SAN DIEGO | CENTER FOR AIDS RESEARCH

Health Equity Community Advisory Board

Community Advisory Board Meeting
March 30, 2021
9:00am - 11:00am
Zoom Conference Call

Participants

Name	Affiliation	CAB Role	Email Address
Judi Patterson	Case Manager, Mental Health America	CAB Co-Chair	jpatterson@mhasd.org
Jamila K. Stockman	Associate Professor and Vice Chief, UC San Diego, Division of Infectious Diseases & Global Public Health	Director, Disparities Core and CAB	jstockman@health.ucsd.edu
Eileen Pitpitan	Associate Professor, San Diego State University and the School of Social Work	Co-Director, Disparities Core and CAB	epitpitan@sdsu.edu
Rajesh Tim Gandhi	Infectious Disease Physician, Massachusetts General Hospital and Harvard University Center for AIDS Research	Guest	rgandhi@mgh.harvard.edu
Elizabeth Johnson	Administrative Director, San Diego Center for AIDS Research and the HIV Institute	CAB Member	liz@ucsd.edu
Janine V. Lopez	UC San Diego, Division of Infectious Diseases & Global Public Health	Research Associate, Disparities Core	jvlopez@health.ucsd.edu
S. Giovanna Carr	UC San Diego, Division of Infectious Diseases & Global Public Health	Clinical Interventionist, Disparities Core	s3carr@health.ucsd.edu
Megan Liang	Project Manager, PATH	Guest	epitpitan@sdsu.edu
Dallas Davis	Program Supervisor, The Neighborhood House Association	CAB Member	drdavis@neighborhoodhouse.org
Suzanne Afflalo	Medical Director, Alliance Health Clinic	CAB Member	suzanneafflalo@sbcglobal.net
Danielle Campbell	UC San Diego, Division of Infectious Diseases & Global Public Health	CAB Member	dacampbe@health.ucsd.edu
Elizabeth Johnson	Administrative Director, San Diego Center for AIDS Research and the HIV Institute	CAB Member	liz@ucsd.edu
Rebecca Zipfel	Program Supervisor, San Ysidro Health	CAB Member	rebecca.zipfel@syhc.org
Wanda London	Community Member	CAB Member	london.wanda@yahoo.com
Christina Williams	Program Manager, San Diego Center for AIDS Research	CAB Member	c4williams@health.ucsd.edu

Commencement
The CAB meeting began at 09:01 a.m.

Welcome from CAB Chair & Co-Chair and Introductions
Dr. Jamila K. Stockman and Ms. Judi Patterson Director Disparities Core CAB and CAB Co-Chair welcomed the group and facilitated introductions of leadership and participants via Zoom video conference. See attendee names, affiliations, and contact information above.

CFAR Updates
Dr. Jamila K. Stockman referenced the San Diego Center for AIDS Research (SD CFAR) News Bulletin and announced the launch of the Health Equity Sociobehavioral Science Core. This properly represents the faculty's expertise and sheds a positive light on the goals of achieving health equity. The Health Equity Sociobehavioral Science Core both rebrands the Disparities Core. It enhances the original core's strengths by adding expertise in qualitative and mixed methods research, intervention development, recruitment of hard-to-reach and underserved populations, psychosocial statistical methods, and co-occurring conditions, such as homelessness and substance use. The launch follows a 10-month strategic planning process spearheaded by both Dr. Stockman and Dr. Eileen Pitpitan. Dr. Stockman introduced Dr. Pitpitan as the new Co-Director of the Health Equity Sociobehavioral Science Core.

SD CFAR has a strong track record of synergizing high-impact, multidisciplinary HIV/AIDS research through four priority research areas: optimizing HIV care, relieving health disparities, finding a cure, and developing vaccines. The Health Equity Sociobehavioral Science Core will add new vision and direction to the first two priorities and ensure that underserved and critical populations' needs are addressed equitably. Core members will foster new collaborations with individual researchers and encourage collaborations with other SD CFAR cores. It will also promote new funding collaborations and publishing opportunities and facilitate the professional development of junior faculty and trainees in health equity research sociobehavioral disciplines.

Open Discussion
Dr. Jamila K. Stockman transitioned to an open discussion for the team.

Dr. Eileen Pitpitan stated that she is looking forward to working alongside this community advisory board. She provided further information about her work and background. Dr. Pitpitan's work focuses on developing and evaluating prevention and treatment interventions for communities affected by HIV and substance use. Some of her work involves marginalized populations, specifically communities who use and inject drugs, female sex workers in Mexico, men who have sex with men, members from Black and Latinx communities. Dr. Pitpitan believes in the importance of engaging the community when developing interventions.

Research Project Presentation: Peer Plus Mobile App for Treatment in HIV (PATH) Study
Dr. Eileen Pitpitan introduced the newly funded PATH project, which stands for Peer Plus Mobile App for Treatment in HIV. Dr. Pitpitan shared her screen and provided a PowerPoint presentation that outlined PATH, which integrates two theoretically grounded interventions – the Peer Navigator component (Conexiones Saludables) and the mHealth component (LinkPositively). Dr. Pitpitan noted their team's partnership with a community-based clinic (San Ysidro Health) serving Latinx and Black persons living with HIV (HBPLH) under the Ryan White model.

Primary goal
To evaluate the efficacy of a novel, sustainable, mHealth approach to (1) strengthen the impact of peer navigators on the HIV care continuum and (2) reduce racial/ethnic disparities in HIV treatment.

Questions for Today's Meeting
- Can you please provide feedback to ensure racial and cultural sensitivity/guidance on culturally-tailored materials?
- Do you have suggestions for other training topics for the peer navigators?
- Can you provide feedback on the look and feel of the web-app?
- Do you have suggestions for other "tip" topics to add for participants in the intervention?

PATH Specific Aims
AIM1: Improve the primary outcome – sustained viral suppression (i.e., suppressed viral load at both 6- and 12-month follow-up), and secondary outcomes (e.g., retention in care) compared to usual care.

- Sub-AIM 1: Explore subgroup differences in efficacy based on factors like race/ethnicity and substance use.

AIM 2: Examine the theory-informed mediators (e.g., self-efficacy to engage in HIV care, HIV stigma) through which PATH has the greatest impact on sustained viral suppression among HBPLH.

AIM 3: Explore whether PATH significantly affects substance use-related outcomes (e.g., frequency of substance use, engagement in substance abuse treatment) when compared to usual care among those using substances (i.e., stimulants and/or opioids).

PATH Study Design

Two-arm Randomized Control Trial (RCT) with follow-up assessments every 3 months.

Sample size: 375 HBPLH across 24-months

- At least 16% Black PLH
- At least 33% will report stimulant and/or opioid use in the past 6 months

Primary outcome: Sustained viral suppression (having an undetectable VL at both 6- and 12-months, i.e., <200 copies/mL)

Secondary outcomes:

- Retention in HIV care (> 2 HIV medical visits at least 90 days apart within the 12-month follow-up)
- Gap in HIV medical visits
- ART adherence

Inclusion criteria:

- 18 years or older
- Can read and speak English or Spanish
- Self-reported diagnosis of HIV by a physician or healthcare provider
- Currently taking HIV medication
- Having access to an internet browser on a home computer or smartphone
- Meets one or more of the following medical-chart verified or self-reported criteria
    - One or more detectable VL test result in the past 12-months while on ART for at least 3 months
    - Having missed 1 or more scheduled HIV care appointments in the last 12-months
    - Last HIV care visit was more than 6 months ago
    - Self-reporting less than 90% ART adherence in the last 4 weeks using the Wilson-3 scale

Exclusion criteria:

- Younger than 18 years old
- Member of San Ysidro Health or SD CFAR Health Equity CAB
- Currently enrolled in any program, intervention, or research study designed to improve ART adherence or engagement in HIV care (e.g., LinkPositively)

PATH Peer Navigator Training Modules
Adapted from Conexiones Saludables: modularized training for peer navigators to build core competences in supporting marginalized PLH. Included peer-delivered Individualized Counseling Sessions to promoted information, motivation, and behavioral skills (self-efficacy) in HIV care engagement and ART adherence. Pilot data demonstrated improvements in HIV continuum of care outcomes among marginalized PLH (e.g., people who use and/or inject drugs) in the U.S.-Mexico border region.

A total of 15 training modules delivered across 3 weeks and each module is approximately 3-4 hours.

Week 1: This week will focus on teaching the peer navigators to understand the basic elements of behavioral change to foster retention in HIV care, self-efficacy, and ART adherence of participants.

- The building blocks of behavior change (IMB basics)
- How to talk about behavior change (MI basics)
- Understanding behavior changes is a process (Cycle of change)
- How clients learn new health behaviors (SCT basics)
- Enhancing behavior change support with PATH Web App

Week 2: This week will focus on establishing trust and rapport.

- Establishing trust and rapport
- Medical mistrust (race-based discrimination and health care system)
- Social and structural barriers to change (SEM, common comorbidities)
- Substance use as a barrier to change (patient and promotor perspectives)
- Bridging stigma, disclosure, and social support (intersectional focus)

Week 3: This week will focus on providing peer navigators with training on what it looks like working within the San Ysidro Health setting.

- Mastering HIV Systems Navigation (SYH & Ryan White systems)
- Support current HIV treatment protocols (work with integrated care teams)
- Building client's patient-provider communication skills
- Building client's ART knowledge
- Supporting client ART adherence and monitoring

Discussion

- Ms. Elizabeth Johnson posed a question and asked whether the peer navigators have been hired.
    - Dr. Eileen Pitpitan responded and stated that they have yet to recruit and hire peer navigators for the PATH study.

    - Ms. Elizabeth Johnson recommended helpful resources that could be a solid foundation on the training and onboarding of new peer navigators for the study. She highlighted the importance of developing a solid training process to overcome future challenges. This work could be challenging for folks living with HIV without prior training. Ms. Johnson described her previous experiences with similar peer navigator onboarding. Ms. Johnson stated challenges with transference and boundaries, especially with folks who have a dual diagnosis of HIV and substance use. Issues could arise regarding reporting for peers with children, and it may also be helpful to do an orientation and training for working in social services before getting into the nuts and bolts of how to deliver this type of intervention. She also found it helpful to have clinical supervision in place. Ultimately, the relationship between the peer and the client must not be jeopardized.

    - Dr. Eileen Pitpitan sought clarification on whether it would be helpful to offer also offer social service training to the peer navigators. Ms. Elizabeth Johnson stated that it would be beneficial to do so for new peer navigators who have no previous history of working in a similar setting. She noted this work could trigger emotions and trauma for peer navigators making it difficult to be successful; having the extra training, clinical support, and supervision will alleviate potential stressors. Dr. Eileen Pitpitan agreed and noted it was something they did outline as part of the proposal with ideally weekly and monthly check-ins with the peer navigators as a team and one on one. Dr. Pitpitan noted the importance of self-care for the peers to ensure they are in a safe headspace and can appropriately guide the clients. She is happy that this topic was mentioned as they are still developing the peer navigation training.

- Ms. Giovanna Carr wanted to mirror the advice of Ms. Elizabeth Johnson and noted the importance of addressing the aspects mentioned because the peers are going to experience secondary trauma without question. There will be issues when transference occurs, and she notes their idea of support needs to be clearly defined, or they will try to solve their client's problems because their paths will be very similar with their clients. There will be a potential for relapse among individuals with a history of substance use. Ms. Carr further emphasized the importance of having a licensed clinician on the team who is an expert in dealing with mental health issues. She noted that it was a good idea to have weekly check-ins to allow peers to express their thoughts better. Ms. Carr expressed her excitement about PATH.

PATH Web-App Feature
The PATH Web-App will feature educational and self-care tips as well as a social networking feature communication. The PATH Web-App will also help clients track their mood, ART adherence, and other features that enhance engagement components.

Next Phases
- Currently focused on adapting the web-app and the training modules.
- Hiring 5-6 peer navigators at San Ysidro Health in April-May
- Expect the RCT to begin enrolling participants in August-September
- Continue to provide updates to CABs
    - Recruitment/enrollment; Progress of intervention
    - Study Results/Interpretation

COVID-19 Vaccines
Ms. Danielle Campbell introduced Dr. Rajesh Tim Gandhi, infectious disease physician at Massachusetts General Hospital. Dr. Gandhi presented on HIV and COVID-19 Vaccines.

Outline
- What do we know about COVID-19 in people with HIV?
- Why people with HIV should be prioritized for vaccine.
- What do we know about COVID-19 vaccines in people with HIV?

Risk Factors for Severe COVID-19
Known Risk Factors:
- Older age
- Comorbidities
    - Cancer, CVD (heart failure, coronary artery disease, cardiomyopathy), CKD, COPD, sickle cell disease, type II diabetes
- Immunocompromised due to solid organ transplant
- Obesity (BMI of > 30)
- Pregnancy
- Smoking

Potential Risk Factors:
- Comorbidities
    - Asthma (moderate to severe), cerebrovascular disease, hypertension, liver disease, neurologic conditions (e.g., dementia), type 1 diabetes
- Other immunocompromised states, including HIV
- Overweight (BMI of > 25 but <30)

Potential Reasons Why PWH (People with HIV) May Have Worse COVID-19 Outcomes
Immunodeficiency or immune dysregulation
- Patients with immunodeficiency, such as organ transplant recipients, are at increased risk for severe COVID-19
- Prolonged SARS CoV-2 replication reported in immunocompromised hosts
- Suggests PWH with low CD4 cell counts may be at increased risk for severe COVID-19 (as they are for influenza)
    - Residual inflammation in PWH on ART
    - Most pronounced in PWH with low CD4 cell count, incomplete CD4 cell reconstitution, low CD4/CD8 ratio
    - Immune dysregulation “legacy effect”: impact on COVID-19 not certain

Comorbidities
- PWH have high rates of comorbidities that are also risk factors for severe COVID-19

Social determinants of health
- PWH more likely to be racial/ethnic minorities, poor --- risk factors for worse COVID-19 outcomes

HIV and COVID-19: High Rates of Comorbidities and Social Vulnerabilities

- Cohort study from March 3 to April 26, 2020: 36 PWH and confirmed COVID019; 11 with probable infection
    - 83% with non-HIV comorbidity associated with severe COVID: obesity, CVD, etc.
    - ~80% Black/Latinx
    - ~50% had exposure to congregate setting

COVID-19 Hospitalizations Among persons with HIV or Solid Organ Transplant

- National COVID Cohort Collaborative
    - Adults who had COVID-19 (n=509,092)
- Primary outcomes
    - Hospitalizations and mechanical ventilation
- Persons with HIV and solid organ transplant recipients
    - More likely to be hospitalized and require mechanical ventilation during hospitalization
    - Increased hospitalization risk driven mostly by the high burden comorbidities in both groups

Factors Associating with Decreased Survival in PWH and COVID-19

- 286 people with HIV and COVID-19 from 36 institutions over 3 mos., mostly from US sites
    - 94.3% on ART; 88.7% with virologic suppression
    - Primary outcome = ICU admission, mechanical ventilation, or death
- Older age, chronic lung disease, hypertension, and lower CD4+ cell counts associated with decreased survival
- Separate analysis of European cohort of PWH demonstrated that CD4+ cell count <350 cells/mm^3 associated with increased risk for severe COVID-19

COVID-19 Outcomes in People with HIV

- Some studies, but not all, have suggested PWH have worse COVID-19 outcomes
- Not yet certain if HIV is a risk factor for worse COVID-19 outcomes independent of comorbidities and socioeconomic factors
- Studies of HIV and COVID-19 outcomes that adequately account for immunologic function, comorbidities, and socioeconomic disparities are needed
- While we await critical studies, several reasons to prioritize PWH for COVID-19 vaccination
    - High rate of comorbidities, particularly as they may occur at an earlier age and may not always be diagnosed
    - Social inequities may make COVID-19 prevention (e.g., social distancing) more difficult for many PWH

When can People with HIV get Vaccinated for COVID-19?

- Based on the Center for Disease Control and Prevention's report, people who are in an immunocompromised state from HIV might be at increased risk for severe illness from the virus that causes COVID-19 and may be considered for vaccination in phase 1c

What do we know about COVID-19 Vaccination in People with and without HIV?

The three authorized vaccines are:

- BNT162B2 (Pfizer): mRNA
- mRNA-1273(Moderna): mRNA
- Ad26.COV2.S (Janssen)

Phase III Trial Assessing Pfizer for Prevention of Symptomatic COVID-19

- Participants > 16 yrs (N=43,448): 2 doses of Pfizer placebo 21 days apart
    - 196 participants with HIV (safety, efficacy results not reported yet)
    - This trial resulted in 100% vaccine efficacy against severe COVID-19 symptoms among PWH
    - No difference in efficacy by age, sex, race/ethnicity

Phase III Trial Assessing Moderna for Prevention of Symptomatic COVID-19

- Participants > 18 yrs (N=30,351): 2 doses of Moderna or placebo 28 days apart
    - 179 persons with stable HIV
    - This trial resulted in 97% vaccine efficacy against severe COVID-19 symptoms among people living with HIV

- Similar efficacy: males vs. females and across racial/ethnic groups

Phase III Trial Assessing Janssen for Prevention of Moderate to Severe/Critical COVID-19

- Adults >18 years of age (N=44,325) received single dose of Janssen of placebo
  - Non-replicating human adenovirus type 26/spike protein DNA
  - 1218 participants with HIV
  - Overall vaccine efficacy against moderate to severe disease after 28 days: 66.1%
  - Protection against severe disease: 85%
  - Protection against hospitalization: 100%

CDC: Interim Clinical Considerations for COVID-19 Vaccines

- PWH might be at increased risk for severe COVID-19
- Persons with stable HIV included in vaccine trials, but data are limited
- Contraindications:
  - Severe allergic reaction (e.g., anaphylaxis) after previous dose or to component of COVID-19 vaccine; immediate allergic reaction of my severity to previous dose or known allergy to component of vaccine

COVID-19 FAQ

- Should someone with previous COVID-19 receive the COVID-19 vaccine?
  - Yes, once their symptoms have resolved and they are no longer infectious
  - Reinfection unlikely for at least 3-6 months so vaccine can be delayed if desired
  - Although people with previous COVID-19 respond quickly to the first dose of a mRNA vaccine, still recommend completing both doses
- When should someone who received a monoclonal antibody for treatment of COVID-19 be vaccinated?
  - Wait at least 90 days to avoid potential for interference with vaccine-induced immune responses

COVID-19 Vaccines in People with HIV (PWH)

- PWH may have worse COVID-19 outcomes than people without HIV
  - Comorbidities, social determinants of health, possibly HIV itself
  - For this reason, would prioritize PWH for vaccination
- mRNA vaccines (Pfizer, Moderna) or Janssen vaccine are likely to be safe and effective in PWH (do not replicate)
- We do not know the extent of protection in people with HIV
- We also do not know how long protection will last and whether vaccine will prevent acquisition, transmission of infection
- For all these reasons, continue to wear mask and maintain social distance

Dr. Rajesh Tim Gandhi concluded his presentation and opened the floor to discussion.

Discussion

- Ms. Judi Patterson posed the question, “Are the COVID-19 vaccines safe for pregnant women?”
  - Dr. Gandhi noted that there have been thousands of women who have been vaccinated and there has been no reported signals of adverse effects. They are still continuing to monitor this as well. He tells his patients and reassures them that it is safe to get the vaccine even when pregnant. Dr. Gandhi stated it is safer to get the vaccine than risk a pregnant woman contracting COVID-19.
- Mr. Dallas Davis posed the question, “What would you say about giving the vaccine to children?”
  - Dr. Gandhi stated right now he does not recommend giving it to children until the vaccine trials are completed. The Pfizer vaccine is authorized for 16 years and above while Moderna and Janssen are authorized for 18 years and above. Dr. Gandhi does not recommend administering the vaccine to children younger than the listed ages. They started trials for 12 years and above as well as infancy and above, but these trials have not concluded. The trouble at this time is the dosage for the vaccinations is unknown and we are unsure of the immune response.

UCAB Updates and Last Gift Debrief

Mr. Dallas Davis provided the team with a summarization of the UCAB meeting held in March. He noted the UCAB meeting consisted of a vaccine presentation by Dr. Susan Little, which was similar to Dr. Rajesh Tim Gandhi's vaccine

presentation, which was on point with the vaccine information. He noted Dr. Little's presentation focused on whether HIV is a risk factor for COVID-19, Her presentation suggested people living with HIV developing COVID-19 symptoms appeared higher than the general population.

Mr. Dallas Davis transitioned to the Last Gift debrief. Last Gift is a program run by UC San Diego, and if an individual has a terminal illness and has less than six months to live, they are essentially donating their organs and body for research purposes. Mr. Davis stated the contacts for this initiative is Dr. Susanna Garcia, contact number: 619-543-5000.

Adjournment
Meeting adjourned at 10:50 am