

CRUSH:
**Connecting Resources for
Urban Sexual Health**

CHRP Consortium Meeting Update

September 18 2013

Oakland, CA

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CRUSH: Specific Aims

Aim 1: Test & link >400 young MSM of color to sexual health services

- Expand referrals to include high risk HIV-
- Add new partner youth agencies, social media
- Youth outreach corps (current & new community partners)
- Social network testing

Aim 2: Enhance & evaluate engagement & retention strategies for young HIV+ MSM of color

- Optimize current HIV care & treatment services at DYC:
- Patient peer mentoring component
- Linkage & retention specialist
- Psychosocial support for program staff

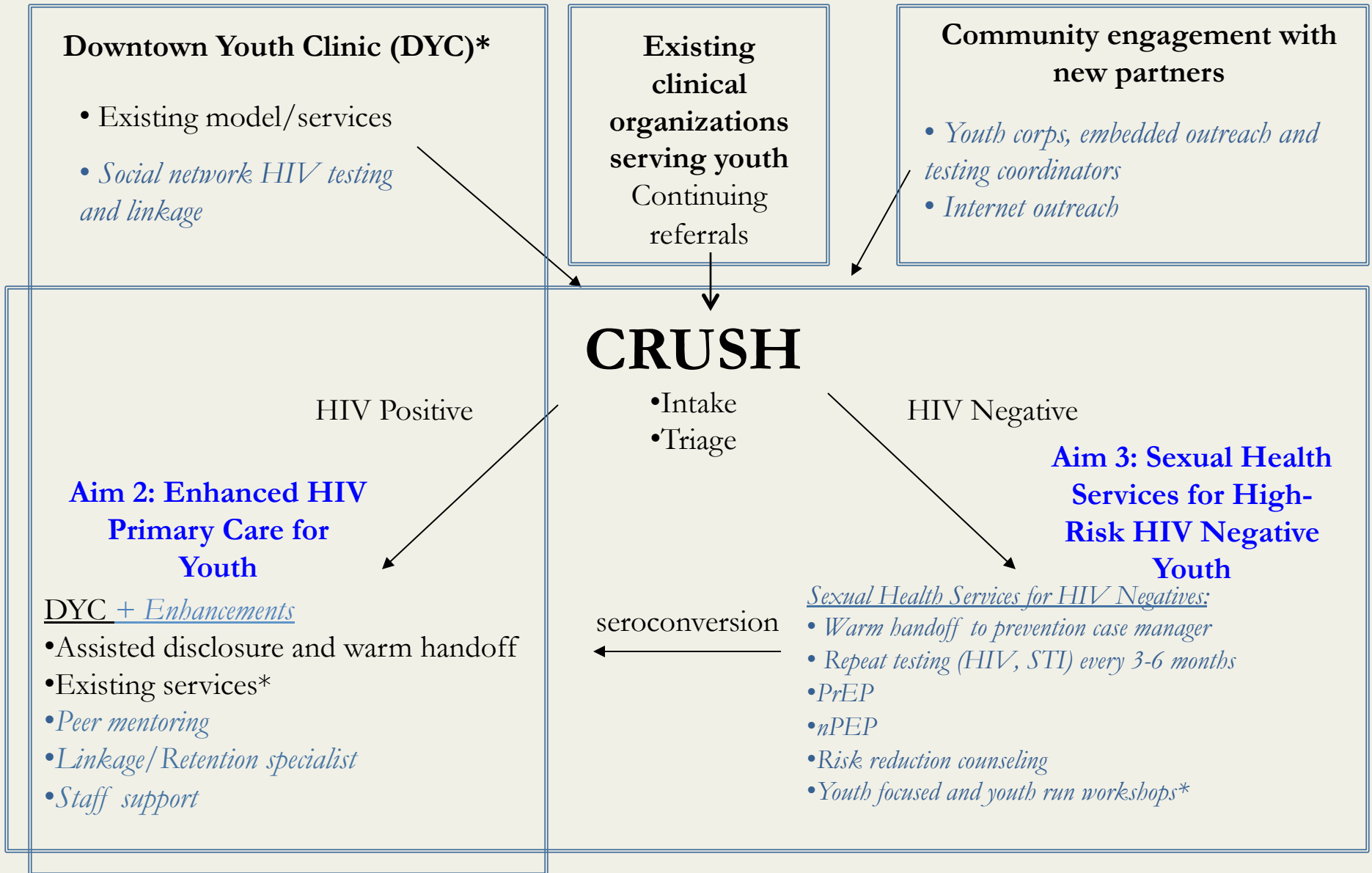
CRUSH: Specific Aims (cont'd)

Aim 3: Engage & retain HIV- young MSM of color in sexual health & preventive services, including PrEP

- Integrate SHS for HIV- into HIV care setting
- **DYC model: developmentally appropriate, culturally sensitive, individually tailored care**
- **Combination HIV prevention strategy, including:**
 - **Warm-hand off for high risk HIV-**
 - **Pre-exposure prophylaxis (PrEP)**
 - **Post-exposure prophylaxis (PEP)**
 - **Risk reduction counseling**
 - **Repeat HIV & STI testing**
 - **Youth-focused education/programming**

Connecting Resources for Urban Sexual Health (CRUSH)

Aim 1: Testing and Linkage

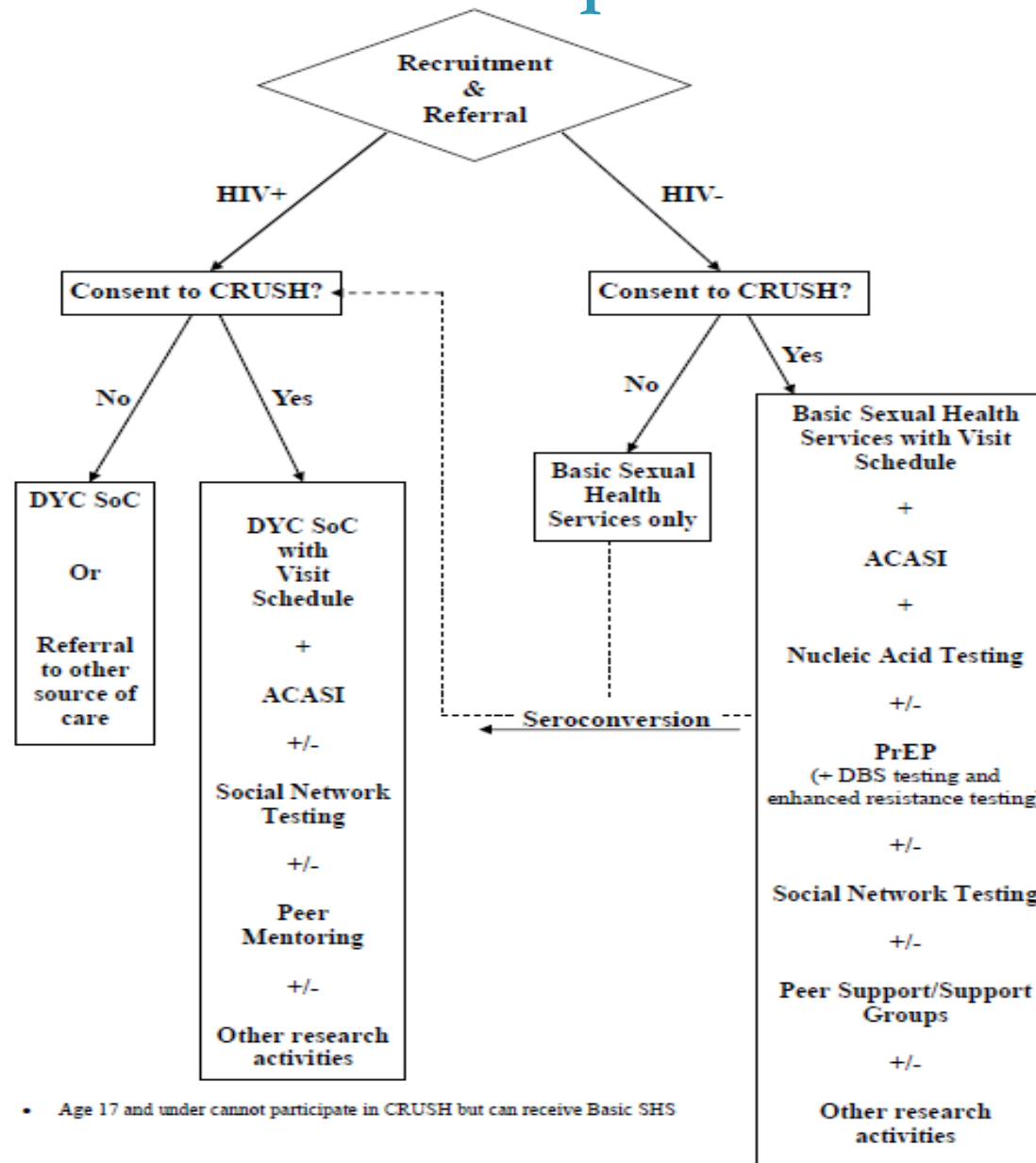


CRUSH

Scientific Collaborations

- Rapid-turnaround NAT testing for HIV, HCV, & HBV (Susan Little, UCSD)
 - Limit of detection 25 copies/ml (approx day 3)
 - Positive results in ≤ 1 week
- Dried blood spot (DBS) assay for intracellular RBC levels of TDF & FTC (Peter Anderson, U Denver)
 - Utility in adherence counseling
- Allele-specific minority variant resistance testing for PrEP seroconverters (Teri Liegler, UCSF)
- *Considering: Single tablet PEP regimen proposal*

CRUSH Participant Flow



- Age 17 and under cannot participate in CRUSH but can receive Basic SHS

CRUSH Status Update

- **Funded for full 4 year project period, April 2013**
- **First 6 months: Focus on collaborations and recruitment strategy; focus on systems (research and clinical); focus on CAB**
- **IRB applications: Alta Bates Summit submitted this morning; UCSF to follow**
- **Evaluation focus: determining data domains; accessing clinic records from EPIC (newly implemented at EBAC in April 2013); ongoing qualitative interviews**
- **Ongoing pilot implementation: enrollment of initial PrEP participants began in April 2013**

Pilot Project Update

Pilot Project Update: PrEP Cohort

- 11 screened (10 enrolled, 1 screen failure)
 - 3 scheduled to be screened next week
- Median age 22
- Race/ethnicity:
 - 5 African American
 - 5 Hispanic
 - 1 Caucasian
- 8 gay + 1 bisexual males
 - 2 female partners of HIV infected young men

Self-Reported Behavioral Risks

- 4 of 10 participants reported alcohol use consistent with heavy/problem drinking
- 2 of 10 participants reported using illegal substances
- 5 of 10 participants reported unprotected receptive intercourse with a partner known to be HIV infected
- All participants reported unprotected oral sex

STIs Among ≈ 100 YMSM at DYC

	2011	2012	2013 YTD
GC	62	42	39
Rectal	20	18	13
Phar.	15	14	16
Urethral	27	9	10
CT	43	41	39
Rectal	23	25	25
Phar.	3	5	2
Urethral	17	11	6
Syphilis	19	12	17

STIs Among PrEP Cohort

5 of 11 participants had 9 active STIs at screening and/or enrollment:

- 1 urethral CT
- 1 rectal CT
- 2 pharyngeal CT
- 3 pharyngeal GC
- 2 late latent syphilis

High Risk Sexual Activity: How Frequent?

- Early data suggest that for CRUSH participants on PrEP, there was no increase in high risk sexual activity. This has also been observed in other PrEP studies (iPrEx, Thai IDU). Does this accurately reflect reality?
- It's extremely difficult to get an accurate assessment of sexual practices- requires a *concentrated effort* towards building trust
- At initial visit: only one patient of the 11 stated that s/he was having unprotected sex. 10 stated that they always practice safe sex.
- After delving a little deeper 7 patients, who originally stated that they always practice safe sex, stated that they 'sometimes' to 'frequently' have unprotected sex (including receptive vaginal and anal intercourse) with their partners. This includes both of the women.

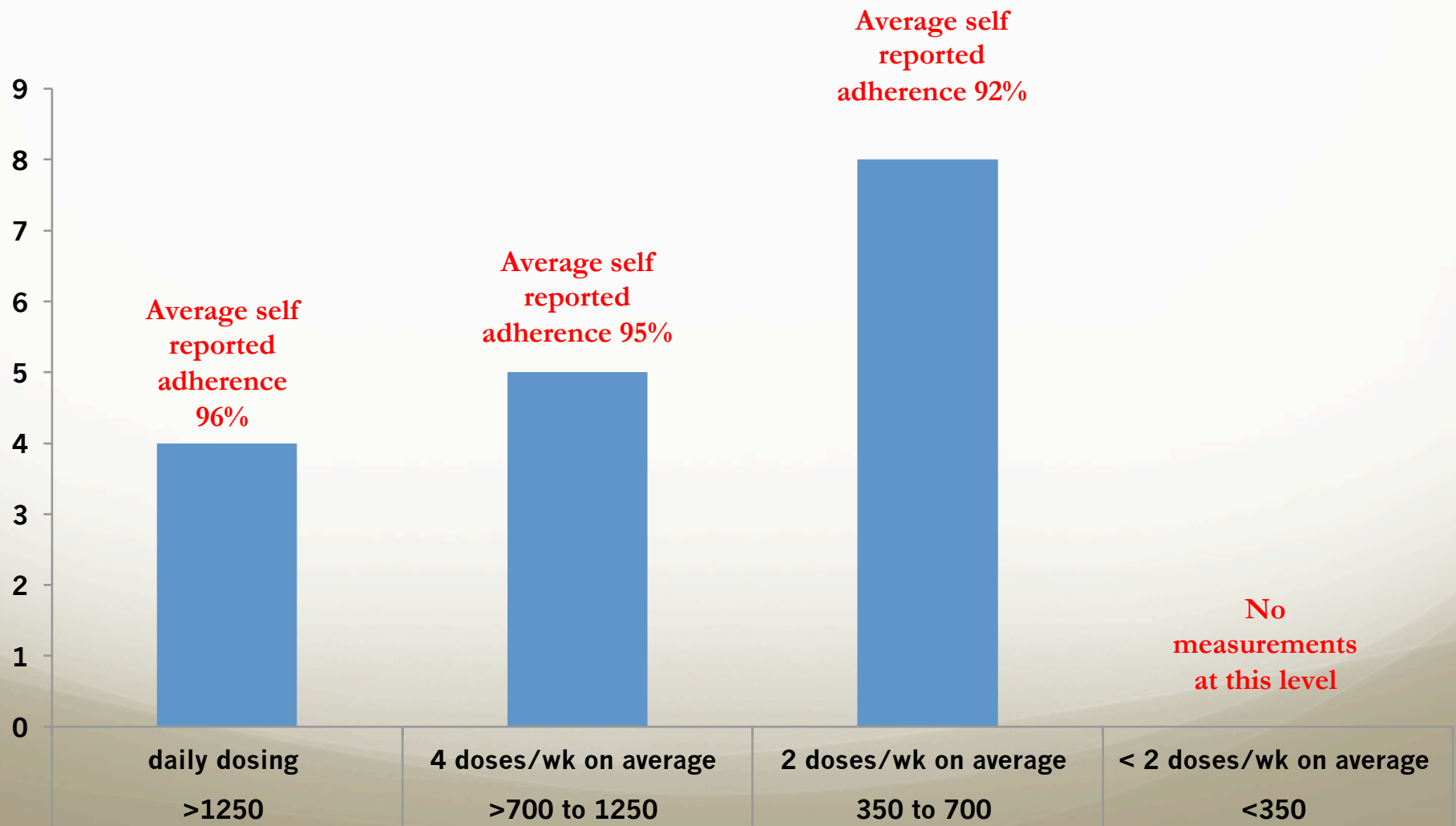
Interpreting Adherence: DBS Monitoring

RBC levels of drug were tested by DBS, and adherence by self report, at each follow up visit

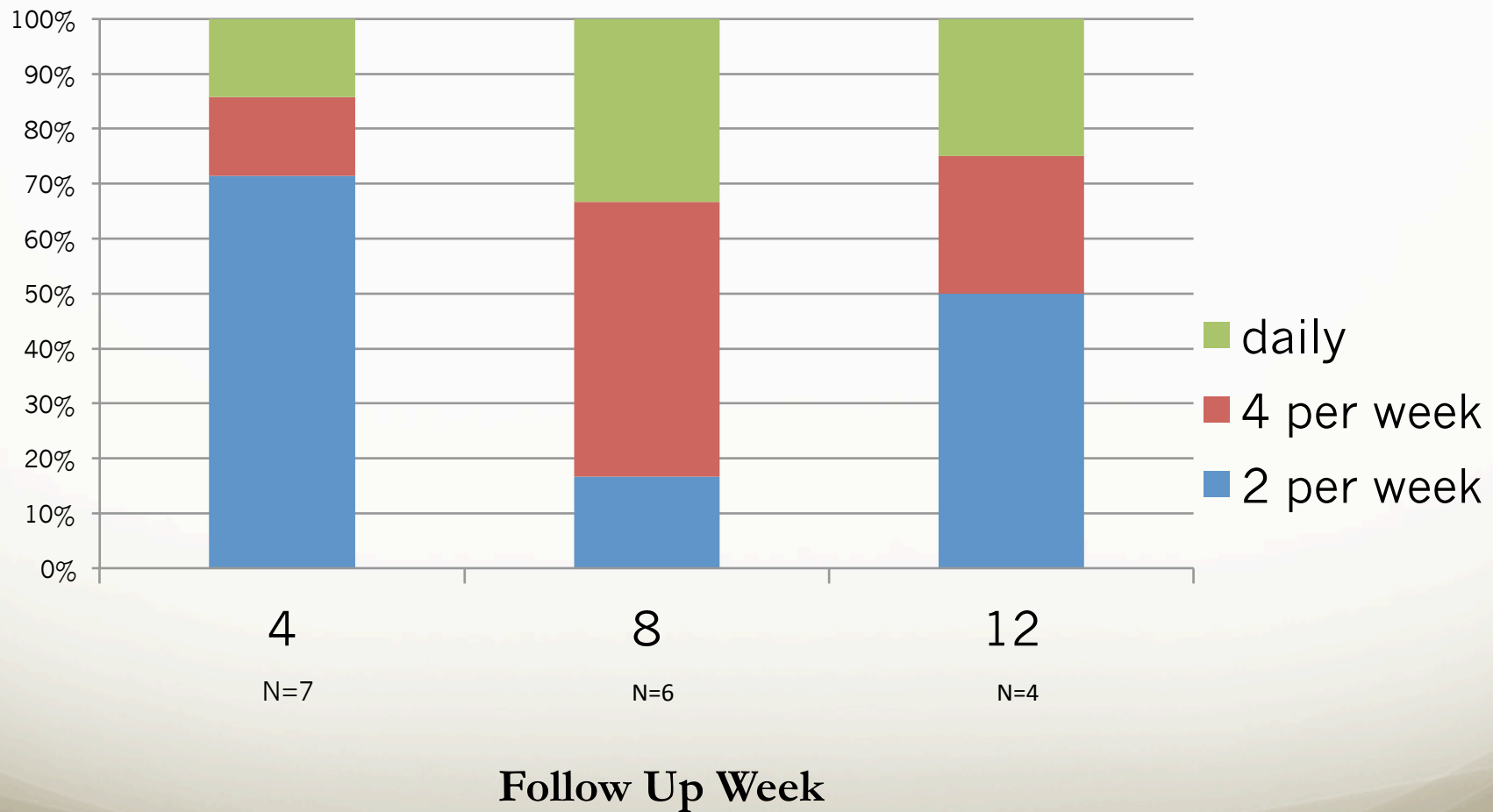
TFV-DP (fmol/punch)	Interpretation
>1250	daily dosing
>700 to 1250	4 doses/wk on average
350 to 700	2 doses/wk on average
<350	< 2 doses/wk on average

Adherence:

By Blood Levels and Self Report



DBS Estimated Adherence by Follow Up Week



Participant A

- 25 year old Latino MSM, rectal and pharyngeal CT, has unprotected receptive anal sex with an HIV infected partner, moderate to heavy alcohol use and reported use of stimulants and poppers.
- PrEP adherence high by both self report and DBS at all visits.

Participant B

- 25 year old African American female, no STIs, reports unprotected vaginal sex with an HIV infected partner, moderate alcohol use
- PrEP adherence high on self report, but DBS levels consistent with average 2x per week dosing

Initial Impressions: Adherence to PrEP

- As in other PrEP studies, self-reported adherence is likely very unreliable.
- Peoples' lives are complex and circumstances fluctuate. Adherence can be difficult because subjects' interest in prophylaxis can fluctuate.
- Those who have stayed most engaged in the study have been those who believe this is bigger than themselves, and that this is important for the community.
- Need a process to give feedback on DBS results, apply Integrated Next Step Counseling at each visit

Lessons From PrEP Cases:

- Very early HIV infection
 - PrEP vs PEP vs HAART?
 - Offering (& obtaining) PEP
- Knowing the source patient:
 - Ethical challenges
 - Tailoring PrEP

Case Study 1:

Early HIV Infection & Multiple STI's

- First person we called for enrollment when pilot initiated in April
- On April 5th, 2013 the patient presented for screening visit. His rapid HIV test was negative at the time but he reported that he had a 5 day flu-like illness in March a few weeks after having unprotected anal receptive sex with a man he met on line who had told him that he was HIV negative.
- HIV RNA test and serum HIV antibody were sent along with GC/CT x 3 and RPR. The HIV antibody test came back positive and the HIV RNA came back at 259,978. He also tested positive for rectal chlamydia.
- He was called in on April 10th and was told of his test results. Intake labs were drawn including an HIV genotype. He was treated for his rectal CT and the pros and cons of early ART initiation were discussed along with the pros and cons of starting an antiviral regimen prior to the return of his genotype.
- The patient decided to start drug immediately; began Stribild® that night.
- Over the next few months his viral load came down to non detectable levels.
- In June of 2013 he was diagnosed with primary syphilis and pharyngeal CT.
- In August 2013 he was diagnosed with rectal GC.
- In September 2013 he was diagnosed with urethral CT.
- Once our expanded protocol is approved he will be enrolled in the HIV + cohort of the study.

Case Study 2:

Intermittent Adherence in Serodiscordant Couple

- 22 year old perinatally infected AA YMSW
- Originally transferred from CHO when he was 19 years old.
- Long history of poor adherence as a child but since his transfer to DYC his HIV RNA has consistently been below 500.
- Currently on ABC/3TC + TDF + DRV/r.
- In April 2013 his HIV RNA was 228 and his CD4 count was 624 (28%).
- Mother states that he goes for long periods of time without taking his meds and that he has a stockpile of meds at home.
- Most likely takes his meds consistently for the month prior to coming in for labs but then slacks off (frequent phenomenon especially among the perinatally infected youth).
- *Has a steady girlfriend who is on PrEP in our study and the two do not always practice safe sex.*

Case Study 3:

Multi-Drug Resistance in Seropositive Partner

- On 08/06/2008 a 16 year old AA boy was brought in by his grandmother. He had tested HIV positive with a group of friends at Planned Parenthood. He did not believe his diagnosis and was coming to me in the hopes that I would tell him that he wasn't HIV positive and that the test had been a mistake.
- Gay identified.
- 3 different sex partners in his life. All teenage boys.
- On PE he had extensive anal warts.
- Lab results showed rectal gonorrhea and chlamydia
- CD4 count came back at 212 (17%)
- HIV RNA came back at 53,811
- Genotype identical to NYC patient: sexually active top in mid-20's

Antiretroviral drugs Resistance Mutations Detected
 Predicted

NRTIs

ZDV (zidovudine or Retrovir) ! PRB! L210W, T215C
 ABC (abacavir or Ziagen) ! (NO!)
 ddI (didanosine or Videx) ! (NO!)
 3TC (lamivudine or Epivir) ! YES! +M184V, L210W
 FTC (emtricitabine or Emtriva) ! YES! +M184V, L210W
 d4T (stavudine or Zerit) ! NO!

TDF (tenofovir or Viread) ! (NO!)

NNRTIs

ETR (etravirine or Intelence) ! NO!
 EFV (efavirenz or Sustiva) ! YES! K101P, K103N
 NVP (nevirapine or Viramune) ! YES! K101P, K103N

PIs

FPV (fos-amprenavir or Lexiva) ! YES! I54V, L10V, L33F, L63P,
 ! L90M, M36I
 IDV (indinavir or Crixivan) ! YES! I54V, I64V, K20K/R,
 ! L10V, L63P, L90M, M36I
 NFV (nelfinavir or Viracept) ! YES! D30N, I54V, I64V,
 ! K20K/R, L10V, L63P,
 ! L90M, M36I
 SQV (saquinavir or Invirase) ! YES! L90M
 LPV (lopinavir or Kaletra) ! (NO!)
 ATV (atazanavir or Reyataz) ! YES! I54V, K20K/R, L10V,
 ! L63P, L90M
 TPV (tipranavir or Aptivus) ! PRB! I13V, I54V, K20K/R,
 ! L10V, L33F, M36I
 DRV (darunavir or Prezista) ! (NO!)

Case Study 3 (cont'd)

- Patient has done poorly over the last 4 years.
- Unable to adhere to medications. In 4 years he has only once had a viral load <1,000 copies/ml.
- Currently on ABC/3TC + TDF + DRV/r; prime candidate for developing further resistance.
- Labs done 3 weeks ago
- Show a CD4 count of 27 (6.7%)
- HIV RNA of 160,410
- Genotype pending.

Case Study 3 (cont'd)

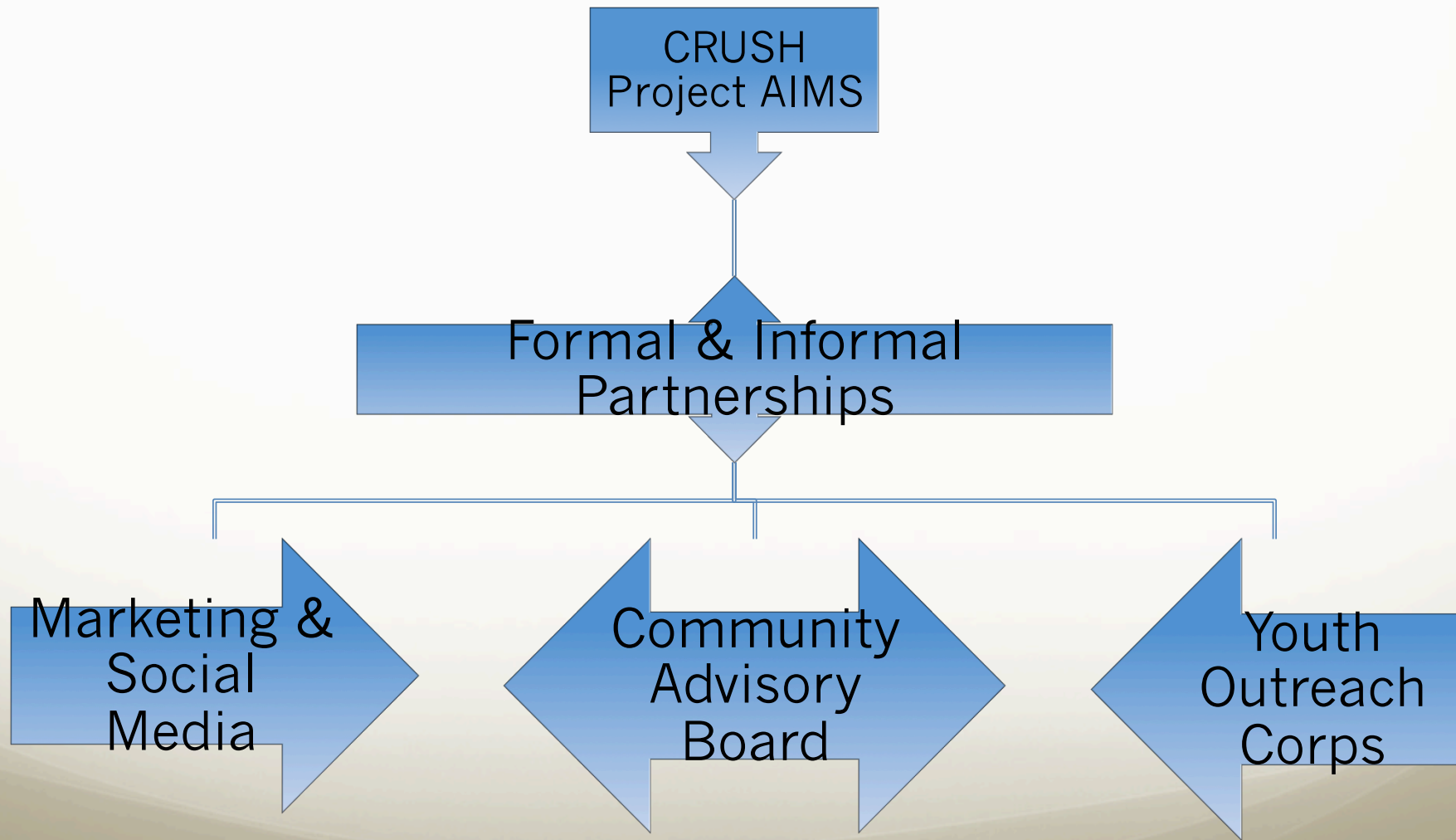
- *Current PrEP patient in our pilot is now in a serious relationship with the above patient.*
- The two do not practice safe sex.
- Index patient's repeat genotype is pending.
 - If it shows resistance to both TDF & FTC, must he come off study and be prescribed a tailored PrEP regimen?
 - What if resistant to just 1 drug?
- To what lengths must we go to try to identify drug-resistant viruses to which a PrEP patient is likely exposed?

Other Lessons Learned from the Frontlines

- Risk reduction counseling is important, but client-centered counseling is most effective
- Important to be clear about inability to provide primary care services
 - Must have active referral links in the community
- Support services are a must. YMSM of color bear the burden of multiple oppressions. Depression is widespread
- While all program staff must have specific roles, they must also be cross-trained and able to do their jobs
- All involved staff must understand and appreciate the complexity of the community project is trying to reach to ensure culturally competent care and “customer service” (including Receptionists and Medical Assistants)
- Must set up systems for data collection, storage, visit coordination, PR so that new hires are well informed and oriented
- Must gain insight from and involve other agencies in the area. Community support is essential

Community Engagement

Community Partnership Structure



CRUSH Project Partners

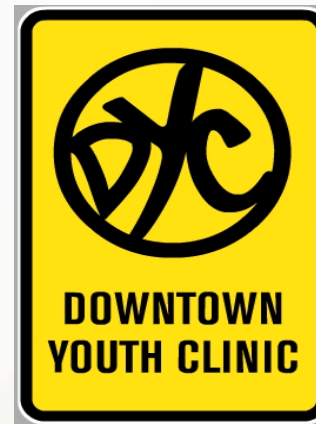


Gladstone Institute
of Virology and Immunology



Pangaea
Global AIDS Foundation

UCSF
University of California
San Francisco



 **ASIAN HEALTH SERVICES**



Status of the CRUSH CAB

- CRUSH CAB “Operating Instructions” drafted
- Member recruitment materials developed
- Strategic recruitment of CAB Members ongoing
- CAB member orientation scheduled September
- Monthly meetings planned starting October
- Outreach Partners ad-hoc members

CAB Membership & Initial Duties:

- Average Age: 25 years
- Race/Ethnicity:
 - 3 African American
 - 2 Latino
 - 1 Caucasian
- HIV Status/PrEP Status
 - 2 HIV +
 - 4 HIV negative, 2 on PrEP
- Varied level of formal education
- Two are non-CRUSH affiliated local HIV advocates
- “How hard to reach are these ‘hard-to-reach’ populations?”
- “What outreach activities should CRUSH use to engage YMSMC?”
- “In which locations and with which ‘scenes’ should CRUSH outreach to reach YMSMC?”

*Incentivized CAB members

Developing Recruitment & Outreach Plan

Youth Outreach Corps:



- Quasi-Ethnography Supports CAB Discussions
- CRUSH Member Card & Social Entrepreneurship
- Multiple Phased & Targeted Promotional Events & Campaigns
- Culturally Sensitive Testing & Outreach Strategies

Outreach and Recruitment: Next Steps

- Developing a multi faceted strategy which integrates testing:
 - Venue and Event Based (First Friday Art Murmur, “Test for Ticket Campaign, access to Ball scene, etc.)
 - Understanding how to integrate CRUSH outreach with “non traditional” settings for youth (RYSE shout-out)
 - Social Media and Promotion Campaign design with Joe Hawkins
- Other Key Activities
 1. Local GIS Social & Sexual Network Mapping
 2. Assess Feasibility & Uptake of Volunteer-Supported HIV/STD In-Field Bundle Testing
 3. Provide access to HIV Home Testing Technology for CRUSH YMSMC (EBAC is study site with Hyman Scott/Bridge HIV)

Next Steps

- IRB approval
- Hiring NP clinician, project coordinator, retention specialist, outreach coordinator
- Refining systems and operations manuals
- Kickoff and recruitment
- Planned World AIDS Day/Week launch activities: Kick off party at Club Rimshot (Bench & Bar)