Board of Scientific Counselors, National Center for Health Statistics, Centers for Disease Control and Prevention, Department of Health and Human Services

Virtual Meeting Summary

January 22, 2019, 11:00 am–2:00 pm ET

Attendees: Dr. Timothy Beebe; Dr. Prashila Dullabh; Dr. Darrell Gaskin; Dr. Sherry Glied; Dr. Robert Hauser; Dr. Mark Hayward; Dr. Mary Ellen Johantgen; Dr. Robert Phillips; Dr. Ninez Ponce; Dr. Robert Santos; Dr. Linette Scott; Dr. Sayeedha Uddin; Dr. Gretchen Van Wye

Agenda

1. Welcome and Call to Order
2. NCHS Update
3. Patient Centered Outcomes Research Trust Fund Drug Workgroup Report
4. BSC Wrap-Up
5. Public Comment

Action Items

- Drs. Scott and Van Wye will draft a cover letter conveying the BSC's approval of the report of findings and requesting that NCHS rank order the BSC recommendations so that the Work Group can devote its efforts to developing and pursuing the highest priority recommendation(s).

Meeting Minutes

On November 29, 2018, the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) convened a meeting of the Patient Centered Outcome Research Trust Fund Drug Work Group of the Board of Scientific Counselors (BSC) ("the Work Group") at the NCHS headquarters in Hyattsville, Maryland. The meeting gathered together a broad range of stakeholders to explore approaches to releasing more detailed drug-related information from death certificates—particularly from the literal text fields—to researchers and public health officials. A resulting report, which included five key takeaway findings from the Work Group discussions was recently distributed to members of the BSC. This virtual meeting was called primarily for BSC members to review and discuss, and to suggest any changes to the Work Group's report of findings. For the full text of the Work Group report, see Appendix 1.

1. Welcome and Call to Order

Linette T. Scott, MD, MPH; Chair, BSC
Sayeedha Uddin, MD, MPH; Designated Federal Officer, BSC

Call attendees identified themselves, and none declared a conflict of interest. Drs. Scott and Uddin then invited Dr. Madans to provide the call attendees with a general NCHS update.

2. NCHS Update

Jennifer H. Madans, PhD, Acting Director, NCHS

Referring to the ongoing partial federal government shutdown, Dr. Madans noted that NCHS remains funded and is largely unaffected. NCHS data collections are still ongoing, even those being conducted by agencies affected by the shutdown. It is unclear, however, for how much longer this can continue. The U.S. Census Bureau is currently collecting data for the National Health Interview Survey using a newly redesigned questionnaire. Once results start to arrive, CDC will assess how the questionnaire changes may affect data processing and response rates.

The National Health and Nutrition Examination Survey (NHANES) is also entering a new phase of its biennial fieldwork following minor survey changes. CDC is currently focused on improving response rates, reducing bias, and expanding the sample for NHANES. The tentative timeline for implementing changes to address these issues is the 2023 wave.

Attendees were encouraged to provide feedback (offline) regarding the virtual meeting format.

3. Patient Centered Outcomes Research Trust Fund Drug Workgroup Report

Gretchen Van Wye, PhD, MA

Dr. Van Wye provided a summary overview of the five key findings that emerged from the Work Group discussion on November 29, 2018 (below). Additional detail regarding each finding can be found in Appendix 1.

The Work Group Key Findings

(1) A supplement is needed that leverages and maps to the existing *International Statistical Classification of Diseases and Related Health Problems* (ICD-10) coding schema to capture more diverse kinds of information.
(2) Researchers want as much detail as possible on drugs related to deaths, but they want this information to be meaningful and truly related to the cause of death. Furthermore, they want to know where on the death certificate this information comes from.
(3) Because the drug use landscape can change quickly, the system should be able to change quickly, and with adequate documentation and transparency.
(4) NCHS's list of drugs should be anchored in some standardized drug classification reference system (e.g., RxNorm or the Anatomical Therapeutic Chemical [ATC] system), which should be carefully selected according to NCHS's needs.
(5) Users need to know how to ask questions about the data so that analyses are appropriate and reasonable. Analyses should be research question-driven.

Discussion

Attendees generally agreed with each finding but raised several questions and potential concerns. For example, the effort to extract information from death certificate literal text fields is only worth pursuing if those fields have been proven to contain consistent and high-quality information. Dr. Warner (NCHS) indicated that efforts to extract and evaluate death certificate literal text have been ongoing for 3-5 years, with NCHS collaborating with state-level partners.

Initial analyses show that, although literal text fields contain substantial variability, approximately 75 percent of literal text fields mention at least one specific drug. Moreover, during the past 2 years, as NCHS has engaged with the community of medical examiners and coroners, this portion has risen to approximately 90 percent. In addition, to account for common misspellings, NCHS has developed a manually curated list of drugs and drug terms that includes misspellings.

Dr. Madans noted that, as the drug landscape evolves, a tension exists between flexibility and consistency in literal text data. That is, researchers understandably want as much information as possible organized into a granular categorization scheme, yet the data and their structure must also remain relatively consistent so that they can be mapped across time and place. Attendees noted that categories should be as granular possible without undermining NCHS's ability to sustainably manage them against dynamic changes to the drug landscape, and without limiting the usefulness of the most granular categories to certain states or localities.

NCHS and the academic research community have somewhat different needs for drug-related literal text data. During the Work Group's November meeting, investigators offered to conduct pilot analyses and to develop use cases to help NCHS better understand who will use these data, and for what purposes. This offer is aligned with overall recommendation 5, which states that analyses of these data should be research question–driven, because in general NCHS and the academic research community will be interested in different, yet overlapping, research questions. These pilot analyses can help to optimize drug categories for the diverse range of jurisdictions producing these data.

An attendee, in addition to supporting the five key findings, suggested developing a more explicit approach to training and providing feedback to medical examiners and coroners in order to improve the completeness and consistency of death certificate literal text data.

Another attendee inquired whether it may be possible to integrate death certificate literal text data with other data sources (e.g., emergency room and hospital visits, overdoses reported to poison control hotlines). Dr. Scott noted that attendees from the Work Group had offered similar ideas, though Dr. Van Wye emphasized the need to avoid expanding the scope of these data beyond what is tractable to manage and interpret. Similarly, an attendee suggested—to widespread agreement—that the Board focus primarily on immediate priorities because the rise in drug-involved deaths is an acute problem that requires urgent action. To that point, Dr. Scott added that these recommendations from the Board are not final: they can be refined iteratively over the next 1 to 2 years. The PCORTF Drug Work Group (Drs. David Gastfriend, Tracy Green, Svetla Slavova, Linette Scott (BSC), and Gretchen Van Wye (BSC)) will continue to meet as needed in order to strategize and develop these plans further.

Dr. Warner, in response to a question, confirmed that RxNorm is currently the favored reference system for anchoring prescription drug classifications from death certificate literal text. NCHS is currently investigating how to curate a list and configure a value set for illicit drugs, because the NCHS database contains both types of substances. Support was expressed for developing use cases in order to optimize how NCHS uses these data.

BSC members discussed whether to accept the Work Group's report of findings and forward recommendations based on the report to NCHS, and whether to prioritize or highlight any of the recommendations for special attention. All present BSC members voted to advance the report findings to NCHS. Drs. Scott and Van Wye will draft a cover letter conveying the BSC's approval of the report and recommendations based on the report's findings. The letter will also request that NCHS rank order the recommendations so that the Work Group can devote its efforts to developing and pursuing the highest priority recommendation(s).

Dr. Phillips recommended that, as the BSC and others at NCHS continue to develop these recommendations, they consult the NCVHS report "Vital Records and the Vital Statistics of the United States: Uses, Users, Systems, and Sources of Revenue." This report contains pithy material that could be useful in explaining to medical examiners and coroners the potentially immense value of the data that they put into death certificates.

4. BSC Wrap-Up

Linette T. Scott and Jennifer H. Madans

During its next meeting scheduled for May, the BSC will review new priorities or findings that have emerged from NCHS, as work on the current recommendations progress over the next several months. In addition, the next BSC meeting may include a brief presentation on the history of NCHS's use of death certificate literal text to provide some added context to the BSC's current activities. In the meantime, Dr. Madans will focus on maintaining momentum for the Work Group's activities.

If any attendees have suggestions for agenda items at the next BSC meeting, they should convey those suggestions to Dr. Uddin. Finally, the BSC will gain four new members: Drs. Helen Levy (University of Michigan, Department of Health Management Policy, School of Public Health), John Lumpkin (Robert Wood Johnson Foundation), Kristen Olsen (University of Nebraska-Lincoln, Department of Sociology), and Andy Peytchev (RTI International).

5. Public Comment

No public comments were submitted.

The meeting was adjourned at 12:20 p.m.

To the best of my knowledge, the foregoing summary of minutes is accurate and complete.

/s/ 3/26/2019

Linette T. Scott, M.D., M.P.H. DATE
Chair, BSC

Appendix 1:
Report of Findings from the NCHS Board of Scientific Counselors Patient Centered Outcome Research Trust Fund Drug Work Group Meeting held on November 29, 2018

Background:
On November 29, 2018, the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) Board of Scientific Counselors (BSC) convened a meeting of the Patient Centered Outcome Research Trust Fund Drug Work Group at the NCHS headquarters in Hyattsville, Maryland. The meeting gathered together a broad range of stakeholders to explore approaches to releasing more detailed drug-related information from death certificates to researchers and public health officials. Currently, vital statistics data from death certificates are used to track the increasing number of deaths from drug overdoses in the United States. Causes of death, including the drugs involved, are coded using the 10th revision of the *International Statistical Classification of Diseases and Related Health Problems* (ICD-10) system, which is limited for identifying specific drugs. However, the literal text portion of the death certificate often contains detailed information about drugs that caused or contributed to death.

Thus, in order to provide ideas to the BSC on maximizing the value of these data for researchers and public health officials, meeting participants considered and discussed what supplemental drug information should be extracted from death certificate literal text and how it should be classified. Topics of discussion included (1) gaps in the current drug classification system, (2) current innovations to extract and use information from the literal text, and (3) alternative classification schemes that would provide additional, useful information to end users.

Key takeaways and findings

1. *A supplement that leverages and maps to the existing ICD coding schema is needed.*

   Participants generally agreed that it is desirable to capture as much information from death certificate literal text as possible. This effort entails both a broad set of inclusion criteria and a granular categorization scheme. However, categories should not be so detailed that managing them becomes unsustainable as new drugs emerge and as the names of drugs and other substances multiply. In addition, the inclusion criteria and category scheme should be dynamic and fully transparent to enable flexible adaptation in real time and novel and unambiguous retrospective analyses.

   For categories such as “drugs” that change frequently, it may be useful to ground NCHS’s categorization scheme to a reference system such as those that exist for prescription drugs (e.g., RxNorm). With a centralized reference system, individual users could customize categorization schemes and inclusion criteria for their unique study purposes. Such a reference would support mapping of death certificate literal text data to other data sources that utilize, or are linked to, that same reference. In addition, it

would help to define the criteria for which substances should be extracted from death certificate literal text and coded, because substances excluded from the reference could be automatically excluded from the coding scheme.

Regardless of what search terms, substances, and inclusion criteria are used to extract and code drug information from literal text, their details and underlying rationales should be well-documented and transparently available. Since ICD-10 is used to classify causes of death in the vital statistics data, including deaths involving drugs, the ability to map back to ICD-10 for both cause of death and drugs involved was stressed. With the supplemental system integrated with ICD-10, users will know how to interpret the data, and information will remain consistent even when the database is modified (i.e., so that past data can be properly modified to suit novel formats or specifications).

2. *Researchers want as much detail as possible on drugs related to deaths but they want it to be meaningful and truly related to the cause of death. Further, they want it to know where on the death certificate it was reported.*

   The workgroup thought that the best approach to coding drugs might be to avoid establishing preset categories, and instead to establish a method of producing custom categories (including custom value sets for drugs) so that the data can best serve the needs of each user or user community. This approach would help to maximize the value of the data for diverse users with different needs. Users could develop innovative categorization approaches and organize a national data set using category schemes and definitions that match those used in their locality. Data pre-processing algorithms that capture useful contextual information could help distinguish cases in which drugs are mentioned for a reason other than cause of death, which are of special concern for those literal text fields that are not specifically intended to capture cause of death.

3. *The group recognized that the drug use landscape can change quickly, and so the system should also be able to change quickly with adequate documentation and transparency.*

   Maintaining a dynamic categorization scheme will require both a technical and an administrative infrastructure that is correspondingly agile. The hope would be that data preprocessing algorithms could facilitate rapid categorization of newly emerging drug names, which could be grouped into existing categories into which they logically fit. This would maintain data consistency while accounting for an evolving drug landscape.

4. *We need to anchor our list of drugs in some reference system.*

   The effort to systematize the collection of drug data from death certificate literal text should include the adoption of a standardized drug classification system. Existing systems, such as Anatomical Therapeutic Chemical (ATC) drug classification and the Established Pharmacological Classes (EPC), use different criteria to categorize and classify drugs, and NCHS must determine what set of criteria best suits the purpose of capturing drug-related mortality information in death certificate literal text.

Classification systems differ in level of granularity, number of category levels, ability to support linkage to administrative data sources, coverage of drug types, and many other factors. Participants agreed on the importance of clearly identifying the general properties of a drug classification system before deciding which one best suits the purposes of the research and the public health communities. With a centralized reference system, individual users could customize categorization schemes and inclusion criteria for their unique study purposes. Such a reference would support mapping of death certificate literal text data to other data sources that utilize, or are linked to, that same reference.

5. *Users need to know how to ask questions about the data so that analyses are appropriate and reasonable. The group wanted analyses to be research question-driven.*

   Participants agreed that literal text drug data should be as granular as possible and should allow for classification flexibility. Such flexibility will necessitate that NCHS maintain transparent documentation so that the full data set can be mapped across time. Before making large resource investments, a priori hypotheses should be tested against use cases to optimize the technical infrastructure that will store, organize, and share drug data extracted from literal text. Although users will not typically be granted access to raw literal text data, they should be aware of what kinds of details from the raw literal text data have been obscured by the curation process. The data and technical infrastructure will often require updates and revisions; thus, NCHS must prioritize developing methods to iteratively evaluate the data set and the database.

   Several interpretive difficulties currently undermine the utility of death certificate literal text. For example, some states lack a centralized reporting system for information derived from death certificates, while some lack a central medical examiner's office to enforce whatever standards exist. The resulting inconsistencies within and across states make it difficult to identify death trends, including across geography and time. In addition, protocols for filling in literal text fields occasionally change, and it can be challenging to determine the nature of the changes and when they occurred. Researchers will need to be warned to take care in analyzing these data.