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>5%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>8%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>3%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>2%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td>Fatigue</td>
<td>&lt; 1%</td>
<td>3%</td>
</tr>
<tr>
<td>Metabolism and Nutrition Disorders</td>
<td>Anorexia</td>
<td>2%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td>Headache</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td>Rash</td>
<td>5%</td>
<td>6%</td>
</tr>
</tbody>
</table>

N: total number of subjects per treatment group

TDF = tenofovir disoproxil fumarate
FTC = emtricitabine

* Excluding laboratory abnormalities reported as ADRs

Less Common Adverse Reactions
Treatment-emergent ADRs of at least moderate intensity (≥ Grade 2) occurring in less than 2% of antiretroviral treatment-naive subjects receiving PREZISTA/ritonavir 800/100 mg once daily are listed below by body system:

Gastrointestinal Disorders: acute pancreatitis, dyspepsia, flatulence

General Disorders and Administration Site Conditions: asthenia

Hepatobiliary Disorders: acute hepatitis (e.g., acute hepatitis, cytolytic hepatitis, hepatotoxicity)

Immun System Disorders: (drug) hypersensitivity

Metabolism and Nutrition Disorders: diabetes mellitus

Musculoskeletal and Connective Tissue Disorders: myalgia

Psychiatric Disorders: abnormal dreams

Skin and Subcutaneous Tissue Disorders: angioedema, pruritus, Stevens-Johnson syndrome, urticaria

Laboratory abnormalities: Selected Grade 2 to 4 for laboratory abnormalities that represent a worsening from baseline observed in antiretroviral treatment-naive adult subjects treated with PREZISTA/ritonavir 800/100 mg once daily are presented in Table 3.
Table 3: Grade 2 to 4 Laboratory Abnormalities Observed in Antiretroviral Treatment-Naïve HIV-1-Infected Adult Subjects

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>Preferred Term, %</th>
<th>Limit</th>
<th>PREZISTA/ritonavir 600/100 mg once daily + TDF/FTC</th>
<th>lopinavir/ritonavir 800/200 mg per day + TDF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biochemistry</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Alkaline Aminotransferase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 2.5 to ≤ 5.0 X ULN 7% 6%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 5.0 to ≤ 10.0 X ULN 3% 3%</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 10.0 X ULN &lt; 1% 3%</td>
<td></td>
</tr>
<tr>
<td>Aspartate Aminotransferase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 2.5 to ≤ 5.0 X ULN 6% 6%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 5.0 to ≤ 10.0 X ULN 4% 2%</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 10.0 X ULN 1% 2%</td>
<td></td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 2.5 to ≤ 5.0 X ULN 2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 5.0 to ≤ 10.0 X ULN 0%</td>
<td>&lt; 1%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 10.0 X ULN 0%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td>Hyperbilirubinemia</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 1.5 to ≤ 2.5 X ULN &lt; 1% 4%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 2.5 to ≤ 5.0 X ULN &lt; 1% 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 5.0 X ULN 0%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td>Triglycerides</td>
<td></td>
<td></td>
<td>Grade 2 5.65-8.48 mmol/L 3% 16%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500-750 mg/dL &lt; 1% 0%</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>751-1200 mg/dL &lt; 1% 0%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; 1200 mg/dL 0%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td></td>
<td></td>
<td>Grade 2 6.20-7.77 mmol/L 16% 23%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>240-300 mg/dL 1% 5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; 300 mg/dL &lt; 1% 1%</td>
<td></td>
</tr>
<tr>
<td>Low-Density Lipoprotein Cholesterol</td>
<td></td>
<td></td>
<td>Grade 2 4.13-4.90 mmol/L 14% 10%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>160-190 mg/dL 5% 5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>≥ 191 mg/dL &lt; 1% &lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Elevated Glucose Levels</td>
<td></td>
<td></td>
<td>Grade 2 69.5-13.88 mmol/L 7% 8%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>128-250 mg/dL 1% 5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; 250 mg/dL &lt; 1% 0%</td>
<td></td>
</tr>
<tr>
<td>Pancreatic Lipase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 1.5 to ≤ 3.0 X ULN 2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 3.0 to ≤ 5.0 X ULN &lt; 1%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 5.0 X ULN 0%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td>Pancreatic Amylase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 1.5 to ≤ 2.0 X ULN 5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 2.0 to ≤ 5.0 X ULN 3%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 5.0 X ULN 0%</td>
<td>&lt; 1%</td>
</tr>
</tbody>
</table>

Table 4: Selected Clinical Adverse Drug Reactions to PREZISTA/ritonavir 600/100 mg Twice Daily* of At Least Moderate Intensity (≥ Grade 2) Occurring in ≥ 2% of Antiretroviral Treatment-Experienced HIV-1-Infected Adult Subjects

<table>
<thead>
<tr>
<th>System Organ Class, Preferred Term, %</th>
<th>PREZISTA/ritonavir 600/100 mg twice daily + OBR N = 298</th>
<th>lopinavir/ritonavir 400/100 mg twice daily + OBR N = 297</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal distension  2%</td>
<td>&lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain  6%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>Diarrhea  14%</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>Dyspepsia  2%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Nausea  7%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Vomiting  5%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td><strong>General Disorders and Administration Site Conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthenia  2%</td>
<td>&lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Fatigue  2%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td><strong>Metabolism and Nutrition Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anorexia  2%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus  2%</td>
<td>&lt; 1%</td>
<td></td>
</tr>
<tr>
<td><strong>Nervous System Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache  3%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td><strong>Skin and Subcutaneous Tissue Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash  7%</td>
<td>3%</td>
<td></td>
</tr>
</tbody>
</table>

N = total number of subjects per treatment group
OBR = optimized background regimen
* Excluding laboratory abnormalities reported as ADRs

Less Common Adverse Reactions

Treatment-emergent ADRs of at least moderate intensity (≥ Grade 2) occurring in less than 2% of antiretroviral treatment-experienced subjects receiving PREZISTA/ritonavir 600/100 mg twice daily are listed below by body system.

**Gastrointestinal Disorders:** acute pancreatitis, flatulence

**Musculoskeletal and Connective Tissue Disorders:** myalgia

**Psychiatric Disorders:** abnormal dreams

**Skin and Subcutaneous Tissue Disorders:** pruritus, urticaria

Laboratory abnormalities:

Selected Grade 2 to 4 laboratory abnormalities that represent a worsening from baseline observed in antiretroviral treatment-experienced adult subjects treated with PREZISTA/ritonavir 600/100 mg twice daily are presented in Table 5.

Table 5: Grade 2 to 4 Laboratory Abnormalities Observed in Antiretroviral Treatment-Experienced HIV-1-Infected Adult Subjects

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>Preferred Term, %</th>
<th>Limit</th>
<th>PREZISTA/ritonavir 600/100 mg twice daily + OBR</th>
<th>lopinavir/ritonavir 400/100 mg twice daily + OBR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biochemistry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alamine Aminotransferase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 2.5 to ≤ 5.0 X ULN 7% 5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 5.0 to ≤ 10.0 X ULN 2% 2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 10.0 X ULN &lt; 1% 2%</td>
<td></td>
</tr>
<tr>
<td>Aspartate Aminotransferase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 2.5 to ≤ 5.0 X ULN 6% 6%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 5.0 to ≤ 10.0 X ULN 4% 2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 10.0 X ULN 1% 2%</td>
<td></td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 1.5 to ≤ 2.5 X ULN 2% 2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 2.5 to ≤ 5.0 X ULN &lt; 1% 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 5.0 X ULN 0% &lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Hyperbilirubinemia</td>
<td></td>
<td></td>
<td>Grade 2 &gt; 1.5 to ≤ 2.5 X ULN 2% 2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 3 &gt; 2.5 to ≤ 5.0 X ULN &lt; 1% 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grade 4 &gt; 5.0 X ULN &lt; 1% &lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td></td>
<td></td>
<td>Grade 2 5.65-8.48 mmol/L 5% 16%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500-750 mg/dL 1% 0%</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>751-1200 mg/dL 5% 5%</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; 1200 mg/dL 0% &lt; 1%</td>
<td></td>
</tr>
</tbody>
</table>

The safety assessment is based on all safety data from the Phase 3 trial TMC114-C214 comparing PREZISTA/ritonavir 600/100 mg twice daily versus lopinavir/ritonavir 400/100 mg twice daily in 595 antiretroviral treatment-experienced HIV-1-infected adult subjects. The mean total exposure for subjects in the PREZISTA/ritonavir 600/100 mg twice daily arm and in the lopinavir/ritonavir 400/100 mg twice daily arm was 80.7 and 76.4 weeks, respectively.

The majority of the ADRs reported during treatment with PREZISTA/ritonavir 600/100 mg twice daily were mild in severity. The most common clinical ADRs to PREZISTA/ritonavir 600/100 mg twice daily (≥ 5%) of at least moderate intensity (≥ Grade 2) were diarrhea, nausea, rash, abdominal pain and vomiting. 4.7% of subjects in the PREZISTA/ritonavir arm discontinued treatment due to ADRs.

ADRs to PREZISTA/ritonavir 600/100 mg twice daily of at least moderate intensity (≥ Grade 2) in antiretroviral treatment-experienced HIV-1-infected adult subjects are presented in Table 4 and subsequent text below the table.
Co-administration of darunavir and ritonavir and other drugs that may inhibit CYP3A may decrease the clearance of darunavir and ritonavir and may result in increased plasma concentrations of darunavir and ritonavir (see Table 6).

### Established and Other Potentially Significant Drug Interactions

Table 6 provides dosing recommendations as a result of drug interactions with PREZISTA/ritonavir. These recommendations are based on either drug interaction studies or predicted interactions due to the expected magnitude of interaction and potential for serious adverse events or loss of efficacy.

#### Table 6: Established and Other Potentially Significant Drug Interactions:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Effect on Darunavir or Ritonavir</th>
<th>Clinical Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>didanosine</td>
<td>↔ darunavir ↔ didanosine</td>
<td>Didanosine should be administered one hour before or two hours after PREZISTA/ritonavir (which are administered with food).</td>
</tr>
<tr>
<td>lopinavir/ritonavir</td>
<td>↓ darunavir ↔ lopinavir</td>
<td>Appropriate doses of the combination have not been established. Hence, it is recommended to co-administer lopinavir/ritonavir and PREZISTA, with or without ritonavir.</td>
</tr>
<tr>
<td>saquinavir</td>
<td>↓ darunavir ↔ saquinavir</td>
<td>Appropriate doses of the combination have not been established. Hence, it is not recommended to co-administer saquinavir and PREZISTA, with or without ritonavir.</td>
</tr>
</tbody>
</table>

#### HIV-1-Antiviral Agents: CCR5 co-receptor antagonists

Maraviroc

Maraviroc concentrations are increased when co-administered with PREZISTA/ritonavir. When used in combination with PREZISTA/ritonavir, the dose of maraviroc should be 150 mg twice daily.

#### Other Agents

**Antiarrhythmics:**

- Bepiridil, lidocaine (systemic), quinidine, amiodarone, flecaïnide, propafenone
  - Concentrations of these drugs may be increased when co-administered with PREZISTA/ritonavir. Caution is warranted and therapeutic concentration monitoring, if available, is recommended for antiarrhythmics when co-administered with PREZISTA/ritonavir.

- Digoxin
  - The lowest dose of digoxin should initially be prescribed. The serum digoxin concentrations should be monitored and used for titration of digoxin dose to obtain the desired clinical effect.

**Anticoagulant:**

- Warfarin
  - Warfarin concentrations are decreased when co-administered with PREZISTA/ritonavir. It is recommended that the international normalized ratio (INR) be monitored when warfarin is combined with PREZISTA/ritonavir.

**Anticonvulsant:**

- Carbamazepine
  - The dose of either darunavir/ritonavir or carbamazepine does not need to be adjusted when initiating co-administration with darunavir/ritonavir and carbamazepine. Clinical monitoring of carbamazepine concentrations and its dose titration is recommended to achieve the desired clinical response.

- Phenoobarbital
  - Co-administration of PREZISTA/ritonavir may cause decrease in the steady-state concentrations of phenytoin and pheno-barbital. Phenytoin and phenobarbital levels should be monitored when co-administering with PREZISTA/ritonavir.
### Table 6: Established and Other Potentially Significant Drug Interactions: Alterations in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction [See Clinical Pharmacology (12.3) in full Prescribing Information for Magnitude of Interaction, Tables 10 and 11] (continued)

**Antidepressant:**

| trazodone, desipramine | ↑ trazodone | ↑ desipramine |

Concomitant use of trazodone or desipramine and PREZISTA/ritonavir may increase plasma concentrations of trazodone or desipramine which may lead to adverse events such as nausea, dizziness, hypotension and syncope. If trazodone or desipramine is used with PREZISTA/ritonavir, the combination should be used with caution and a lower dose of trazodone or desipramine should be considered.

**Anti-inflammatory:**

| clarithromycin | ↔ clarithromycin |

No dose adjustment of the combination is required for patients with normal renal function. For patients with renal impairment, the following dose adjustments should be considered:
- For subjects with CLcr of <30 mL/min, the dose of clarithromycin should be reduced by 50%.
- For subjects with CLcr of <20 mL/min, the dose of clarithromycin should be reduced by 75%.

**Antifungals:**

| ketoconazole, itraconazole, voriconazole | ↑ ketoconazole | ↑ itraconazole (not studied) | ↓ voriconazole (not studied) |

Ketoconazole and itraconazole are potent inhibitors as well as substrates of CYP3A. Concomitant systemic use of ketoconazole, itraconazole, and darunavir/ritonavir may increase plasma concentration of darunavir. Clinical monitoring of plasma concentrations of ketoconazole, itraconazole, and/ or voriconazole may be increased in the presence of darunavir/ritonavir. When co-administration is required, the daily dose of ketoconazole or itraconazole should not exceed 200 mg.

**Calcium Channel Blockers:**

| felodipine, nifedipine, nicardipine | ↑ calcium channel blockers |

Plasma concentrations of calcium channel blockers (e.g., felodipine, nifedipine, nicardipine) may increase when PREZISTA/ritonavir is co-administered. Caution is warranted and clinical monitoring of patients is recommended.

**Corticosteroid:**

| fluticasone | ↑ fluticasone |

Concomitant use of inhaled fluticasone and PREZISTA/ritonavir may increase plasma concentrations of fluticasone. Alternatives should be considered, particularly for long term use.

**Endothelin receptor antagonists:**

| bosantan | ↑ bosantan |

Co-administration of bosantan in patients on PREZISTA/ritonavir:
- In patients who have been receiving PREZISTA/ritonavir for at least 10 days, start bosantan at 62.5 mg once daily or every other day based upon individual tolerability.
- Discontinue use of bosantan at least 36 hours prior to initiation of PREZISTA/ritonavir. After at least 10 days following the initiation of PREZISTA/ritonavir, resume bosantan at 62.5 mg once daily or every other day based upon individual tolerability.

**HMG-CoA Reductase Inhibitors:**

| pravastatin | ↑ pravastatin |
| atorvastatin | ↑ atorvastatin |
| rosvastatin | ↑ rosvastatin |

Use the lowest possible dose of atorvastatin, pravastatin or rosuvastatin with careful monitoring, or consider other HMG-CoA reductase inhibitors such as fluvastatin in combination with PREZISTA/ritonavir.

**Immunosuppressants:**

| cyclosporine, tacrolimus, sirolimus | ↑ immunosuppressants |

 Plasma concentrations of cyclosporine, tacrolimus or sirolimus may increase when co-administered with PREZISTA/ritonavir. Therapeutic concentration monitoring of the immunosuppressive agent is recommended when co-administered with PREZISTA/ritonavir.

**Inhaled beta agonist:**

| salmeterol | ↑ salmeterol |

Concurrent administration of salmeterol and PREZISTA/ritonavir is not recommended. The combination may result in increased risk of cardiovascular adverse events associated with salmeterol, including QT prolongation, palpitations and sinus tachycardia.

**Other:**

| metoprolol, timolol | ↑ beta-blockers |

Caution is warranted and clinical monitoring of patients is recommended. A dose decrease may be needed for these drugs when co-administered with PREZISTA/ritonavir.

**Parenteral Antimycobacterial:**

| rifabutin | ↓ rifabutin |
| 25-O-desacetylrifabutin | ↑ 25-O-desacetylrifabutin |

Dose reduction of rifabutin by at least 75% of the usual dose (300 mg once daily) is recommended (i.e., a maximum dose of 150 mg every other day). Increased monitoring for adverse events is warranted in patients receiving this combination and further dose reduction of rifabutin may be necessary.

The reference regimen for rifabutin was 200 mg once daily.

Table 6: Established and Other Potentially Significant Drug Interactions: Alterations in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction [See Clinical Pharmacology (12.3) in full Prescribing Information for Magnitude of Interaction, Tables 10 and 11] (continued)
paroxetine, sertraline, (SSRIs): Reuptake Inhibitors
Selective Serotonin Reuptake Inhibitors (SSRIs): sertraline, paroxetine

Other nucleoside reverse transcriptase inhibitors (NRTIs):
Based on the different elimination pathways of the other NRTIs (zidovudine, zalcitabine, emtricitabine, stavudine, lamivudine and abacavir) that are primarily renally excreted, no drug interactions are expected for these drugs and PREZISTA/ritonavir.

Other PIs:
The co-administration of PREZISTA/ritonavir and PIs other than lopinavir/ritonavir, saquinavir, atazanavir, and indinavir has not been studied. Therefore, such co-administration is not recommended.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category C: PREZISTA should be used during pregnancy only if the potential benefit justifies the potential risk.

Nursing Mothers
The Centers for Disease Control and Prevention recommend that HIV-infected mothers in the United States not breastfeed their infants to avoid risk of perinatal transmission of HIV. Although it is not known whether darunavir is secreted in human milk, darunavir is secreted in the milk of lactating rats. Because of both the potential for HIV transmission and the potential for serious adverse reactions in nursing infants, mothers should be instructed not to breastfeed if they are receiving PREZISTA.

Geriatric Use
Clinical studies of PREZISTA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. In general, caution should be exercised in the administration and monitoring of PREZISTA in elderly patients reflecting the greater frequency of decreased hepatic function and of concomitant disease or other drug therapy [see Clinical Pharmacology (12.3) in full Prescribing Information].

Hepatic Impairment
No dose adjustment of PREZISTA/ritonavir is necessary for patients with either mild or moderate hepatic impairment. No pharmacokinetic or safety data are available regarding the use of PREZISTA/ritonavir in subjects with severe hepatic impairment; therefore, PREZISTA/ritonavir is not recommended for use in patients with severe hepatic impairment [see Dosage and Administration and Clinical Pharmacology (12.3) in full Prescribing Information].

Renal Impairment
Population pharmacokinetic analysis showed that the pharmacokinetics of darunavir were not significantly affected in HIV-infected subjects with moderate renal impairment (CrCl between 30-60 mL/min, n=20). No pharmacokinetic data are available in HIV-1-infected patients with severe renal impairment, or end stage renal disease. The removal clearance of darunavir is limited, a decrease in total body clearance is not expected in patients with renal impairment. As darunavir and ritonavir are highly bound to plasma proteins, it is unlikely that they will be significantly removed by hemodialysis or peritoneal dialysis [see Clinical Pharmacology (12.3) in full Prescribing Information].

OVERDOSE
Human experience of acute overdose with PREZISTA/ritonavir is limited. Single doses up to 3200 mg of the oral solution of darunavir alone and up to 1600 mg of the tablet formulation of darunavir in combination with ritonavir have been administered to healthy volunteers without untoward symptomatic effects.

No specific antidote is available for overdose with PREZISTA. Treatment of overdose with PREZISTA consists of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. If indicated, elimination of unabsorbed active substance is to be achieved by emesis or gastric lavage. Administration of activated charcoal may also be used to aid in removal of unabsorbed active substance. Since PREZISTA is highly protein bound, dialysis is unlikely to be beneficial in significant removal of the active substance.
Patients should be informed that PREZISTA/ritonavir may interact with many drugs; therefore, patients should be advised to report to their healthcare provider the use of any other prescription or nonprescription medication or herbal products, including hormones. Patients should be informed that redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy, including PREZISTA/ritonavir, and that the cause and long-term health effects of these conditions are not known at this time. Patients Taking PREZISTA Twice Daily

If a patient misses a dose of PREZISTA or ritonavir (NORVIR®) by more than 12 hours, the patient should be told to wait and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If the patient misses a dose of PREZISTA or ritonavir (NORVIR®) by less than 12 hours, the patient should be told to take PREZISTA and ritonavir (NORVIR®) immediately, and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If a dose of PREZISTA or ritonavir (NORVIR®) is skipped, the patient should not double the next dose. Inform the patient that he or she should not take more or less than the prescribed dose of PREZISTA or ritonavir (NORVIR®).

Hepatotoxicity

Patients should be informed that Drug-induced hepatitis (e.g., acute hepatitis, cytolytic hepatitis) has been reported with PREZISTA co-administered with 100 mg of ritonavir. Monitor liver function before and during therapy, especially in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pre-treatment elevations of transaminases. Post-marketing cases of significant liver injury, including some fatalities, have been reported. Patients should be advised about the signs and symptoms of liver problems. These may include jaundice of the skin or eyes, dark (tea colored) urine, pale colored stools, nausea, vomiting, loss of appetite, or pain, aching or sensitivity in the right-upper quadrant of the abdomen.

Skin Reactions

Patients should be informed that skin reactions ranging from mild to severe, including Stevens-Johnson Syndrome and toxic epidermal necrolysis, have been reported with PREZISTA co-administered with 100 mg of ritonavir. Patients should be advised to discontinue PREZISTA/ritonavir immediately if signs or symptoms of severe skin reactions develop. These can include but are not limited to severe rash or rash accompanied with fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, hepatitis and/or eosinophilia.

Drug Interactions

PREZISTA/ritonavir may interact with many drugs; therefore, patients should be advised to report to their healthcare provider the use of any other prescription or nonprescription medication or herbal products, including hormonal levels may decrease.

Fat Redistribution

Patients should be informed that redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy, including PREZISTA/ritonavir, and that the cause and long-term health effects of these conditions are not known at this time.

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BEST PRACTICES, continued from page 8 represents only a small sampling of data on this subject. However, to date observational and other study designs have shown similar incidence and prevalence of anal dysplasia and cancer in these groups.

I would argue that indeed, we need further research in this area but that meanwhile, screening Anal Cytology and High Resolution Anoscopy could greatly benefit our HIV-infected patients.

So…...if the data are true and we have the opportunity for detecting dysplastic changes in ano-rectal tissue, intervening and preventing pre-cursor lesions from becoming SCCA, then why are most of our patients not getting the benefit of anal cytology and high resolution anoscopy?

Your next opportunity to become certified in High Resolution Anoscopy by the American Society of Colposcopy and Cervical Pathology (ASCCP), in conjunction with UCSF, will be in Providence, RI, April 27-29, 2012. You may access this information at ascsp.org.
Pharmacists and the Older Patient:
What’s In It for Me?

POLYPHARMACY is estimated to occur in 20-50 percent of HIV-infected patients, with adverse drug reactions (ADRs) being more common and serious in older patients. As the number of medications increases, the potential for side effects and non-adherence increases correspondingly.

Thus, as we treat our aging patient and their comorbidities, we, as providers, expose them to a relatively high likelihood of ADRs and drug interactions unless we take steps to manage their risk. Providers can best mitigate that risk by collaborating with pharmacists, as they are the experts in pharmacotherapy, ADR identification and management, drug interactions and adherence assessment/counseling.

Here are some areas where and how pharmacist involvement can help provide optimal care for our patients:

Medication Reconciliation
Medication reconciliation (establishing a comprehensive, accurate medication list by using information from all sources about a patient’s medications) is a key factor in identifying and avoiding ADRs, drug-drug interactions, and unnecessary or redundant medications.

Pharmacists can perform or assist with medication reconciliation, updating the medication list and ensuring that no clinically relevant interactions are present. Patients frequently buy and use over-the-counter (OTC) medicines, herbal supplements, ethnically or culturally specific remedies, nutritional supplements, street medications, and/or Internet medications. They also may see other providers who prescribe medications for them. Rash, transaminitis, confusion, anterograde amnesia and loss of virological control are just a few ADRs that don’t happen yet the issue is present (but not recognized), does this not make the case for a pharmacist consult or medication review on a regular basis and for all patients?

Disease State Co-management
It is usually possible for the pharmacist to see the patient more often than most other providers, and older patients, more susceptible to ADRs and interactions, do need to be assessed more frequently.

Pharmacists can assist the HIV provider in co-managing concomitant medical issues. This could be a telephone consult, or a referral to a clinical pharmacist working under a collaborative agreement. This greatly facilitates patient care and disease state co-management. Even for simple dosing questions, formulation options, and dose adjustments for renal or hepatic dysfunction, all providers should have at least one pharmacist who can assist them in their practice.

Adherence Counseling
Recent hypertension studies have shown that when even brief adherence counseling is discontinued, adherence with anti-hypertensive medications falls. Medication adherence must be reinforced at every visit, however briefly.

Pharmacists can perform adherence assessment at pre-ART initiation, during initiation and provide follow-up after the regimen change. Along with this, older patients generally require more patient education, particularly on side effects and medication management.

Pharmacists are experts in providing patient education on the disease state, non-pharmacologic/lifestyle modification management, specific lab tests, adherence and of course medications. Pharmacists discuss and educate on indication, dose, route, frequency, expectations, common ADRs, important ADRs to notify the clinician about, proper dosing/administration technique, food requirements, if any and provide adherence aids as indicated.

While older patients will be on more medications due to a greater incidence of concomitant medical problems, all of the above holds true for any HIV patient -- not just our older patients. I advise all of you that if you are not working with a pharmacist at your practice site, develop a relationship with a pharmacist who is interested in caring for HIV patients. Your patients will thank you for it.
ONE DAY SOON, PERHAPS AS EARLY AS 2015, more than half of those in America who are infected with the HIV virus will be over the age of 50. Even now more than half of all patients cared for in some clinics have reached that milestone.

That is a remarkable development and a direct result of antiretroviral therapies that prolong the lives of patients by preventing the collapse of the immune system. Today, as we mark the 30th year of this epidemic, there are 1.25 million people in the U.S. living with HIV.

In 2006, 26 percent of HIV-infected adults in the US were at least age 50, and in 2011 estimates place that number at almost 40 percent. The most recent data from the Centers for Disease Control and Prevention (CDC) shows that individuals in that age group accounted for 17 percent of all new HIV diagnoses each year.

“HIV patients are getting older, living longer, and older adults are becoming infected,” said Jonathan Appelbaum, MD, FACP, AAHIVS, a member of the American Academy of HIV Medicine (AAHIVM) Board of Directors and associate professor and education director for internal medicine in the Department of Clinical Sciences at Florida State University College of Medicine. “As you get older, more things can go wrong and that can challenge both the HIV provider who is accustomed to treating younger patients with HIV, and the geriatrician who is used to treating elderly patients, but may not be comfortable with treating HIV.”

In a nutshell, that is why AAHIVM partnered with the American Geriatrics Society (AGS) and the AIDS Community Research Initiative of America (ACRIA) to develop the first clinical recommendations for managing older HIV patients: The HIV and Aging Consensus Project: Recommended Treatment Strategies for Clinicians Managing Older Patient with HIV.

The key objectives of the HIV and Aging Consensus Project are to assess how the presence of both HIV and common age-associated diseases alter the optimal treatment of HIV as well as other co-morbidities.

The purpose of the report, developed by a panel of experts with experience both in the fields of HIV and geriatrics, is to provide best practice guidance for HIV practitioners and other health care providers who treat, diagnose and refer older patients with HIV disease, explained Ken South, director of membership services at AAHIVM. South provided staff support for the two-year study.

The report is summarized on the pages that follow.

“This is absolutely cutting edge work that has never been done before,” said South, noting the lack of peer-reviewed scientific literature to specifically guide clinicians who are challenged with treating older patients with HIV. “We know a lot about HIV and we know a
lot about aging, but this is new. We never thought we would be here.”

That, of course, is because the epidemic for so many years claimed so many lives, mostly young. Its victims, generally, did not grow old.

Said Stephen Karpiak, PhD, ACRIA’s researcher on the project and a faculty member of New York University, “I was part of a process where the clinical and research domains of HIV and Geriatrics were intersecting. Who would have ever thought this would happen 30 years ago, 20 years ago, 10 years ago, even five years ago. The epidemic is much like the HIV virus, forever mutating in ways that cannot be easily predicted.”

**Meeting the Challenge**

During the first 15 years of the epidemic which largely affected young men, an HIV diagnosis meant one’s life would end very soon. No one could have imagined the majority of HIV patients would live past 40 and 50 and 60 years of age. The consequences of this great success are today’s challenges and the guidance offered in the report is designed to help clinicians meet them.

“This will be a valuable reference resource, an informed guide for the physician who has HIV patients manifesting multiple age-related diseases and is not sure how best to approach such challenges,” said Dr. Appelbaum, co-leader of the study project.

“It gives the HIV clinician who has a patient with multiple issues something to go on,” noted project co-leader Wayne McCormick, MD, MPH, a professor of geriatric medicine at the University of Washington’s Division of Gerontology and Geriatric Medicine in Seattle. “There is so much we don’t know about older people with HIV. This is an effort to begin to help.”

There is considerable research that indicates older adults with HIV are developing some of the illnesses typically seen in the elderly. Today, many adults with HIV age 50 to 65 are developing osteoporosis, cardiovascular diseases, multiple cancers, hypertension, diabetes, kidney and liver dysfunction. This phenomenon provides challenges to the HIV clinician who may lack expertise in managing multiple co-morbidities as well as to the geriatrician who typically treats chronologically older patients whose health is not complicated by HIV.

“When I’m in an HIV clinic, it is very common to be asked how to handle these multiple illnesses,” said Dr. McCormick, “and it’s the same thing in geriatrics clinics. People like Jon and I can bridge that. We will need more of that.”

“We found an astonishing pattern of co-morbidities in an ACRIA study of nearly 1,000 individuals over age 50 (average age was 55) with HIV,” pointed out Dr. Karpiak. “The average number of co-morbid conditions for each person was three with the most common disorders being depression (52 percent), hepatitis (31 percent), neuropathy (30
percent), and hypertension (27 percent).”

ACRIA’s research, Dr. Karpiak explained, has focused on older adults with HIV and their psychosocial characteristics.

“At times I feel as if I am a proxy for that invisible older adult with HIV whose voice is too often muffled by beliefs that HIV is a disease only of the young,” he said. “Our research shows that these older adults, many who are long-term survivors of HIV, while resilient, find themselves significantly affected by persistent AIDS-related stigma.”

More than 70 percent of older adults with HIV live alone and fewer than 15 percent have a spouse or partner, Dr. Karpiak said. “As a result, they are often socially isolated from family and friends, have fragile social networks, and lack the support of caregivers as they and their health care providers attempt to effectively manage their health challenges as they age.”

All of these factors, as well as medical considerations and the resources of the patient, must be considered and addressed by the clinician, regardless of their areas of expertise, if the older individual with HIV can age successfully. Like the older adult with HIV who must now develop new coping strategies, medical practices, of necessity, must evolve and change.

**The Study Experience**

Being a part of the team that produced the consensus report was a positive experience, Dr. Karpiak noted.

“Without extensive data on the older adults with HIV, I watched a group of leading researchers and clinicians willingly discuss the issues and shift opinions as data and clinical experiences were shared,” he said. “These decisions were driven by present data and prevailing thinking. I was most impressed by the panel members who at one time would talk about often-complex data and yet always use their clinical experience with patients to reinforce conclusions, which the report will detail. The Project Leaders on this effort were sensitive and skilled in assembling a group of experts who had significant clinical and research experience.”

For AAHIVM’s Ken South, who has been working on aging issues for 15 years and in the HIV arena for 30, it was easy to identify with the focal point of the research because he is part of it as one of the first of the baby boomers, born in late December 1945.

“It’s been a pleasure to work with such a gifted, committed and esteemed group of physicians and researchers,” he said. “It was an honor, really, and the need for this work could not be more clear.”

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**The Timeline**

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<th>2008</th>
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<th>2011</th>
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<td>JANUARY</td>
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<td>ACRIA’s Stephen Karpiak, PhD, presents to the AAHIVM staff on the ROAH study</td>
<td>Co-Project Investigators named: Dr. Jonathan Appelbaum for AAHIVM and Dr. Wayne McCormick for the American Geriatrics Society</td>
<td>Funding from Campbell Foundation, Tebotec Pharmaceuticals and Strativa Pharmaceuticals secured</td>
<td>All Panel Conference call</td>
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<td>Proposals for funding submitted</td>
<td>1st All Panel conference call</td>
<td>Expert Panel and Planning Committee Formed</td>
<td>Final draft of the document: The HIV and Aging Consensus Project: Recommended Treatment Strategies for Clinicians Managing Older Patients with HIV</td>
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<td>2nd All Panel conference call</td>
<td>NOVEMBER Recommended Treatment Strategies for Clinicians Managing Older Patients with HIV: Report and executive summary published by the HIV &amp; Aging Consensus Project</td>
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<td>AUGUST New-revised version of the Working Document posted</td>
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<td>NOVEMBER Panel Meeting and vote on recommendations</td>
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**About the Author:** *Editor of HIV Specialist, Bob Gatty* is a Washington, DC-area health policy writer and publications professional. He is founder of G-Net Strategic Communications and can be reached at bob@gattyedits.com.
By the middle of this decade, most individuals with HIV in the US will be over 50 years old. Most will have had HIV infection, and will have been on antiretroviral therapy, for over 15 years. As these adults develop illnesses more commonly associated with aging than with HIV, they represent a unique challenge for their medical providers. An HIV clinician, very comfortable with the nuances of antiretroviral therapy, may be increasingly uncomfortable managing multiple age-related, but not necessarily HIV-related, illnesses in older patients. While these patients have substantial medical morbidity, and may appear considerably older than their chronological age, they are typically too “young” to be seen by a geriatrician, who may be more comfortable with multimorbidity, but less comfortable managing antiretroviral therapy.

This summary represents the results of a two-year collaboration among members of the American Academy of HIV Medicine (AAHIVM), the American Geriatrics Society (AGS), and the AIDS Community Research Initiative of America (ACRIA) regarding the clinical management of HIV-infected older persons. As the lines of communication have grown between HIV providers and geriatricians, common themes have emerged regarding the care of HIV-infected older adults. Recognizing the lack of information from clinical studies pertinent to the care of these older individuals, an Expert Panel was formed in 2009 to formulate clinical treatment approaches to these patients. The Panel adopted the convention that the term “older”, in the context of persons with HIV infection, pertained to age 50 or greater. The composition of the Panel was made up of equal proportions of experts from a geriatrics background and an HIV medicine background (7 each), many of who were also acknowledged leaders in research. The Panel developed a working document, using the Modified Delphi technique. The working document evolved after multiple iterations of input/feedback which contributed to consensus on a list of areas most in need of clinical guidance. Six independent reviewers (half geriatricians, half HIV clinicians) then reviewed the document. Because this area of interest is rapidly evolving, with new information being published almost weekly, the results of the Panel’s work now appear in a discussion forum format at the following web site: www.aahivm.org/hivandagingforum. The recommended treatment strategies are not guidelines – they represent consensus opinions of the Expert Panel.

Older persons with HIV often have multiple illnesses of aging and HIV, and can be thought of as having multi-morbidity. Multi-morbidity is a syndrome; it is more than simple co-morbidity. Multi-morbidity is conceptualized as several serious health conditions that cannot be cured, occurring in an older person and engendering functional and/or cognitive debility. When considering persons with multi-morbidity, the sum is greater than the parts – aging plus debilitating conditions have the propensity to synergize to make morbidity and mortality worse than might otherwise seem apparent.

The Panel sought to incorporate geriatric, syndromic thinking in considering clinical treatment suggestions, taking into account multi-morbidity and frailty, separate from chronological age. These considerations pervade the treatment strategies. Multi-morbidity is increasingly becoming the norm rather than the exception among HIV-infected older people. Non-AIDS-defining conditions including chronic kidney disease, metabolic and cardiovascular disease, and malignancies have been observed to increase in incidence in recent years. These trends are expected to continue. We invite readers to visit our website at www.aahivm.org/hivandagingforum to participate in the ongoing evolution of the complex care of HIV-infected older persons.

The American Geriatrics Society (AGS) participated as supporting organization of the HIV & Aging Consensus Project. In keeping with both the AGS’ Guidelines policies and the Council of Medical Specialty Societies Code for Interactions with Companies, AGS did not accept Company support for Guideline developmental activities.
in HIV-infected patients over 50, the Expert Panel reached consensus on the following treatment strategies

(Supporting literature can be found at www.aahivm.org/hivandagingforum)

Screening, Monitoring, and Initiating Antiretroviral Therapy in HIV and Aging

- Providers must reduce barriers to effective prevention and detection of HIV in older adults. However, because providers and patients are unable to reliably estimate HIV risk in older patients, we suggest that primary care providers perform routine, opt-out HIV screening in all adults, regardless of age or individual factors, with repeat HIV screening at least annually in patients at known risk.

- Antiretroviral therapy should be initiated in all patients older than 50 who have a CD4 count less than 500 cells/mm$^3$.

- Antiretroviral therapy should be initiated in all patients older than 50, regardless of CD4 cell count, with the following conditions: AIDS-defining illness, HIV-associated nephropathy, or chronic hepatitis B virus infection.

- For patients over age 50 who have a CD4 count greater than 500 cells/mm$^3$, antiretroviral therapy should be considered. Factors favoring initiating therapy include plasma HIV RNA levels greater than 50,000 copies/ml, greater than 100-point decline in CD4 count in prior 12 months, or risk factors for cardiovascular disease.

- For patients who have diabetes or hyperinsulinemia (and no baseline antiretroviral drug resistance), an initial ritonavir-boosted protease inhibitor-based regimen should be avoided, if possible.

- The routine monitoring of CD4 cell counts and HIV RNA levels in patients older than 50 should follow the same general approach recommended for all HIV-infected patients. A CD4 cell count and HIV RNA level should be obtained at the initial evaluation and followed every 3-4 months prior to initiating antiretroviral therapy. Patients initiating antiretroviral therapy should have more intensive monitoring of HIV RNA levels, including a baseline HIV RNA level prior to starting therapy, a follow-up 2-4 weeks after initiating therapy, and continued monitoring every 4-8 weeks until HIV RNA levels become undetectable. Once HIV RNA levels become undetectable, the frequency of monitoring HIV RNA can revert to routine checks every 3-4 months. Monitoring of CD4 cell count and HIV RNA level can be extended to every 6 months in adherent patients who have sustained suppression of HIV and stable clinical status for at least 2-3 years.
Cardiovascular Risk Reduction, Diabetes in HIV and Aging

• Providers should counsel patients at every visit to stop smoking. Providers should make use of community smoking cessation resources, on line quit sites, and pharmacotherapy to assist patients in quitting tobacco use.

• There is insufficient evidence to alter current recommendations for management of dyslipidemia or CVD/cerebrovascular disease screening by specific age criteria. It is reasonable to recommend Framingham Risk Score assessment in addition to aggressive primary prevention using standardized guidelines for cholesterol and blood pressure (JNC-8). Whether or not screening for CVD/cerebrovascular disease and treatment of hyperlipidemia in the setting of HIV should be modified for age and/or for HIV itself remains unknown and will require further study.

• The most important prevention for adult onset diabetes mellitus is to avoid excess weight gain. Since most HIV patients come into care at or below normal weight, patients initiating ART should be encouraged to avoid excess weight gain.

• Screening for diabetes should be done regularly, before and after the initiation of antiretroviral therapy, using glycosolated hemoglobin with appropriate diagnosis follow up. For patients with diabetes, glycosolated hemoglobin should be checked at least twice yearly.

• The target glycosolated hemoglobin (6.5 percent for younger patients) should be increased to 8 percent for frail patients, especially if their life expectancy is less than 5 years, since they are at high risk for hypoglycemia, polypharmacy or drug interactions.

• Older HIV-infected persons with chronic kidney disease of known etiology who are being managed by current NKF Kidney Disease Outcomes Quality Initiative guidelines should be referred for discussions of renal replacement therapy (dialysis or transplantation) when eGFR reaches 15-29 ml/min. As in all individuals evaluated for renal replacement therapy, issues of co-morbidities, life expectancy, and functional status should be considered during joint decision making.

• Because hypertension accelerates the rate of progression of cardiovascular disease, kidney disease, and complications of diabetes, as well as risk for stroke, it is an important contributor to the overall impact of multi-morbidity. For this reason, special attention should be paid to modiﬁng factors (e.g. salt intake, weight, exercise) that reduce hypertension. When medication is required, hypertension should be treated in older HIV-infected individuals using recommended guidelines and goals, with avoidance of pressures < 130/70 mm Hg. Selection of speciﬁc agents will also need to be tailored to the complex multi-morbid state of the patient and their overall drug regimen, while preventing development of hypotension.

• Although some individuals, particularly older individuals, lack evidence of activation of the renin-angiotensin-aldosterone system, they may still respond to angiotensin converting enzyme inhibitors and angiotensin receptor blockers. As these agents confer better risk reductions for cardiovascular events and ESKD, their use may be considered in all individuals with hypertension.

• Because of the increased risk for orthostatic hypotension and electrolyte abnormalities, treatment of hypertension in older persons should

Monitoring Renal Function / Hypertension in HIV and Aging

• Older individuals should have annual measurements of serum creatinine, eGFR and urinary protein excretion, including those with known HIV infection.

• All older individuals with a history of injection drug abuse or new onset proteinuria should be screened for HIV and other infections (e.g. HCV, HBV, SBE).

• Individuals with an acute change in kidney function need to be evaluated for all causes of kidney disease. Because of the broad differential diagnosis in older, HIV-infected persons, consultation with a nephrologist is appropriate, and kidney biopsy may be indicated.

• Careful consideration of the need to adjust drug dosage of all medications in older patients is essential.
be initiated with low doses of medications and monitoring for side effects before increasing the dose to achieve therapeutic goals.

Drug-drug Interactions and Polypharmacy in HIV and Aging
• The primary care provider is highly encouraged to perform annual medication reconciliation and a medication review at every visit so that a complete and active medication list is available. This process is not complete until the prescriber discontinues medications no longer indicated and notifies the dispensing pharmacy and patient thus reducing the risk for toxicity and/or drug-drug interactions.
• To reduce the risk of polypharmacy, it is recommended that patients utilize one pharmacy or a pharmacy with an integrated pharmacy computer network and where possible, utilize a HIV specialty pharmacy.
• For patients with renal insufficiency, the Cockcroft-Gault derived creatinine clearance calculation should be used to determine the appropriate medication dosage or frequency adjustments. While less accurate in older patients, this equation is still widely used in renal dosing charts by the FDA and within package inserts. The renal function estimated by MDRD if unadjusted for body surface area may also be a reasonable substitute.
• In the setting of hepatic dysfunction certain medications need dose adjustment.

Viral Hepatitis Screening in HIV and Aging
• All HIV-infected patients should be screened for hepatitis A, hepatitis B and hepatitis C upon entry into care.
• Any unexplained elevations in liver enzymes should prompt a rescreening in those with negative screening tests at initial evaluation. Screening for occult HBV can be considered in this setting, particularly in HCV/HIV coinfected patients. However, until there are more prospective studies on occult HBV disease, it is not practical to recommend general screening for this entity with HBV DNA testing on those without serologic evidence of chronic HBV infection. Screening for acute HCV infection is important because therapy may be more effective and of shorter duration than in chronic HCV / HIV coinfected. Treatment of HCV may be improved if initiated at an earlier age.
• No formal recommendation can be made at this time for ongoing routine screening in asymptomatic HIV-infected patients at high risk for HCV. However, given increasing evidence of sexual transmission of HCV in high risk populations of men who have sex with men, the increased sexual activity among older individuals, and the lower rates of sustained virologic response to HCV treatment in older patients, sexual behavior counseling as it relates to HCV transmission may be warranted in older individuals living with HIV.

Cancer Screening in HIV and Aging
• As part of general health maintenance practices, cancer screening in clinically stable HIV-infected patients 50 years and older should be in accordance to current guidelines for the general population.
• For cervical cancer, anal cancer and liver cancer where HIV-specific recommendations exist, these guidelines should be adhered to instead.
• For all patients, providers should take into consideration functional status and life expectancy in applying these recommendations.

COPD in HIV and Aging
• In the absence of data on treatment of COPD specifically in the setting of HIV infection, current therapy of COPD in HIV-infected persons should follow the management guidelines proposed for HIV-uninfected patients.

Immunizations in HIV and Aging
• There is a large body of data that vaccine preventable illnesses occur with greater frequency and are more severe in HIV-infected patients than in age-matched control subjects. Thus, a number of vaccines are indicated in HIV-infected subjects.

Sexual Health in HIV and Aging
• Consistent with HIV primary care guidelines, the health care team should screen older persons at each visit for high-risk behavior or evidence of sexually-transmitted diseases, and then provide a tailored prevention message. A more general prevention message should be given at each visit to all patients. Developing a routine way to elicit the patient’s sexual history that avoids judgmental attitudes and asks the patient for permission to discuss sexual function will make it easier to gather the necessary information.
• In HIV discordant couples, there is a special need to emphasize safe sexual practices and full adherence to ART use.
• Use of erectile dysfunction medications or other measures for impotence in men and topical estrogen products for vaginal dryness in women can enhance sexual satisfaction, but care in their use is necessary. The prescription should be linked to specific educational efforts on safe sexual practices.

Osteoporosis in HIV and Aging
• Since older patients have bone loss due to osteoporosis, and since many HIV-infected patients on ART have accelerated bone loss, screening for (and aggressive treatment of) osteoporosis should be done.
• Since vitamin D deficiency is prevalent in older HIV-infected persons, screening for vitamin D deficiency is warranted.

Advance Directives in HIV and Aging
• Older HIV-infected patients, especially those with substantial illness burden, should be counseled in completing a durable power of attorney for health care and an advance directive, such as the Physician Order for Life Sustaining Treatment (POLST), or similar document.

Neuro-cognitive Changes, Psychiatric Illness and Substance Use in HIV and Aging
• Screening for cognitive impairment is important. A two-tiered approach, assessing symptoms with follow up testing, is a reasonable paradigm for busy practices.
• Older HIV-infected patients should be screened for depressive disorder with an appropriate standardized measure (such as the Geriatric Depression Scale) that minimizes the impact of somatic depressive symptoms.
• Many anxiety disorders can be addressed with SSRIs rather than benzodiazepines with fewer consequences.
• If pharmacotherapy is indicated for acute control of anxiety, the short to intermediate acting benzodiazepines with no active metabolites are preferred.
• Non-benzodiazepine agents are preferred for longer term anxiety control, when longer term pharmacotherapy is judged to be warranted.
• Patients should be encouraged to discontinue or minimize their alcohol and substance use and be referred to a counseling program or offered pharmacologic treatment.
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Acknowledgement: We thank Elizabeth C White and Brendan O’Connell for editorial assistance.

*Expert Panel Member  *Reviewer  *Contributor  *Staff

The Expert Panel members and other participants in the HIV & Aging Consensus Project invite interested readers to become actively involved in advancing the knowledge and communication in this area of medical uncertainty. We are most hopeful that as more medical knowledge becomes available from observational studies and clinical trials, the care of HIV-infected patients over age 50 can be more evidence-based. Because this area of interest is rapidly evolving, with new information coming forth weekly, the results of the Panel’s work now appears in blog / wiki format at the following web site: www.aahivm.org/hivandagingforum.
“So many people are under-educated and misinformed... One lady told me she was scared to sit next to someone with HIV. There are so many myths about how the virus is transmitted. It is a challenge.”

Anna Fowlkes, 64
HIV does not discriminate.
Seniors need counseling so they can protect themselves.

BY BOB GATTY

WHEN AMERICANS THINK ABOUT HIV, the face they imagine isn’t someone who has lived over half a century and beyond. In fact, for many health care providers who treat older patients, the last diagnosis possibility might well be HIV.

Why is that? Is it the perception that people whose faces are lined from the years, who may be grandmothers or grandfathers and on Medicare, would not engage in risky behaviors that can spread HIV?

“Get your heads out of the sand and realize that older people are having sex,” said Jane Fowler, a 76-year-old Kansas City, MO grandmother, diagnosed with HIV in 1991 when she was 55 after having unprotected sex with a man, a close lifelong friend, after a divorce. “Older people are getting HIV. If you, the provider, are trying to help these people, understand that.”

Presented here are the stories of five seniors, all of whom have HIV and are hoping to help stop the spread of the disease by speaking out and sharing their experiences. Like Fowler, they do not mince words.

Jane Fowler, 76

On the first Sunday in January 1991, Fowler, a journalist, had returned to her apartment from celebrating the holidays with friends in San Francisco. She was greeted by a letter from an insurance company that rejected her application for medical coverage because of a “significant blood abnormality” revealed in a routine test. When she called to inquire, she was told to speak to her doctor.

A few hours later, her family practitioner told her the insurance company said her blood tested positive for HIV. A second test two days later confirmed the diagnosis.

“I didn’t consider myself promiscuous,” Fowler wrote in an article published in June 2003 in JAIDS: Journal of Acquired Immune Deficiency Syndromes. “I didn’t frequent the singles bars; I went out with men my age who, like me, had been married and were divorced. And, in those days, I knew little about HIV, only that a mysterious, fatal ailment was affecting the gay community. It didn’t occur to me that I would put myself at risk by engaging in unprotected sex with an attractive, intelligent, amusing man of many interests, a man who had been a close friend my entire adult life. But what happened to me... was infection with HIV.”

For four years, Fowler withdrew, taking her antiretroviral drugs as prescribed and staying healthy and free of opportunistic infections, but associating only with close friends and family who were supportive and non-judgmental.

But then, encouraged by family and friends, she decided to act.

“I decided to put another face to the epidemic – an old, white, wrinkled, heterosexual face – to show people that HIV does not discriminate, that it’s not who you are or how old you are, but what you do and don’t do in regard to transmission of HIV,” she wrote.

Since 1995, Fowler has given hundreds of educational programs to audiences young and old. She was a founder of the National Association of HIV Over Fifty and now directs a new national program, HIV Wisdom for Older Women. And although she is beginning to experience some common problems associated with aging, such as hearing loss, she continues to speak out whenever she can.

She says she has been fortunate to have outstanding care, once she was diagnosed. Two years before that fateful date, she had asked her doctor if she thought she should be tested because she had heard HIV was moving into the heterosexual community.
“Oh, no, Jane, not you,” the doctor replied. “You don’t need that test.”

Unfortunately, it was that same physician who had to deliver the news from the insurance company, and who when asked what she should do, advised Fowler to get a tetanus booster shot.

Fowler says she was fortunate to find a new primary care physician with experience in geriatrics as well as HIV medicine. “She can do everything that I need done, from PAP tests to blood draws to testing my HIV to see how I’m doing. I don’t know how many older HIV patients have an opportunity to have a physician with experience like that, but it is a blessing,” she said.

Fowler has a clear message for physicians:

“Along with asking about alcohol and cigarette use, bring up sex. Take a sexual history as part of a lifestyle history. Find out about sex practices, and ask if the patient is aware of the fact that older people are at the same risk as younger people, depending on their behaviors. I wish that all physicians would just assume there is a good chance that an older person is still sexually active and then talk about their partners and what this person knows about STDs, not just HIV. The physician should be checking for that and talking about it.”

Fowler disagrees with the guidance from the Centers for Disease Control and Prevention (CDC) that recommends that health care settings should provide routine testing for all patients age 13-64. “I think everyone should be tested. Neither sex, nor HIV stops when you turn 65,” she said. “The earlier you find out, the better.”

Anna Fowlkes, 64
Diagnosed with HIV in 2006 after unprotected sex with an old high school friend, Fowlkes, of Baltimore, MD, visits senior centers and senior housing facilities and shares her story. She speaks at conferences and discusses the challenges facing HIV positive older adults, as well as risk factors facing seniors and needs for prevention.

“So many people are under-educated and misinformed,” she said. “One lady told me she was scared to sit next to someone with HIV. There are so many myths about how the virus is transmitted. It is a challenge.”

But Fowlkes is open and honest. She explains that her friend knew he was HIV positive, but didn’t want to tell her for fear she would break up with him. She says she was too trusting, and “didn’t even think about HIV – even though I knew better.”

She went to Chase Brexton Health Services, Inc. in Baltimore to be tested. “I was tired all the time,” she explained. “They took me into a private room, did a mouth swab, and told me the results. They were more upset than I was. I was fully prepared; I was ready for the answer. Since then, my care has been excellent. Maybe it’s because I’ve become so public.”

Now, during her presentations before seniors, she explains that just because they no longer can get pregnant does not mean they should not protect themselves against transmission of STDs, including HIV. She explains what constitutes risky behavior, and she passes out condoms and dental dam.

“These need to be put in senior centers,” Fowlkes said. “In the heat of the moment, no one is going to stop, go to the drug store and buy something.”

For Fowlkes, contracting HIV is seen as somewhat of a blessing in disguise.

“I knew I could live well with my meds and by taking care of myself,” she said. “I got rid of some bad habits, like smoking. And it’s given me a purpose in life.”

Bill Rydvels, 79
“i decided to put another face to the epidemic – an old, white, wrinkled, heterosexual face – to show people that HIV does not discriminate, that it’s not who you are or how old you are, but what you do and don’t do in regard to transmission of HIV”

“I’ve been 26 years for me. I’m doing pretty good, although I had my first AIDS diagnosis in January 1996.”
Bill Rydwels, 79

Rydwels, Chicago, IL, was 53 when he was diagnosed in 1985.

“I was healthy and was with a mate,” he explained. “He kept asking his doc to check him, but the doc didn’t want to believe he was gay. It took two years. By the time he was checked, he had a serious brain condition, one of the manifestations of AIDS. He died on October 9, 1989, just three months after Rydwels received his diagnosis. “It’s been 26 years for me. I’m doing pretty good, although I had my first AIDS diagnosis in January 1996.”

“I never told my mother I was gay. She knew,” Rydwells told writers at Graying of AIDS, an online project that presents portraits of HIV patients over age 50 as a way of increasing awareness, sensitivity, and collaboration among care-giving professionals.

“She says: What did your friend die from? And she went through a long list of diseases, and then she said: ‘Did he have AIDS?’ And I said: Yeah, he did have AIDS.”

His mother then asked Rydwels if he had AIDS.

“No, mom, I have HIV”

“Well, that’s the same thing”

“I informed her. Well, she lived in a senior residence; she had friends.”

“She said: ‘Please, don’t tell them because they won’t come around.’ Among seniors, it’s still that way,” said Rydwels. “They are not educated as to how it is transmitted. They have fears of eating from plates that people have, shaking hands, using the same bathroom. And none of these are ways of transmission. Sometimes the wrong things we believe stick with us, because it’s easier to want to believe that if I don’t touch that doorknob, I won’t get the disease. So I won’t visit that person.”

Rydwels said he started a group in Chicago to support older people with HIV, and believes there generally is greater understanding about HIV and that life is easier today for newly diagnosed older Americans. Still, he said, there are those, including physicians, who are surprised that seniors are still having sex.

“I say, ‘What do you mean you are surprised?’” Rydwels remarked. “The pharmaceutical industry is promoting drugs that are promoting sex among older people. Older people are active sexually; they need it.”

Rydwels told Graying of AIDS that he feels guilty for surviving while so many others have died.

“I’m a very religious person. I pray every day and I feel that in my prayer I have to mention the names. I mention 70 names every day, but there are hundreds of others who died. We lost magnificent people. Don’t know what the world would have been like if we had these people and had all the wonderful things they had to offer us. We don’t have to lose those beautiful people today because we have the drugs to hold them. Give them a little better health. Or maybe, if you get the right education, prevent them from becoming infected.”

“People are living longer… I just assumed that I would be dead by the time I was 50. So geriatric care and HIV care are going to have to be more blended. It’s going to be an increasing population, but we have to look at the issues.”

Ronald Johnson, 63

KATJA HEINEMANN/GRAYINGOFAIDS.ORG
Ronald Johnson, 63
Vice president for policy and advocacy at AIDS United, Washington, DC, Johnson learned of his HIV infection in October 1989 and enjoyed an asymptomatic period until 2004, but now has moved onto AIDS.

However, he has done well on his medication and is amazed at how disciplined he has become in taking them. “I’ve had a very good experience in my treatment, overall,” he said, explaining that the two physicians who have cared for him since his diagnoses – first in New York City and now in Washington, DC – are both considered experts in their field.

But patients’ needs change as they become older, Johnson noted, so physicians need to adapt as well.

“We are living longer,” he told Graying of AIDS. “I just assumed that I would be dead by the time I was 50. So geriatric care and HIV care are going to have to be more blended. It’s going to be an increasing population, but we have to look at the issues.”

“How is HIV going to increasingly affect Medicare when more and more people who are HIV-positive are eligible? And as people get older, that’s going to be more and more of a burden.”

Johnson says it is important for physicians called upon to treat older patients “not to have some preconceived notions as to who is affected. Any person who has been or is sexually active should consider an HIV test. That should be a question for everybody. The whole idea that sexual activity ceases when you are 50, 60, or 70 is wrong. We have to get of rid that. People are sexually active well into their senior years. That should not be a taboo topic in the doctor-patient relationship.”

Sue Saunders, 78
Soon after Saunders was diagnosed in 1989, a nurse at the clinic asked her for her age.

“I said, ‘fifty-eight,’” Saunders recalled. “She said, ‘how did you get it, through needles?’”

“I said, ‘No, I got it through sex.’

“She said, ‘You’re having sex at your age? That’s disgusting!’”

That was the prevalent attitude, said Saunders, in 1997 and 1998 when she worked at the Broward County, FL Health Department as spokesperson for elderly people with HIV.

“They didn’t even know that older people had sex,” she recalled. “They went, ‘Oh, no!’ Absolutely no one had ever heard of anyone elderly having sex, let alone getting HIV.”

Thus, Saunders, too, believes it is time for people to get real – including health care professionals. Just because a patient might remind them of their grandmother, doctors should not assume she is not sexually active and questions about sexual practices should be asked.

For Sue Saunders, life with HIV has lasted 20 years and counting. She had a rough time with her meds, she’ll be the first to tell you. But she credits her doctor – she’s had the same one in Fort Lauderdale, FL for the past 15 years – with helping her survive.

Today, aside from her own health – she is now having difficulty walking and must use a cane – Saunders is worried that older Americans just assume that since pregnancy is no longer a concern, protection isn’t necessary.

“So many people are having so much fun having sex without worrying about getting pregnant,” she said. “It’s a state of mind. They don’t worry about getting HIV.”

That is exactly what happened to her, she says.

In 1978, Saunders, her boyfriend and four kids moved to Bimini. She was madly in love with him, she said. But then, he lost 50 pounds.

“He couldn’t go out dancing all night. We used to go fishing all day, dance all night. He could hardly walk. I said, ‘What’s the matter with you?’ He wouldn’t say anything.”

But then, the doctor gave her the news. “The guy I was so madly in love with had tested positive for HIV.”

She asked him why he had not told her.

“I’m 68 years old; I’ve never worn a condom in my life, and I’m not gonna start now,” was his reply.

Saunders also told her story to Graying of AIDS.

“If somebody told you that if you went and did this, you wouldn’t have a heart attack tomorrow, you’d go and do it, wouldn’t you? Or if you did this, you wouldn’t have breast cancer tomorrow, you’d do it. Right? Wouldn’t you? Don’t you think you would?

“But all you have to do is wear a condom to keep from getting HIV, and that’s too much to ask. Isn’t that something, huh? I should have been dead. But I’m not. So maybe that’s my purpose in life, to keep this movement going, to make people aware that this disease is not going to quit.”

About the Author: Editor of HIV Specialist, Bob Gatty is a Washington, DC-area health policy writer and publications professional. He is founder of G-Net Strategic Communications and can be reached at bob@gattyedits.com.
The Challenge of Treating the Aging HIV-Positive Adult

Doing the right prevention screening and therapeutic interventions in this increasingly complex patient

C
S LOOKED AT ME disappointedly. His neuropsychiatric tests were normal – no cognitive deficits, as he had thought. Yet he was unconvinced, adamant that something had changed because he could not recall job-related formulas he had used for over 20 years as readily as similarly aged colleagues.

Then he asked it, “How do we know that I wouldn’t have scored higher before? Maybe I’ve declined from a high level.”

I didn’t have a great answer for him. There weren’t any good studies to address his question or the role of baseline cognitive assessments in aging HIV-positive patients. In fact, there is very little we knew about how we should change our health screenings for HIV-positive adults over 50. I had similar feelings almost a decade earlier when we discovered rapidly progressive lung cancer in one of my patients, a non-smoker who was getting his six-month chest x-ray follow up for a small incidental lung nodule, or when I found terminal anal cancer in two of my patients with well-controlled HIV prior to our routine screenings.

I could provide more anecdotes, but suffice it to say that like many HIV providers today, I worry about doing the right prevention screening and therapeutic interventions in the increasingly complex aging HIV-positive adult.

Of course, most virologically controlled HIV-positive individuals are doing well today without any significant complications. Yet, as one of my patients shared: “I look great and I feel great... but it takes a lot of work to do it.”

It’s a theme I have heard from several patients in different ways. Some have had or complained of significant physical or cognitive issues compared to their peers. There is evidence that older HIV-positive adults are experiencing high rates of aging-related comorbid illnesses two decades earlier than their non-infected peers (Havlik, 2009). These HIV associated non-AIDS or HANA conditions include the early onset of liver disease, cardiovascular disease, kidney dysfunction, non-AIDS cancers, osteoporosis, neurocognitive decline, and even “frailty” – conditions affected by HIV disease, HIV treatments, and behavioral factors common to our patients.

As noted in the statement from the HIV and Aging Consensus Project, “these older adults with HIV are not typical (Karpiak et al, 2006; Brennan et al., 2009)...they are experiencing high rates of comorbid illnesses two decades earlier than their non-infected peers (Havlik, 2009)...and have high rates of depression and suicidal ideation that contribute to reduced health outcomes (Havlik et al., 2011; Gonzalez et al, 2011). Many use alcohol, tobacco, and/or illicit drugs, further compromising their health (Grov et al., 2010; Golub et al. 2011”).

Of note, the health of HIV-infected adults is also affected by the fact that many have more limited social networks than their HIV-negative colleagues – due to a loss of companions from HIV, estrangement and isolation from AIDS associated stigma (Brennan et al, 2009), and more. Social isolation can have wide
reaching psychosocial and physical effects (e.g. depression, cognitive function, and physical activity); yet it can be a real challenge to address.

It is increasingly clear that the health of older HIV-positive adults is complicated by multiple factors, of which the relative contributions remain to be determined. Yet, not all may not be as it seems.

For example, while cognitive complaints are common among aging HIV-positive individuals, recent findings suggest most of these are not corroborated on neuropsychiatric testing. In one recent study, about half of HIV-positive older adults were found to have an abnormal neuropsychiatric test, yet 70 percent were asymptomatic and those with symptoms tended to be significantly compromised (Valcour et al. 2011 and personal communication). Understanding who is most likely to have clinically significant complications is critical to managing the ageing HIV-positive population. Our clinic, like many, is already challenged to provide high level multidisciplinary care to our patients in a time of decreasing resources for HIV care and services.

So, what’s a clinician to do?

Today, there are several plausible theories on how HIV causes damage to the body – immune senescence, “leaky gut”, oxidative stress, HIV and HIV medication toxicity, and HANA conditions – not to mention the effect of behavioral factors and co-infections such as hepatitis C and cytomegalovirus.

However, there is still uncertainty over the clinical significance of some of these theories and even less on how to intervene. Do we use medications to decrease inflammatory responses to HIV such as aspirin, statins, toll-like receptor inhibitors or other drugs? Should we look instead at ways to decrease microbial translocation from “leaky gut” with drugs such as bovine clostrum, pre-biotics, pro-biotics, rifaximin, mesalamine, or others? Do we focus on aggressively treating co-infections such as HCV and CMV? Or do we focus on healthcare maintenance and behavioral modifications such as alcohol consumption reduction and smoking cessation?

As primary providers of HIV-positive individuals, we need guidance on clinical management. We must be able to see patients and assess whom we need to monitor more closely or differently to avoid and ameliorate some of the HANA conditions. What specialists do clinicians need to engage to best optimize the care of their aging HIV patients? How should the medical home of our patients change to adapt to increased awareness of premature or increased rates of certain clinical complications?

Some have looked towards the field of geriatrics for guidance. The different perspective geriatricians bring to their patients may be increasingly relevant to the ageing HIV-positive patient with multiple medical problems, especially those regarding multimorbidity, polypharmacy, domains important for sustaining high functional capacity, and care in blindly applying screening and treatment guidelines developed for primary care populations free of major co-morbidity to populations with complex chronic disease and multi morbidity (Tinetti, Bogardus et al. 2004; Boyd, Darer et al. 2005).

However, I like many others wonder how to apply the lessons of geriatric field to our patients.

Geriatricians generally work with older persons than our HIV-positive patients and deal with geriatric syndromes that may not readily apply to a younger population, even one with increased incidence of conditions associated with aging.

Expert opinion, consensus recommendations and ultimately clinical studies will play an important role in preparing for the future increase in HIV-positive patients over the age of fifty. We need to find tools to better assess or triage our patients to best direct our resources. Here in San Francisco, our clinic 360: The Positive Care Center is part of collaboration with the San Francisco Public Health Department and the San Francisco General Hospital’s Positive Health Program to develop and evaluate a medical home model for the aging HIV patient. We will look at ways to efficiently assess important functional domains and biological parameters to help stratify patients according to clinical needs and risks for complications.

Tools such as the VACS index referenced in the statement from the HIV and Aging Consensus Project may prove immensely useful in this process. Importantly, we will look at ways to tailor the medical home model to meet various patient needs with an emphasis on health maintenance, physical and nutritional health, and social connectedness. It’s a challenging endeavor, but ones like these will be important companions to the biological studies of HIV pathogenesis and aging. Perhaps someday in the near future, we can help patients like CS continue to live and work as long as his HIV-negative peers.

As primary providers of HIV-positive individuals, we need guidance on clinical management. We must be able to see patients and assess whom we need to monitor more closely or differently to avoid and ameliorate some of the HANA conditions.
Connecting AAHIVM Members
One Chapter at a Time

When a provider becomes a Member of the American Academy of HIV Medicine, he or she is also automatically placed in one of the thirteen AAHIVM Regional Chapters. Our Chapters exist to encourage our Members to work together on local HIV-related issues and help establish connections to other local HIV practitioners.

To better facilitate communication between our Chapter Members and between Chapters coast to coast, AAHIVM has created Chapter Connections, an online Chapter portal designed to create a way for Members to be more engaged with their regional chapters. Chapter Connections allow Members to stay current on HIV care topics impacting them locally, and to view HIV care topics affecting other chapters across the country.

From the main page, the Chapter Module appears as a graphic map of the United States. Each regional chapter is color-coated. By scrolling over the map, Members can see which states comprise which chapters.

Clicking on a particular chapter activates a pop-out window containing that Chapter Page. The Chapter Page acts as a landing page from which a Member has several options and can access various data about the chapter including:

Chapter Composition
The top of the Chapter Page details which states comprise that chapter. Some chapters are comprised of only one state, such as our Florida Chapter. Others are comprised of several, such as our Southeast Chapter.

Chapter Chair Information
The Chapter Page tells the Member who the Chapter Chair is for the chapter. It includes the Chair’s name, professional degrees, the institution where the Chair practices HIV care and a headshot photograph. For chapters that are chaired by Co-Chairs, information for both Chapter Chairs is displayed.

Chapter Chair Contact
There is a link to each Chair’s AAHIVM email address on the Chapter Page. Members can now communicate directly with their Chapter Chairs by writing to them at their aahivm.org addresses.

Hot Topic
The Chapter Chair, together with his/her regional steering committee, will provide regularly updated “Hot Topics.” These topics may vary to include many things including: pending state legislation that may impact HIV care providers locally within that chapter, upcoming educational or community events that may be of interest to HIV care providers, local initiatives impacting HIV care, local AIDS walks, local needle exchanges, scientific or clinical findings from studies of local medical schools, etc. These hot topics may be updated as often as the Chapter Chair sees fit to draw attention to specific events/activities/topics that he/she would like to bring to the attention of Members within his/her chapter.

Hot Topic Links
From the Chapter Page, Academy staff will provide links to more information about the Hot Topic from reputable sources on the Internet.

Hot Topic Discussion Board
There is a direct link to AAHIVM’s Discussion Board from the Chapter Page. Each Hot Topic will have a corresponding Discussion Board, specific to that chapter, where Members can communicate about the Hot Topic.

Member/Credentialed Count
The bottom of the Chapter Page provides an up-to-the-minute count of how many people within that chapter are AAHIVM Members and how many are credentialed as HIV Specialists/Experts/Pharmacists with AAHIVM.

Membership Join/Renewal Link
If a person viewing the Chapter Page is not logged in to their AAHIVM account as an active Member of the Academy, a link will appear by which that person may be directed to AAHIVM’s Membership Page and he or she can join or renew his/her Membership. Non-Members may view the Chapter Pages, but may not access the Discussion Boards to discuss and gain further information about the Hot Topics.

It is important to remember that Members have access not only to their own Chapter Page, but to all regional Chapter Pages. For instance, if a Member in Florida sees that the Hot Topic being highlighted in Texas is something that he or she would like to share information about or ask questions about, he or she has access to that chapter’s page and may participate in that chapter’s discussion board.

About the Author: Aaron Austin is the Director of Finance for the American Academy of HIV Medicine and also leads the chapter activities for AAHIVM.
Am I a Member or am I Credentialed?

Since its inception more than 10 years ago, the American Academy of HIV Medicine (AAHIVM, or more simply just “the Academy”), has grown to become one of America’s most important providers of professional services for HIV caregivers and their support teams.

Largely gone are the early days of disarray as the profession of “HIV care provider” is now much more clearly identified and understood by governments, healthcare organizations, third party insurers and patients... all thanks to the coordinated efforts of major provider organizations like AAHIVM.

The Academy is a number of things, but most importantly, we are a professional trade association of Members, and we are a “Certifying body” in professional HIV care. Most of our constituent providers are actually both a Member and Credentialed, but neither program is required for the other.

As a matter of fact, Membership at AAHIVM is open to just about anyone whose work life involves some aspect of HIV care, whereas our Credentialing offerings are more technical clinical certifications for direct caregivers.

Academy Members support the broad and critical coalition mission of our organization through the financial support of their dues, and earn the unification of their voices on matters essential to their everyday work. They support broad initiatives such as our HIV Specialist magazine, projects focusing on AIDS and Aging, and many other endeavors. They also enjoy a number of Member-only benefits, such as an online job board, online discussion modules for topics of all kinds in clinical care, a “chapter module” with specific tools and information related to their own region, a powerful State Legislation Tracker (this amazing resource must be seen to be believed), official and cordial gatherings at major conventions, free bulk copies of the patient magazine Positively Aware, free bulk copies of our own provider magazine HIV Specialist, discounts on our major publications such as Fundamentals on HIV Medicine, and much more.

Academy Credentialed Providers hold the most widely-recognized professional certification in HIV care; something that did not even exist a mere 10 years ago. This program creates a level playing field for providers from all areas of clinical training (not just infectious disease) who do intensive daily HIV primary care work, and is a highly robust professional development opportunity. Perhaps most importantly though, our certifications serve as a defensible means of protection for the healthcare-consuming public. They offer method to identify and access HIV care providers who have not only demonstrated their knowledge, but have also documented their experience and continuing education habits – all of which may be regarded as the foundation of excellence in HIV care. As I noted above, many of our providers are both Members and Credentialed.

As with many things in HIV medicine, the rapid cultural shift to the now-clear identity of the HIV care provider is at once both surprising and reassuring. The recognition we are building for the trade helps to bolster its reputation within professional medical circles, attracts new clinical talent, offers a more robust and clear voice that speaks directly to the legislature on all manner of issues such as care equity, resource allocation, budget and finance, insurance regulation, reimbursement issues and much, much more – all from the perspective of the provider who works in such a time-demanding area of medicine. Also, the clarity of access to overall quality primary care that we now provide to the HIV-interested healthcare consumer far exceeds that of only a decade ago. In those days, word-of-mouth was a patient’s best and only method to find skilled HIV primary and pharmacy care.

In addition to the major AAHIVM identities cited above, the Academy also provides a number of related services, all in the interest of advancing excellence in HIV care. These functions include our role as a major clinical publisher, offering one of the nation’s most renowned core clinical resources, Fundamentals of HIV Medicine.

We also serve as a broad educational resource, offering our renowned trade magazine HIV Specialist, as well as a host of printed, live and online educational opportunities in HIV care. Lastly, but perhaps most importantly, we are a powerful political presence at the federal and state level, advocating and interpreting information in the complex arena of legislation, funding and focus on HIV healthcare. The public policy unit is a function at AAHIVM that may give the average Member provider the greatest sense of belonging, as we consume and digest a vast array of information, and boil it all down to concise concepts that are useful to the everyday practitioner.

We often hear the question “but I am Credentialed, aren’t I a Member?” Technically, no, these two programs are separate, but we are always pleased to have your affiliation in either. Moreover, we most appreciate those providers who are both Members and Credentialed, for they are fully supporting our mission to broaden the technical capacity and recognition in this field, expand its resources, improve outcomes, and provide expert guidance and tools on accessing the highest levels of care.

About the author: Peter Fox is the Director of Credentialing at AAHIVM. He has been with the Academy since 2004 and is a former clinician working in emergency services and HIV primary care.
Robert James “Bob” Frascino, MD, AAHIVE fought HIV professionally for over 30 years, and personally for 20. He died suddenly on September 17 this year in the emergency room of El Camino Hospital in Mountain View, CA. He was 59.

The cause of his death was non-typable Haemophilus influenza sepsis. Bob’s sister Linda and I were there when he died. Our dog Presto was also close by. Bob and I were wed in 2008 and spent the last 18 years of our lives together. I am also an experienced HIV care provider who has worked with (and been certified by) AAHIVM since its inception over 10 years ago.

Bob was a physician, educator and tireless advocate for the HIV/AIDS community. He was the vice-chair of the Oberlin College Board of Trustees, a columnist, a commentator, and so much more. Interestingly, he was also an amazing concert pianist. His love of life, keen intellect, sense of humor and ever-present smile will be deeply missed.

Bob trained as an immunologist at UCSF and served as Associate Clinical Professor of Medicine, Division of Immunology, Rheumatology & Allergy at Stanford for over 18 years. One of the first physicians to treat HIV in the early ‘80s, he subsequently founded two medical clinics devoted to comprehensive and compassionate HIV care. As the primary investigator for several early HIV trials, he published articles on evolving new treatments and quality of life issues. These papers appeared in such journals as International Journal of STD & AIDS, Western Journal of Medicine, JAIDS, TheBody.com, Blood and many more.

Bob crossed the line from physician to patient when an occupational exposure resulted in his own positive HIV test. In early 1996, when his health began to fail, he gave up his HIV practice and turned his efforts to education and fundraising.

That same year, he and I planted the seed for what would later become The Robert James Frascino AIDS Foundation, performing benefit piano concerts at our home in Los Altos. Overwhelmingly successful, we then founded the Concerted Effort HIV/AIDS Benefit Concert series, through which we performed classical and popular piano concerts all over California. To date we’ve raised over $1.5M for crucial HIV/AIDS services worldwide, ranging from hospice care in LA, to clean needle-exchange programs in Washington, DC, and provision of anti-HIV medication to pregnant women in Africa (thereby helping prevent HIV transmission to their newborns).

Concerted Effort 2011 would have been the 17th show in the series, and was scheduled to take place at the Mountain View Center for the Performing Arts on September 18, the day after Bob’s death.

Since May of 2000 Bob has served as a physician subject matter expert on two online educational HIV forums – Fatigue/Anemia and Safe Sex/HIV Prevention – both at TheBody.com, an important online resource for patients. He has posted answers to some 30,000 questions over the years. In December 2010 he started a witty, insightful and well-read blog titled Life, Love, Sex, HIV and Other Unscheduled Events.

Known simply as “Dr. Bob” to the world, he touched the lives of millions through his humorous and thoughtful forums, blogs and writings. Bob truly lived with HIV.

Reflecting on his years with the virus, he said, “In many ways, I’ve never felt more alive, and this new perspective has had some amazingly positive influences in my life.... As physicians, we tend to measure life in terms of length, when really, life might be much better measured in depth.”

Bob will be deeply missed by the leadership and Member providers of the Academy, and the AIDS community at large. Together with them, I salute a man who gave more than his fair share in this fight. Memorial donations may be made in Bob’s name to our nonprofit charitable organization, The Robert James Frascino AIDS Foundation (www.ConcertedEffort.org).

ABOUT THE AUTHOR:
Steven Natterstad, MD. AAHIVS is president of The Frascino Medical Group in Los Altos, CA, and has been a continuously certified HIV SpecialistTM since the inception of the program over a decade ago. Bilingual in Spanish, Dr. Natterstad is a member of G.L.M.A., and is also an accomplished concert pianist.
Recommended Treatment Strategies for Clinicians Managing Older Patients with HIV

Complete Report NOW AVAILABLE ONLINE
Offer your expertise and opinion on the interactive discussion forum
www.aahivm.org/hivandagingforum