The Data to Care (D2C) Public Health Strategy: Successes, Challenges, and Lessons Learned in Identifying, Linking, and Reengaging Persons Diagnosed with HIV to Medical Care

Generic Information Collection under OMB #0920-1091

Section A: Supporting Statement

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CONTACT

James W. Carey, PhD, MPH
Project Officer

Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
1600 Clifton Road, NE, Mailstop E-37
Atlanta, GA 30333
Phone: 404-639-1903

Fax: 404-639-1950
E-mail: jfc9@cdc.gov

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EXHIBITS

LIST OF ATTACHMENTS

- **Goals of the study:** The goal of this qualitative research study is to identify approaches that have been effective in implementing Data to Care (D2C) programs and how health departments use D2C strategies to link and (re)engage persons living with HIV (PLWH) in

care.

- **Intended use:** Study outcomes will be communicated to local stakeholders and organizations in positions to consider and implement site-specific improvements in their HIV Data to Care programs; the results of this study are not intended to be generalized to the larger population. The results also will provide CDC an increased understanding of the factors that contribute to effective D2C programs.
- **Methods to be used to collect data:** Data will be collected from 90 individuals through semi-structured, qualitative in-depth interviews (IDIs).
- **The subpopulation to be studied:** We will target 60 PLWH who previously have received D2C services and 30 health department/D2C program personnel (i.e., health department staff, healthcare providers). Participants will be from Florida, Louisiana, and Virginia.
- **How data will be analyzed:** Qualitative coding of 90 IDI transcripts using computer-assisted qualitative data analysis software.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for a qualitative extramural research study entitled, "The Data to Care (D2C) Public Health Strategy: Successes, Challenges, and Lessons Learned in Identifying, Linking, and Reengaging Persons Diagnosed with HIV to Medical Care" under the Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States Generic Clearance (OMB #0920-1091, expires 12/31/2018). CDC will sponsor this data collection activity. Data collection will be carried out by the CDC's contractor, Research Support Services, in conjunction with its subcontracting partners, Emory University and IMPAQ International.

This project will conduct detailed case studies of the approaches that have been successful in implementing D2C programs in five jurisdictions across three states in the United States from the perspective of D2C program staff and the D2C clients. This study will yield four separate reports that present a comprehensive picture of jurisdictional efforts, successes, and needs concerning D2C programs. By learning from the experiences of program staff running D2C programs, and the experiences of D2C clients, the proposed study will offer a unique perspective on how D2C programs function and the impact they have on client's lives. The results will help inform design of new D2C programs and strengthen current D2C programs, as well as provide effective linkage and reengagement services to persons living with HIV (PLWH) who historically have had difficulties obtaining HIV medical care.

It is essential for PLWH to become engaged in medical care and begin treatment as quickly as possible after they learn their HIV diagnosis. Once in medical care, PLWH are prescribed antiretroviral treatment (ART). ART helps by reducing HIV viral load in the bloodstream, thereby protecting the patient's immune system from deterioration and reducing transmission of the virus to uninfected persons by as much as 90%. (1-10) However, not all PLWH are linked to and engaged in care and receiving ART. (10) When PLWH are not in care, not only does it adversely affect their health, but it becomes more difficult to reach national HIV public health goals for reducing the number of new HIV infections. (1,2)

"Data to Care" (D2C) is a public health strategy that uses data within state and local public health surveillance databases to identify PLWH who do not appear to be receiving HIV medical care. (11) After verifying PLWH who are truly out of care and still residing in the jurisdiction, health department or affiliated non-governmental personnel reach out to these PLWH to help link them to medical care for the first time, or to reengage them if they have fallen out of care. Over the past few years, a small number of state and local public health departments in different parts of the United States have implemented D2C programs. (12-16) However, to date there only have been a few studies that report the perspectives from program staff and PLWH clients about services provided by D2C program. (16, 17)

In 2018, all U.S. state health department HIV control programs will begin receiving new federal funds from the Centers for Disease Control and Prevention (CDC) to implement, expand and support D2C efforts. However, there is insufficient knowledge regarding the factors that promote or hinder effective and efficient implementation of D2C programs. These factors may include the specific structure and function of local D2C programs, as well as the personal circumstances that affect the ability of PLWH to access and remain in medical care. Because all HIV control programs in state health departments soon will be asked to implement D2C programs, there is an urgent need to learn from existing D2C programs the successes, challenges, and what does and does not work when designing and implementing D2C programs.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to identify approaches that have been effective in implementing D2C programs and how health departments use D2C strategies to link and (re)engage PLWH in care. The study will take place in five jurisdictions within Louisiana, Florida, and Virginia, three states that have existing D2C programs. Study outcomes will be shared with local stakeholders and organizations who may use the results implement site-specific improvements in their HIV Data to Care programs.

The qualitative data collected through this study will be used to generate separate reports that present a comprehensive picture of jurisdictional efforts, successes, and needs concerning D2C services in the study locations. Results from this data collection will be communicated to relevant public health officials and community stakeholders in the study locations. These public health officials and stakeholders include personnel involved with implementing local HIV D2C programs. These local public health officials and community stakeholders will use the study results to guide strategies to further strengthen their local HIV D2C programs within their regions. The results also will provide CDC an increased understanding of the factors that contribute to effective D2C programs. Study findings will provide a much-needed understanding of D2C from the perspective of PLWH clients who have received D2C services, as well as from the point of view of personnel who implement D2C programs in different geographic locations.

A total of 90 participants, including 30 D2C program staff and 60 D2C clients will be recruited for in-depth interviews (IDIs) across all sites. Contractor staff will identify eligible D2C program staff by examining lists D2C program personnel. The program staff may include health department personnel or other program staff involved in D2C programs. They will have knowledge of D2C funding, implementation, partnerships, and evaluation as well as organizational successes and challenges in meeting D2C goals. For programs that draw clients from surveillance data and from local partners, we will make a special effort to recruit and track program personnel from both program types. Once project clearances have been obtained, we will request name and contact information for all staff on the list, and will use that list to recruit participants in the program staff sample. Participation in this study will not impact D2C program personnel job performance, and there is no requirement to participate in this study

as a function of job performance. No screening tool is needed for D2C program staff participants because they will be purposively recruited based on the roles they play in implementing the local D2C programs.

Recruitment of D2C clients will be accomplished by referral from D2C program staff at each site. D2C program staff will have study information as well as a set of study recruitment flyers with unique ID numbers to distribute to their D2C clients (**Attachment 1**). The D2C program staff will share this study information with their program's D2C clients, and give them a copy of one of the flyers. This information includes details on how a client can contact study staff, if they are interested in being a participant. However, the D2C program staff will never learn which of their clients contacted study staff after referral. Likewise, D2C program staff also will never learn which of their clients subsequently became enrolled as participants in the study. Finally, to help protect participant identities, CDC staff will never learn the identities of either the D2C program staff or clients enrolled in the study. (For additional details on how we protect the identities of study participants, see the **Protection of the Privacy and Confidentiality of Information Provided by Respondents** section included below in this document.)

If a D2C client is interested in being a study participant, they will call study staff from the contractor team, using the information provided in the recruitment flyers **(Attachment 1)**. Study staff will screen potential D2C client participants for study eligibility with the D2C client screening tool (**Attachment 3a)**. Eligible client participants who choose to enroll in the study will be scheduled for an interview **(Attachment 3b)** at a time and location that is convenient to them. At the beginning of each interview with D2C program staff or clients and before any data collection starts, study staff will review the study procedures with each participant. Participants will be asked to complete an informed consent form **(Attachment 2**). There are two consent forms; one for eligible D2C clients and one for eligible D2C program staff. The wording of these forms has been reviewed and approved by the CDC IRB (**Attachment 4a**).

We will use qualitative interview guides to collect information for this study, one for D2C clients, and the other for D2C program staff (**Attachments 3b-c)**. Both types of interviews include a short, structured response section to collect participants' demographic information. For D2C program staff, the interviews will primarily include open-ended questions designed to elicit information on the landscape of HIV care in the jurisdiction, identifying and working with the out of care population in their jurisdiction, D2C activities, implementation and competing priorities, factors that have facilitated or impeded D2C implementation, factors that have facilitated or impeded D2C client's linkage to and maintenance in care, and their recommendations for change and lessons learned. For D2C clients, the interviews will include open-ended questions that cover facilitators and barriers to engagement in care, D2C experience, maintenance in care, and questions about the D2C program and out of care population.

Key variables to be explored through the participant interviews are described in Exhibit 2.1 below. All data collection instruments have been approved by the CDC IRB **(Attachment 4a)**.

Exhibit 0.1: Overview of Key Variables

D2C Program Staff (Att. 3b)	D2C Program Clients (Att. 3c)
• Landscape of HIV care in the jurisdiction. • Identifying and working with the out of care population in their jurisdiction. • D2C activities, implementation and competing priorities. • Factors that have facilitated or impeded D2C implementation. • Factors that have facilitated or impeded PLWH's linkage to and maintenance in care, and their recommendations for change and lessons learned. • Lessons learned about strategies that have yielded greatest success in linking PLWH to care and maintaining them in care.	• Individual, social, and structural domains that influence linkage to and retention in care. • General treatment history, sociodemographics, and sexual risk behaviors. • HIV treatment history and insurance status. • Facilitators and barriers to engagement in care. • D2C experience, maintenance in care, and questions about the D2C program and out of care population.

3. Use of Improved Information Technology and Burden Reduction

The contracting team will screen potential D2C client participants by telephone, Study staff from the contracting team will conduct individual IDIs at a time and location that is convenient to the participants. Telephone interviews or visual remote interviews (such as web or Skype interviews) are not a good vehicle for developing the necessary rapport between interviewer and D2C client participant for a successful qualitative interview on a sensitive topic. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer's ability to read both. Thus, the contracting team will conduct the individual IDIs in person.

A member of the study contractor team will invite D2C program staff to participate, either by telephone or by email. When possible, the contractor team will conduct face-to-face interviews with the D2C program staff participants. However, this may not always be possible because of busy work schedules for the D2C program staff. In those situations, some program staff may be conducted by phone instead of face-to-face.

D2C client and D2C program staff will all be asked to provide a signed consent form prior to doing the interview. Two versions of the form will be used for the two groups (**Attachment 2**). After asking for and receiving signed consent forms from the participant, the contracting team will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the participant (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the participant.

4. Efforts to Identify Duplication and Use of Similar Information

This study will gather information about approaches that have been effective in implementing D2C programs and how health departments use D2C strategies to link and (re)engage PLWH in care. With very few exceptions, there is insufficient information on how D2C clients or D2C program staff view the strengths and challenges of their local D2C programs, (16) data crucial to developing sustainable D2C programs. Therefore, it would be beneficial for CDC and new D2C programs to learn successes, challenges, and lessons learned from well-established D2C programs. While we expect that some of the factors associated with D2C programs will be similar across all the sites, we also expect that many of the findings will be unique to each jurisdiction. Thus, The Agency believes this information is not captured elsewhere, and that no other data collection effort has been conducted or has been planned to collect

similar information for this population in these jurisdictions. Additionally, the Agency conducted a review of similar studies and determined that this study is collecting unique information. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate these research questions.

5. Impact on Small Businesses or Other Small Entities

This information collection does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

This information collection will provide the primary qualitative data needed to understand how health departments use D2C to link and (re)engage PLWH in care. If this case study were not conducted, it would not be possible to form an in-depth contextual understanding of local jurisdictional needs for improving D2C programs. Collecting this type of jurisdiction-specific information is important, as it will allow us to provide feedback to health department staff and other stakeholders that is relevant to the local context and can be used to develop and tailor D2C programs. The total length of data collection is 3-4 months and data will only be collected once.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection effort does not involve any special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60 day FRN notice to solicit public comments was published for the Generic umbrella collection (0920-1091) in the Federal Register on 02/24/2015, Volume 80, Number 36, Page Number 9727-9728. No public comments were received.

In addition, Emory University, Research Support Services, and IMPAQ International were consulted for the development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60 day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.

Paula Frew, Emory Team Lead Emory University Rollins School of Public Health 1518 Clifton Rd Atlanta, GA 30322 Phone: 404-712-8546 pfrew@emory.edu	Laura Randall, Project Manager Emory University Rollins School of Public Health 1518 Clifton Rd Atlanta, GA 30322 Phone: 404-727-2994 laura.randall@emory.edu
Alisu Schoua-Glusberg, Project Director Research Support Services, Inc. 906 Ridge Ave. Evanston, IL 60202-1720 Phone: 847-864-5677 alisu@researchsupportservices.com	Casey Tesfaye, Project Manager Research Support Services, Inc. 906 Ridge Ave. Evanston, IL 60202-1720 Phone: 847-864-5677 casey@reserachsupportservices.com

Bryan Gale, Project Manager IMPAQ International 10420 Little Patuxent Parkway, Suite 300 Columbia, MD 21044 443-259-5186 bglae@impaqint.com	Valerie Betley, Senior Research Analyst IMPAQ International 10420 Little Patuxent Parkway, Suite 300 Columbia, MD 21044 443-259-5196 vbetley@impaqint.com
Elizabeth Gall, Team Member IMPAQ International 10420 Little Patuxent Parkway, Suite 300 Columbia, MD 21044 443-259-5216 egall@impaqint.com	Nanette Benbow, D2C Subject Matter Expert Northwestern University 750 N Lake Shore Drive Rubloff Building, Suite 10-126 Chicago, IL 60611 773-539-5239 n.benbow@gmail.com

9. Explanation of Any Payment or Gift to Respondents

Interview participants who are D2C program staff will not receive token of appreciation funds. However, interview participants who are D2C clients will each receive a $40 token of appreciation. Forty U.S. dollars has been used in prior OMB-approved collections under this generic umbrella mechanism including LEAP (OMB 0920-0840) and LEAP Part II (OMB 0920-1091). In addition, this amount is consistent with similar studies and accounts for the inconvenience of travel and time. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of tokens of appreciation is expected to enhance survey response rates without biasing responses. (18, 19)

Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups in to research. In a recent study of recruitment and retention of black men who have sex with men by a community-based organization, recruiters found it difficult to obtain information from participants because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to an HIV prevention program. However, in this study, offering a token of appreciation improved participation. (20) In addition, a meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among this group. (21)

Remuneration has been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), which included similar populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates. Tokens of appreciation also were successfully used in prior information collections completed under this existing generic ICR, and they helped encourage respondent recruitment. Numerous other studies have shown that tokens of appreciation can significantly increase response rates and the use of tokens of appreciation is expected to enhance survey response rates without biasing responses. This improves the validity and reliability of the data, which is of utmost importance in this scientific study. In addition, HIV has a stigma that other health issues do not have, which makes it difficult to recruit participants for research when compared to other diseases.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC Privacy Officer has assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does apply to the overall information collection. CDC has completed a Privacy Impact Assessment of the data system used by the study contractor team (**Attachment 6**).

Potential respondents will be screened for eligibility using a screening tool (**Attachment 3a**). If they are eligible, they will be invited to provide their contact information (name, phone, email), in order to schedule the in-depth interview. This contact information will be hand written on paper, and not be computerized on a form. When not in active use, the papers containing the contact information will be stored in locked cabinets separate from other study data at the contractor's office facility. These papers with the participant's contact information will be destroyed after the interview is completed and the interview data have been fully transcribed and verified for accuracy.

At the beginning of the in-depth interview, a member of the contractor team will review the purpose of the study with the participant and answer any questions they might have. The participant will be asked to provide signed informed consent (**Attachment 2**). This includes permission to audio record the interview. After the consent process is finished, the interview will begin. The study data sharing and use agreement describes in detail how data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights (**Attachment 5**).

Only project staff will have access to the records, study documents, and data. CDC staff will not be involved with sample recruitment and will never know the identities of any study respondents.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This study has been reviewed and approved by the CDC IRB **(Attachment 4a)**. Emory University IRB has declared that no IRB review is required **(Attachment 4b)**.

Sensitive Questions

This study is an initiative to better understand approaches that have been effective in implementing D2C programs and how health departments use D2C strategies to link and (re)engage PLWH in care. As such, our information collection entails measurement of HIV-related information. All contracting staff will be trained to provide participants with referrals for prevention and care, such as mental health care organizations, as needed. We will inform all participants that they may skip any question or stop interviews at any time for any reason. Sensitive information is not transferred to CDC, and the results are transmitted to CDC in aggregate.

12. Estimates of Annualized Burden Hours and Costs

The recruitment and enrollment period is four months. This data collection will include 90 individuals. Sixty individuals will be adult D2C clients 18 ≥ years of age who have previously been linked to or reengaged in HIV medical care through the D2C program's efforts. We expect to screen 120 D2C clients, and we expect 50% to be eligible and to participant in the data collection, which yields a final D2C client sample size of 60. Contractor staff will screen potential D2C client participants for eligibility

by phone, which will take approximately five minutes **(Attachment 3a).** The D2C client interview **(Attachment 3b)** will take 60 minutes to complete and will be administered once.

We will also interview 30 D2C program staff. The D2C program staff IDI **(Attachment 3c)** will take 60 minutes to complete and will be administered once. No separate screening instrument will be used to identify eligible D2C staff because they will be identified directly through existing D2C program staff rosters.

Exhibits 12.1 and 12.2 provide further details about how the estimates of burden hours and costs were calculated. The estimated annualized burden is 100 hours.

12A. **Estimated Annualized Burden Hours**

Exhibit 12.2: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (hours)	Total Burden Hours
General Public-Adults	D2C Client Screener (Att. 3a)	120	1	5/60	10
General Public-Adults	D2C Client Interview (Att. 3b)	60	1	1.0	60
General Public-Adults	D2C Program Staff Interview (Att. 3c)	30	1	1.0	30
				Total	**100**

12B. **Estimated Annualized Burden Costs**

The annualized costs to the participants are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May 2016 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to participants is approximately $2,386.00. This cost represents the total burden hours of general participants multiplied by the average hourly wage rate $23.86).

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	D2C Client Screener (Att. 3a)	10	$23.86	$238.60
General Public-Adults	D2C Client Interview (Att. 3b)	60	$23.86	$1,431.60
General Public-Adults	D2C Program Staff Interview (Att. 3c)	30	$23.86	$715.80

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
				Total $2,386.00

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to participants for participating in this survey.

14. Annualized Cost to the Federal Government

Exhibit 14.1 provides the annualized cost to the government, which totals $318,381 using the 2017 Atlanta locality salary schedule. CDC supports costs for HIV prevention program task orders using funds budgeted for these purposes. Additional expenses may be incurred by CDC for attending site visits. Managing the project, providing technical assistance, monitoring and analyzing the submitted data, and generating assorted reports will require the expertise of three CDC staff.

Exhibit 14.4: Annualized Cost to the Government (2017 scale)

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs	CDC, Project Officer (GS-14, 0.20 FTE)	$21,276
	CDC Scientist (GS-13, 0.20 FTE)	$18,004
	CDC Project Coordinator (GS-12, 0.30 FTE)	$22,712
	Subtotal, Direct Costs	**$61,992**
Contract Costs	**Annual Contract Costs (RSS, #200-2013-57341)**	**$256,389**
	TOTAL COST TO THE GOVERNMENT	**$ 318,381**

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of participants collected in the first part of the interview (e.g., city, age, race/ethnicity, job category). Data collection will occur between May 2018 and August 2018, analyses will be carried out in September-November 2018, and the final data set and report will be submitted in December 2018. The project timeline is detailed in exhibit 16.1.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol	March 2017 – October 2017
OMB Submission	January 2018
Recruitment	1-4 months after OMB Approval (May-August 2018)
Data Collection	1-4 months after OMB Approval (May-August 2018)
Data analysis finalized and report drafted	5-7 months after OMB Approval

	(September-November 2018)
Final data set and final report submitted to CDC	8 months after OMB Approval (December 2018)

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other PII, and locations will be removed) qualitative database for this study along with the corresponding data documentation. Public access to the final data will be provided at the completion of the study and after the dissemination of the main outcome findings. The study data sharing and use agreement describes in detail how de-identified data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights. A copy of the Data Use Plan is provided (**Attachment 5)**.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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