SUPPORTING STATEMENT: PART B

March 15, 2019

Traumatic Brain Injury Disparities in Rural Areas (TBIDRA)

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LIST OF ATTACHMENTS

Attachment 1. Public Health Service Act (42 U.S.C. 241)

Attachment 2. 60-Day Federal Register Notice (FRN)

Attachment 3. Public Comments and responses

Attachment 4. Focus group invitation email

Attachment 5. Focus group screener

Attachment 6. Focus group consent form

Attachment 7. Focus group questionnaire

Attachment 8. Focus group discussion guide

Attachment 9. Privacy Impact Assessment

Attachment 10. IRB approval

SECTION B – COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The respondent universe for this study is rural physicians, nurse practitioners (NPs), and physician assistants (PAs) practicing in primary care settings and/or emergency departments. For the administration of the focus groups, CDC and NORC will work with the National Rural Health Association (NRHA) to identify a convenience sample during one or more NRHA national meetings. Table B.1 summarizes the potential respondent universe, target sample size, and methods for selecting the samples for the focus groups. Below, we discuss the targeted respondents and methods in more detail.

Table B.1. Summary of the data collection activities

Data collection method	Respondent universe	Targeted Samples	Methods for Sample Selection
Focus Groups	• Rural emergency physicians • Rural primary care physicians • Rural nurse practitioners and physician assistants	A convenience sample of up to 60 respondents participating in up to six focus groups	National Rural Health Association (NRHA) will identify sample from NRHA conferences registered attendees that meet inclusion criteria
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[1] Details of the universe are provided in the next section

CDC will conduct focus groups with a cross-section of providers from across the country (**Attachments 7 and 8**). To minimize travel costs and seek national representation, CDC will leverage several national conferences organized by the National Rural Health Association (NRHA) to host up to six focus groups of 8-10 physicians, NP, and/or PA attendees. At a minimum, CDC will host four focus groups at gatherings of rural clinical professionals and will seek regional diversity. CDC will conduct these focus groups at the NRHA Rural Health Clinic and Critical Access Hospital Conferences, the NRHA Annual Conference, and/or NRHA Policy Institute (venue to be determined upon receipt of OMB approval). NRHA will lead the recruitment of focus group participants. NRHA will provide CDC with the conference registration list; CDC will review the list and select potential focus group participants based on geographic distribution and certification (MD, NP, and PA). CDC will send email invitations to the selected individuals (**Attachment 4**) and then send additional invitations as needed to reach our participant goal for each focus group. In order to ensure that all those who expressed interest in participating in the focus group are eligible, they will be emailed a screener to complete and return before the conference (**Attachment 5**). Once all responses to the email invitations and the screener have been received, CDC will schedule up to 6 focus groups at the conference. Should CDC need broader representation of provider types and/or geographic regions, up to two of these

focus groups will be conducted by telephone/webinar. We will work with the National Rural Health Association to recruit the virtual focus group participants (**Attachment 4**). CDC will not offer incentives to focus group participants. CDC will explain the benefits of participation in the focus groups to potential participants, specifically the opportunity to voice their challenges and ideas regarding TBI diagnosis and treatment. CDC believes that NRHA's existing relationships with potential participants will facilitate participation.

2. Procedures for the Collection of Information

CDC proposes a 24-month data collection period for the focus groups. Each focus group will last approximately 90 minutes. For each focus group, a trained and experienced lead moderator will be responsible for guiding and facilitating the discussion, while an assistant moderator will ensure all major themes included in the interview guide are discussed as extensively as possible. The first ten minutes of each focus group will be used to obtain written consent, explain the goals of the discussion, provide information on confidentiality and voluntary participation, and provide the opportunity for participants to ask questions. Participants will also be asked to complete a paper and pencil questionnaire about their professional background and demographic information. This information will be used for analysis only (**Attachment 7**). By way of introduction and "ice-breaker," we will allow sufficient time for each participant to introduce themselves before the formal discussion commences. Personal engagement and an opportunity for participants to be able to "tell their story" will help participants feel comfortable sharing their experiences and help facilitate a meaningful discussion. Ultimately, focus groups allow for a guided, yet free-flowing conversation through which participants may gain new perspectives from fellow participants so that we may better understand the effects of the intervention (**Attachment 8**). All information will be collected orally in person or by telephone/webinar using discussion guides, supported by digital recordings. Focus group transcripts will be analyzed using NVivo 11, a software system used for the qualitative analysis of large amounts of data collected in text format.

Informed Consent

Prior to participating in the focus groups, all respondents must provide their consent to participate (**Attachments 6**). The data collection process will need to be stated upfront and explicitly to assure that participants understand although verbatim records of their statements will be shared with CDC, the records will not be connected to their personally identifying information. Consent forms will provide plain language information on the project, consent, and contact information for the NORC team and the NORC IRB in case participants have questions about the study or the use of their data.

Prior to any focus group, CDC will provide participants with a written consent form. Focus group participants will receive the sheet in person, will have it summarized for them, and will have a chance to read it and ask questions (**Attachment 6**).

We will ask permission from every participant during the consent process to audio-record the focus groups. If we receive permission from every participant in the consent process, we will audio-record and transcribe the discussion. A NORC Research Assistant will take accurate and comprehensive notes about the focus groups, including detailed notes on who said what, and make notes of non-verbal cues so that notes can be combined with audio recordings to create a comprehensive data set from each focus group. If we are not able to record the focus groups for any reason (for example, we do not receive consent from participants), we will use our notes to prepare a summary of the meeting or interview. Following the conclusion of each focus group, the Research Assistant will develop transcripts for analysis.

3. Methods to Maximize Response Rate and Deal with Nonresponse

Response to focus group invitations is expected to be high because they will be conducted during times when participants are attending an NRHA conference. We anticipate at least 90 percent of the of those invited will participate in the focus groups, based on experience with similar activities and a typically high level of motivation from NRHA conference attendees. NORC has a good working relationship with NRHA and its members, and has conducted focus groups with NRHA in the past.

4. Test of Procedures or Methods to be Undertaken

Cognitive interviewing is a process for pre-testing instruments such that problematic questions may be identified and adjusted before fielding the focus group guide to the full sample. NORC conducted a pre-test of the focus group discussion guide with a convenience sample of 5 physicians/NPs/PAs currently practicing in primary care settings and emergency departments. Participants were selected in coordination with NRHA. Each participant was emailed an invitation letter to participate in the cognitive interview. All interviews were conducted by telephone. Respondents read and responded to each question, providing a rating of clarity (clear or unclear) and difficulty in answering. If a respondent indicated that a question was not clear or difficult to answer, the interviewer followed up with additional questions to probe what made the question unclear or difficult to answer. Questions that were identified as unclear or difficult to answer were reviewed and revised, as approved by CDC.

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

The following individuals inside the agency have been consulted on the design and statistical aspects of this information collection as well as plans for data analysis:

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