Disclosures

• I have received an investigator initiated grant from Merck Pharmaceuticals

• I have served on an advisory board for Theratechnologies
Objectives

• Discuss current recommendations for initiating antiretroviral therapy in patients with newly diagnosed HIV infection

• Outline the approach for preventing HIV infection transmission with pre-exposure prophylaxis

• Describe new and ongoing challenges for patients and providers in terms of healthcare coverage and access to HIV care

• Identify opportunities to advocate for patients living with HIV in order to reduce barriers to HIV treatment and prevention services

• Discuss ACCP Advocacy resources on the website

• End with a call to advocate
Initiation of Antiretroviral Therapy

Current Recommendations

DHHS Panel’s Recommendations for Initiating Antiretroviral Therapy in Treatment-Naive Patients

• Antiretroviral therapy (ART) is recommended for all individuals with HIV, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection (AI).

• ART is also recommended for individuals with HIV to prevent HIV transmission (AI).

• When initiating ART, it is important to educate patients regarding the benefits and considerations of ART, and to address strategies to optimize adherence. On a case-by-case basis, ART may be deferred because of clinical and/or psychosocial factors, but therapy should be initiated as soon as possible.

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion
Initiation of Antiretroviral Therapy
Recommendations Have Evolved

<table>
<thead>
<tr>
<th>CD4 Count (cells/mm³)</th>
<th>1998</th>
<th>2001</th>
<th>2006</th>
<th>2009</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 500</td>
<td>Treat if VL &gt;20,000</td>
<td>Treat if VL &gt;55,000</td>
<td>Consider if VL &gt;100,000</td>
<td>Consider in certain patients</td>
<td>Consider in certain patients</td>
</tr>
<tr>
<td>350-500</td>
<td>Treat if VL &gt;20,000</td>
<td>Treat if VL &gt;55,000</td>
<td>Consider if VL &gt;100,000</td>
<td>Consider in certain patients</td>
<td>Treat</td>
</tr>
<tr>
<td>200-350</td>
<td>Treat if VL &gt;20,000</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
</tr>
<tr>
<td>&lt;200 or symptomatic</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
</tr>
</tbody>
</table>

Present: Treat

Treat

Treat
Early ART Reduces AIDS and Non-AIDS Events

The START Study

• ART-naïve adults (n=4685)
  • CD4 cell counts >500
  • Randomized to initiate ART immediately or after a CD4 count decline to <350
  • Primary endpoint was a composite of serious AIDS and non-AIDS events

• Immediate ART reduced risk of serious events or death by 57%

• Most events (59%) in the deferred ART arm occurred with CD4 counts > 500

ART Reduces HIV Transmission

The HPTN-052 Study

- HIV-serodiscordant couples (n = 1763)
  - Partner with HIV was ART naive with a CD4 count of 350 to 550 cells/mm³ at enrollment
  - Randomized to immediate ART versus delayed therapy (CD4 count <250)
  - Most (97%) reported to be in a heterosexual monogamous relationship
  - All were counseled on risk and condom use
  - Primary outcome: HIV transmission events

- A 96% reduction in transmission with early ART
  - HR 0.04; 95% CI, 0.01–0.27; P < 0.001

ART Reduces HIV Transmission
Undetectable = Untransmittable (U = U)

• PARTNER-1 study
  • Assessed rate of HIV transmission within sero-different heterosexual and MSM couples during periods of condomless sex while HIV-positive partner had HIV-1 RNA < 200 copies/mL
    • No linked within-couple transmissions observed
    • Upper 95% CI for rate of transmission between MSM was 0.84/100 CYFU vs 0.46/100 CYFU in heterosexuals

• Opposites Attract study
  • Assessed rate of HIV transmission within sero-different MSM couples during periods of condomless sex while HIV-positive partner had HIV-1 RNA < 200 copies/mL
    • No linked within-couple transmissions observed
    • Upper 95% CI for rate of transmission was 1.59/100 CYFU
ART Reduces HIV Transmission

Undetectable = Untransmittable (U = U)

• PARTNER study enrolled sero-different couples in 75 European sites
  • PARTNER-1 followed heterosexuals and MSM from 2010-2014
  • PARTNER-2 followed MSM from 2014-2018 (included some MSM couples from PARTNER-1)

• Primary aim of PARTNER-2:
  • Improve accuracy of estimated within-couple HIV transmission risk among MSM during periods of condomless sex while HIV-positive partner had HIV-1 RNA < 200 copies/mL

• Eligibility for inclusion (all must apply within time period between HIV tests):
  • Couple reported within-couple CL sex
  • No PEP or PrEP use by HIV-negative partner
  • HIV-1 RNA < 200 copies/mL in HIV-positive partner at all assessments within prior 12 months

Rodger A, et al. IAS 2018; Abstract WEAX0104LB.
ART Reduces HIV Transmission
Undetectable = Untransmittable (U = U)

• PARTNER-2: Rate of HIV transmission according to sexual behavior reported by the negative partner

<table>
<thead>
<tr>
<th>Sexual Behavior</th>
<th>Linked Transmissions</th>
<th>Upper 95% CL</th>
<th>Couple Years of Follow-up</th>
<th>Condomless Sex Acts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Sex</td>
<td>0</td>
<td>0.23</td>
<td>1,596</td>
<td>76,991</td>
</tr>
<tr>
<td>Anal Sex</td>
<td>0</td>
<td>0.24</td>
<td>1,546</td>
<td>70,743</td>
</tr>
<tr>
<td>Insertive anal Sex</td>
<td>0</td>
<td>0.27</td>
<td>1,345</td>
<td>52,572</td>
</tr>
<tr>
<td>Receptive Anal Sex with Ejaculation</td>
<td>0</td>
<td>0.57</td>
<td>652</td>
<td>20,770</td>
</tr>
<tr>
<td>Receptive Anal Sex without Ejaculation</td>
<td>0</td>
<td>0.43</td>
<td>867</td>
<td>23,153</td>
</tr>
<tr>
<td>Any Sex with a STI</td>
<td>0</td>
<td>2.74</td>
<td>135</td>
<td>6,301</td>
</tr>
</tbody>
</table>

• Among serodifferent gay couples who had sex ~77,000 times without condoms with an undetectable viral load, zero linked transmissions were identified.
Advocacy

Undetectable = Untransmittable (U = U)

People who take ART daily as prescribed and achieve and maintain an undetectable viral load have **effectively no risk** of sexually transmitting the virus to an HIV-negative partner.

September, 2017

Initiation of Antiretroviral Therapy
Current Recommendations

<table>
<thead>
<tr>
<th>DHHS Panel's Recommended Initial Regimens for Most People with HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dolutegravir/abacavir/lamivudine (AI)</td>
</tr>
<tr>
<td>• Dolutegravir plus tenofovir/emtricitabine (AI)</td>
</tr>
<tr>
<td>• Elvitegravir/cobicistat/tenofovir/emtricitabine (AI)</td>
</tr>
<tr>
<td>• Raltegravir plus tenofovir/emtricitabine (AI)</td>
</tr>
<tr>
<td>• Bictegravir/tenofovir alafenamide/emtricitabine (AI)</td>
</tr>
</tbody>
</table>

• An antiretroviral (ARV) regimen for a treatment-naive patient generally consists of two nucleoside reverse transcriptase inhibitors in combination with a third active ARV drug from one of three drug classes: an integrase strand transfer inhibitor, a non-nucleoside reverse transcriptase inhibitor, or a protease inhibitor.
Initiation of Antiretroviral Therapy
Current Recommendations

### DHHS Panel's Recommended Initial Regimens in Certain Clinical Situations

- Darunavir plus tenofovir/emtricitabine (AI)
- Atazanavir plus tenofovir/emtricitabine (BI)
- Efavirenz plus tenofovir/emtricitabine (BI)
- Rilpivirine plus tenofovir/emtricitabine (BI)
- Darunavir plus raltegravir (CI)

- These regimens are effective and tolerable, but have some disadvantages when compared with regimens recommended to be used in most patients, or have less supporting data from randomized clinical trials. However, in certain clinical situations, one of these regimens may be preferred.
Integrase inhibitors have high rates of virologic suppression and often greater tolerability than PI- or NNRTI regimens.

<table>
<thead>
<tr>
<th>Study</th>
<th>Integrase Agent</th>
<th>Comparator(s)</th>
<th>Follow-up</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>STARTMRK</td>
<td>Raltegravir</td>
<td>Efavirenz</td>
<td>192 Weeks</td>
<td>Raltegravir superior to efavirenz</td>
</tr>
<tr>
<td>ACTG 5257</td>
<td>Raltegravir</td>
<td>Darunavir/ritonavir</td>
<td>96 Weeks</td>
<td>Raltegravir superior to darunavir/ritonavir</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Atazanavir/ritonavir</td>
<td></td>
<td>Raltegravir superior to atazanavir/ritonavir</td>
</tr>
<tr>
<td>GS-102</td>
<td>Elvitegravir</td>
<td>Efavirenz</td>
<td>144 Weeks</td>
<td>Elvitegravir non-inferior to efavirenz</td>
</tr>
<tr>
<td>GS-103</td>
<td>Elvitegravir</td>
<td>Atazanavir/ritonavir</td>
<td>144 Weeks</td>
<td>Elvitegravir non-inferior to atazanavir</td>
</tr>
<tr>
<td>WAVES</td>
<td>Elvitegravir</td>
<td>Atazanavir/ritonavir</td>
<td>48 Weeks</td>
<td>Elvitegravir superior to atazanavir/ritonavir</td>
</tr>
<tr>
<td>SINGLE</td>
<td>Dolutegravir</td>
<td>Efavirenz</td>
<td>48 Weeks</td>
<td>Dolutegravir superior to efavirenz</td>
</tr>
<tr>
<td>FLAMINGO</td>
<td>Dolutegravir</td>
<td>Darunavir/ritonavir</td>
<td>48 Weeks</td>
<td>Dolutegravir superior to darunavir/ritonavir</td>
</tr>
<tr>
<td>GS-US-380-1489</td>
<td>Bictegravir</td>
<td>Dolutegravir</td>
<td>48 Weeks</td>
<td>Bictegravir non-inferior to dolutegravir</td>
</tr>
<tr>
<td>GS-US-380-1490</td>
<td>Bictegravir</td>
<td>Dolutegravir</td>
<td>48 Weeks</td>
<td>Bictegravir non-inferior to dolutegravir</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Raltegravir | • Longest experience  
• Fewest drug interactions  
• Twice or once daily dosing | • **Not a single tablet regimen**  
• Daily dose is two tablets in addition to nucleoside reverse transcriptase inhibitors |
| Elvitegravir | • Single tablet regimens  
• Once daily dosing | • **Requires boosting with cobicistat**  
• Many drug interactions  
• SCr elevations with cobicistat |
| Dolutegravir | • **Single tablet regimen**  
• Once daily dosing  
• **High barrier to resistance**  
• Few drug interactions  
• Can be given as a two-drug regimen? | • Risk of neural tube defects in pregnancy?  
• Co-formulated with abacavir  
• Co-formulated with lamivudine  
• SCr elevations with dolutegravir |
| Bictegravir | • **Single tablet regimen**  
• Once daily dosing  
• **High barrier to resistance**  
• Few drug interactions | • Only available in a single tablet  
• SCr elevations with bictegravir |
• Bictegravir and dolutegravir do not require boosting, have a high barrier to resistance, and are part of regimens with a low pill burden and toxicity.

• Raltegravir is well tolerated with few drug interactions, but has a low barrier to resistance and a high pill burden.

• Elvitegravir has a lower barrier to resistance and requires boosting, resulting in more drug interactions.
## Initiation of Antiretroviral Therapy
### Choosing Between The Integrase Inhibitors

<table>
<thead>
<tr>
<th>Agent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Raltegravir | • Longest experience  
• Fewest drug interactions  
• Twice or once daily dosing | • Not a single tablet regimen  
• Daily dose is two tablets in addition to nucleoside reverse transcriptase inhibitors |
| Elvitegravir | • Single tablet regimens  
• Once daily dosing | • Requires boosting with cobicistat  
• Many drug interactions  
• SCr elevations with cobicistat |
| Dolutegravir | • Single tablet regimen  
• Once daily dosing  
• High barrier to resistance  
• Few drug interactions  
• **Can be given as a two-drug regimen?** | • Risk of neural tube defects in pregnancy?  
• Co-formulated with abacavir  
• Co-formulated with lamivudine  
• SCr elevations with dolutegravir |
| Bictegravir | • Single tablet regimen  
• Once daily dosing  
• High barrier to resistance  
• Few drug interactions | • Only available in a single tablet  
• SCr elevations with bictegravir |
Initiation of Antiretroviral Therapy
Two versus Three Drug ART

In single-arm pilot studies, first-line DTG plus 3TC was effective and well tolerated

- PADDLE: 18/20 (90%) patients had HIV-1 RNA < 50 copies/mL at Week 48
- ACTG A5353: 108/120 (90%) patients had HIV-1 RNA < 50 copies/mL at Week 24

GEMINI-1 and GEMINI-2 (n = 1,433)

- Two double-blind, Phase III studies comparing efficacy and safety of DTG+3TC to DTG+TDF/FTC in treatment-naïve adults with baseline HIV-1 RNA ≤500,000 copies/mL

<table>
<thead>
<tr>
<th></th>
<th>GEMINI-1</th>
<th>GEMINI-2</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTG+3TC</td>
<td>320/356</td>
<td>335/360</td>
<td>655/716 (91%)</td>
</tr>
<tr>
<td>DTG+TDF/FTC</td>
<td>332/358</td>
<td>337/359</td>
<td>669/717 (93%)</td>
</tr>
<tr>
<td>Difference (95% CI)</td>
<td>-2.6 (-6.7, 1.5)</td>
<td>-0.7 (-4.3, 2.9)</td>
<td>-1.7 (-4.4, 1.1)</td>
</tr>
</tbody>
</table>

- DTG+3TC demonstrated non-inferior efficacy to DTG+TDF/FTC
- Both regimens were well tolerated. Biomarkers of bone turnover and renal function favored DTG+3TC
## Initiation of Antiretroviral Therapy
### Choosing Between The Integrase Inhibitors

<table>
<thead>
<tr>
<th>Agent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Raltegravir | • Longest experience  
• Fewest drug interactions  
• Twice or once daily dosing | • Not a single tablet regimen  
• Daily dose is two tablets in addition to nucleoside reverse transcriptase inhibitors |
| Elvitegravir| • Single tablet regimens  
• Once daily dosing | • Requires boosting with cobicistat  
• Many drug interactions  
• SCr elevations with cobicistat |
| Dolutegravir| • Single tablet regimen  
• Once daily dosing  
• High barrier to resistance  
• Few drug interactions  
• Can be given as a two-drug regimen? | • Risk of neural tube defects in pregnancy?  
• Co-formulated with abacavir  
• Co-formulated with lamivudine  
• SCr elevations with dolutegravir |
| Bictegravir | • Single tablet regimen  
• Once daily dosing  
• High barrier to resistance  
• Few drug interactions | • Only available in a single tablet  
• SCr elevations with bictegravir |
Dolutegravir and Neural Tube Defects
Evidence as of May 1, 2018

• NIH-funded surveillance study of birth outcomes in Botswana

• Originally began in 2014 as a 4-year study of the prevalence of neural tube defects in live-born and stillbirths among women on efavirenz at conception versus other exposure groups

• In 2016, Botswana switched first line ART from TDF/FTC/EFV to TDF/FTC/dolutegravir for all adults (including pregnant women)

• In April 2018, investigators were asked to provide preliminary data on outcomes for women who started DTG before pregnancy

Dolutegravir and Neural Tube Defects
Evidence as of May 1, 2018

Neural tube defects found in 86 of 88,755 births (0.10%; CI_{95} 0.08%-0.12%) as of May 1, 2018.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Infants with Neural-Tube Defect (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTG from Conception</td>
<td>4/426 (0.94%; CI_{95} 0.37%, 2.4%)</td>
</tr>
<tr>
<td>Non-DTG from Conception</td>
<td>14/11,300 (0.12%; CI_{95} 0.07%, 0.21%)</td>
</tr>
<tr>
<td>EFV from Conception</td>
<td>3/5,787 (0.05%; CI_{95} 0.02%, 0.15%)</td>
</tr>
<tr>
<td>DTG During Pregnancy</td>
<td>0/2,812 (0.00%; CI_{95} 0.0%, 0.13%)</td>
</tr>
<tr>
<td>Non-DTG During Pregnancy</td>
<td>3/5,624 (0.05%, 95% CI 0.02%, 0.16%)</td>
</tr>
<tr>
<td>HIV Negative</td>
<td>61/66,057 (0.09%, 95% CI 0.07%, 0.12%)</td>
</tr>
</tbody>
</table>
## Dolutegravir and Neural Tube Defects
### Evidence as of July 15, 2018

- From May 1st to July 15th, there were 2 more NTDs; 1 in an infant exposed to DTG started during pregnancy and 1 birth to an HIV-uninfected woman.

<table>
<thead>
<tr>
<th>Infants with Neural-Tube Defect (%)</th>
<th>0</th>
<th>0.5</th>
<th>1.0</th>
<th>1.5</th>
<th>2.0</th>
<th>2.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTG from Conception</td>
<td></td>
<td>⬤</td>
<td>⬤</td>
<td>⬤</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-DTG from Conception</td>
<td></td>
<td></td>
<td>⬤</td>
<td>⬤</td>
<td>⬤</td>
<td>⬤</td>
</tr>
<tr>
<td>DTG During Pregnancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-DTG During Pregnancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **DTG from Conception:** 4/596 (0.67%, CI 0.26%, 1.7%)
- **Non-DTG from Conception:** 14/11,300 (0.12%; CI 0.07%, 0.21%)
- **DTG During Pregnancy:** 0/2,812 (0.00%; CI 0.0%, 0.13%)
- **Non-DTG During Pregnancy:** 3/5,624 (0.05%, 95% CI 0.02%, 0.16%)
- **HIV Negative:** 61/66,057 (0.09%, 95% CI 0.07%, 0.12%)
## Dolutegravir and Neural Tube Defects
### Current Recommendations

<table>
<thead>
<tr>
<th>ART history</th>
<th>Clinical Scenario</th>
<th>Recommendations/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARV-naive or On ART (but not DTG) and contemplating switching to a DTG-based regimen</td>
<td>Pregnant, less than 8 weeks from last menstrual period</td>
<td>• <strong>Do not initiate a DTG-based regimen</strong></td>
</tr>
</tbody>
</table>
| | Pregnant, 8 weeks or longer from last menstrual period | • If ARV-naive, use DTG or another ARV drug  
• If currently on a non-DTG regimen, continue current regimen or switch to DTG or another option |
| | Those who desire pregnancy or are not using effective contraception | • **Do not initiate a DTG-based regimen** |
| | Those who do not desire pregnancy and who are using effective contraception | • DTG can be considered as part of an ARV regimen  
• Pregnancy testing is recommended prior to initiation of DTG  
• Discuss the potential of DTG to the fetus and the effective use of contraception  |
| Currently receiving DTG | Pregnant, less than 8 weeks from last menstrual period | • Switch DTG to an alternative option or continue DTG after weighing risks and benefits  
• Do not stop DTG without replacing it with another effective ARV drug  
• Discuss the potential risk of DTG to the fetus, and explain that switching regimens after the neural tube has formed is unlikely to confer benefits  |

Advocacy
Women and Children

Start Free, Stay Free, AIDS Free is a unified framework to end vertical HIV transmission, cut new infections among adolescents and young women, and increase and sustain access to antiretroviral treatment by children and adolescents.

Led by the Joint United Nations Program on HIV/AIDS (UNAIDS) and the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), Start Free, Stay Free, AIDS Free brings together a coalition of partners to build on the tremendous progress achieved under the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive (Global Plan).

https://free.unaids.org/ and http://www.pedaids.org/
Access To Antiretroviral Therapy

The Benefits

Death Rate, Ever AIDS

- 382 per 100,000 in 1987
- 20 per 100,000 in 2013

Age at Death, HIV Infection

- Median Age at Death: 36 years in 1987, 51 years in 2013

Access To Antiretroviral Therapy

The Benefits

Adapted from Lohse et al, 2007; Hogg et al, 2008; May et al, 2011; & Hogg et al, 2013
Access To Antiretroviral Therapy
The Benefits

UNDETECTABLE = UNTRANSMITTABLE

Prevention Access Campaign

People who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner.

September, 2017

Access To Antiretroviral Therapy
The Barriers – Not Being Tested

In 2015, nearly 40,000 people in the US received an HIV diagnosis.

- 1 in 2 had been living with HIV 3 years or more.
- 1 in 4 had been living with HIV 7 years or more.
- 1 in 5 already had the most advanced stage of HIV (AIDS).

Many people at high risk* for HIV aren’t getting tested every year:

- 59% Heterosexuals at increased risk
- 42% People who inject drugs
- 29% Gay and bisexual men

*People at high risk for HIV include: 1) sexually active gay and bisexual men, 2) people who inject drugs, and 3) heterosexuals who have sex with someone who is at risk for or has HIV.

Dailey et al., MMWR Morb Mortal Weekly Rep, 2017; 66(47): 1300-1306
HIV Transmission is Most Common from Persons Undiagnosed or Not in Care

Estimated Number of HIV Transmissions Along the HIV Care Continuum, U.S. 2009

<table>
<thead>
<tr>
<th>Population</th>
<th>Transmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undiagnosed</td>
<td>18.1%</td>
</tr>
<tr>
<td>Not Retained</td>
<td>45.2%</td>
</tr>
<tr>
<td>Total</td>
<td>62.3%</td>
</tr>
</tbody>
</table>

The Overall Incidence of HIV has Declined, But Progress is Uneven

Annual incidence of HIV in the US declined **18%**

Between 2008 - 2014 infections fell from 45,700 to 37,600

- **56%** decline among people who inject drugs
- **36%** decline among heterosexuals
- **26%** decline among gay and bisexual men aged 35-44 years
- **18%** decline among gay and bisexual men aged 13-24 years

Gay and bisexual men remain most affected

- **37,600** New HIV Infections in 2014
- 23% Heterosexuals 8,600 infections
- 5% People who inject drugs 1,700 infections
- 3% Gay and bisexual men who inject drugs 1,100 infections
- 7% gay and bisexual men 26,200 infections

Progress is Uneven

- Gay/bisexual men were the only group that did not have an overall decline in annual HIV infections from 2008 to 2014.
- Reductions in infections among whites and young gay and bisexual men were offset by increases in other groups.
- Annual infections remained stable among gay/bisexual men overall and among black gay/bisexual men
- Most concerning are trends among groups, where the annual rate of infections are increasing:
  - 35% among 25-34 year-old gay/bisexual males
  - 20% among Latino gay/bisexual males
Improving Diagnosis
Can Pharmacists Be Part of the Solution?

• Partnership between the Virginia Department of Health and Walgreens

• Incorporated HIV testing into 32 retail pharmacies located in high-minority and high-poverty areas of Virginia

• Walk-in testing using the 1-minute finger-stick Insti® rapid HIV test during all pharmacy hours

• Clients testing positive were referred to confirmatory testing at a health department

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of tests performed</strong></td>
<td>3,221</td>
</tr>
<tr>
<td>Never been tested or unsure</td>
<td>1,481 (46%)</td>
</tr>
<tr>
<td>Positive Tests*</td>
<td>25 (0.8%)</td>
</tr>
<tr>
<td>Those with positive tests that had never been tested or unsure</td>
<td>16 (64%)</td>
</tr>
<tr>
<td>Tests provided at night or over the weekend</td>
<td>1,965 (61%)</td>
</tr>
<tr>
<td>Cost per positive test**</td>
<td>$4,300</td>
</tr>
</tbody>
</table>

*Nearly all linked to confirmatory testing and medical care

**$14,900 at other community based health centers

Improving Diagnosis
Can Pharmacists Be Part of the Solution?

HIV testing in community pharmacies and retail clinics: a model to expand access to screening for HIV infection.

Weidie DJ, Leecher SE, Brotze LW, Jones L, Gonzalez A, Jones R, Thomas Y

Abstract
OBJECTIVE: To test the feasibility of offering rapid point-of-care human immunodeficiency virus (HIV) testing at community pharmacies and retail clinics.

DESIGN: Pilot program to determine how to implement confidential HIV testing services in community pharmacies and retail clinics.

SETTING: 21 community pharmacies and retail clinics serving urban and rural patients in the United States, from August 2011 to July 2013.

PARTICIPANTS: 105 community pharmacy and retail clinic staff members.

INTERVENTION: A model was developed to implement confidential HIV counseling and testing services using community pharmacy and retail clinic staff as certified testing providers, or through collaboration with organizations that provide HIV testing. Training materials were developed and sites selected that serve patients from urban and rural areas to pilot test the model. Each site established a relationship with its local health department for HIV testing policies, developed referral lists for confirmatory HIV testing, secured a CLIA Certificate of Waiver, and advertised the service. Staff were trained to perform a rapid point-of-care HIV test on oral fluid, and provide patients with confidential test results and information on HIV. Patients with a preliminary positive result were referred to a physician or health department for confirmatory testing and, if needed, HIV clinical care.

MAIN OUTCOME MEASURES: Number of HIV tests completed and amount of time required to conduct testing.

RESULTS: The 21 participating sites administered 1,540 HIV tests, with 1,067 conducted onsite by staff during regular working hours and 453 conducted at 37 different HIV testing events (e.g., local health fairs). The median amount of time required for pretest counseling/consent, waiting for test results, and posttest counseling was 4, 23, and 3 minutes, respectively. A majority of the sites (17) said they planned to continue HIV testing after the project period ended and would seek assistance or support from the local health department, a community-based organization, or an AIDS service organization.

CONCLUSION: This pilot project established HIV testing in several community pharmacies and retail clinics to be a feasible model for offering rapid point-of-care HIV testing. It also demonstrated the willingness and ability of staff at community pharmacies and retail clinics to provide confidential HIV testing to patients. Expanding this model to additional sites and evaluating its feasibility and effectiveness may serve unmet needs in urban and rural settings.
Improving Diagnosis
Can Pharmacists Be Part of the Solution?

Pharmacist testers in multidisciplinary health care team expand HIV point-of-care testing program.

Sherman EM, Elrod S, Allen D, Eckardt P.

© Author(s) 2013.

Abstract
Knowledge of HIV serostatus is the first step to accessing treatment, reducing transmission, and mitigating public health challenges. We describe the expansion of an HIV point-of-care testing (POCT) program within a health care system utilizing pharmacists as testers. The testing program’s expansion is detailed and its impact assessed. The POCT program was evaluated by comparing the number of traditional HIV venipuncture tests to the number of POCTs performed across the health system as well as comparing the number of POCTs performed by clinical pharmacists to the number of tests at other POCT locations. Although pharmacists’ contributions to HIV prevention are well documented, pharmacists’ involvement in HIV testing initiatives is still nascent. Our POCT program demonstrates an effective HIV testing initiative driven by pharmacists and other health care providers.

KEYWORDS: HIV; pharmacists; pharmacy services; point of care; rapid testing

RESULTS: The 21 participating sites administered 1,540 HIV tests, with 1,067 conducted onsite by staff during regular working hours and 453 conducted at 37 different HIV testing events (e.g., local health fairs). The median amount of time required for pretest counseling/consent, waiting for test results, and posttest counseling was 4, 23, and 3 minutes, respectively. A majority of the sites (77%) said they planned to continue HIV testing after the project period ended and would seek assistance or support from the local health department, a community-based organization, or an AIDS service organization.

CONCLUSION: This pilot project established HIV testing in several community pharmacies and retail clinics to be a feasible model for offering rapid, point-of-care HIV testing. It also demonstrated the willingness and ability of staff at community pharmacies and retail clinics to provide confidential HIV testing to patients. Expanding this model to additional sites and evaluating its feasibility and effectiveness may serve unmet needs in urban and rural settings.
Improving Diagnosis
Can Pharmacists Be Part of the Solution?

Evaluation of Pharmacy-Based HIV Testing in a High-Risk New York City Community.

...
Improving Diagnosis
Can Pharmacists Be Part of the Solution?

 статья

**Pharmacists’ perspectives on HIV testing in community pharmacies.**

Rydz PT, Meyerson BE, Coy KC, van Hoppel CD.

**Abstract**

**OBJECTIVE:** To assess the feasibility, readiness, and acceptability of offering rapid human immunodeficiency virus (HIV) testing in community pharmacies.

**DESIGN:** Qualitative study.

**SETTING:** Community pharmacies in Indiana from May to September 2012.

**PARTICIPANTS:** 17 licensed community pharmacists.

**INTERVENTION:** Semistructured interviews among a convenience sample of community pharmacists.

**MAIN OUTCOME MEASURES:** Community pharmacists’ self-reported attitudes toward rapid HIV testing in community pharmacies, perceptions of peer acceptability, and opinions about readiness for implementation of the practice in community pharmacies.

**RESULTS:** Participants accepted the idea of pharmacy-based HIV testing, describing it as accessible, convenient, and nonstigmatizing. Acceptability was closely linked to positive patient relationships and pharmacist comfort with consultation. Identified challenges to pharmacy-based HIV testing included starting issues, uneasiness with delivering positive test results, lack of information needed to link patients to care, insufficient consulting space, and need for additional training. Participants indicated that peer beliefs about the acceptability of pharmacist-based HIV testing would vary but that more recently trained pharmacists likely would be more accepting of the practice.

**CONCLUSION:** Most participants felt that offering HIV testing was a reasonable addition to the evolving role of the community pharmacist, pending resolution of personal and institutional barriers.
Improving Diagnosis
Can Pharmacists Be Part of the Solution?

Consumer interest in community pharmacy HIV screening services.
Darina KM, Scarlata KX, Klepsky DG, Klepsky SA, Reeves A, Young M, Klepsky ME.

Abstract
OBJECTIVE: To evaluate consumers’ interest in pharmacist-provided human immunodeficiency virus (HIV) screening and to evaluate potential barriers and facilitators to HIV screening in the community pharmacy setting.

METHODS: Cross-sectional survey of adult patients who presented to one of five community (chain and independent) pharmacies from November 2010 to August 2011.

RESULTS: Based on 380 usable surveys, 135 (35.8%) participants were interested in pharmacy-based HIV screening. Independent predictors of interest in HIV screening identified in multivariate analysis (reference groups: ages 30 to 49 years old and white, non-Hispanic race) included younger age (18 to 29 years old) (odds ratio [OR], 2.48; 95% confidence interval [CI], 1.31 to 4.71), black, non-Hispanic race (OR, 2.37; CI, 1.40 to 4.03), and other race (OR, 4.58; CI, 1.63 to 12.87). Lack of perceived risk for HIV was the most commonly cited barrier to HIV screening; and free, rapid, or confidential HIV testing were identified as potential facilitators.

CONCLUSION: Interest in pharmacy-based HIV screening was high among participants representing age and race groups disproportionately affected by HIV. Expansion of HIV screening efforts to community pharmacies warrants further consideration.

Revised naming issues, unreadability with delivering positive test results, lack of information needed to link patients to care, insufficient counseling space, and need for additional training. Participants indicated that peer beliefs about the acceptability of pharmacist-based HIV testing would vary but that more recently trained pharmacists likely would be more accepting of the practice.

CONCLUSION: Most participants felt that offering HIV testing was a reasonable addition to the evolving role of the community pharmacist, pending resolution of personal and institutional barriers.
**Abstract**

**OBJECTIVE:** To evaluate the acceptability and feasibility of pharmacist-provided rapid testing for human immunodeficiency virus (HIV) infection in community pharmacies.

**PRACTICE DESCRIPTION:** A pharmacist-provided HIV testing model, including rapid HIV testing, counseling, and linkage to confirmatory HIV testing services, was developed and implemented.

**SETTING:** Two independent pharmacies located in Michigan cities of different size and with different prevalence of HIV infection.

**MAIN OUTCOME MEASURES:** Number of HIV tests performed, time required for HIV testing services, description of participants who received an HIV test, and pharmacist and participant perception of the HIV testing experience.

**RESULTS:** From October 2011 to March 2013, pharmacists provided HIV tests to 60 participants. One (1.5%) participant had a reactive HIV test and was immediately referred to an appropriate health care provider for confirmatory testing. HIV testing services required a median time of 30 (range, 20-90) minutes. Participants had a median age of 33 (range, 18-61) years and were diverse by gender (58.3% women) and race (46.4% black, 39.1% white).

**CONCLUSIONS:** This project demonstrates the acceptability and feasibility of pharmacist-provided rapid HIV testing in two community pharmacies with diverse characteristics. Further development of HIV testing services in this practice setting is warranted.
HIV Prevention
Access to Pre-Exposure Prophylaxis (PrEP)

• About 1.1 million Americans overall are at substantial risk for HIV and should be offered PrEP.

• However, only 90,000 PrEP prescriptions were filled in commercial pharmacies in 2015.

• Two-thirds of people who could potentially benefit from PrEP are African-American or Latino
  • They account for the smallest percentage of prescriptions to date.

Improving Prevention with PrEP
Can Pharmacists Be Part of the Solution?
Kelley-Ross Pharmacy in Seattle, WA
Pharmacist-run comprehensive HIV PrEP clinic in a community-based pharmacy
Collaborative drug therapy agreement allows pharmacists to perform all necessary duties:
  • Screen for qualified patients, order labs, prescribe PrEP, and dispense the medication
Protocol-guided services provided under a physician medical director

<table>
<thead>
<tr>
<th></th>
<th>Between March 2015 – March 2016</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients seeking service</td>
<td></td>
<td>373</td>
</tr>
<tr>
<td>Patient evaluated in the clinic</td>
<td></td>
<td>251</td>
</tr>
<tr>
<td>Patients qualified for PrEP at their initial visit</td>
<td></td>
<td>245 (97%)</td>
</tr>
<tr>
<td>Patients with primary care provider</td>
<td></td>
<td>57 (23%)</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>241 (98%)</td>
</tr>
<tr>
<td>Age (mean)</td>
<td></td>
<td>34 y</td>
</tr>
<tr>
<td>MSM</td>
<td>210 (84%)</td>
<td></td>
</tr>
<tr>
<td>HIV-positive tests</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Clinic retention rate</td>
<td></td>
<td>75%</td>
</tr>
</tbody>
</table>

New PrEP Guidelines Recently Published by the Centers for Disease Control

<table>
<thead>
<tr>
<th>Detecting substantial risk of acquiring HIV infection</th>
<th>Clinically eligible</th>
<th>Prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive sexual partner</td>
<td>Documented negative HIV test result before prescribing PrEP</td>
<td>Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply</td>
</tr>
<tr>
<td>Recent bacterial STI†</td>
<td>No signs/symptoms of acute HIV infection</td>
<td></td>
</tr>
<tr>
<td>High number of sex partners</td>
<td>Normal renal function; no contraindicated medications</td>
<td></td>
</tr>
<tr>
<td>History of inconsistent or no condom use</td>
<td>Documented hepatitis B virus infection and vaccination status</td>
<td></td>
</tr>
<tr>
<td>Commercial sex work</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed medications</td>
<td>Other services</td>
<td></td>
</tr>
<tr>
<td>Do oral/rectal STI testing</td>
<td>Follow-up visits at least every 3 months to provide the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HIV test, medication adherence counseling, behavioral risk reduction support,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>side effect assessment, STI symptom assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>At 3 months and every 6 months thereafter, assess renal function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Every 3-6 months, test for bacterial STIs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persons Who Inject Drugs</td>
<td>Access to clean needles/syringes and drug treatment services</td>
<td></td>
</tr>
<tr>
<td>HIV-positive injecting partner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sharing injection equipment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Access To Antiretroviral Therapy
The Barriers – Engagement in Care and Adherence

1.1 million people living with HIV in the US in 2014

- 85% diagnosed
- 62% received care
- 48% retained in care
- 49% virally suppressed

* Had 2 tests at least 3 months apart to measure level of virus in the body. ** Virus at low enough level to stay healthy and reduce transmission risk. Based on most recent test.
Poor Engagement and Adherence are Linked to an Increased Risk of Mortality

- A retrospective study of 2197 persons in the state of South Carolina examined newly diagnosed patients for 2-year intervals from 2004-2009
  - Poor retention was linked to an increased risk of mortality

- Retrospective analysis of 3,672 patients establishing care for HIV at the University of Alabama from 2000-2010
  - The risk of mortality was increased in patients missing visits despite meeting DHHS and IOM definitions of retained

Access To Antiretroviral Therapy
The Barriers – Engagement in Care and Adherence

- Unmet Socioeconomic Needs
- Complexity of Care
- Lack of Financial Resources
- Language and Cultural Differences
- ART-Related Challenges
- Substance Use
- Mental Health
- Unsure How to Navigate Healthcare
- Lack of Health Insurance
- Stigma
- Availability of Appointments
- Low Trust in Providers
- Lack of Social Support
- Fear

Improving Engagement and Adherence
Can Pharmacists Be Part of the Solution?

12-month ART Adherence: Multidisciplinary Care Teams vs. HIV Physician Specialist Only

New Regimen Starts (n=10,601) from 1996–2006 at Kaiser Permanente California
(ART Naïve: n=7071; Treatment Experienced: n=3730)

<table>
<thead>
<tr>
<th>Multidisciplinary Care Team</th>
<th>Difference Over Reference, %*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist plus care coordinator plus PCP</td>
<td>8.1</td>
</tr>
<tr>
<td>Nurse plus social worker plus PCP</td>
<td>7.5</td>
</tr>
<tr>
<td>Specialist plus mental worker</td>
<td>6.5</td>
</tr>
<tr>
<td>Pharmacist plus social worker plus PCP</td>
<td>5.7</td>
</tr>
<tr>
<td>Pharmacist plus PCP</td>
<td>3.3</td>
</tr>
</tbody>
</table>

*P<0.05 for each combination

Access To Antiretroviral Therapy
The Barriers – Payment

Medicaid is the largest source of coverage for individuals with HIV – The ACA’s Medicaid expansion, with enhanced funding, covers many with HIV who were previously excluded until they became disabled.
Access To Antiretroviral Therapy
The Barriers – Payment

Prior to the ACA, people with HIV faced limited access to insurance coverage due to barriers, including pre-existing condition exclusions, high costs, and Medicaid eligibility limitations.

The ACA has played a significant role in increasing insurance coverage for people with HIV through Medicaid expansion.

- Prior to expansion, most states required persons living with HIV to become disabled by AIDS before being Medicaid eligible.

To the extent that ACA repeal efforts include elimination of the Medicaid expansion option for states, most people with HIV who gained coverage would likely lose it unless states adopt alternative approaches to retaining the newly covered population in the program.
People of color have experienced the largest gains in coverage since ACA implementation

Access To Antiretroviral Therapy

Current Threats

• ACA Repeal
  • A full or partial repeal that includes the elimination of the Medicaid expansion option for states, would cause most people with HIV who gained coverage to lose it
  • This will increase pressure on safety net programs like Ryan White and AIDS Drug Assistance Programs

• Short Term, Limited Duration Insurance Plans
  • Designed to provide temporary coverage, are less costly because they provide little insurance
  • Limited under the ACA to 3 months, are now available for 1 year and renewable for up to 3 years
  • Can exclude individuals with pre-existing conditions and impose annual/lifetime limits
  • Could increase costs for those relying on coverage through the ACA

• Copay accumulators
  • A practice health insurance and pharmacy benefit managers are instituting that prevents manufacturer copay assistance from counting towards a member's deductible and out-of-pocket maximum
Advocacy
Access to Care and Antiretroviral Therapy

• The AAHIVM Policy Department and Policy Committee
  ◦ https://aahivm.org/advocacy-and-policy/

• HIVMA Policy and Advocacy
  ◦ https://www.hivma.org/Policy-Advocacy.aspx

• Advocacy in Action – POZ
  ◦ https://www.poz.com/tag/advocacy

• ADAP Advocacy Association
  ◦ http://www.adapadvocacyassociation.org/

• The International HIV/AIDS Alliance
  ◦ http://www.aidsalliance.org/about/policy-and-advocacy

• AIDS United
  ◦ https://www.aidsunited.org/Policy-0024-Advocacy.aspx

• AVAC – Global Advocacy for HIV Prevention
  ◦ https://www.avac.org/

• Elizabeth Glaser Pediatric AIDS Foundation
  ◦ http://www.pedaids.org/
Summary

• ART is recommended for all individuals with HIV, regardless of CD4 T lymphocyte cell count, to reduce HIV-related morbidity and mortality as well as HIV transmission.

• Integrase inhibitor-based ART regimens are currently preferred; bictegravir and dolutegravir have few drug interactions, low pill burdens and higher barriers to resistance.

• Multidisciplinary teams are best to improve patient access and maintain engagement in care or preventative services that can improve outcomes due to HIV infection

• Advocacy remains essential to ensure that ALL patients living with HIV have access to life saving treatment without interruption