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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[30Day-18-17AZI]

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 Understanding Decisions and Barriers about PrEP Use and Uptake Among Men Who Have Sex With Men 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 October 10, 2017 to obtain comments from the public and affected agencies. CDC did not receive 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 or send an email to omb@cdc.gov. 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

Understanding Decisions and Barriers about PrEP Use and Uptake Among Men Who Have Sex With Men - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project involves original, formative research toward improving the uptake and adherence necessary to achieve efficacious levels of protection offered by pre-exposure prophylaxis (PrEP) among the most highly affected population. HIV incidence and prevalence are higher among gay, bisexual, and other men who have sex with men (MSM) than any other risk group in the U.S. Approximately half of all diagnosed HIV infections are among gay, bisexual, and other MSM. The FDA-approved PrEP regimen, daily Tenofovir/emtricitabine (aka Truvada®), has shown greater than 90% efficacy in reducing HIV infections among MSM when taken in accordance with its prescribed daily schedule. In 2014, CDC published clinical practice guidelines for the use of PrEP in high-risk populations, and began national promotion of PrEP as an effective HIV prevention strategy for MSM. While hailed as an HIV-prevention "game-changer," in reality PrEP uptake has been slow. Some studies report a wide range in the percentages of MSM (28-81%) interested in PrEP. In addition,

other studies indicate that specific cities have alarmingly low rates of PrEP uptake (for example, the estimate for Atlanta is 2%). Moreover, recent survey findings have shown that less than 1 in 10 MSM on PrEP are adherent to their PrEP regimen; adherence is necessary to optimize efficacy.

In order to develop effective programs that increase PrEP uptake among MSM at greatest risk for HIV, studies are needed to better understand the decisions men make about their HIV prevention needs. Qualitative methods will be used to explore in-depth the "Whys" and "How's" of MSM's decisions to refuse or use PrEP, and barriers and challenges to successfully undertake a PrEP medication regimen. Quantitative methods will be used to understand the HIV risk behavior context, attitudes towards PrEP, health seeking behavior, and acceptability of new modes of PrEP delivery (that differ from current recommendation of daily PrEP and that are in development or discussion) and emerging biomedical HIV prevention options.

The purpose of this research is to explore decisions, barriers, and facilitators about PrEP use among MSM: 1) who were offered PrEP but refused it; 2) who were interested in or started a PrEP regimen but did not follow through; and (3) who are eligible for PrEP per CDC guidelines (report condomless anal sex within last three months) but not currently on PrEP.

This study will provide insight on individual and community level PrEP-related decision-making, and identify barriers and facilitators to successful PrEP initiation and PrEP acceptability. Findings will improve programming, in line with the CDC Division of HIV/AIDS Prevention goal of high-impact prevention to reduce HIV infections in the U.S. Findings will assist the CDC and frontline public health programs in identifying and designing programs and intervention approaches that encourage, support, and maintain appropriate PrEP uptake among eligible MSM and anticipate future HIV prevention needs, including anticipated changes in PrEP delivery.

The total annual burden hours are 335. There are no other costs to the 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)
General Public-Adults	Screenener	600	1	5/60
General Public-Adults	Contact Information Form	300	1	1/60
General Public-Adults	In-Depth Interview Guide	60	1	45/60
General Public - Adults	Focus Group Moderator Guide	60	1	1
General	Eligibility	300	1	5/60

Public - Adults	verification (verification of continuing eligibility)			
General Public- Adults	Structured response self- administered behavioral assessment	300	1	30/60

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Office of the Director,
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