

NIOSH “Training for Nurses on Shift Work and Long Work Hours.” Part 1 will be a secondary analysis of pre-existing CDC data from individuals who have received continuing professional licensing education credits following the NIOSH nurse training completion. There are no associated burden hours with Part 1 since data were previously collected by CDC.

**Part 2:** Part 2 goal is to evaluate the effectiveness of the NIOSH nurse training on objective (i.e., sleep duration, efficiency, and timing with actigraphy watches) and subjective (i.e., sleep quality, daytime sleepiness) sleep health measures, and self-reported well-being. Part 2 will be a field study requiring recruitment of 50 RNs to volunteer to participate. Recruitment will take approximately three months through online platforms and with assistance of the nursing and health care connections through the NIOSH Health Care and Social Assistance Program, and NIOSH subject matter experts.

During Part 2, NIOSH will collect data before and after RNs complete the NIOSH Training for Nurses. RNs enrolled in the Part 2 study will be

asked to complete online surveys and wear an actigraphy watch during this study. Actigraphy watches are research grade sleep activity data collection instruments, similar to a wristwatch. Actigraphy watches will be supplied by NIOSH for participant use during the study. As part of baseline measures, RNs will be asked to complete an online survey with questions about demographics, workplace characteristics (i.e., job tenure, shift length), sleep quality, daytime sleepiness, and well-being. In addition, RNs will be asked to wear an actigraphy watch and complete online daily sleep diaries for seven days.

One month after baseline measures, participants will be asked to take the NIOSH online nurse training. The training takes approximately 3.5 hours to complete and participants will have the opportunity to receive continuing education credits for professional licensure upon training completion. After the online nurse training, participants will answer four immediate post-training online questions regarding behavioral intention and feedback on the participant training experience. The

participant will then be scheduled for the one-month post-training data collection period.

At each post-training follow-up period, participants will be asked to follow the same sampling protocol they completed at baseline: online survey (i.e., sleep quality, daytime sleepiness, wellbeing) and seven-day actigraphy and sleep/wake diary. Participants will also be asked three open-ended questions about adopted behavior strategies to improve sleep, as well as facilitators and barriers to adoption.

Data collected during Part 2 will allow us to compare sleep and well-being measures at baseline with 1-, 3-, and 6-months post-training. We will also examine the relationship between nurse characteristics (e.g., age, work tenure) and behavioral intention, and the relationship between behavioral intention and sleep health post-training at 1-month, 3-months, and 6-months.

CDC requests OMB approval for an estimated 341 annual burden hours. There are no costs to respondents other than their time to participate.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Registered Nurses .....	Baseline Survey .....	50	1	23/60
	Online Nurses Training .....	50	1	3.5
	Immediate Post-Training Survey .....	50	1	7/60
	Post-Training (1-, 3-, and 6-month) Surveys	50	3	16/60
	Consensus Sleep Diary .....	50	4	21/60
	Actigraphy Watch Training .....	50	1	10/60
	Actigraphy Watch Fitting .....	50	4	7/60

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[FR Doc. 2022-12698 Filed 6-10-22; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-22-22FZ; Docket No. CDC-2022-0075]

**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 mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings. The collection is part of a research study designed to implement and evaluate the effectiveness of an intervention that utilizes evidence-based education and support tools to

improve preexposure prophylaxis (PrEP) adherence among young men who have sex with men (YMSM).

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

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2022-0075 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:**

mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings—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 data collection entitled, “mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings.” 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 improve preexposure prophylaxis (PrEP) adherence among young men who have sex with men (YMSM). The goals of this research study are to: (1) improve the overall PrEP experience of providers and YMSM patients; and (2) increase our understanding of provider and patient factors that influence the choice of PrEP regimen by MSM in clinical settings. This study will be carried out in four clinics located in New York, NY (NYC) (two clinics) and Birmingham, AL (two clinics).

Aim 1 of the study will enroll 400 YMSM (ages 18–39) who identify as male, non-binary, or genderqueer; were assigned male sex at birth; are taking or initiating PrEP; own a smartphone; understand and read English or Spanish; have a self-reported history of sex with men in the past 12-months; and live in the NYC or Birmingham, AL areas. Participants may identify as any race or ethnicity, but to ensure a diverse sample comprised mainly of racial/ethnic minority participants, the study will utilize recruitment controls to enroll at least 50% African American/Black and/or Hispanic/Latino participants. Patient participants will be recruited to the study through a combination of approaches including flyers and social media, referral, in-person outreach, and through word of mouth. Rolling enrollment will continue until enrollment targets are reached. Each Aim 1 participant will be followed for 12 months. All participants will receive PrEP clinical services congruent with CDC PrEP guidelines. Participants using oral PrEP will receive CleverCap, an electronic medication monitoring device, that will track and support medication adherence. At the three-month study visit, participants using oral PrEP will receive the mChoice mobile phone application, an evidence-based intervention that supports PrEP use through medication monitoring, study staff interaction, and other resources. Aim 1 assessments include: a baseline survey of self-reported

demographic factors, sexual and drug use behaviors, and potential cofactors of sexual and drug use behavior including attitudes, beliefs, knowledge, traits, and other psychosocial factors; follow-up surveys at 3-, 6-, 9-, and 12-month study visits which will assess experiences with PrEP, PrEP adherence, and behavioral and social factors; medication adherence data from CleverCap; participant use and voluntary self-reported adherence and HIV exposure risk-related data from the mChoice app; PrEP clinical care data from clinic electronic medical records; and urine studies assessing PrEP adherence. The information collected in Aim 1 will be used to evaluate the effectiveness of the mChoice intervention to improve PrEP adherence and persistence, and to increase understanding of PrEP experiences and factors that influence PrEP choices among MSM in clinical settings.

Aim 2 of the study will enroll 30 YMSM who participated in Aim 1; 15 from New York and 15 from Alabama. Participants will be recruited at Aim 1 study visits. Study staff will conduct in-depth interviews with Aim 2 participants exploring their experiences with PrEP, reasons for PrEP choices, and thoughts about the mChoice intervention. Data collected in Aim 2 will contribute to the evaluation of the mChoice intervention, implementation, and contribute to understanding factors that influence PrEP choices by MSM in clinical settings.

Aim 3 of the study will include 20 health care providers (10 from New York and 10 from Alabama) involved in the direct delivery of PrEP services at participating clinical sites. Providers may include nurse practitioners, physicians, PrEP coordinators/navigators, medical assistants, and other cross-trained coordinators from the participating clinics. Providers will be recruited via flyers, emails to clinic staff, and referrals. Providers will receive education and training designed to improve knowledge of PrEP options and clinical recommendations and enhance provider communications with patients. Aim 3 includes practice facilitation, an intervention that includes identification of a clinic champion who will engage other providers in embracing PrEP recommendations, as well as ongoing support from a practice coach who will offer tools, resources, hands-on guidance, and content expertise to assist the clinic team in developing strategies to improve clinical PrEP services. Aim 3 assessments include notes from practice facilitation coaching sessions; in-depth interviews of participating

providers exploring their experiences with the intervention and thoughts about providing PrEP clinical services; and a clinic assessment completed by clinic staff every six months to describe the current implementation of PrEP services at their clinical site. These data will inform ongoing practice improvement in PrEP clinical services and increase understanding of provider experiences with providing PrEP clinical services.

It is expected that half of screened persons will meet study eligibility. For all Aims we anticipate that screening and completion of the locator form will each take five minutes. Study staff will

assist Aim 1 participants with onboarding the CleverCap device and mChoice app, a process that will take 20 minutes. Aim 1 participants will complete the baseline survey once (anticipated 30 minutes completion time) and the follow-up survey four times (anticipated completion time 30 minutes each) over their 12-month participation period. Total study enrollment for Aim 1 is 400, over the three-year data collection period the estimated annual enrollment is 134. Aims 2 and 3 interviews will take 60 minutes to complete. For Aim 2, total study enrollment is 30, over the three-

year data collection period the estimated annual enrollment is 10. For Aim 3, total study enrollment is 20, over the three-year data collection period the estimated annual enrollment is seven. Additionally, a single Aim 3 participant at each of the four participating clinic sites will complete a clinic assessment form every six months throughout the study period.

The total number of burden hours is 1,323 across 36 months of data collection. The total estimated annualized burden hours are 441. There are no costs to the participants 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)
Aim 1 participants—YMSM General public, adults.	Aim 1 Participant Eligibility Screener	268	1	5/60	22
Aim 1 participants—YMSM General public, adults.	Aim 1 Participant Locator Form .....	134	1	5/60	12
Aim 1 participants—YMSM General public, adults.	Aim 1 mChoice Onboarding Guide ..	134	1	20/60	45
Aim 1 participants—YMSM General public, adults.	Aim 1 Participant Baseline Survey ..	134	1	30/60	67
Aim 1 participants—YMSM General public, adults.	Aim 1 Participant Follow-up Survey	134	4	30/60	268
Aim 2 participants—YMSM General public, adults.	Aim 2 Participant Eligibility Screener	20	1	5/60	2
Aim 2 participants—YMSM General public, adults.	Aim 2 Participant Locator Form .....	10	1	5/60	1
Aim 2 participants—YMSM General public, adults.	Aim 2 Participant Interview Guide ...	10	1	1.0	10
Aim 3 participants—providers General public, adults.	Aim 3 Participant Eligibility Screener	14	1	5/60	2
Aim 3 participants—providers General public, adults.	Aim 3 Participant Locator Form .....	7	1	5/60	1
Aim 3 participants—providers General public, adults.	Aim 3 Participant Interview Guide ...	7	1	1.0	7
Aim 3 participant—clinic staff respondent, 1 per clinic site General public, adults.	Aim 3 Clinic Assessment .....	4	2	30/60	4
<b>TOTAL</b> .....	.....	.....	.....	.....	<b>441</b>

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[FR Doc. 2022-12697 Filed 6-10-22; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10237 and CMS-10407]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed