

**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 Request under OMB #0920-1091

Section B: Supporting Statement

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## 1. Respondent Universe and Sampling Methods

### Site Selection

The study will be carried out in five jurisdictions within three states: New Orleans, Louisiana; Baton Rouge, Louisiana; Richmond, Virginia; Miami-Dade County, Florida; and Broward County, Florida. The states were selected because each state's health department has established Data to Care (D2C) programs, and experience with linking and reengaging persons living with HIV (PLWH) to HIV medical care.

Louisiana (New Orleans and Baton Rouge). Louisiana was ranked the 2<sup>nd</sup> in the nation for highest rates of HIV cases and 9<sup>th</sup> highest for the number of HIV cases in 2013, (1) and continued to have high rates of HIV diagnoses in 2015 at an estimated 29.2 per 100,000 population. (2) Baton Rouge and New Orleans-Metairie metropolitan statistical areas (MSAs) also had 2<sup>nd</sup> and 3<sup>rd</sup> highest HIV infection diagnosis rate in the United States, respectively. (2) In 2014, 73.9% of the newly diagnosed cases were among men, and the rate has continued to increase to 40.1 per 100,000. (2) The state conducts D2C work through the Louisiana Public Health Information Exchange (LaPHIE), which is a secure, bi-directional exchange of data between the Louisiana Department of Health and Hospital's Office of Public Health (OPH) and eight medical centers across the state. (3) This data exchange system uses the OPH surveillance registry data to alert clinicians at the participating facilities that a patient with HIV may either be unaware of their status or out of care; this healthcare provider model allows clinicians to directly contact patients and facilitate linkage to or re-engagement in care. During the initial implementation, the LaPHIE identified over 1,000 PLWH out of care, reengaging 69% of them to care within 90 days. (3)

Virginia (Richmond). Virginia ranked 13<sup>th</sup> in the U.S. in the number of HIV diagnoses in 2013, with an estimated 67% of diagnoses among MSM. (4) Virginia continued to have high rates of HIV diagnoses in 2016, with 232.7 HIV diagnoses per 100,000 population, of which an estimated 47% were MSM. (5) Approximately 19% of the estimated new HIV diagnoses in Virginia in 2014 were in the Richmond MSA. (6) Virginia's D2C program is a joint initiative between the Virginia Department of Health's HIV Surveillance, Prevention, Care Services, and STD Surveillance, Operations, and Data Administration (SODA) units. Since implementation, this D2C program has over 25 entities that play a role, including local health departments, medical sites, and CBOs in order to identify out of care clients who need to be linked to or reengaged in HIV care and treatment, as well as maintain and update the state's surveillance data. (6) As of July 2017, 1,671 PLWH were considered "out of care" in Virginia. Out of 422 D2C clients investigated, only 31 clients were found to be truly out of care (defined as having no evidence of care (e.g., CD4 or viral load lab values, a provider visit, or ART prescription in the past year). This highlights the important role of D2C programs in keeping HIV surveillance systems up to date. (7) Twenty four of these 31 clients have been linked to or reengaged in HIV care through the D2C program's efforts.

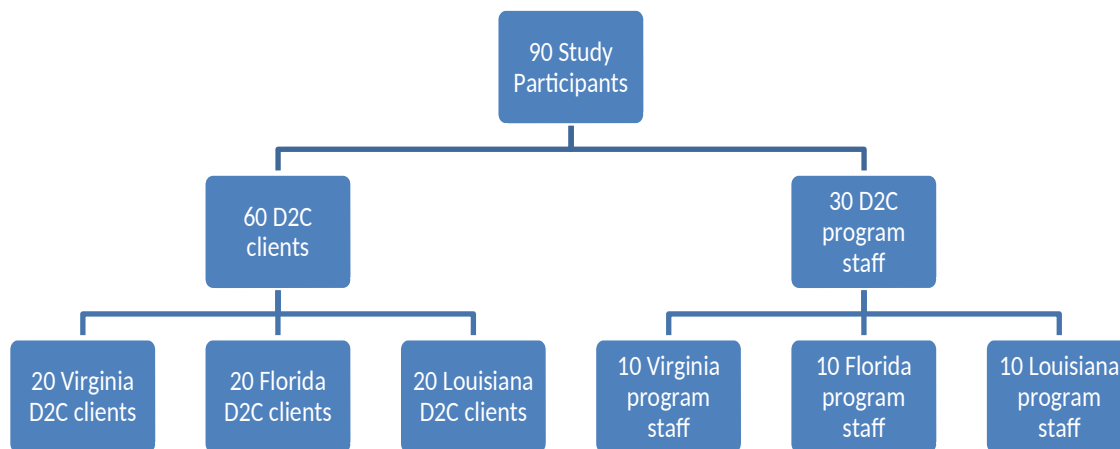
Florida (Miami-Dade and Broward counties). Florida ranked 1<sup>st</sup> in the U.S. in number of HIV diagnoses in 2015, with an estimated 64% of diagnoses among MSM. (8) Approximately 18% of the estimated new HIV diagnoses in Florida in 2014 were in Fort Lauderdale (Broward County), and 78% of new diagnoses between 2010 and 2014 in Broward County were men. (6) Approximately 25% of the estimated new HIV diagnoses in Florida in 2014 were in Miami (Miami-Dade County), and 79% of new diagnoses in Miami-Dade County between 2010 and

2014 were men. (6) Florida’s D2C program falls under the Partnerships for Care (P4C) program, which promotes partnerships between health centers and the Florida Department of Health (FDOH) for bi-directional client data exchange via the P4C portal as well as verbal data sharing via case conferencing. (9) As reported in May 2017, P4C successes thus far include increases in number of persons linked to care and decreases in the time from diagnosis to first lab (January 2015 – March 2016), as well as updates to the eHARS database for over 50% of potential engagement/reengagement cases ([http://theaidsinstitute.org/sites/default/files/attachments/LRC%20D2C%20Panel\\_r.pdf](http://theaidsinstitute.org/sites/default/files/attachments/LRC%20D2C%20Panel_r.pdf)).

**Target Population**

This study plans to select 90 individuals to participate in in-depth interviews across the three study states: Florida, Virginia, and Louisiana (30 individuals from each state). Of the 90 participants there will be two distinct groups: 30 participants will be D2C program staff directly involved in implementing D2C programs (10 per state) and 60 participants will be D2C clients aged 18 ≥ years of age who have previously been linked to or reengaged in HIV medical care through a D2C program (20 per state). Exhibit 1.1 below presents the sample size distribution for each group, according to participant role.

**Exhibit 1.1 Summary of Recruitment Targets**



*Inclusion criteria:*

D2C program staff must be

- ≥18 years of age;
- able to speak English and consent to participate;
- D2C program staff or health department staff directly involved in implementing D2C activities.

Additionally, D2C program staff need knowledge of D2C funding, implementation, partnerships, and evaluation as well as organizational successes and challenges in meeting D2C goals.

D2C clients must be

- ≥18 years of age;
- able to speak English and consent to participate;
- linked to or reengaged in HIV medical care via their jurisdiction's D2C program.

*Exclusion criteria:*

D2C program staff and D2C clients will be excluded from the study if they

- are unwilling or unable to provide consent;
- do not meet the other eligibility criteria.

This distribution of respondents may vary somewhat from place to place based on local particularities, but we will strive for a reasonable balance of different types of respondents in each of the relevant categories. This is a qualitative research study and is not designed to make comparisons between groups or to make generalizations. We intend to use a standard qualitative sampling methodology that ensures a wide range of experiences are captured. Rather than using probabilistic methods (i.e., random selection with known, non-zero chances of selection for each unit in the population) to generate a sample, non-probability sampling requires researchers to use their subjective judgments, drawing on theory (i.e., the academic literature) and practice (i.e., the experience of the researcher and the evolutionary nature of the research process). Unlike probability sampling, the goal is not to achieve objectivity in the selection of the sample, or necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest.

## **2. Procedures for the Collection of Information**

To recruit D2C clients, local D2C program staff will give the D2C clients' study Recruitment Flyer (**Attachment 1**). The flyers contain information on how a D2C client can call the study contractor team if they are interested in participating in the study. The D2C program staff will never learn which of their clients called the contractor team, and likewise will never learn which clients were enrolled in the final D2C client sample.

When a D2C client calls, a member of the contractor team will screen potential client participants 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.

To recruit the D2C program staff, the contractor will obtain a list of the personnel who are involved in implementing the local D2C program from the three state health departments. 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. Based on the names on this list, the contractor will invite D2C program staff to be interviewed, either face-to-face, or by phone. D2C staff who choose to enroll in the study will be scheduled for an in-depth interview at a time and location that is convenient to them. Authorized contractor staff will confirm that participants are at least 18 years old during recruitment, but because participants will be selected from a pre-determined list, no additional screening will be required. At the time of the interview, staff will review the study procedures, after which participants will complete the informed consent and will receive a copy of the consent for their records (**Attachment 2**). CDC staff will not be involved with sample recruitment and will never know the identities of any study respondents.

For both the D2C client and the D2C staff participants, contractor staff will conduct qualitative, in-depth interviews lasting one hour, on average, to collect information for this study (**Attachments 3b-c**). Interviews will be conducted in a private setting by trained interviewers. With the respondent's permission, interviewers will digitally audio record each interview and will remind participants not to use their full names or other identifying information. Interviews will include a short, structured response section to collect participants' demographic information. The interviews will primarily include open-ended questions designed to elicit information on HIV prevention and care, and their perspectives on the D2C program in their jurisdiction.

Copies of the signed consent forms will be kept as required for possible IRB review for up to 10 years in a locked vault, located in the contractor's office facility. No data set file will contain any personally identifiable information from the participant; instead, a unique study ID number will be used to label each study participant's data records.

All interview audio files will be stored on the recorders; transcription will be done in house by contractor team members by listening to the recording device and transcribing to stand-alone computers that are not networked, taking care to remove any personally identifiable information (PII) that may have been transcribed accidentally. Data brought to study offices will be securely managed by securing the paper and recordings in separate locked offices, cabinets, drawers, and briefcases. Only project staff will have access to the records, study documents, and data. Electronic files will be password protected and stored on a secure server. No final interview transcript or other computerized data file will contain any personally identifiable information from the participant.

Each interview will be transcribed into an encrypted MS Word document. Transcripts and NVivo files for individual cases will be stored on and edited from a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer (without Internet access) at study offices. NVivo analysis files will be stored in a FISMA-compliant enclave on a dedicated data server. Backup files will be encrypted and maintained on flash drives securely kept under lock and key.

Authorized contractor staff will keep paper and audio files of the interviews as well as the completed interview guides, screeners, contact information and other project materials through the period of transcription, quantitative data entry, and QA/QC processes. Participant contact information will be destroyed after completing the transcription process. All consent documents

will be maintained in locked cabinets within a secured, physical space, separate from other study data, of which only key study staff have access to records. All electronic study data (transcripts without PII) will be kept in encrypted or password protected files. Analysis will be done on secure network systems or stand-alone (non-networked) password protected computers in secure locations. Study participants will only be labeled with unique numeric ID numbers in the final computerized data sets.

To protect study participant identities, CDC has completed a Privacy Impact Assessment of the data system used by the contractor team (**Attachment 6**). The contractor team also completes an annual renewal process for their data system, and has a current Authority to Operate approval (**Attachment 6**). Public access to the 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 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.

### **3. Methods to Maximize Response Rates and Deal with No Response**

Contractor staff will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Participants will be identified through state health department D2C program staff who may have trusted relationships with eligible participants.
- A \$40 token of appreciation will be provided to key participants upon completion of the interview. Only D2C Clients will receive the token of appreciation. This will not be offered to D2C Program Staff who participate.
- All recruitment materials indicate the voluntary nature of the study.

### **4. Tests of Procedures or Methods to be Undertaken**

The research team includes experts with experience conducting HIV research with health departments, community-based organizations, vulnerable populations and qualitative research, including screening and interview development and testing. The contracting team will conduct pretesting of the screening tool and interviews on three to five mock respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and to estimate response burden for each respondent. Health department staff will be responsible for recruiting respondents. Non-CDC members of the research team will be responsible for collecting data, as well as for generating transcripts that contain no PII.

### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Exhibit 5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments

for CDC IRB review; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC staff will neither collect data from nor interact with research participants. Data will be collected by members of contractor project staff listed. No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff. All members of the research team will work together to analyze the data and generate reports containing summaries of the findings.

### Exhibit 5.1: Statistical Consultants

Team Member	Organization	Phone	Email
James Carey	CDC	404-639-1903	Jfc9@cdc.gov
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Valerie Betley	IMPAQ International	443-259-5196	vbetley@impaqint.com
Elizabeth Gall	IMPAQ International	443-259-5216	egall@impaqint.com
Nanette Benbow	Northwestern University	773-539- 5239	n.benbow@gmail.com

### References

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10. Patton MQ. *Qualitative evaluation and research methods*. SAGE Publications, Inc; 1990.