

PRE-EXPOSURE PROPHYLAXIS FOR HIV PREVENTION: A COMMUNITY- BASED APPROACH TO INCREASED AWARENESS AMONG VERMONT PRIMARY CARE PROVIDERS

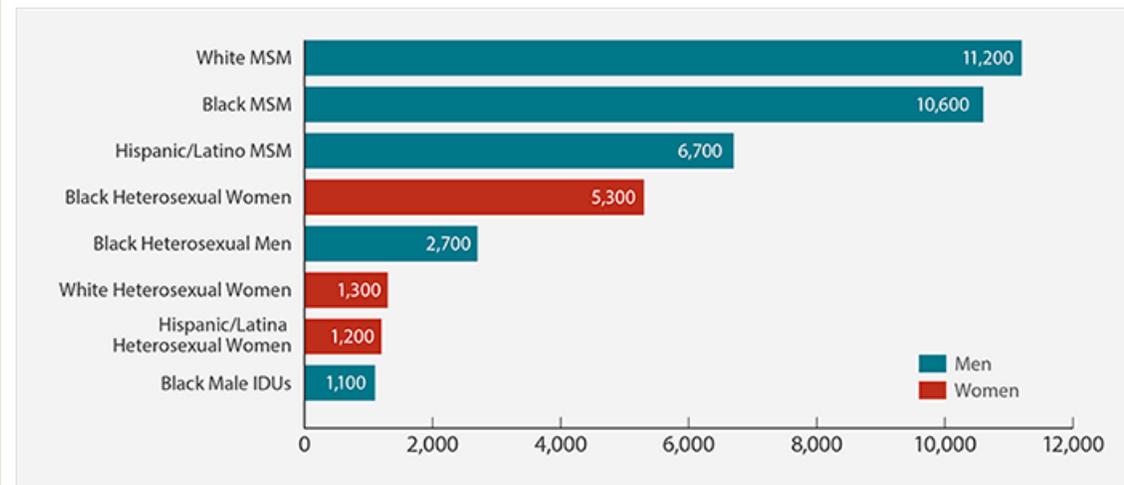
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What's the problem?

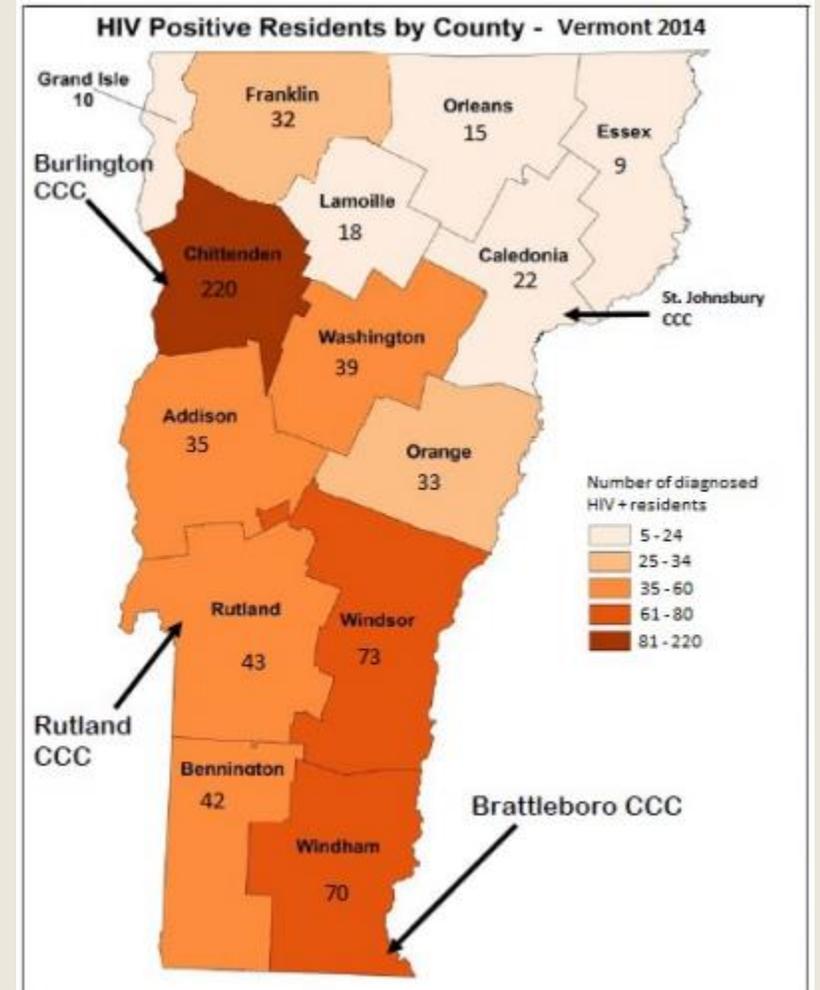
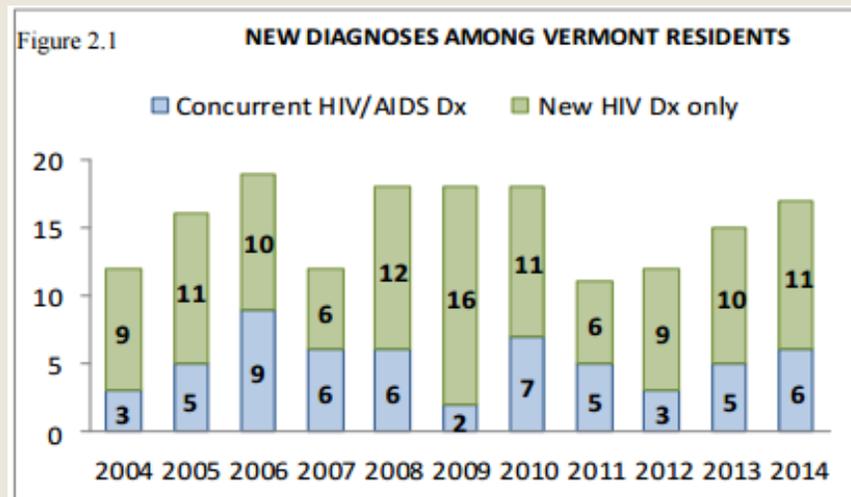
- >1.2 million Americans are living with HIV and nearly 1 in 8 (12.8%) are unaware of their status.
- Nationally, incidence has been consistently around 50,000 new infections per year with the men who have sex with men (MSM) population carrying the largest burden. **25% of new infections are among youth (13-24yo), many of whom don't know they're infected and can unknowingly pass the virus on to others**
 - MSM population represents about 4% of the total US population but they accounted for **78% of new HIV infections among men in 2010.**
 - 2012 CDC survey demonstrated that from 2005-2011, the number of gay men reporting anal sex without barrier protection rose by 20%.

Figure 1: Estimated New HIV Infections in the United States, 2010, for the Most Affected Subpopulations



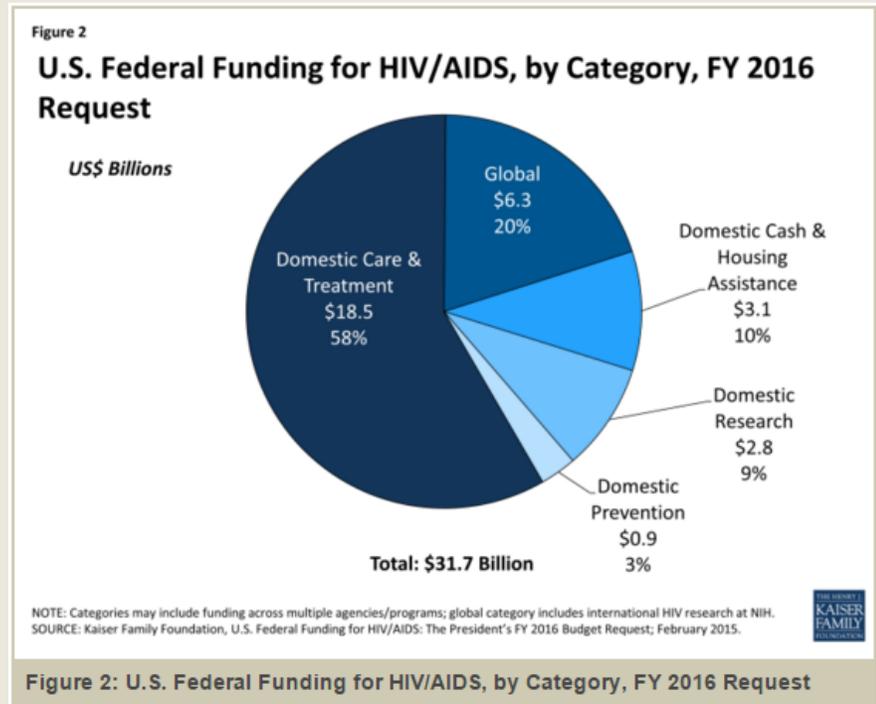
What's the problem like in Vermont?

- Over the past 10 years, new diagnoses range from 11-19 per year
- VT Dept. of Health: 670 HIV+ Vermonters
 - Estimated to be closer to 800 HIV+ individuals when including those who are likely unaware of their status.
 - 56% fall into the MSM population.
- In 2012, a pre-exposure prophylaxis (PrEP) medication, Truvada, was FDA approved for HIV prevention. Despite this and clear evidence of its prophylactic effect from multiple clinical trials, **community and provider awareness remains limited in Vermont** with a most recent estimate of only 9 providers, not including Planned Parenthood offices, who have actively prescribed PrEP.



Public Health Costs of HIV/AIDS

- US 2016 federal budget request included **\$31.7 billion dollars** for combined domestic and global HIV efforts, with domestic funding estimated at \$25.3 billion. This represents a 3.1% increase from the 2015 federal budget.
 - Largest portion is for health care services & treatment for HIV+ individuals (\$18.5 billion)
 - Smallest portion is for domestic HIV prevention, totally \$940 million, which has remained largely unchanged over the past 6 years in the federal budget.
- **Estimated lifetime costs for a new, early diagnosis of HIV infection is \$400,000.**
- VT Medicaid annual coverage for 300 HIV/AIDS patients in 2011 exceeded \$3.6 million dollars.

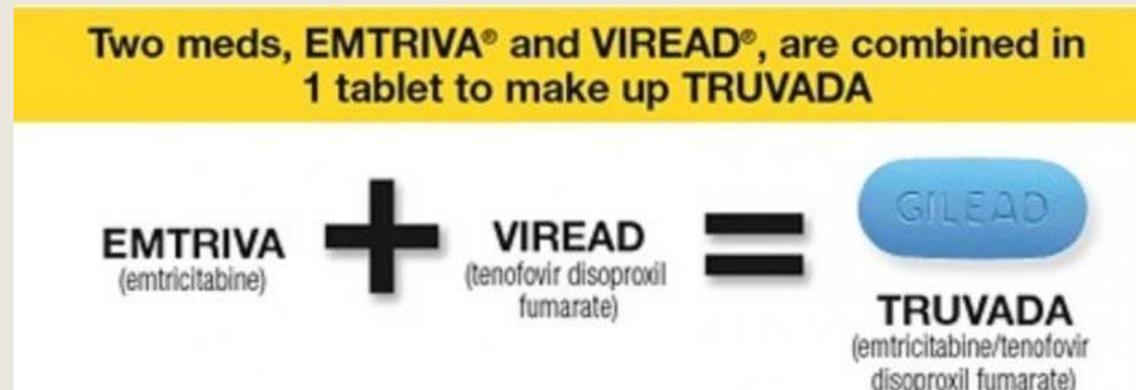


What are the possible interventions?

- HIV testing centers and linkage to care
- Antiretroviral therapy
- Prevention programs for HIV+ individuals and partners
- Substance abuse treatment programs
- Access to condoms and sterile syringes
 - Despite many advances in the treatment and prevention of HIV infections, the incidence rate has remained consistently around 50,000 new infections per year.
 - *“Doctors and policy makers need to admit that 30 years of the ABC mantra – abstain, be faithful, and use condoms – has failed. Men generally hate condoms, their lovers usually give in, almost no one abstains, precious few stay faithful” –*
 - Donald G McNeil, Jr is a New York Times science and health reporter who covers diseases of the world’s poor, including AIDS.
- Pre-exposure prophylaxis (PrEP)

What is PrEP?

- Pre-exposure prophylaxis
- FDA approved in 2012 for HIV prevention in HIV-negative individuals
- **Truvada** (combination of two medications)
 - Emtricitabine (Emtriva) and tenofovir (Viread)
 - Nucleoside reverse transcriptase inhibitors
 - Preventing HIV viral enzyme from making more copies of itself



Does PrEP actually work?

- The studies to date are very promising (iPrEx study)
 - 2,500 HIV-seronegative men & transgender women who have sex with men.
 - *NEJM; Pre-exposure prophylaxis for HIV prevention in MSM, Jan. 2011*
- Participants who took Truvada **daily**, estimated protection was **99%**
- Participants who took it **4 days** per week, estimated protection was **96%**
- Participants who took it **2 days** per week, estimated protection was **76%**

Detectable blood levels strongly correlated with the prophylactic effect

What about other at risk populations?

- Heterosexual men and women in serodiscordant relationships
- Partners PrEP Study
 - Truvada vs. placebo in 4,500 participants in Kenya & Uganda
 - Reduction of new infections by 75% (of those assigned to take Truvada)
 - When the researchers measured blood levels of the medication, the reduction rate was **90%**
 - What does this mean?

Adherence to taking this medication daily matters!

Who else would benefit from PrEP?

- Bangkok Tenofovir Study

- Truvada vs. placebo in 2,400 participants who reported intravenous drug use during the previous year
- Overall, Truvada demonstrated reduction in risk of HIV infection by **49%**
- But, again, when researchers looked at the participants who were directly observed taking Truvada daily, they found that protection increased to **74%**

Questions remain about Truvada's effect on parenteral HIV acquisition

Most Recent Research

- Kaiser Permanente SF Medical Center Study (September 2015)
 - N=657 individuals started PrEP, 99% MSM population
 - **No new HIV diagnoses**
- 74% reported no change in number of sexual partners
 - 15% decreased the number of partners; 11% increased
- 41% reported decreased risk of condom use
- 30% diagnosed with an STI in first 6-months, 50% in 12-months
 - Chlamydia (33%), gonorrhea (28%), syphilis (5.5%)
- **Limitations:** no control group, study population

At Risk Populations

- The studies to date have demonstrated Truvada's potential in helping reduce the rate of HIV infection in the following at risk populations
 - *Men who have sex with men (MSM)*
 - *Heterosexual serodiscordant (magnetic) couples*
 - *Intravenous drug users (IVDU)*

Important take away...

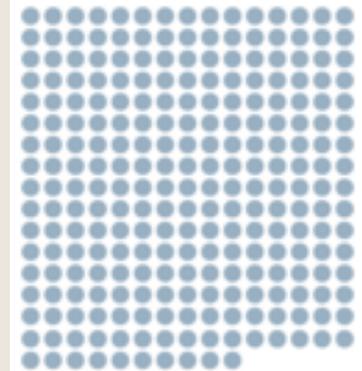
Compliance with this medication is crucial to its prophylactic effect!

How to get the word out about PrEP?

- PCP and community awareness & education
- The ID community is well aware of PrEP
 - 2013 national survey of ID physicians demonstrated that 74% supported the use of PrEP, yet only 9% had actually prescribed it.
- HIV-negative, or assumed to be, gay men have no reason to see an ID specialist. If they're seeing anyone for healthcare, it's their PCP.
 - Within marginalized communities, word spreads quickly about which providers are open and “safe” to talk to.

To Save a Life

Scientists have compared the effectiveness of two preventive drug regimens: a daily dose of Truvada, against H.I.V.; and statins to prevent heart attacks. By that measurement (called “number needed to treat”), the Truvada regimen is far more likely to save lives.



250

Number of people taking **statins** for one year to prevent **one heart attack**.



61

Average number of people given **Truvada** for one year to prevent **one H.I.V. infection**.

Source: David V. Glidden,
University of California at San
Francisco

Section 1 Patient/Provider Checklist

Organization/Clinic Name

CHECKLIST FOR INITIATING PREEXPOSURE PROPHYLAXIS (PrEP)

Print name of provider

Print name of patient

Today's date (month/day/year)

Provider Section

I have provided this patient with the following: (check all as completed):

- Assessment for possible acute HIV infection
- Indicated laboratory screening to determine indications for these medications
- An HIV risk assessment to determine whether PrEP is indicated for this patient
- A medication fact sheet listing dosing instructions and side effects
- Counseling or a referral for counseling on condom use and any other HIV risk-reduction methods this patient may need
- Advice on methods to help the patient to take medication daily as prescribed
- Information about PrEP use during conception and pregnancy (when indicated)
- A prescription for Truvada (300 mg tenofovir disoproxil fumarate, 200 mg emtricitabine)
- A follow-up appointment date

As the provider, I will:

- Limit refill periods to recommended intervals for repeat HIV testing (at least every 3 months)
- Conduct follow-up visits at least every 3 months that include the following:
 - Assessment of HIV status (including signs or symptoms of acute HIV infection)
 - Assessment of side effects and advice on how to manage them
 - Assessment of medication adherence and counseling to support adherence
 - Assessment of STI symptoms, HIV risk behavior and counseling support for risk-reduction practices
- Inform the patient of any new information about PrEP and respond to questions

MSM Risk Index²⁵

1	How old are you today?	If <18 years, score 0 If 18-28 years, score 8 If 29-40 years, score 5 If 41-48 years, score 2 If 49 years or more, score 0	_____
2	In the last 6 months, how many men have you had sex with?	If >10 male partners, score 7 If 6-10 male partners, score 4 If 0-5 male partners, score 0	_____
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?	If 1 or more times, score 10 If 0 times, score 0	_____
4	In the last 6 months, how many of your male sex partners were HIV-positive?	If >1 positive partner, score 8 If 1 positive partner, score 4 If <1 positive partner, score 0	_____
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV-positive?	If 5 or more times, score 6 If 0 times, score 0	_____
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	If yes, score 6 If no, score 0	_____
Add down entries in right column to calculate total score			_____
			TOTAL SCORE*

* If score is 10 or greater, evaluate for intensive HIV prevention services including PrEP.
If score is below 10, provide indicated standard HIV prevention services.

What are the side effects of PrEP?

- **Most people** taking Truvada report **no side effects**.
- Those that are reported are generally mild...
 - Nausea (9%), headaches (5%), weight loss (2%) and increased serum creatinine (0.3%)
- As with many medications, there is a risk of serious side effects:
 - Lactic acidosis, hepatic dysfunction, worsening of hepatitis B infection
- Recommended labs every 3 months to monitor for:
 - HIV status, other STI's, LFT's, and serum BUN/Cr

Patient Section

It has been explained to me that:

- Taking a dose of PrEP medication every day may lower my risk of getting HIV infection
- This medicine does not completely eliminate my risk of getting HIV infection, so I need to use condoms during sex
- This medicine may cause side effects so I should contact my provider for advice by calling _____ if I have any health problems
- It is important for my health to find out quickly if I get HIV infection while I'm taking this medication, so
 - I will contact my provider right away if I have symptoms of possible HIV infection (fever with sore throat, rash, headache, or swollen glands)
- My provider will test for HIV infection at least once every 3 months

Therefore, I will:

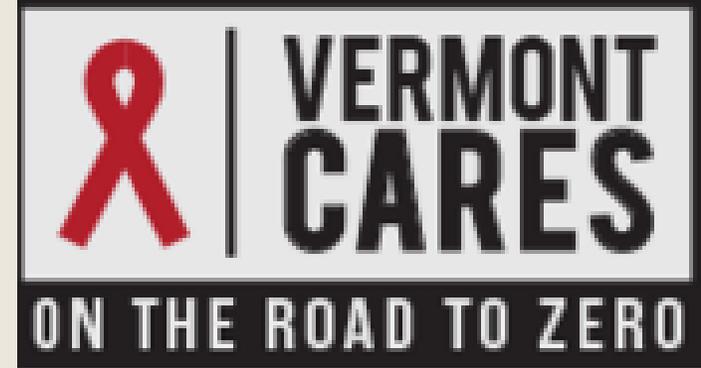
- Try my best to take the medication my provider has prescribed every day
- Talk to my provider about any problems I have in taking the medication every day
- Not share the medication with any other person
- Attend all my scheduled appointments
- Call _____ to reschedule any appointments I cannot attend

What are the barriers to PrEP use in VT?

- UVM COM Class of 2018: public health project
- What are Vermont providers saying? (N=79)
 - **Lack of knowledge about PrEP**
 - **Concerns about insurance coverage**
 - Development of a treatment resistant HIV
 - Will this lead to riskier sexual behaviors?
 - Concerns about increasing rates of other STI's (gonorrhea, syphilis)

 - Open and honest sexual behavior conversations
 - Stigma - “slut shaming” by physicians; “Truvada whores” in the communities

Road to Zero



- Campaign whose goal is to achieve zero new HIV infections in Vermont by 2020
 - Average of 20 new diagnoses per year (over the past 5 years)
 - **“Vermont is in striking distance of becoming the first state ever to achieve this goal”** – VT Cares

- **PrEP is front and center**

- Major limitation?
 - Currently only 9 providers actively prescribing PrEP
 - *“Insufficient to fully demonstrate the public health impact PrEP can have”*
 - Peter Jacobsen, Executive Director of VT Cares

What can be done to overcome these barriers?

- **Provider education** about PrEP
 - Indications (at risk populations)
 - Provider role in monitoring patients on PrEP
 - Truvada is covered by Vermont Medicaid and Blue Cross-Blue Shield
- **Patient awareness, education, and counseling**
 - VT Cares: counseling services currently, plans to expand
 - Grant information??

What does the future hold for PrEP?

- Current research for new pharmaceutical options for PrEP:
 - **Maraviroc** – daily pill
 - **Rilpivirine** – monthly injection
 - **Dapivirine** – vaginal ring, changed monthly
 - **Tenofovir** (alone) – rectal/vaginal gel
- Discussions about a Truvada injection, every 3 months.
 - *NYU survey demonstrated that 79% of young gay men would prefer this option over a daily pill*

Questions?

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