



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-21AC]

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 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) 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 December 21, 2020 to obtain comments from the public and affected agencies. CDC received two 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

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, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Pre-exposure prophylaxis (PrEP) can prevent HIV acquisition among persons at risk. To prevent the emergence of drug-resistant HIV strains, prior to initiating PrEP, persons must be tested for HIV to ensure that they are not infected. Current rapid point-of-care (POC) 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 are still at high-risk to become HIV infected. 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.

CDC requests OMB approval to conduct the GAIN (Greater Access and Impact with NAT) study at two clinics in Seattle, Washington. 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. 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.

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.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden is 1,067 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)
Participating clinic	Baseline data collection variables list	2	1	2
	Monthly study report form	2	12	15/60
Participants in prospective study of HIV-negative patients seeking HIV testing and/or PrEP services	Release of information form	1530	1	10/60
	Study visit survey	1530	1	15/60
Participants in prospective study of HIV-positive patients seeking STI testing	Release of information form	165	1	10/60
	Study visit survey	165	1	15/60
Participants in RCT of POC NAT or Standard of Care for HIV-positive patients	Release of information form	333	1	10/60
	Study visit survey	333	1	15/60
Participants in survey group examining POC NAT acceptability	POC NAT acceptability survey	117	1	20/60
Participants in cross-sectional comparison of several point-of-care NATs	Release of information form	333	1	10/60
	Study visit survey	333	1	15/60
Acceptability/feasibility assessment among clinical and community providers	POC NAT acceptability survey, focus group, or interview	33	1	1

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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