**Supporting Statement for Office of the National Coordinator for Health Information Technology (ONC)**

**Access, Exchange and Use of Social Determinants of Health (SDOH) Data in Clinical Notes**

**PART A. JUSTIFICATION**

1. **Circumstances Making the Collection of Information Necessary**

The access, exchange, and use of electronic health information is essential for clinicians and patients to better manage their health care needs and share information with other providers and with caregivers. Many hospitals and physicians possess capabilities that enable patients to view and download their health information. Yet, additional steps are needed to make health information more accessible and useful to both clinicians and patients.

The 21st Century Cures Act (Cures Act) requires the Department of Health and Human Services (HHS) and ONC to improve the interoperability of health information. ONC’s Cures Act final rule identifies important data elements that should be made electronically available and exchanged through the use of health information technology (IT).[[1]](#footnote-1)

A growing body of research highlights the importance of social determinants of health (SDOH) – the conditions in which people live, learn, work, and play – in access to care and health outcomes.[[2]](#footnote-2) However, the collection and use of SDOH data remains much more limited across healthcare.[[3]](#footnote-3) Capturing and accessing SDOH data during the course of care would allow providers to more easily address non-clinical factors, such as food, housing, and transportation insecurities, which can have a profound impact on a person’s overall health.[[4]](#footnote-4)

In a 2018 report,[[5]](#footnote-5) researchers conducted interviews with six electronic health records (EHRs) vendors with large market shares in both ambulatory and inpatient settings. Vendors described a number of places where SDOH data could be documented or found. These include EHR specific data sets or forms, problem tables, free-text fields located in various places (e.g., social history section, clinical notes and assessments section, details section of structured screening tools), the demographic section of the patient’s health record, and the patient portal. Researchers also found that in a clinical encounter, the person collecting and entering SDOH data into the EHR varies based on the available resources of the clinical setting, time allocated for the visit, availability of kiosks at check-in, and the sensitivity of the data to be captured. Variation in how SDOH data is collected and captured in a clinical setting makes it difficult to ensure that the information can be exchanged in a standardized way and ultimately used by health care providers.

Additionally, patients might not be willing to share SDOH data with their health care providers.[[6]](#footnote-6) There are a number of sensitivities surrounding SDOH data. Patients may not feel comfortable sharing sensitive matters such as intimate partner violence, homelessness, or child abuse directly with their health care provider. There are also a number of concerns regarding what the information will be used for and whether the information could lead to future discrimination. Additionally, patients may feel comfortable sharing information with a provider that they have established a relationship with but would be concerned about the information being shared with a different provider.

The federal government has made significant investments to accelerate the development and use of health IT to exchange clinical data. As a result, today, nearly all hospitals and 8 in 10 office-based physicians have a certified EHR. Adoption and use of health IT has led to an increase in health information exchange. However, with the emergence of new technologies and growing number of entities such as social service providers that could benefit from use of these technologies, it is critical to measure how to advance the access and use of SDOH data and to take into account both providers’ and patients’ perspectives.

1. **Purpose and Use of Information Collection**

The purpose of the information collection is for ONC is to obtain data from health care providers and patients through qualitative research (focus groups) and analysis to understand:

1. To what extent do health care providers document and use SDOH information to treat a patient or offer referral services;
2. How do health care providers leverage open text fields, specifically clinical notes and assessments sections of an EHR, to document SDOH data;
3. Challenges clinicians experience when using SDOH data, including data captured in open text fields;
4. The types of SDOH data that individuals (both providers and patients) want collected, shared and used;
5. Methods individuals (both providers and patients) currently use or would like to use in the future to collect, share and use SDOH data, including smartphone apps or improvements to patient portals; and
6. Barriers individuals (both providers and patients) perceive with the exchange of SDOH data, including privacy and security issues as well as secondary uses of the data.

Through qualitative data collection, this project will collect information from health care providers (including behavioral health providers) and patients/caregivers to inform ONC’s work on SDOH data collection and exchange. Specifically, it will inform:

* The creation of tools and resources, such as updates to the Health IT Playbook, to assist health care providers with documenting and acting upon SDOH data; and
* Identifying SDOH data elements that both health care providers and patients agree are important to capture and exchange for future data standardization efforts.

Ultimately, ONC is seeking to understand how patients and health care providers understand social determinants of health, how these data are currently documented in the electronic health record, and how they are used in care.

**3. Use of Improved Information Technology and Burden Reduction**

ONC has contracted with OpenNotes/Beth Israel Lahey Health (BILH) on 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.

The study will use a secure online prescreening questionnaire for participant recruitment. The prescreening questionnaire will be accessible using a link that will be sent out to participants. Study participants will be recruited from pre-existing databases owned and maintained by OpenNotes/BILH’s, subcontractor, MedPanel and from databases maintained by members of MedPanel’s association network. To ensure an adequate representative sample of focus group participants, ONC has set a target of 1,500 individuals to complete the prescreening questionnaires. Based on responses, 200 questionnaire respondents will be chosen to participate in the focus groups.

The study will use a mix of synchronous and asynchronous focus groups. For the synchronous (conducted virtually) focus groups, participants will need to have a computer or phone to access the videoconferencing platform used for the virtual session. The sessions will be audio recorded (participants will be informed in advance that it is being recorded and will sign a release form). There will be no video recordings of the sessions. The subcontractor facilitating the focus groups will provide OpenNotes/ BILH with a transcript of each session.

For the asynchronous focus groups, participants will need access to a computer to log in to the online “discussion board” where the questions and probes will be posted. 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.) OpenNotes/BILH’s subcontractor, MedPanel, will keep all personal information on a secure server and will only send de-identified information to OpenNotes/BILH. The de-identified transcripts and data (from both synchronous and asynchronous focus groups) will be stored on a secure server at BILH and only the OpenNotes/BILH project team will access it. OpenNotes/BILH will keep the de-identified data for 3 years after the end of the project period. OpenNotes/BILH’s subcontractor, MedPanel, will destroy all personal information, and all audio recordings, at the end of the project period.

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

OpenNotes/BILH staff conducted an environmental scan of existing literature relating to the collection and documentation of SDOH information. While there have been surveys of healthcare providers about SDOH, the types of providers surveyed is limited. There are also very few studies of patients’ comfort with documenting and sharing their SDOH data. Moreover, OpenNotes/BILH found that there is minimal information about current documentation practices for SDOH, particularly within the free text / clinical notes fields of the EHR, and how, from the perspectives of care providers and patients, the information should be collected, documented and utilized. There is currently no other effort ONC or OpenNotes/BILH is aware of to gather this kind of information.

Further, close-ended survey items do not allow for more in-depth discussion and probing of why and how SDOH data is documented in clinical settings. Additionally, with focus groups OpenNotes/BILH can ensure that the groups represent varied points of view, experiences, and demographics, both on the provider and patient/caregiver sides. OpenNotes/BILH’s subcontractor MedPanel’s moderators can ask probing questions of focus group participants, for example, how social workers collect and utilize SDOH data and how they would like to use it, or what patients with disabilities or chronic conditions think should be collected and what they are comfortable sharing with their providers. This information is vital to understanding the benefits and challenges associated with SDOH data documentation and exchange.

**5. Impact on Small Businesses or Other Small Entities.**

This collection of information does not impact small businesses or other small entities.

**6. Consequences of Not Collecting the Information.**

Currently, there is a government-wide effort to address health equity. The ONC goals include supporting the collection and use of SDOH data to improve care delivery and patients’ outcomes and reduce health disparities. If this collection is not conducted, ONC will not have sufficient information to fully inform its efforts to standardize documentation and encourage the use of SDOH data in a way that helps to achieve these goals. This information will help inform the development of tools necessary to assist providers with documenting sensitive SDOH data in the clinical notes section of the EHR. This information will also help to inform ONC’s data standardization efforts. Data standardization ensures that electronic health information is collected in a uniform way across providers and organizations. Such uniformity will allow for greater data interoperability and utilization – both key elements in coordinated, equitable care. Currently, SDOH data is collected in non-standard ways across health care systems and there is minimal uniformity. This project will greatly inform that work. In terms of frequency, for this project OpenNotes/BILH, through its subcontractor, MedPanel, will conduct a series of focus groups over a period of several months beginning in **early 2022**. This study will not repeat the focus groups in future years.

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

This data collection request is fully consistent with the guidelines. There are no special circumstances required for the collection of information in this data collection.

**8. Comments in Response to the Federal Register Notice**/**Outside Consultation**

On March 11, 2021, a 60-Day Federal Register Notice was published at 86 FR 13908 pages 13.

We received thirteen comments in response to the 60-day federal register notice; two were substantive, four were requests for the complete information collection request (ICR) package and seven were out of scope for this ICR.

Of the substantive comments, one commenter requested that we add questions to measure well-being of focus group participants. While that information may be valuable, we found that such questions would be out of scope for this ICR.

A different commenter requested that we recruit registered dietitian nutritionists to participate in the research and add them as an option on the prescreening questionnaire. In response, we will recruit registered dietitian nutritionists for the focus groups, and we have updated the prescreening questionnaire to include registered dietitian nutritionists on the list of non-physician professionals. Complete table of comments and responses can be found in attached supplement document (see attachment A1).

**9. Explanation of any Payment/Gift to Respondents**

OpenNotes/BILH will not offer payments or gifts directly to study participants. However, OpenNotes/BILH’s subcontractor, MedPanel, is responsible for participant recruitment, focus group facilitation, and disseminating data to OpenNotes/BILH. The subcontractor will use its standard organizational techniques to encourage study participation to achieve ONC’s specified study participation targets.

**10. Assurance of Confidentiality Provided to Respondents**

A10.A Privacy Act Determination

The only personal identifiers involved in this information collection will be names and contact information of patients and providers recruited to participate in the focus groups. The identifiers will be in pre-existing proprietary recruitment records of the subcontractor, MedPanel, which are not under federal agency control. Therefore, this will not constitute Privacy Act records, even if the subcontractor, MedPanel, uses the identifiers for retrieval.

A10.B Consent

Participation in this study will require written consent. During the recruitment process the subcontractor, MedPanel, will provide prospective participants with a document that describes its privacy policy and terms and conditions. The document will provide a brief general overview of the ONC research project and allow disinterested respondents to withdraw from receiving survey invites and/or focus group participation (see attachments D1 - D5).

A10.C Safeguards

Limited personal identifiable information will be collected during this data collection. The names and contact information collected will be used only by MedPanel, for participant recruitment purposes. All other personally identifiable information involved will be characteristics about the patients and providers. However, personal identifying information will not be linkable at any time to response data collected during focus group discussions.

MedPanel screeners will collect data from interested respondents by means of an initial, brief prescreening questionnaire for the purpose of selecting, participants based on demographic characteristics, to ensure diversity in the research. Respondents who are selected for participation and agree to participate in the focus groups will be sent a detailed letter about confidentiality ahead of their designated session.

The asynchronous platform that MedPanel will use for online focus groups, Focus Vision, has an "Obscure Profile Personally Identifiable Information" that masks participants’ personal information (first and last name, email address). For synchronous live groups, MedPanel and observing team members from OpenNotes/BILH and ONC will only see blocks labeled "Patient 1, 2" or “Provider 1,2” to protect privacy of participants. The sessions will only be audio recorded, not video recorded. When focus groups are complete, MedPanel will send the de-identified transcripts to the prime contractor OpenNotes/BILH. OpenNotes/BILH will prepare an aggregate, qualitative analysis of the results of the session. OpenNotes/BILH will provide only the analysis to ONC.

Patient and provider information shared with MedPanel in order to join MedPanel’s existing panels is self-reported by the participants/respondents. MedPanel allows participants to access and delete their profile data (not project specific screening data) that MedPanel maintains on them, to exercise their right to privacy. MedPanel follows the International Standards Organization (ISO) standards for information security, in addition to safeguarding participants' personal information, and MedPanel’s information system is compliant with the ISO standards for market research and public opinion research agencies.

The information for this study is being collected by OpenNotes/BILH, through its subcontractor MedPanel, on behalf of ONC. Based on Beth Israel Deaconess Medical Center’s Human Research Protection Program Institutional Review Board (IRB) review, an exempt certification was granted for this study.

**11. Justification for Sensitive Questions**

The focus group questions will not ask participants to share sensitive personal information such as sexual behavior, religious beliefs or other personal matters. However, many issues related to SDOH can be considered sensitive. As part of the patient/caregiver focus groups, there may be times when participants volunteer sensitive information about themselves as this information relates to SDOH. Everyone in the focus group will be informed that the session is being recorded and that OpenNotes/BILH may use quotes in reporting but without individual identification. MedPanel will inform participants that they can stop participating at any time. MedPanel will also inform them that they can contact the project team at any time if they have any concerns or questions.

**12. Estimates of Annualized Hour and Cost Burden**

A prescreening questionnaire will be sent to approximately 1500 individuals (see attachments B1 – B3). The questionnaire will take 5 minutes to fill out. From that group, subcontractor, MedPanel, will recruit up to 100 patient and caregiver participants (10 individuals in each of 10 groups) and up to 100 clinician and professional participants (10 individuals in each of 10 groups). For both the synchronous and asynchronous focus groups the total time requested of participants will be 90 minutes (that is the total annual hour burden per participant per group) (see attachments C1 – C5).

Exhibit 1: Estimated Annualized Burden Hours and Respondent Costs

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Form name | Respondents | Number of Responses | Number of Responses per Respondent | Average Burden per Response (x/60) | Total Burden Hours | Wage | Respondent  Total Costs |
| Prescreening Questionnaire  (English) | Patients and Care Partners | 675 | 1 | 5/60 | 56.25 | $25.72 | $1,446.75 |
| Prescreening Questionnaire (Spanish) | Patient and Care Partners (Spanish speakers) | 75 | 1 | 5/60 | 6.25 | $25.72 | $160.75 |
| Prescreening Questionnaire | Clinicians and Healthcare Professionals | 750 | 1 | 5/60 | 62.5 | $96.00 | $6,000 |
| Asynchronous Focus Group | Patients and Care Partners | 10 | 1 | 90/60 | 15 | $25.72 | $385.80 |
| Synchronous Focus Group (English) | Patients and Care Partners | 80 | 1 | 90/60 | 120 | $25.72 | $3,086.40 |
| Synchronous Focus Group (Spanish) | Patients and Care Partners (Spanish speakers) | 10 |  | 90/60 | 15 | $25.72 | $385.80 |
| Asynchronous Focus Group | Clinicians and Healthcare Professionals | 90 | 1 | 90/60 | 135 | $96.00 | $12,960.00 |
| Synchronous Focus Group | Clinicians and Healthcare Professionals | 10 | 1 | 90/60 | 15 | $96.00 | $1,440.00 |
| Grand Total |  | 1700 | 1 |  | 425 |  | $25,865.50 |

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There are no annualized capital/startup or ongoing operation and maintenance costs involved in collecting the information.

**14. Annualized Cost to Federal Government**

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| --- | --- |
| Estimated Annualized Cost to the Government | |
| Cost Category | Estimated Annualized Cost |
| Year 1 |  |
| Federal employee costs, 30 staff hours at GS-13 step 5 and 15 staff hours at a GS-15 step 5 salary | $2,863.50 |
| Contractual costs for development of focus group questions and pre-screening questionnaire, and pilot testing | $97,921.62 |
| **Year 1 Sub-total** | **$100,785.12** |
| Year 2 |  |
| Federal employee costs, (10 staff hours at GS-13 step 5 and 5 staff hours at a GS-15 step 5 salary) | $954.50 |
| Contractual costs for participant recruitment, conducting the focus groups, publication costs and licensing software for data analysis | $230,384.16 |
| **Year 2 Sub-total** | **$231,338.66** |
| **Total** | **$332,123.78** |

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

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

The project contract period is from September 30, 2020 until September 30, 2022. The focus groups will take place January-March 2022. Results will be analyzed starting in April 2022. A final report will be submitted to ONC by September 30, 2022. OpenNotes/BILH will work with ONC to determine the timing and method of dissemination of the final report.

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 the report.

OpenNotes/BILH will submit a manuscript based on the final report to a peer-reviewed journal. All final deliverables will be posted on the OpenNotes/BILH website and disseminated through OpenNotes/BILH social media channels. Deliverables may also be made available or referenced on ONC’s website: healthit.gov.

|  |  |
| --- | --- |
| **Dates** | **Major Tasks/Milestones** |
| October 2021-December 2021 | * Recruit for and schedule focus groups |
| January 2022-March 2022 | * Conduct focus groups |
| April 2022-June 2022 | * Qualitative analysis |
| August 15, 2022 | * Draft of final report submitted |
| September 30, 2022 | * Final report |

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

All data collection materials will display the OMB expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

1. 1. Office of the National Coordinator for Health Information Technology, “Cures Act Final Rule: United States Core Data for Interoperability” (Washington D.C., n.d.), https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf.

   2. Centers for Disease Control and Prevention, “About Social Determinants of Health (SDOH),” CDC.gov, 2020, https://www.cdc.gov/socialdeterminants/about.html; Erika K Cottrell et al., “Using Health Information Technology to Bring Social Determinants of Health into Primary Care: A Conceptual Framework to Guide Research,” *Journal of Health Care for the Poor and Underserved* 29, no. 3 (2018): 949–63; National Association of Community Health Centers, “PRAPARE Implementation and Action Toolkit,” 2019 [↑](#footnote-ref-1)
2. . Centers for Disease Control and Prevention, “About Social Determinants of Health (SDOH),” CDC.gov, 2020, https://www.cdc.gov/socialdeterminants/about.html; Erika K Cottrell et al., “Using Health Information Technology to Bring Social Determinants of Health into Primary Care: A Conceptual Framework to Guide Research,” *Journal of Health Care for the Poor and Underserved* 29, no. 3 (2018): 949–63; National Association of Community Health Centers, “PRAPARE Implementation and Action Toolkit,” 2019. [↑](#footnote-ref-2)
3. 3. National Academy of Medicine, “Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2,” *The National Academies Press* (Washington D.C., 2014); Siren UCSF, Robert Wood Johnson Foundation, and EMI Advisors, “The Gravity Project : A Social Determinants of Health Coding Collaborative,” 2019; Maysoun Freij et al., “Incorporating Social Determinants of Health in Electronic Health Records: A Qualitative Study of Perspectives on Current Practices among Top Vendors,” *U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, Office of Health Policy*, 2018, https://aspe.hhs.gov/pdf-report/incorporating-social-determinants-health-electronic-health-records-qualitative-study-perspectives-current-practices-among-top-vendors. [↑](#footnote-ref-3)
4. 4. Alex A. Azar II, “The Root of the Problem: America’s Social Determinants of Health” (Hatch Foundation for Civilty and Solutions, 2018). [↑](#footnote-ref-4)
5. 5. Freij et al., “Incorporating Social Determinants of Health in Electronic Health Records: A Qualitative Study of Perspectives on Current Practices among Top Vendors.” [↑](#footnote-ref-5)
6. 6. The Pew Charitable Trusts, “Patients Seek Better Exchange of Health Data Among Their Care Providers,” 2020, https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2020/03/patients-seek-better-exchange-of-health-data-among-their-care-providers. [↑](#footnote-ref-6)