PrEP 2016: What will it take to generate demand, increase access, and accelerate uptake?

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Disclosures: Research grants from Gilead Sciences and Viiv Healthcare
Crystal Ball, or Through A Glass Darkly.......
PrEP Is Effective: Adherence Is Critical

Pearson correlation: 0.86 ($P=0.003$).

Analysis of PrEP use and HIV/STI incidence in PrEP users in large healthcare system (Kaiser Permanente San Francisco) from 2012 to 2015

1045 referrals for PrEP; 801 individuals with ≥ 1 intake visit
657 initiated PrEP (82%*); mean duration of use 7.2 mos

Key results (PrEP initiators):
- After 12 months, 50% diagnosed with any STI
  - 33% rectal STI; 33% chlamydia; 28% gonorrhea
- No HIV diagnoses (388 PY follow-up)
- After 6 mos PrEP, self-reported condom use was decreased in 41% of individuals

*Of persons with ≥ 1 intake visit.

If PrEP works why is it not SOP?

- Dis- and mis-information
- Phobias: sex, gender, substance use
- Clinicians and patients are not comfortable talking about sex and drug risks
- Institutional inertia: system disrupter
- PrEP may not be a stand-alone, needs to be part of “one stop shopping” package for some
- Regulatory hurdles globally, desire for locally-specific data
- But, the times they are a’changing
• 24.7% sexually active MSM=492,000
• 18.5% of PWID=115,000
• 0.4% of heterosexual adults=624,000
• Data derived from national probability surveys
New PrEP Starts per Quarter

Total Unique Individuals = 8,512

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

732% increase

Bush, S. et al; IAPAC Adherence 2015; #74
Changes in PrEP Use Among U.S. MSM

(3 web surveys, N=10,097)
Delaney et al, CROI, 2016

- PrEP was first used by 5 pts outside of a clinical trial in 2011.
- More than 83% of PrEP initiators still using PrEP.
- Since 2005, 1/2 of new syphilis diagnoses were in HIV+ patients, while 80% of incident GC/CT infections were in HIV- MSM.
- More than one third (36%) of MSM who initiated PrEP in 2014 had a recent bacterial STD.

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<th>No PrEP</th>
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<td>1209</td>
<td>7904</td>
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<tr>
<td>2011</td>
<td>1329</td>
<td>8155</td>
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</table>

Total

- Patients who indicated they were MSM when registered for care, i.e. overestimate of those at risk
- **p<0.001
Pre-exposure Prophylaxis Implementation Program
The Miriam Hospital Immunology Center

Reporting period: 10/30/2013-11/30/2014

1,086 Clinical visits from 10/30/14-11/30/14

100% (234)
PrEP Education and Counseling

56%(130)
Interested in PrEP

29%(69)
Successfully Contacted

15%(35)
Scheduled Appointment

12% (27)
Made Appointment

11%(25)
Rx PrEP

Not Interested (N=104)
• Low-risk (44%)
• Other (20%)
• Did not say (15%)
• Would think about it (12%)
• Side-effects (6%)
• Insurance (3%)

Did Not Schedule (N=34)
• Low-risk (38%)
• Other (24%)
• Would think about it (15%)
• Side-effects (12%)
• Insurance (6%)
• Appointment with PMD (3%)
• Moved Away (3%)
“Postcards from the (cutting) edge

- Work in progress
- Some countries which hosted successful efficacy trials, are moving forward, others are dragging their heels
- Some communities are more engaged than others
- Regulatory vacuum in resource rich environments may create informal markets
From Research to Rollout

- **Post-trial access**
  - Intervention provided to trial participants and, sometimes, their communities, after trial & before product is available for widespread use

- **Open label extensions**
  - Intervention made available in follow-on protocol in which participants from previous RCT know they are receiving active intervention
  - Gather information about how product use in people who are now aware of potential benefit

- **Open label/Implementation studies**
  - Research protocols similar to above but enrolling new participants

- **Demonstration projects**
  - “Road test” use of new option in real-world settings – not in trial site
  - Address both infrastructure needs to deliver intervention and ways individuals integrate it into daily activities and decision making.
  - Help answer core questions about for whom and how

- **Product introduction**
  - Complex process of formally making new options widely available. Can include meeting regulatory requirements, WHO prequal, various country-specific requirement, logistical challenges

- **Scale-up**
  - Ramping up access to new options for all who need them – mobilization of resources for procurement, distribution, delivery, worker training and other costs associated with rollout; quick ID and resolution of bottlenecks
PrEP Demonstration Projects: Planned, ongoing and completed project locations

36
OLE, demo, feasibility, implementation studies planned, ongoing, completed globally

17
In Africa

1
Regulatory approval (US, 2012)

Global recommendation (WHO, 2015)

- United States: 9 ongoing
- Canada: 1 ongoing
- United Kingdom: 1 ongoing
- Belgium: 1 ongoing
- Netherlands: 1 ongoing
- France: 1 ongoing
- Senegal: 1 ongoing
- United Kingdom: 1 ongoing
- Belgium: 1 ongoing
- Germany: 1 ongoing
- India: 1 planned
- Thailand: 1 completed
- Australia: 2 ongoing
- New Zealand: 1 planned
- United States: 1 completed
- Peru: 1 completed
- Ecuador: 1 completed
- Brazil: 1 ongoing; 1 completed
- Nigeria: 1 ongoing
- Benin: 1 ongoing
- South Africa: 3 ongoing; 3 planned; 1 completed
- Tanzania: 1 planned
- Kenya: 3 ongoing; 1 planned; 1 completed
- Uganda: 1 ongoing; 1 completed
- Mozambique: 2 planned
- Zimbabwe: 1 ongoing
- Botswana: 1 completed
PROUD Study: Results

- Significantly fewer new HIV infections with immediate versus deferred PrEP (3 versus 20 cases)
  - 86% reduction ($P=0.0002$)
- Incident HIV infection in the immediate group
  - HIV infection predated start of ART (n=1)
  - No drug/not adherent (n=2)
- Number needed to treat to prevent 1 HIV infection: 13

Shocked HIV Charities Blast NHS For “U-Turn” On Drug That Prevents HIV

The NHS has scrapped plans to make Truvada available, prompting fury from HIV organisations.

posted on Mar. 21, 2016, at 7:28 p.m.

Patrick Strudwick
BuzzFeed LGBT Editor, UK
Pissed off HIV activists storm London’s NHS HQ
Buy PrEP Now

Where to buy PrEP online, now, in the UK

So far we have independently verified 4 different companies who reliably sell PrEP that you can trust. For full details on our independent verification process, click here.

**United Pharmacies UK** (£44 per month)

United Pharmacies UK is our personally recommended supplier of PrEP, you do not need to upload a prescription after purchasing and they have some of the cheapest prices on the internet. In addition to independently verifying their product, we also use United Pharmacies to buy PrEP ourselves. The only minor issue is that due to running out of stock, orders occasionally have a delay of around 1 - 2 weeks.

1 months supply = £45.79 per month.
3 months supply = £41.69 per month, (£125.07 in total).

Delivery to the UK costs £6.75 and takes 7 - 14 business days.
Latin America: Steady Progress

- A project funded by UNITAID will support the implementation of demonstrative research on for MSM in Mexico, Peru and Brazil.

- Information and awareness about PrEP in Spanish is needed.

- An article prepared by Ravasi G, Grinsztejn B, Baruch R, Guanira JV, Luque R, Caceres C and Ghedinelli M will discuss more of the challenges.

ricardo.baruch@insp.mx
Regional Consultation on PrEP for MSM in Asia

Attendance included 135 representatives from the region, including Community, Civil Society, Government, Policy Makers, Clinical and Health Service Providers and Development Partners*

The three day programme discussed the current barriers to implementing PrEP for MSM in different countries throughout Asia. With a focus on developing country advocacy plans that could be used for follow up country discussions.

Organized by APCOM and supported by UNAIDS, WHO, UNICEF, the USAID LINKAGES Project managed by FHI 360, and UNDP and the Multi-Country South Asia Global Fund HIV Programme.
Currently there is little information about PrEP available in local languages. Meaning there is poor knowledge about PrEP in the region.

There is a low knowledge about the existence of PrEP.

There is a low belief in efficacy of PrEP and concern about moving away from condom-based messages and prevention.
South African PrEP Review

- **Patient/ Clients - MSM**
  - self perspective, see as at risk and vowed to protect oneself through the use of PrEP
  - published in local e-news online

- **Provider- Human Resources and Task Shifting**
  - Demo projects (MSM, Sex Workers, Young women)
    - Acceptability outside strict clinical trails settings
    - Tailor methods to attract the right populations through targeted designed advertisement
  - Nurses initiated projects (Anova Health Clinics, Joz i& Cape town)
  - Demo projects so far not so populations representative in terms of race – a need to build social acceptability of PrEP
How to improve outcomes in the “PrEP Cascade”?

• Paying for PrEP-related services: PrEP-DAP
• Academic detailing
• Intensive PrEP Ed: on line and off
• PrEP navigators
• Local PrEP champions
• PrEP apps: Healthminder, SexPro and Nurx
• Other PrEP resources on line
• Providers remain a challenge
• Tailoring for key populations is needed
Paying for PrEP: CDC

Resources

To apply for health insurance on the federal exchange: www.healthcare.gov

Community Health Center Locator: http://findahealthcenter.hrsa.gov/

Washington state (residents):
PrEP drug assistance program (PrEP-DAP)
http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIV/AIDS/HIVCareClientServices/PrEPDAP

New York state (residents):
PrEP assistance program (PrEP-AP)
Call 1-800-542-2437

Gilead Sciences:
Medication Assistance Program and Co-Pay Assistance
https://start.truvada.com/individual/truvadaprep-copay

Patient Advocate (PAF) Foundation:
Co-Pay Relief Program
https://www.copays.org/diseases/hiv-aids-and-prevention

Division of HIV/AIDS Prevention,
National Center for HIV/AIDS,
Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027 USA
Phone: 800-232-4636
December 2015
Covering the Cost of PrEP Care

Insured

- **Medication**
  - Bill insurance
  - Apply for copay assistance from Gilead or PAF

- **Lab Test**
  - Bill insurance

- **Clinic Visits**
  - Bill insurance

Not insured

- But may be eligible for Medicaid or ACA Plans

- Apply

- **Household Income**
  - 500% FPL or less

  - **Medication**
    - Gilead Medication Assistance Plan
    - WA State Medication Assistance
  
  - **Lab Test**
    - Care at CHC with sliding fee scale
  
  - **Clinic Visits**
    - NY State PrEP Assistance Plan
    - NY State PrEP Assistance Plan

- Not eligible for Medicaid or ACA plans OR Insurance denies claim

  - **Household Income**
    - More than 500% FPL

  - **Medication**
    - Bill insurance
    - Apply for copay assistance from Gilead or PAF
  
  - **Lab Test**
    - Bill insurance
  
  - **Clinic Visits**
    - Bill insurance

**PrEP Medication Assistance Program**

*(Gilead Sciences)*

People eligible for this program must:

- Be 18 years of age or older
- Be without insurance or have payment declined by their insurance carrier
- Be resident in the US (social security number not required)
- Have family income ≤ 500% of the federal poverty level

Once enrolled in this program:

- Medication will be sent to the provider, a pharmacy, or the patient’s home
- Patients can get their medication at no charge from their provider or pharmacy for as long as they are eligible
- Eligibility must be confirmed every 6 months by the provider

**Abbreviations**

- ACA - Affordable Care Act
- FPL - Federal Poverty Level
- CHC - Community Health Center
- PAF - Patient Advocate Foundation

**Definitions:**

- **PrEP**
  - Daily pill to prevent HIV infection (pre-exposure prophylaxis)
- **Co-pay**
  - Fixed amount to be paid by insured person per prescription
- **Co-insurance**
  - Fixed percentage of prescription cost to be paid by insured person
- **Deductible**
  - Amount of health care cost (including prescriptions) that must be paid by the insured person before insurance begins to cover costs

**PrEP Medication Assistance Program**

*Source: https://www.healthcare.gov/glossary/federal-poverty-level-fpl/*

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<tr>
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<tr>
<td>5</td>
<td>$142,050</td>
</tr>
<tr>
<td>6</td>
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Public Health Detailing Action Kits

**Detailing Action Kits** - contain clinical tools, resources for providers and patient education materials, which promote evidence-based best practices and chronic disease management. These materials are available for health care providers and their practices to help improve patient care related to key public health challenges. Clinical topics have been chosen largely because of their anticipated impact on morbidity and mortality. Click on the images below to view the contents of the Public Health Detailing Action Kits.

PrEP and PEP Action Kit

The PrEP and PEP Action Kit includes provider and patient resources. It is structured around these core HIV prevention practices:

- *Take a thorough sexual history*
- *Screen sexually active patients*
- *Talk about PrEP & PEP*
- *Prescribe PrEP & PEP*

Download the PrEP & PEP Action Kit
Events Calendar

Free Webinar: Preventing HIV with PrEP: A Clinical Update

HIV/STI Treatment and Prevention
April 25, 2016 | Webinar

Pre-exposure prophylaxis, or PrEP, is a pill taken once daily to help prevent HIV infection in uninfected people. In this webinar, Kevin Ard, MD, MPH will share clinical approaches to managing patients on PrEP based on cutting-edge research data, including recent findings reported at CROI. Through clinical case scenarios, Dr. Ard will help providers understand how to apply research findings to their own clinical practice. This webinar will also include a discussion of the status of new innovations in PrEP, such as injectable medications, rectal microbicides, and vaginal rings.

Faculty

Kevin Ard, MD, MPH, Medical Director, National LGBT Health Education Center; Massachusetts General Hospital

Date/Time

Monday, April 25, 2016, 2:00-3:00pm ET

Register
To have successful implementation of PrEP it is a delicate balance between demand generation and supply creation and then it is a reiterative process.
HealthMindr Pilot Study
P Sullivan et al

**Participants**
- 121 MSM enrolled
  - 72 in Atlanta, GA
  - 49 in Seattle, WA
- 18+ years
- Never tested HIV positive
- Only available to Android users

**Recruitment Strategy**
- Facebook banner ads
- Grindr mass text messages & banner ads
- 4 month study
  - Recruited from May-Aug
  - Finish in December
- 99 have completed Final Evaluation
Preliminary Results (n=99)

• 78% of those reported dissatisfied with current condoms ordered new condoms

• 87% report using the ordered condoms

• 2/3 of test kit orders were not planning on being tested soon

• 50% of users who did not have a testing schedule now do

• 10% of PrEP-eligible men started PrEP
PrEP delivered to your home  http://app.nurx.co/prep

The Fastest way to PrEP

Get on PrEP with Nurx!

What is PrEP?
PrEP Web Resources

- AIDS Foundation of Chicago (www.myprepexperience.blogspot.com/)
- Project Inform (www.projectinform.org/prep/)
- San Francisco AIDS Foundation (www.prepfacts.org)
- The Fenway Institute (www.thefenwayinstitute.org/prepinfo/)
- The US Centers for Disease Control and Prevention (www.cdc.gov/hiv/prevention/research/prep/)
- The AIDS Vaccine Advocacy Coalition (www.avac.org)
A majority of HIV specialists would prescribe PrEP; only 1 in 3 has done so

- Consider part of clinical role
- Have done in practice

- Counseling about PrEP: 59% have done, 87% consider it part of their role
- Visits for HIV-neg partner: 41% have done, 71% consider it part of their role
- Prescribing PrEP: 32% have done, 68% consider it part of their role
- None of the above: 11% have done
- No answer: 25%

National survey of ID physicians (n=415) from IDSA’s Emerging Infections Network

Many HIV specialists do not feel prepared to provide PrEP or other preventive interventions to persons who inject drugs

- Should be offered routinely
- Feel adequately prepared to provide

Sterile syringes
- 80%
- 10%

Opiate substitution therapy
- 68%
- 7%

PrEP if HIV-neg
- 42%
- 26%

None of the above
- 13%
- 18%

None
- 6%
- 51%

No answer

National survey of ID physicians (n=415) from IDSA’s Emerging Infections Network

Need to improve communication about sexual risk behaviors and PrEP in primary care

- Survey of 1,394 MSM using partner-seeking website
- 42% were uncomfortable discussing male-male sex with their PCP
- Even when comfortable, few MSM had discussed PrEP with their PCP
- Most MSM perceived that PCPs would be unwilling to prescribe PrEP

<table>
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<th>Have not discussed CAS w/PCP</th>
<th>Have not discussed PrEP w/PCP</th>
<th>Perceive that PCP would not be willing to prescribe PrEP</th>
<th>Would prefer to obtain PrEP from source other than PCP**</th>
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<tr>
<td>82%</td>
<td>75%</td>
<td>33%</td>
<td>89%</td>
</tr>
<tr>
<td>41%</td>
<td>86%</td>
<td>77%</td>
<td>81%</td>
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</table>

Comfortable discussing male-male sex w/PCP (n=805; 58%)  
Not comfortable discussing male-male sex w/PCP (n=589; 42%)

**Versus other healthcare provider, the Internet, or other source

Krakower et al. IAS 2015
Tailoring PrEP for Key Populations

• ATN 110 (Hosek)
  – Young MSM, mainly of color, 18 to 22 y.o.
  – PrEP plus individual versus group behavioral risk reduction interventions
  – HIV incidence 3.3% (better than HPTN 061, but suboptimal)

• HPTN 073: (Wheeler and Fields)
  – Client-centered care coordination (C4)
  – HIV incidence lower in those who used more C4 (NS, but small sample)

• At risk Women in the U.S.
  - Needs more attention, 30% new infections
Other musings…

• “Planned PrEP” programs, building on Planned Parenthood model (specialized sexual health)
• PrEP home monitoring/self-screening (P Sullivan)
• ONE SIZE WILL NOT FIT ALL
• Mandatory PrEP CME/CEU (generalist training), i.e. lobby ABIM, AAFP, ANA, etc.
• PrEP Ambassadors: your favorite star(s)
• More integration in media-e.g. Sanjay Gupta, & more than “How to get away with murder”
• Generic PrEP (e.g. TDF/3TC) in richer countries?
Remember, PrEP today is PrEP 1.0

New oral PrEP drugs and dosing strategies

Vaginal & Rectal Microbicides (e.g. Tenofovir rectal gel)

Intravaginal rings (Dapivirine, Tenofovir +/-)

Injectables: ARVs and mAbs (Cabotegravir, VRC01)

Novel adherence strategies

Hard-to-reach populations; PWUD

Alternative delivery systems and formulations

TAF/FTC
Conclusions

• PrEP use continues to increase globally
• Many institutional impediments remain, including regulators, providers and costs
• Best practices are emerging from all over
• New models are needed, e.g. use of home monitoring, peer navigation, referral clinics
• Local champions can play a key role
• Web resources can ↑ knowledge and uptake
• Delays in PrEP access could lead to ↑ informal use or non-use, and missed opportunities to improve global sexual health
Antiretrovirals alone are not sufficient

Interventions to Increase Testing

Test

HIV Negative
- Risk Assessment
- PrEP, Adherence Counseling

HIV Positive
- Linkage To Care
- Positive Prevention

HIV Positive
- Enroll in Care
- ART Initiation
- Treat
- Adherence to ART
- Maintain Viral Suppression

Address concomitant concerns:
- depression, substance use, relationship dynamics

Decrease in HIV Transmission
Thank You

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Ken Levine
Albert Liu
Harvey Makadon

Kevin Maloney
Matthew Mimiaga
Amy Nunn
William Nuttland
Rupa Patel
Viraj Patel
Jim Pickett
Midnight
Poonkasetwattana
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