DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21AC; Docket No. CDC-2020-0110]

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 and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs). GAIN is an implementation study to compare a point-of-care nucleic acid HIV test (HIV RNA POC NAT) to standard lab-based HIV testing.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0110 by any of the following methods:

- Federal eRulemaking Portal: 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, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (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, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: 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; and
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.
5. Assess information collection costs.

Proposed Project

The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV

Point-of-Care Nucleic Acid Tests (NATs) - NEW - National Center for HIV/AIDS, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Current rapid point-of-care (POC) HIV testing technologies do not reliably detect the earliest HIV infections and lab-based testing can introduce delays while patients wait for test results. During this time, patients can drop out of care and remain at high-risk to acquire HIV. Direct molecular detection of HIV through nucleic acid tests (NATs) can identify early HIV infections, which have high potential for transmission. NATs that are used at the point-of-care (POC NAT) can provide results in 60 to 90 minutes. Obtaining timely molecular test results from a POC NAT in clinics or community settings can expand prevention as well as HIV treatment services, improve our reach into disproportionately affected populations, and provide opportunities to approach the goal of no new HIV infections. The purpose of this research is to develop feasible and effective models for using HIV POC NATs to: (1) improve PrEP initiation, and duration of PrEP use, among persons at high-risk for acquiring HIV infection; and (2) reduce the time between testing in community-based and clinical-based settings and linkage to HIV care, ART initiation, and viral suppression.

GAIN is an implementation study to compare a point-of-care nucleic acid HIV test (HIV RNA POC NAT) to standard lab-based

HIV testing. Study activities include: 1. Retrospective baseline data collection from clinical site electronic medical records. This will establish baseline PrEP and HIV care metrics for comparison after study implementation; 2. A longitudinal, prospective study of HIV-negative patients seeking HIV testing and/or PrEP services; 3. A longitudinal, prospective study of HIV-positive patients seeking STI testing; 4. An RCT of POC NAT or Standard of Care for HIV-positive patients; 5. A survey, interviews, and focus groups examining POC NAT acceptability among HIV-negative and HIV-positive patients; 6. A cross-sectional comparison of several point-of-care NATs among HIV-positive patients; 7. Acceptability/feasibility assessment among clinical and community providers and costing analyses. These data will be analyzed and disseminated to describe the real-world performance and clinical effects of HIV RNA POC NAT testing technology. This study will develop functional models to integrate HIV RNA POC NAT testing technology into HIV prevention and treatment services. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden (in Hours)

Participants in prospective study of HIV-negative patients seeking HIV testing and/or PrEP services	Consent form	1150	1	30/60	575
	HIPPA form	1150	1	10/60	192
	Release of information form	1150	1	10/60	192
	Study visit survey	1150	1	15/60	288
Participants in prospective study of HIV-positive patients seeking STI testing	Consent form	125	1	30/60	63
	HIPPA form	125	1	10/60	21
	Release of information form	125	1	10/60	21
	Study visit survey	125	1	15/60	31
Participants in RCT of POC NAT or Standard of Care for HIV-positive patients	Consent form	250	1	30/60	125
	HIPPA form	250	1	10/60	42
	Release of information form	250	1	10/60	42
	Study visit survey	250	1	15/60	63
Participants in survey group examining POC NAT acceptability	POC NAT acceptability survey	87	1	20/60	29

Participants in cross-sectional comparison of several point-of-care NATs	Consent	250	1	30/60	125
	Release of information form	250	1	10/60	42
	Study visit survey	250	1	15/60	63
Acceptability/feasibility assessment among clinical and community providers	POC NAT acceptability survey, focus group, or interview	25	1	1	25
Total					1,667

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2020-28113 Filed: 12/18/2020 8:45 am; Publication Date: 12/21/2020]