A Sex-Positive Approach to Healthcare, and Truvada as HIV Pre-Exposure Prophylaxis (PrEP)

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Planning Committee Members: John King, MD, MPH, Melisa Gibson, MD, Anne Morris, MD, Whitney Calkins, MD, Joanne Hunt, NP

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Workshop #: 18-101-16
Learning Objectives
1.
2.
3.

DISCLOSURE:
Is there anything to disclose? Yes ☐ No ☑

Please list the Potential Conflict of Interest (if applicable):

All Potential Conflicts of Interest have been resolved prior to the start of this program. Yes ☐ No ☑
(If no, credit will not be awarded for this activity.)

All recommendations involving clinical medicine made during this talk were based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. Yes ☑ No ☐

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Note – an update

- This presentation is an updated and expanded version of the 2016 presentation
- This version was created as part of the fourth year scholarly project in medicine, and what was presented at the January 2018 University of Vermont Medical Center Family Medicine Grand Rounds
Why are we talking about Sex-Positivity?

- Medical training so focused on “prevention” and “risk”
  - This is NOT how people live their lives
- May be awkward for some – why do we keep using language that makes this worse?
- Research demonstrates patients have tremendous willingness / desire to speak about sexual health / function, but are unlikely to initiate discussions
  - Docs also don’t initiate discussions
- Med students and clinicians good at taking sexual history when the CC is directly related, but fail to opportunistically do so

Ultimately:
- Sexual health related outcomes are not improving (STIs, HIV, unplanned/teenage pregnancy, preventative screening)
- Patients don’t feel they are adequately attended to re: sexual health and function
  - “Pleasure gap” for women
- For “sexual minorities” (i.e. LGBT), sex positivity is critical to trust and therapeutic relationship
- Our clinicians should be our advocates – more than anyone else – but we aren’t having discussions
  - Discomfort? Lack of familiarity? General sex-shaming culture?
What is “Sex Positivity”

“An attitude towards human sexuality that regards all consensual sexual activities as fundamentally healthy and potentially pleasurable, encouraging sexual pleasure and experimentation.

The movement advocates sex education and safer sex, but generally makes no moral distinctions among types of sexual activities, regarding these choices as matters of personal preference”

“Too often sex is presented to our youth as something abnormal, immoral, and “other”, and when it finally rears its head, it does so often in unhealthy, irresponsible, and uninformed fashions”

- Do we really think people avoid sex in order to minimize their risk of STIs or pregnancy?
  - So why does our healthcare approach it this way?
How a sex-negative culture impacted *me* while trying to get on PrEP

- Initial encounter
- Subsequent encounter: clinical trials, CDC guidelines
- Pass the buck → bounce around
- Avoidance of discussion
  - Discomfort?
  - Personal bias re: medicine?
- Finally referred to Infectious Disease
  - How this feels

- No sexual history taken
- No site-specific STI testing
- Feeling uncomfortable with my provider
  - Would I truly want to disclose more?
  - Sense of being judged
The experiences of others here in VT

- Similar “pass the buck”
- Similar referral to ID
- Docs willing to continue PrEP but not initiate it
- “You’re sure you don’t have HIV?”

- Assumption about being married, therefore, monogamous
  - Burdens patient to feel obligated to disclose more information to get doc on board to test STIs
So what’s the big deal?

- Sex is incredibly loaded with emotions: intimacy, vulnerability, pleasure, +/- pain, “coming of age”, +/- love and security. At times, negative associations for some.

- Even more loaded for the LGBT community ... “sexual orientation” ... it’s our core identity
  - *In particular, the gay community:*
    - HIV/AIDS epidemic and inadequate/inappropriate response by gov’t
      - “the gays deserve to die”
    - Core individual identity related to who you have sex with. Gay culture is a sexual culture
    - Sex linked to illegality, death, torture in many places
    - Previously related to mental disorder in DSM
    - Our lives are *inherently* political – filing taxes, estate protection, healthcare decisions, employment security
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 ~ 50,000 new infections per year
  - (MSM) population carrying the largest burden. 25% of new infections are among youth (13-24yo)
  - MSM represents about 4% of the total US population but accounted for 78% of new HIV infections among men in 2010.
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 or student health, 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 are the barriers to PrEP use in VT?

- Lack of training about PrEP
- Concerns about costs and 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
- Nearly half of providers consider themselves “not confident at all” about having an informed discussion with patients regarding PrEP
What is PrEP?

- Pre-exposure prophylaxis – differs from PEP (post-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 rock solid (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*
The big picture:

- Estimated 1/4 of all sexually active MSM have indication for PrEP
  - (2014 US Public Health Service; PrEP Clinical Practice Guideline)

- Estimated 1/5 of IV Drug Users have indication for PrEP

- Estimated 1/200 heterosexual sexually-active adults have an indication for PrEP
What about other at risk populations?

- Heterosexual men and women in serodiscordant relationships
- Partners PrEP Study
  - Truvada vs. tenofovir vs. placebo in 4,500 participants in Kenya & Uganda
  - Reduction of new infections by 73% (of those assigned to take Truvada)
  - When the researchers measured blood levels of the medication, the reduction rate was **90% fewer new infection**
- 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%

Further studies evaluation Truvada’s effect on truly parenteral HIV acquisition
Follow-up 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 condom use; 56% unchanged (people already do what they want)

- 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 in SF has baseline higher rates HIV / viral undetectability
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.
  - UVM practice so far has been “refer to ID” ... let’s stop this

- **HIV-negative, or assumed to be, MSM 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.
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:
  o Assessment of HIV status (including signs or symptoms of acute HIV infection)
  o Assessment of side effects and advice on how to manage them
  o Assessment of medication adherence and counseling to support adherence
  o 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
<table>
<thead>
<tr>
<th></th>
<th>MSM Risk Index</th>
<th></th>
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</table>
| 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/renal dysfunction, worsening of hepatitis B infection if stopped
- Recommended labs every 3 months to monitor for:
  - HIV status, other STI’s, LFT’s, and serum BUN/Cr
Lab Tests and Evaluation

- **1) HIV antibody test**
  - Confirm HIV (-) status before initiating, and every 3 months *(ideally within the week before refilling Rx)*
  - Accomplish via serum HIV ELISA or rapid POC FDA approved fingerstick blood test
    - Do NOT use oral rapid tests in PrEP monitoring due to less sensitivity
    - Do NOT accept self-reported results or documented anonymous results
  - **If positive HIV antibody: follow normal procedure for confirmatory testing**
  - **If acute infection suspected, must defer to HIV RNA test for acute exposure**
Reminder: Which HIV test?

- General Screening: Fourth generation immunoassay (detects antibodies)
  - If positive, reflex to HIV 1 / HIV 2 Differentiation
    - Confirms the fourth generation test, also gives info on type of virus if present
  - If within “window period” and concern for acute HIV infection/exposure, order tests for direct viral detection
    - P25 antigen, HIV RNA
Lab Tests and Evaluation

2) Renal Function
   - Obtain serum Cr and eCrCl
     - Minimum eCrCl of 60ml/min
     - Among HIV+ persons prescribed Truvada-containing regimens, decreases in renal function (eCrCl) have been documented. Occasional cases of acute renal failure in HIV+ individuals
     - In HIV negative individuals, eCrCl may decrease initially, eventually returning to baseline

3) Test for active HVB/HCV infection
   - MSM and IVDU at increased risk
   - Tenofovir has activity against HBV, thus if pt stops med, reactivation of HBV $\rightarrow$ hepatic damage

4) Consider bone density evaluation if pt may be at risk

5) Serum and Site-specific STI testing
   - Oropharyngeal and anal swabs for GC / Chlamydia
   - Urine GC/Chlamydia
   - Syphilis RPR serology
Please see handout for “schedule” of labs for PrEP

- Essentially, no harm in running all of these routinely q3months for simplicity’s sake. It’s all the same blood draw
Importance of the Sexual History and site-specific STD testing

- Q3month visits provide regular opportunities with obtaining a sexual history
- Importance of site-specific testing (2010 CDC STD guidelines for MSM screening)
  - Urethral G/C if insertive intercourse in past year
    - Usually urine sample will suffice for this
  - Rectal G/C if receptive anal sex in past year
  - Pharyngeal G/C if receptive oral sex in past year

- Anal Paps?
  - NY State Dept. of Health recommends for HIV+ patients
  - CDC/USPSTF/ACS do not recommend
  - Recommendations? HIV- patients = baseline, q2-3 years (however still being studied)
For all sexually active pts:
- *Consider dx of bacterial STIs in past 6 months as evidence of potential HIV-exposure sexual activity, therefore, risk*

- Alcohol use / abuse screening (especially before sexual activity)

- Screening for use of non-injection drugs
  - *Amyl nitrite (“poppers”) – assoc’d w/ sexual encounter enhancement*
    - Smooth muscle (sphincter) relaxation, vasodilation and reflexive tachycardia (sensation of “excitement”)
  - *Stimulants*
Having The Talk: Approach to Clinical Assessment of the Patient – Sexual HIV Acquisition Risk

Sexual history taking:
- 76% of MSM surveyed in 2008 in 21 US cities reported a health care visit in the past year
  - However, many providers don’t ask about (and pts don’t disclose) same-sex behaviors
  - Language unique to MSM: “bottoming” vs. “topping”, “bareback”/”raw”

*** “Are you and your partner exclusive or open?” ***
- San Francisco State Univ “Gay Couples Study”: found 47% of gay relationships are open, 45% monogamous, and 8% disagreed about their categorization
  - Married / partnered does not mean monogamous! Many seeking PrEP are married/partnered
Cost Concerns

■ Truvada is covered by nearly all major insurance in VT:
  - VT Medicaid
  - VT Blue Cross – Blue Shield
  - Other private insurances

■ Gilead “Advancing Access” Copay Card
  - [https://www.gileadadvancingaccess.com/copay-coupon-card](https://www.gileadadvancingaccess.com/copay-coupon-card)
  - Covers drug copay cost
    ■ U.S. residents
    ■ Available for each valid prescription, no other purchase necessary
    ■ Pt cannot be currently receiving other free drug assistance through Gilead patient assistance programs

■ Gilead Financial Assistance Card

It is rare for an individual to pay full out-of-pocket cost for PrEP – especially in Vermont
HIV risk is not static throughout lifetime – “seasonality” of risk

Identification of high-risk people might be less helpful than identification of high-risk moments and the situations that cause them, for example:

- Leaving home
- Becoming an adult
- Coming out as a MSM
- Immigrating to a new city
- Ending a relationship

** Family Medicine again is perfectly poised to intervene **

PROUD study reported that unexpectedly high HIV incidence (9 infections per 100 person-years) in men who asked for PrEP and who were asked to defer

- HIV incidence was 3x expected based on epidemiologic trends
- People at higher risk of HIV infection were more likely to seek PrEP services, stay in care, and be adherent = the motivation is already there

iPrEx study: Evidence that PrEP is a strong attractor for those entering into a “season of high exposure to HIV”

- Temporal variation in risk behavior
The Condom Conundrum

■ Many people do not like sex with condoms
  – Diminished sensation – acknowledge impact on intimacy and privacy
  – Increased anxiety and ED? Caused by condoms? ED treatments
  – Poor fit and the “I only use Magnum” issue
  – Tissue irritation – know your lube options

■ Many people who do want to use condoms and need help
  – Encourage open conversation. Ask, if yes, ask again. If no, ask why not.
  – Strategies to respond when partner protests condom use
  – www.condomania.com and www.luckybloke.com
  – Alternatives to latex
Rectal Self-Swab Collection Instructions

Step 1
Open kit and remove tube and package with green writing. Remove the swab with the BLUE shaft. USE BLUE SHAFT SWAB ONLY.

Step 2
Insert swab 1 inch into the anus and turn for 5 – 10 seconds.
If needed, before inserting swab, wet swab with water or saline solution.

Step 3
Remove cap from test tube. Place swab in test tube. Do not puncture the foil cap.
Break swab shaft at the score mark.

Step 4
Put cap back tightly on test tube to prevent any leaking. Try not to splash the liquid out the tube.

Step 5
Discard wrapper and unused swab. Wash your hands. Return the tube to the health worker.

http://www.sfcityclinic.org/providers
http://fenwayhealth.org/
Road to Zero

- Campaign whose goal is to achieve zero new HIV infections in Vermont by 2020
  - Average of 11-19 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
  - *** HAVE THE CONVERSATION ***
  - Truvada is covered by Vermont Medicaid and Blue Cross-Blue Shield

- Patient awareness, education, and counseling
  - VT Cares: counseling services currently, plans to expand
PrEP Updates: The Regimen

- **Preferred regimen remains TDF-FTC** (tenofovir DISOPROXIL fumarate – emtricitabine) = Truvada
  - Counsel to still use condoms 1 week after initiating (anal sex), 21 days (vaginal)

- New TAF (“Descovy” - tenofovir ALAFENAMIDE) form
  - Decreased renal/bone toxicity; already used in treating HIV
  - However, NOT indicated for prophylaxis (PrEP) due to conflicting reports about having lower anal mucosal levels vs TDF
  - Large multinational trial is underway
PrEP Updates: The Dosing Schedule

- Preferred / approved dosing schedule remains **daily** (protection depends on total drug levels in mucosa)

- Alternative dosing regimens have been studied and show promise:
  - **IPERGAY Study**: “Event-Driven” / “On-Demand” therapy
    - relative reduction of 86% in the risk of HIV-1 infection.
    - Loading dose 2 tabs, 24 hours before unprotected sex
    - 1 tab daily while sexually active, continued 2 days after sexual activity ends
  - **Discrete period of sex** (i.e. going on a trip) = start daily PrEP 1 wk prior, continue until 1 month after
    - Supported by pharmacokinetic data for predicting protective levels of intracellular Tenofovir
    - Not completely evaluated in trials

- **NOTE**: alternate dosing regimens not yet approved by FDA
  - Also not evaluated in heterosexual men/women and sub-daily dosing not recommended for women having vaginal sex due to longer time needed to achieve adequate vaginal mucosa
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
  - Cornell University currently recruiting for clinical trial
The Take-Home

- Truvada is **SO** much more than just a medication
- HIV for the MSM community is **SO** much more than just a chronic disease
  - Remember the historical context
  - Remember how it’s in the back of all of our minds
- Individuals coming to you asking for PrEP have already self-identified as higher-risk individuals
- Prescribing PrEP is incredibly simple – literally just a 5-item checklist. Requires no nuanced clinical judgment
  - No more excuse for “not being comfortable”
- We need advocates, not judges
  - Approach healthcare from a sex-positive, non-judgmental mindset
  - “The Ethical Slut” by Dossie Easton and Janet Hardy
  - Dan Savage: “Savage Lovecast”
- Zero new HIV infections is ACHIEVABLE in Vermont
Clinician Resources

  11:00 a.m. - 6:00 p.m. ET Monday through Friday
- Laura Catoe, NP – UVMMC Infectious Disease outpatient clinic
- UpToDate articles:
  - “Patient evaluation and selection for HIV pre-exposure prophylaxis”
  - “Administration of pre-exposure prophylaxis against HIV infection”
PLEASE TAKE A HANDOUT!

Questions? (sorry I have to run to ACLS training)

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References cont’d


