Pre-Exposure Prophylaxis for HIV

Patient Education, Adherence and Risk Reduction

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Nurse Case Manager, Vanderbilt Comprehensive Care Center
April 19, 2018
Disclosures

- None Declared
A Tale of Two Clinics

Vanderbilt Comprehensive Care Clinic

My House Neighborhood Health HRSA Supported Health Center

Katie White MD Sean Kelly MD

Kim Rivers FNP-C
Agenda

- Building Trust
- Why Adherence Matters
- Barriers to Adherence
- Patient Education
- Financial Support
Building Trust

- Building trust is crucial to patient education, adherence and risk reduction.

- Starts at the Call Center
  - Create an environment of safety and trust throughout your clinic.
Building Trust

The importance of the patient-clinician relationship in adherence to antiretroviral medication

Alex Molassiotis RN PhD, Kate Morris B. Pharm, Ian Trueman RN MSC

First published: 15 November 2007

CDC Emphasizes Importance of Building Trust


Partnership for Health - Medication Adherence

Ways to Build Trust and Communication

One goal of the Partnership for Health - MA strategy is to increase your patients’ knowledge about ART and the importance of adherence. Patients may not fully understand or have misconceptions about how ART works to keep them healthy. This lack of understanding or misconceptions about ART and adherence could lead to skipped doses or stopping medication. In addition, side effects associated with ART may also lead to skipped doses. Describing how the medication works, possible side effects and their duration, and the consequences of missed doses engages the patient as an informed participant in this partnership.

Establishing trust and communication is a core component of the Partnership for Health - MA strategy. Fostering a respectful, open, and honest relationship will enhance your patients’ willingness to speak truthfully about their struggles with adherence. Ways to encourage open communication and build trust include the following.
Barriers to Adherence

- Stigma
- Educational
- Motivation
- Financial
- Social Determinants of Health
  - Be aware of local resources for transportation, housing, food, etc
- Mental Health / Substance Abuse Concerns
  - Don’t assume that mental illness will result in poor adherence
  - Know local resources for substance abuse and mental health services
Barriers to Adherence - Stigma

- Stigma regarding HIV in general
- Stigma regarding PrEP
  - Judgment from providers
  - Judgment from partners
  - Partner could find out about sex outside of the relationship
  - Partner would misinterpret taking PrEP as having HIV
Stigma

A preventative measure against the consequences of sexual activity

... condones sexual activity

... promotes sexual activity

... causes sexual activity
Stigma

- PrEP is a “party drug”
- PrEP promotes “bareback sex”
- PrEP users will stop using condoms
- PrEP users will acquire more STIs
But actually…

- Pre-Contemplation
- Contemplation
- Planning
- Action
- Further risk reduction
- Fewer sexual partners
- Stronger relationship
- Confidence in sexual health
- Active commitment to health
- Confidence in sexual health
- Fewer sexual partners
- Stronger relationship
- Active commitment to health
- Further risk reduction
No evidence of sexual risk compensation in the iPrEx trial of daily oral PrEP

For patients believing they were on PrEP, the number of receptive anal intercourse partners decreased.

For patients believing they were on PrEP, condom use increased.

Syphilis incidence also decreased in both study arms

Stigma

As a society, we treat any HIV-related health care activities differently.

As healthcare providers, we need to accept our responsibility to protect our patients.

Sean Kelly, MD
Assistant Professor
Vanderbilt Division of Infectious Diseases
Risk Reduction

Set realistic expectations.

My personal mantra:
People are people and they are going to have sex.
Risk Reduction

Role of Adherence

PrEP Works .......... WHEN YOU TAKE IT
Risk Reduction

iPrEX

44% HIV risk reduction
But, 92% risk reduction when taken consistently among MSM and transgender women
Risk Reduction
TDF2 Study Group

62.2% HIV risk reduction among heterosexual men and women
(100% in open-label extension with regular follow-up)
75% HIV risk reduction among heterosexual sero-discordant couples

90% among those with detectable drug levels
Risk Reduction
Bangkok Tenofovir Study Group

48.9% risk reduction
But, 74% HIV risk reduction when taken consistently, among IDUs (TDF only)
Risk Reduction
Dosing matters

Using drug concentrations in iPrEX and STRAND, pharmacokinetic models predict:

- **76%** risk reduction with 2 doses/week
- **96%** with 4 doses/week
- **99%** with 7 doses/week.

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## Risk Reduction Studies Summary

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Dosing</th>
<th>Risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEX</td>
<td>MSM</td>
<td>Daily</td>
<td>44% (92% with ideal adherence)</td>
</tr>
<tr>
<td>TDF2</td>
<td>Heterosexual men and women</td>
<td>Daily</td>
<td>62.2% (100% in open-label extension with regular follow-up)</td>
</tr>
<tr>
<td>Partners</td>
<td>Sero-discordant heterosexual couples</td>
<td>Daily</td>
<td>75% (90% with ideal adherence)</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study Group</td>
<td>Intravenous drug users</td>
<td>Daily</td>
<td>48.9% (74% with ideal adherence)</td>
</tr>
</tbody>
</table>
# Risk Reduction

## Probability of Acquiring HIV from an Infected Source

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>Risk per 10,000 Exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenteral</td>
<td></td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>9.250</td>
</tr>
<tr>
<td>Needle-Sharing During Injection Drug Use</td>
<td>63</td>
</tr>
<tr>
<td>Percutaneous (Needle-Stick)</td>
<td>23</td>
</tr>
<tr>
<td>Sexual</td>
<td></td>
</tr>
<tr>
<td>Receptive Anal Intercourse</td>
<td>138</td>
</tr>
<tr>
<td>Insertive Anal Intercourse</td>
<td>11</td>
</tr>
<tr>
<td>Receptive Female-Vaginal Intercourse</td>
<td>8</td>
</tr>
<tr>
<td>Insertive Female-Vaginal Intercourse</td>
<td>4</td>
</tr>
<tr>
<td>Receptive Oral Intercourse</td>
<td>Low</td>
</tr>
<tr>
<td>Insertive Oral Intercourse</td>
<td>Low</td>
</tr>
<tr>
<td>Other*</td>
<td></td>
</tr>
<tr>
<td>Biting</td>
<td>Negligible</td>
</tr>
<tr>
<td>Spitting</td>
<td>Negligible</td>
</tr>
<tr>
<td>Throwing Body Fluids (including semen or saliva)</td>
<td>Negligible</td>
</tr>
<tr>
<td>Sharing Sex Toys</td>
<td>Negligible</td>
</tr>
</tbody>
</table>

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

* HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

**Source**
## Risk Reduction

### Probability of Acquiring HIV from an Infected Source

<table>
<thead>
<tr>
<th>Sexual</th>
<th>Probability</th>
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<td>Low</td>
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<td>Insertive Oral Intercourse</td>
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Risk Reduction

Probability of HIV Transmission per every 10,000 sex acts without protective barriers

https://wwwn.cdc.gov/hivrisk/estimator.html#~sb
Risk Reduction
Receptive Vs Insertive Sex

Receptive Versus Insertive Sex

During anal sex, the partner inserting the penis is called the insertive partner (or top), and the partner receiving the penis is called the receptive partner (or bottom).

Receptive anal sex is much riskier for getting HIV. The bottom partner is 13 times more likely to get infected than the top. However, it’s possible for either partner to get HIV through anal sex from certain body fluids—blood, semen (cum), pre-semenal fluid (pre-cum), or rectal fluids—of a person who has HIV. Using condoms or medicines to protect against transmission can decrease this risk.

- **Being a receptive partner during anal sex is the highest-risk sexual activity for getting HIV.** The bottom’s risk of getting HIV is very high because the lining of the rectum is thin and may allow HIV to enter the body during anal sex.
- **The insertive partner is also at risk for getting HIV during anal sex.** HIV may enter the top partner’s body through the opening at the tip of the penis (or urethra) or through small cuts, scratches, or open sores on the penis.

https://www.cdc.gov/hiv/risk/analsex.html
Risk Reduction

Condom Use

- Education from a perspective of pleasure / quality of life vs fear.
Risk Reduction
Barrier to Condom Use

- Power issues and self esteem are often barriers to condom use.
  - Dominant partner
  - Domestic violence
  - Sex workers
  - People trading sex for housing, food or drugs

- Teach negotiation skills
  - International Planned Parenthood Federation
    - https://www.ippf.org/blogs/condom-negotiation
Risk Reduction
Condom Negotiation

Here are some lines you could use to persuade a partner to use a condom:

She says, "I'm on the pill, don't worry."
You say, "I trust you. But I want to protect both of us just in case."

He says, "We already did it without a condom once."
You say, "And that was a mistake. I worried about being pregnant all month!"

She says, "What — a condom? Are you trying to say that I've cheated on you?"
You say, "I trust you. I use condoms because I care about you, and me, and our future together."

He says, "I always pull out in time, don't worry."
You say, "I know, but when we use a condom you don't have to pull out. It can feel even better."

She says, "I can't feel anything when you wear a condom."
You say, "That's awful! Let's wait then and try another brand or size that fits me better and some special 'warming' lubricant tomorrow."

He says, "I can't keep a hard on with a condom."
You say, "I can't relax and enjoy sex without a condom. So I'll help you stay hard."
## Risk Reduction

### Ineffective Strategy

<table>
<thead>
<tr>
<th>Population</th>
<th>Effectiveness Estimate</th>
<th>Source</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSM</td>
<td>54%</td>
<td>Kennedy, 2013</td>
<td>When compared to condomless anal sex with either HIV-positive or unknown status partners, HIV-negative MSM who self-report serosorting reduce their risk of HIV acquisition by 54%. When compared to no condomless anal sex, serosorting results in increased risk of acquiring HIV.</td>
</tr>
<tr>
<td>Heterosexual Men and Women</td>
<td>54%</td>
<td>Kennedy, 2013</td>
<td>There is no direct evidence for effectiveness of serosorting in reducing the risk of acquiring HIV among HIV-negative heterosexual men and women. There is no reason, however, to believe serosorting wouldn’t also be effective in heterosexual men and women. When compared to condomless sex with either HIV-positive or unknown status partners, HIV-negative heterosexual men and women who self-report serosorting may reduce their risk of HIV acquisition by 54%. When compared to no condomless sex, serosorting may result in increased risk of acquiring HIV.</td>
</tr>
</tbody>
</table>

https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html
Risk Reduction
Ineffective Strategy

Circumcision of Adult Males

<table>
<thead>
<tr>
<th>Population</th>
<th>Effectiveness Estimate</th>
<th>Source</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSM, Insertive Anal Sex</td>
<td>Inconclusive</td>
<td>Wylsonge, Sanchez, Doerner, 2011; 2013</td>
<td>Based on observational studies of circumcision among adult males, there is insufficient evidence at this time to conclude that male circumcision reduces the risk of the insertive partner acquiring HIV during anal sex among MSM.</td>
</tr>
<tr>
<td>MSM, Receptive Anal Sex</td>
<td>Inconclusive</td>
<td>Wylsonge, Schneider, 2011</td>
<td>Based on observational studies of circumcision among adult males, there is insufficient evidence at this time to conclude that male circumcision (of the insertive partner) reduces the risk of the receptive partner acquiring HIV during anal sex among MSM.</td>
</tr>
<tr>
<td>Heterosexual Men</td>
<td>50%</td>
<td>Siegfried, 2009</td>
<td>Based on trials of circumcision among adult males, male circumcision reduces the risk of heterosexual men acquiring HIV during sex by 50%.</td>
</tr>
<tr>
<td>Heterosexual Women</td>
<td>Inconclusive</td>
<td>Wawer, Weiss, Baeten, 2009</td>
<td>Based on several trials and observational studies of circumcision among adult males, there is insufficient evidence at this time to conclude that male circumcision reduces the risk of heterosexual women acquiring HIV during sex.</td>
</tr>
</tbody>
</table>

https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html
Patient Education

- Establish Trust
- Assessment
- Face to Face
- Tailor the education to your patient
- Printed Material / Web Resources
- Life happens – situations change
Patient Education - Assessment

- Great education starts with a great assessment.
- Get to know your patient and establish trust.
- Things to look for:
  - Cognitive Barriers
  - Stigma
  - Treatment Concerns
  - Social Support
  - Mental Health Concerns
  - Structural Barriers
    - i.e. housing, transportation, insurance, etc
  - Baseline Knowledge of HIV and how to prevent it
Patient Education - Face to Face

- Pick up on visual cues.
- Helps to establish rapport.
- Helps to engage patient is communicating about their care.
- Helps make active listening more effective.
# Patient Education – Face to Face


<table>
<thead>
<tr>
<th>Key Elements of Active Listening</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ask open-ended questions</strong></td>
</tr>
<tr>
<td>Closed-ended questions make it easy for patients to dismiss concerns or questions they may have had about their treatment or adherence. Closed-ended questions also make it easy for the provider to quickly assess the patient’s immediate needs and make it possible to keep the visit and conversation short. However, open-ended questions invite the patient to discuss their concerns. Providers might ask:</td>
</tr>
<tr>
<td>“What makes it difficult to take every dose, every day?”</td>
</tr>
<tr>
<td>“Tell me more about what has changed in your daily routine that may be making it difficult for you to take every dose, every day.”</td>
</tr>
<tr>
<td>“What could you do to help remind yourself to take every dose, every day?”</td>
</tr>
<tr>
<td><strong>Reflect</strong></td>
</tr>
<tr>
<td>“I understand how frustrating it can be to forget taking your doses every day.”</td>
</tr>
<tr>
<td><strong>Restate</strong></td>
</tr>
<tr>
<td>“You’re finding it difficult to take your pill with food because you’re not able to wake up early enough to fix breakfast.”</td>
</tr>
<tr>
<td><strong>Redirect</strong></td>
</tr>
<tr>
<td>Redirecting involves bringing the patient back to the discussion when he or she has strayed off track. Most providers are quite skilled at redirecting. The trick is to redirect, so that the patient feels like he or she is still being heard.</td>
</tr>
<tr>
<td><strong>Affirm</strong></td>
</tr>
<tr>
<td>“You recognized the importance of getting back to taking your dose every day.”</td>
</tr>
<tr>
<td><strong>Non-verbal communication</strong></td>
</tr>
<tr>
<td>Maintain eye contact when the patient speaks, nod your head, and wait for him or her to finish speaking before responding.</td>
</tr>
</tbody>
</table>
Patient Education Materials
CDC Downloadable Documents

https://www.cdc.gov/actagainstaids/campaigns/starttalking/materials/prepresources.html
Patient Education Materials

New Patient Folder
Patient Education Materials

AIDSinfonet.org

WHAT IS PRE-EXPOSURE PROPHYLAXIS? (PrEP)?
Pre-exposure prophylaxis (PrEP) is a strategy for preventing HIV infection in individuals who are at high risk of acquiring HIV. PrEP is highly effective and can prevent HIV infection in individuals who take it consistently and as prescribed.

How to take PrEP:
- Take one tablet every day as directed by your healthcare provider.
- Do not take PrEP if you are pregnant or planning to become pregnant within the next 3 months.
- PrEP is not a cure for HIV. It must be taken consistently and as prescribed to be effective.

Possible side effects include:
- Nausea
- Diarrhea
- Headache
- Fatigue

What to do if you miss a dose:
- Take it as soon as possible but not within 12 hours of the missed dose.
- Do not take a double dose to make up for a missed dose.

What to do if you have symptoms:
- If you have symptoms of HIV infection or if you are unsure if you have been exposed to HIV, contact your healthcare provider immediately.

PREGNANCY WARNING:
PrEP is not approved for use during pregnancy. If you are pregnant or plan to become pregnant within the next 3 months, do not take PrEP.

TRUVADA (Tenofovir + Emtricitabine)

WHAT ABOUT RESISTANCE?
Truvada can develop resistance to other antiretroviral drugs or combinations of drugs. Resistance can develop quickly and may limit the effectiveness of Truvada as a treatment for HIV.

To prevent resistance:
- Take Truvada exactly as prescribed by your healthcare provider.
- Do not skip doses or stop taking Truvada without first discussing it with your healthcare provider.
- Do not take Truvada with other medications without first discussing it with your healthcare provider.

What to do if you miss a dose:
- Take it as soon as possible but not within 12 hours of the missed dose.
- Do not take a double dose to make up for a missed dose.

What to do if you have symptoms:
- If you have symptoms of HIV infection or if you are unsure if you have been exposed to HIV, contact your healthcare provider immediately.

PREGNANCY WARNING:
Truvada is not approved for use during pregnancy. If you are pregnant or plan to become pregnant within the next 3 months, do not take Truvada.

Additional information:
- Truvada is available in 200 mg tablets and 400 mg tablets.
- Truvada is not approved for use in children under 16 years of age.

Reviewed August 28, 2014

AIDSinfoNet

www.aidsinfonet.org

Fact Sheet Number 421

NOTICE: This fact sheet is for informational purposes only and is not intended to provide medical advice, diagnosis, or treatment. Always consult with your healthcare provider about any questions you may have regarding a medical condition. This fact sheet is not a substitute for professional medical advice.

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Patient Education

Adherence Tools

- Med boxes
- Key fobs
- Cell phone reminders
- Apps
- Accountability partner
Patient Education

Financial Support

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

YES

1. Gilead Advancing Access Co-pay Card
gileadacpy.com 1-877-585-6995
- $5 per month and year
- No income restrictions
- Covers co-pay, deductibles and co-insurance
- Reapply annually as needed
- U.S. resident
- Not available for persons with Medicare, Medicare, VA or other state/local prescription drug programs
- If pharmacy is unable to process Gilead's Co-pay Card, call Gilead toll-free at 1-800-332-2787

2. Patient Access Network Foundation
patientfoundation.org/hiv-treatment-and-prevention
866-316-7263
- $50 per month, re-apply
- Income <50% FPL ($40,300)
- Based on taxable income
- Must be insured (not listed under "YES" above)
- Covers copays, deductibles and co-insurance
- U.S. resident
- Pharmacies can bill PAF Foundation directly

3. Patient Advocate Foundation (PAF)
https://www.paf.org/discount-pharmacy-advice-and-prevention
- $7,500 max/year, re-apply
- Income <100% FPL ($68,240)
- Based on taxable income
- Must be insured (not listed under "YES" above)
- Covers co-pays only
- Proof of U.S. residency (utility bill, etc.)
- Call managers available to help resolve medical cost issues 800-533-5274

These programs may be subject to funding shortages, which may limit enrollment.

NO

U.S. RESIDENT?

- Nov 1 – Jan 31
- Below 138% FPL/yr
  - >$143/yr to cover cost of Gilead MAP

- Feb 1 – Oct 31
- Above 138% FPL/yr
  - >$5,143/yr to cover cost of Gilead MAP

Non-Resident/Undocumented?

- Check if you can get an insurance plan through enlacecountysmiles.com

FSA/Medical Assistance

- Below $60,300
- Retail cost of Truvada

- Above $60,300
- Check if you can get an insurance plan through enlacecountysmiles.com

Special enrollment

- You may be eligible to enroll as soon as 1/1 of next year for "enrollment by special enrollment" due to pregnancy, loss or change of job, change in insured family composition, or gain in citizenship.

On Medicaid?

- Individual should review medical costs related to PrEP. If yes, contact local Medicaid offices to review coverage or receive legal advice.

If you're a resident, these state plans may also help:
- [Organizations listed on MAP site]
- [HealthFirst website]
- [AIDS Healthcare Foundation]
- [PositiveCare.org]
- [Health First website]
- [HealthFirst website]
- [HealthFirst website]

Updated as of February 10, 2017

Patient Education

Co Pay Card

- Assess your patient’s ability to facilitate obtaining a co pay card.
  - They may need assistance navigating this process.

- Two ways to obtain a co pay card:
  - Phone
    - 1-877-505-6986
  - On line
    - www.gileadadvancingaccess.com
Your personal information is required for security purposes and is used to confirm your identity as a cardholder.

Are you a current resident of the United States, Puerto Rico, or U.S. Territories?  
- Yes  - No

Are your prescriptions paid for in part or in full under any state or federally funded program, including but not limited to Medicare or Medicaid, Medigap, VA, DOD, or TRICARE?  
- Yes  - No

Are you in the Medicare Part D coverage gap (Donut Hole)?  
- Yes  - No

If you begin receiving prescription benefits from such state, federal, or government-funded program at any time, you will no longer be eligible to use the Gilead Advancing Access® co-pay coupon card.  

Do you acknowledge your agreement with this statement?
Patient Education

Co Pay Card

Enrollment

Step 2 of 3

*First name: 
*Last name: 
*Date of birth: MM DD YYYY 
*Address 1: 
Address 2: 
*City: 
*State: Select 
*Zip code: 
*E-mail: 
*Phone number: ( ) - 
*Required fields

Gender: Select [Optional]
Additional Adherence Tactics

- Follow up phone calls
  - My House
    - Walgreens Specialty Pharmacy
    - PrEP Navigator

- Appointment Reminders
  - VCCC – automated text messaging
Conclusion

In order for any of this to work, building a trusting relationship with your patient is essential.
Conclusion

- PrEP is an extremely effective preventive strategy
- Look at the whole person
- Above all – create a culture of safety and trust
- Ask for help! Sherise.stogner@vumc.org
Thank You!!

Questions??
Sources