

individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity. GAO is now accepting nominations for HITAC appointments that will be effective January 1, 2023. Members serve 3-year terms, with the terms subject to renewal, for a total not to exceed 6 years of service on the committee. From these nominations, GAO expects to appoint at least 4 new HITAC members, focusing especially on patients or consumers, health care providers, ancillary health care workers, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information. Nominations should be sent to the email address listed below.

**DATES:** Letters of nomination and resumes should be submitted no later than July 22, 2022, to ensure adequate opportunity for review and consideration of nominees prior to appointment.

**ADDRESSES:** Submit letters of nomination and resumes to [HITCommittee@gao.gov](mailto:HITCommittee@gao.gov).

**FOR FURTHER INFORMATION CONTACT:** Shannon Legeer at (202) 512-3197 or [legeers@gao.gov](mailto:legeers@gao.gov) if you do not receive an acknowledgment within a week of submission or need additional information. For general information, contact GAO's Office of Public Affairs, (202) 512-4800.

*Authority:* Pub. L. 114-255, sec. 4003(e) (2016), 42 U.S.C. 300jj-12.

**Gene L. Dodaro,**

*Comptroller General of the United States.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-22-22GA; Docket No. CDC-2022-0076]

### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public

burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Expanding PrEP in Communities of Color (EPICC). The proposed study is designed to deliver training to health providers 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, and to test the effectiveness of the EPICC intervention.

**DATES:** CDC must receive written comments on or before August 12, 2022.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2022-0076 by either of the following methods:

- **Federal eRulemaking Portal:** [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.
- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

*Please note: Submit all comments through the Federal eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.*

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the

collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

### Proposed Project

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

### Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) is requesting approval for 36 months of a data collection titled 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).

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. 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 also

utilize a mobile app-based platform, HealthMPowerment (HMP) to support ongoing participant engagement and monitoring, as well as to provide additional adherence support. In Aim 2b the study team will conduct focus groups with providers to gather feedback on overall perceptions of the barriers and facilitators to implementation of evidence-based tools (EBT) within their clinical site.

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 EPIC+ mobile app among YMSM on PrEP; and (4) evaluate the feasibility and acceptability of implementing a provider training.

This study will be carried out in 10 clinics located in Chicago, IL; New York City, NY; Philadelphia, PA; Charlotte, NC; Raleigh, NC; Tuscaloosa, AL; Montgomery, AL; Tampa, FL; Orlando, FL; and Houston, TX. Aim 1 will include 30 health care providers from the 10 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 400 YMSM ages 18–39. Participants will identify as a cisgender male; report sex with a man in the past 12 months; have an active prescription for PrEP; receive care at one of the 10 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.

Quantitative and qualitative assessments will be used to collect information from providers and YMSM participants. For the Aim 1 provider training, assessments will include pre, post, 3-month, and 6-month surveys to evaluate provider information retention. Providers will also be asked to complete a brief survey at baseline, 3- and 6-months to assess their new patient interaction skills. For Aim 2a, YMSM participants will be asked to complete a baseline assessment and quarterly assessments at 3-, 6-, 9-, 12-, 15-, and 18-months to assess PrEP adherence; PrEP knowledge, usage and choice; sexual risk behaviors; HIV status of partners; and substance use assessment. A subset of YMSM participants from Aim 2a will be asked to complete an exit interview that will focus on understanding factors that influenced participants' selection of PrEP regimens, changes and/or discontinuations, as well as perceptions of the counseling they received by providers at PrEP initiation and follow-up, receipt of tools or materials that influenced choice and feasibility/acceptability of the HMP app. We will also conduct focus groups with providers in Aim 2b to gather feedback on overall perceptions of the barriers and facilitators to EBT implementation within their clinical site. The study will also collect data through from electronic health records; biological specimens collected at quarterly intervals; and a clinic assessment tool delivered every six months.

For the Aim 1 provider training, we estimate the collection of contact information will take five minutes. Pre-training, baseline and follow up surveys at 3- and 6-months will take approximately 15 minutes each to complete. Patient interaction

assessments delivered at baseline, 3-, and 6-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 five minutes to complete and the collection of contact information to take five minutes. The baseline assessment will take approximately 45 minutes to complete. The follow-up assessments will take 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 to setup the HMP app, a process that will take 30 minutes. The patient exit interview takes approximately 60 minutes to complete and will be delivered one time to a subset of 48 YMSM participants. For the Aim 2b provider focus groups, we estimate it will take approximately 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.

Total study enrollment for Aim 1 is 30, over the three-year study period the estimated annual enrollment is 10. Total enrollment for aim 2a is 400, over the three-year study period the estimated annual enrollment is 134. For the Aim 2a exit interview, 45 will participate for an annual enrollment of 15. For Aim 2b, total study enrollment is 48 and the estimated annual enrollment is 16. Additionally, a clinic staff member at each of the ten participating clinic sites will complete a clinic assessment form every six months throughout the study period.

The total number of burden hours is 2,055 across 36 months of data collection. The total estimated annualized burden hours are 685. There are no costs to the participant other than their time to participate.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
General Public—Adults .....	Aim 1 Provider Contact Information	10	1	5/60	1
General Public—Adults .....	Aim 1 Provider Training Survey .....	10	4	15/60	10
General Public—Adults .....	Aim 1 Patient Interaction Assessment.	10	3	15/60	8
General Public—Adults .....	Aim 2a Participant Eligibility Screen-er.	268	1	5/60	23
General Public—Adults .....	Aim 2a Participant Contact Informa-tion.	134	1	5/60	12
General Public—Adults .....	Aim 2a Baseline Assessment .....	134	1	45/60	101
General Public—Adults .....	Aim 2a Quarterly Assessments .....	134	4	45/60	402
General Public—Adults .....	Aim 2a HMP App Setup .....	134	1	30/60	67

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
General Public—Adults .....	Aim 2a Exit Interview .....	15	1	1	15
General Public—Adults .....	Aim 2b Provider Focus Group Contact Information.	16	1	5/60	2
General Public—Adults .....	Aim 2b Provider Focus Group Survey.	16	1	5/60	2
General Public—Adults .....	Aim 2b Provider Focus Group Guide	16	1	2	32
General Public—Adults .....	Clinic Assessment .....	10	2	30/60	10
Total .....	.....	.....	.....	.....	685

Jeffrey M. Zirger,

Lead, Information Collection Review Office,  
Office of Scientific Integrity, Office of Science,  
Centers for Disease Control and Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-22-21FC]

#### 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 “Nurse Fatigue-Mitigation Education: Does it Change Nurse Sleep Behavior?” 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 May 14, 2021 to obtain comments from the public and affected agencies. CDC received four 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](http://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

Nurse Fatigue-Mitigation Education: Does it Change Nurse Sleep Behavior?—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Many nurses in the United States work in around-the-clock healthcare facilities, providing necessary care to patients and the public. Providing these services requires nurses to work nonstandard hours, including shift work (e.g. early mornings, over-nights,

rotating between days and nights) and long work hours. These work organizational characteristics are primary factors contributing to sleep-related fatigue, and decreased health and well-being for nurses. Studies have found 36% of healthcare workers (including nurses) report sleeping less than the recommended 7–9 hours of sleep/24 hours, with prevalence rates climbing to a little over 50% for those working night shift. This is concerning, as insufficient sleep not only increases the risk for a patient care error to occur but can also jeopardize the health of nurses.

In 2015, the National Institutes for Occupational Safety and Health (NIOSH) published a free, publicly available, online resource to address the risks associated with shift work and other nonstandard work hours. This program, “Training for Nurses on Shift Work and Long Work Hours” provides information to nurses, nurse managers and other interested healthcare workers on the health and safety risks associated with nonstandard work hours. In addition, the training provides strategies for improving sleep and reducing fatigue-related risks when working shift work in the healthcare setting.

Over five years have passed since the training was published online. Since then, the nursing workforce has faced a changing healthcare landscape. In response, the two studies in this project have been designed to evaluate the effectiveness of the NIOSH Training for Nurses at improving nurses’ sleep and well-being, as well as assess the reach of training dissemination. This evaluation project will help NIOSH determine gaps in training distribution, identify needs to enhance training content and ensure the training is meeting its purpose.

This evaluation project consists of 2 studies.

**Part 1:** Part 1 goal is to provide a description of the registered nurses (RNs) who have already completed the