

National Institutes of Health
National Institute on Aging

Invitational Meeting on Access to Death Records to Support Health Research

The Keck Center of the National Academies
Washington, DC
September 30, 2014

Meeting Summary

For Administrative Use
Revised August 24, 2015

This meeting summary was prepared by Samuel Thomas, Rose Li and Associates, Inc., under contract to the National Institutes of Health (Contract no. HHSN271201400038C). The views expressed in this document reflect both individual and collective opinions of the meeting participants and not necessarily those of the National Academy of Sciences, National Institutes of Health, and the U.S. Department of Health and Human Services. Reviews of earlier versions of this workshop summary by the following individuals are gratefully acknowledged: John Haaga, Emily Holubowich, Michael Lauer, Rose Li, John W. R. Phillips, Patricia Potrzebowski, Mona Rowe, and Mandi Yu.

Table of Contents

Acronyms and Abbreviations ii

Meeting Summary 1

Utility of Research Access to Death Records1

 Clinical Trials, Prospective Cohort Studies, and Observational Studies 2

 Clinical Quality Control 3

 Longitudinal Population Studies..... 3

 Health Care Utilization and Patient Safety Research 4

Issues for the States4

 Vital Records: A State Responsibility..... 4

 Electronic Death Registration Systems 5

 Controlled Access to State-Owned Data 5

Roundtable Discussion: Possible Solutions.....6

Appendix 1 Meeting Agenda..... 8

Appendix 2 List of Meeting Participants 9

Acronyms and Abbreviations

Acronym	Definition
AHRQ	Agency for Healthcare Research and Quality
CNSTAT	Committee on National Statistics
DBASSE	Division of Behavioral and Social Sciences and Education
DMF	Death Master File
EDRS	Electronic death registration systems
HRS	Health and Retirement Study
MEPS	Medical Expenditure Panel Survey
NAPHSIS	National Association for Public Health Statistics and Information Systems
NAS	National Academy of Sciences
NCHS	National Center for Health Statistics
NCI	National Cancer Institute
NDI	National Death Index
NIA	National Institute on Aging
NIH	National Institutes of Health
NRC	National Research Council
NTIS	National Technical Information Service
SEER	Surveillance, Epidemiology, and End Results Program
SSA	Social Security Administration

Meeting Summary

Timely access to death records is crucial for many kinds of health research. Prior to November 2011, researchers could access comprehensive death records from the Social Security Administration (SSA) Death Master File (DMF) via contracts with the National Technical Information Service (NTIS) in the Department of Commerce. The DMF, which was established to minimize social security benefits paid after death, obtains death records from state vital registrars, hospitals, funeral homes, and family members and is updated on a flow basis, as deaths are reported to SSA. Researchers with a DMF subscription received copies of the full file and were able to conduct an unlimited number of searches for a fixed cost. However, the SSA's agreement with the states prohibits public release of state-owned data and, beginning in November 2011, SSA has omitted state data from the public DMF.¹

The other major source of death records is the National Death Index (NDI), which the National Center for Health Statistics (NCHS) has compiled since 1982. The NDI is comprehensive and, in its full form, "NDI Plus," contains information on cause of death, which is not included in the DMF. Nevertheless, the NDI's utility for research is limited by delays in incorporating new data, costs that are higher than a DMF subscription, paperwork burdens for end users, and restrictions that prohibit researchers from conducting their own queries.

The Division of Behavioral and Social Research at the National Institute on Aging (NIA) convened an invitational meeting at the National Academy of Sciences (NAS) to (1) better understand how the health research community uses death records and how the loss of access to the full DMF affects health research; (2) better understand the issue from the perspective of the states as represented by the National Association for Public Health Statistics and Information Systems (NAPHSIS); and (3) discuss promising ideas that could facilitate timely, comprehensive, cost-beneficial, and user-friendly means of research access to death records that are consistent with state interests and compliant with state and federal laws.

This document summarizes the proceedings of the meeting. Appendix 1 contains the meeting agenda, and Appendix 2 contains a list of meeting participants.

Utility of Research Access to Death Records

Meeting participants discussed several categories of health research that rely on timely access to death records, including clinical trials and prospective cohort studies, clinical quality control, cancer surveillance, longitudinal population surveys, and health care utilization and patient safety research. Common themes included the need to learn about deaths of patients on study as quickly as possible, the value of researchers being able to conduct database queries themselves, and the desire to control costs and administrative burdens. The following sections detail the importance of death records for research and the challenges posed by the loss of access to the full DMF for each category of research activity.

¹ The full DMF, including state data, is still available for internal use by some federal agencies and contractors, but is not available to grantees for research purposes.

Clinical Trials, Prospective Cohort Studies, and Observational Studies

Death records can serve several purposes in clinical trials, prospective cohort studies, and observational studies, including support for adverse event detection, a low-cost means for passive follow-up, triggers to prompt alternative protocols, and even endpoints for studies examining mortality. Obtaining fact of death information as soon as possible is key for some purposes, while others require more complete information, such as cause of death, to be useful. In many cases, it is ideal to have both types of information: provisional data that may be incomplete but quickly available can be used for operational analyses during the study period, and final, verified data can be used later for final analysis prior to publication.

Clinical trials that rely on death records for adverse event reporting or as a passive follow-up mechanism require the fastest possible notification of fact of death to protect patient safety. Although final data, including information about cause of death, are needed to close clinical trials and publish results, provisional fact of death data alert investigators to potentially serious adverse events that could impact the health of study participants. After a study closes, death records can be used to monitor mortality of the study cohort passively, which may yield information on delayed adverse events. Such passive follow-up also saves considerable resources compared to long-term active follow-up, where investigators remain in direct contact with study participants, but may be impractical with death data delays of more than 6 months.

Prospective cohort studies use death records to notify investigators when a study participant dies. Attempting to contact a study participant who is discovered to be deceased consumes time and resources and often upsets the decedent's family. Furthermore, cohort and observational studies sometimes incorporate alternative protocols, such as next-of-kin protocols, that are triggered by the death of a study participant. If not initiated soon after death, then such alternative protocols often fail because of outdated contact information or diminished interest of family members.

Some observational studies require information on cause of death for death records to be useful at all. For example, the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) Program reports data on vital status and cancer-related mortality from the NDI and would not benefit from faster access to fact of death information from the DMF. SEER was, therefore, unaffected by the loss of research access to the DMF. Nonetheless, SEER has a vested interest in improving timeliness of the NDI. SEER and several other NCI initiatives link data from multiple sources to ensure robust data quality and to identify otherwise undetected trends. Linked databases are only as valuable as their weakest—or slowest—link. Delays in receiving death records limit the utility of the entire enterprise.

Another challenge of using the NDI is the fact that researchers cannot obtain NDI data directly to conduct their own searches. Instead, investigators must send a list of identifiers, such as social security numbers, to NCHS to conduct a search on their behalf. In addition to being slow and costly, NCHS provides candidate matches, or records with a high probability of matching the requested identifiers, rather than the fully matched records themselves. Researchers must then clean the data and judge which records are correct matches, which can be difficult without

accessing the complete database. For research that did not require information on cause of death, the DMF was ideal because researchers were able to conduct their own searches on the full database.

Although some research is delayed, diminished in quality, or made more expensive by the lack of timely and inexpensive access to death records, other research may not be conducted at all. For example, Michael Lauer (National Heart, Lung, and Blood Institute) conducted research at the Cleveland Clinic beginning in the 1990s that relied on inexpensive access to death records from the DMF. Dr. Lauer's research, which examined relationships between common cardiovascular tests and mortality in a sample of tens of thousands of people, was funded by small grants that could not afford NCHS data. According to Dr. Lauer, this research, which pioneered a new field of study, would not have been conducted without affordable access to the full DMF.

Clinical Quality Control

Although not strictly a research function, hospitals and clinics sometimes use death records as a tool for quality control. It is usually impractical to track mortality of patients treated in clinical practice who are not enrolled in clinical trials; however, the DMF provided a cost-effective means to do so. If, for example, a hospital introduced a new surgical procedure, then it could track patients through the DMF and compare their mortality to benchmarks based on standard care. This function may become increasingly important as the pace of medical innovation continues to accelerate, but delays of more than 3-6 months limit the value of death records for clinical quality control.

Longitudinal Population Studies

Longitudinal population studies, such as the Health and Retirement Study (HRS) and the Wisconsin Longitudinal Study, use death records to monitor the vital status of respondents between sample periods, to know when to contact next-of-kin for information about end-of-life circumstances, and to verify fact and cause of death.

Prior to 2011, the HRS, which comprises a nationally representative sample of about 25,000 adults over age 50 that generates about two deaths per day, used the DMF to monitor the vital status of all survey respondents regularly. In doing so, HRS investigators started each biennial sampling period knowing which study participants had died, saving time and resources. Investigators were also able to contact next-of-kin quickly for exit interviews to obtain information on end-of-life circumstances.

Since losing access to the full DMF, HRS investigators now begin biennial field surveys with no knowledge of which respondents died in the preceding 2 years. Vital status of respondents is ascertained through field sampling itself, and deaths are eventually verified using the NDI. Limitations of the NDI include the need to disclose identities of study participants to NCHS and the inability to monitor vital status of the entire sample routinely because of the cost-per-lookup fee structure, delays of at least 1-2 years, and possible limitations of NCHS matching algorithms. In the current setting, death records may not be available to end users of HRS data until as late as 2-4 years after the death occurred. The public version of the DMF is still available

at least 6 months before any other source of death records; however, it is no longer useful because of the absence of state-provided data.

Health Care Utilization and Patient Safety Research

The Agency for Healthcare Research and Quality (AHRQ) Medical Expenditure Panel Survey (MEPS) uses death records as an outcome measure rather than as a tool to monitor study participants. MEPS includes a nationally representative household component that provides estimates of health care utilization, expenditures, insurance coverage, and access to and quality of care. To incorporate a measure of mortality, MEPS data were linked to the NDI. The matching algorithm that paired NDI records with MEPS respondents was robust, with a failure rate of approximately 1 percent. After linking MEPS to the NDI, researchers used a logistic regression model to identify likely predictors of mortality, including age, sex, level of education, health insurance status, medical expenditures, and other parameters. The results revealed correlations between higher health care expenditures and increased risk of death in subsequent years in multiple age categories. The utility of the MEPS-NDI linkage study would be improved if the NDI were timelier; at the time of analysis in 2011, the NDI was complete only through 2006.

Issues for the States

Note: This section summarizes comments by Patricia Potrzebowski, executive director of the National Association for Public Health Statistics and Information Systems (NAPHSIS).

Vital Records: A State Responsibility

Collection of vital records, including information on births, deaths, marriages, adoptions, citizenship, and other life events, is the legal responsibility of the states—not the federal government. Although each state has its own laws and collection systems, each must strive to meet the mandatory and universal reporting requirements of NCHS to compile a common national vital statistics database.

NAPHSIS is a nonprofit association of vital records offices of all 57 jurisdictions (50 states, 5 territories, the District of Columbia, and New York City) responsible for collecting vital records in the United States. Its mission is “to provide national leadership for both vital records and related information systems in order to establish and protect individual identity and improve population health.”²

Vital records are used for many purposes. The two primary uses of vital records are administrative (individuals use them to prove citizenship, age, and parentage, to obtain identity documents, to enroll in benefits programs, and to settle estates) and public health (they are a primary source of data for calculating vital statistics and are also used for health research).

State vital records offices are responsible for registering vital events, providing certified copies and paternity acknowledgments, maintaining adoption records, preserving and securing vital records, and preventing fraud and identity theft. Fees for certified copies and other services partly or wholly fund vital records offices of most states. In Michigan, for example, the

² See the NAPHSIS website for details about its mission and operations <http://www.naphsis.org>

processing of vital records requests funds the entire operations of the vital records office, state cancer registry, and state birth defects registry. Vital records fees are usually established by state statute or regulation—not by the office that relies on the proceeds to operate.

Electronic Death Registration Systems

Electronic death registration systems (EDRS) facilitate rapid reporting by funeral directors and medical certifiers of the information collected on deaths to the state vital records office. This helps improve the timeliness of reporting. While 39 jurisdictions have implemented some form of EDRS, only 12 jurisdictions electronically certify at least 80 percent of deaths, and 16 jurisdictions electronically certify fewer than 40 percent of deaths.³ In contrast to births, 98 percent of which are reported electronically nationwide—usually by hospital “birth clerks,” deaths must be certified by physicians, coroners, medical examiners, or other qualified medical certifiers. Incentivizing physicians to use EDRS has proved challenging. Further complicating electronic death registration is the fact that funeral directors are usually responsible for filing the record and must correspond with the certifying physician, who provides the cause of death. Some forms of EDRS are a hybrid of paper and electronic where the funeral director initially files the death electronically and the physician signs a paper copy.

Developing and implementing EDRS is expensive. Many state vital registrars are underfunded and unable to implement new reporting systems. Where EDRS do exist, obtaining high-quality data, especially accurate information about cause of death, is challenging because of lack of full participation by medical certifiers in many states. NAPHSIS supports state efforts to implement EDRS by advocating for funding and providing technical assistance. Promoting greater adoption of EDRS and providing training for users would speed data reporting.

Controlled Access to State-Owned Data

States collect and own death data, and individual state laws regulate access to death records. In most states, death records—sometimes including both fact and cause of death—are confidential to protect privacy. Most states allow limited use of death records by federal, state, and local government agencies and for medical or health research. Inclusion of state data in the public DMF violated state laws because it was available to anyone who purchased it for any purpose—not just research or government use—and the states did not control access to their own data. Even now, the states do not control how SSA shares the full DMF with other federal agencies, and states do not receive reimbursement for these data releases even though SSA sometimes does.

In contrast to the DMF, the NDI was established through contracts between NCHS and the states specifically for sharing death data with approved researchers for individual research projects. The states are involved in controlling access to the NDI; there are 12 NDI advisors, 4 of whom are state vital records representatives, and all 12 must unanimously approve each researcher requesting access. Confidentiality is protected because researchers supply NCHS with their data and do not receive NDI data directly. States also receive funding from NCHS to

³ This information is current as of the date of this meeting, September 30, 2014.

participate in the NDI: 34 cents per record, an amount that has not changed since 1979, and additional funds for supplying cause of death information to NDI Plus users.

Roundtable Discussion: Possible Solutions

It is clear that researchers will not regain access to the full DMF. New solutions for timely and affordable access to death records are therefore necessary. Participants discussed three primary ideas:

- Work with NCHS to improve the NDI, especially by making it timelier.
- Create a secure data enclave in which approved researchers could search provisional death data directly.
- Support state initiatives to adopt EDRS to speed data reporting to NCHS.

Working with NCHS to improve the timeliness and general utility of the NDI is a possible solution because state contracts and reporting mechanisms already exist. The NCHS policy is to release data only when it receives, processes, and edits death records from each vital statistics office. With funding from NIH, NCHS is piloting an early release program to provide preliminary NDI data within 6 months of the end of a given calendar year. Eventually NCHS plans to provide partial fact of death information within 3 months of the end of a given calendar year. The pilot early release program remains batch-oriented, releasing 1 year's worth of data at a time, and does not allow researchers to conduct their own searches directly. Even if NCHS agreed to release provisional data on a flow basis, as it is received from the states, it would be slower than the DMF because states do not register a death until they receive both the demographic information from the funeral director and the cause of death information from the medical certifier, whereas SSA receives fact of death directly from funeral homes and other reporters more promptly, although the SSA data are incomplete and more prone to error.

Creating a secure data enclave for approved researchers to access provisional data directly on a flow basis is another possibility. In this model, approved researchers could conduct their own searches on preliminary fact and date of death information without relying on NCHS matching algorithms and without revealing the identities of study participants. To create such an enclave, new agreements with NCHS and the states would likely be needed, along with an appropriate funding structure. Federal agencies with experience in data security, data sharing agreements, and database linkage algorithms could help develop appropriate infrastructure.

Another indirect way to improve timeliness of the NDI is to support infrastructure at the state level, thereby facilitating faster reporting of death records to NCHS. Three steps could be taken:

1. Develop a common EDRS system that can be distributed to the states.
2. Support state transitions to EDRS.
3. Support training of personnel, including physicians and funeral directors, who would use EDRS.

NAPHSIS, which already supports state adoption of EDRS, would be willing to help coordinate federal agency investments in state infrastructure. Better electronic reporting infrastructure may improve both timeliness and data quality.

Appendix 1

Meeting Agenda

Purposes of meeting—

- To learn of researcher uses of death records,
- To learn of developments in access to death records, and
- To consider potential ways to facilitate timely, comprehensive, cost-beneficial, and user-friendly means of research access to death records

2:30 pm – Welcome from Committee on National Statistics (CNSTAT) and the NIA

- Introductions (Constance Citro, CNSTAT)
- Purposes of the Meeting (John Phillips, NIA)

2:45 pm – Utility of Research Access to Death Records

- Importance for clinical trials and prospective cohort studies and experience with various sources of death records
 - National Cancer Institute (Deborah Winn and colleagues)
 - National Heart, Lung, and Blood Institute (Michael Lauer)
- Importance for longitudinal population surveys and experience with various sources of death records
 - Health and Retirement Study (David Weir, University of Michigan)
 - Wisconsin Longitudinal Study (Robert Hauser, DBASSE, NRC)
- Importance for other health researchers
 - Agency for Healthcare Research and Quality (Steven Cohen)
- Questions to researchers and discussion about priorities for improvements in access to death records in an ideal world and what might be possible in the real world

3:45 – Issues for the States

- Views/thoughts of the National Association for Public Health Statistics and Information Systems (NAPHSIS) (Patricia Potrzebowski and Emily Holubowich)
- Questions to NAPHSIS and discussion about priorities for further improvement in access to death records in an ideal world and what might be possible in the real world

4:15 – Going Forward

- Ideas for fruitful areas for dialogue and action that could facilitate timely, comprehensive, cost-beneficial, and user-friendly means of research access to death
- General discussion

5:00 – Adjourn

Note: A background document will be provided in advance of the meeting. There will be no written product from CNSTAT from the meeting. NIA staff will take notes and determine what follow-up steps seem feasible and desirable for them to pursue.

Appendix 2

List of Meeting Participants

Invited Participants

Emily Holubowich, Cavarocchi Ruscio Dennis Associates, LLC (NAPHSIS Consultant)

Patricia Potrzebowski, National Association for Public Health Statistics and Information Systems

David Weir, University of Michigan

Federal Agency Representatives

Agency for Healthcare Research and Quality

Steven Cohen

National Institute of Environmental Health Sciences

Deborah Bittner, Social and Scientific Systems, Inc. (Contractor)

National Cancer Institute

Paul Pinsky

Scott Rogers

Deborah Winn

Mandi Yu

National Heart, Lung, and Blood Institute

Michael Lauer

National Institute on Aging

Evelyn Neil

Georgeanne Patmios

John Phillips

Richard Suzman

Samuel Thomas, Rose Li and Associates, Inc. (Contractor)

National Academy of Sciences

Constance Citro

Jacqui Sovde