Generic Clearance for CDC/ATSDR

Formative Research and Tool Development

Title: ***Formative Testing of CDCs Mild Traumatic Brain Injury and Concussion Discharge Instructions for American Indian and Alaska Native Adult Patients***

Supporting Statement A

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Summary

Goal of the study: The goal of the study is to modify CDC's mild traumatic brain injury (TBI) and concussion discharge instructions for American Indian/Alaska Native (AI/AN) adults aged 18 years and older, build upon previously funded work to improve outcomes for patients with mild TBI, and enhance CDC's efforts to address TBI-related health inequities among AI/AN adults.

Intended use of the resulting data: The study will help CDC's Division of Injury Prevention effectively provide updates to CDC's mild TBI and concussion discharge instructions to better meet the needs of AI/AN adults and develop a dissemination plan to enhance outreach to AI/AN adults in rural and urban areas.

Methods to be used to collect data: Qualitative data collection will occur via in-depth interviews with Tribal Health Care Providers (up to 16 participants) and Tribal Leaders (up to 16 participants), and focus group discussions with AI/AN adults (up to 4 focus group discussions with up to 8 participants each, for a total of up to 32 participants).

How data will be analyzed: Qualitative data will be analyzed using grounded theory (Corben & Strauss, 2008) and narrative analysis (Riessman, 2008) strategies to answer the formative research questions and identify translatable findings into communication strategies. For both focus group data analysis and interview data analysis, a codebook will be developed consisting of deductive and inductive codes to identify and compare themes within and across focus groups, as well as within and across interviews. Findings will be compiled into a report that will highlight recommendations for message and material development.

SUPPORTING STATEMENT: PART A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new GenIC under OMB Control No. 0920-1154, titled "Formative Testing of CDCs Mild Traumatic Brain Injury (TBI) and Concussion Discharge Instructions for American Indian and Alaska Native Adult Patients." The purpose of this study is to obtain qualitative findings on information gaps among AI/AN adults, aged 18 years and older, who experienced a mild TBI/concussion and obtain information about the suitability (e.g., clarity, applicability) of current adult patient discharge materials from Tribal health care providers, Tribal leaders, and AI/AN adults from urban and rural areas.

AI/AN populations have higher rates of TBI-related hospitalizations and deaths than other racial or ethnic groups (Daugherty et al., 2017). However, there is a gap in research for this population and reasoning behind the high rates of TBI continues to go unexplained. CDC's Division of Injury Prevention (DIP) is acutely aware of the problem of high rates of TBIs among the AI/AN population and is working to update TBI-related content to be more accessible and more frequently used by this audience.

2. Purpose and Use of Information Collection

The information collected for this qualitative formative testing will be used to inform CDC's efforts to understand information gaps among AI/AN adults and obtain information about the suitability (e.g., clarity, applicability) of current adult patient mild TBI and concussion discharge materials from Tribal Health Care Providers, Tribal leaders, and AI/AN adults from urban and rural areas. Research from this study will help CDC's DIP effectively provide updates to CDC's discharge instructions to better meet the needs of AI/AN adults and develop a dissemination plan to enhance outreach to AI/AN adults in rural and urban areas.

Each Tribal Healthcare Provider will need to complete one eligibility screener (ATTACHMENT 2) and participate in one in-depth interview (ATTACHMENT 7). The eligibility screener contains 11 questions. The in-depth interview guide consists of 22 questions.

Each Tribal Leader will need to complete one eligibility screener (ATTACHMENT 3) and participate in one in-depth interview (ATTACHMENT 8). The eligibility screener contains 13 questions. The in-depth interview guide consists of 20 questions.

Each AI/AN Adult will need to complete one eligibility screener (ATTACHMENT 1) and participate in one focus group discussion (ATTACHMENT 6). The eligibility screener contains 12 questions. The focus group discussion guide consists of 20 questions.

3. Use of Improved Information Technology and Burden Reduction

Focus group discussions (FGD) and in-depth interviews (IDI) will be conducted online via the online video-conferencing platform Zoom. We believe this approach is appropriate in order to include geographically disparate participants and will allow for national recruitment, which reaches a wider, more diverse target audience, including those in rural areas. Additionally, this approach was selected to maximize efficiency, minimize costs, and avoid safety concerns and risks of disruptions due to the ongoing COVID-19 pandemic.

Each FGD and IDI will be video-recorded and data will be transferred and stored on a shared information system with access restricted to authorized study personnel. This reduces the number of research staff who will be required to conduct focus groups and those who are present can focus on facilitation. Each FGD and IDI will be transcribed and imported into a qualitative research software (e.g., Atlas.TI, MaxQDA) for coding. The use of a transcription service allows the research team to process and analyze the data quickly and monitor for data saturation.

4. Efforts to Identify Duplication and Use of Similar Information

A literature review found no instances of similar information to be available. To our knowledge, there are no prior or ongoing information collections like this one.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments In Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Federal Register Notice has already been published for the Generic Clearance. No Federal Register Notice is required for this GenIC submission.

CDC consulted with Banyan Communications, a public health communications consultancy agency.

9. Explanation of Any Payment or Gift to Respondents

Each focus group and interview participant will receive $50 as a token of appreciation and reimbursement for opportunity costs and expenses (i.e., babysitter, loss of work) incurred due to participation. Providing incentives to respondents is necessary to successfully recruit individuals. All participants are part of a hard-to-reach population. Research suggests that incentives have proven helpful in recruitment of hard-to-reach groups (Bonevski et al. 2014; George et al. 2014). Incentives can increase the likelihood of obtaining a diverse sample of participants, which would include individuals in hard-to-reach and minority populations who encounter complex social problems that place limitations on their desire and time to volunteer for research studies (Ellard-Gray et al. 2015; Knoll et al. 2012). Literature also reveals the payment of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality. It also should be noted that message testing is a marketing technique, and it is standard practice among commercial market researchers to offer incentives as part of respondent recruitment.

CDC will apply a health equity lens when selecting our recruitment sample, prioritizing populations that are hardly reached by CDC or concussion prevention information. DIP has had difficulties recruiting sufficient samples of these subpopulations in previous messaging projects. Having insufficient representation from this subgroup means their perspectives are not adequately included in message development which results in less effective messaging to support DIP's goals. An appropriate incentive improves the chances that these subgroups will engage and participate, therefore increasing the government's efficiency in data collection and reducing redundancies for future efforts.

These subgroups have been difficult for DIP to reach for several reasons.

1. For rural AI/AN communities, the social economic situation makes it harder for individuals to utilize PTO or miss work to participate in such projects. Though the data collection will be virtual, low-income populations are less likely to have jobs with remote flexibility, and may have to miss or leave work in order to participate. An appropriate token of appreciation may address this issue.
2. AI/AN subgroups who are being asked to participate are historically less likely to participate in research activities due to mistrust in the medical system fostered by research institutions. Offering a higher token of appreciation addresses health equity

issues brought on by historically unjust research practices, by encouraging participation from a more diverse pool of participants.

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

This submission has been reviewed by the NCIPC's Information Systems Security Officer, who has determined that the Privacy Act does not apply (Att.11). The proposed formative research does not involve the collection of personally identifiable information (PII) or sensitive data. No questions will be asked that are of a personal or sensitive nature. This submission has been reviewed by the NCIPC's Information Systems Security Officer, who has determined that the Privacy Act does not apply. At no time does CDC have access or will receive potentially identifiable information. During the interviews and focus groups (ATTACHMENTS 6, 7 and 8), participants will be asked to provide a "nickname," rather than their full name, so as to avoid collecting personally identifiable information (PII); they will also be asked to only provide an email that contracting study personnel may use to contact them. All procedures have been developed in accordance with federal, state, and local guidelines.

Throughout the formative research, the research team will store all files in a password-protected folder on secure servers; the research team will store the Excel contact file in a subfolder that is separate from the remaining documentation. The research team will include double checkers and removal of any PII that is included in the collection.

- The research team will protect PII and will store PII in secure environments.
- At the end of data collection, the research team will electronically download the Excel contact and dataset files. During this phase of the study, the research team will store all Excel and analysis files in a password-protected folder on secure servers.
- The research team will not disclose identifiable, sensitive research information to anyone not connected to the research.
- The research team will not share individual-level data beyond the immediate project team unless CDC approves data sharing and a Data Use Agreement, developed in collaboration.

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

IRB Approval

The CDC National Center for Injury Prevention and Control's OMB and human subject's liaison has determined that IRB approval is not needed for this non-research activity (Att. 10).

Sensitive Questions

No questions on the interview and focus group guides will be asked that are personal or sensitive in nature. The team has developed a protocol to ensure questions are not sensitive to provide less burden on the participants.

12. Estimates of Annualized Burden Hours and Costs

At most, sixteen (16) Tribal Health Care Providers, sixteen (16) Tribal Leaders, and thirty-two (32) AI/AN adults will be recruited for this study, for a maximum of sixty-four (64) individuals.

At most, four (4) focus group discussions will be conducted, with a maximum of eight participants in each. Focus group discussions will occur with AI/AN adults and will take no more than 60 minutes. There is no cost to participants beyond the participation burden time. The table below provides the burden estimates for this study.

At most, thirty-two (32) interviews will be conducted; sixteen (16) with Tribal Health Care Providers, and sixteen (16) with Tribal Leaders. Each interview will take approximately 60 minutes to conduct. There is no cost to participants beyond the participation burden time. The table below provides the burden estimates for this study.

Table 1. Estimated Annualized Burden Hours

Types of Respondents	Form Name	No. of Respondents	Average Burden per Response (hour)	Total Burden (in minutes per hour)
Tribal Health Care Providers, Tribal Leaders and AI/AN Adults	Screening survey for focus groups and interviews **(Att. #1)**	64	8/60	9
	Email AI/AN Adults for focus groups **(Att. #2)**	32	3/60	2
	Follow-up email AI/AN Adults **(Att. #3)**	32	3/60	2
	Email Tribal Health Care Providers **(Att. #4)**	16	3/60	1
	Follow-up email Tribal Health Care Providers **(Att. #5)**	16	3/60	1
	Email Tribal Leaders **(Att. #6)**	16	3/60	1
	Follow-up email Tribal Leaders **(Att. #7)**	16	3/60	1
	Focus group discussion guide AI/AN Adults **(Att. #8)**	32	1	32
	Interview guide Tribal Health Care Providers and Tribal Leaders **(Att. #9)**	32	1	32
Total				**81**

Table 2. Estimated Annualized Burden Costs

Types of Respondents	Form Name	Total Burden (hour)	Hourly Wage Rate[1]	Total Respondent Costs
Tribal Health Care Providers, Tribal Leaders and AI/AN Adults	Screening survey for focus groups and interviews **(Att. #1)**	9	29.76	268
	Email AI/AN Adults for focus groups **(Att. #2)**	2	29.76	60
	Follow-up email AI/AN Adults **(Att. #3)**	2	29.76	60
	Email Tribal Health Care Providers **(Att. #4)**	1	29.76	30
	Follow-up email Tribal Health Care Providers **(Att. #5)**	1	29.76	30
	Email Tribal Leaders **(Att. #6)**	1	29.76	30
	Follow-up email Tribal Leaders **(Att. #7)**	1	29.76	30
	Focus group discussion guide AI/AN Adults **(Att. #8)**	32	29.76	952
	Interview guide Tribal Health Care Providers and Tribal Leaders **(Att. #9)**	32	29.76	952
Total				**2,412**

[1] *The estimates of the annualized cost to respondents for the burden hours for the collection of information is derived from the 2022 mean hourly wage of $29.76 across all occupations, per the Department of Labor website.*

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

This data collection does not involve other annual cost burdens to respondents or record keepers.

14. Annualized Cost to the Government

The contractor's costs are based on estimates provided by the contractor, who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government is estimated to be $123,723.38. This is the cost estimated by the contractor, Banyan Communications, and includes the estimated cost of coordination with CDC, data collection, analysis, and reporting.

Table 3. Annualized Costs to the Government

Type of Cost	Description of Services	Estimated Annualized Cost
Labor	Recruitment, data collection, analysis, and report. Contractor labor hours and other direct costs	$118,861.38
Federal Government Personnel Costs	CDC oversight of contractor and project, including CDC Project Officer and CDC Co-Principal Investigator	$4,862.00
Total		**$123,723.38**

15. Explanation for Program Changes or Adjustments

No change in burden is requested as this is a new information collection.

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

Individual data collection under this generic clearance will be time-limited and conducted only once. No data collection activity will last longer than nine months from inception of information collection to the first report of internal findings to the research team.

Table 4. Project Timeline

Project Time Schedule	
Activity	**Time Schedule**
Begin Recruitment	Immediately upon OMB approval
Conduct Focus Groups and Interviews	Within 6 months of OMB approval
Final Report	Within 12 months of OMB approval

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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