LONG-ACTING INJECTABLE WORKGROUP

October 2023

LONG-ACTING INJECTABLE WORKGROUP CHARGE:

Providing input to the CHAC for consideration and deliberation on addressing current and emerging issues related to use of long-acting injectable PrEP and treatment, including identification of system and clinic-level barriers and opportunities (including cost and access issues) and identification of best practices and potential models of care.

Workgroup Meetings:

May 1, July 6, August 8, September 25, 2023

- Shannon Dowler, Co-Chair
- Kneeshe Parkinson, Co-Chair
- Wendy Armstrong
- Daniel Driffin
- Christine Markham
- Richard Haverkate, IHS Ex-Officio
- Christopher Gordon, NIH/NIMH Ex-Officio
- Marah Condit, CDC DFO
- Shalonda Collins, HRSA DFO

SUMMARY OF LEARNINGS

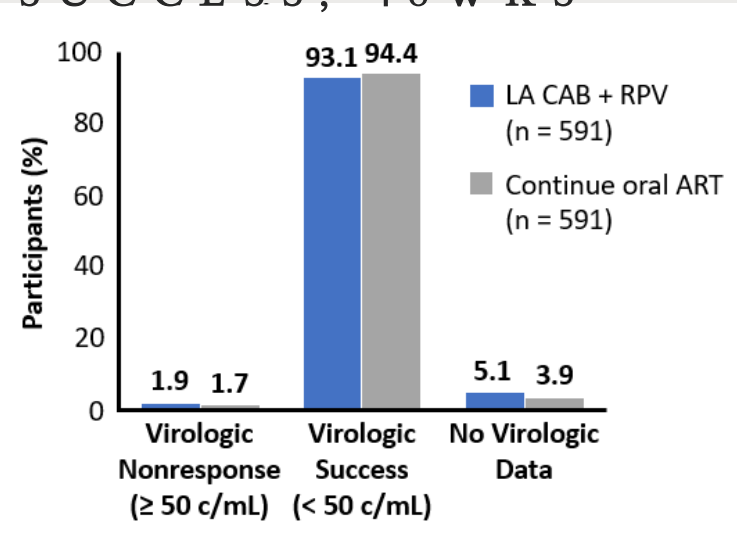
LAI PrEP:

4570 cisgender men and transgender women who have sex with men; CAB-LA vs oral FTC/TDF; Superiority of CAB-LA with 66% risk reduction of incident HIV infection

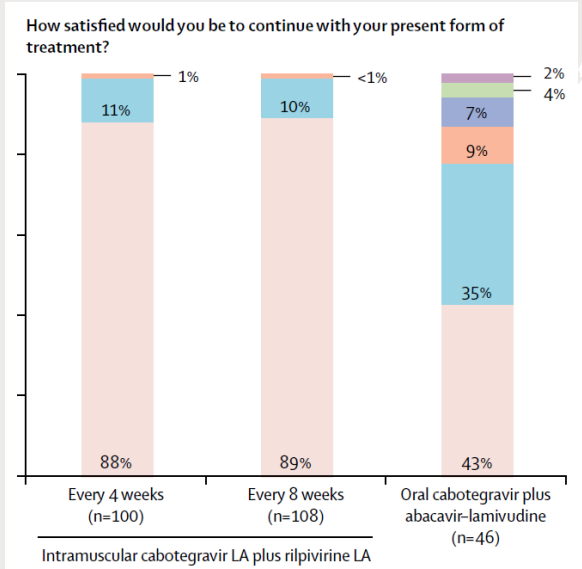
3200 (projected) cisgender women; CAB-LA vs oral FTC/TDF; Study stopped early with superiority of CAB-LA with 89% risk reduction of incident HIV infection

LAI Treatment:

TREATMENT SUCCESS, 48WKS



Satisfaction



NASTAD hivma hiv medicine association

Long-Acting Antiretroviral Treatment: Considerations for Health Care Providers
Version: July 2023

Open Forum Infectious Diseases
MAJOR ARTICLE

IDSA hivma OXFORD

Early Experience Implementing Long-Acting Injectable Cabotegravir/Rilpivirine for Human Immunodeficiency Virus-1 Treatment at a Ryan White-Funded Clinic in the US South

Lauren F. Collins, Della Corbin-Johnson, Meron Azmi, Zoey P. Morton, Kaylin Dance, Alton Combs, Kimberly Jenkins, Marie Todd-Turner, Juri Sumitani, Bradley L. Smith, Wendy S. Armstrong, and Jonathan A. Colasanti

Clinical Infectious Diseases
MAJOR ARTICLE

IDSA hivma OXFORD

First Demonstration Project of Long-Acting Injectable Antiretroviral Therapy for Persons With and Without Detectable Human Immunodeficiency Virus (HIV) Viremia in an Urban HIV Clinic

Katerina A. Christopoulos, Janet Grochowski, Francis Mayorga-Munoz, Matthew D. Hickey, Elizabeth Imbert, John D. Szumowski, Samantha Dilworth, Jon Oskarsson, Mary Shiels, Diane Havlir, and Monica Gandhi

Annals of Internal Medicine

ORIGINAL RESEARCH

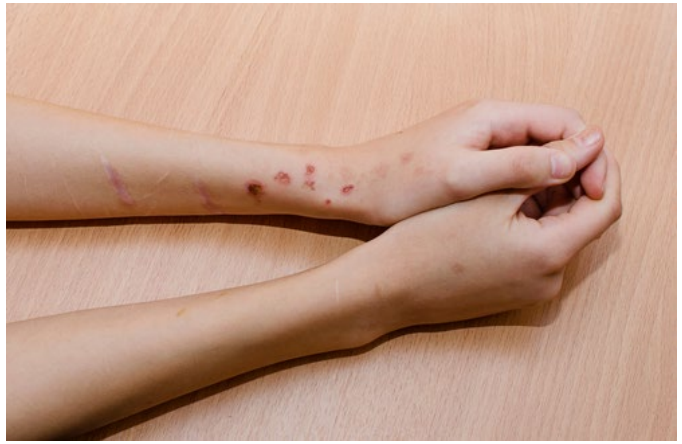
Demonstration Project of Long-Acting Antiretroviral Therapy in a Diverse Population of People With HIV

Monica Gandhi, MD, MPH; Matthew Hickey, MD; Elizabeth Imbert, MD; Janet Grochowski, PharmD; Francis Mayorga-Munoz, PhT; John D. Szumowski, MD; Jon Oskarsson, RN; Mary Shiels, RN; John Sauceda, PhD; Jorge Salazar, MD; Samantha Dilworth, MS; Janet Q. Nguyen, MPH; David V. Glidden, PhD; Diane V. Havlir, MD; and Katerina A. Christopoulos, MD, MPH

EXTERNAL EXPERTS/ADVISORS

Session 1: IHS

Andrew Yu, *MS, BSN, RN, ACRN, HIV/HCV/STI Clinical Coordinator, Division of Clinical and Community Services, IHS*



- Competing priorities: HIV prevalence in Indian Country is much lower than HCV and STIs. Utilize a syndemic approach and the Indigenous HIV/AIDS Strategy (Indigi-HAS) to weave together HIV with HCV, STIs, substance use to highlight shared vulnerability factors and the importance of HIV testing, treatment and prevention.
- Awareness: Incorporate long-acting injectables in all syndemic-related trainings (Indian Country ECHO, webinars, on-site education) as a method of providing HIV treatment and prevention.
- Infrastructure: Need for **sufficient cold storage space** to maintain the medications, availability of private rooms and point-of-care HIV antibody/antigen testing. In addition, prior to formal adoption, the IHS will need to increase local clinical staffing and their capacity to provide the added duties associated with long-acting injectable HIV medications. Also, Case Management personnel and time needed to conduct benefits investigation, provide adherence support, recall anyone who has missed doses, review lab results.
- Learning needs: Provide education on how to provide a ventrogluteal injection (uncommon injection site).
- Adding to the formulary by allowing tribes to supplement the cost of medication could allow certain localities to have access based on need without creating an overwhelming financial hardship.

Session 2: Medical/Pharmacy Provider Experience

(Academic, Health System, FQHC, Local Health Department, Private clinic):

1. Harder to get this covered by **commercial payers** than public payers.
   - Commercial payers will change criteria spontaneously which results in barriers to continuing care.
   - Hospital based facility preclusions disadvantageous to communities.
2. Challenging **facility requirements** with separate refrigeration from vaccines.
3. **Injection training** barriers because some clinics do not allow "sales teams" on site and misunderstandings on those requirements.
4. **Staffing requirements** are significant due to the PA processes and coordination of receiving medication and administering; requires dedicated staff with expertise.
5. **Major issue** of medications falling on **Medical Benefit** (vs. Pharmacy Benefit)
   - Longer time to receive medication.
   - "Buy and Bill" in Medicaid benefit often not reimbursed.
   - Higher administrative burden.
6. Having a **pharmacy led** clinic or clinical pharmacist is critical for success.
7. Allow medication to be **shipped to clinic** from Specialty Pharmacies (not to patient).
8. **"Profoundly Positive"** experience for people who receive LAI.
   - Some people virally suppressed for the first time in their lives.
   - People able to "live beyond their diagnosis" with removal of daily impact of medications.

Monica Gandhi, MD, MPH, Director | UCSF-Bay Area Center for AIDS Research (CFAR), Professor of Medicine and Associate Chief | Division of HIV, Infectious Diseases, and Global Medicine, Medical Director | "Ward 86" HIV Clinic, San Francisco General Hospital

Ana Simonyan, PharmD, BCACP, *Clinical Pharmacy Specialist, Infectious Diseases, Clinical Team Lead, Vanderbilt Specialty Pharmacy, Core Faculty, Southeast AIDS Education and Training Center, Vanderbilt University Medical Center*

Kara Lewis, PharmD, AAHIVP, Director of Clinical Pharmacy Services, Community Health Center, Inc., Middletown, CT

Jennifer Abbott, MD, WNC Community Health Services

Quintin Robinson, MD, *Deputy Medical Director, AvitaCare Atlanta*

Victoria Mobley, MD MPH, Medical Director, HIV/STI, Director, Field Services Unit, N.C. Division of Public Health

MISSING VOICES

The Voice of Lived Experience is needed to complete the arc of this workgroup.

BIG THING 1: MEDICAL VS. PHARMACY BENEFIT

- Most medications are traditionally covered as a pharmacy benefit.
- Because Cabenuva is administered in a clinical setting, some insurers cover it as a medical benefit while others cover it as a pharmacy benefit and some as both.
  - Creates confusion and increased burden for practices to manage dozens of insurance benefits with different approaches to coverage.
- Pharmacy benefits are processed in real time, are generally easier to submit, and drugs are listed on the formulary for transparency.
- Medical benefits are:

  Administratively more complicated and burdensome to process

  Accompanied by fewer rebates

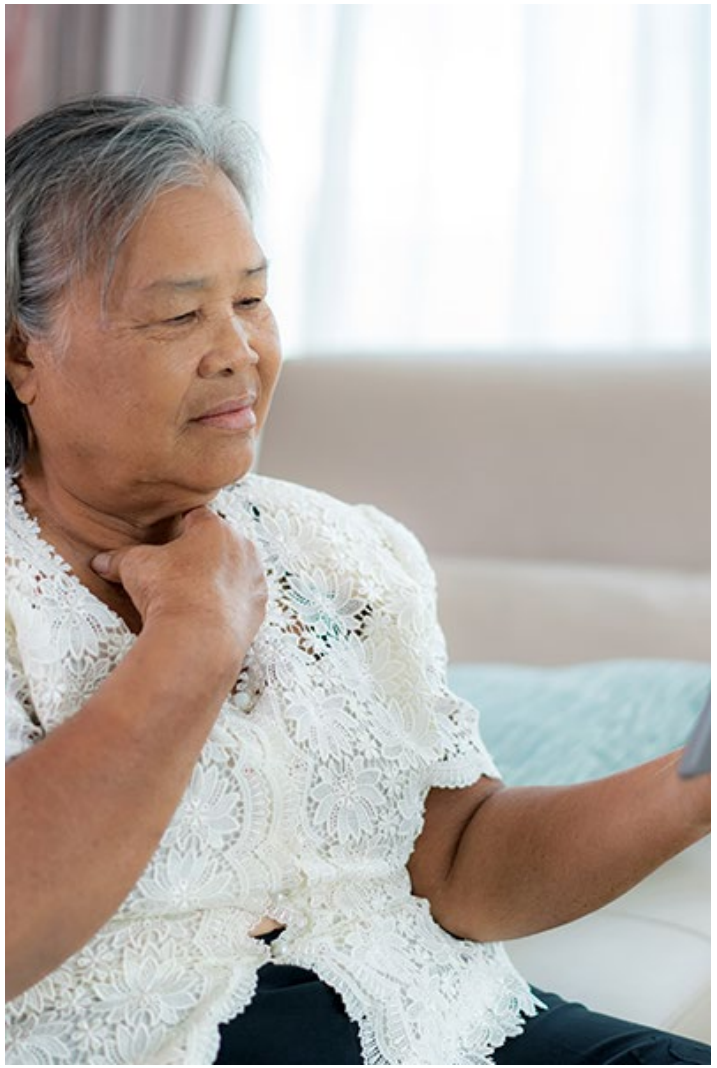
  Requires more documentation to reduce the risk of denials

  Reimbursement is slower and often not rendered

Guidelines for LAI PrEP Creates Barrier

- Switching to LAI for PrEP requires more office visits overall than oral PrEP.
  - Increased transportation costs.
  - Missed work.
  - Increased impact on staffing.
- Viral load requirements create disruptions in the care continuum.
- Viral load requirements add significant expense to clinics.

- Philosophical Issue
  - Is the theoretical risk of missing an early infection worse than the risk of not providing PrEP at all to a population of high-risk people?



BIG THING 3: LAI VIRAL SUPPRESSION REQUIREMENT

- FDA approval for Cabenuva® - for those who are virologically suppressed on a stable regimen with no history of treatment failure
- Small studies with encouraging results for "direct to inject" or use of Cabenuva in those who are not virologically suppressed (VS)

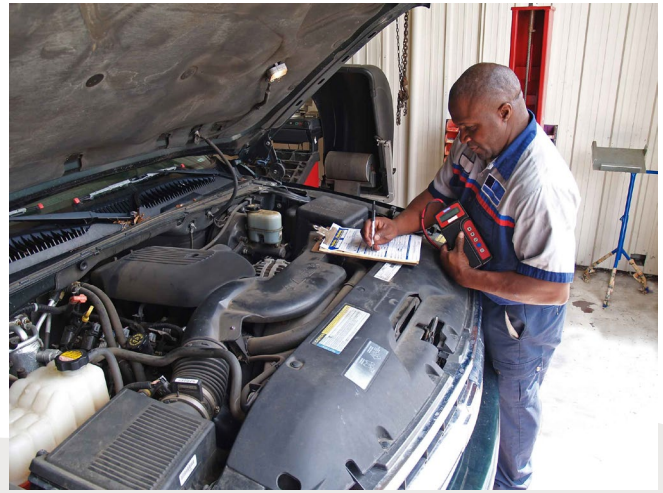
  UCSF Ward 86 – July 2023: 54 of 57 with viremia maintained VS (2 failures)

  Mississippi – Sept 2023: 12 of 12 with viremia achieved VS

  Modeling study - July 2023: CAB-RPV + wraparound services would improve life expectancy and VS compared to oral therapy in viremic patients with adherence barriers.

  Many anecdotal reports of success

- Philosophical Issue: With growing evidence that patients in selected circumstances have better outcomes with CAB-RPV, can guidelines be updated or permissive utilization allowed?



RED FLAG TOPIC

Disparities have continued to accompany access/utilization of biomedical advances (e.g., PrEP); to prevent this pattern, implementation issues needing attention are:

Systems factors: Infrastructure issues such as availability of sufficient cold storage, staff training, clinical protocols

Provider factors: Capacity to overcome prescribing/reimbursement barriers, competencies in care for racial, sexual, and gender diverse patients, and staffing availability for robust retention and follow-up efforts

Patient factors: Medical mistrust, transportation, missed work, and other social needs

NEXT STEPS

1. Request to Extend LAIWG

- To engage more people with lived experience to guide our learning, we request that CHAC extend this workgroup until the Spring 2024 meeting

2. Need Guidance

- Identifying PLWH for sharing their experience poses a challenge
- What are the best practices and/or resources for the workgroup(and future workgroups)?

3. Any Action Now?

- Are any of the already flagged items deserving of “early intervention” while work group completes?

Mobilizing & Powering Community Partnerships to Increase Engagement and Health Equity: Challenges, Lessons, & Opportunities

October 25, 2023

CHAC Community Partnerships Workgroup

Roster:

- Kali Lindsey (Chair)
- Meredith Greene
- Johanne Morne
- Marah Condit (CDC DFO)
- Shalonda Colins (HRSA DFO)

Meetings: 6/5, 7/24, 9/19, 10/4

Scope: The Community Partnerships Workgroup's primary charge is to provide research to CHAC regarding best strategies and consistent barriers encountered in the development, capacity, and retention of community partnerships that increase health equity by identifying and eliminating disparities.

Foundation: Community Partnership and Engagement

- Community Partnerships:
  - Community partnerships are relationships that are developed over time and facilitate shared decision making and accountability. Each partner looks for ways to strengthen the partnership. The marginalization and ongoing vulnerability of communities disproportionately impacted by HIV, STI and Hepatitis C create a difficult power and trust dynamic to navigate between government and academic agencies and community stakeholders.
- Background on Community Engagement:
  - CDC is committed to conducting meaningful, ongoing community engagement efforts with a number of community partners to advance health equity and EHE goals. In 2022, CDC began convening a number of community engagement events with community leaders and members to discuss community-driven solutions to advance HIV prevention, diagnosis, treatment, and outbreak response. These engagement events will continue throughout 2023.
  - Laying the foundation for multiple levels of community involvement: both agencies frame as continuum with increasing level of community involvement, impact, trust, communication with goal of shared leadership (CDC) and "voices of community from beginning to end" in all phases of project planning and implementation (HRSA) ; often discussed in EHE context especially through listening sessions and events (text above CDC)

Source: CDC, HIV Community Engagement

Community Engagement Continuum

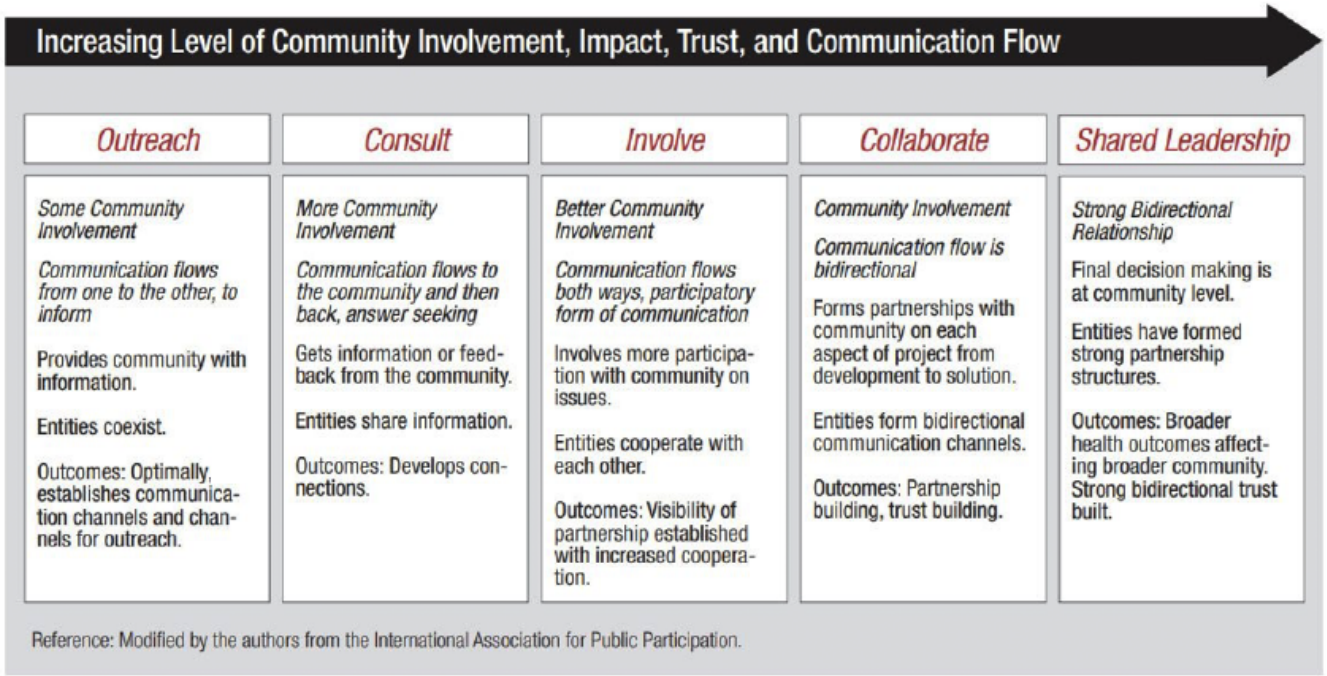
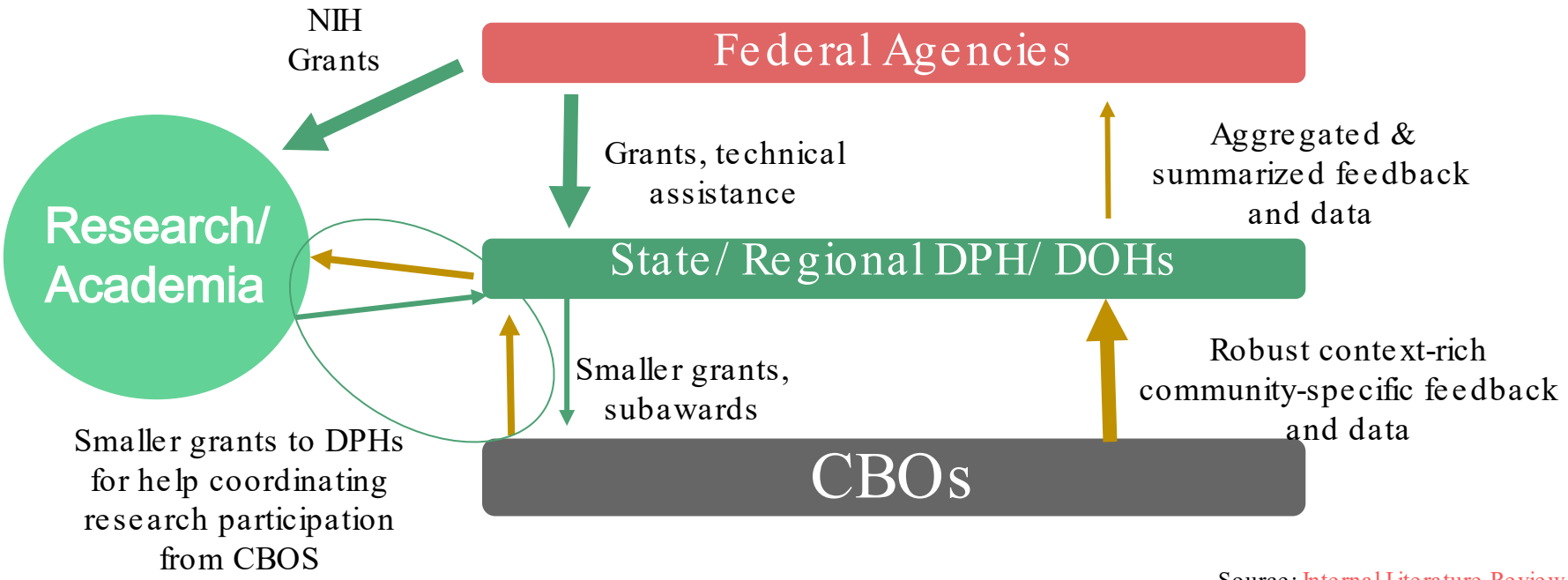


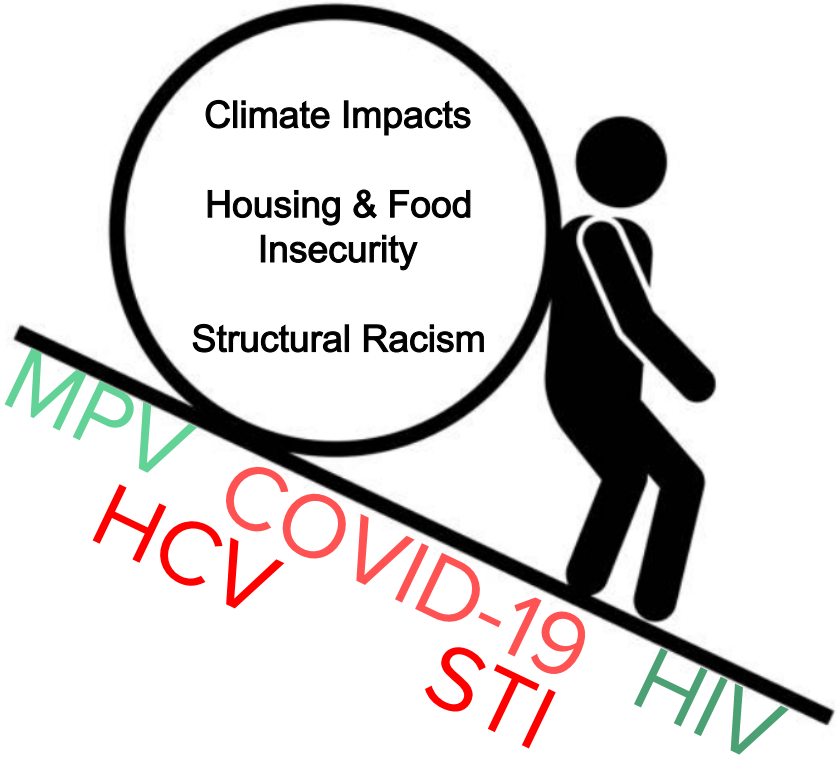
Figure adapted from the International Association for Public Participation and titled "Increasing Level of Community Involvement, Impact, Trust, and Communication Flow."

Source: https://www.atsdr.cdc.gov/communityengagement/community-engagement-continuum.html#print

Community Engagement Operational Framework



Source: Internal Literature Review, 9-1-23



HIV, COVID-19, & MPV: Converging Epidemics

Sources: Hybrid Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment April 18-19, 2023, Ending the HIV Epidemic in the U.S. Initiative 2021 Community Engagement Listening Sessions

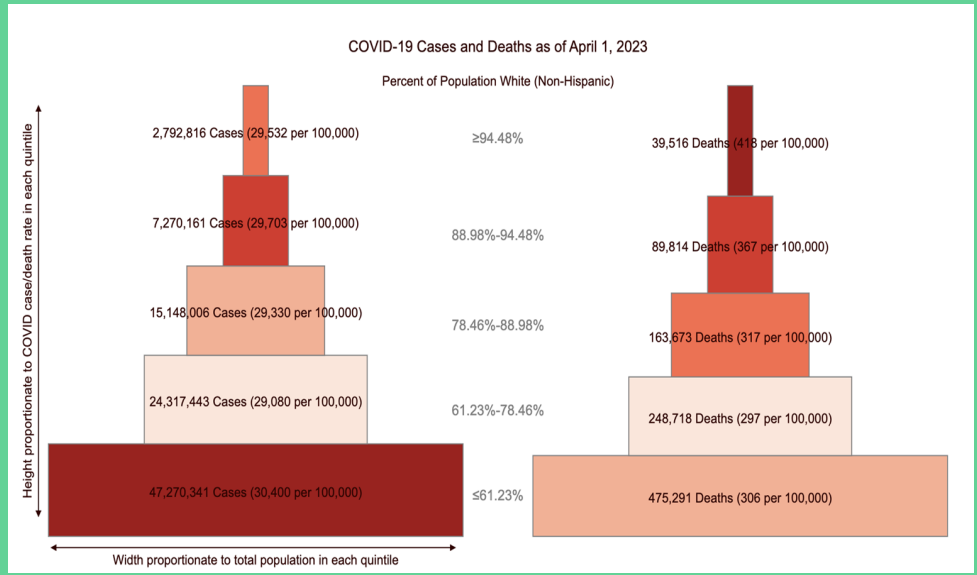
Syndemics & Community Impacts

COVID-19 Impacts

- Whether evaluating for cases or deaths, **COVID-19 has impacted more diverse communities** than predominantly Non-Hispanic White communities

MPV Impacts:

- **84% of MPV cases** nationally were men who have sex with men (MSM)
- 41% were also **HIV-positive**



Sources: EHE amFAR Database, FCAA & Elton John Foundation Converging Epidemics: COVID-19, HIV & Inequality Community-led Lessons for Funders

Epidemic of Dis/Misinformation and Stigma

Content Experts and Matters

"disinformation is polarizing public debate on topics related to COVID-19; amplifying hate speech; heightening the risk of conflict, violence and human rights violations; and threatening long-terms prospects for advancing democracy, human rights and social cohesion."
- **Joint statement by WHO, UN, UNICEF, UNDP, UNESCO, UNAIDS, ITU, UN Global Pulse, and IFRC** September 23, 2020

Because HRSA HAB recognizes the value of people with lived experience and the ways their input and expertise contribute to the delivery of services that are tailored to the needs of people with HIV, this letter articulates three mechanisms that RWHAP recipients and subrecipients can utilize to maximize community input.
- HAB **Community Engagement** Program Letter, February 28, 2023

Monitoring the Information Environment by Person, Place, and Time
Identifying trends and patterns of misinformation, disinformation, information voids, perceptions, and questions of public health concern over time is critically important because the goal is to detect infodemics and respond quickly and effectively with public health action. An early warning system, for example, might detect an acute rise in misinformation that could be addressed through community engagement and targeted and tailored communications.
- The Future of Infodemic Surveillance as Public Health Surveillance. Emerg Infect Dis. 2022;28(13):121-128. https://doi.org/10.3201/eid2813.220696

Context Experts and Matters

"both infodemic and traditional public health surveillance systems are reliant on epidemiologic thinking. Critics might highlight that traditional public health surveillance seeks to detect disease, whereas infodemic surveillance systems fundamentally seek to detect ideas. However, the core concepts of person, place, and time are as valuable for understanding the transmission of ideas throughout a population as they are for disease."
- The Future of Infodemic Surveillance as Public Health Surveillance. Emerg Infect Dis. 2022;28(13):121-128. https://doi.org/10.3201/eid2813.220696

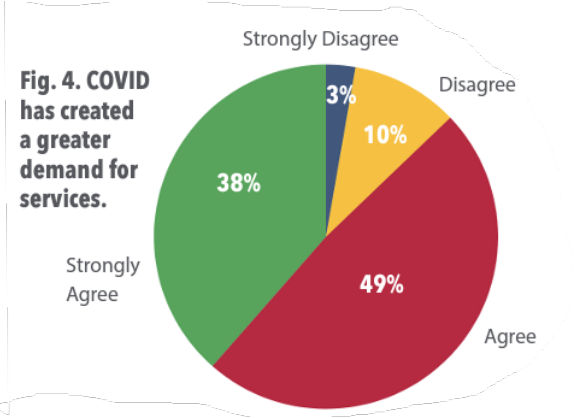
"There is a sense of PTSD of another epidemic. Watching the government response has been hard … We see some of the same things we saw in HIV around stigma with COVID. The disproportionate impact on Black and Brown people. We're seeing the same social justice implications now." - Executive Director, U.S. HIV/AIDS organization.

"These are programs that have already been stigmatized and torn apart and never funded appropriately. [They] became the heroes in the communities when the health department programs shut down. The CBOs continued to serve sandwiches, provide tents and safe harbors for the protesters." - Executive Director, private foundation

Governments and philanthropic entities seemed to have minimal communication, particularly in the U.S. context, causing overlaps in funding in some areas, while leaving other important areas unfunded.
- FCAA & Elton John Foundation Converging Epidemics: COVID-19, HIV & Inequality Community-led Lessons for Funders

Feedback from the Community

- Lack of coordination and collaboration across CDC/HRSA EHE/STD/Hep partners and other Federal agencies led to under resourcing and duplication.
- Predominate mechanisms for input were listening sessions and EHE strategy meetings, which cut many community-driven ideas when shared with CDC for approval
- Engagement of community partners by CDC and HRSA felt like an afterthought



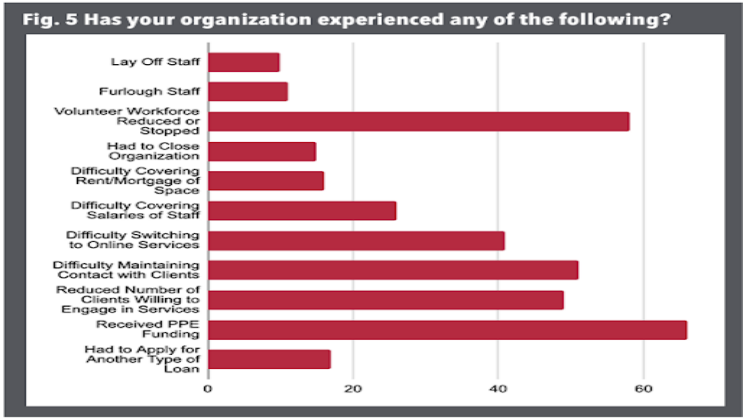


Chart & Table Source: https://southernaidscoalition.org/covid-cbo-report-2021/

Syndemic Preparedness: The Need to Engage CBOs

CBOs require resources to invest in technology upgrades, and to provide adequate outreach to communities of need for current HIV and COVID-19, but also for emergency preparedness capacity in the event of another ~~outbreak~~. Pandemic instead?

- CBOs require financial and technical resources that are built to not only meet one emergency, but the potential for another wave of syndemic scenarios. Many CBOs reported not applying for additional DOH grant money because they did not have the time and resources required to complete the RFPs. Complicated grant applications can prevent grant funds from going to where investment is most needed.

Reality and Limitations:

- Between increased demand for outreach on multiple diseases, reduced volunteer support, and uncertain pathways to receiving additional resources, these CBOs are frustrated and feeling left behind.

Source: FCAA & Elton John AIDS Foundation Converging Epidemics: COVID-19, HIV & Inequality Community-led Lessons for Funders

Lessons Learned

"As the HIV field continues to further integrate meaningful community engagement into programming and practices, it is imperative to recognize the emotional labor this task places on the many staff of color and individuals who identify as LGBTQIA+, and many other identities. BIPOC and those in the LGBTQIA+ community engage in a disproportionate amount of emotional labor in the workplace due to navigating the daily macro and microaggressions that historical and cultural norms have indoctrinated over time. The more public health communities realize and address the emotional labor experienced by many of these individuals, the more we can truly support our colleagues, partners, and the communities we serve."

- NASTAD, Re-envisioning Community Engagement: A Practical Toolkit to Empower HIV Prevention Efforts with Marginalized Communities

- CBOs require resources for now and the future that **reflect a deep understanding** of their needs and leverage their existing assets
- Complex grant applications and **opaque processes** can still be be barriers to entry
- LGBTQIA communities of color are **being left behind again** both in resources and in discourse

Other Hot Topics

- High levels engagement: including community partners (such as CBOs) in the grant review process to ensure projects funded meet needs community

- Find ways to continue some of the supportive capacity building especially tech support including data and leadership development to organizations that have received funding

Community Engagement : One Model of Success

All of Us℠ | The Precision Medicine Initiative®

THE FUTURE OF HEALTH BEGINS WITH YOU

Source: NIH *All of Us* Research Program

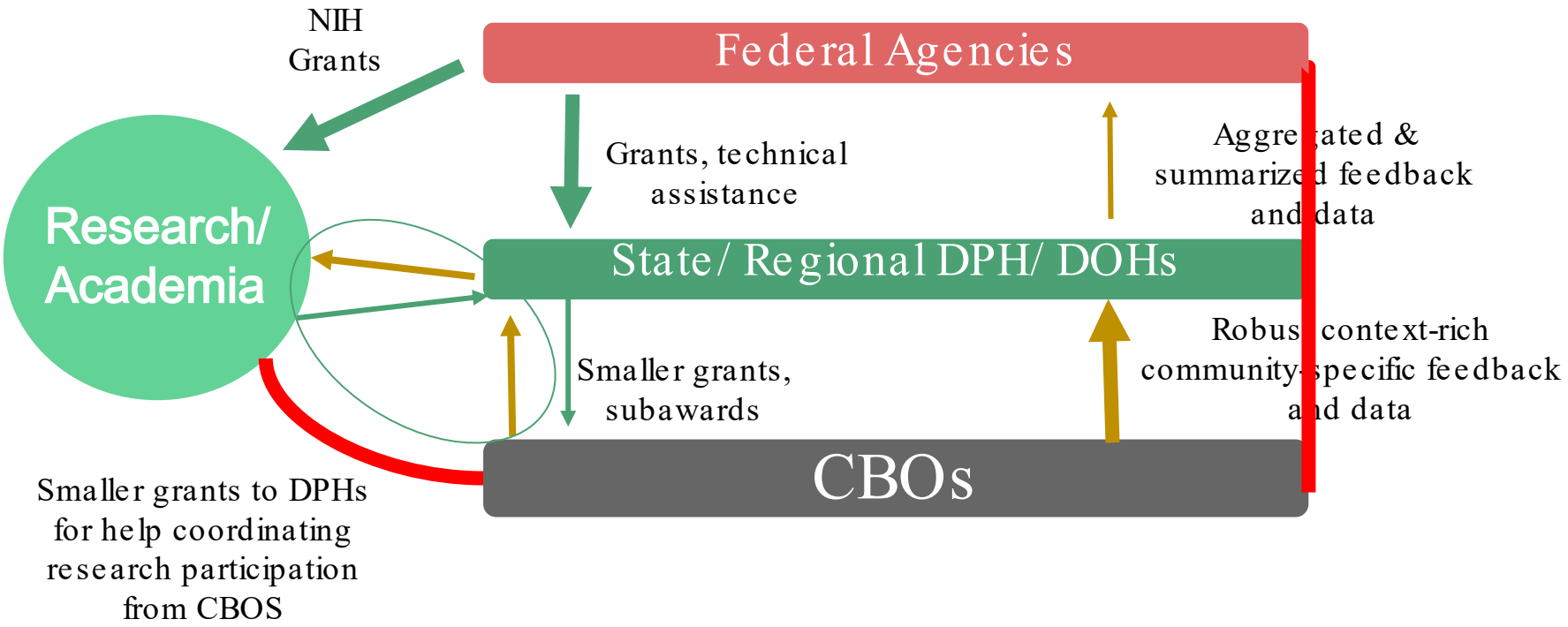
The Approach: The NIH *All of Us* Research Program

- One model for successful and intentional Federal agency integration with CBOs can be seen in the NIH *All of Us* Research Program, which is a precision medicine initiative whose mission is to enroll one million Americans for more diverse and informed clinical research. Using a social ecological approach, it heavily leverages community engagement to build long standing relationships between and among federal, local, and community stakeholders and build trust within communities while maintaining a commitment to bidirectional resource and information sharing.

- Effective community engagement is achieved through a Community Partners Gateway Initiative (CPGI) model. A broad range of healthcare, multicultural, and faith-based organizations that represent national, regional and local-level reach into communities who have been historically underrepresented in biomedical research are provided with funding and communication support to build deep and lasting relationships within those communities that begin to repair trust. It is a sustained effort aimed at creating meaningful relationships ahead of short-term enrollment goals.

Source: NIH *All of Us* Research Program, Community and Engagement Partners

Innovative Partnerships



Takeaways and Recap on New and Innovative Partnerships

- There is significant opportunity to take the existing framework for community engagement and identify new innovative partnerships that focus on longevity and sustainability in order to better understand community capacity assets and needs, and also to improve trust within communities that have been historically marginalized.

- In order to retain the richness of the information that exists at the CBO-level and create funding streams that more effectively target CBO needs, sustained partnerships and be built directly between CBO stakeholders and Federal agencies.

- Increasing trust in biomedical research and health programs while also more fully understanding the realities of communities on the ground, research institutions can build sustained relationships with the communities they intend to serve.

Citations

1. CDC, HIV Community Engagement. https://www.cdc.gov/hiv/capacity-building-assistance/community-engagement/
2. https://www.atsdr.cdc.gov/sites/brownfields/actionmodeltoolkit/
3. hhttps://partnerships.ucsf.edu/center-community-engagement
4. NYC. Lit Review https://docs.google.com/document/d/14fF4FV2IiUdFBw1IRLdUKLaWs5-jq_Nce8-w1500FkE/edit?usp=sharing
5. Hybrid Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment
6. April 18-19, 2023, Ending the HIV Epidemic in the U.S. Initiative 2021 Community Engagement Listening Sessions
7. EHE amFAR Database. https://ehe.amfar.org/inequity?_ga=2.252112463.756296515.1696872435-1189395044.1696872435
8. FCAA & Elton John Foundation Converging Epidemics: COVID-19, HIV & Inequality Community-led Lessons for Funders
9. Joint statement by WHO, UN, UNICEF, UNDP, UNESCO, UNAIDS, ITU, UN Global Pulse, and IFRC September 23, 2020
10. HAB Community Engagement Program Letter, February 28, 2023
11. The Future of Infodemic Surveillance as Public Health Surveillance. Emerg Infect Dis. 2022;28(13):121-128. https://doi.org/10.3201/eid2813.220696
12. Southern AIDS Coalition: https://southernaidscoalition.org/covid-cbo-report-2021/
13. NASTAD, Re-envisioning Community Engagement: A Practical Toolkit to Empower HIV Prevention Efforts with Marginalized Communities
14. NIH. All of Us Research Program. https://allofus.nih.gov
15. NIH. All of Us Community Engagement Partners. https://allofus.nih.gov/funding-and-program-partners/communications-and-engagement-partners

Thank You!

CHAC Community Partnerships Workgroup
CDC & HRSA Survey Respondents
CDC & HRSA CHAC Support Staff
CHAC Survey Respondents
Publishers & Researchers Cited in this Presentation