SARS-CoV-2 Epidemiologic Data Collections

Request for OMB approval of a New Information Collection

April 27, 2020

Supporting Statement B

Contact:
Lee Samuel
Emergency Operations Center
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404) 718-1616
Email: llj3@cdc.gov

Table of Contents

The collections associated with these tools do not involve statistical methods and the purpose is not to make statistical generalizations beyond the individual respondents.

The methods for respondent selection and recruitment vary for each study and are dependent in part on the goal of the investigation, time frame under which data is needed, the capacity and needs of the local site and efforts to limit burden. In general, the purpose of these investigations is not to make statistical generalizations beyond the individual respondent.

1. Respondent Universe and Sampling Methods

1. COVID-19 Case Investigation Form – This form is intended to describe characteristics of COVID-19 cases. Respondents could include any member of the general public who tested positive for SARS-CoV-2. In an attempt not to overburden state and local health departments, we are aiming for 5-10 cases (or more if feasible) per jurisdiction, with a cumulative total of approximately 300 cases nationally. Ideally, we would receive forms from a variety of ages and illness severities, but we have not established a more formal sampling scheme. No sample size calculations were performed. Throughout the data collection, we will continue to assess if we have the necessary data to address the important epidemiologic questions. If needed, we may continue to collect a greater number of forms, or over-sample from a particular group or location, as necessary.
2. Household transmission questionnaires – We largely are using a convenience sample for this investigation based on when index cases are lab-confirmed and are notified to the local health department. Our CDC field teams are to be in the local jurisdiction to the cases and will enroll households based on referrals from local health departments. Some households may refuse, as participation is not mandatory. These household are somewhat limited to a specific geographic area based on local health departments that are willing and interested in partnering on this investigation. We do not use a predetermined sample size and instead enrollment numbers are dictated based on convenience and feasibility of field work.
3. Homeless shelter intake form – Homeless study aims to screen all individuals experiencing homelessness in the major shelters in the Atlanta metro area. Our partner, MercyCare, has provided estimates of the number of individuals seeking shelter and we aim to screen close to that estimate. Additionally, CDC is partnering with the local public health department (Fulton County) to reach smaller shelters in the Atlanta Metro area.

4. COVID-19 Pregnancy module – State, territorial, and local health departments have the option to participate in the COVID-19 Pregnancy Module. We expect approximately 20 jurisdictions to participate in this information collection. Participating health departments will complete the pregnancy module once for every pregnant individual reported through routine case surveillance and her neonate. Identification of pregnant cases will be through the pregnancy status variable included on the COVID-19 Case Report Form.
5. Risk factor interview – Currently, these data collection tools are being utilized in an investigation in Colorado, although there is a potential for these forms to be used in other states. In Colorado, the respondent universe includes any member of the public who is a CO resident and who was known (by the Colorado Department of Public Health and Environment (CDPHE)) to have a positive SARS-CoV-2 test during March. The primary aim for this analysis explores risk factors for severe illness, requiring hospitalization. We therefore grouped potential respondents into those who were hospitalized and those who were not. We aimed to collect information on 100 hospitalized patients and 200 non-hospitalized individuals; this number and ratio was chosen, in part, based on available resources and, in part, to generate sufficient power to identify possible risk factors for hospitalization, including underlying medical conditions of varying prevalence. To allow for a 50% non-response rate in either group, we oversampled and randomly selected 200 hospitalized individuals and 400 non-hospitalized individuals to be contacted by telephone interview. For individuals who are successfully interviewed, medical chart abstractions are planned.

2. Procedures for the Collection of Information

1. COVID-19 Case Investigation Form – The form includes components of a patient interview and a medical chart abstraction (for hospitalized cases). Some jurisdictions may choose to complete this form based on information they have already collected from their cases for public health response purposes. Instructions are provided on how to complete the from, but there is no additional training unless offered at a given jurisdiction. Some forms have been (or will be) completed by staff at the HDs, and other forms have been completed by CDC field teams, supporting the HDs.
2. Household transmission questionnaires – Interviews are conducted by CDC investigation team members who have been oriented to the investigation goals, objectives, and questionnaires. Once an index case has been identified by the local health department, they pass along their name/contact info to the CDC field team. A CDC field team member then calls the index case to introduce the investigation and determine their interest in participation. After the index case and/or head of household consents to participation, a household questionnaire and any applicable pet questionnaires are completed over the phone or in person (depending on the specific situation). Subsequently, each individual household member is also consented and completes a household member questionnaire. Daily symptom diaries are shared with households during the enrollment visit, completed for that day, and then left with household members to complete on their own during the 14-day follow-up period. At the completion of 14-day follow up, a household close-out form is completed, and daily symptom diaries are collected from all participants.

3. Homeless shelter intake form – After our partner MercyCare registers clients for services (part of their normal operations), CDC and MercyCare staff will get verbal consent from each client to collect subjective symptom information and be tested via a nasal swab. Subjective symptom information will be collected on paper forms (Attachment 9) from clients. Individuals conducting the screening are medical professionals and will be in proper PPE. They have been trained to collect specimens, and have previously worked with populations experiencing homelessness. Respondents are sheltered and unsheltered persons experiencing homelessness.
4. COVID-19 Pregnancy module – Data for the COVID-19 Pregnancy Module will be collected by health department staff from existing data such as maternal/infant medical records, vital records, and electronic laboratory reporting. Identification of pregnant cases will be through the pregnancy status variable included on the COVID-19 Case Report Form. No information will be collected directly from pregnant persons for the Pregnancy Module.
5. Risk factor interview – Respondents identified as per the methods described above are contacted by telephone to participate in a phone interview. CDC staff and staff at CDPHE are performing these interviews and were trained to do so before the investigation began. At the start of each day, each interviewer is provided with a list of respondents and their contact details. Respondents are given the opportunity to do the interview upon first call or given the opportunity to call back at another time. For individuals who are successfully interviewed, medical chart abstractions are planned. Charts will be reviewed by CDC staff with clinical expertise.

3. Methods to maximize Response Rates and Deal with No Response

1. COVID-19 Case Investigation Form – Initial implementation of this form was via CSTE. For jurisdictions that have expressed interest in completing this form, we have sent at least two reminder emails. In addition, we are coordinating with CDC liaisons to HDs to help facilitate data collection. We are also offering CDC staffing support where necessary.
2. Household transmission questionnaires – CDC field investigation team members follow up with phone calls and/or visits as needed to optimize response rates and minimize “no response” data capture. If household members refuse data capture, enrollment is reviewed and/or withdrawn, where appropriate.
3. Homeless shelter intake form – Verbal consent from clients to participate will be obtained. If a substantial number of individuals are missed while CDC/MercyCare staff are providing screening, the staff may decide to return to a specific shelter on a different date.
4. COVID-19 Pregnancy module – For the COVID-19 Pregnancy Module, participating jurisdictions will receive reports on data quality and completeness to limit missing data.
5. Risk factor interview – The list of eligible respondents was oversampled to allow for non-response. Respondents are given the opportunity to decline the interview. If the respondent does not answer the phone, the interviewer has been instructed to leave a voicemail, and to call back on 2 additional occasions on different days and at different times of the day.

4. Tests of Procedures or Methods to be undertaken

1. COVID-19 Case Investigation Form – No pre-tests.

2. Household transmission questionnaires – CDC field teams test questionnaire completion and processes prior to approaching households. This is done internally as a team.
3. Homeless shelter intake form – No pre-tests.
4. COVID-19 Pregnancy module – There will be no pilot testing of the COVID-19 Pregnancy Module. The module was developed using subject matter experts, and variables were obtained from other systematic collection of mother-infant linked longitudinal surveillance systems.
5. Risk factor interview – The interview tool was informally piloted on a selection of individuals (<10) to ensure that questions could be appropriately interpreted. The chart abstraction tool was also piloted on a selection of medical charts (<10).

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

- The Epidemiology Task Force, Epidemiology Studies Team (eocevent330@cdc.gov) and the Community Intervention/At-Risk Team (eocevent269@cdc.gov; eocevent366@cdc.gov) will collect data and analyze data for CDC.
- The Pregnancy and Infants Linked Outcomes Team of the Epidemiology Studies Task Force (eocevent397@cdc.gov) will collect and analyze information for the agency. The Data Management Team of the Case Surveillance Task Force will continue to be a critical partner in the collection and management of data coming to CDC from the COVID-19 Pregnancy Module.