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ORIGINAL ARTICLE

Historical perspective on the department of energy mortality studies: focus on the collection and storage of individual worker data

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ABSTRACT

Purpose: To present how the Department of Energy's (DOE) Comprehensive Epidemiologic Data Resource (CEDR) is integrated into the Million Person Study of Low Dose Health Effects (MPS). The history of DOE's worker health surveillance and its epidemiology program are described.

Methods and materials: A standard protocol is used to extract data from CEDR for use in the MPS. The data files are pulled from CEDR to form the basis for the cohort analyzed in the MPS. The previous study data are reviewed to formulate the protocol for the MPS study cohort. The activities needed to update the data to construct the new analytic files are carried out in parallel. The primary efforts relate to updating the vital status, retrieving cause of death information and calculating annual radiation doses for the specific organs of interest. Working data files containing the updated data are produced for construction of analytic data files used in the biostatistical analysis. At study completion the working and analytic data files are placed into CEDR for use by other researchers.

Results: The use of CEDR to study the scientific and maintenance workers at the Los Alamos National Laboratory which is currently underway is used to demonstrate the process.

Conclusions: There is a pressing need to answer the question of the health risk of exposure to chronic low-level exposure to ionizing radiation. Using CEDR as the starting point to identify new cohorts to include in the MPS is a cost-effective and a time efficient way to expedite answering this question.

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Epidemiology; database; low dose effects; radiation

Introduction

From its roots in the Manhattan Project (MP), the Department of Energy (DOE) and its predecessors have had a concern about the possible health effects among workers in its nuclear facilities and have taken a proactive approach in surveillance of exposure and health. Beginning in 1943, MP workers in the uranium processing operations were receiving annual medical examinations, being monitored for radiation exposure by wearing film badges, pocket chambers and finger rings, providing breath radon samples, and radium and uranium urinalysis samples (Mears and Engel 1945; USAEC 1949). Area dust monitoring began at the same time. With the growth of the DOE complex to include about 80 facilities, the total number of individuals ever employed in a DOE facility is estimated to be about 600,000 (Lushbaugh et al. 1983).

The ability to include the DOE nuclear workers in the Million Person Study of Low Dose Health Effects (MPS) hinges on the existence of the various types and completeness of the records required to carry out a retrospective occupational epidemiologic mortality study. The MPS is an epidemiologic study of US workers who were exposed to radiation at low doses and dose rates gradually over time. The goal is to provide relevant and needed data on radiation risks at low doses, particularly below 100 mGy (Boice 2012). DOE's early and continued focus on the effects of radiation exposure on the health of its workforce makes the DOE workers a significant component of the MPS. Their inclusion in the MPS is important because of the size of the workforce, the unique radiation exposures in these facilities, and the extended length of follow up of these workers. The DOE Comprehensive Epidemiologic Data Resource (CEDR) is an invaluable resource to the MPS (https://apps.orau.gov/cedr/default.aspx accessed 6 Sep 2018). CEDR is an electronic database made up of the analytic (AF) and working (WF) data files used in retrospective cohort mortality studies of DOE workers. Its stated purpose is to 'provide independent researchers and educators with access to .... data collected since the Department's early production years'. CEDR will be used to prioritize studies added to the MPS and to expedite the updates to past studies by leveraging the effort already expended by DOE to study health effects in its nuclear workforce.

The early history of the DOE epidemiology program (1960–1979)

In the early 1960s the Atomic Energy Commission (AEC), the successor to the MP, began to evaluate the feasibility of using the existing employee and other facility records to conduct epidemiologic mortality studies to investigate the

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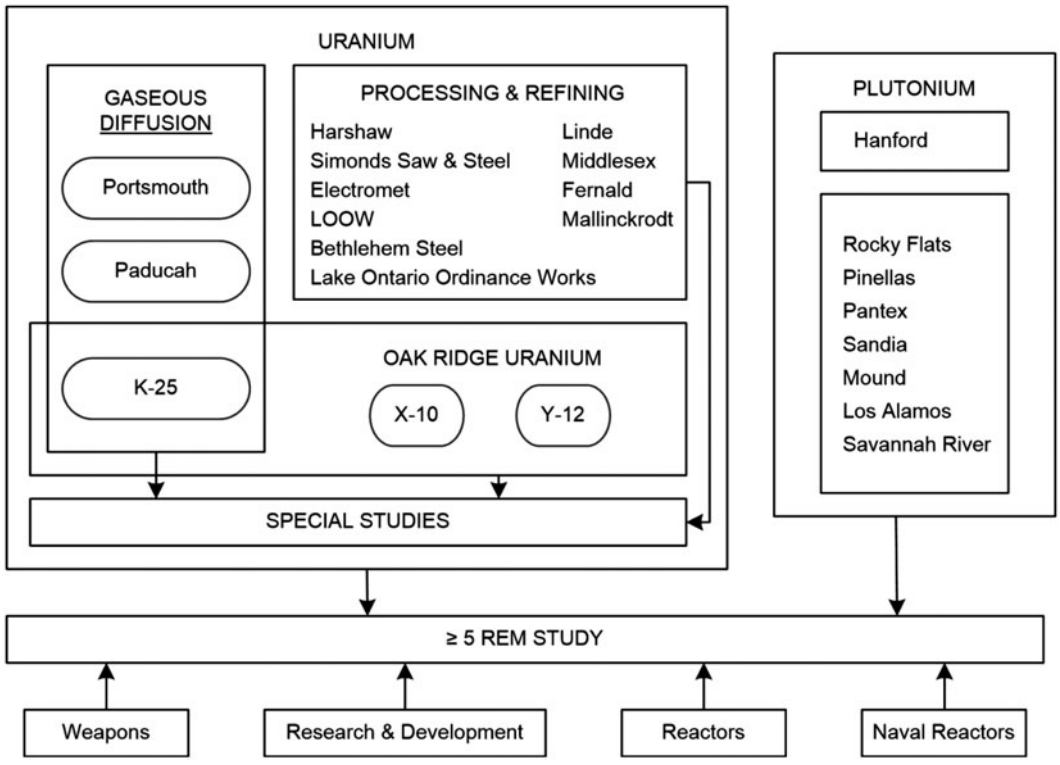

Figure 1. Facilities included in the Department of Energy Health and Mortality Studies.

relationship between occupational radiation exposure and mortality. Carried out by the University of Colorado, looking at records of two uranium processing sites that began operations in the 1940s and early 1950s, the study demonstrated the feasibility of using plant records to carry out such studies (Bell et al. 1965; 1966; Quigley 1967).

From 1964–1969 the AEC funded a more broadly based five-year pilot study which confirmed the suitability of the existing records in conducting retrospective epidemiology mortality studies that could provide an upper bound of cancer risk associated with exposure to chronic low levels of ionizing radiation. This study conducted by the University of Pittsburgh added several more facilities and concentrated on identifying relevant original records located at the facilities and at off-site federal and other records repositories. Protocols and procedures for records preservation, storage and retrieval, and computer entry were developed. Records that might have been destroyed over time were identified and preserved for future studies. Few records were in electronic machine-readable form. The most relevant data elements for constructing a worker roster and ascertaining the vital status of the workers were abstracted and processed into machine-readable form. The University of Pittsburgh established a process of vital status determination of the workers. The researchers established interfaces with the Social Security Administration (SSA) to determine vital status and with the 50 states to retrieve death certificates (DC) to establish the cause of death. From 1970–1977 focus shifted to completing a mortality analysis of the workers at the Hanford site which was published in 1977 (Mancuso et al. 1977).

At the end of 1977 the Energy Research and Development Administration (ERDA), the predecessor to the DOE, transitioned the project to three epidemiology groups: Oak Ridge Associated Universities (ORAU), Los Alamos National Laboratory (LANL), and Hanford Environmental Health Foundation/Pacific Northwest Laboratory (HEHF/PNL). Each site was assigned specific programmatic responsibilities. HEHF/PNL was responsible for Hanford, LANL for selected sites that processed plutonium, and ORAU for the selected sites that processed uranium (Figure 1). ORAU was also given the responsibility to manage the interface between ERDA and the SSA obtaining the vital status for the worker rosters constructed by all three epidemiology groups as well as DC retrieval as requested by each epidemiology group. In 1979 the DOE accepted ORAU's proposal for a 'Comprehensive Epidemiologic Study of Atomic Workers' which expanded the study to all inactive and active DOE facilities. It was understood that the 80 identified sites with an estimated total workforce of 600,000 would be studied as funding allowed. Except for the interaction required with ORAU to interface with SSA, the three DOE epidemiology programs worked independently to establish the framework for studying their assigned portion of the DOE workforce.

ORAU's epidemiology program (1979–1990)

The epidemiology program set up by ORAU which is referred to as the Health and Mortality Study of DOE Workers (HMS) is germane to this paper because the data structure developed for this program formed the backbone of DOE's

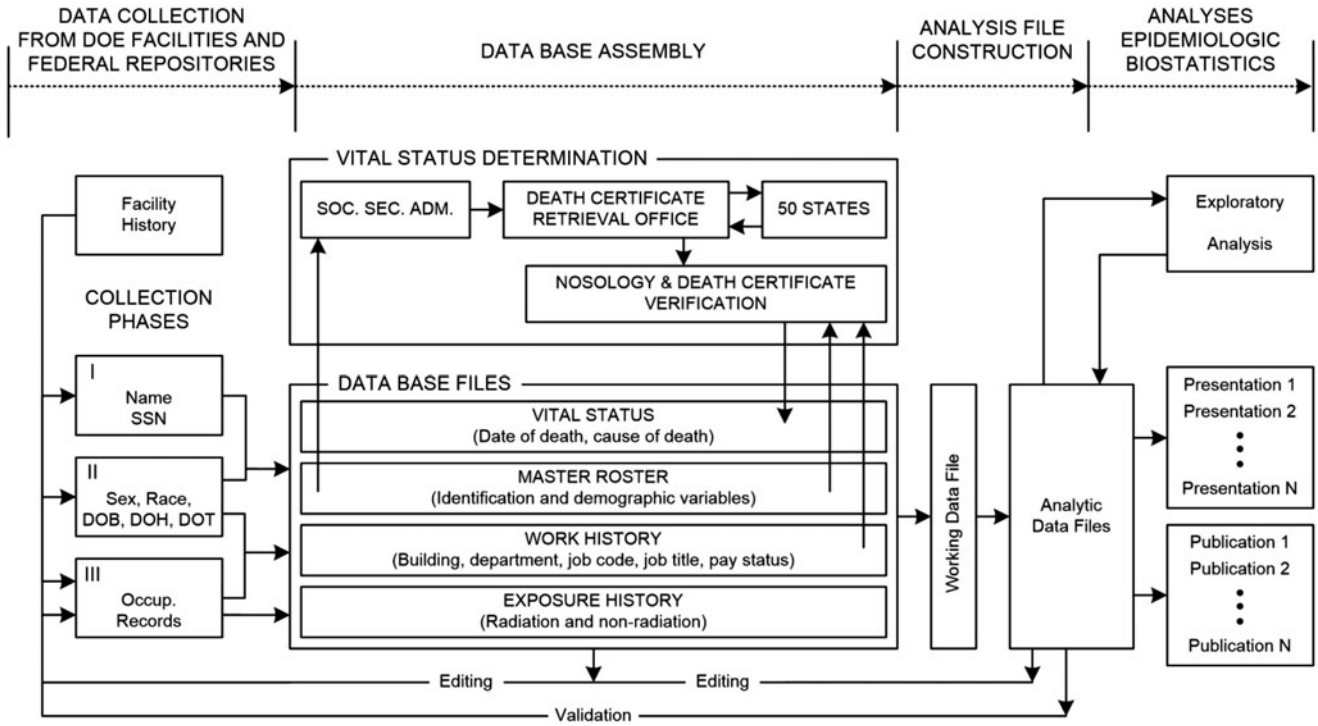

Figure 2. The process used to assemble and analyze the data needed to carry out the epidemiologic studies for the Department of Energy Health and Mortality Studies.

Comprehensive Epidemiologic Data Resource (CEDR) which is a major source of data used to define worker cohorts for the MPS.

The principal purpose of the HMS was to evaluate the effects of chronic occupational exposure to low dose ionizing radiation from external and internal radiation sources on the health of the DOE nuclear workers (Lushbaugh et al. 1983). Since multiple DOE sites were included in the HMS, a standardized study process was developed to ensure consistency in the way data were collected, compiled and processed for analysis (Figure 2). Major components of this process were data collection, data management, study file construction, statistical analysis and presentation. The intent was to ensure consistency in the methods used when working concurrently with data from multiple facilities and to minimize the introduction of systematic bias. An integrated relational database was developed to facilitate the incorporation of information from multiple facilities and the linkage of all data for a given worker.

The study process began with a collection of occupational records from the facility and records storage areas. The focus of the data collection was on records containing information useful for construction of worker rosters, personal identifying information (PII), demographic data, job history and radiation exposure history. With the nuclear operations at these facilities dating back to World War II much of the data collected was in the form of hard copy records. Pertinent information on the hard copy records was computerized. The data in the new electronic files were added to the appropriate table in the relational database. At that time, each worker was assigned a unique pseudo-ID. Since seven percent of the individuals worked at more than one DOE facility, this identifier was useful to link all the records for a given worker together across multiple facilities and record types in the database, and allowed the removal of PII (i.e. name and Social Security number) for sequestration in two tables, a 'Key' table which contains the SSN and the 'Name' table which contains full names. The pseudo-ID protected the privacy of the workers by restricting access to PII to only those tasks for which it was required. Data went through a series of logic checks prior to and during loading to the relational database. Errors were identified and flagged for resolution.

Personal radiation monitoring data were not added to the relational database. The pseudo-ID was linked to the exposure data for each worker. The sheer volume of these data files exceeded the capability of what the relational databases could accommodate at the time. Because of the differing radiation risks across the DOE facilities and the autonomy of each site to set up its health physics program, the variability in the type of monitoring and in the formatting both within and between sites precluded the standardization of the exposure record formats across the DOE facilities. These files were maintained separately for each facility.

Since vital status and cause of death were not widely available from facility records, the HMS built upon the system set up by the University of Pittsburgh. Briefly, the Social Security Administration (SSA) was the primary source for determining the current vital status of the workers. For workers identified as deceased, the state and date of death identified by SSA were used as the starting point for requesting the DC from a state. If the DC was not found in the SSA state, additional states were queried using an algorithm based on the state in which the facility was located. Once the DC was located, it was verified as belonging to the worker, and underlying cause of death and any cancer cause not selected as the underlying cause were coded according to the rules of the Eighth Revision of the International

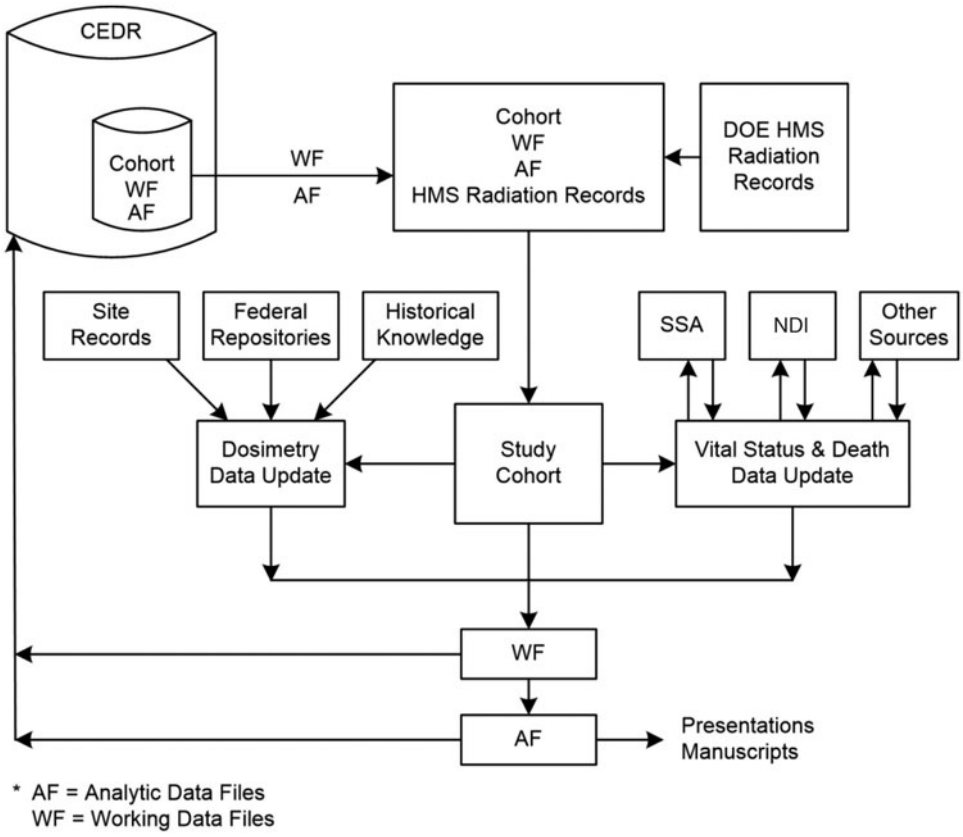

Figure 3. The interaction between of the Department of Energy Comprehensive Epidemiologic Research Database and the Million Person Study of Low Dose Health Effects.

Classification of Diseases, Adapted (ICDA-8; WHO 1968) by a trained nosologist. After its inception in the early 1980s, the National Death Index (NDI) was used to ascertain causes of death for deaths occurring in or after 1979, the first year of data in the NDI. The date of death and causes of death were entered into the Death table. If the worker was not found to be alive or deceased by SSA, other records systems used to determine vital status included state's Department of Motor Vehicles, Civil Service Retirement Board, Centers for Medicare and Medicaid Services and credit bureaus.

When a researcher was ready to put together files for analysis, the worker data specific for the study were assembled into Working files (WF) to facilitate the creation of the Analysis files (AF) used for the statistical analysis that resulted in a presentation or publication. The WF contained data that would be needed for the variables in the AF. However, the data that went into the WF could still contain errors which were corrected as they were detected. The radiation monitoring data which were kept in separate files were never cleaned prior to use in a study. The AF could contain variables that were derived from manipulation of data in the WF.

Comprehensive epidemiologic resource (CEDR) (1990-present)

In 1989 the DOE commissioned two independent but complimentary committees to review the epidemiologic research efforts within the Department (NRC 1990; SPEERA 1990). The recommendation to make the data collected under the DOE epidemiology research programs available to the broader research community to permit independent analysis and to provide a resource for training in research resulted in CEDR (NRC 1990; SPEERA 1990). The data from the three DOE epidemiology programs were consolidated into CEDR. To preserve worker privacy and confidentiality, the full name and SSN of each worker were replaced with the pseudo-ID, dates of birth and death were truncated to year and all other dates truncated to month and year. A unique pseud-ID was assigned to each worker. The AF and WF for each completed study were compiled and placed in CEDR. The structure and content of the data files varied widely based on the nature of the study. In order to be placed into CEDR, each file had to be accompanied by a data dictionary providing the name, definition, and all values for each variable in the file (https://apps.orau.gov/cedr/data-file-sets.aspx accessed 6 Sep 2018).

Usefulness of CEDR to the MPS

The overall goal of the MPS is to include all DOE nuclear workers. The near-term goal is to update the studies that have already been published from these cohorts. This approach furthers the investment that DOE has already made in studying the possible health effects of working in its nuclear facilities. Many of these studies are ripe for an update with the potential to add up to 25 additional years of follow up to the study. CEDR contains the AF and WF for most of these mortality studies with those studies that have

internal and external radiation monitoring data of primary interest. By focusing on these studies first, the time frame for completion of the MPS is dramatically reduced since the cohort is already defined and initial vital status follow up and death certificate retrieval have already been done.

Methods

A standard protocol is followed for updating previous cohort mortality studies. This protocol includes internal radiation analyses to determine disease risk per unit of dose for organ/tissues of specific interest for that cohort. The study of the Mallinckrodt Chemical Works uranium processing workers by Golden et al. (2019) included in this issue of this journal is a good example.

When the decision is made to bring a cohort into the MPS, the AF and WF are downloaded from CEDR (Figure 3). An inventory and review of the available CEDR data are done with particular attention given to the inclusion of women in previous studies; the last date of vital status and DC ascertainment; and the type of radiation data available for the site, its completeness and the extent to which it has been analyzed. In earlier DOE worker cohort studies, women were rarely included because of small numbers, generally lower radiation exposure levels and the difficulty in determining vital status and retrieving DCs. With greater emphasis on including women in the occupational epidemiologic studies, a review is done to decide whether to expand the cohort to include women. The decision is made based on the availability of data on women in the CEDR files and the number employed at the site. For most cohort studies that are in CEDR, radiation exposure was included as no more than annual film badge readings and annual response of 'yes/no' to 'ever monitored for internal radiation exposure'. In addition, the amount of time that has elapsed since the most recent publication of these studies is at least 10 years and the dosimetry methodology to calculate annual organ/tissue radiation doses from internal and external radiation monitoring results has advanced significantly in that time period. Therefore, the vital status and causes of death have to be updated, and the dosimetry calculations have to be done to produce the annual organ-specific doses for each worker. Since these three activities tend to take the longest time to complete, starting each of them as early as possible in the process expedites completion of the study. To accomplish the updates to vital status and dosimetry, the personal identifying information for each cohort member is required. With permission from DOE to use the identifiable information to update the study and approval of the study protocol by the Institutional Review Board, the pseudo-ID is replaced with the personal identifying information and complete dates.

Updating vital status and retrieving DCs for workers identified as deceased follow the procedure outlined in the article by Mumma et al. (2019) in this issue of the journal. Before the inception of the NDI, the practice of the DOE HMS was to code only the underlying cause of death and one cancer cause if it was found on the DC but was not the underlying cause, to the 8th revision of the ICD-A for all deaths prior to 1979. The current study protocol requires all causes of death to be coded to the ICD revision in effect at the time of death. The hard copy DCs are available for deaths prior to 1979. For deaths that occurred before 1969, the hard copy is pulled for all-cause coding to the ICD revision appropriate for the date of death by a nosologist trained in coding the 5th through the 7th revisions of the ICD.

An inventory of the personal radiation monitoring data available in the AF and WF drives what has to be done with respect to the data needed to produce the annual organ/tissue doses needed to the study. The most extreme case is the absence of any annual radiation monitoring data for the worker cohort. The methods described using this extreme case as the starting point for producing the annual organ/tissue doses. Concurrently with the records inventory, any documents describing the activities at the facility are collected. The site profiles, technical basis documents (TBD) and technical information bulletins (TIB) created by the Centers for Disease Control National Institute of Occupational Safety and Health Radiation Dose Reconstruction Program (NIOSH-DR) are a valuable source of information concerning the history of the site, the radiation monitoring practices and the availability of radiation monitoring data (https://www.cdc.gov/niosh/ocas/ocastbds.html accessed 6 Sep 2018). While the purpose of the MPS is different from the NIOSH-DR, particularly with respect to assumptions made to reconstruct doses, the content of these documents is a valuable source of historical information. Current and former employees knowledgeable about the radiation monitoring at the site, are identified. The results of the data inventory of CEDR data combined with the potential contacts and information collected about the facility are used to develop a specific plan to acquire the data needed to produce the annual organ-specific radiation doses for the study. The approach for the dosimetry is detailed in the forthcoming National Council on Radiation Protection and Measurements (NCRP) Report 178 (Bouville et al. 2015).

When the vital status follow-up and DC retrieval efforts are completed and the annual organ doses have been calculated, WF are produced containing the information needed to populate the variables in the AF which is used for the statistical analysis, manuscript and presentation development. Within a year of the first publication, the WF and AF will be added back to CEDR for use in future studies.

An example of the use of CEDR can be demonstrated with the worker cohort at the Los Alamos National Laboratory (LANL) which is the most recent study to be added to the MPS. Within CEDR there are 2 worker cohorts at LANL, the employees of LANL and the employees of the Zia Company (Zia) which is a principal subcontractor for LANL. Within CEDR, there are a number of paths to identify the site of interest. The approach that is the most inclusive is the following starting at the CEDR homepage: select Browse Data Sets > Analytic Data File Sets > Select a Site. Since this study is of LANL and Zia workers, a separate selection was made for each site. Another selection is LANL (including Zia), but the results returned are for a case-control study which is not of interest for the MPS since its focus is on updating

cohort mortality studies. The AF files for both the cohort study of females and of males at LANL and the AF for the 1992 cohort study for Zia were downloaded. The option of 'Working Data File Sets' was made to identify any files associated with these two sites. Brief descriptions of the contents of each data file are listed on the 'Data File Set Results' page. By clicking on the data file, the first 10 records of the file are displayed. Clicking on any variable name links to the page containing a description of the variable, its unit of measure and a link to the allowable codes for the variable (as applicable). No WF are available for Zia. The nine data files listed by selecting the 'Combined LANL and Zia Working files' were downloaded. These files were reviewed with special attention given to the end of follow-up, the number of women, the completeness of the data for each worker, and the type of personal radiation exposure data available. In parallel, the NIOSH-DR website was queried for site profiles, TBDs, and TIBs available for LANL and Zia. No entry was listed for Zia. A site profile containing six TBDs and two TIBs was downloaded for LANL. Each was reviewed for information pertinent to the occupational cohort study.

This study is currently in progress with the following decisions made and subsequent activities being carried out in parallel. Based on the evaluation of the collective material, the decision was made to combine the LANL and Zia populations into one study since all employees were employed on the LANL site. Women are included in the study. This decision was made based on the fact that a cohort of over 6000 women was already identified in a previous study with vital status follow up through at least 1981 (Wiggs 1987). Once this decision was made, the potential study cohort was created from the previous AFs for the LANL Female and Male cohort studies and the Zia cohort study (Wiggs et al. 1994). This study cohort file was used to create the file used for vital status follow up and DC retrieval. The vital status file contained anyone without a cause of death in the previous studies. The algorithm described by Mumma et al. (2019) is being executed. Current and former staff at LANL have been contacted to participate as subject matter experts in efforts to identify the location of files needed to update personal radiation exposure and to provide details about the radiation monitoring programs at LANL.

In addition to the use of subject matter experts from the site, autopsy data from the U.S Transuranium and Uranium Registry (USTUR) will be used to refine the brain dosimetry for alpha emitters through model validation. There is increased interest in the potential adverse effects of alpha emitters on the brain as surrogates for the exposures that astronauts will receive during space travel to Mars. The most relevant brain-specific data available for modeling brain kinetics from alpha emitters are USTUR autopsy data from Pu workers, many of whom worked at LANL. Post-mortem measurements of ^{239}Pu activity in the brain are being used to improve brain dosimetry by explicitly modeling brain kinetics to replace the current implicit approach of including brain as a fraction of 'other tissue'. These improved models will be used to calculate brain dose in the LANL study and is an example of how different DOE assets (like CEDR and USTUR) can be leveraged to improve study quality.

Discussion

The DOE has a long history of concern of health issues among its nuclear workers resulting from exposures received in its facilities. Its focus on epidemiologic studies of this workforce began in 1960 with the initial pilot studies and culminated with the assembling of the data files used in these epidemiologic studies into the on-line electronic data repository called CEDR. The inclusion of the DOE worker cohorts in the MPS would be impossible today without the data in CEDR. The efforts at the University of Pittsburgh prevented the destruction of essential occupational records essential for an epidemiologic study. The current difficulties and expense of retrieving DCs for deaths occurring prior to 1979 would increase many-fold the cost and time required to complete the studies. In addition, the success in retrieving these pre-1979 DCs might be low enough to jeopardize the results of the studies.

The data in CEDR provide a valuable resource for educators. Most conventional data sets used in the classroom have been 'cleaned' so that no errors exist and the decisions required to assemble the data for analysis have already been made. This deprives the student of getting practice with the messy data that exists in the 'real world'. Using the actual data from DOE facilities in the classroom provides the opportunity for the student to become familiar with issues that arise, and the decisions and assumptions that have to be made to assemble the data needed to do an epidemiologic study. The CEDR data are also a source of data for a thesis or dissertation. Several of the studies in CEDR were done as dissertations (Wiggs 1987; Dupree 1989).

The data in CEDR are the products of previous epidemiologic studies and contain the limitations of those studies. Given the overall goal of the MPS to investigate the relationship between health outcomes and radiation exposure, limitations related to the disease outcomes of interest and the exposures may affect the dose-response relationships identified. The standard methods used to update vital status and DC retrieval ameliorate issues with the disease outcomes. To date, vital status follow-up and DC retrieval for MPS cohorts exceed 95% which is considered good practice for a cohort study. Addressing issues with the exposure data are more difficult. Standardization of monitoring practices for radiation exposure across the DOE complex was minimal. Gaps in knowledge around these data can result in random and systematic misclassification of exposure. Random misclassification typically results in exposure estimates biased toward the null so that the resulting disease risk is overestimated. The effects of systematic misclassification are more difficult to determine and the effect on the disease risk can be in either direction. Knowledge of chemical exposures is even more limited than radiation monitoring but is important with respect to confounding in the disease-response relationship. The established practice for consideration of chemical exposures is a job-exposure matrix. A limited number of studies in CEDR have included such a matrix (Dupree et al. 1987; Kubale et al. 2008). Because of the level of effort required to develop and implement these matrices is labor intensive and

time-consuming, the inclusion of chemical exposures in the MPS studies will be limited.

Despite the numerous limitations described, CEDR serves as an excellent starting point for cohort and data identification so that efficiencies can be gained where resources are limited for extended the follow-up for radiation-exposed cohorts that are part of the MPS. One of the main tenants of the MPS is to build on past studies instead of starting from scratch. For instance, in the example presented in this paper for LANL, significant time and effort were saved by using the CEDR analytic files from the previous studies as the foundation of the cohort. This allows us to focus on updating the vital status, refining the dosimetry, and standardizing the dosimetric and analytic methods with those of other studies in the MPS. Coming full circle, as MPS cohorts are finalized, the updated data will be placed into CEDR to allow for pooling on a larger scale (i.e. international) and for use by researchers in the future for the next follow-up of these important populations. To date, small study populations have contributed to the ambiguous results from previous studies addressing the health effects of chronic low dose radiation exposure on human populations. Pooling data from multiple studies will increase statistical power and the likelihood of answering this important question. The standardization of methods used in the MPS, especially for vital status ascertainment and for calculation of organ doses, increases the successful pooling of the data to better refine risk estimates for the health effects of human exposure to radiation.

Disclosure statement

The authors report no conflicts of interest. This report was prepared as an account of work sponsored by the United States Government. Neither the United States Government nor the U.S. Department of Energy, nor any of their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe on privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, mark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement or recommendation, or favor by the U.S. Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the U.S. Government or any agency thereof.

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David Girardi is a scientific computer programmer at Oak Ridge Associated Universities. He has over 15 years programming experience working with epidemiologists and statisticians and has been working with the Million Person Study for over five years. He is a member of the Project Management Institute and has been a certified Project Management Professional (PMP) for over 5 years.

Ashley P. Golden is a biostatistician at Oak Ridge Associated Universities. She supports multiple research efforts requiring her expertise. She has been a collaborator on the MPS for over 5 years.

Phillip W. Wallace was Information Technology Manager, supporting epidemiological research. He semi-retired in 2016 after 32 years in this position, and contributed 10 years to the MPS. He was responsible for managing the databases at ORAU containing DOE rosters, work history information, radiation exposure data, and vital status. He was also one of the original developers of the DOE Comprehensive Epidemiologic Data Resource in 1990.

Joyce Phillips is a senior scientific programmer analyst at Oak Ridge Associated Universities. She serves as database administrator with over 30 years of experience providing technical support and maintaining data integrity and accuracy of the Center for Epidemiological Research historical data.

Donna L. Cragle is an occupational epidemiologist at Oak Ridge Associated Universities (ORAU). She has been studying the health effects of radiation and chemical exposures related to work in the nuclear industry for over 35 years. She is currently the Senior Vice President for Health, Energy, and Environment at ORAU.

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