Generic Information Collection under Formative Research and Tool Development
**OMB #0920-0840**

Virtual Focus Groups with Primary Care Physicians and OBGYNs:
Attitudes about Proposed Hepatitis C Screening Guidelines
DVH 2019

# Section A: Supporting Statement

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**CONTACT**

Cynthia Jorgensen, DrPH
Alycia Downs, MPH
NCHHSTP/DVH/OD Communication Team Lead
Co-Principal Investigators

NCHHSTP/DVH/OD Communication Team Lead
Principal Investigator

Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)
Division of Viral Hepatitis
1600 Clifton Road, NE, Mailstop G-37
Atlanta, GA 30333
Phone: 404-718-8534

E-mail: cxj4@cdc.gov

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## EXHIBITS



## LIST OF ATTACHMENTS



- **Goals of the study:** This qualitative research focuses on primary care physicians (PCPs) and

obstetrician-gynecologists (OBGYNs) with the goal of gathering insights about their practices, knowledge, and attitudes around testing for hepatitis C and their attitudes and intentions to a universal testing recommendation for all adults and all pregnant women during each pregnancy.

- **Intended use:** Study outcomes will inform DVH's educational efforts around hepatitis C testing and are not intended to be generalized to the entire physician community. The results will provide CDC an increased understanding of provider-related motivators and barriers related to screening for hepatitis C among all adults and women during each pregnancy, and will help inform education, outreach, and other strategies as appropriate.
- **Methods to be used to collect data:** Data will be collected from a total of 128 individuals through semi-structured, qualitative virtual focus groups.
- **How data will be analyzed:** Data will be analyzed via direct observation as well as analysis of transcripts to identify themes and patterns.

**Supporting Statement**

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of Viral Hepatitis, (DVH) requests OMB approval for a qualitative research study entitled, "Virtual Focus Groups with Primary Care Physicians and OBGYNs: Attitudes about Proposed Hepatitis C Screening Guidelines " under the Formative Research and Tool Development Generic Clearance (OMB #0920-0840, expires 1/31/2019). CDC sponsors this current data collection activity. Data collection will be carried out by the CDC's contractor, KRC Research (KRC), in conjunction with its subcontracting partners. CDC will not receive any personally identifiable information.

There are an estimated 2.4 million people living with hepatitis C in the United States, about 50% of whom are unaware they are currently infected. Hepatitis C is a liver infection caused by the hepatitis C virus. Hepatitis C can range from a mild illness lasting a few weeks to a serious, lifelong illness. Approximately 75%–85% of people who become infected with hepatitis C virus will develop a chronic infection that, if untreated, can lead to liver damage, cirrhosis (scarring of the liver), liver cancer, and even death.

Testing identifies people living with hepatitis C, which is the first step in the linkage to care and treatment. There have been tremendous advancements in hepatitis C treatment over the last decade; improved treatments can cure the disease for over 90% of people within 8-12 weeks. This effort will help identify barriers and motivators to hepatitis C testing by physicians, and will inform CDC's educational efforts and campaign activities, as well as help inform other potential interventions.

To identify people with chronic hepatitis C, CDC currently recommends the following people be tested:

- Everyone born from 1945 to 1965;
- Anyone who received clotting factor concentrates made before 1987;
- Recipients of blood transfusions or solid organ transplants prior to July 1992;
- Long-term hemodialysis patients;

- People with known exposures to the hepatitis C virus, such as health care workers or public safety workers after needle sticks involving blood from someone infected with hepatitis C virus, and recipients of blood or organs from a donor who tested positive for the hepatitis C virus;
- People with HIV infection;
- Children born to mothers with hepatitis C; and
- Current or former injection drug users, including those who injected only once many years ago.

Other experts, including the U.S. Preventive Services Task Force, also recommends testing for:

- People in jails or prisons;
- People who use drugs snorted through the nose (in addition to people who inject drugs); and
- People who get an unregulated tattoo.

Getting tested for hepatitis C is not part of routine prenatal care, except for pregnant woman who have risk factors.

Current recommendations have not been sufficient for identifying all the people living with hepatitis C. Nearly half with chronic hepatitis C are unaware they are currently infected. As a result, CDC is considering recommending one-time hepatitis C antibody testing for all adults including those with no risk factors and for pregnant women during each pregnancy.

If CDC's universal recommendation is implemented by physicians, more chronic hepatitis C can be identified and the morbidity and mortality associated with hepatitis C can be reduced once those identified get curative treatment. Physicians, and their decision whether or not to implement these recommendations, are the critical element in getting people who are chronically infected tested so they can get treatment and get cured.

## 2. Purpose and Use of the Information Collection

CDC wishes to conduct this formative research in order to understand physicians' attitudes, beliefs and behaviors around hepatitis C testing and get their reaction to a proposed universal testing recommendation. This work falls within the scoop of what is outline for NCHHSTP's 4 priority diseases, which includes hepatitis C. The methodology of information collection is approved under the generic package and will use qualitative interviewing using volunteer respondents for exploratory and formative research to develop intervention methods and materials. Interviews will consist of groups conducted virtually via the internet (i.e. internet focus groups). Results of qualitative interviews will be used to develop population-appropriate methods, interventions, messages, products, and campaigns.

Thus, DVH requests OMB approval to explore reactions to the universal recommendation, as well as barriers and motivators to physician hepatitis C testing. DVH will use these insights to inform education, outreach, and other strategies as appropriate. CDC is sponsoring this effort to ensure high quality, actionable information is available for health care providers.

Interview data will be gathered from a total of 128 practicing physicians across 16 virtual (online) focus groups comprised of 8 physicians per group. Half of the groups will be comprised of primary care physicians, and half will be comprised of OBGYNs. Physicians will be recruited for virtual focus groups from across the United States and the District of Columbia. Contractor team members and associated vendors involved with this study will screen potential participants for study eligibility with the physician screening tool (**Attachment 3)**. Eligible physicians who choose to participate will be scheduled for a group at a time that is convenient to them.

Participants will be asked to complete an informed consent form **(Attachment 4**).

We will use a semi-structured qualitative interview guide to collect information (**Attachment 7)**. This research will explore knowledge and attitudes among physicians about hepatitis C screening practices, implementation of CDC's current hepatitis C testing recommendations, as well and reactions to the new universal hepatitis C screening recommendation from CDC.

The qualitative data collected will be used to prepare a report that summarizes current physician mind states and influences with regard to hepatitis testing, to the current and new universal screening recommendation, and barriers and motivators to screening all U.S. adults.

The purpose is practical and necessary. The findings will be communicated to relevant CDC leadership to use to strengthen its hepatitis C education, outreach, and other strategies as appropriate. Specifically, the information will be used by CDC to inform its communication and education efforts with health care providers in support of the ***Know More Hepatitis (KMH*) educational campaign**. The KMH campaign is designed to support CDC hepatitis C testing recommendations among primary care physicians (PCPs) and obstetrician-gynecologists (OBGYNs) whose direct responsibility is patient care among the primary consumer audience.

Information gained from the focus groups will be shared with CDC by the contractor team in aggregate note format and will not contain any names or other personally identifiable information. See response to **Question 10** for more information on confidentiality and privacy.

### 3. Use of Improved Information Technology and Burden Reduction

The contracting team will screen potential physician participants by telephone using a screening tool **(Attachment 3)**. Qualifying physicians will all be asked to provide a signed consent form prior to participating in and for recording focus groups (**Attachment 4**).

After asking for and receiving signed consent forms from participants, staff from the contracting team will conduct the groups virtually using a web-based platform with webcams and voice for phone to allow qualifying physicians to gather virtually from the convenience of their office or home across the fifty states and Washington, D.C., without traveling to a physical location. Furthermore, they will conduct the focus groups at a time that is convenient to participants. These technologies reduce the burden of time and travel.

Virtual groups work well for the physician audience. The platform is web-based, meaning that it does not download anything to a person's personal computer (participants and viewers need only have an internet connection and the latest version of Adobe on their computers). Civicom allows for virtual focus groups with webcams to be conducted seamlessly, drawing upon all of the benefits of in-person focus groups without the limitation of geography. Respondents see and hear each other and interact in real-time.

To mitigate any technological complications, the contracting team has a technician virtually present at each of the focus groups to help as needed with any technology (phone, internet, and webcam) challenges for respondents, viewers, and the moderator, should they arise.

The contracting team will record the focus group conversations 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 participants.

### 4. Efforts to Identify Duplication and Use of Similar Information

The Agency is considering a universal patient screening recommendation based on expert opinion and scientific evidence.

To the Agency's knowledge, there is no other available research to guide the agency in its communications related to its proposed universal patient screening recommendation. There is no reason for another Federal Agency to collect this information.

In summary, the Agency has determined that the information it needs is essential, unique, does not exist and is not planned from other sources, and so requests to obtain this information from among physicians using primary research. CDC desires to effectively communicate this universal hepatitis C screening recommendation to physicians to make them aware *and* motivate them to implement the recommendation.

### 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 effectively communicate the universal hepatitis C screening recommendation to physicians and to understand any identified barriers so CDC can address those issues in education, outreach and other strategies as appropriate. .

If these groups are not conducted, CDC will be lacking an in-depth contextual understanding of factors that may affect the success of implementation of new recommendations.

### 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 (0920-0840) in the Federal Register on 04/23/2018, Volume 83, Number 78, Page Number 17663-17664. No public comments were received.

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.

### 9. Explanation of Any Payment or Gift to Respondents

Voluntary physician participants will each receive a $100 token of appreciation. Offering tokens of appreciation is necessary to subject matter experts, like physicians. This amount is consistent with the hourly wage rate of physicians. DVH is requesting 75 minutes of physician 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 among subject matter experts without biasing responses. This improves the validity and reliability of the data, which is of utmost importance in this scientific study.

## 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 10**).

Information gained from the focus groups will be in aggregate narrative note format and will not contain any names or other personally identifiable information. The information gained from the focus groups will be qualitative in nature, and not used to generate statistical information.

Following the groups, a report will be prepared of content from the groups and will analyze the information to identify key themes, insights, and findings. The information will be used by CDC staff to inform education, outreach, and other strategies as appropriate. Information is internal and is not intended for release outside of the agency.

KRC's recruitment partner is Reckner Healthcare (Reckner). Potentially qualifying study participants will be drawn from the Reckner Healthcare physician panel, a volunteer national panel of physicians. Physician panelists will first be contacted by Reckner via email and invited to participate **(Attachment 2)**. If potential participants are interested in participating, Reckner will screen them by telephone using a screening tool **(Attachment 3)** to determine if they qualify.

CDC will be identified as the sole sponsor of the activity. Individuals will be advised that participation is voluntary and their responses will be treated with confidentiality. They will be asked to read and sign a consent form **(Attachment 4)**.

Personally identifiable information from qualifying individuals will not be distributed outside of Reckner. Other information gathered by Reckner from qualifying respondents in the screening tool will be summarized in an anonymized spreadsheet which will be distributed to KRC Research and CDC (**Attachment 6**).

Thus, only Reckner staff will have access to personally identifiable information (full respondent name, phone number, and email). 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 Review

This study has been reviewed and approved by the Ethical & Independent Review Services **(Attachment 8)**. The approved IRB protocol is also included as a supplemental document to Part B.

Sensitive Questions

This study among physicians will not involve questions considered sensitive.

## 12. Estimates of Annualized Burden Hours and Costs

The recruitment period is six weeks. This data collection will include 128 physicians. We expect to screen 400 physicians, and we expect 32% to be eligible and to participant in the data collection, which yields a final client sample size of 128. Contractor staff will screen potential physician participants for eligibility by phone, which will take approximately ten minutes **(Attachment 3).** The consent form **(Attachment 4)** will take approximately 3 minutes to complete and will be administered once. The focus group discussion **(Attachment 7)** will take 75 minutes to complete and will be administered once.

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 233.4 hours.

12A. **Estimated Annualized Burden Hours**

**Exhibit 12.1: Estimated Annualized Burden Hours**

| Category of Respondent Activity | No. of Respondents | Participation Time (min.) | Burden Hours |
|---|---|---|---|
| Physicians – Screener | 400 | 10 | 67 |
| Physicians – Consent Form | 128 | 3 | 6 |
| Physicians – Focus Group | 128 | 75 | 160 |
| **Total** | **528** | **85** | **233** |

12B. **Estimated Annualized Burden Costs**

The annualized costs to the participants are described in Exhibit 12.2. To estimate the hourly wage rate of those involved in this study, we have used information from the United States Bureau of Labor Statistics (BLS). Results from the latest BLS Occupational Employment Statistics survey (conducted in May 2018) were released on March 29, 2019 and form the basis of the estimates below. (Source: https://www.bls.gov/news.release/ocwage.t01.htm)

The mean hourly wage for "family and general practitioners," the best available analogue for this study's primary care physician audience, is $101.82. The mean hourly wage for obstetricians and gynecologists is $114.58. Because an equal number of respondents from both groups will participate in this study, and because we anticipate no differences in their rate of qualification, we have used the average of these two hourly wages ($108.20) below.

The total estimated cost of the burden to participants is approximately $25,253.88, which represents the total burden hours multiplied by the average hourly wage rate ($108.20).

**Exhibit 12.2: Estimated Annualized Burden Costs**

| Category of Respondent Activity | Burden Hours | Hourly Wage Rate | Respondent Costs |
|---|---|---|---|
| Physicians – Screener | 67 | $108.20 | $7,249.40 |
| Physicians – Consent Form | 6 | $108.20 | $649.20 |
| Physicians – Focus Group | 160 | $108.20 | $17,312.00 |
| **Totals** | **233** | | **$25,210.60** |

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

There are no other costs to respondents or record keepers for participating in this research.

## 14. Annualized Cost to the Federal Government

Exhibit 14.1 provides the annualized cost to the government, which totals $25,253 using the 2019 Atlanta locality salary schedule. CDC supports costs for hepatitis C task orders using funds budgeted for

these purposes. Managing the project, providing technical assistance, monitoring and analyzing the submitted data, and generating assorted reports will require the expertise of two CDC staff.

**Exhibit 14.3: Annualized Cost to the Government (2019 scale)**

| Expense Type | Expense Explanation | Annual Costs (dollars) |
|---|---|---|
| Direct Costs | CDC, Health Education Specialist (GS-13, 0.10 FTE) | $9,328.20 |
| | CDC Health Scientist (GS-14, 0.05 FTE) | $5,511.55 |
| | **Subtotal, Direct Costs** | **$14,839.75** |
| Contract Costs | **Annual Contract Costs (200-2016-F-90427)** | **$107,000** |
| | **TOTAL COST TO THE GOVERNMENT** | **$ 121,839.75** |

## 15. Explanation for Program Changes or Adjustments

This is a new genIC request under Generic request 0920-0840.

## 16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics and feedback from participants in narrative form. Data collection will occur between 2-4 months after OMB approval with analysis carried our 5-8 months after OMB approval, and the final report will be submitted 10-12 months after OMB approval. The project timeline is detailed in exhibit 16.1.

**Exhibit 16.4: Project Time Schedule**

| Activity | Time Schedule |
|---|---|
| Develop data collection tools, sampling and data plans, study protocol | March to September 2019 |
| OMB Submission | October 2019 |
| Recruitment | 1 months after OMB Approval |
| Data Collection | 2-4 months after OMB Approval |
| Data analysis finalized | 5-8 months after OMB Approval |
| Draft report and final report written | 7-9 months after OMB approval |
| Final data set and final report submitted to CDC | 10-12 months after OMB Approval |

The information gained will be used by an internal CDC audience to understand provider-related motivators and barriers related to screening for hepatitis C among all adults and women during each pregnancy and will help inform education and outreach strategies. The population most likely to use the information is an internal CDC audience. The expected volume of use would not be large enough to justify the resource costs in making the dataset available.

## 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

The activities comply with the requirements in 5 CFR 1320.9.