



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-24-1402]

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 “Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD)” 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 06, 2023, to obtain comments from the public and affected agencies. CDC received two comments 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

Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD) (OMB Control No. 0920-1402, Exp. 05/31/2026) – Revision - National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

National HIV Surveillance System (NHSS) data indicate that 36,940 adolescents and adults received an HIV diagnosis in the United States and dependent areas in 2019. During 2015-2019, the overall rate of annual diagnoses decreased only slightly, from 12.4 to 11.1 per 100,000 persons. Although not every jurisdiction reports complete laboratory data needed to identify the stage of infection, data from the majority of jurisdictions show that many of these cases were classified as Stage 0 (6.9%) or Stage 3 (21.5%) infection (i.e., cases diagnosed in early infection or late infection, respectively). Early and late diagnoses represent recent failures in prevention and testing systems, and opportunities to understand needed improvements in these systems.

The NHSS would classify HIV infections as Stage 0 if the first positive HIV test were within six months of a negative HIV test. Persons who received a diagnosis at Stage 0 (i.e., early diagnosis) could access HIV testing shortly after infection yet could not benefit from biomedical and behavioral interventions to prevent HIV infection. The federal Ending the HIV Epidemic in the U.S. (EHE) initiative prioritizes the provision of HIV preexposure prophylaxis (PrEP), syringe services programs, treatment as prevention efforts, and other proven interventions — as part of the Prevent pillar of the EHE initiative — to prevent new HIV infections.

HIV infections are classified as Stage 3 (AIDS) by the presence of an AIDS-defining opportunistic infection or by the lowest CD4 lymphocyte test result. Persons with Stage 3 infection at the time of their initial HIV diagnosis (i.e., late diagnosis) did not benefit from timely receipt of testing or HIV prevention interventions. They were likely unaware of their infection for a substantial length of time.

Nationally, an estimated 13.3% of persons with HIV are unaware of their infection, contributing to an estimated 40% of all ongoing transmission. Increasing early diagnosis is a crucial pillar of efforts to end HIV in the United States. Given the continued occurrence of HIV infections in the United States, the barriers and gaps associated with low uptake of HIV testing and prevention services must be addressed to reduce new infections and facilitate timely diagnosis and treatment. Individual- and systems-level factors likely contribute to barriers and gaps in testing and prevention. Therefore, CDC is sponsoring this data collection to improve understanding of barriers and gaps associated with new infection and late diagnosis in the era of multiple testing modalities and prevention options such as PrEP. These enhanced surveillance activities will identify actionable missed opportunities for early diagnosis and prevention, thus informing allocation of resources, development and prioritization of interventions, and evidence-based local and national decisions to improve HIV testing and address prevention gaps.

The changes proposed in this request add a new qualitative data collection activity that encompasses a new consent form and a new data collection tool (In-depth Interview Guide) to

conduct qualitative interviews to meet prevailing information needs and enhance the value of SHIELD data and minor edits to the approved SHIELD survey while remaining within the scope of the currently approved project purpose. The annualized burden hours of the project increased by 158 hours with these additions, for a total of 3,074 annualized burden hours. There are no costs to respondents other than time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)
Potential Eligible Participant	Recruitment Script English	2,000	1	15/60
Potential Eligible Participant	Recruitment Script Spanish	500	1	15/60
Eligible Participant	Consent for quantitative survey – English	2,000	1	5/60
Eligible Participant	Consent - Spanish	500	1	5/60
Eligible Participant	Survey – English	2,000	1	50/60
Eligible Participant	Survey – Spanish	500	1	50/60
Eligible Participant	Consent for qualitative interview– English	50	1	5/60
Eligible Participant	Consent for qualitative interview - Spanish	50	1	5/60
Eligible Participant	In-depth Interview – English	50	1	90/60
Eligible Participant	In-depth Interview – Spanish	50	1	90/60

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