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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-22GA]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Expanding PrEP in Communities of Color (EPICC)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 13, 2022, to obtain comments from the public and affected agencies. CDC received 4 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW,

Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

"Expanding PrEP in Communities of Color (EPICC)– New - National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting approval for 36 months of data collection entitled, "Expanding PrEP in Communities of Color (EPICC)". The purpose of this study is to implement and evaluate the effectiveness of a clinic-based intervention that utilizes evidence-based education and support tools to 1. increase provider knowledge of and comfort with preexposure prophylaxis (PrEP) modalities in clinical practice and 2. improve PrEP adherence among young men who have sex with men (YMSM).

The information collected in this study will be used to 1) describe real-world PrEP use including factors influencing selection and change of PrEP regimens; 2) understand and describe barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; 3) evaluate the feasibility and acceptability of the EPICC+ mobile app among YMSM on PrEP;

and 4) evaluate the feasibility and acceptability of implementing a provider training.

This study has two aims: In aim 1 the study team will deliver training to health providers that will focus on implementation of evidence-based tools to enhance the providers' ability to engage in PrEP screening, counseling, initiation and to provide support for adherence and persistence. The study will utilize web-based computer-assisted surveys to measure healthcare provider knowledge both pre- and post-training. Post-training and at three months, providers will complete a patient interaction assessment via teleconference and receive personalized feedback to assess and enhance their tailored motivational interviewing skills.

For aim 2a, the study will initiate an effectiveness-implementation trial with 400 YMSM to test the effectiveness of the EPICC+ intervention package in increasing PrEP adherence and persistence among YMSM. The intervention will utilize a mobile app-based platform, EPICC+, to support ongoing participant engagement and monitoring, as well as to provide additional adherence support. YMSM participants will complete quarterly web-based computerized assessments during the 18-month follow up period. The assessments will measure PrEP knowledge, usage, and choice, and gather information about sexual behaviors, HIV status of partners, and substance use. YMSM participants will be mailed four dried blood spot collection kits to measure PrEP metabolites

(baseline, 6, 12, and 18 months). To further examine the participant experience and intervention satisfaction, a subset of YMSM participants (45) will be invited to participate in a web-based exit interview at the close of the follow up period (18 months). Additionally, study staff will collect paradata to measure mobile app use and conduct medical record abstractions three times during the follow up period (6, 12, and 18 months). In aim 2b the study team will conduct focus groups with health providers from the participating clinics to gather feedback on overall perceptions about the effectiveness of the intervention and the barriers and facilitators to implementation of the evidence-based tools (EBT) within their clinical site. Providers will complete a short web-based computer-assisted pre-focus group survey prior to the virtual two-hour focus group. To describe PrEP services implementation at the facility level, each participating clinic will complete a web-based computer-assisted clinic assessment at six-month intervals during the three-year data collection period (baseline, 6, 12, 18, 24, 30, and 36 months).

This study will be carried out in nine clinics located in Chicago, IL; Bronx, New York City, NY; Philadelphia, PA; Charlotte, NC; Raleigh, NC; Tuscaloosa, AL; Tampa, FL; Orlando, FL; and Houston, TX.

Aim 1 will include healthcare providers from the nine clinic sites, all involved in the direct delivery of PrEP services. Providers may include but are not limited to medical doctors, nurses, adherence counselors, pharmacists, and social workers. Health providers will be recruited via staff emails.
Aim 2a participants will include YMSM ages 18-39, inclusive. Participants will identify as a cisgender male; report sex with a man in the past 12 month; have an active prescription for PrEP; receive care at one of the nine participating study sites; provide a mailing address within the 50 states where packages can be received; have daily smartphone access; and be fluent in written/spoken English or Spanish. We will use purposive sampling to ensure at least 60% patient sample is African American or Black or Hispanic/Latino/Latinx. Patient participants will be recruited to the study using a combination of approaches including social media, referral and in-person outreach.
Aim 2b will include healthcare providers from the nine clinic sites, all involved in the direct delivery of PrEP services. Providers may include but are not limited to medical doctors, nurses, adherence counselors, pharmacists, and social workers. Health providers will be recruited via staff emails.

Overall, this study will enroll up to 487 participants. Total study enrollment for Aim 1 is 30 healthcare providers; over the

three-year study period, the estimated annual enrollment is 10. Total enrollment for Aim 2a is 400 YMSM; over the three-year study period, the estimated annual enrollment is 134. For Aim 2b, total study enrollment is 48 healthcare providers, and the estimated annual enrollment is 16. Additionally, a clinic staff member at each of the nine participating clinic sites will complete a clinic assessment form every 6 months throughout the study period.

For the Aim 1 provider training, it is expected that 50% of providers screened will meet eligibility and decide to enroll in the study. we estimate that screening and the collection of contact information will each take five minutes. Pre-training and post-training surveys will take approximately 15 minutes each to complete. Patient interaction assessments delivered at baseline and 3 months will take approximately 15 minutes each to complete. For Aim 2a, the effectiveness-implementation trial, it is expected that 50% of YMSM screened will meet study eligibility. The initial screening will take approximately five minutes to complete. The collection of contact information and the completion of the HIPAA form will take approximately five minutes each to complete. The baseline assessment will take approximately 45 minutes to complete. The follow-up assessments will take approximately 45 minutes to complete and will be administered quarterly for a total of six times during the 18-month follow up

period. Study staff will assist participants during the EPICC+ app setup, a process that will take 30 minutes. The app setup is required of all participants but app use after the setup is voluntary. Participants will be mailed a dried blood spot (DBS) specimen collection kit that will take approximately 30 minutes to read, collect the specimen, and ship. The patient exit interview takes approximately 60 minutes to complete and will be delivered one time to a subset (45) of YMSM participants.

For the Aim 2b provider focus groups, it is expected that 50% of providers screened will meet eligibility and decide to enroll in the study. We estimate it will take approximately five minutes to conduct the screening, five minutes to collect contact information, and another five minutes to conduct the pre-focus group survey. Providers will attend one focus group that is expected to take 120 minutes to complete.

Clinic-level assessments will be completed by clinic staff. The baseline and study end assessments are estimated to take 120 minutes to complete. The assessments conducted at six-month intervals between the baseline and study end points are expected to take 90 minute to complete.

CDC is requesting 3,535 total burden hours across 36-months of data collection. The total estimated annualized burden hours are 759. Participation of respondents is voluntary. There is no cost to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Health Practitioners	Aim 1 Provider Training Screener	20	1	2
Health Practitioners	Aim 1 Provider Training Contact Information	10	1	1
Health Practitioners	Aim 1 Provider Pre-Training Survey	10	1	3
Health Practitioners	Aim 1 Provider Post-Training Survey	10	1	3
Health Practitioners	Aim 1 Provider Patient Interaction	10	2	5
General Public - Adults	Aim 2a Cohort Screener	267	1	22
General Public - Adults	Aim 2a Cohort Contact Information	134	1	11
General Public - Adults	Aim 2a Cohort HIPAA Form	134	1	11
General Public - Adults	Aim 2a Cohort Baseline Survey	134	1	101
General Public - Adults	Aim 2a Cohort Follow-Up Survey	134	3	302
General	Aim 2a	134	1	67

Public - Adults	Cohort App Setup			
General Public - Adults	Aim 2a Cohort Blood Collection Instructions	134	2	134
General Public - Adults	Aim 2a Cohort Exit Interview	15	1	15
Health Practitioners	Aim 2b Provider Focus Group Screener	32	1	3
Health Practitioners	Aim 2b Provider Focus Group Contact Information	16	1	1
Health Practitioners	Aim 2b Provider Pre-Focus Group Survey	16	1	1
Health Practitioners	Aim 2b Provider Focus Group Guide	16	1	32
Health Practitioners	Aims 1&2 Clinic Assessment (Baseline and Final)	9	1	18
Health Practitioners	Aims 1&2 Clinic Assessment (every 6 months)	9	2	27

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