

Project NICE: Navigating Insurance Coverage Expansion

OMB No. 0920-NEW

Supporting Statement A

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38.

- The goal of the study is to evaluate the efficacy of a point of care, in-person health insurance assistance structural intervention on HIV-related health outcomes.
- If the intervention is determined to be efficacious, the intended use of the resulting data will be to disseminate among HIV programs and health departments to encourage adoption and implementation of the intervention.
- The study design is a randomized control trial. Data will be collected via surveys and electronic medical record abstraction.
- The population to be studied includes Black and Hispanic men who have sex with men, and transgender persons age ≥ 18 years living in the Chicago, Illinois metropolitan area.
- Data will be analyzed using intent to treat comparison, two-sided Cochran-Mantel-Haenszel test, overall comparisons made with Breslow-Day tests, and Generalized Linear Models for secondary endpoints.

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40. Section A. Justification

1. Circumstances Making the Collection of Information Necessary

41. The Centers for Disease Control and Prevention (CDC) requests a 3 year approval for a new data collection effort for the research study "Project NICE: Navigating Insurance Coverage Expansion".

42. The collection of data for this study is authorized by Title III-General Powers and Duties of Public Health Service, Part A Research and Investigation in General (**Attachment 1**).

43. Background

44. In 2013, men who have sex with men (MSM) accounted for 65% of all new infections in the United States. In 2010 African Americans comprised only 12% of the U.S. population, but Black MSM nearly equaled white MSM in numbers of new HIV infections;¹ and while Hispanics comprised 17% of the U.S. population, Hispanic MSM accounted for 22% of all new HIV infections.¹ HIV rates among Black and Hispanic transgender women have been reported at 56% and 16%, respectively.²

45. Black and Hispanic MSM and transgender persons face barriers to HIV medical care, such as healthcare costs, lack of health insurance, or low literacy skills.^{3,4,5} Approximately 40% of Black MSM are uninsured or had a lapse in health insurance coverage in the previous 12 months.^{5,6} Some 31% of Hispanics⁷, 31% of Black transgender persons and 28% of Hispanic transgender persons lack health insurance.⁸ The fact that HIV-infected Black MSM have positive health outcomes once they become engaged in care argues for the cost-effectiveness of removing obstacles to health care access.^{9,10}

46. An intervention to help Black and Hispanic MSM and transgender persons overcome obstacles to health care can improve the health of all Black and Hispanic MSM and transgender persons, and can prevent transmission and acquisition of HIV among at-risk persons. Historically, HIV prevention has been addressed through

biomedical and behavioral interventions. Structural interventions, however, address the context and environment within which people live, therefore are more successful than interventions that focus solely on individual behavior, and may have the greatest effect over the long term in reducing the number of new HIV infections.^{11,12} This new data collection activity aims to evaluate a *structural* intervention that removes an obstacle to health care access--lack of health insurance. The project will implement and evaluate provision of point of care, in-person health insurance enrollment assistance to help eligible Black and Hispanic MSM and transgender persons in the Chicago, Illinois metropolitan area, regardless of their HIV status, to enroll in private health insurance or Medicaid for the first time, change to a different insurance plan, or understand how to use current insurance policies at the end of their HIV testing session.¹³

47. The goal of this study is to test whether the intervention will (1) increase the proportion of participants who obtain health insurance; (2) result in better health outcomes among participants (e.g., achieving viral suppression, remaining HIV negative); (3) improve the linkage and retention rates for HIV care (i.e., HIV treatment, Pre-exposure Prophylaxis (PrEP)) and other HIV-associated health services (e.g., mental health counseling, substance use treatment) of participants, especially

those diagnosed with HIV; and (4) increase HIV care linkage and retention rates sufficiently to justify the cost of implementing the intervention (cost-benefit analysis). The goal of this study aligns with the National HIV/AIDS Strategy 2020 and Health People 2020 objectives, which outlines reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV, and reducing HIV-related health disparities.

48. This structural intervention design aligns with the Office of Management and Budget's emphasis on application of behavioral insights.^{14,15} Behavioral insights are used to restructure the context in which health-related decision-making occurs, in order to promote the selection of beneficial options. In-person health insurance enrollment assistance changes the context within which individuals make health insurance choices by improving the convenience of the enrollment process, reducing anxiety about making mistakes, providing guidance on choice of insurance plans, and reducing participants' time costs because health insurance enrollment is combined with another activity (HIV testing). Often, a patient is offered health insurance enrollment assistance during their first clinical appointment after their HIV test. However, this study will move health insurance enrollment assistance from the first clinical visit earlier in the process, to the point of HIV testing, thus

removing lack of insurance or inadequate insurance as a barrier to attending the first HIV-related care visit.

49. The study is funded through a cooperative agreement between CDC's Division of HIV/AIDS Prevention and the University of Chicago Medicine (UCM). Two community-based organizations (CBOs) in Chicago that provide outreach and health services to the target population, Howard Brown Health and Chicago House Social Service Agency (Chicago House), are partnering with UCM, through a sub-award agreement, to implement and evaluate the intervention. These three partner agencies currently provide in-person health insurance enrollment assistance, linkage to care (HIV-related treatment, primary care), and patient navigation services to the study population. Because this study is not evaluating a new intervention, but evaluating whether moving the delivery of in-person health insurance enrollment assistance from the first clinic visit after receipt of an HIV test result, to earlier in the care continuum during the HIV testing event, this study does not introduce new intervention activities. It only reorders the sequence of delivery of standard practice. Therefore, the burden to the participant experience will be data collection forms and research procedures only.

50.

51.2. Purpose of Use of the Information Collection

52. The purpose of this study and information collection is to design and implement a structural intervention, and to evaluate the effects of the intervention on health outcomes. Analyses will be used to assess the efficacy of the intervention as an emerging public health practice. CDC plans to disseminate study findings through reports to partner agencies and interested participants, journal publications, and conference presentations, at a minimum.

53. This intervention will employ a randomized controlled trial design (RCT). Using an RCT design will enhance scientific validity and the policy impact of the intervention, and help researchers assess the efficacy of this intervention as an emerging practice prior to dissemination to HIV prevention service providers nationwide. This study proposes to enroll and collect data from 1,000 Black and Hispanic MSM and transgender persons ages ≥ 18 years living in the Chicago, Illinois Metropolitan Statistical Area. At least 800 of the participants will be Black and Hispanic MSM.

54. Participants will be recruited to the study over a 12-month period from clinics and community-based HIV testing outreach events. Individuals who attend HIV testing outreach events organized by UCM or Chicago House, or who are patients in Howard Brown Health clinics will be invited to participate in the study after an HIV testing session. If individuals are eligible

to participate, agree to participate and provide consent, their sociodemographic (date of birth, race/ethnicity, gender identity, zip code of residence, current sexual practices, current housing situation [whether they are living in their own place, staying with a family member or friend, in a temporary shelter, foster group home, or are homeless], history of incarceration [whether they have been incarcerated in jail for longer than one night], travel time to study site), risk behavior, and insurance coverage information will be collected at that time using the participant enrollment form. This study is not collecting participant social security number. This is the only time data will be collected directly from the study participant. There will be no in-person contact with the study participant after study enrollment. Those randomized into the intervention arm of the study will be offered in-person health insurance enrollment assistance, and those randomized into the control arm will receive a handout with publically-available information about health insurance policies and instructions for how to sign up for health insurance.

55. After enrollment, participant electronic medical record (EMR) data will be abstracted quarterly over a 12-month period to assess whether study participants who received in-person health insurance enrollment assistance at the point of HIV testing (intervention group) experienced overall increases in attendance at first HIV-related (HIV treatment or PrEP) medical visit,

subsequent medical care visits, and medication adherence (as measured by achieving viral suppression and remaining HIV negative) during the 12-month evaluation period compared to study participants who did not receive in-person health insurance enrollment assistance after their HIV testing session (control group).

56. UCM, Howard Brown Health, and Chicago House will enroll participants and collect data. The two CBOs will only have access to the data of participants recruited at their sites. UCM will clean, and de-identify all data before granting access to CDC. UCM, Howard Brown Health, and Chicago House will use the REDCap study database to collect and store participant information collected from the participant enrollment form and EMR abstraction.

57. Participant data will be linked and stored in REDCap using a unique study ID for the participant. Data are retrieved from the REDCap database using a unique study ID that is randomly generated in REDCap. For each participant, their personally identifiable information (PII) will be accessible only by the specific partner agency staff (Chicago House, Howard Brown Health, or UCM) that recruited them to the study, and by study data managers at the University of Chicago Medicine.

58. The University of Chicago Medicine will prepare a Data Management Plan as a requirement for their annual non-competing review.

59.

3. Use of Improved Information Technology and Burden Reduction

60. Data will be collected directly from study participants one time, at study enrollment. Data will be entered by the participant and partner agency staff directly into the study database (REDCap) from a password-protected, encrypted handheld tablet, eliminating potential data entry errors and duplication of effort.

61.

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

63. Because this is a novel study and data collection effort, and because of the one-site study location, CDC believes there are no similar complimentary data collection efforts targeting this study population.

64.

65. 5. Impact on Small Business or Other Small Entities

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

67.

6. Consequences of Collecting the Information Less Frequently

68. This study will collect data directly from the study participant one time, at study enrollment, and then via EMR abstraction quarterly over a 12-month period. University of Chicago Medicine will make de-identified medical record data available to the CDC on a semiannual basis. Less frequent data collection and submission would result in a lag time between the occurrence of program problems and their identification. This lag time could result in costly program inefficiencies, defects, and failures to continue or worsen without opportunity for CDC to provide valuable assistance and corrective measures in a timely manner.

69.

70. **7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5**

71. This data collection effort does not involve any special circumstances.

72.

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

74. A 60-day FRN to solicit public comments was published in the *Federal Register* on 11/13/2017, Volume 82, Number 217, Page 52302 (**Attachment 2**). One comments were received from the public.

75. Project team members, listed below, include investigators with the partner agencies and CDC.

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<p>99. Rebecca Eavou, LCSW</p> <p>100. University of Chicago Medicine</p> <p>101. (Project Manager)</p> <p>102. Phone: 773-834-2336</p> <p>103. E-mail: reavou@medicine.bsd.uchicago.edu</p> <p>104. 5837 S. Maryland Ave.</p> <p>105. Rm. L-038, MC5065</p> <p>106. Chicago, IL 60637</p>	<p>107. Adrienne Herron, PhD</p> <p>108. CDC (Project Manager and Evaluation Advisor)</p> <p>109. Phone: 404-718-5591</p> <p>110. E-mail: xwj9@cdc.gov</p> <p>111. 1600 Clifton Road, NE, MS E-37</p> <p>112. Atlanta, GA 30329</p>
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9. Explanation of Any Payment or Gift to Respondents

154. A \$25 token of appreciation will be provided to all study participants after study enrollment and completion of study activities. The token of appreciation will be cash, and every participant will complete a receipt which includes their unique participant ID, the date of the study visit, the amount provided and the name of the staff member providing the token of appreciation. All tokens of appreciations will be logged and tracked by the partner agency. The study is providing a token of appreciation to all participants, including controls, in order to avoid participant selection bias and perceived inequity of treatment in the study population.

155. Racial/ethnic minority populations historically have low levels of participation in health-related research. A systematic literature review of effective recruitment strategies of racial/ethnic minorities found that tokens of appreciation do

increase response rate in research studies, and are considered a “tangible” recognition of the value of the participant’s time and efforts.¹⁶ Numerous randomized control trials targeting risk behaviors and HIV testing of MSM, studies very similar to this study in design and focus, have utilized tokens of appreciation with their participants.¹⁷⁻¹⁹ Additionally, in-depth interviews with 41 African-American drug users with or at risk for HIV infection conducted to elicit perceptions of financial payment for research participation found that study participants viewed payment for research as essential to attract participation, and many reported tokens of appreciation as another means of income.²⁰ This study will be recruiting high-risk individuals (Black and Hispanic MSM and transgender persons) from marginalized communities. Study researchers view the provision of tokens of appreciation as necessary to meeting recruitment numbers. In addition, the lead partner agency (University of Chicago Medicine) has been conducting research with racial/ethnic-minority MSM and transgender persons for many years, and have frequently utilized cash tokens of appreciation. Providing tokens of appreciation to study participants would be consistent with previous research study design and implementation, and will aid in recruiting the number of participants necessary to draw conclusions about the efficacy and significance of the intervention.

156.

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

158. The CDC Privacy Officer has reviewed this package and determined that the Privacy Act does apply. Data collected are safeguarded as described in the Privacy System of Records Notice (SORN) #0920-0136, Epidemiologic Studies and Surveillance of Disease Problems. A privacy impact assessment was conducted to ensure the protections of the collected information. **(Attachment 8)**.

159. Participant data will be maintained in a secure, database system called REDCap, which is utilized by research institutions nationally. At the University of Chicago, all database information transmission is encrypted and data is stored on VM servers at a University of Chicago datacenter. Servers are physically secure and are protected by enterprise grade firewalls (Palo Alto). The datacenter is equipped to house systems that may fall under certain federal guidelines, including the Federal Information Security Management Act (FISMA).

160. Each individual who has access to the database will have a unique username and password to log-in, enter data and access previously entered data. Each individual will be assigned to their partnering agency data access group, which will limit access to participant data by enrollment site, only allowing them

to see data for the participants they recruited. Only the University of Chicago Medicine PI and project and data managers will have access to the full data set that includes all participant data. This is required in order to review the system for duplicate participants and submit requests for data to Chicago Department of Public Health. Data shared with CDC will not be linked to participant name, date of birth, or medical record number. All download data sets will be password protected and stored on encrypted laptops that require a username and password to access. Collaborator accounts in REDCap will be verified every 6 months and any staff changes will be noted at that time. All REDCap users will be prompted to change their password every 6 months.

161.

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

163. IRB Approval

164. This project relies on local IRB approval through the University of Chicago Medicine (**Attachment 4**). The CDC Project Determination Form (**Attachment 3**) indicates that CDC involvement does not constitute engagement in human subjects research, and thus CDC IRB does not provide IRB oversight.

165. Sensitive Questions

166. Some of the personal data to be collected from study participants are highly sensitive. HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. These modes of transmission necessitate the collection of sensitive data regarding sexual practices (whether the participant engaged in anal or oral sex with a man in the previous 2 years) as well as substance use (whether the participant used drugs or alcohol in the previous 3 months) and mental health (whether the participant had feelings of depression or anxiety in the previous 2 weeks). This data collection also includes participant demographics (race and ethnicity questions, gender identification), which may also be viewed as sensitive by some respondents. These data will be used to improve HIV prevention services to the target population and other high-risk populations, and to design and evaluate appropriate interventions and programs.

167.

168. 12. Estimates of Annualized Burden Hours and Costs

169. Annualized burden hours estimates are provided in Table 12A. All data will be collected electronically on password-protected, encrypted handheld tablets.

170. The study will enroll 1,000 participants over 12 months (500 into the intervention arm, and 500 into the control arm).

After an HIV testing session, an individual will be invited to participate in the study. If they are interested, they will be screened for eligibility using the Participant Eligibility Form **(Attachment 5)** which will take approximately 5 minutes to complete. Approximately 1,500 individuals will need to be screened to identify and enroll 1,000 eligible study participants.²¹ If they are eligible and interested in participating, individuals will complete an Informed Consent Form **(Attachment 6)** which will take approximately 10 minutes, and the Participant Enrollment Form **(Attachment 7)**, which will take approximately 35 minutes to complete. The total estimated annualized hourly burden anticipated for this study is 875 hours.

171.

172. Table 12A Estimated Annualized Burden Hours (ESTIMATES)

173.

174. Type of Respondent	175. Form Name	176. Number of Respondents	177. Number of Responses per respondent	178. Average Burden per Response (in hours)	179. Total Burden Hours
180. Study participant	181. Participant Eligibility Form (Att 5)	182. 1,500	183. 1	184. 5/60	185. 125
186. Study participant	187. Informed Consent Form (Att 6)	188. 1,000	189. 1	190. 10/60	191. 167
192. Study participant	193. Participant Enrollment Form (Att 7)	194. 1,000	195. 1	196. 35/60	197. 583
198. Total	199.	200.	201.	202.	203. 75

204.

205. B. Annualized Cost to Respondent

206. Annualized cost to respondents for the burden hours is provided in Table 12B. Because it is not known what wage rate category will be appropriate across all study participants, and whether they will be employed at all, the figure of \$23.86 per hour (mean hourly wage of “all occupations”) was used as an estimate of average hourly wage. The estimate of hourly wages were obtained from the United States Department of Labor’s Bureau of Labor Statistics and is based on the May 2016 National Occupational Employment and Wage Estimates.

207.

208. Table 12B. Estimated Annualized Burden Costs

209. Type of Respondents	210. Form Name	211. Number of Respondents	212. Number of Responses per respondent	213. Average Burden per Response (in hours)	214. Hourly Wage Rate	215. Total Respondent Cost
216. Study participant	217. Participant Eligibility Form (Att 5)	218. 1,500	219. 1	220. 125	221. \$23.86	222. \$2,983
223. Study	224. Informe	225. 1,000	226. 1	227. 250	228. \$23.	229. \$5,965

particip ant	d Cons ent Form (Att 6)					8 6	
230. St udy particip ant	231. Partici pant Enro llme nt Form (Att 7)	232. 1,000	233. 1	234. 583	235. \$23. 8 6	236. \$13,910	
237. To tal	238.	239.	240.	241.	242.	243. \$22,858	

244. Sources:

245. https://www.bls.gov/oes/2016/may/oes_nat.htm

246.

247.

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

249. There are no other costs to respondents participating in this study.

250.

251. 14. Annualized Cost to the Federal Government

252. Table 14A provides the annualized cost to the government for this study (cooperative agreement number 1U01PS005143), which totals \$565,880 using the Atlanta locality salary schedule. CDC supports costs for HIV prevention program cooperative agreements 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 are projected to require the expertise of five CDC staff.

253. Table 14A. Estimated Annualized Cost to the Government (2017 scale) (cooperative agreement number 1U01PS005143)

254. Expense Type	255. Expense Explanation	256. Annual Costs (dollars)
258. Key Study Staff	259. Behavioral Scientist, GS-13, (.50 FTE) 260. Behavioral Scientist, GS-12, (.20 FTE) 261. Economist, GS-13, (.02 FTE)	262. \$45,011 263. \$15,141 264. \$1,800
265. Data Management	266. Statistician, GS-14 (.02 FTE)	267. \$2,128
268. Subject Matter Expert	269. Behavioral Scientist, GS-13 (.02 FTE) 270.	271. \$1,800
272. Study Funding	273. 1,500,000 over three years to University of Chicago Medicine	274. 500,000
275.	276. Subtotal - Direct Costs to the Federal Government	277.
278.	279. TOTAL COST TO THE GOVERNMENT	280. \$565,880

281. Source: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/GS.pdf>

282.

283. 15. Explanation for Program Changes or Adjustments

284. This is a new data collection.

285.

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

287. Data collection will be conducted during a 2-year period after OMB approval. De-identified study data will be available to CDC at the end of the study. Initial data analysis will begin within 15 months of first data collection.

288. A data sharing plan will be developed explaining how and when CDC will make study data publically available. Publication guidelines and agreements will be developed as well. Study results may be disseminated through peer-reviewed journals, conference presentations, and research briefs, at a minimum.

289. Project Time Schedule

290.	291.
292.	293. approval, April 2018
294. CDC	295. OMB approval, October 2018, April 2019, October 2019, April 2020
296. CDC	297. approval, April 2020
298.	299. approval, July 2019
300.	301. approval, April 2020
302.	303. approval, May 2020
304.	305. approval, April 2021

306.

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

308. The display of the OMB expiration date is not inappropriate.

309.

310. 18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

311. There are no exceptions to the certification.

312.

313.

314.

315. References

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337. ¹² Hecht R, Bollinger L, Stover J, et al. Critical choices in financing the response to the global HIV/AIDS pandemic. *Health Aff (Millwood)*. 2009; 28:1591-1605.

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