RAPID & PrEP Implementation

Getting to Zero SF Initiatives

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“Getting to Zero” in San Francisco

Consortium

Zero new HIV infections
Zero HIV deaths
Zero stigma and discrimination

Photo by Jim Herd
How it began....

World AIDS Day Forum
Monday, December 2, 2013
Getting to Zero in San Francisco: How Close Are We?
6:30–8:30 PM
Rainbow Room, LGBT Community Center
1800 Market St., San Francisco

“This is all interesting, but are you working together?”

--Community member
Getting to Zero SF: What are we?

- Multi-sector independent consortium—operates under principles of collective impact:
  “Commitment of groups from different sectors to a common agenda to solve a specific problem.”
Strategic priorities for San Francisco
Getting to Zero Consortium

City-wide coordinated PrEP program
Rapid ART start with treatment hubs
Linkage-engagement-retention in care
Reducing HIV stigma

Vision
Become the first municipal jurisdiction in the United States to achieve the UNAIDS vision of “Getting to Zero”

HIV Prevention, Care, and Treatment Programs
Universal ART = better care, better prevention

• Delivering ART as early as possible after a new diagnosis of HIV:
  – improves morbidity and mortality in all stages of infection (START INSIGHT Team *NEJM* 2015)
  – reduces transmission by 96% (HPTN052--Cohen et al. *NEJM* 2011)
Persons Living with Diagnosed or Undiagnosed HIV Infection
HIV Care Continuum Outcomes, 2012 — United States and Puerto Rico

N = 1,218,400

2012

<table>
<thead>
<tr>
<th></th>
<th>Diagnosed</th>
<th>Received medical care</th>
<th>Prescribed ART</th>
<th>Viral Suppression</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>87.2</td>
<td>39.1</td>
<td>36.2</td>
<td>30.2</td>
</tr>
</tbody>
</table>

National HIV Surveillance System: Estimated number of persons aged ≥13 years living with diagnosed or undiagnosed HIV infection (prevalence) in the United States at the end of 2012. The estimated number of persons with diagnosed HIV infection was calculated as part of the overall prevalence estimate.

Medical Monitoring Project: Estimated number of persons aged ≥18 years who received HIV medical care during January to April of 2012, were prescribed ART, or whose most recent VL in the previous year was undetectable or <200 copies/mL—United States and Puerto Rico.
Care Cascade in San Francisco

1: confirmed HIV test
2: latest VL<200 c/ml within 12 mo of diagnosis
Table 3.2 Care indicators among persons newly diagnosed with HIV in 2014 by demographic and risk characteristics, San Francisco

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number of diagnoses(^1)</th>
<th>% Linked to care within 1 month of diagnosis(^2)</th>
<th>% Linked to care within 3 months of diagnosis(^2)</th>
<th>% Retained in care 3-9 months after linkage(^2)</th>
<th>% Virally suppressed within 12 months of diagnosis(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>334</td>
<td>84%</td>
<td>91%</td>
<td>73%</td>
<td>75%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>313</td>
<td>85%</td>
<td>90%</td>
<td>72%</td>
<td>74%</td>
</tr>
<tr>
<td>Female</td>
<td>14</td>
<td>64%</td>
<td>93%</td>
<td>93%</td>
<td>79%</td>
</tr>
<tr>
<td>Transfemale</td>
<td>7</td>
<td>71%</td>
<td>100%</td>
<td>86%</td>
<td>71%</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>White</td>
<td>143</td>
<td>87%</td>
<td>94%</td>
<td>76%</td>
<td>76%</td>
</tr>
<tr>
<td>African American</td>
<td>36</td>
<td>67%</td>
<td>81%</td>
<td>64%</td>
<td>53%</td>
</tr>
<tr>
<td>Latino</td>
<td>96</td>
<td>81%</td>
<td>88%</td>
<td>71%</td>
<td>78%</td>
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<tr>
<td>Asian/Pacific Islander</td>
<td>42</td>
<td>88%</td>
<td>93%</td>
<td>76%</td>
<td>86%</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>17</td>
<td>94%</td>
<td>94%</td>
<td>65%</td>
<td>65%</td>
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<tr>
<td>Age at Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13-24</td>
<td>37</td>
<td>76%</td>
<td>84%</td>
<td>65%</td>
<td>73%</td>
</tr>
<tr>
<td>25-29</td>
<td>54</td>
<td>93%</td>
<td>98%</td>
<td>81%</td>
<td>81%</td>
</tr>
<tr>
<td>30-39</td>
<td>101</td>
<td>75%</td>
<td>85%</td>
<td>63%</td>
<td>67%</td>
</tr>
<tr>
<td>40-49</td>
<td>81</td>
<td>89%</td>
<td>91%</td>
<td>79%</td>
<td>78%</td>
</tr>
<tr>
<td>50+</td>
<td>61</td>
<td>87%</td>
<td>97%</td>
<td>77%</td>
<td>77%</td>
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<td>Transmission Category</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>MSM</td>
<td>253</td>
<td>84%</td>
<td>91%</td>
<td>75%</td>
<td>78%</td>
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<tr>
<td>PWID</td>
<td>19</td>
<td>79%</td>
<td>95%</td>
<td>63%</td>
<td>63%</td>
</tr>
<tr>
<td>MSM-PWID</td>
<td>37</td>
<td>86%</td>
<td>89%</td>
<td>65%</td>
<td>57%</td>
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<tr>
<td>Heterosexual</td>
<td>11</td>
<td>82%</td>
<td>100%</td>
<td>82%</td>
<td>91%</td>
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<tr>
<td>Other/Unidentified</td>
<td>14</td>
<td>79%</td>
<td>86%</td>
<td>57%</td>
<td>57%</td>
</tr>
<tr>
<td>Housing Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housed</td>
<td>298</td>
<td>83%</td>
<td>90%</td>
<td>73%</td>
<td>77%</td>
</tr>
<tr>
<td>Homeless</td>
<td>36</td>
<td>89%</td>
<td>94%</td>
<td>69%</td>
<td>53%</td>
</tr>
</tbody>
</table>

1 Includes persons diagnosed in 2014 based on a confirmed HIV test and does not take into account patient self-report of HIV infection.  
2 Percent of total diagnoses.
What about truly immediate ART?
(if soon is good, what about sooner?)

- Typical interval of weeks to months between diagnosis, ART, and virologic suppression = lost opportunities
  - Delayed or dropped linkage, retention
  - More immunologic dysfunction
  - More onward Transmission
  - INCREASED disparities in care?
Pilot: RAPID at Zuckerberg San Francisco General Hospital HIV Clinic
RAPID Demonstration Project  
July 2013-December 2014

- Overall feasibility of a health systems intervention for same-day outpatient ART for newly diagnosed HIV infection
- Deployed in context of extensive existing services for navigation, linkage and retention
- Initially targeted to new patients with acute HIV infection (HIV Ab – within 6 months)
- Extended in 2014 to include active 0I, CD4<200

Pilcher, IAS 2015
Milestones of care: SFGH, 2006-2013

Pilcher, IAS 2015
The SFGH RAPID Model

HIV+ Diagnosis
- Disclosure
- Referral
- Scheduling

1st Clinic Visit
- Registered
- Insured
- Housing/SU/MH
- Counseling
- Labs

1st PCP Visit
- Medical evaluation
- ART criteria met

ART start
- Pills taken

Viral load suppressed
- VL monitoring
- Adherence
- Retention

RAPID visit: ART start
- Disclosure, counseling
- Registration
- Insurance
- Housing/SU/MH
- Labs
- Counseling
- Medical eval

PCP Visits
- VL monitoring
- ART management
- Adherence
- Retention

Pilcher, IAS 2015
RAPID

Intervention Components

- Facilitation of same day appointments (PHAST* Team)
  - paged with any new confirmed HIV+ patients on SFGH campus
  - paged by testing sites in SF with any new HIV+ with no/public insurance (i.e., SFGH eligible)

- Flexible scheduling for providers (on-call back-up)
- ART regimens pre-approved for use prior to genotyping or lab testing
- Available as 5 day starter packs
- Accelerated process for health insurance initiation (PHAST Team)
- Recommendation for 1st dose to be taken observed in the clinic

*Positive Health Access to Services and Treatment

Adapted from Pilcher, IAS 2015
New SFGH patients, RAPID era: 2013-4

<table>
<thead>
<tr>
<th>Indicator</th>
<th>RAPID Cohort (n=39)</th>
<th>Universal ART (n=47)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age: mean(range)</td>
<td>32 (21-47)</td>
<td>35 (19-68)</td>
<td>NS</td>
</tr>
<tr>
<td>Male: n (%)</td>
<td>39 100%</td>
<td>43 92%</td>
<td>NS</td>
</tr>
<tr>
<td>Non-white ethnicity</td>
<td>23 59%</td>
<td>34 71%</td>
<td>NS</td>
</tr>
<tr>
<td>Homeless</td>
<td>11 28%</td>
<td>13 25%</td>
<td>NS</td>
</tr>
<tr>
<td>Uninsured</td>
<td>39 100%</td>
<td>47 100%</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Staging</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute (Ab- &lt;6m)</td>
<td>21/30 70%</td>
<td>8/31 26%</td>
<td>0.001</td>
</tr>
<tr>
<td>Log$_{10}$VL</td>
<td>4.9 (2.8-6.6)</td>
<td>4.5 (1.6-6.1)</td>
<td>NS</td>
</tr>
<tr>
<td>CD4 mean (range)</td>
<td>474 (3-1391)</td>
<td>417 (11-1194)</td>
<td>NS</td>
</tr>
</tbody>
</table>
# RAPID program era 2013-4: acceptability and safety

Pilcher, IAS 2015

<table>
<thead>
<tr>
<th>Indicator</th>
<th>RAPID (n=39)</th>
<th>Universal (n=47)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acceptability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall ART uptake</td>
<td>39 (100%)</td>
<td>40 (85%)</td>
<td>NS</td>
</tr>
<tr>
<td>Engaged in care (appt &lt;6 mos)</td>
<td>35 (90%)</td>
<td>40 (85%)</td>
<td>NS</td>
</tr>
<tr>
<td>Transferred care</td>
<td>8 (21%)</td>
<td>11 (23%)</td>
<td>NS</td>
</tr>
<tr>
<td>Provider switched</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART simplification</td>
<td>10 (26%)</td>
<td>0 (0%)</td>
<td>0.001</td>
</tr>
<tr>
<td>ART Toxicity</td>
<td>2 (5%)</td>
<td>0 (0%)</td>
<td>NS</td>
</tr>
<tr>
<td>Genotype-driven modification</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

*all outcomes determined as of last followup (up to 18 months post referral)*
Median Time to VL suppression by ART initiation strategy: SFGH 2006-2014

RAPID vs. universal ART
P<0.001

Proportion <200 copies

Rapid ART
Universal ART
CD4-guided ART

Pilcher, IAS 2015
Patients want same day ART.

Acceptance of same day ART

Proportion of patients on ART

Days after ART offer

RAPID
Universal

Pilcher, IAS 2015
Qualitative Lessons from Interviews with RAPID Pilot Team Members: Keys to Success

1. Single point-of-contact for referrals activates the team (e.g. PHAST Pager)
2. Committed team is essential (Counseling, Benefits Navigation, Clinical)
3. Avg. RAPID intake 2 hours
4. Minimize handoffs: Every handoff is a warm handoff
5. Have a plan for medication access
   – Emergency ADAP
   – Presumptive Medi-Cal
   – Pharma Patient Assistance Cards
   – Starter packs?
6. Schedule follow-up in 5-7 days and check in with patient in the 1-2 days after he/she leaves the appointment
Goals of Citywide RAPID (by 2020)

1. ALL newly diagnosed HIV(+)s navigated to HIV care, including ART, within 5 days of confirmed diagnosis

2. HIV providers receiving a RAPID patient start ART on the day of intake

3. Ongoing program evaluation to ensure/improve quality of care, outcomes
**Step I**
*Day one*
- Confirmed new HIV diagnosis
- Navigation to ART referral
- Partner Services

**Step II**
*expedited intake for ART*
- Medical/psychosocial evaluation
- Start ART

**Step III**
- Follow-up with HIV 1° care
- Review baseline Labs
- Modify ART as needed

The Goal of RAPID is to improve the health of newly diagnosed patients by eliminating delays in ART and access to high-quality HIV care. This means:
- Starting ART the same day as someone is newly diagnosed with HIV (or within 5 days if same-day start is impossible)
- Their first follow-up visit with HIV 1° care within a week after starting ART
- Sometimes RAPID patients will be referred to you at Step III, having already completed Steps I and II.
- Sometimes RAPID patients will undergo all Steps I-III or II-III at your clinic (especially if they were your patients when they were HIV-uninfected)
Plan for Taking RAPID ART Citywide

**Capacitating Testing/Linkage Sites**
*Goal: ≤ 5 days to*
- Disclosure
- Counseling
- Benefits navigation and enrollment
- Linkage to ART/HIV 1° care intake

**Approach**
- Buy-in from Leadership at testing, linkage sites
- In-service training
- Linkage Protocol
- RAPID Provider Directory

**Capacitating ART Providers**
*Goal: at intake*
- Medical evaluation
- Baseline testing
- Offer immediate ART

**Approach**
- Protocol
- Outreach
  - HIV prevalence
  - Special populations
- In-services
- Academic Detailing
- Ongoing Support

**Data**
- Mapping the Landscape of testing, linkage, care
- Interviews w Patients, Care Teams
- Collection of performance data
  - Uptake
  - Time to ART start
  - Regimens used
  - % linked
  - Sites of care
  - Retention
  - Time to viral suppression
  - Durable suppression

**Approach**
- Local Surveillance data
- LINCS data
- Sentinel sites?
Mapping the City for RAPID: Where do New Cases Test, Link

**Testing Sites**

- AHP/Magnet/Glide/DPH (CHN+ Consortium) (37%)
- Private/UC SF/StM/CP MC (22%)
- SF City Clinic (14%)
- SFGH (13%)
- Kaiser (9%)
- Other (5%)

**RAPID PROCESS: within 48 hours of Diagnosis**
- Disclosure
- Counseling
- Partner Services
- Medical Evaluation
- Benefits/Insurance Navigation and Rapid Enrollment
- Linkage to HIV Primary Care within 5 Days
- Immediate ART (Starter Pack or Prescription)

**HIV Primary Care Sites**

- Private/UC SF/StM (32%)
- SFGH (26%)
- Kaiser (14%)
- SFCC/DPH (12%)
- Other/AHP/VA/OOJ/Jail (9%)
- Unknown (7%)
Citywide RAPID SOP: Clinical Issues
Who is eligible for immediate ART?

- Anyone with a new, confirmed HIV diagnosis unless there is a clear contraindication to starting immediate ART.

Who is not eligible for immediate ART?

- Patients for whom immediate ART might be medically dangerous and who should undergo a thorough evaluation and stabilization before ART:
  - Untreated cryptococcal meningitis (defer ART for 5 weeks after the diagnosis, antifungal treatment initiation)
  - Pulmonary or gastrointestinal kaposi sarcoma before chemotherapy (usually Doxil) has been started

Who might be eligible for immediate ART?

- Patients re-engaging in care with clear, uncomplicated ART history, low likelihood of resistance?
Laboratory Evaluation for RAPID Patients

- Confirmatory HIV testing (if needed)
- HIV RNA
- HIV genotype
- Integrase genotyope (if available)
- CD4+ T cell count
- HLAB5701 polymorphism testing
- RPR, HAV IgG antibody, HBsAg, HBcAb, HBsAb, HCV antibody
- CBC
- Renal
- Liver
- Lipids
- QFT
- Toxo
# Recommended RAPID Treatment Regimens

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Pill Burden</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>dolutegravir 50 mg once daily tenofovir-DF 300mg/emtricitabine 200mg once daily</td>
<td>2 pills once daily</td>
<td>• Rapid drop in VL with INSTI class&lt;br&gt;• DTG well tolerated&lt;br&gt;• DTG appears to have high genetic barrier to resistance&lt;br&gt;• once daily dosing</td>
<td>• Limited experience</td>
</tr>
<tr>
<td>darunavir 800 mg once daily ritonavir 100 mg once daily tenofovir-DF 300mg/emtricitabine 200mg once daily</td>
<td>3 pills once daily</td>
<td>• PI class has high genetic barrier to resistance&lt;br&gt;• clinical experience suggests efficacy even if M184V present&lt;br&gt;• once daily dosing</td>
<td>• Drug interactions (ritonavir a CYP3A4 inhibitor)</td>
</tr>
<tr>
<td>raltegravir 400 mg twice daily tenofovir-DF 300mg/emtricitabine 200mg once daily</td>
<td>1 pill BID + 1 pill daily</td>
<td>• Rapid drop in VL with INSTI class&lt;br&gt;• RAL well tolerated</td>
<td>• BID dosing for RAL</td>
</tr>
<tr>
<td>Once daily coformulated TAF 10mg/emtricitabine 200mg/elvitegravir 150mg/ cobicistat 150mg</td>
<td>1 pill once daily</td>
<td>• Rapid drop in VL with INSTI class&lt;br&gt;• Lowest pill burden&lt;br&gt;• once daily dosing</td>
<td>• Drug interactions (cobicistat a CYP3A4 inhibitor)&lt;br&gt;• possibility of INSTI, NRTI resistance with failure seen in licensing trials&lt;br&gt;• Not for use if CrCl&lt;30 mL/min</td>
</tr>
</tbody>
</table>

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FTC/TDF can be replaced by FTC/TAF when used with an integrase inhibitor. The combination of FTC/TAF plus a boosted PI was studied with TAF 10mg. The renal effects of TAF 25mg (the dose available in the US) when given with a boosted PI are uncertain.
ARVs to AVOID until results of genotype, HLAB5701 are known

- 1st, 2nd generation NNRTIs (efavirenz, nevirapine, etravirine, rilpivirine): NNRTI class most associated with transmitted drug resistance; efavirenz neuropsychiatric side effects; nevirapine associated with hepatotoxicity; rilpivirine less potent if baseline VL>100,000 c/mL

- Abacavir-containing regimens (including abacavir co-formulations such as Epzicom® and Triumeq ®): high risk of fatal abacavir hypersensitivity reaction if HLA-B5701(+).
Prevalence of Drug Resistance Mutations in Treatment-Naive Patients, 2000-2013

- Baseline plasma samples from 4 phase III trials (GS 903, 934, 104, 111, N = 2531)
  - 1617 samples analyzed for integrase mutations
  - 2531 analyzed for protease or RT mutations
- Substantial ↑ in prevalence of NNRTI resistance, modest ↑ in PI resistance
- Stable prevalence of NRTI resistance (mostly TAMs)
  - M184V/I ≤ 0.2%; K65R ≤ 0.2%

### Antiretrovirals used in RAPID Pilot

<table>
<thead>
<tr>
<th>Combination</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTC/TDF + DTG</td>
<td>26</td>
<td>67%</td>
</tr>
<tr>
<td>EVG/COBI/FTC/TDF</td>
<td>7</td>
<td>18%</td>
</tr>
<tr>
<td>FTC/TDF + DRV/r</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>FTC/TDF + RAL</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>DTG/3TC/ABC</td>
<td>1</td>
<td>2%</td>
</tr>
</tbody>
</table>
RAPID era 2013-4: transmitted resistance and drug regimens

<table>
<thead>
<tr>
<th>Indicator</th>
<th>RAPID (n=39)</th>
<th>Universal ART (n=47)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmitted resistance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>8/32, 25%</td>
<td>18/43, 42%</td>
<td>NS</td>
</tr>
<tr>
<td>Major NNRTI-R</td>
<td>7, 22%</td>
<td>11, 26%</td>
<td>NS</td>
</tr>
<tr>
<td>Major PI-R</td>
<td>1, 3%</td>
<td>2, 5%</td>
<td>NS</td>
</tr>
<tr>
<td>Major NRTI-R</td>
<td>0, 0%</td>
<td>1, 2%</td>
<td>NS</td>
</tr>
<tr>
<td>Regimen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INI-based</td>
<td>35, 90%</td>
<td>31, 83%</td>
<td>NS</td>
</tr>
<tr>
<td>PI-based</td>
<td>4, 10%</td>
<td>5, 10%</td>
<td>NS</td>
</tr>
</tbody>
</table>
RAPID Insurance Issues

- Insured with affordable co-pay covered
- Insured, high copay + PAN, PAF
- Uninsured ≥ 5x FPL ACA
- Uninsured <138% FPL** Medi-Cal*
- <5x FPL, Medi-Cal ineligible ADAP/HSF*

*Emergency ADAP, presumptive Medi-Cal activated within 24h by navigators
**$16,395 = 138% of FPL for a single person (2016)
Lessons Learned in 2016:
Outreach to HIV 1º Care Sites

**Strategy**
1. Outreach to Clinic Leadership
2. All-staff discussion/In-service
3. Individual provider detailing
4. Follow-up

**Implementing RAPID**
- Positive Health Program (W86)
- Kaiser SF
- San Francisco City Clinic
- Larkin (youth)
- Family Health Center

**In-Process**

**DPH/COPC**
- Castro Mission
- Southeast
- Tom Waddell

**On the List**
- Private Practices
- UCSF
- St Mary’s
- SFVAMC
- One Medical
- Community Consortium Clinics

47%
Lessons Learned: 2016

1. Provider acceptance generally high

2. Greatest challenge: linkage/insurance navigation
   1. Medi-Cal/eligible: easy
   2. Insured (incl Kaiser): easy
   3. ACA-eligible or enrolled, but not established in care most difficult: drug studies fill a gap, for now.....
   4. Student visas: more difficult

3. Disparities a challenge
Goals for 2016-17

• Implement, evaluate systematic RAPID detailing
• Detail all HIV providers on RAPID
• RAPID linkage navigation “bootcamp” for navigators/test sites
• “Bridging” RAPID ART site to care for difficult-to-link patients using Ryan White funds while they are being navigated?
• Evaluation metrics
Evaluation Goals

• Working with Surveillance to refine citywide RAPID Metrics: for new outpatient HIV diagnoses
  - Days from diagnosis to first care visit
  - Days from first care visit to ART start
  - Days from ART start to virologic suppression
  - % with ART start within 1, 3, 5, 7 days of diagnosis
  - 6, 12 month retention

• Patient experience of RAPID
• Provider experience of RAPID

Qualitative Interviews
New HIV Cases and HIV-related Deaths, by Year: 2006-2015

- **2006**: HIV test w/o written consent
- **2008**: LINCS
- **2010**: ART at diagnosis; HIV test scale-up
- **2011**: LINC
- **2012**: PrEP
- **2013**: RAPID Pilot

SFDPH HIV Epidemiology Annual Report 2015
It Takes a Village

G2Z Rapid Committee
  – Diane Havlir
  – Diane Jones
  – Stephanie Cohen
  – Chris Pilcher
  – Hiroyu Hatano
  – Susa Coffey
  – Janet Grochowski

G2Z Steering Committee
  – Shannon Weber
  – Courtney Liebi

PHAST
  – Clarissa Ospina-Norvell
  – Sandra Torres
  – Fabi Calderon

Kaiser-SF
  – Brad Hare
  – Marc Solomon
  – Ed Chitty

SFDPH
  – Jonathan Fuchs
  – Darpun Sachdev
  – Andy Scheer
  – Susan Scheer
PREP
PrEP can prevent HIV infection

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>POPULATION</th>
<th>LOCATION</th>
<th>Active arm(s)</th>
<th>EFFICACY (mITT-analysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>2499 MSM and TGF</td>
<td>South America, USA, Thailand, South Africa</td>
<td>FTC/TDF</td>
<td><strong>42%</strong> (95% CI 18-60)</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>4758 serodiscordant heterosexual couples</td>
<td>Kenya and Uganda</td>
<td>FTC/TDF, TDF</td>
<td><strong>75%</strong> (95% CI 55-87) <strong>67%</strong> (95% CI 44-81)</td>
</tr>
<tr>
<td>TDF-2</td>
<td>1219 heterosexual men and women</td>
<td>Botswana</td>
<td>FTC/TDF</td>
<td><strong>63%</strong> (95% CI 22-83)</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study</td>
<td>2413 injection drug users</td>
<td>Thailand</td>
<td>TDF</td>
<td><strong>49%</strong> (95% CI 6-72)</td>
</tr>
</tbody>
</table>
Pragmatic Open-Label Randomized Trial of Pre-Exposure Prophylaxis: PROUD Study

Randomized, multicenter, open-label pilot study in the UK

High-risk, HIV-uninfected MSM engaging in CAI N=544

Immediate FTC/TDF (n=275)

Deferred FTC/TDF (start at Month 12) (n=269)

Primary endpoint: HIV seroconversion between randomization and Month 12
Secondary endpoints: Safety, adherence, sexual behavior, resistance development

Oct 16, 2014: the PROUD Trial Steering Committee announced that participants on the deferred arm of the study, who had not yet started PrEP, would be offered the opportunity to begin PrEP ahead of schedule

CAI: Condomless anal intercourse
All subjects received comprehensive HIV prevention services, including condoms, risk-reduction counseling, testing and treatment for sexually transmitted infections, and HIV pre- and post-test counseling

McCormack Lancet. 2015 Sep 9
# PROUD Results

## HIV Incidence

<table>
<thead>
<tr>
<th>Group</th>
<th>Infections, n</th>
<th>Follow-up (PY)</th>
<th>Incidence/100 person-years (90% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>22</td>
<td>453</td>
<td>4.9 (3.4-6.8)</td>
</tr>
<tr>
<td>Immediate</td>
<td>3</td>
<td>243</td>
<td>1.2 (0.4-2.9)</td>
</tr>
<tr>
<td>Deferred</td>
<td>20</td>
<td>222</td>
<td>9.0 (6.1-12.8)</td>
</tr>
</tbody>
</table>

86% (90% CI 64-96%) Risk Reduction $P=0.0002$

Number needed to treat=13 (90% CI: 9-23)

Resistance: 2 individuals developed M184V/I, no K65R
No HIV Infections in Kaiser PrEP Clinic

- 657 people initiated PrEP between 7/2012 and 2/2015
  - Mean age 37 (20-68) and 99% MSM
  - 50% with an STI after 12 months of follow-up
Adherence, drug levels, and efficacy

No HIV infections seen in those taking equivalent > 4 doses/week

Grant. Lancet ID. 2014 Sep;14(9):820-9
Significant Increase in PrEP Uptake

870% increase in PrEP Starts
172% for women and 1,450% for men.

Unique Individuals

Quarters

Slide courtesy of Keith Rawlings
Bush, S. et al. HIV Drug Therapy 2016; Glasgow, Scotland
Racial Distribution of PrEP Users 2016 Compared to Newly Diagnosed HIV Cases 2015

- **Black**: 17% New HIV Infections, 0% Kaiser SF, 10% SFDPH PC Clinics, 17% STD Clinic, 0% Strut, 17% CBO Testing Sites
- **Latino**: 26% New HIV Infections, 26% Kaiser SF, 26% SFDPH PC Clinics, 26% STD Clinic, 26% Strut, 26% CBO Testing Sites
- **API**: 12% New HIV Infections, 12% Kaiser SF, 12% SFDPH PC Clinics, 12% STD Clinic, 12% Strut, 12% CBO Testing Sites
- **White**: 42% New HIV Infections, 42% Kaiser SF, 42% SFDPH PC Clinics, 42% STD Clinic, 42% Strut, 42% CBO Testing Sites

Scheer S et al. HIVR4P 2016 abstract OA24.03
# CDC Guidelines

<table>
<thead>
<tr>
<th>MSM</th>
<th>Heterosexual women and men</th>
</tr>
</thead>
</table>
| - HIV positive sex partner  
- Recent bacterial STI  
- High number of sexual partners  
- History of inconsistent or no condom use  
- Commercial sex worker | - HIV positive sex partner  
- Recent bacterial STI  
- High number of sexual partners  
- History of inconsistent or no condom use  
- Commercial sex worker |

<table>
<thead>
<tr>
<th>PWID</th>
<th></th>
</tr>
</thead>
</table>
| - HIV-positive injecting partner  
- Sharing injection equipment  
- NOT in drug treatment  
- Risk of sexual acquisition (see above) |
# Who We Target

## MSM
- More than 1 HIV-negative, monogamous partner
- Sex partner with HIV
- History of rectal STIs
- Inconsistent condom use with multiple or unknown partners
- Commercial sex workers

## Heterosexual women and men
- Sex with MSM
- Sex partner with HIV
- History of STIs
- Inconsistent condom use with multiple or unknown partners at risk for HIV
- Commercial sex workers

## Transgender Individuals
- Sex with MSM
- Sex partner with HIV
- History of rectal/vaginal STIs
- Inconsistent condom use with multiple or unknown partners
- Commercial sex workers

## PWID
- HIV-positive injecting partner
- Sharing injection equipment
- NOT in drug treatment
- Risk of sexual acquisition (see above)

## Anticipated risk or asking for PrEP

*Based on previous six months’ practices.*
Targeting PrEP for MSM

Condomless receptive anal sex: Highest PAF and low NNT

Risk Scores

• MSM
• People who inject drugs
• Heterosexual men and women – Pending

CDC HIV Risk Estimator:
http://wwwn.cdc.gov/hivrisk/estimator.html
Clinical Guidelines for Providing PrEP

Available at:

hiv.ucsf.edu/care/prep.html
Providing PrEP

Initiation → 1 month Follow-up → q 3month Follow-up
Exploring HIV Risk

• Open ended questions about risk behaviors and other concerns.

• The 5 P’s of a sexual history
  PPartners (#, gender) over given time
  PPractices (oral, anal, vaginal)
  PProtection (condoms, when, how often; status discussions)
  PPast STI history (pathogen, location, frequency)
  PPregnancy (desire for it, prevention methods)
PrEP Evaluation

Desire for PrEP; questions/concerns re: PrEP

• Risk assessment
  – e.g., CDC tool for MSM
  – PEP indication?

• Past Medical History review
  – Especially history of kidney or bone disease

• Medications
  Assessment for symptoms of Acute HIV
Baseline Lab testing - HIV

• Laboratory screening – important to assess for acute HIV
  – 4th gen HIV Ag/Ab assay
  – HIV viral load – individual, pooled, quant., qual.

• If concerned about acute HIV, postpone PrEP until RNA result/window received or start ART (Start while awaiting false positive results?)
HIV Testing Algorithm

**Lab-based 4th gen (Ag/Ab combo)**
Siemens ADVIA Centaur, Abbott ARCHITECT, Bio-Rad GS or Bio-Rad BioPlex 2200

(+)

**HIV-1/2 antibody differentiation assay**
Bio-Rad Multispot Rapid or Bio-Rad Geenius Supplemental

(–)

**Ag & Ab (–)**
HIV-1 and HIV-2

* Replaces Western blot for confirmation; Multispot being phased out in 2016

§ Only FDA-approved NAT for HIV-1 diagnosis

**Antibodies detected**
HIV-1 and/or HIV-2 infected

ANY rapid (+) should be retested starting with lab-based 4th gen

**HIV-1 (–) or indeterminate**
HIV-2 (–)

**HIV-1 NAT (+)**
Acute HIV-1 infection

**HIV-1 NAT (–)**
Negative for HIV-1

**HIV-1 nucleic acid test**
Hologic APTIMA HIV-1 RNA

Timeline following HIV Infection

- RNA precedes p24 Ag by 5-7d
- Earliest Ab detection around 20-25d (IgM in 3rd and 4th gen)
- Earliest 2nd gen Ab detection at 35-40d (as IgG begins rising)
- Rapid tests with oral transudate may take up to 90d to convert (self-test implications)
Additional Lab testing

• Complete Metabolic Panel (baseline and follow-up)
• STI testing
  • GC/CT- pharyngeal, urethral, vaginal, rectal
  • syphilis serology
• Hepatitis screening
  • HAV Ab
  • HBV (sAg, cAb, sAb)
  • HCV Ab (baseline; and follow-up for MSM)
• Pregnancy test
Access Assistance Programs

PrEP Assistance Programs

Uninsured
- Gilead Medication Assistance Program
gileadadvancingaccess.com

Insured
- Gilead Copay Assistance (up to $3,600/year)
gileadadvancingaccess.com
- Patient Access Network (up to $4,000/year, income ≤$58,850)
panfoundation.org/hiv-treatment-and-prevention
- Patient Advocate Foundation (up to $5,000/year, income ≤$47,080)
copays.org/diseases/hiv-aids-and-prevention

PEP Assistance Programs
- See Insured above
- fairpricingcoalition.org/patient-assistance-programs-and-co-pay-programs-for-pep/
- San Francisco General Hospital Sliding Scale Program
# PrEP Adverse Events And Resistance

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start-up Syndrome</td>
<td>1-18.5% with nausea, vomiting +/- dizziness</td>
</tr>
<tr>
<td>Renal Toxicity</td>
<td>0.2% Grade 2-4 Creatinine elevations among 5469 pts randomized to TDF/FTC</td>
</tr>
<tr>
<td>Bone Mineral Density</td>
<td>0.4-1.5% BMD loss. Return toward baseline after d/c. No increased fracture risk.</td>
</tr>
<tr>
<td>HIV Resistance among seroconverters</td>
<td>3.7% (9/243) 0.06% of those receiving PrEP after excluding likely transmitted resistance</td>
</tr>
</tbody>
</table>

Landovitz CROI 2015Abstract #20
Kidney safety and PrEP

- Kidney safety of TDF/FTC evaluated in MSM and TGW in iPrEx OLE (1224 ppts) and US PrEP Demo (557 ppts)
- Small declines (~2.6%) in mean eGFR (kidney function) at week 12 which remained stable through 48 weeks (PrEP Demo)
- PrEP held in only 3 ppts due to elevated Cr – resumed without event (PrEP Demo)
- Hair and DBS drug tenofovir levels associated with greater loss
- Risk of eGFR <70 was higher in those with low baseline eGFR (<90) and older individuals (both studies)
Acknowledgments

Many thanks to the >200 members for all of their volunteer work!

- Oliver Bacon
- Albert Liu
- Stephanie Cohen
- Oliver Bacon
- Jonathan Fuchs
- Darpun Sachdev
- Susan Buchbinder
- Diane Havlir
GETTING TO ZERO
SAN FRANCISCO
www.GettingToZeroSF.org
EXTRA SLIDES
SFDPH PrEP Navigation Services at SF City Clinic

DISCUSS INSURANCE STATUS and current ACCESS to CARE

Insured w/ PCP
- Health Systems Navigation
- Goal = Access PrEP at medical home

Uninsured, No PCP, Other barriers
- Initiated on PrEP
- Benefits counseling
- Referral to PrEP provider
STD Clinic as a Sentinel Site for PrEP surveillance

• Since 2011, HIV-negative MSM seeking routine sexual health services have been asked:
  – Have you heard of PrEP?
  – Are you currently on PrEP?
PrEP knowledge and use among HIV-negative MSM at SFCC

![Graph showing PrEP knowledge and use among HIV-negative MSM at SFCC]
PrEP Use by Self-Reported Risk, SFCC Clients, April 2014-Sept 2015 (N=5971)

ncRAI = non-condom receptive anal intercourse

% currently on PrEP

# ncRAI sex partners last 3 months

0 1 2 3 to 5 6 or more

N=1764 N=2470 N=725 N=666 N=346

ncRAI = non-condom receptive anal intercourse
PrEP in the SF Health Network

- SF Health Network is an integrated primary care delivery model across SF
  - 14 Community Based Clinics and 4 hospital based clinics
- PrEP Program started in early 2015:
  - Develop local clinical PrEP guidelines
  - Establish PrEP referral clinic at Ward 86
  - Provider trainings on PrEP implementation: Over 100 clinicians (MDs, NPs) trained since 1/2015
How do demographics of PrEP use compare with newly diagnosed in 2015?

<table>
<thead>
<tr>
<th>Category</th>
<th>New Infections</th>
<th>Kaiser SF</th>
<th>SFDPH PC Clinics</th>
<th>STD Clinic</th>
<th>Strut</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>99%</td>
<td>86%</td>
<td>100%</td>
<td>96%</td>
<td>100%</td>
</tr>
<tr>
<td>Black</td>
<td>88%</td>
<td>17%</td>
<td>26%</td>
<td>12%</td>
<td>42%</td>
</tr>
<tr>
<td>Latino</td>
<td>99%</td>
<td>3%</td>
<td>8%</td>
<td>10%</td>
<td>25%</td>
</tr>
<tr>
<td>API</td>
<td>96%</td>
<td>69%</td>
<td>8%</td>
<td>18%</td>
<td>17%</td>
</tr>
<tr>
<td>White</td>
<td>86%</td>
<td>3%</td>
<td>10%</td>
<td>12%</td>
<td>43%</td>
</tr>
<tr>
<td>White</td>
<td>9%</td>
<td>17%</td>
<td>12%</td>
<td>12%</td>
<td>42%</td>
</tr>
<tr>
<td>White</td>
<td>100%</td>
<td>55%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GTZ PrEP committee

Co-chairs: Brad Hare & Al Liu

**PrEP User Subcommittee** Co-chair: Pierre Crouch & Stephanie Goss

**PrEP Provider Subcommittee** Co-chairs: Tracey Packer & Stephanie Cohen

**PrEP Metrics Subcommittee** Co-chairs: Susan Scheer & Jen Hecht

**Members:** Oliver Bacon, Halvard Bagoien, Jackson Bowman, Susan Buchbinder, Megan Canon, Jim Dilley, Edvard Engesaeth, Jonathan Fuchs, Jesus Gaeta, Jayne Gagliano, Ruben Gamundi, Hans Gangeskar, Ron Goldschmidt, Robert Grant, Geoff Hart-Cooper, Mike Hickey, Anne Hirozawa, Alison Hughes, Skot Land, Paul Marcelin, Julia Marcus, Erick Martinez, Julia Marcus, John Melichar, Gavin Morrow-Hall, Austin Nation, Trang Nguyen, Miranda Nordell, Aliza Norwood, Sergio Paz, Susan Philip, Greg Rebchook, Michael Reyes, Hyman Scott, Matt Sharp, Lisa Stern, Adam Taylor, EB Troast, Paul Urban, Dana van Gorder, Jonathan Volk, Shannon Weber, Sophy Wong
2016 GTZ PrEP Goals and Priorities

• Create a **sustainable** city-wide model of delivery
  – Build capacity
  – Enhance funding
  – City-wide PrEP Navigators

• Reach those populations that are currently **underserved**
  – Youth, transwomen and men, MSM of color, people who use drugs, incarcerated
  – Expand and diversify Ambassador program
  – Reach into neighborhoods and community organizations

• **Monitor** our progress and use data to inform strategies and decisions
  – Integrate data from diverse sources
Collective PrEP expansion efforts

• PrEP delivery sites >30 clinics
• >100 clinical providers and >50 HIV test counselors trained on PrEP delivery and referrals/navigation
• >10 PrEP navigators funded across clinics and CBOs
The Getting to Zero PrEP User Group is getting the word out about PrEP in the SF Bay Area!

We have several outreach events scheduled each month and would love for you to join us.

Anyone interested in raising awareness about PrEP in our community is welcome. If you are taking PrEP and would like to share your experiences with others, here’s your opportunity! If you’re a PrEP provider and would like to help provide education about PrEP, we’d love to have you.

If you’re interested in becoming a Getting to Zero PrEP Ambassador or finding out more about our PrEP Ambassador program, please fill out the form below. You can also sign up for specific outreach events on the calendar to the left below.

Thanks!

**PrEP Ambassadors outreach at Folsom Street Fair**

**PrEP Ambassadors at Castro St. Fair**
Citywide PrEP Navigator’s group

• Created in April 2016
  – ~25 attended first meeting representing PrEP navigators in SF, East Bay, and South Bay

• Provide networking, support, share best practices, troubleshooting

• Key issues
  – What is a PrEP navigator?
  – Different organizations have different capacity for delivering PrEP vs. identifying those at risk and referring / assisting with access to PrEP
  – Training needed:
    • Addressing access barriers
    • Transgender competency
    • PrEP and youth – helping folks on parents’ insurance
    • PrEP and HIV – using common language and consistent messages
      – Effectiveness of PrEP
      – Toronto patient
PrEP Access

• Majority (90%?) in SF wanting PrEP can access it for little or no costs through insurance, Medi-Cal, assistance programs for out-of-pocket costs and for uninsured.

• Access at SF AIDS Foundation/Strut, Kaiser, SF City Clinic, API Wellness, SF Health Network clinics, private providers

• Gaps:
  – Youth w/parents’ insurance who don’t want their parents to know they are on PrEP
  – Access for uninsured adolescents
  – Some Medicare plans have high out-of-pocket costs for PrEP and don’t accept assistance programs
  – Pts with “bronze” insurance plans have high out-of-pocket costs and assistance programs don’t cover all costs
• SFDPH is one of 12 jurisdictions nationally participating in this CDC-funded 3 year demonstration project
  – Increase uptake of PrEP among MSM of color and transgender persons
  – Enhance Data to Care activities
    • D2C uses HIV surveillance and other data to identify HIV-diagnosed persons not in care, and to link, engage, or re-engage them in HIV medical care
Strategies to increase PrEP uptake among MSM of color and transgender persons

- **Formative work** with actual/potential users as well as providers
- Increase **user knowledge and interest** in PrEP
  - Social marketing campaign, Popular Opinion Leader
- Increase **linkage** of focus populations to PrEP
  - City-wide PrEP navigator using innovative social media strategies
  - “Data-to-PrEP”— use of STI surveillance to link patients diagnosed with rectal STIs and syphilis to PrEP
  - Learning community for PrEP navigators across SF: share best practices
- Increase **primary care provider engagement** in PrEP
  - Public Health Detailing
CHRP-funded Transgender PrEP Demonstration Project

• CHRP 4-year program to increase PrEP access, uptake, adherence and retention in transgender individuals

• PrEP integrated with transgender care
  – Transgender Tuesdays (Tom Waddell)
  – Dimensions Clinic (Castro Mission Health Center)
  – Transthrive (API Wellness Center)
  – Transvision (Tri-City Health Center)
San Francisco City Clinic

• Only municipal STD clinic in San Francisco (SF)
• 20,000 visits annually
• 48% of clients are MSM
• Diagnose approx 14% of HIV, 20% of gonorrhea and 20% of syphilis identified in SF
• High proportion of new HIV diagnoses have acute or early HIV
Conclusions

• High uptake, retention and adherence when PrEP integrated into sexual health services

• Even if not doing direct PrEP delivery, STD clinics can:
  – Help link individuals to PrEP-friendly providers
  – Support PrEP trainings to clinical and non-clinical providers
  – Monitor trends in community level PrEP uptake and knowledge

• Navigators/counselors critical members of PrEP team

• Additional outreach needed to reach youth, transgender individuals and MSM of color

• Citywide efforts to coordinate PrEP effort can maximize resources and impact