**GenIC Clearance for CDC/ATSDR**

**Formative Research and Tool Development**

##  Hospital System Approach to Collecting Race, Ethnicity, and Language Data

### OMB Control No. 0920-1154

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#### Supporting Statement A

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* **Goal of the study:** Get a baseline description of how hospital systems approach the collection of race, ethnicity, and language data and validate a standard practice
* **Intended use of the resulting data:** Develop guidance for U.S. hospitals that provides a standardized approach to collecting race, ethnicity, language, and interpreter use including scripting, onboarding training, and a minimum standard language data dictionary
* **Methods to be used to collect:** cross-sectional survey
* **The subpopulation to be studied:** U.S. Hospital Systems
* **How data will be analyzed:** descriptive analysis

# Circumstances Making the Collection of Information Necessary

CDC requests approval for a new Gen-IC under OMB Control No. 0920-1154.

Information collection activities are limited to formative work that will result in the development of a standardized approach to the collection of race, ethnicity, language, and interpreter use among U.S. hospital systems.

Underlying racial and ethnic inequities and systems barriers for other language speakers significantly affect health outcomes. However, few studies have systematically addressed these factors and their impact on hospital acquired infections (HAI). Race, ethnicity, language, and interpreter use data fields already exist in most electronic health record (EHR) systems, and there are rapidly evolving requirements on the horizon to collect these essential data elements. By looking at traditional race and ethnicity categories, and diving deeper into population sub-groups who speak languages other than English, more specific and actionable differences in infection risk may be identified. We hypothesize that hospital systems will have significantly varied approaches to race, ethnicity, language, and interpreter use data collection, data fields, and workflows and that because of this lack of standardization, it is difficult to validate any shared data with NHSN in the current state.

# Purpose and Use of Information Collection

The proposed information will be collected by the Surveillance Branch (SB) of the Division of Healthcare Quality and Promotion (DHQP) in the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), which oversees the National Healthcare Safety Network surveillance system. Leveraging the National Healthcare Safety Network Collaborative (NHSNCoLab), SB will invite current NHSNCoLab sites (n=13) to participate in a one-time REDCap survey. The survey will be completed by Social Determinants of Health (SDOH) leads and Chief Medical Information Officers (CMIOs) at each NHSNCoLab site. Respondents will also be asked to participate in the publication of a manuscript summarizing the findings from the survey.

The purpose of this data collection is to understand the baseline approach used by each NHSNCoLab site in collecting race, ethnicity, language, and interpreter use data within their respective health systems.

The information will be collected once from each participating site. The frequency of data collection is limited to this one-time event.

By gathering these data, we are attempting to address health disparities related to hospital-acquired infections (HAIs) and improving patient outcomes.

* Understanding Baseline Approaches: Collecting this information allows us to gain insights into the current approaches used by different hospital systems in collecting race, ethnicity, language, and interpreter use data. This understanding is crucial for identifying variations in data collection practices and workflows across healthcare facilities.
* Standardization Efforts: By identifying variations in approaches to data collection, we can develop standard practices that can be suggested to hospitals across the U.S. Standardization enables better validation of shared data with NHSN and facilitates improved evaluation of race, ethnicity, language, and interpreter use data as they relate to HAIs.
* Addressing Health Disparities: Through more specific and actionable differences identified in infection risk based on race, ethnicity, language spoken, and interpreter use, we can better address health disparities among diverse populations. This information provides valuable insights into potential underlying factors contributing to inequities in healthcare outcomes.
* Improved Data Validation: The lack of standardization in race, ethnicity, language, and interpreter use data collection poses challenges in validating shared data with NHSN. By understanding baseline approaches across participating sites, we can work towards developing standardized methods that enhance the accuracy and reliability of collected data.

Not having access to this information would limit our ability to provide guidance to U.S. hospitals on the best practices for reporting these data and ultimately our ability to understand and mitigate health disparities as it relates to HAIs.

* Limited Understanding of Disparities: Without comprehensive data collection on these social determinants of health, there will be limited understanding of the disparities and barriers faced by diverse populations in healthcare settings. This lack of understanding hinders efforts to address health inequities effectively.
* Inability to Identify Targeted Interventions: The absence of these data prevents the identification of specific population sub-groups that may be at higher risk for hospital-acquired infections (HAIs). This limits the ability to develop targeted interventions and strategies to mitigate infection risks among these vulnerable populations.
* Missed Opportunities for Quality Improvement: Accurate and standardized collection of these data provides valuable insights into potential areas for quality improvement within healthcare systems. Without this information, opportunities to identify gaps in care delivery or implement tailored interventions may be missed.
* Impaired Resource Allocation: The lack of comprehensive data on these data makes it challenging to allocate resources effectively. Without a clear understanding of the needs and characteristics of diverse patient populations, healthcare systems may struggle to allocate resources appropriately, potentially exacerbating existing disparities in care.
* Inaccurate Evaluation of Healthcare Outcomes: Reliable data on social determinants of health factors is essential for evaluating healthcare outcomes accurately across different demographic groups. Without this information, assessments of patient safety, infection rates, and overall quality measures may not adequately account for variations in risk factors related to race, ethnicity, language spoken, or interpreter use.
* Hindered Policy Development: The absence of standardized data collection practices impedes the development and implementation of evidence-based policies aimed at reducing health disparities. Policymakers rely on accurate data to inform decision-making processes and design targeted interventions that address specific challenges faced by diverse populations.

# Use of Improved Information Technology and Burden Reduction

All survey questions will be distributed using the REDCap platform. REDCap is a secure web-based application designed specifically for electronic data capture in research studies. REDCap offers a user-friendly interface that allows respondents to easily navigate through the survey questions. It provides features such as branching logic, skip patterns, and validation checks to ensure accurate and consistent responses. The platform also ensures data security by employing encryption protocols and access controls. In addition, given its wide use, especially among hospitals, REDCap is an ideal choice for distributing the survey in this project. By utilizing a platform that respondents are already accustomed to using, it reduces any potential learning curve or additional burden associated with adopting a new system.

Once the completed surveys are submitted through REDCap, the collected data can be securely stored and accessed by authorized personnel for analysis purposes. This electronic submission process eliminates the need for manual handling of paper forms or physical documents, reducing administrative burden and potential errors associated with manual data entry.

# Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of the availability of any similar information.

# Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

# Consequences of Collecting the Information Less Frequently

This is one-time information collection.

# Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

# Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

1. A *Federal Register* notice was published for this generic package July 22, 2022, Vol. 87, No. 140, pp.438360.. No public comments were received.

For subcollection requests under an approved generic ICR, Federal Register notices are not required, and none were published.

B. No consultations outside of CDC occurred.

# Explanation of Any Payment or Gift to Respondents

No incentives will be provided to respondents for this data collection effort.

# Protection of the Privacy and Confidentiality of Information Provided by Respondents

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act does not apply.

The SDOH REDcap survey includes collection of the respondent’s hospital name. However, the introductory letter specifies that neither hospital systems nor electronic health record vendors will be identified in any future publications. The purpose for including hospital name in the survey is simply for tracking those who have responded to the survey versus those whose response we are still awaiting. Individual respondents may choose to provide their contact information by email to be part of publication efforts, but this is not included in the survey and therefore not linked to responses.

# Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID’s Human Subjects Advisor has determined that information collection is not research involving human subjects (Attachment 2). IRB approval is not required.

Justification for Sensitive Questions

There are no planned sensitive questions.

# Estimates of Annualized Burden Hours and Costs

The total estimated time burden is 7 hours (rounded) as described in Table 12A. This is based on 13 respondents, one for each CoLab site. It is estimated that accumulating the files and answering each question would take about 60 minutes. The survey includes skip logic, so each question in the survey is not applicable to each respondent. With an average response time of 60 minutes per respondent multiplied by the total respondents apart of NHSN CoLab (13), we get a total time burden of 13 hours (rounded) for this information collection.

A. Estimated Annualized Burden Hours

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
| NHSN CoLab Sites  | SDOH REDCap Survey | 13 | 1 | 1 | 13 |
| **Total** | 13 hrs. |

The total estimated cost burden is $1,053.39 as described in Table 12B. The cost burden has been calculated using median hourly wages for Hospital Top Executives (111000) from the U.S. Bureau of Labor Statistics (BLS) May 2022 National Occupational Employment and Wage Estimates. According to BLS, the hourly wages are $81.03, which when multiplied by the total time burden for this collection totals to $1,053.39.

B. Estimated Annualized Burden Costs

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
| Top Executive | SDOH REDCap Survey | 13 | $81.03 | $1,053.39 |
| [Occupational Employment and Wage Statistics (bls.gov)](https://data.bls.gov/oes/#/indOcc/Multiple%20occupations%20for%20one%20industry). Accessed: 3/28/2024. **Total** | $1,053.39 |

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

There are no costs to respondents other than their time to participate.

# Annualized Cost to the Government

Fewer than 10 FTE/contractor staff will be involved in development, distribution, and analysis for this research project. The estimated cost to the government for this OMB package is based on expenses incurred for personnel activities. The items and their costs relevant to this research project are shown in the table below. The total cost to the government is estimated to be **$38,846** as described in Table 14A.

1. Estimated Annualized Cost to the Government per Activity

|  |  |  |
| --- | --- | --- |
| Expense Item | Description | Estimated Annual Cost |
| Personnel | Personnel activities include recruitment, survey development and distribution, data analysis, and drafting a manuscript for publication.The personnel and their hourly contributions are listed below. |  |
| Medical Officer | 6 hrs | $744 |
| Health Scientist | 140 hrs | $12,320 |
| Consultant | 120 hrs | $24,042 |
| Health Scientist Contractor | 5 hrs | $435 |
| Health Scientist Contractor  | 15 hrs | $1,305 |
| Total | **$38,846** |

# Explanation for Program Changes or Adjustments

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

# Plans for Tabulation and Publication and Project Time Schedule

|  |
| --- |
| Project Time Schedule |
| Activity | Time Schedule |
| Distribute Introductory Letter to NHSNCoLab sites | 1 month after OMB approval |
| Survey Data Collection | 1-2 months after OMB approval |
| Data Review/Analysis | 2-3 months after OMB approval |
| Qualitative Data Collection | 4-5 months after OMB approval |
| Analyses | 6 months after OMB approval |
| Publication | 8 months after OMB approval |

# Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

# Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

# Attachments

1. Information Collection instrument: REDCap Survey
2. IRB Determination
3. Introductory Letter
4. Reminder Letter 1
5. Reminder Letter 2