Field Assessment of a Comprehensive Manual for Hepatitis C Counseling and Testing

Generic Information Collection request under 0920-0840
Formative Research and Tool Development

Section A: Supporting Statement

January 31, 2012

CONTACT

Rebecca Cabral, Ph.D
Centers for Disease Control and Prevention
Division of Viral Hepatitis
Prevention Branch
Phone: 404.639.8508
Fax: 404.718-8595
rcabral@cdc.gov

Table of Contents

38. Field Assessment of a Comprehensive Manual for Hepatitis C Counseling and Testing

39.

40. Supporting Statement A

41.

42. A. JUSTIFICATION

43.

44. A.1 Circumstances Making the Collection of Information Necessary

45.

46. <u>Background</u>

47.

48. The Centers for Disease Control and Prevention, Division of Viral Hepatitis, requests approval for a term of 3 years for a new data collection called, "Field Assessment of a Comprehensive Manual for Hepatitis C Counseling and Testing. This is a genIC requested under the OMB approved Generic Clearance #0920-0840, "Formative Research and Tool Development". The manual includes several modules that are intended to educate counselors and primary care providers on procedures for conducting counseling and testing of Hepatitis C with their patients and clients in the following situations: (1) pretest HCV antibody testing, (2) posttest HCV antibody-negative, (3) posttest HCV antibody-positive and (4) post-test PCR RNA-positive. This manual is intended to be used by two groups: counselors in public health clinics and other venues serving those at risk of HCV infection, primarily through injection drug use (Group I), and clinicians/health care providers in primary care settings providing routine care for people born between 1945-1964; the birth cohort at highest risk of being chronically infected, often for 20 or more years (Group II).

49.

50. The field assessment of the Comprehensive Manual for Hepatitis C Counseling and Testing will enable CDC to examine the practicality of the curriculum modules, understand their usefulness in practice, and to obtain suggestions for improving the manual's utility. The proposed field assessment will accomplish this through key informant interviews to gather end-user feedback on the modules. As such, this field assessment fits under the OMB approved Generic Clearance formative research because it will assess the usability of the manual and the information gained from the field assessment will help CDC improve the effectiveness of the modules for use in public health and primary care settings.

51.

52. Hepatitis C virus (HCV) infection is the most common blood-borne infection in the United States. HCV is most efficiently transmitted through large or repeated percutaneous exposure to infected blood (e.g., through use of injecting drugs or, rarely, through transfusion of blood from unscreened donors). HCV can develop into chronic infections. No vaccine exists to prevent infection with HCV. Chronic HCV infection is the leading indication for liver transplants in the United States and accounts for an estimated 12,000 deaths each year. While at least 75% of persons who acquire HCV infection become chronically infected – and among the chronically infected, as many as 25% will ultimately have advanced liver disease - symptoms associated with HCV infection usually do not become evident for several decades.

53.
54. Because of the high disease burden, the low rate of testing in affected persons, and the fact that most persons who become infected do not have obvious signs of hepatitis C for many years, HCV infection has been described as a "silent epidemic." Acute HCV infection does not usually cause symptoms, and thus only a small proportion of persons with acute infections seek medical attention. Still a smaller percentage of those acutely infected are tested, diagnosed, and reported.
55.
56. National recommendations for prevention and control of HCV infection and HCV-related chronic disease were last issued in 1998. CDC is currently undertaking a process to review and expand the guidelines, but does not expect an update to be published prior to the summer of 2012, with a full revision sometime thereafter. Current guidelines emphasize primary prevention, including screening and testing of blood donors, inactivation of potentially infectious materials in plasma-derived products, risk-reduction counseling, and screening of persons at risk for HCV infection. Recommendations for screening of high risk groups are not expected to change, however, the expanded guidelines will likely call for screening individuals born in the birth cohort at highest risk for chronic infection. While this recommendation is under review, it is probable that the recommendations will include those born between 1945 and 1965.
57.
58. It is estimated that 18,000 people become infected with HCV yearly in the U.S. Injecting drug use is the primary mode of transmission of HCV in the US. The CDC and the American Association for the Study of Liver Diseases
59. (AASLD) guidelines recommend that all injecting drug users (IDU) be tested for Hepatitis C antibodies. Although all health care providers should screen their patients for behaviors associated with injecting drug use, venues that serve people with high risk behaviors are more likely to reach IDUs at risk for or already infected with HCV.
60.
61. Many people born between 1945 and 1965, commonly known as the "baby boomer generation" are chronically infected with Hepatitis C and are unaware of their infection. Chronic HCV infection can lead to fibrosis, cirrhosis, and liver cancer. Hepatitis C is a leading cause of liver cancer and the principal cause of death from liver disease. The societal burden of liver disease can be mitigated by identifying those with chronic Hepatitis C and getting them into health care. Many people from this large age cohort are unlikely to be identified through venues such as drug treatment facilities and STD clinics. Broader testing can be implemented in primary and specialty care settings, where people aged 45-65 come for routine health care. Patients may know little or nothing about Hepatitis C or may associate it with stigmatized behaviors. Most are unlikely to spontaneously request a Hepatitis C antibody test. This places a burden on the clinician to initiate, educate, and provide counseling about the tests, the results, and follow up. In many cases, clinicians have not commonly conducted this type of counseling.
62.
63. Testing is an effective tool in limiting the spread of Hepatitis C, as HCV infection is often asymptomatic and people are unaware of their infection and the risk of transmission to others. Identification of their infection provides persons with the information to

prevent HCV transmission to others, such as through needle sharing. They can also get appropriate health care and take steps to prevent liver damage.

64.

65. There are no standardized protocols/curricula for conducting Hepatitis C counseling and testing across different venues. The protocols that do exist are typically based on STD and HIV counseling models. In response to this need, the Education and Training Branch in the Division of Viral Hepatitis has developed a comprehensive HCV counseling and testing manual that includes common elements that can be used in a variety of settings. The modules in the manual are intended to provide guidance and support to outreach staff, counselors, clinicians and others who counsel people who are at risk for or are infected with HCV.

66.

67. In order to determine how best to tailor the Division of Viral Hepatitis's manual for Hepatitis C counseling and testing for use by public health counselors and clinicians, we need to gather information/feedback from potential users. The proposed field assessment will provide valuable information that will enable CDC to obtain end-user feedback on the manual and better understand its practicality, usefulness, and ways to improve it.

68.

69.

70. A.1.2 Privacy Impact Assessment

71.

72. CDC will not receive any personally identifiable information. The main purpose of the field assessment will be to collect information on the utility of the HCV testing manual and how it could be improved. Respondents' names will not be used in the data collected. The contractor will summarize respondent data for use in revising the manual. No research data will be collected and no research papers will be published from the data. No names or identifying information will be kept.

73.

74. A.1.3 Overview of the data collection system

75.

76. Qualitative interviewing will be used to collect end-user feedback on the HCV counseling and testing manual with volunteer respondents (20 counselors and 20 primary care clinicians.) To recruit participants for the field guide assessment, the contractor will consult with the DVH network of Adult Viral Hepatitis Coordinators to identify potential venues that would be appropriate to reach high-risk counselors (Group I). Once these venues have been identified, the contractor will contact these organizations to request staff participation in the field assessment as referenced in the recruitment script (**Attachment 1**). Venues serving primary care clinicians (Group II) will be identified through the American Academy of Family Physicians (AAFP). Once these primary care venues are identified, the consultant will work with the AAFP to also contact these organizations to explain the field assessment and ask if they would be willing to participate (**see Attachment 1**). Once venues have expressed an interest in participating in the field assessment, the consultant will work with the venues to identify staff that might be appropriate to include in the field assessment. The field assessment volunteers that will be selected to participate in the assessment will be given the manual to review and use over a four-week period. After this four-week period, an in-person interview

(**Attachment 3)** will be conducted to obtain their feedback on the manual and recommendations for improving its utility. The information obtained from these qualitative interviews will be used to refine the manual for future use in public health and primary care settings.

77.

78. In addition to the interviews that will be conducted at the end of the four-week period (**Attachment 3**), the contractor will also engage in brief periodic telephone check-ins with volunteers to gauge their initial impressions of the manual and see if they have any questions or concerns about it(**Attachment 2)**. These check-ins are expected to be very brief and are geared more to answer any questions that the volunteers might have about reviewing or using the manual.

79.

80. A.1.4 Items of Information to be collected

81.

82. The qualitative interviews will be conducted with the 40 volunteer participants (20 counselors and 20 primary care clinicians). The interviews will be about:

83.

1) Prior experiences with HCV counseling and testing
2) The formatting and organization of the manual
3) The usefulness of the manual
4) Suggestions for improving the manual

84.

85.

86. Attachment 3 is a comprehensive list of the questions that will most likely be used in the field assessment qualitative interviews. The feedback summaries created for CDC will not include personal information.

87.

88. A.1.5 Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

89. This information collection does not involve websites or website content directed at children under 13 years of age.

90.

91. A.2. Purpose and Use of Information Collection

92. The primary goal of the field assessment is to conduct a comprehensive review of the utility of the existing DVH HCV counseling and testing manual among potential end-users serving two distinct groups: (1) counselors in public health venues likely to reach adults at risk for Hepatitis C (HCV) (Group I); and (II) clinicians in primary care settings that reach age appropriate (born between 1945- 1965) HCV antibody positive and negative patients (Group II). As part of the assessment the contractor, Battelle, will work with counselors and clinicians from both groups to review the HCV manual, use it in practice and provide detailed feedback on it, including its applicability, ease of use, functionality and suggestions for improvement. Battelle, with CDC input, will revise the counseling modules based on feedback received during the field assessment.

93. This assessment will not produce results that can be generalized beyond the scope of the project. The objective of this request is solely to enable DVH to respond to the needs of

counselors and clinicians who are conducting Hepatitis C testing.

94.

95. A.2.1 Qualitative interviewing for surveillance, research and intervention methods and material development

96.

97. Qualitative interviewing will be used with volunteer counselors and clinicians who will be conducting Hepatitis C counseling and testing. The interviews will be used to assess the acceptability and feasibility of the counseling manual in their respective sites. Results from the assessment will help improve the quality and applicability of the Hepatitis C counseling and testing manual.

98.

99.

100. A.2.5 Field Testing of New methodologies and Materials

101.

102. The purpose of this data collection is to carry out a field assessment of new materials/methods for counseling and testing for Hepatitis C. The objective of such testing is to assess the utility and practicality of the manual/curriculum among potential end users. The manual will ultimately assist CDC's constituents in conducting HCV counseling and testing in a variety of settings. Since there have never been any standardized counseling modules that have been used across multiple venues for Hepatitis C, the manual represents a "new" methodology. The manual will be a valuable resource to counselors and clinicians who will be conducting HCV counseling and testing.

103.

104. A.3. Use of Improved Information Technology and Burden Reduction

105.

106. Participants will not be expected to provide any written information. All of the interviews will be recorded on digital recorders. Upon completion of the interviews, the digital recordings will be downloaded to a computer and then will be professionally transcribed into a word processing file to accurately capture the data. The data will then be used to summarize the feedback on the modules and the recommendations for its improvement.

107.

108. A.4. Efforts to Identify Duplication and Use of Similar Information

109. DVH has verified that there are no other federal collections that duplicate the data collection methods included in this request. The information collected will be specific to this product assessment.

110.

111. A.5. Impact on Small Businesses and Other Small Entities

112. No small businesses will be involved in this data collection.

113.

114. A.6. Consequences of Collecting the Information Less Frequently

115.

116. The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden.

117.

118. **A.7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5**

119. This request fully complies with the regulation 5 CFR 1320.5.

120.

121. A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

122.

123. A Federal Register Notice for the generic clearance 0920-0840 was published on January 15, 2010. For sub-collection requests under an approved generic ICR, federal register notices are not required and none were published, therefore no comments were received.

124. A.9. <u>Explanation of Any Payment or Gift to Respondents</u>

125. Counselors and clinicians will receive a token of appreciation of $25 for each week that they use the manual with their client(s) over the four-week period. Volunteer participants will also receive $40 for participating in the wrap-up interview at the end of the four-week period, to obtain their detailed impressions of the manual and recommendations for improving it. This compensation is needed to facilitate the timely and adequate recruitment of volunteers to participate in the field assessment and improve the quality of the information that is collected. These amounts were determined to be appropriate and fair through consultation with the CDC Adult Viral Hepatitis Coordinators, with the American Academy of Family Physicians (AAFP), and with practicing co4unselors and clinicians. The consultants for this project will include:

126.

127. DVH Contacts: 128. 129. Katherine Bornschlegel, MPH 130. New York City Department of Health and Mental Hygiene 131. kbornsch@health.nyc.gov 132. 2 Gotham Center, CN 22A 133. 42-09 28th St. 6th floor, 6-15 134. LIC, NY 11101 135. phone (347) 396 2649 136. 137. Susan Thompson, RN, MPH 138. Hepatitis B/C Coordinator 139. CD Regional Nurse Consultant 140. Communicable Disease Branch 141. NC Division of Public Health 142. 919-733-3419 (main) 143. 919-733-9601 (office) 144. 919-306-5539 (cell) 145. susan.thompson@dhhs.nc.gov 146. 147. J. Leahy, MPH 148. Adult Viral Hepatitis Prevention Coordinator 149. Oregon Health Authority 150. judith.m.leahy@state.or.us 151. Phone 971-673-1130 152. Fax 971-673-1100 153. 800 NE Oregon Street Suite 772 154. Portland, OR 97232 155. 156. Cameron Lewis 157. Adult Hepatitis Coordinator/Manager	**165. AAFP Contact:** 166. Name 167. 168. Kim Kimminau, PhD: Research Principal Investigator 169. kkimminau@aafp.org 170. 913-906-6000 ext 3184 171. AAFP Headquarters (Kansas City) Mailing Address: 172. The American Academy of Family Physicians 173. National Research Network 174. 11400 Tomahawk Creek Parkway 175. Leawood, KS 66211 176. 177.

158. Arizona Department of Health Services 159. Office of HIV, STD and Hepatitis Services 160. 150 N 18th Ave, Suite 110, Phoenix, AZ 85007-3233 161. Cameron.Lewis@azdhs.gov 162. landline 602-364-3655 163. Blackberry 602-904-2517 164.	

178. A.10. Assurance of Confidentiality Provided to Respondents

179.

180. Participation in the field assessment is completely voluntary. Prior to participating in the field assessment, each potential participant will receive a written informed consent that describes the study, expectations, risks and benefits, privacy and confidentiality and who to contact with any questions (**Attachment 5**). The participant will not be required to sign the consent form to participate but will be asked to acknowledge receiving it and provide verbal consent. This verbal consent will be obtained during the first check-in call where participants will also be given the opportunity to ask any questions about the project or their participation in it (**Attachment 2**). During subsequent interviews and calls, participants will be reminded that their participation is completely voluntary.

181.

182. The interviews will be audio-taped for clarifying purposes only. All audio tapes from the interviews will be deleted from the computer and erased from the recorder after the interviews have been transcribed. The transcribed materials will only be identified by a general I.D. (such as respondent #1)and will not contain any identifying names. Respondents will be told that no identifying information will be collected from them or given to the CDC. Any data that are shared with CDC or with anyone outside of CDC will not contain any identifying information.

183.

184. A.11. Justification for Sensitive Questions

185. There will be no questions about sensitive topics. Participants will only be asked questions relating to the manual and its usability.

186.

187. A.12. Estimates of Annualized Burden Hours and Costs

188.

189. **A.12.A. Estimated Annualized Burden Hours**

190.

191. The two types of respondents that will participate in the field assessment include counselors in public health clinics and other venues serving those at risk of HCV infection, primarily through injection drug use (Group I), and clinicians/health care providers in primary care settings providing routine care for people born between 1945-1965 (Group II) A total of forty respondents (20 counselors and 20 primary care clinicians) will participate in the thirty minute wrap-up interview. In addition to the wrap-up interviews, participants will engage in weekly check-in calls. The time required

for these calls will vary based on the participants' and should take approximately 15 minutes and include discussion about participating in the field assessment.

192.

193.

194. Exhibit A.12.A Estimated Annualized Burden Hours

195. Type of Respondent	196. Form Name	197. Number of Respondents	198. Number of Responses Per Respondent	199. Average Burden Per Response (in Hours)	200. Total 201. Burden 202. Hours
203. Group I and Group II Potential Participants	204. HCV Field Assessment Recruitment Script 205.	206. 40	207. 1	208. 15/60	209. 10
210. Group I and Group II participants	211. Field Assessment Wrap-up interview 212.	213. 40	214. 1	215. 30/60	216. 20
217. Group I and Group II participants	218. Weekly check-in interviews 219.	220. 40	221. 4	222. 15/60	223. 40
				224. Total	**225. 70**

226.

227. A.12.B. Estimated Annualized Burden Costs

228.

229. The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2010. http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for family practitioners and substance abuse/public health counselors for the purpose of this generic request. The figure of $83.59 per hour was used as an estimate of average hourly wage for family practitioners and the figure of $19.62 is used as an estimate of the average hourly wage for public health/behavioral counselors. These two figures were averaged to arrive at an average wage of $51.60 per hour. Thus, the total anticipated annual cost to participants for collection of information in this project will be $3,612.00.

230.

231. **Exhibit A.12.B: Estimated Annualized Burden Costs**

232.

233. Type of Respondent 234. (Form Name) 235.	236. Total Burden Hours	237. Hourly Wage Rate	238. Total Respondent Costs
239. Group I and Group II potential participants (HCV Field	241. 10	242. $ 51.60	243. $516.00

Assessment Recruitment Script) 240.			
244. Group I and Group II(Field Assessment Wrap-up interview) 245.	246. 20	247. $ 51.60	248. $1,032.00
249. Group I and Group II (weekly check-in interviews) 250.	251. 40	252. $ 51.60	253. $2,064.00
254. Total	**255. 70**	**256. $ 51.60**	257. $3,612.00

258. A.13. <u>Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers</u>

259.

260. There are no other costs to respondents or record keepers.

261.

262. A.14. <u>Annualized Cost to the Government</u>

263.

264. This activity will require the participation of CDC staff members. The technical monitor will be responsible for communicating about the project with others inside and outside CDC, preparing the IRB and OMB human subjects documents, working with the designated contractor, and providing project oversight. In addition, there may be travel expenses associated with monitoring sites.

265.

266. **Exhibit A.14: Estimates of Annualized Cost to the Government**

267.

270.

268. Expense Type	**269. Expense Explanation**	**271. Annual Costs (dollars)**
272. Direct Costs to the Federal Government	273. CDC, Principal Investigator (GS-13,0.25 FTE)	274. $27,000
275.	276.	277.
278.	279.	280.
281.	282. CDC Travel for site visits	283. $2500

284.	285. **Subtotal, Direct Costs**	**286.**
287. Cooperative Agreement or Contract Costs	**288.** Contractor Costs, (Battelle)	289. $390,000
290.	**291. Subtotal, Cooperative Agreement or Contract Costs**	**292.**
293.	**294. TOTAL COST TO THE GOVERNMENT**	**295.$419,500**

296.
297.
298. **A.15.Explanation for Program Changes or Adjustments**
299.
300. Not applicable – request is for a sub-collection under a generic approval.
301.
302. **A.16. Plans for Tabulation and Publication and Project Time Schedule**
303.
304. Field assessment will be conducted over a 6-month period. In each site, collection of information will be conducted within a 6-week period. No quantitative statistical analyses will be conducted. Data summaries will take approximately 2-3 months to complete, after which manual revisions will begin.

305.
306.

307. Exhibit A.16: Project Time Schedule

308.

309.

310. **311. Activity**	312. **313. Time Schedule**
314. Recruit counselors and clinicians to participate in the field assessment	315. 1-2 months after OMB approval
316. Conduct key informant interviews	317. 4-6 months after OMB approval
318. Analyze data from interviews	319. 6-9 months after OMB approval
320. Contractor will revise the manual based on data from the field assessment	321. 9-12 months after OMB approval

322.

323. A.17. <u>Reason(s) Display of OMB Expiration Date is Inappropriate</u>

324. OMB Expiration Date will be displayed.

325. A.18. <u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>

326. There are no exceptions to the certification.

327.