



Published in final edited form as:

Eval Program Plann. 2022 February ; 90: 101999. doi:10.1016/j.evalprogplan.2021.101999.

Informing the future of PrEP navigation: Findings from a five-site cluster evaluation

Yamir Salabarría-Peña^{a,*}, Chelsea Douglas^a, Meredith Brantley^b, Amy K. Johnson^c

^aCenters for Disease Control and Prevention, 1600 Clifton Road, MS US8-5, Atlanta, GA 30329, USA

^bTennessee Department of Health, Andrew Johnson Tower, 4th Floor, 710 James Robertson Pkwy, Nashville, TN 37243, USA

^cAnn & Robert H. Lurie Children's Hospital and Northwestern University, 225 East Chicago Avenue, Box 161, Chicago, IL 60611-2605, USA

Abstract

The PrEP (pre-exposure prophylaxis) Implementation, Data to Care and Evaluation (PrIDE) demonstration project funded 12 health departments (HD) (2016–2019) to scale up PrEP among sexual minorities at risk for HIV. Each health department (HD) conducted an evaluation of at least one local strategy, and, to maximize crossvalidation, an adapted cluster evaluation approach was employed. As a result, five HDs with similar evaluation questions regarding PrEP navigation were identified.

Overall, PrEP navigation fit in well with HD clinics and community-based organizations.

A hybrid model of patient, peer, and systems navigation linking clients to PrEP and social services was commonly used. Although there were no differences by setting regarding linking clients to PrEP providers, one HD demonstrated that having all PrEP services in the same location contributed the most to PrEP uptake. Navigator skill for case management and rapport building facilitated navigation, whereas staff turnover and lack of client health insurance were challenges. While one HD in a non-Medicaid expansion state was affected by health insurance issues the most, another HD demonstrated that providing payment assistance increased client PrEP use. The findings pinpoint PrEP navigation hybrid modality and having health insurance as promising strategies to increase PrEP uptake among priority groups.

This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

*Corresponding author. ycs8@cdc.gov (Y. Salabarría-Peña).

Author statement

Yamir Salabarría-Peña: Article's Conceptualization, Methodology, Analysis, Writing Original Draft, Supervision, and Project Administration.

Chelsea Douglas: Analysis, Co-Writing Original Draft.

Meredith Brantley: Co-Writing Original Draft and Reviewing/Editing.

Amy K. Johnson: Co-Writing Original Draft and Reviewing/Editing.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.

Declaration of Competing Interest

None

Keywords

HIV; Navigation; PrEP; PrEP navigation; MSM; Transgender; Cluster evaluation; Patient navigation; Peer navigation; Systems navigation

1. Background

Navigation has been widely defined as a patient-centered model that empowers individuals and families by reducing barriers and increasing access to relevant services in order to receive optimal care (Broeckaert & Challacombe, 2014; Freeman & Rodriguez, 2011). Patient navigation, the first navigation modality, was originally implemented for low-income women with breast cancer (Hede, 2006). It has expanded to other chronic diseases and the Human Immunodeficiency Virus (HIV) (Broeckaert & Challacombe, 2014; Marks, Crepaz, Senterfitt, & Janssen, 2005). At first patient navigators were lay community health workers, but have evolved to include nurses, case managers and social workers (Broeckaert & Challacombe, 2014; Cunningham et al., 2018; Koester et al., 2014). Patient navigation also occurs in different settings such as hospitals, community health clinics, and community-based organizations (CBOs). In addition to linking individuals to health care services, navigation activities address social determinants of health (WHO, 2010) and structural barriers (e.g., lack of transportation, lack of linguistically appropriate services), and the complexities of communicating and coordinating with multiple agencies and providers to meet individuals' needs (Bishop, Edwards, & Nadkarni, 2009; Hendren et al., 2011; Thoms & Moore, 2012).

Patient navigation is also the modality frequently used in HIV care delivery to support persons who are recently diagnosed with HIV (PWH) or have been previously disengaged from care in an effort to link them to HIV care and treatment (Bradford, Coleman, & Cunningham, 2007; Freeman & Rodriguez, 2011; Mizuno et al., 2018; NMAC, 2012; Vargas & Cunningham, 2006). While patient navigation is the primary modality used in HIV, there are two other modalities pertinent to this article that are rooted in patient navigation and emerge in the HIV literature (i.e., systems navigation and peer navigation) (Cunningham et al., 2018). Systems navigation (also known as system navigation, or systems navigation support, or supportive services) is characterized by easing access to health care by offering social services for patients/clients such as assistance with health insurance and communicating with multiple agencies on clients' behalf (Carter et al., 2018). Peer navigation provides social support and role modeling via a navigator who shares similar characteristics with clients (e.g., PWH released from jail, transgender woman) (Carter et al., 2018; Dohan & Schrag, 2005; Ferrante, Cohen, & Crosson, 2010; Koester et al., 2014; Manderson, McMurray, Piraino, & Stolee, 2012; Pagkas-Bather et al., 2020; Sofaer, 2009; Westergaard et al., 2017).

More recently with the use of pre-exposure prophylaxis (PrEP), a daily pill that helps prevent HIV in persons at elevated risk of HIV, navigation is being used to connect people to PrEP education, counseling, and uptake (AIDSinfo, 2020). Often, PrEP navigation includes the use of peer navigators to bridge the communication gap between patients and

providers (Pagkas-Bather et al., 2020; Reback, Clark, Rünger, & Fehrenbacher, 2019). Peer navigators are essential as they help clients confront medical mistrust which is a deterrent to care among racial/ethnic minorities (Galvan, Bogart, Klein, Wagner, & Chen, 2017; Pellowski, Price, Allen, Eaton, & Kalichman, 2017), address PrEP-related knowledge gaps among minority men who have sex with men (MSM) (Eaton, Driffin, Bauermeister, Smith, & Conway-Washington, 2015; Grov, Whitfield, Rendina, Ventuneac, & Parsons, 2015; Parsons, Rendina, Whitfield, & Grov, 2016; Underhill et al., 2016), improve medication adherence (Beach et al., 2018; Karwa et al., 2017; Westergaard et al., 2017), and provide role modeling (Cunningham et al., 2018; Pagkas-Bather et al., 2020; Westergaard et al., 2017). PrEP navigation also integrates systems navigation/support services to better address PrEP initiation and sustainability (Spinelli et al., 2018). Otherwise, delays in addressing systems-related barriers may result in HIV seroconversion given cost and competing priorities (Belfon et al., 2018; Serota et al., 2018).

Given the recency of PrEP navigation, there is still a dearth of literature on PrEP navigation implementation. Therefore, the objectives of this paper are to (a) describe a cluster evaluation approach used in PrEP implementation, Data to Care, Evaluation (PrIDE) project and highlight overarching findings across funded recipients that evaluated PrEP navigation, including barriers and facilitators to implementation faced by navigators, and lessons learned to inform future PrEP navigation services and uptake¹; and (b) introduce four individual PrIDE site evaluations of navigation that will appear in this special issue (i.e., Frank et al., Green et al., Parrish et al., and Pichon et al.).

1.1. What navigation was in project PrIDE

Project PrIDE was a 4-year multi-site demonstration project funded in 2015 by the Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP). Project PrIDE awarded 12 health departments (hereinafter referred to as funded recipients) to build their capacity to implement PrEP among MSM and transgender persons, particularly those who identify as Blacks/African Americans and Hispanics/Latinos/as. In addition, five of the twelve jurisdictions also implemented Data to Care (strategy that uses surveillance data to identify and engage/re-engage into HIV care individuals diagnosed with HIV). In Project PrIDE, navigation was generally defined as a process of identifying clients in need of PrEP and other needs (e.g., culturally and linguistically appropriate services), and successfully linking them to appropriate services. All funded recipients (n = 12) used navigation to: (a) provide health education on PrEP and link eligible HIV negative MSM and transgender persons to PrEP providers and services; and (b) assess structural barriers to HIV prevention and care services and link persons to supportive services by addressing these barriers that may affect PrEP uptake (e.g., lack of health insurance, homelessness). Those implementing Data to Care (n = 5) used navigation to link MSM and transgender PWH into care.

¹Uptake in Project PrIDE: progress made in the PrEP continuum (i.e., referred to PrEP services, linked to a PrEP provider, PrEP prescription, and PrEP use).

2. Evaluation approach

2.1. Cluster evaluation approach

Each funded recipient conducted a local evaluation (LE) of at least one strategy and adhered to the steps and standards of the CDC Framework for Program Evaluation in Public Health (CDC, 1999). In addition, a cluster evaluation approach was used in Project PrIDE (Millet, 1995; Sanders, 1997). Cluster evaluation looks across a group of programs/projects that share similarities and identifies common high-level themes (Bitar, Hbeichi, & Al-Zou'bi, 2015). This was a collaborative process between funded recipients and CDC that took place between 2017 and 2019.

As part of this cluster evaluation process, funded recipients identified questions to be addressed in evaluating their PrIDE strategies/activities and independently developed data collection instruments. Of these questions, across all LEs, CDC identified those that were similar across strategies. For example, HD1 and HD2 posed similar questions: How well did PrEP navigation fit in the local setting? (HD1) and How well did PrEP Navigation fit into agencies settings? (HD2). Similar evaluation questions across funded recipients were grouped into five distinct project strategies (i.e., community engagement, provider capacity building, health equity, navigation, and media). Other questions, instrumental to understanding the implementation of strategies and the evaluation process (e.g., What were the lessons learned?) were also identified by both funded recipients and CDC. CDC shared these grouped questions with the funded recipients, and in turn, the funded recipients reviewed and provided feedback regarding the cluster evaluation process (including evaluation questions, data collection and reporting, and a data use plan). Specifically, over a seven-month time period, CDC and funded recipients participated in monthly conference calls that revolved around the thematic clusters to share progress and findings. Primary data sources of the analysis included funded recipients' 2018 and 2019 annual progress reports, notes from site visits and two in-person meetings with evaluators and program staff, and the final local evaluation reports submitted between the end of calendar years 2018 and 2019.

In cluster evaluation, data collection methods such as interviews with evaluation staff and documentation of site visits are used as data sources for analysis (Barley & Jenness, 1993; Bitar et al., 2015; Sanders, 2013). However, to prevent data burden on funded recipients, project documents became the main data source (i.e., LE protocol, a preliminary LE report, final LE report, notes from site visits and monthly cluster calls, and annual project meetings presentations). Document review analysis, a method used in evaluation, depends on the quality of the documents and how these help answer evaluation questions (Bowen, 2009; Caulley, 1983; Gross, 2018). Therefore, each LE protocol, preliminary report and final report were assessed at CDC by a multidisciplinary review team against all quality evaluation standards (i.e., utility, feasibility, propriety, and accuracy) (CDC, 1999; Yarbrough, Shulha, Hopson, & Caruthers, 2011), feedback was provided, and these documents were not approved until all standards were met. In addition, the preliminary LE report was submitted to CDC to ensure that local evaluations were answering the evaluation questions and measuring progress. This process was conducted with the final LE report crafted to capture contextual factors that affected the project and LE (e.g., state

and local policies affecting racial/ethnic, sexual and gender minorities, PrEP implementation maturity), facilitators and challenges of each evaluation stage (i.e., protocol development, implementation, analysis, utilization and dissemination), findings per question, a section dedicated to the cluster evaluation questions, and a utilization plan. Additionally, specific questions regarding LE and cluster questions were shared in preparation to annual site visits and discussed accordingly. Presentations at the monthly cluster calls and annual project meetings also aided in this process.

Two independent reviewers abstracted information from the cluster evaluation questions (see Table 1) that belong to the five funded recipients that evaluated PrEP navigation and used a health-framework method with a simplified qualitative content analysis for identifying themes (Gale, Heath, Cameron, Rashid, & Redwood, 2013). This was an interactive process that also involved discussions to reach consensus about themes and conclusions until both colleagues agreed 100 % and conferred with funded recipients as needed.

2.2. Cluster description

Of 12 PrIDE funded recipients, five examined similar questions related to PrEP navigation (i.e., Chicago Department of Public Health, New York City Department of Health and Mental Hygiene, Colorado Department of Public Health and Environment, California Department of Public Health Office of AIDS, and the Tennessee Department of Health; hereinafter called by the state or city they represent). Table 1 summarizes the navigation setting, modalities used by the funded recipients, and the cluster evaluation questions.

Based on Table 1, all cluster funded recipients (i.e., California, Chicago, Colorado, New York City, Tennessee) implemented PrEP navigation at health department clinics (HDCs) and four of them (i.e., California, Chicago, Colorado, Tennessee) also implemented it at community-based organizations (CBOs). Chicago was the only funded recipient that also implemented navigation at hospitals. For the purpose of this article, the designation of the modality derived from conversations with funded recipients about the type of navigation modality they used (see Background for definitions). The patient navigation modality was implemented by all funded recipients followed by systems ($n = 4$) and peer ($n = 4$) navigation. Most funded recipients (i.e., California, Chicago, New York City, Tennessee) combined the three navigation modalities. However, despite the type of services provided by navigators (e.g., linkage to housing) or the characteristics they shared with clients (e.g., being a transgender woman), Tennessee and California, in practice, did not label their PrEP navigation modalities as systems or peer navigation.

The types of evaluations conducted by funded recipients in this cluster were influenced by program maturity (i.e., program's stage of development) (CDC, 1999). For instance, PrEP navigation was implemented by funded recipients in this cluster for the first time with Project PrIDE. Therefore, it was not surprising to see that most of them (i.e., Chicago, Colorado, New York City, and Tennessee) conducted process evaluations to determine if navigation fit in their PrEP delivery settings rather than the impact of navigation. The use of process evaluation with a combination of outcome monitoring occurred in a couple of instances (i.e., California, Tennessee). Colorado was the only funded recipient that compared two navigation approaches (i.e., co-located and distributed) via mixed methods. (For more

specifics, please see Frank et al., Green et al., Parrish et al., and Pichon et al., in this special issue).

3. Overarching findings

3.1. How was PrEP Navigation defined?

Irrespective of the nascency of PrEP Navigation all five funded recipients defined PrEP navigation as a service where a navigator (peer or non-peer) helped an individual receive timely, essential, and appropriate PrEP and social supportive services (e.g., insurance enrollment, transportation, adherence counseling, PrEP prescription pick-up). This was unexpected given the lack of consensus on a standard definition of patient navigation (Mizuno et al., 2018). Such similarity was likely influenced by multiple interactions among funded recipients, including local evaluation meetings and funded recipient meetings, which sparked collaboration and relationship building. At a minimum, navigators provided PrEP and sexual health education, referral and linkage to PrEP and other services (e.g., support groups) and providers, guided individuals through the health care system (e.g., appointment scheduling, obtaining the medication in a timely manner), enrolled clients in PrEP financial assistance (e.g., insurance co-pay) and other social services (e.g., transportation, language interpretation), and advocated for the clients' right to receive high quality services.

3.2. Did PrEP Navigation fit into agency settings?

Evaluation findings from Chicago, Colorado, New York City, and Tennessee concluded that PrEP navigation fit well with both local government and community clinics delivering PrEP as per their definitions of "fit" (see Table 1). Navigators helped clients: accept PrEP referrals and linked them to a PrEP provider in New York City, link to PrEP providers in Tennessee, obtain PrEP prescription in Colorado, and both clients and agency staff felt satisfied with navigation services in Chicago. Although California did not measure navigation fit, their outcome monitoring data showed that navigators referred and linked clients to PrEP providers. (For more details on the fit of navigation see Green et al., Frank et al., Parrish et al., and Pichon, et al. in this special issue).

3.3. What did result from different navigation modalities?

The PrEP navigation modality undertaken was a hybrid of patient, peer, and systems navigation for four of the five sites. The hybrid modality is consistent with the definition of PrEP navigation in Project PrIDE and reflects the roles and responsibilities of navigators facilitating the removal of structural barriers to access PrEP and other health and social services. Colorado was the only funded recipient that implemented and compared two navigation approaches (see Table 1) and demonstrated that compared to on site navigators linking to external PrEP providers, navigation services with clinical provider(s) on site (i.e., co-located) and with payment assistance and insurance navigation had the greatest PrEP uptake. This finding highlights the benefit of offering clinical and non-clinical PrEP services to clients in one place which facilitates clients' access to PrEP services (see Franck et al., in this special issue). A co-located approach can ameliorate barriers such as time constraints (Felsher et al., 2018), PrEP cost and lack of insurance (Wood et al., 2018), and low/limited income. This is particularly important when there is a low PrEP uptake

among racial and gender minorities who are disproportionately affected by HIV (Mayer, Agwu, & Malebranche, 2020). Besides modalities and approaches, findings from three sites (California, Chicago and Tennessee) found no differences in linkage to a PrEP provider by type of agency in which navigation services were offered (i.e., CBO versus health clinic).

3.4. What were PrEP navigation facilitators and barriers?

Several cross-site factors were found to facilitate PrEP navigation implementation. These were navigator skills (i.e., case management, rapport building), behaviors (i.e., consistent follow-up with clients, staff easing client navigation process such as scheduling appointments), and other characteristics (i.e., willingness of navigators to receive client feedback and agency input into the navigation process). Barriers to PrEP navigation included staff turnover at two sites (Chicago and Tennessee) which indicated that navigators then needed to start the relationship building process over with the new staff. Moreover, private space constraints (Chicago), two sites (California and Tennessee) noted as a barrier the need for navigators to advocate for clients who experienced medical mistrust, and in one location (Tennessee) the limited number of providers willing to provide PrEP was also a barrier. Furthermore, assistance with payment was also an issue for navigators in multiple locations (California, Chicago, Tennessee, and New York City). In Tennessee, a state that has not expanded Medicaid as part of the Affordable Care Act (U.S. Centers for Medicare & Medicaid, 2016), navigators needed to support patients through a fragmented health care system to find coverage for PrEP. (For more details on navigation facilitators and barriers, see Frank et al., Green et al., Parrish et al., and Pichon et al. in this special issue, and Saleh, 2019 about New York City).

4. Limitations

In cluster evaluation, funders do not dictate how programs will be implemented or evaluated (Sanders, 2013). Hence, it was appropriate for Project PrIDE. On one hand, it allowed implementers to learn from each other, share evaluation findings, and cross collaborate (e.g., sharing data collection instruments). On the other hand, findings across the five HDs increased funder's understanding of the contexts surrounding the fit of navigation in different settings, navigation modalities and contribution to PrEP outcomes, including uptake. However, there are some limitations to be highlighted. Although in cluster evaluation quantitative outcome data tends to be aggregated across sites (Sanders, 2010), this was not possible because PrEP navigation fit varied across sites and was mainly assessed qualitatively. In addition, even when there were common evaluation questions across sites and outcome definitions, program strategies were implemented differently, including data collection methods and instruments. This underscores the importance of discussing with funded recipients during LE protocol development questions they have in common, and feasibility of at least using the same data collection sources, methods, and data collection instruments.

5. Conclusions and future directions for public health and evaluation

Five funded recipients demonstrated PrEP navigation delivered in a variety of settings and for sexual, gender and racial/ethnic minority groups as a promising strategy for

PrEP uptake. Navigators' management and rapport building skills as well as consistently following-up with clients and welcoming feedback from clients and employers are critical when implementing PrEP navigation. These findings are valuable as the United States of America embarks on ending the HIV epidemic by 2030 as PrEP is an important part of the "Prevent" pillar which consists of using proven interventions, including PrEP, to stop new HIV infections (Fauci, Redfield, Sigounas, Weahkee, & Giroir, 2019).

Although only one funded recipient (i.e., Colorado) evaluated and demonstrated the benefit of co-located navigators and PrEP prescribers, further evaluations are needed to assess this co-location in other settings (e.g., CBOs) and geographical regions like the Southern United States, where there is a disproportionate burden of new HIV diagnoses (CDC, 2019b). Since most of the evaluations conducted were process, effectiveness type of questions were not posed by most funded recipients. Therefore, it is necessary to: (a) determine if and how navigation settings or services for different populations (e.g., CBO vs. clinical, MSM vs. transgender focused) affect PrEP use and adherence or persistence among racial/ethnic groups; (b) identify which components of PrEP navigation are the most effective among sexual and racial/ethnic minorities; and (c) identify key characteristics of PrEP navigators (e.g., cultural competence, work engagement, empathy) to support training and workforce development. As PrEP navigation matures as an HIV prevention strategy, outcome evaluation and economic evaluation (i.e., cost analysis, cost-effectiveness evaluation) will be needed. Outcome evaluation will help determine the effectiveness of PrEP navigation at increasing PrEP uptake by sexual and racial/ethnic minorities in different settings. Cost analysis will help health departments in understanding the costs of implementing navigation, and cost-effectiveness evaluation will quantify the cost of PrEP navigation relative to the program benefits to guide resource allocation decisions (CDC, 2019a).

When working with racial/ethnic and sexual minorities it is essential not only to assess if a person is eligible for PrEP, but also to understand any social and structural barriers they face that may precipitate HIV inequities (e.g., disproportionately low use of PrEP) (Arnold et al., 2017). Therefore, the use of systems navigation to address social and structural barriers becomes important. For example, providing health insurance payment and other supportive services (e.g. transportation assistance, co-pay assistance, housing services, and employment resources) were highlighted as helpful components of navigation across funded recipients since this helps address structural factors that affect accessibility of PrEP services for priority populations (Patel et al., 2017). This finding underscores the need to educate clinical providers about supportive/social services, including payment options for clients, and how federal/state policies can contribute or become a barrier to the achievement of HIV elimination by 2030.

The delivery of culturally appropriate services is vital (Cargill & Stone, 2005; Dean & Fenton, 2010). For instance, during the delivery of PrEP navigation services in Project PrIDE, navigators became a primary resource for clients for PrEP and other related needs (e.g., health insurance). The fact that the navigator was a trusted resource for PrEP education was a remarkable finding considering the potential medical mistrust among priority groups as a result of racist historical medical studies (e.g., Tuskegee Syphilis Study, U.S. Public

Health Service STD Studies in Guatemala) (Brandt, 1978; Presidential Commission for the Study of Bioethical Issues, 2011; Washington, 2006) and institutional racism, xenophobia, homophobia and transphobia, all of which contribute to medical mistrust and HIV disparities (Arayasirikul, Wilson, & Raymond, 2017; Eaton, Driffin, Kegler et al., 2015; Guilamo-Ramos et al., 2020).

Besides cluster evaluation findings, there were lessons relevant to program planning to be shared with those intending to implement PrEP navigation among racial/ethnic, sexual and gender minorities. For instance, to make sure that services provided by navigators were appropriate for and well received by priority groups, cultural humility and culturally appropriate PrEP care trainings were part of navigators' training curriculum. This effort was driven by funded recipients and they shared materials with each other and contracted out facilitators specialized in health equity with experience working with priority groups.

At site visits and meetings with HDs there were opportunities to hear directly from navigators. Exhaustion due to constant follow-up with clients (e.g., taking clients to PrEP appointments), difficult life situations among clients (e.g., being homeless), and navigator turn over were recurrent themes. Therefore, having an appropriate caseload to prevent navigator burn out and having access to counseling sessions to learn how to manage negative emotions need to be considered when planning and implementing this strategy.

6. Next site-specific evaluations

The next four manuscripts represent individual evaluations of PrEP navigation programs conducted in Project PrIDE by the California Department of Public Health Office of AIDS, the Chicago Department of Public Health, the Colorado Department of Public Health and Environment, and the Tennessee Department of Health. Each manuscript provides background information regarding HIV among racial/ethnic minorities and among MSM and transgender populations in their jurisdictions, the evaluation methodology used, findings, conclusions and lessons learned. Information about LE conducted by the New York City Department of Health and Mental Hygiene can be found at Saleh et al. (2019).

Acknowledgements

We express our appreciation to Dr. Zoe Edelstein (New York City Department of Health and Mental Hygiene), Ms. Christine Borges (New York City Department of Health and Mental Hygiene), Dr. Sarah McKenney (New York City Department of Health and Mental Hygiene), Ms. Kolbi Parrish (California Office of AIDS), Dr. Sheryl Williams (California Department of Health Office of AIDS), Ms. Hannah Johnson (California Department of Health Office of AIDS), Dr. William Robinson (Louisiana Department of Health), Ms. Leslie Frank (Colorado Department of Public Health and Environment), Dr. Erin Starzyk (Colorado Department of Public Health and Environment), Dr. Linda Koenig, (CDC), and Dr. Yuko Mizuno (CDC) for their valuable feedback on an early draft of this manuscript. Project PrIDE was funded by the Centers for Disease Control and Prevention (PS15-1506: Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons).

Biographies

Yamir Salabarría-Peña, DrPH, MPHE is a Senior Health Scientist at the Centers for Disease Control and Prevention (CDC) where she has led the local evaluation component of various multi-site demonstration projects, including PrEP, Data-to-Care, and Evaluation

(PrIDE). For more than 20 years, Dr. Salabarría-Peña has provided expert consultation to public health programs US domestically and internationally. She has academic training and several years of experience in program planning and evaluation. Dr. Salabarría-Peña holds a Doctor of Public Health in Health Promotion and Education from Loma Linda University, and a Master's and Bachelor of Science degrees in Health Education from the University of Puerto Rico.

Chelsea Douglas, MPH was an ORISE Fellow at the Centers for Disease Control and Prevention in the Division of HIV/AIDS Prevention when this manuscript was developed. She supported Project PrIDE, a 3-year multi-site demonstration project implemented in 12 health departments in the U.S. to increase their capacity to deliver pre-exposure prophylaxis services and re-engage people with HIV into medical care. She is a behavioral researcher trained in qualitative methods and health education sciences. Her domestic research experiences have centered on examining the social contexts and structural exposures that increase HIV/STI risk among Black/African American women.

Meredith Brantley, PhD, MPH is the HIV Program Director at the Tennessee Department of Health. Previously, Dr. Brantley held roles at the Health Resources and Services Administration HIV/AIDS Bureau, Johns Hopkins University Center for Child & Community Health Research, and the Centers for Disease Control and Prevention Divisions of Global HIV/AIDS and Viral Hepatitis. Dr. Brantley received her BS in Molecular Biology from the University of Michigan, her MPH in Epidemiology from Emory, and her Doctorate in Social and Behavioral Sciences from Johns Hopkins University.

Amy K. Johnson, PhD MSW is a Research Assistant Professor at Ann and Robert H. Lurie Children's Hospital of Chicago and Northwestern University where her focus is on high priority areas of HIV intervention implementation, risk assessment and developing/assessing prevention packages. Dr. Johnson has over a decade of experience in the HIV field, as both a community-engaged researcher and as a program evaluator.

References

- AIDSinfo. (2020). PrEP navigation definition. Retrieved from <https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/4692/prep-navigation>.
- Arayasirikul S, Wilson EC, & Raymond HF (2017). Examining the effects of transphobic discrimination and race on HIV risk among transwomen in San Francisco. *AIDS and Behavior*, 21(9), 2628–2633. 10.1007/s10461-017-1728-3 [PubMed: 28220311]
- Arnold T, Brinkley-Rubinstein L, Chan PA, Perez-Brumer A, Bologna ES, Beauchamps L, et al. (2017). Social, structural, behavioral and clinical factors influencing retention in Pre-Exposure Prophylaxis (PrEP) care in Mississippi. *PloS One*, 12(2), e0172354. 10.1371/journal.pone.0172354 [PubMed: 28222118]
- Barley ZA, & Jenness M (1993). Cluster evaluation: A method to strengthen evaluation in smaller programs with similar purposes. *The American Journal of Evaluation*, 14(2), 141–147.
- Beach LB, Greene GJ, Lindeman PT, Johnson AK, Adames CN, Thomann M, et al. (2018). Barriers and facilitators to seeking HIV services in Chicago among young men who have sex with men: Perspectives of HIV service providers. *AIDS Patient Care and STDs*, 32(11), 468–476. 10.1089/apc.2018.0094 [PubMed: 30398956]

- Belfon K, Cheek J, Irvine M, Penrose K, Carmons J, & Harriman G (2018). Addressing barriers to PrEP through client-centered care coordination [Conference presentation]. In 2018 Ending the Epidemic Summit.
- Bishop SE, Edwards SJ, & Nadkarni SE (2009). Charlottesville health access: A locality-based model of health care navigation for the homeless. *Journal of Health Care for the Poor and Underserved*, 20, 958–963. 10.1353/hpu.0.0219 [PubMed: 20168009]
- Bitar K, Hbeichi R, & Al-Zou'bi L (2015). Evaluation capacity development through cluster evaluation. *Journal of Multidisciplinary Evaluation*, 11(24), 68–75. ISSN 1556–8180.
- Bowen G (2009). Document analysis as a qualitative research method. *Qualitative Research Journal*, 9(2), 27–40. 10.3316/QRJ09020
- Bradford JB, Coleman S, & Cunningham W (2007). HIV system navigation: An emerging model to improve HIV care access. *AIDS Patient Care and STDs*, 21. 10.1089/apc.2007.9987. S–58.
- Brandt AM (1978). Racism and research: The case of the Tuskegee syphilis study. *The Hastings Center Report*, 8(6), 21–29. 10.2307/3561468
- Broeckaert L, & Challacombe L (2014). Health navigation: A review of the evidence. Retrieved from <https://www.thebodypro.com/article/health-navigation-a-review-of-the-evidence>.
- Cargill VA, & Stone VE (2005). HIV/AIDS: A minority health issue. *The Medical Clinics of North America*, 89(4), 895–912. 10.1016/j.mcna.2005.03.005 [PubMed: 15925655]
- Carter N, Valaitis RK, Lam A, Feather J, Nicholl J, & Cleghorn L (2018). Navigation delivery models and roles of navigators in primary care: A scoping literature review. *BMC Health Services Research*, 18(1), 96. 10.1186/s12913-018-2889-0 [PubMed: 29422057]
- Caulley D (1983). Document analysis in program evaluation. *Evaluation and Program Planning*, 6, 19–29. 10.1016/0149-7189(83)90041-1
- Centers for Disease Control and Prevention. (1999). Framework for program evaluation in public health. *MMWR*, 48(RR11). Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm>.
- Centers for Disease Control and Prevention. (2019a). Cost-effectiveness analysis (CEA). Retrieved from <https://www.cdc.gov/policy/polaris/economics/cost-effectiveness.html>.
- Centers for Disease Control and Prevention. (2019b). HIV in the southern united states. Retrieved from <https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf>. Accessed April 21, 2020.
- Cunningham WE, Weiss RE, Nakazono T, Malek MA, Shoptaw SJ, Ettner SL, et al. (2018). Effectiveness of a peer navigation intervention to sustain viral suppression among HIV-Positive men and transgender women released from jail: The LINK LA randomized clinical trial. *JAMA Internal Medicine*, 178(4), 542–553. 10.1001/jamainternmed.2018.0150 [PubMed: 29532059]
- Dean HD, & Fenton KA (2010). Addressing social determinants of health in the prevention and control of HIV/AIDS, viral hepatitis, sexually transmitted infections, and tuberculosis. *Public Health Reports*, 125(Suppl. 4), 1–5. 10.1177/00333549101250S401
- Dohan D, & Schrag D (2005). Using navigators to improve care of underserved patients: Current practices and approaches. *Cancer*, 104(4), 848–855. 10.1002/cncr.21214 [PubMed: 16010658]
- Eaton LA, Driffin DD, Bauermeister JA, Smith HI, & Conway-Washington C (2015). Minimal awareness and stalled uptake of pre-exposure prophylaxis (PrEP) among at risk, HIV-negative, black men who have sex with men. *AIDS Patient Care and STDs*, 29(8), 423–429. 10.1089/apc.2014.0303 [PubMed: 26083143]
- Eaton LA, Driffin DD, Kegler C, Smith H, Conway-Washington C, White D, et al. (2015). The role of stigma and medical mistrust in the routine health care engagement of black men who have sex with men. *American Journal of Public Health*, 105(2), e75–e82. 10.2105/AJPH.2014.302322
- Fauci AS, Redfield RR, Sigounas G, Weahkee MD, & Giroir BP (2019). Ending the HIV epidemic: A plan for the United States. *Journal of the American Medical Association*, 321(9), 844–845. 10.1001/jama.2019.1343 [PubMed: 30730529]
- Felsher M, Szep Z, Krakower D, Martinez-Donate A, Tran N, & Roth AM (2018). “I don’t need PrEP right now”: a qualitative exploration of the barriers to PrEP care engagement through the application of the health belief model. *AIDS Education and Prevention*, 30, 369–381. [PubMed: 30332306]

- Ferrante JM, Cohen DJ, & Crosson JC (2010). Translating the patient navigator approach to meet the needs of primary care. *The Journal of the American Board of Family Medicine*, 23(6), 736–744. [PubMed: 21057069]
- Freeman HP, & Rodriguez RL (2011). History and principles of patient navigation. *Cancer*, 117(Suppl. 15), 3539–3542. 10.1002/cncr.26262 [PubMed: 21780088]
- Gale NK, Heath G, Cameron E, Rashid S, & Redwood S (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13(117), 1–8. 10.1186/1471-2288-13-117 [PubMed: 23297754]
- Galvan FH, Bogart LM, Klein DJ, Wagner GJ, & Chen YT (2017). Medical mistrust as a key mediator in the association between perceived discrimination and adherence to antiretroviral therapy among HIV-positive Latino men. *Journal of Behavioral Medicine*, 40(5), 784–793. 10.1007/s10865-017-9843-1 [PubMed: 28337560]
- Gross JM (2018). Document analysis. In Frey BB (Ed.), *The SAGE encyclopedia of educational research, measurement, and evaluation* (pp. 545–548). 10.4135/9781506326139.n209
- Grov C, Whitfield TH, Rendina HJ, Ventuneac A, & Parsons JT (2015). Willingness to take PrEP and potential for risk compensation among highly sexually active gay and bisexual men. *AIDS and Behavior*, 19, 2234–2244. 10.1089/lgbt.2015.0123 [PubMed: 25735243]
- Guilamo-Ramos V, Thimm-Kaiser M, Benzekri A, Chacón G, López O, Scaccabarrozzi L, et al. (2020). The invisible US Hispanic/Latino HIV crisis: Addressing gaps in the national response. *American Journal of Public Health*, 110(27), 31. 10.2105/AJPH.2019.305309
- Hede K (2006). Agencies look to patient navigators to reduce cancer care disparities. *Journal of the National Cancer Institute*, 98(3), 157–159. 10.1093/jnci/djj059 [PubMed: 16449671]
- Hendren SK, Chin N, Fisher S, Winters PE, Griggs J, Mohile SG, et al. (2011). Patients' barriers to receipt of cancer care, and factors associated with needing more assistance from a patient navigator. *Journal of the National Medical Association*, 103 (8), 701–710. 10.1016/S0027-9684(15)30409-0 [PubMed: 22046847]
- Karwa R, Maina M, Mercer T, Njuguna B, Wachira J, Ngetich C, et al. (2017). Leveraging peer-based support to facilitate HIV care in Kenya. *PLoS Medicine*, 14(7), Article e1002355. 10.1371/journal.pmed.1002355
- Koester KA, Morewitz M, Pearson C, Weeks J, Packard R, Estes M, et al. (2014). Patient navigation facilitates medical and social services engagement among HIV-infected individuals leaving jail and returning to the community. *AIDS Patient Care and STDs*, 28(2), 82–90. 10.1089/apc.2013.0279 [PubMed: 24517539]
- Manderson B, McMurray J, Piraino E, & Stolee P (2012). Navigation roles support chronically ill older adults through healthcare transitions: A systematic review of the literature. *Health & Social Care in the Community*, 20(2), 113–127. 10.1111/j.1365-2524.2011.01032.x [PubMed: 21995806]
- Marks GW, Crepaz N, Senterfitt JW, & Janssen RS (2005). Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: Implications for HIV prevention programs. *Journal of Acquired Immune Deficiency Syndromes*, 39(4), 446–453. 10.1097/01.qai.0000151079.33935.79 [PubMed: 16010168]
- Mayer KH, Agwu A, & Malebranche D (2020). Barriers to the wider use of pre-exposure prophylaxis in the United States: A narrative review. *Advances in Therapy*, 37, 1778–1811. 10.1007/s12325-020-01295-0 [PubMed: 32232664]
- Millet R (1995). W. K. Kellogg Foundation cluster evaluation model of evolving practices. Battle Creek, MI: W. K. Kellogg Foundation.
- Mizuno Y, Higa DH, Leighton CA, Roland KB, Deluca JB, & Koenig LJ (2018). Is HIV patient navigation associated with HIV care continuum outcomes? *AIDS*, 32(17), 2557–2571. 10.1097/QAD.0000000000001987 [PubMed: 30102661]
- National Minority AIDS Council. (2012). HIV navigation services toolkit. Retrieved from http://nmac.org/wp-content/uploads/2012/08/OES-HNS_FINAL_9-3-2015.pdf.
- Pagkas-Bather J, Jaramillo J, Henry J, Grandberry V, Ramirez LF, Cervantes L, et al. (2020). What's PrEP?: Peer navigator acceptability among minority MSM in Washington. *BMC Public Health*, 20(1), 248. 10.1186/s12889-020-8325-5 [PubMed: 32070318]

- Parsons JT, Rendina HJ, Whitfield TH, & Grov C (2016). Familiarity with and preferences for oral and long-acting injectable HIV pre-exposure prophylaxis (PrEP) in a national sample of gay and bisexual men in the U.S. *AIDS and Behavior*, 20, 1390–1399. 10.1007/s10461-016-1370-5 [PubMed: 27000145]
- Patel RR, Mena L, Nunn A, McBride T, Harrison LC, Oldenburg CE, et al. (2017). Impact of insurance coverage on utilization of pre-exposure prophylaxis for HIV prevention. *PloS One*, 12(5), Article e0178737. 10.1371/journal.pone.0178737
- Pellowski JA, Price DM, Allen AM, Eaton LA, & Kalichman SC (2017). The differences between medical trust and mistrust and their respective influences on medication beliefs and ART adherence among African-Americans living with HIV. *Psychology & Health*, 32(9), 1127–1139. [PubMed: 28475365]
- Presidential Commission for the Study of Bioethical Issues. (2011). ‘Ethically Impossible’ STD Research in Guatemala from 1946 to 1948. Washington, D.C. September 2011 STD. 10.13016/p3t8-tf3y.
- Reback CJ, Clark KA, Rünger D, & Fehrenbacher AE (2019). A promising PrEP navigation intervention for transgender women and men who have sex with men experiencing multiple syndemic health disparities. *Journal of Community Health*, 44 (6), 1193–1203. 10.1007/s10900-019-00705-x [PubMed: 31317438]
- Saleh L, Borges C, Hedberg T, Klajman J, Edelstein Z, Jamison K, et al. (2019). A tale of two models: Outcomes of PrEP navigation performed by community-based organization staff in CBO settings and embedded in sexual health clinics. In National HIV Prevention Conference [Abstract]. 2019. Abstract Book ([cdc.gov](https://www.cdc.gov)).
- Sanders JR (1997). Cluster evaluation. In Chelimsky E, & Shadish WR (Eds.), *Evaluation for the 21st century: A handbook* (pp. 396–404). Thousand Oaks, CA: Sage.
- Sanders JR (2010). The oral history of evaluation; the professional development of James R. Sanders. *The American Journal of Evaluation*, 31(1), 118–130. 10.1177/1098214009346332
- Sanders JR (2013). Cluster evaluation. In Chelimsky E, & Shadis WR (Eds.), *Evaluation for the 21st century: A handbook* (pp. 396–404). Thousand Oaks, CA: SAGE Publications, Inc.. 10.4135/9781483348896
- Serota DP, Rosenberg ES, Lockard AM, Rolle CM, Luisi N, Cutro S, et al. (2018). Beyond the biomedical: Preexposure prophylaxis failures in a cohort of young black men who have sex with men in Atlanta, Georgia. *Clinical Infectious Diseases: an official publication of the Infectious Diseases Society of America*, 67(6), 965–970. 10.1093/cid/ciy297 [PubMed: 29635415]
- Sofaer S (2009). Navigating poorly charted territory patient dilemmas in health care “nonsystems”. *Medical Care Research and Review*, 66(1 suppl), 75S–93S. 10.1177/1077558708327945 [PubMed: 19074306]
- Spinelli M, Scott H, Vittinghoff E, Liu A, Morehead-Gee A, Gonzalez R, et al. (2018). Brief report: A panel management and patient navigation intervention is associated with earlier PrEP initiation in a safety-net primary care health system. *Journal of Acquired Immune Deficiency Syndromes*, 79(3), 347–351. 10.1097/QAI.0000000000001828. [PubMed: 30085955]
- Thoms EJ, & Moore D (2012). The emerging field of patient navigation: A golden opportunity to improve healthcare. *The Centre for Health Affairs*, 1, 16.
- U.S. Centers for Medicare & Medicaid Services. Coverage Expansion as of July 2016. Accessed from <https://www.medicaid.gov/media/1821> on March 5, 2020.
- Underhill K, Morrow K, Collieran C, Calabrese SK, Operario D, Salovey P, et al. (2016). Explaining the efficacy of pre-exposure prophylaxis (PrEP) for HIV prevention: A qualitative study of message framing and messaging preferences among US men who have sex with men. *AIDS and Behavior*, 20, 1514–1526. 10.1007/s10461-015-1088-9 [PubMed: 25963772]
- Vargas RB, & Cunningham WE (2006). Evolving trends in medical care-coordination for patients with HIV and AIDS. *Current HIV/AIDS Reports*. 10.1007/s11904-006-0009-y
- Washington HA (2006). *Medical apartheid: The dark history of medical experimentation on Black Americans from colonial times to the present*. New York: Doubleday.
- Westergaard RP, Genz A, Panico K, Surkan PJ, Keruly J, Hutton HE, et al. (2017). Acceptability of a mobile health intervention to enhance HIV care coordination for patients with substance

use disorders. *Addiction Science & Clinical Practice*, 12(1), 11. 10.1186/s13722-017-0076-y [PubMed: 28441962]

Wood BR, McMahan VM, Naismith K, Stockton JB, Delaney LA, & Stekler JD (2018). Knowledge, practices, and barriers to HIV preexposure prophylaxis prescribing among Washington State medical providers. *Sexually Transmitted Diseases*, 45, 452–258. [PubMed: 29465664]

World Health Organization. (2010). A conceptual framework for action on the social determinants of health. Social determinants of health discussion paper 2. Geneva, Switzerland: World Health Organization (who.int) [ConceptualframeworkforactiononSDH_eng.pdf](#).

Yarbrough DB, Shulha LM, Hopson RK, & Caruthers FA (2011). *The program evaluation standards: A guide for evaluators and evaluation users* (3rd ed.). Thousand Oaks, CA: SAGE Publications, Inc.

Table 1

Description of Navigation Cluster.

Funded Recipient (City/State Health Department)	PrEP Navigation Setting	Navigation Modality	Cluster Evaluation Questions		Type of Evaluation
1. California	Health department clinics (HDC) and community-based organizations (CBOs)	Patient, Peer and Systems	a.	How did funded recipients define PrEP navigation?	Process evaluation and outcome monitoring
			b.	Did Navigation fit into agency settings? Fit was defined as follows: <ul style="list-style-type: none"> Chicago: staffing and client satisfaction 	
2. Chicago	CBOs, HDCs, hospitals and community health centers	Patient, Peer and Systems		<ul style="list-style-type: none"> Colorado: PrEP use NYC: accepting PrEP referrals, linkage to a PrEP provider, and PrEP care 	Process evaluation
3. Colorado	HDC and Health Systems CBOs	Patient and Systems with two approaches <ul style="list-style-type: none"> <i>Co-located:</i> Navigator and prescriber on site <i>Distributed:</i> Navigator on site and external prescriber 	c.	What did result from different navigation modalities?	Outcome evaluation without a control group
			d.	What were PrEP navigation facilitators and barriers?	
4. New York City (NYC)	Sexual Health Clinics (HDC)	Patient, Peer and Systems			Process evaluation
5. Tennessee	CBOs and HDC	Patient, Peer, and Systems			Process evaluation and outcome monitoring

Note. HDC = health department clinics; CBOs = Community-based organizations; PrEP = pre-exposure prophylaxis.

^aPerson's attendance at the first appointment.