



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-24-1402; Docket No. CDC-2023-0081]

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 or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comments on a proposed information collection titled Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD), which collects information from people who were recently diagnosed with HIV at early (Stage 0) or late diagnosis (Stage 3) to understand barriers to HIV prevention and testing services to contributing to transmission.

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-2023-0081 by either of the following methods:

- ☐ Federal eRulemaking Portal: 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.

Please note: Submit all comments through the Federal eRulemaking portal

(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; 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 the 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 using 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

Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD) (OMB Control No. 0920-1402, Exp. 5/31/2026) – 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 37,968 adolescents and adults received an HIV diagnosis in the United States and dependent areas in 2018. During 2015-2019, the overall rate of annual diagnoses decreased only slightly, from 12.4 to 11.1 per 100,000. Although not every jurisdiction reports complete laboratory data needed to identify stage of infection, data from most jurisdictions show that many of these cases were classified as Stage 0 (7.9%) or Stage 3 (20.2%) infection (i.e., cases diagnosed in early infection or late infection, respectively). Early and late diagnoses represent recent failures in prevention and testing systems, respectively, and opportunities to understand needed improvements in these systems.

The NHSS classifies HIV infections as Stage 0 if the first positive HIV test was within six months of a negative HIV test. Persons who received a diagnosis at Stage 0 (i.e., early diagnosis) were able to access HIV testing shortly after infection yet were unable to 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 and were likely unaware of their infection for a substantial 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. 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 the 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 Revision 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 is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
Potential Eligible Participant	Recruitment Script English	2,000	1	15/60	500
Potential Eligible Participant	Recruitment Script Spanish	500	1	15/60	125
Eligible Participant	Consent for quantitative survey – English	2,000	1	5/60	167
Eligible Participant	Consent for quantitative survey - Spanish	500	1	5/60	42
Eligible Participant	Survey – English	2,000	1	50/60	1,666
Eligible Participant	Survey - Spanish	500	1	50/60	416
Eligible Participant	Consent for in-depth interview – English	50	1	5/60	4
Eligible Participant	Consent for in-depth interview - Spanish	50	1	5/60	4
Eligible Participant	In-depth Interview – English	50	1	90/60	75
Eligible Participant	In-depth Interview - Spanish	50	1	90/60	75
Total					3,074

Jeffrey M. Zirger,

Lead,

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Office of Public Health Ethics and Regulations,

Office of Science,

Centers for Disease Control and Prevention.

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