



National Death Index (NDI) Non-Economic Barriers Report:

*Strengthening the NDI For Research,
Surveillance and Quality Assurance*

September 2019

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Paul Sutton
Deputy Director, Division of Vital Statistics
National Center for Health Statistics
Centers for Disease Control and Prevention

NDI Non-Economic Barriers Report

Introduction

Access to timely, affordable and accurate mortality data is vital to medical and social research and public health surveillance. The National Death Index (NDI), as an extension of the National Vital Statistics System (NVSS) mortality component, adds direct personal identifiers to death records allowing linkage of mortality records to researchers' data files to determine the fact and the cause of death for research participants. Prior to the development of the NDI, researchers had to contact each jurisdiction to request information on vital status and cause of death from each vital records jurisdiction which was a time consuming and complicated effort. While researchers' use of the NDI has increased over the years, concerns have been raised pertaining to the economic and non-economic barriers that prohibit or limit its use. In response to this growing concern, the National Center for Health Statistics (NCHS) undertook an evaluation to identify non-economic barriers to the optimal use of the NDI.

Background

In the United States, the states and territories (hereafter referred to as jurisdictions) have the sole authority and responsibility for recording of vital events---births, deaths and fetal deaths. These events are recorded in 57 registration jurisdictions comprised of the 50 states, the five (5) United States territories (American Samoa, Guam, Virgin Islands, Commonwealth of the Marianna Islands and Puerto Rico), New York City, and the District of Columbia - Washington D.C. The jurisdictions register these events according to state, not federal, laws and statutes and transmit the relevant information from those certificates data to the National Center for Health Statistics (NCHS).

Through its Vital Statistics Cooperative Program, NCHS contracts with each jurisdiction to provide fact and cause of death information from the death certificates for statistical analysis. NCHS edits and compiles the mortality information, codes the causes of death (COD) using the ICD-10 Mortality rules and returns the cause-of-death codes to the jurisdictions.

Through a separate National Death Index (NDI) contract, NCHS also receives the name and social security number on the submitted death certificates. This direct personally identifiable information is only used in the production of the NDI file. This NDI file is a comprehensive collection of death records with personal identifiers to facilitate public health and medical research and analysis. NDI is the only national data source with direct identifiers needed for linking to researcher's data sets that contain both the fact of death and the cause of death for all deaths occurring within the United States. The NDI also includes all military deaths occurring overseas, which are not included in the NVSS statistical files. Records for participants in research studies are matched to the NDI to determine if the person has died and if so, the cause(s) of death. Researchers approved to use this matching service must: (1) submit an NDI application which specifies the research proposal, (2) agree to destroy the records after the research is completed, (3) provide the required personally identifiable information (PII) needed for matching, and (4) remit a fee based on the volume of records in the search and the type of search requested.

While researchers' use of the NDI has increased substantially over the years, concerns have been raised about both the high cost to use the NDI and the technical, administrative, operational, legal, policy and other non-economic barriers that prohibit or limit its use. As a result of these concerns, NCHS undertook two studies to identify barriers to the optimal use of

the NDI. MITRE, a Federally Funded Research and Development Contractor (FFRDC) was retained in 2016 to explore through interviews with federal officials and researchers the issues of NDI cost barriers and sustainability (not included in this summary report). And in 2017, NCHS obtained funding from the Patient-Centered Outcomes Research Initiative (PCORI) to assess the non-economic barriers for accessing and using NDI. The assessment of non-economic barriers included:

- Interviews with NDI users including academic, industry, state and federal researchers;
- Contracting with the National Association of Public Health Statistics and Information Systems (NAPHSIS) to explore laws and policies in the jurisdictions on the use of mortality data and their perceptions about the non-economic barriers for accessing and using the NDI; and
- Convening an NDI stakeholder meeting to review and discuss non-economic barriers.

A wide-range of non-economic barriers to NDI use were identified in this three-part evaluation, including legal issues, NDI specific issues, and broader issues related to the larger National Vital Statistics System (NVSS) and the mortality data on which the NDI is based. These non-economic barriers are summarized in this report.

Non-Economic Barriers to Use of the NDI

An array of NDI users including researchers, research project managers, states, and federal officials were interviewed to obtain their assessment of NDI. Individuals selected were either those with previous experience/association with NCHS or those broadly recognized as experts in their respective field(s). The interviewees identified from their perspective the issues

and barriers that limited or prohibited their use of the NDI. Additionally, jurisdictions were surveyed using a NAPHSIS-developed questionnaire to identify the statutes, regulations, rules and policies limiting or prohibiting the use of mortality data on death certificates---both actual and perceived limitations. The vast majority of both the researchers and jurisdictions surveyed believed that the NDI was underutilized and had the potential for much greater use. Related to this belief, several significant barriers and/or issues were cited that limited or restricted access to and/or use of the NDI. They were as follows:

1. Statutes, Regulations, Policies and Rules

Using PCORI funding, NCHS contracted with the National Association of Public Health Statistics and Information Systems (NAPHSIS) to evaluate jurisdictional laws, policies, and perceptions about the technical, operational, legal, policy, administrative and other non-economic barriers for accessing and using the NDI, particularly the cause of death. NAPHSIS developed and administered the survey to its 57 jurisdictional members. Fifty jurisdictions responded and they were asked to provide their perceptions of the legal barriers limiting or inhibiting the use of mortality data for matching purposes, and to cite the specific law and provide documentation of the actual law or statute.

NAPHSIS reviewed the actual statutes, regulations, rules and policies from 49 of the 50 jurisdictions that provided them. The responses were compiled and analyzed to examine variations based on jurisdiction size, geographic region and respondent years in their current vital records position. The analysis identified fourteen legal barriers that affect the utilization of mortality data, data sharing, IRB need, cost sharing, fees and data linkage to other data bases. Respondents attributed other non-economic issues and barriers to differing release protocols,

formats for data sharing agreements and application of security and privacy requirements.

Moreover, NAPHSIS compared the responses with the actual language in the jurisdictions' laws and statutes.

Mortality data are derived from death certificates at the jurisdictional level. These certificates are legal documents and thus are governed by state not Federal laws and regulations. With no overriding Federal law, this governance structure has led to 57 different sets of statutes, rules, regulations and policies in how mortality data can be handled through NDI. In fact, the variations in the jurisdictions' laws has meant that in its contract with jurisdictions NCHS has had to apply the most restrictive jurisdictional legal limitations in order to establish and operate a national NDI database.

An analysis of the NAPHSIS survey data found inconsistencies between the interpretations of the statutes/laws/rules and the actual language in the them, resulting in the application of more stringent data use restrictions than may actually exist. Eighteen (18) percent of respondents referred to restrictions due to the Health Insurance Portability and Accessibility Act (HIPAA) policies regarding data security, privacy and confidentiality requirements; however, vital records are not a covered entity under HIPAA. The following are examples of the discrepancy between the jurisdictions' perceptions and actual stipulated legal restrictions or limitations:

- Use of data. Seventy-nine percent of respondents reported having statutes, regulations and/or rules that affect the use of mortality data in the NDI. However, upon analysis 88% of the jurisdictions have stipulated language that defines the uses for vital statistics

data and that language primarily limits data use to statistical, administrative or research purpose.

- Restrictions on data for NDI. Forty-eight (48) percent of responding jurisdictions (primarily from the Southeast) reported legal restrictions on data elements submitted to the NDI. However, upon review there was no specific language in the statute, regulations and/or rules identified pertaining to mortality data or submission of data to the NDI.
- Restricted linkage to other databases. Thirty-nine (39) percent reported rules that address or limit linkage of death certificate data to other databases. Upon review, only 10 percent of the jurisdictions had language addressing or limiting linkages to other databases.

2. NDI Specific Barriers

Application Process

While the NDI staff were complimented for their assistance, researchers believed that the application process was counterintuitive and required extensive assistance to complete. They noted the following issues:

1. Application length (25 pages long) and wordiness, especially for first time users;
2. Confusing and difficult to complete supplemental documents (particularly the fee worksheet) required with each application;
3. Redundant and time-consuming need for a separate worksheet for each batch of records, due to the record size limitation; and

4. Lengthy approval process for short-term studies and studies involving multiple centers, especially with two to three months lag between application submission and receipt of data.

Institutional Review Board (IRB)

The requirement of an IRB review as part of the application process was identified as a barrier by some but not all researchers. Some questioned the need for a review for every study and request, for every query in a surveillance study, and/or for multiple sites of the same study. Some noted that an IRB review is needed to protect human subjects while others questioned whether deceased persons are considered human subjects with a need for protection.

Record Size

The NDI can currently only process 500,000 records at a time requiring search requests involving large numbers of records to be batched into multiple files of 500,000 records, each of which is accompanied by multiple worksheets and transmittal forms. As a result, large data matching requests can take an unusually long time to process, resulting in delays for all users and a lot of additional work for the NDI staff.

Data Security

Concerns about security of both the NDI and the researcher's data were expressed in this evaluation. The matched NDI data are currently being sent to the researcher using compact discs (CDs) and secure file transfer protocol (SFTP) sites. Researchers are held to the honor system that the data they receive will not be shared or used for other purposes and the CD would be disposed at the completion of its intended use. However, because NCHS/DVS has limited ability to ensure compliance with these rules, it is not truly known what happens to the data provided on the CDs after it has been issued to the researchers. The results of the

jurisdictional survey suggest that the jurisdictions sometimes impose greater restrictions than may be necessary based on perceived data security concerns.

Data Linkage

The value of the NDI come from the ability to link death information to researchers' databases. To further enhance their research, researchers want to be able to link their research files that have already been linked to the NDI to other datasets such as Electronic Medical Record/Electronic Health Records (EMR/EHR), clinical trials, and claims data files to expand the types of analyses that may be undertaken. While not the case in all jurisdictions, some jurisdictional laws limit the reuse of the mortality data in this manner.

Matching Process

Data matching is a critical function of the NDI Program. Yet, concerns were expressed with the current method for the NDI probability matching of the requested file and with the NDI data---in particular, the burden of manually reviewing many possible matches. The NDI program currently returns potential matches to researchers for them to determine if they are true matches. This determination is difficult for the researcher to do especially when the probability score is not high.

Geographic Specificity

The NDI file does not include geographic detail (i.e. city and county) that is reported to NCHS and available in the NVSS statistical files.

Data Use

As owners of the mortality records, the complete governance of the records rest with the jurisdictions as to how data are to be accessed, distributed and used. Researchers felt that

data limitations and restrictions affect the quality and granularity of the studies. Multiple issues were cited pertaining to data use including:

- Restriction of the NDI files to “medical research” versus “health surveillance”.
- Prohibition on the re-use of cause of death data, the re-submission from previous submissions, and the sharing of NDI data with researchers involved in the study but had not been identified in the study application.

3. NVSS Mortality Issues Affecting Use of NDI

Data Timeliness

While improvements have occurred in the timeliness of the transmission of mortality data to NCHS, data timeliness remained an issue for some researchers.

Quality of the Cause of Death

The quality of the cause of death (COD) reporting was depicted as being troublesome, particularly the completeness, accuracy and reliability of the information. Being able to attribute (tag) COD to a specific event, and to improve the indication of the preceding incidence that led to the subsequent death are two of the quality issues noted. While NCHS has specified standards in its contract for the collection of the mortality data, variations in jurisdictional performance has led some researchers to believe that not all states are strictly adhering to those standards in completing their death certificates. From the NAPHSIS survey, registrars felt that as with timeliness the primary quality hindrance was reliance on external source document providers, old or non-existent technology, and workload or staffing issues of state personnel.

Deaths Outside the United States

Jurisdictions do not record deaths of Americans that occurred outside the United States (U.S.) and the U.S. Territories, and as a result these deaths are not included in the NVSS statistical file. Through a separate agreement with the Department of Defense the data on fact of death, but not cause of death, of military personnel that occur overseas are sent to NCHS for inclusion in the NDI. No mechanism currently exists for reporting deaths of Americans that occur overseas that are not in the military to NCHS.

III. Conclusion

Great strides have been made with improving access and utilization of the NDI. However, significant non-economic barriers remain inhibiting the effective use of and access to NDI. Expanding NDI use will need to address many of the barriers and issues identified in this report. Improving the NDI application and data matching processes, improving the laws governing the use of mortality data, strengthening the infrastructure and security of the NDI system and data, and educating jurisdictions and researchers are required. In addition, improving the timeliness and quality of the NVSS mortality data will have a positive impact of the usefulness of the NDI. NCHS has begun to move forward to address the issues raised. Work has already begun to improve the application process and the frequency/timeliness of NDI updates. Plans to address other, more complex issues are being developed.