

**Supporting Statement for Office of the National Coordinator for Health
Information Technology (ONC)
Access, Exchange and Use of Social Determinants of Health Data in Clinical
Notes (SDOH)**

**PART B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL
METHODS**

1. Respondent Universe and Sampling Methods

ONC has contracted with OpenNotes/Beth Israel Lahey Health (BILH) to complete this study. OpenNotes/BILH will use a subcontractor to conduct the data collection associated with this study. OpenNotes/BILH's subcontractor, MedPanel, will be responsible for participant recruitment, focus group facilitation, and disseminating data to OpenNotes/BILH. MedPanel, is using a convenience sample to recruit participants for this qualitative study. Because this is a convenience sample, statistical analysis is not appropriate, and OpenNotes/BILH will not generalize back to the larger population of patients, caregivers, and healthcare professionals.

The 10 clinician/healthcare professional groups will include those practicing in the following care settings: primary care, specialty care, pediatrics, emergency medicine, case management, mental health care, safety net/rural underserved settings. The 10 patient/caregiver groups will include the following: Black/African American individuals, Spanish-speakers, E-patients, parent/guardian caregivers, individuals with disabilities or multiple chronic conditions, those age 65+, rural residents, members of the LGBTQ+ community.

MedPanel, the subcontractor on this project, will oversee recruitment. The potential respondent universe is all health care providers within MedPanel's clinician panels working in the specified settings and all patients and caregivers within MedPanel's networks that fit within the designated groups for the focus groups. MedPanel will recruit patients and caregivers from MedPanel's network of patient support groups and associations and will recruit physicians and other healthcare professionals from MedPanel's proprietary panel.

MedPanel's proprietary panel includes 250,000 healthcare professionals. To build its panel, MedPanel reaches out to associations, advocacy organizations, nursing homes, hospitals, and obtains specialized lists. MedPanel uses this information to target the appropriate groups for its studies. If an individual expresses interest in being part of the panel, they are asked to "double opt in" using MedPanel's joiner survey. For this project MedPanel will reach out to about 5,000 of the clinicians enrolled in their proprietary panel, expecting approximately 750 to fill out the prescreening questionnaire.

MedPanel will also contact 100 or more patient support groups and associations. Most of these organizations have 1,000 or more members each to whom they can send the link to the prescreening questionnaire. MedPanel expects approximately 750 patients/caregivers to fill out the prescreening questionnaire.

From the 1,500 individuals who complete the prescreening questionnaires, MedPanel will recruit 200 individuals to participate in the focus groups. There will be 10 individuals per focus group in a total of 20 focus groups. Because MedPanel has many years of experience recruiting for and overseeing focus groups, MedPanel expects to be able to recruit the full slate of 200 participants for the focus groups.

2. Procedures for the Collection of Information

Information will be collected in two ways: through a prescreening questionnaire and through focus groups. There will be two types of focus groups: synchronous (virtual) and asynchronous (online “discussion board”).

MedPanel’s proprietary clinician panel includes 250,000 healthcare professionals. To build that panel, MedPanel reaches out to associations, advocacy organizations, nursing homes, hospitals, and specialized lists they build to target the appropriate groups for their studies. If they express interest in being part of the panel, they are asked to “double opt in” using MedPanel’s joiner survey. For this project, prescreening questionnaires will be sent to about 5,000 of these individuals.

For building the patient list, MedPanel will ask the patient support groups and associations in its networks to send out a letter describing the focus groups, the length of time involved, and any payment. If someone receives the letter and is interested, then they click on a link to answer the prescreening questions. All respondents completing the prescreening questions will be notified about their eligibility for the project. The notification will also state that their candidacy is being reviewed and they will hear back soon to further discuss their interest. MedPanel will send similar information, also with a link to prescreening questions, to approximately 5,000 clinicians on its proprietary panel.

Two sets of prescreening questions will be utilized—one for patients/caregivers and one for clinicians/professionals. The patient/caregiver questionnaire is also available in Spanish. (see attachments B1-B3).

Selected participants will get an introductory letter with technical instructions as to when, where and how to join the group.

The study will use synchronous and asynchronous focus groups. Four focus group interview guides will be utilized, one for each of these groups (synchronous patient/caregiver group, asynchronous patient/caregiver group, synchronous clinician/professional group, asynchronous clinician/professional group). The patient/caregiver synchronous focus group guide has also been translated into Spanish (see attachment C5). Prior to conducting focus groups, participants will provide consent via a signed release form (see attachments D1-D5).

For the synchronous (conducted virtually) focus groups, participants access a videoconferencing platform used for the virtual session. The sessions will be audio recorded. Participants will be informed in advance that the focus group is being recorded and will sign a release form (see

attachments D1 - D5). Trained moderators will conduct the 90-minute focus groups. For the asynchronous focus groups, participants will log in to the online “discussion board” where the questions and probes will be posted by a trained moderator. They will go online and contribute to the discussion when they are able, at any point over a defined period of time (e.g. The board will be monitored for 3 days and an individual participant can join at any time for any amount of time until they reach 90 minutes over those 3 days.) Because the asynchronous groups take place over a period of days, the moderator will meet periodically with the OpenNotes/BILH project staff to review the discussion at that point and determine if there are any questions that need to be raised or if participants need to be reminded of the topics of focus, etc. The OpenNotes/BILH team will be able to observe both the asynchronous and synchronous focus groups but will not actively participate in the discussions.

Using an inductive coding method for qualitative analysis, the OpenNotes/BILH project team will use Atlas.ti, a qualitative data analysis tool, to sort, code, and analyze data from the focus groups. Two members of the OpenNotes/BILH study team will independently review a randomly selected subset of transcripts to develop our initial set of codes. OpenNotes/BILH will calculate a kappa statistic to ensure quality. All disagreements around this initial set of codes will be resolved through discussion. OpenNotes/BILH will then apply these initial codes to all transcripts and use Atlas.ti to categorize these codes into themes. OpenNotes/BILH will present the findings to the project advisory panel and ONC and will use their feedback in drafting a final report.

3. Methods to Maximize Response Rates and Deal with Nonresponse

MedPanel will recruit over a period of 1-2 months. MedPanel expects to send a prescreening questionnaire to 1,500 individuals. Based on the results of the prescreens, MedPanel will contact each potential participant up to 2 times. For those who agree to participate, there are staff at MedPanel who will work to ensure they show up to the focus groups.

4. Test of Procedures or Methods to be Undertaken

OpenNotes/BILH tested the 2 prescreening questionnaires and the 4 focus group interview guides. OpenNotes/BILH tested the patient/caregiver prescreening questionnaire on 1 patient. It took that person 1 minutes and 20 seconds to complete. OpenNotes/BILH tested the clinician/healthcare professional prescreening questionnaire on 1 clinician. It took that person 1 minute and 41 seconds to complete. OpenNotes/BILH tested the asynchronous clinician/healthcare professional focus group guide on 2 clinicians. It took them an average of 63.5 minutes to complete. OpenNotes/BILH tested the synchronous clinician/healthcare professional focus group guide on 1 clinician. It took 31 minutes to complete. OpenNotes/BILH tested the asynchronous patient/caregiver focus group guide on 2 patients. It took them an average of 82.5 minutes to complete. OpenNotes/BILH tested the synchronous patient/caregiver focus group guide on 2 patients. It took 45 minutes to complete.

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

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