Data Dissemination Policies and Guidelines for Requesting Access to Data from the National Child Death Review Case Reporting System

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NCFRP Data Dissemination Policy and

Guidelines for Requesting De-identified Dataset

DATA DISSEMINATION POLICY

Mission

The purpose of the Fatality Review Case Reporting System (NFR-CRS) of the National Center for Fatality Review and Prevention (NCFRP) is to systematically collect, analyze, and report on information surrounding stillbirths and deaths of individual infants and children around the country. The information can then be used at the local, state, and national levels to inform improvement in maternal and child health and safety and to prevent deaths. The data collected with the System includes the following:

- information about the child, family, supervisor and perpetrator;
- the types of action taken during the investigation;
- the scene, incident, and background information on the cause of death, including the risk and protective factors;
- the services provided or needed as a result of the death;
- a descriptions of the teams' recommendations, as well as the policies, practices, and other actions taken to prevent other fetal, infant, and child deaths; and
- factors affecting the quality of the case review.

The web-based NFR-CRS was first implemented in May 2004 in 14 pilot states. Version 1 was made available for widespread use in January 2005. Since 2005, the software has been upgraded several times, including the addition of several new questions, most notably to support the Sudden Unexpected Infant Death Case Registry and the Sudden Death in the Young Case Registry. Effective with Version 5, the NFR-CRS collects detailed information about fetal and infant deaths. Updated information on the number of participating states, number of entered cases and number of cases migrated into the system from older state reporting systems is available from NCFRP. The NFR-CRS is supported primarily by the HRSA Maternal and Child Health Bureau and secondarily by the US Centers for Disease Control and Prevention. Data submitted by states resides on servers at the Michigan Public Health Institute (MPHI).

Data Sources

Data collected by the NFR-CRS are the result of multi-disciplinary processes that bring together state and/or community agencies to share information on maternal health, fetal, infant and child death events and to identify the risk factors in these deaths. Data entered into the System may include, but are not limited to, information gathered from the following data sources: birth certificates, death certificates, law enforcement records, medical records, autopsy reports, child protective services reports, and Emergency Medical Services run reports.

Fatality Review Programs in States
Fatality review programs vary by jurisdiction and state with respect to case selection; the maximum age of children whose deaths are reviewed (0-14, 0-17, 0-25, etc.); and the average time between review and death (ranges from 1 to 36 months). Due to these variances, the data are not universally consistent from site to site or state to state.

Because most states do not review or enter every fetal, infant and child fatality into the System, the NFR-CRS should not be directly compared with vital statistics data nor should it be used to compute incidence rates. All of these distinctions among sites and states and limitations must be accounted for and noted in any analysis of the data. More information about fatality review programs and case selection can be found at http://www.nfrp.org.

Prior to the development of the NFR-CRS, local FIMR programs had been using a variety of systems to collect and report their data. Typically, most FIMR information is collected from maternal interviews, birth and death certificates, autopsy reports, hospital records including labor and delivery, newborn, neonatal and pediatric care units, emergency department, and outpatient records including prenatal care, pediatric well baby and sick baby visits, and other service providers such as WIC, public health, home visits, and department of human and social services records. FIMR data is meant to complement other population data. Collection of FIMR data into the NFR-CRS did not begin until 2018.

Data Ownership
Fatality review data entered into the NFR-CRS are owned by the individual program that entered it (per the data use agreement executed between each local program or state and MPHI/NCFRP). Requests for de-identified, individual case report data will be submitted to the NCFRP Data Dissemination Committee, per guidelines contained in this document.. For any research request that proposes to identify data by state in any published or publicly released analysis or results, local programs and states will be provided an opportunity to have their state's data excluded from the study.

Data Inclusion
Cases included in the de-identified dataset will include all cases that are at least 24 months from the end of the calendar year for the preceding January-December time frame. For example, the death cohort from calendar year 2015 (deaths that occurred in January-December 2015) and earlier will be made available in a researcher de-identified dataset on January 1, 2018. The death cohort from calendar year 2016 and earlier will be made available in a researcher de-identified dataset on January 1, 2019. Cases migrated from previous fatality review reporting systems into the NFR-CRS will not be included in a standard dataset but may be provided upon further consultation between the researcher and NCFRP.

Removal of Identifiable Data Elements for Dataset

No data file that includes HIPAA-defined personally identifiable elements is available to researchers. Although states often enter HIPPA-defined personally identifiable data elements (child's name, address, date of birth, date of death, date and time of incident, and incident county) into the NFR-CRS, all personally identifiable data elements will be removed from any dataset made available to researchers. The data elements that will be removed from the dataset are listed in Attachment 1 of the Application for Access to De-identified Dataset (Application for Data). The "Narrative" field contained in Section O of the Case Report form will only be released to researchers under special circumstances.

Although no HIPAA defined personally identifiable data elements should be included in the Narrative field of Section O, should there by ANY identifying elements contained in this section, it is to be considered an inadvertent disclosure and (1) shall not be used or disclosed by researchers, (2) shall be immediately deleted by researchers and (3) be immediately reported to MPHI/NCFRP with written confirmation by the researchers that the confidential information cannot be used.

If any HIPAA personally identifying data elements are included in other free text fields in the researcher dataset, it is also considered to be an inadvertent disclosure and the confidential information (1) shall not be used or disclosed by researchers, (2) shall be immediately deleted by researchers and (3) be immediately reported to MPHI/NCFRP with written confirmation by the researchers that the confidential information cannot be used.

To further protect anonymity of states, NCFRP will create and provide a unique code for each state for each approved research project so that researchers can evaluate variation and control for potential bias in the dataset without identifying the individual states. NCFRP will retain the coding key.

Permitted Data Uses

NCFRP may use de-identified case report data for its own research and reports. NCFRP only has access to de-identified case report data; NCFRP does not have to obtain permission from the Data Dissemination Committee (see Guidelines below) in order to have access to the de-identified data. NCFRP has access to all de-identified data entered into the NFR-CRS and is not limited to only those cases in the researcher dataset. The NCFRP may report aggregated, de-identified data identified by state to requesting parties such as agencies or organizations without state permission. The NCFRP will only report aggregated data with cell counts of six or more cases. Requests by researchers for de-identified datasets must be made in accordance with the Guidelines for Requesting De-identified Dataset (Guidelines), below, and NCFRP will only release de-identified datasets in accordance with the Guidelines.

Required Fees

A fee may be charged to each applicant for preparation of the requested dataset. The amount of the fee will be determined by NCFRP staff. An estimate of any fee will be provided to the applicant upon a preliminary review of the proposal by staff. Fees will be determined based on a price equal to the number of staffing hours estimated to prepare the dataset using the federally approved MPHI MOBUS rates. Fees must be paid in full prior to the release of the dataset to the applicant. NCFRP reserves the right to waive fees in certain situations.

Data Quality

In order to standardize the collection and interpretation of data elements, the NFR-CRS contains a comprehensive Data Dictionary that is readily available online when entering cases into the System or as a standalone PDF document that can be used by fatality review teams during review meetings. Additionally, NCFRP is readily available to provide technical assistance about the Case Report tool and is in constant communication with states about data and reporting questions. Since the data are owned by the individual participating states, states are responsible for cleaning data records, and states vary in the degree to which they review data for inconsistencies, incompleteness, or inaccuracies. NCFRP has found that data quality appears to improve with increased time and training on the System. The Case Report tool contains by design some subjective questions to engage team discussion (e.g., “Was the death preventable?” or ”Did a person or persons other than the child do something that caused or contributed to the death?”). The subjective nature of some of the questions can, however, make data analysis more problematic. Finally, although teams record in the System which agencies participated in the fatality review, the primary data source for each data element is not collected as part of the Case Report tool. If there is a discrepancy in information shared by the different agencies at the review meeting, it is up to the fatality review teams to determine the best answer and there is no set primacy rule for data sources.

More information about the CDR Case Reporting System and limitations on the use of the data can be found in the February 2011 Supplement to *Injury Prevention* (Covington TM. The US national child death review case reporting system. *Injury Prevention* 2011; 17 Suppl 1:i34-i37).

GUIDELINES FOR REQUESTING DE-IDENTIFIED DATASET

Researchers affiliated with eligible Receiving Institutions may apply for access to a de-identified dataset. The Receiving Institution must be an institution of higher education, research organization, non-profit agency or government agency that either employs or contracts with the Investigator. The Institution must be registered with the U.S. Office for Human Research Protections. Any release of data will be subject to a signed Contract for Access to and Use of Data (Contract for Data) between NCFRP and an authorized representative of the Receiving Institution. The Contract for Data is set out after these Guidelines.

An Application for De-identified Dataset (Application for Data) must identify a principal investigator (PI). The PI serves as the primary point of contact for all communications involving the Contract for Data. The PI must sign the Contract for Data, by which the PI assumes responsibility for compliance with all terms of the Contract for Data by employees of the Receiving Institution, including the day-to-day security of the electronic data and all printed output derived from the files.

Each additional researcher who will have access to the NCFRP dataset must be identified on the Application for Data and must sign the Confidentiality Agreement attached (Attachment 3). The applicants may not release or permit others to release the dataset in whole or in part to any persons other than those identified in the Application for Data.

Access to the dataset is also subject to the following requirements:

1. The researchers given access to the Center's dataset may not conduct analyses of the data for purposes other than those described in the approved Application for Data. Applicants will not alter the approved use of the data in the research design unless they have notified and obtained written permission for the alteration from NCFRP.
2. The PI must obtain IRB approval for the proposed research. Letters of approval must be submitted to NCFRP prior to release of data for approved analyses.
3. All data shared are and shall at all times remain the sole property of the state and local county teams which performed the fatality reviews that are the source of the data. States have the right of first refusal to participate in this research project if the PI plans to publish or publicly release any analysis or results that identifies individual states. It is permissible, however, to list the states included in the dataset, as long as no data are attributed to specific states, and the states have authorized this acknowledgement. States will be asked whether they wish to be specifically acknowledged in any project publication or presentation.
4. The researchers must not attempt nor permit others to attempt to use the dataset to

learn the identity of any decedent. If the identity of a decedent should be inadvertently discovered by the PI or any other individual, the PI must make no use of this knowledge, permit others to use the knowledge, or inform anyone else of this knowledge, and must inform NCFRP of the discovery so it can prevent future discoveries of this nature.

5. Although no HIPAA defined personally identifiable data elements should be included in the free text fields or the Narrative field of Section O, should there be ANY identifying elements in these variables, it is considered to be an inadvertent disclosure and (1) shall not be used or disclosed by researchers, (2) shall be immediately deleted by researchers and (3) be immediately reported to MPHI/NCFRP with written confirmation by the researchers that the confidential information cannot be used.
6. No data will be released that identifies data by state jurisdiction without the explicit approval of the state(s).
7. Only aggregated data with cell counts of six or more cases will be released and reported in any analysis. Cells less than six cases will be aggregated with other like cells.
8. All oral and written presentations or other distribution of information resulting from the use of this dataset must be developed with adequate provision for the accuracy, reliability and integrity of the data.
9. All oral and written presentations or other distribution of information resulting from the use of the requested data must be submitted to NCFRP for review at least two weeks prior to presentation or submission to a journal or other source of publication. The purpose of this review is to determine whether the research was completed in the manner specified in the Application and whether the analysis is in the spirit of Fatality Review and the NCFRP mission, and to permit NCFRP to have advance notice of potential issues pertaining to the analysis and/or results. Any additional or other use of these data will be considered a breach of the Contract for Data, unless agreed upon in writing by both parties beforehand.
10. NCFRP may terminate its contract with the recipient if the recipient is in violation of any condition of the contract and such violation is not remedied within 30 days after the date of written notice of the violation. Furthermore, failure to comply with the contract terms will result in the disqualification of the PI, along with any collaborators implicated in the violation, from receiving additional NCFRP data.
11. All presentations and publications making use of this dataset must be provided to NCFRP in a timely manner so that it is a repository of the various uses of the data.
12. All presentations or other distribution resulting from use of the requested dataset must include an acknowledgement of the participating states and NCFRP. They must include the following language: "This dataset was provided by the NCFRP, which is funded in part by Grant Number UG7MC28482 from the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) and in part by the US Centers for Disease Control and Prevention Division of Reproductive Health. The contents are solely the responsibility of the authors and do not necessarily represent the official views of NCFRP, HHS or the participating states. The following states contributed data from their fatality review: (list states)."

13. Within three years of completion of the project, all hard copies of the dataset generated by the researchers must be destroyed with a cross-cut shredder or returned to NCFRP, and all electronic data must be destroyed/deleted within the same time frame. Written confirmation that the dataset has been destroyed is required.
14. All installations of the data must have electronic security measures in place to prevent unauthorized access, by electronic or physical means, to the confidential data provided or to output from that data.

Data Inclusion

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Application Process

To request a de-identified dataset from the NCFRP, the PI must complete the Application for Data, including a detailed proposal to NCFRP describing the purpose of the data request, methods for study, and mechanisms that will be used to keep the data secure (see Application form). Upon receipt, the Data Dissemination Committee (consisting of representatives of participating states, scientists, members of the NCFRP National Center Advisory Committee, and other relevant individuals) will evaluate the application on the basis of the following criteria:

- Quality of the research question(s) and objectives for use of the dataset;
- Whether the requested data elements are clearly described and whether access to those elements is necessary for the research questions;
- Applicant's understanding of the strengths and limitations of the database and analysis plan that is appropriate for this type of dataset;
- Qualifications of researchers who will have access to the dataset;
- Sufficiency of safeguards in place to maintain the data security, confidentiality, and prevent unauthorized access to data and evidence that the institution is registered with the U.S. Office for Human Research Protections;
- Extent to which the proposal is in accordance with the mission of Fatality Review, which is to better understand how and why children die and use the findings to take action that can prevent other deaths and improve the health and safety of children;
- Whether NCFRP is conducting similar research or has plans to do so; and
- Whether anticipated presentations, publications, or other dissemination of results from the research is consistent with the NCFRP mission.

At a minimum, the Committee will review applications on a quarterly basis. All applicants will be notified in writing by NCFRP of the Committee's decision. Proposals will be scored using the above criteria and given one of three grades:

1. Rejected for not meeting the criteria
2. Preliminary approval but requesting revision
3. Approved

After approval by the Committee, NCFRP will inform the states participating in the NFR-CRS of the Committee's decision. For any research request that proposes to identify data by state in any published or publicly released analysis or results, states will be notified and given the opportunity to have their state's data excluded from the study (Attachment 2). States will also be asked whether they wish to be specifically acknowledged in any project publication or presentation.

Requests for more information about the data file and the process for obtaining permission to access the dataset should be directed to:

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