As of 1 Oct 2018, Dr. Hurt serves as UNC site PI for a Gilead-funded study of PrEP (DISCOVER, comparing FTC/TAF vs FTC/TDF).

Dr. Hurt is supported by the Centers for Disease Control and Prevention (ELC-2017-J3), Health Resources and Services Administration (U1OHA30535), Eunice Kennedy Shriver National Institute of Child Health & Human Development (U19HD089881), the National Institute on Drug Abuse (UG3DA044823), and the National Institute of Allergy and Infectious Diseases (P30AI50410, UM1AI069423, UM1AI068619).

The views expressed are not necessarily those of CDC, HRSA, or the NIH.
Objectives

• Describe current trends in PrEP access and uptake in the US

• Explain what the “pipeline” for biomedical prevention looks like as of 2019

• Outline the challenges in PrEP science that our CFAR PrEP Scientific Working Group is well-positioned to address
PrEP users per 100,000 population, 2012

NC: 3 per 100,000

Data from AIDSVu: http://map.aidsvu.org/map?prep=1
PrEP users per 100,000 population, 2017

NC: 21 per 100,000

Data from AIDSVu: http://map.aidsvu.org/map?prep=1
PrEP has taken off in the US...

177,268 recipients by end of 2017

Magnuson D. et al. IAS Amsterdam 2018, abstract #TUAC0305
...but its distribution remains uneven...

25% of all new infections in 2015 among 13-24 yo

Magnuson D. et al. IAS Amsterdam 2018, abstract #TUAC0305
...but its distribution remains uneven...

18% of all new infections in 2015 among women

...and it’s not reaching those most at risk

US Population 2015
- Black: 62%
- Hispanic: 13%
- Asian: 18%
- Multi/Other: 10%
- White: 7%

- Black: 73%
- Hispanic: 10%
- Asian: 13%
- Multi/Other: 1%
- White: 10%

New Infections 2015 (estimated)
- Black: 26%
- Hispanic: 44%
- Asian: 24%
- Multi/Other: 9%
- White: 4%

Mera Giler R. et al. IAS Paris 2017, abstract #WEPEC0919
https://www.poz.com/article/estimated-136000-people-prep-us
New data show racial disparities persist

NHBS MSM: % aware of PrEP

Other = Native American, Asian/Pacific Islander, Multiple Races
New data show racial disparities persist

NHBS MSM: % reporting PrEP use in past 12m

<table>
<thead>
<tr>
<th>Race</th>
<th>2014</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>Black</td>
<td>4</td>
<td>26</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>4</td>
<td>30</td>
</tr>
<tr>
<td>Other *</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>White</td>
<td>8</td>
<td>42</td>
</tr>
</tbody>
</table>

Other = Native American, Asian/Pacific Islander, Multiple Races

PrEP is now a matter of social justice...
...which requires addressing privilege...
...and affordability of biomedical prevention

$1,600 per month if paid totally out-of-pocket (excluding lab costs & provider fees)

Break the Patent ➔ https://slate.com/human-interest/2018/05/act-up-is-challenging-gilead-to-make-truvada-more-accessible.html
Oral PrEP is poised for additional growth
Indicated... in combination with safer sex practices ... to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg.

15 May 2018

https://www.accessdata.fda.gov/
But what’s the right tone in messaging?
STIs in United States, 2000-2016
All Americans, all ages

Reported GC & Ct cases per 100,000 population

Chlamydia

Gonorrhea

Primary & Secondary Syphilis

Reported P&S syphilis cases per 100,000 population

https://gis.cdc.gov/grasp/nchhstpatlas/charts.html
STIs in United States, 2000-2016

Men, all ages

Reported GC & Ct cases per 100,000 population


100 200 300 400 500

Gonorrhea

Chlamydia

Primary & Secondary Syphilis

<table>
<thead>
<tr>
<th>Pregnancy Prevention</th>
<th>HIV Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education &amp; behavior modification</strong></td>
<td><strong>Education &amp; behavior modification</strong></td>
</tr>
<tr>
<td><strong>Condoms</strong></td>
<td><strong>Condoms</strong></td>
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<tr>
<td><strong>Rings</strong></td>
<td><strong>Rings</strong></td>
</tr>
<tr>
<td><strong>Birth control pill &amp; injection</strong></td>
<td><strong>PrEP (oral &amp; injectable)</strong></td>
</tr>
<tr>
<td><strong>“Morning-after pill”</strong></td>
<td><strong>Post-exposure prophylaxis</strong></td>
</tr>
<tr>
<td><strong>Spermicide</strong></td>
<td><strong>Topical microbicides</strong></td>
</tr>
<tr>
<td><strong>Implantable birth control</strong></td>
<td><strong>Broadly neutralizing Abs Implantables</strong></td>
</tr>
<tr>
<td><strong>Vasectomy/Tubal Ligation</strong></td>
<td><strong>Vaccination</strong></td>
</tr>
</tbody>
</table>

Adapted from HPTN
<table>
<thead>
<tr>
<th>Efficacy Trial</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaginal Ring</strong>&lt;br&gt;Dapivirine Ring</td>
<td></td>
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<tr>
<td>HOPE (MTN 025)</td>
<td></td>
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<tr>
<td>Open-label trial of the once-monthly slow-release dapivirine vaginal ring; ongoing in 2,500 women in Malawi, South Africa, Uganda, Zimbabwe</td>
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<tr>
<td>DREAM (IPM 032)</td>
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<tr>
<td>Open-label trial of the once-monthly slow-release dapivirine vaginal ring; ongoing in 1,400 women in South Africa and Uganda</td>
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<tr>
<td><strong>Antibody</strong>&lt;br&gt;VRCo1</td>
<td></td>
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<tr>
<td>AMP (HVTN 704/HPTN 085)</td>
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<tr>
<td>Randomized controlled trial of the VRCo1 antibody infused every two months; ongoing in 2,700 MSM and transgender men &amp; women in Brazil, Peru, Switzerland, US</td>
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<tr>
<td>AMP (HVTN 703/HPTN 081)</td>
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<tr>
<td>Randomized controlled trial of the VRCo1 antibody infused every two months; ongoing in 1,900 women in Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe</td>
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<tr>
<td><strong>Oral PrEP</strong>&lt;br&gt;F/TAF (Descovy)</td>
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<tr>
<td>DISCOVER</td>
<td></td>
<td></td>
<td></td>
<td>End September 2020</td>
</tr>
<tr>
<td>Randomized controlled trial of once-daily F/TAF as PrEP; ongoing in 5,400 MSM and transgender women in Austria, Canada, Denmark, France, Germany, Ireland, Italy, Netherlands, Spain, UK, US</td>
<td></td>
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<tr>
<td><strong>Long-Acting Injectable</strong>&lt;br&gt;Cabotegravir</td>
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<tr>
<td>HPTN 083</td>
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<tr>
<td>Randomized controlled trial of injectable cabotegravir every two months; ongoing in 4,500 MSM and transgender women in Argentina, Brazil, Peru, South Africa, Thailand, US, Vietnam</td>
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<tr>
<td>HPTN 084</td>
<td></td>
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<tr>
<td>Randomized controlled trial of injectable cabotegravir every two months; ongoing in 3,200 women in Botswana, Kenya, Malawi, South Africa, Uganda, Zimbabwe</td>
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</tr>
</tbody>
</table>
TAF non-inferior to TDF for MSM & TGW…

5313 MSM
74 transgender women

Hare B. et al. CROI 2019, abstract 104
...without kidney or bone density issues

F/TAF  
emtricitabine / tenofovir alafenamide

F/TDF  
emtricitabine / tenofovir disoproxil

Baseline vs. Week 48

BMD
Six big challenges that UNC is well-positioned to address
#1: Measuring PrEP “success”

Suggested reading:


#2: Characterizing barriers and intervening

## HIV-NEGATIVE

<table>
<thead>
<tr>
<th>Linkage to primary care</th>
<th>Screen for risk factors and barriers</th>
<th>Retention in care and services</th>
<th>Continued risk reduction, PrEP, PEP</th>
<th>Remain HIV-negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV risk screenings, linkage case management for high-risk individuals, ACA navigation</td>
<td>Screen for STIs, mental health issues, drug use, domestic violence, trauma</td>
<td>Case management and linkage to housing and other ancillary services</td>
<td>+ Regular HIV testing and reevaluation of risk factors; adherence support</td>
<td></td>
</tr>
<tr>
<td>Assess attitudes, beliefs, behaviors, education, and problem-solving skills</td>
<td>Mental health and drug-use counseling</td>
<td>Peer support/navigation</td>
<td>Outreach and reengagement</td>
<td></td>
</tr>
</tbody>
</table>

Suggested reading:


#3: Disentangling STIs and PrEP

Suggested reading:


#4: Staying ahead of the curve with PrEP 2.0

Suggested reading:


#5: Leveraging big(ger) data

Suggested reading:


#6: Perfecting the evaluation of failure

Suggested reading:


Let’s discuss…

- Strategic priorities for UNC?
- Where do you think things are headed?

bit.ly/FMC31519