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Cohort Profile - MSK Radiation Workers: a Feasibility Study to Establish a Deceased Worker Sub-Cohort as part of a Multicenter Medical Radiation Worker Component in the Million Person Study of Low-Dose Radiation Health Effects

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ABSTRACT

Background: The National Council on Radiation Protection and Measurements (NCRP) is coordinating an expansive epidemiologic effort entitled the Million Person Study of Low-Dose Radiation Health Effects (MPS). Medical workers constitute the largest occupational radiation exposed group whose doses are typically received gradually over time.

Methods: A unique opportunity exists to establish an Institutional Review Board/Privacy Board (IRB/PB) approved, retrospective feasibility sub-cohort of diseased Memorial Sloan Kettering Cancer Center (MSK) medical radiation workers to reconstruct occupational/work history, estimate organ-specific radiation absorbed doses, and review existing publicly available records for mortality from cancer (including leukemia) and other diseases. Special emphasis will be placed on dose reconstruction approaches as a means to provide valid organ dose estimates that are as accurate and precise as possible based on the available data, and to allow proper evaluation of accompanying uncertainties. Such a study that includes validated dose measurements and information on radiation exposure conditions would significantly reduce dose uncertainties and provided greatly improved information on chronic low-dose risks.

Results: The feasibility sub-cohort will include deceased radiation workers from MSK who worked during the nearly seventy-year timeframe from 1946 through 2010 and were provided individual personal radiation dosimetry monitors. A feasibility assessment focused on obtaining

records for about 25-30,000 workers, with over 124,000 annual doses, including personnel/work histories, specific dosimetry data, and appropriate information for epidemiologic mortality tracing will be conducted. MSK radiation dosimetry measurements have followed stringent protocols complying with strict worker protection standards in order to provide accurate dose information for radiation workers that include detailed records of work practices (including specific task exposure conditions, radiation type, energy, geometry, personal protective equipment usage, badge position, and missed doses), as well as recorded measurements. These dose measurements have been ascertained through a variety of techniques that have evolved over the years, from film badges to thermoluminescent dosimetry technology to optically stimulated luminescent methodologies. It is expected that individual total doses for the sub-cohort will have a broad range from <10 mSv to >=1000 mSv.

Conclusions: MSK has pioneered the use of novel radiation diagnostic and therapeutic approaches over time (including initial work with x-rays, radium and radon), with workplace safety in mind, resulting in a variety of radiation worker exposure scenarios. The results of this feasibility sub-cohort of deceased radiation workers, and associated lessons learned may potentially be applied to an expanded multicenter study of about 170,000 medical radiation worker component of the MPS.

Introduction

Previous attempts to estimate cancer and non-cancer risk from radiation exposures at low doses (<100mGy) and low dose rates (<5mGy per hour) have significant uncertainties, but have suggested that risks following low-dose rates may be as harmful as those reported among Japanese atomic-bomb survivors. Even today, 70 years after the exposure, 18,443 atomic-bomb survivors exposed to >100mSv form the basis of radiation protection standards (NRC 2006; Cardis 2007; ICRP 2007; UNSCEAR 2008; Jacob et al. 2009; Wakeford 2005; Dauer 2011; NCRP 2018a) and scientific and medical committees grapple over how best to estimate and apply a "dose and dose rate effectiveness factor" (ICRP 2005; Tubiana et al. 2006; ICRP 2007; Tenforde and Schauer 2008; NCRP 2018a) to scale the risks to situations involving chronic exposures relevant to occupational, environmental, and medical imaging circumstances.

The National Council on Radiation Protection and Measurements (NCRP) is coordinating an expansive epidemiologic effort entitled the Million Person Study of Low- Dose Radiation Health Effects (MPS) (Boice 2012a; Bouville et al. 2015; NCRP 2018b). The primary aim of the MPS is to provide scientifically valid information and improve precision on the estimated level of radiation risk when exposures are received gradually over time, as opposed to the acute exposure of the Japanese atomic-bomb survivors. The primary health outcome of interest for the MPS is cancer mortality, but other causes of death such as cardiovascular disease and cerebrovascular disease will also be evaluated. The validity of the MPS is a function of the accuracy of the organ dose estimates (i.e., the absorbed dose averaged over all parts of an organ or tissue) and their accompanying uncertainties. Thus, the focus is on providing the best estimate of organ dose and uncertainty for each individual, and to (when possible) characterize shared uncertainties that affect groups of individuals within the various cohorts considered. The study populations include atomic veterans, Department of Energy workers, nuclear power plant workers, industrial radiographers, and medical radiation workers.

Memorial Sloan Kettering Cancer Center (MSK) consisting of Memorial Hospital (MH) and the Sloan Kettering Institute (SKI) laboratories, has a unique history with regard to the use of radiation for the diagnostic and therapeutic treatment of cancer and allied diseases. The initial New York Cancer Hospital (NYCH) was founded in 1884, barely a decade before the seminal burst of discoveries in radiation. Wilhelm Roentgen discovers "X-Rays" in 1895 and a week later makes his famous first X-ray images of the hand of Mrs. Roentgen (Anna Bertha Ludwig) wearing her wedding ring (Pietzch 2018). Henri Becquerel subsequently discovered "radioactivity" and radioactive materials in 1896 and this was quickly followed by the discovery of "polonium" and "radium" by the Curies (Nobel 2018). Immediate attention is given to the application of these rays and materials to the healing arts. Research and use began almost immediately across the world, even in New York where Thomas Edison demonstrated fluoroscopes in 1896 (King 2012). As early as 1902, the NYCH employed X-Rays and X-ray therapies, practices that continue through the present. Also, as early as 1902, several adverse biological effects began to be identified in some medical radiation workers, both short-term (e.g., reddening of the skin, dermatitis, skin ulceration, epilation, eye irritation) and longer-term (e.g., skin cancers, cataracts, and other cancers) (Linet et al. 2010).

Radium was incredibly scarce in the early years of the 20th century, especially in the United States. In 1913, with help from the US government, Dr. James Douglas, a scientist and mining engineer, formed the National Radium Institute, significantly increasing the amount of radium available. In 1917, Dr. Douglas gave his entire share – worth about $300,000 at the time

– to Memorial Hospital (the new name for the NYCH), with a stipulation that radiation would be studied and used to treat cancer (Totonoz 2016a; 2016b).

At MH, Giocchino Failla headed up the development of radium to be safely used for treatment, either as a teletherapy (packing a radium source in a shielded lead box for protection along with an opening for treatment), or as implanted needles of radium or later radium "emanations" (radon gas) as some of the earliest forms of brachytherapy. Failla, who received his PhD with Mme. Curie in Paris, developed methods for radium use in treatment and constructed a semi-automatic radon collection system to safety extract and package radon gas in glass tubing or gold needles. By 1926, MH owned and utilized more radium than anywhere else in the world, about one-third of the world's supply at the time (Totonoz 2016a; 2016b).

One of Failla's major professional accomplishments included those in radiation protection, particularly for the physicians and technologists who handled radium. Over long periods of time, he made careful observations of the changes in their skin and nails and convinced himself that inexperienced and careless individuals exposed themselves the most. Dr. Edith Quimby, Failla's assistant, was concerned with radiation protection of patients and staff. She developed standard dosing tables for safe and effective radiation treatment (Quimby 1934). For staff exposures, although radiologists had previously used either a "reddening of the skin" or X-ray film to estimate radiation exposure, by 1926, Failla and Quimby were the first to start a full-scale film-badge program using dental film with a filter to distinguish exposure to gamma or beta radiation (Quimby 1926). They employed the use of standard 'dose' films for comparison and later developed the use of densitometers for reading badges.

Although some radioactive isotopes were able to be synthesized prior to the war using cyclotrons (e.g., ^{130}I and ^{131}I in small amounts), after World War II, it became possible to create large amounts of man-made radioactive elements in nuclear reactors. Such development was enhanced beginning in 1953 with the "Atoms-for-Peace" program (Eisenhower 1953). These new isotopes (e.g., ^{32}P, ^{60}Co, ^{137}Cs, ^{125}I, ^{103}Pd, and many others) were much safer to handle and administer than radium or radon seeds and were employed at MSK for therapeutic purposes. In addition, a revolution in imaging and treating thyroid cancer was enabled by the more general availability of ^{131}I.

Later, with collaboration of the US Department of Energy and National Laboratories, a cyclotron (affectionately known as "Betsy"), one of the earliest hospital-based cyclotrons in the world and the first in the country, was installed in the SKI laboratory building in order to enable safe research and development and production of other radionuclides for imaging and therapy. Subsequent cyclotrons were installed, including a dual-beam instrument enabling both liquid and solid targets, as well as the most recent Radiochemistry and Cyclotron Facility which routinely produces positron-emitting radionuclides and develops and performs organic synthesis of both single-photon-emitting as well as positron-emitting radiotracers. These facilities were heavily supported with medical health physics engineering, design, and operational assistance to incorporate safety features while facilitating radionuclide production, research, and patient care.

The unique history of radiation use at MSK as well as the associated plethora of occupational exposure scenarios and data collection, suggests that establishing a feasibility sub-cohort of deceased radiation workers from MSK could help inform a larger multicenter medical radiation worker cohort as part of the MPS.

Key Considerations in Establishing the Feasibility for the MSK Sub-Cohort of Deceased Radiation Workers

Selection of the MSK Sub-Cohort

Across the nation and all occupations, medical radiation workers represent a large fraction of radiation-exposed workers, with ~2.5 million monitored workers in 2006 (NCRP 2009a). Historically, the average annual occupational effective dose estimates were higher in the past and have trended downward for the medical radiation worker populations (Linet et al. 2010). Most present day medical radiation workers generally experience very low radiation exposures, almost exclusively from external irradiation. Those individuals who currently perform certain fluoroscopically guided interventional procedures and potentially those who prepare or administer radionuclides for nuclear-medicine procedures are an exception to this generalization (Dauer 2014).

The MPS includes a large medical radiation worker cohort initially assembled using very preliminary estimates of lifetime doses contained in a database supplied by a commercial provider of personal monitoring services (Landauer Inc., Glenwood, IL). Workers were selected to be included in the MPS medical radiation worker cohort so as to ensure complete coverage of the lifetime dose range, and considering the costs associated with epidemiological tracing. To that end, all workers having lifetime doses equal to or greater than 50 mSv (based on personal dose equivalent, $H_P(10)$) were automatically selected. Adding to this group was a random selection of 50% of workers with lifetime doses between 10 and 50 mSv and 2% of those workers with a lifetime dose less than 10 mSv. The initial identified medical radiation worker cohort study population totals 168,601 individuals selected from an eligible population of 1.71 million medical workers. However, there are large uncertainties regarding the lifetime dose estimates from such national databases and the dose reconstruction process as the derivation of organ doses from such monitoring data poses difficult problems for the medical worker cohort because of, among other factors:

- difficulties assigning workers to a specific exposure scenario;
- often extreme inhomogeneity of exposure over the body of personnel for any given procedure type;
- differing degrees and methods of radiation protection;
- inconsistent wearing of dosimeters by personnel (i.e., at times choosing not to wear dosimeters in order to avoid investigations) (NCRP 2010), combined with poor information, as well as high variability, on the workloads of physicians and technologists (i.e., the number of procedures of a given type conducted monthly or annually); and
- changing technology and medical procedure protocols.

Recognizing the need for more specific guidance on these challenges, NCRP recently chartered Scientific Committee 6-11 to provide dosimetry guidance for medical workers with a focus on lung dose reconstruction (Yoder et al. 2018).

Typically, local medical health physics or radiation safety sections at hospitals collect and maintain additional data on medical radiation workers including: job titles (i.e., exposure scenario), average radiation energies, use of protective aprons, dosimeter placement, and minimal detectable doses over time. A deceased medical radiation worker feasibility sub-cohort study that includes validated dose measurements and information on radiation exposure conditions would significantly reduce dose uncertainties and provided greatly improved information on chronic low-dose risks.

The feasibility sub-cohort will include deceased radiation workers from MSK who worked during the nearly seventy-year timeframe from 1946 through 2010 and were provided individual personal radiation dosimetry monitors. A feasibility assessment focused on obtaining records for about 25-30,000 workers, with over 124,000 annual doses, including personnel/work histories, specific dosimetry data, and appropriate information for epidemiologic mortality tracing will be conducted.

Initial epidemiology considerations

Although leukemia and/or solid cancers have been observed among pioneering radiologists and early radiation technologists (Berrington et al. 2001; March 1944; Lewis 1963; Matanoski et al. 1975; Smith and Doll 1981; Wang et al. 1990), more recent studies of medical x-ray technologists have been less clear in revealing excess cancers (Doody et al. 1998; Jablon and Miller 1978; Mohan et al. 2003; Yoshinaga et al. 1999; Yoshinaga et al. 2004). However, the absence of reliable dosimetry in these studies has limited risk interpretation (Bhatti et al. 2007; Simon et al. 2006; Simon et al. 2014). In contrast, the MPS, including a multicenter cohort of medical radiation workers, has excellent individualized annual dosimetry measurements, and linkages to worker dosimetry from other occupational exposures received by workers as they may have moved from workplace to workplace over their careers, to ensure as complete as possible information on lifetime doses for individuals in the study. Further, a specific MSK sub-cohort can provide validated dose measurements and information on radiation exposure conditions could significantly reduce dose uncertainties and provide greatly improved information on potential risks.

As a pilot feasibility epidemiologic study, the primary aim is to establish the MSK Medical Radiation Worker Cohort of deceased radiation exposed workers in order to: assess the feasibility of collecting complete dosimetry and personnel records from about 1946-2016; assess the feasibility of retrieving personnel/work histories, dosimetry data, and personal identifiers suitable for tracing to determine the earliest acceptable date to include; and finally to assess the feasibility of obtaining outcome and overall career doses (e.g., mortality tracing; matching Social Security Number [SSN] for vital status; linking national dosimetry databases for career dose determination). Adverse outcomes will be correlated initially with cumulative whole-body or appropriate organ radiation dose. The secondary aim is to provide dosimetric uncertainty considerations for a larger multicenter medical radiation worker cohort included in the MPS using the more detailed and complete MSK records to ascertain inaccuracies in the MPS dosimetry databases. In addition, appropriate modeling parameters will be suggested for assessing organ doses from dosimetry badge results based on specific radiation worker tasks over time.

Sources of vital status and cause of death will be the Social Security Master Death File and other Social Security Administration (SSA) vital status files, Pension Benefit Information files, Comserv (a computer services firm specializing in mortality searches), state death indexes (e.g., New York) and the National Death Index, LexisNexis search, MicroBilt, credit bureaus and Comserv a computer services firm specializing in locating persons. In a few instances for deaths occurring prior to 1979 when the National Death Index began, death certificates would be requested from states and cause of death coded by a trained nosologist. For linkage with the SSA Master Death File of 83 million deaths, large-scale probabilistic matching programs will be applied to account for the possibility of potential errors in names, dates of birth or SSN.

It is anticipated that the employee data will be more readily available for deceased employees who were employed in recent years (1977-2010) and the employee data collected prior to 1977 will be more difficult to retrieve. We will determine completeness of the available correctly recorded annualized dosimeter information, overall career doses, and cause of death data. As "proof of principle" we will examine mortality from leukemia associated with cumulative whole-body radiation dose and only generate data in aggregate format.

Source of dosimetry information

The effort and resources required for dose reconstruction depend largely on the availability and form of the dosimetry records. Such records exist at specific institutions under various filing and archival systems. Throughout the study period, MSK personal radiation dosimetry measurements have followed stringent regulatory (e.g. federal, state, and local) requirements and protocols to provide accurate dose information for radiation workers that include detailed records of work practices (including specific task exposure conditions, radiation type, energy, geometry, personal protective gear usage, badge position, and missed doses), as well as specific recorded measurements. Existing data on the workers from about 1946-1976 is captured on paper/microfilm logbook and personnel records, while data on workers from 1976-2010 is primarily captured in electronic dose measurements and personnel records at MSK. The data includes information such as date of birth, full job history at MSK, SSN, and series code (indicating type of radiation, exposure conditions, protection, and badge position).

Personal dosimetry considerations

The MSK radiation dosimetry measurements have followed stringent protocols to provide accurate dose information for radiation workers that include detailed records of work practices (including specific task exposure conditions, radiation type, energy, geometry, personal protective gear usage, badge position, missed dose), plus recorded measurements.

Personal monitoring and dose measurements have been ascertained through a variety of techniques that have evolved over the years, from film badges to thermoluminescent dosimetry technology to optically stimulated luminescent methodologies. The MSK Department of Medical Physics has maintained several index card and log-book data sets that could be utilized to reconstruct annual worker doses from about 1946-1977. Pilot work with these paper records demonstrated the likelihood of >7,000 usable annual entries from 1967-1976 alone, however the completeness of the data is uncertain. Since 1977, the MSK Department of Medical Physics has maintained an electronic database of >20,000 individual medical radiation workers with >124,000 individual annual entries. The records include available personal identifiers, employment data (specific work function in the hospital, dosimetry inception, termination dates, etc.), and most importantly dose data (annual, cumulative, and previous whole body-deep dose).

A dosimetry service provider managed radiation dosimetry services for MSK since about 1946 and computerized the initial measurement files as of 1977. It is expected that individual total career doses for the sub-cohort will have a broad range from about >10mSv to ≥1000mSv. Further modeling can be developed to assess organ doses from dosimeter data by accounting for different average radiation energies, use of protective aprons, dosimeter placement, and minimal detectable doses over time (Gilbert et al. 1996; Simon et al. 2006; Simon et al. 2014; Bouville et al. 2015; Yoder et al. 2018). In addition, an assessment of natural background radiation will be made for the MSK site.

Radiation exposure scenarios for MSK deceased medical radiation workers

Radiation worker exposure scenarios include: radiology x-ray, radiology fluoroscopy, nuclear medicine, radiation oncology, radiation protection, radiochemistry, medical physicists, research laboratories, inpatient nursing, brachytherapy, imaging and localization procedures, and others. The source of employee information is dependent on the year in which the data were collected by the MSK Human Resources Department, as various databases have been used over the years to collect employee information, including scanned paper archives, early databases, and present information systems.

MSK workers were assigned each year an occupational code that often reflected a department or specialty within the hospital or laboratory and this code was updated for each worker if their job or area changed. These codes may be useful for understanding the radiation exposure scenarios to which workers in that code were exposed and may be useful for aggregate data analyses.

Dose reconstruction methods

The specifics of practical dose reconstruction and uncertainty analysis discussions for the epidemiologic studies that will be included in the MPS are specific applications of the previous guidance provided in NCRP Reports Nos. 158, 163, 164, and 171 (NCRP 2007; 2009b; 2009c; 2012). More recently, the NCRP has provided focused guidance on the derivation of organ doses and their uncertainty in NCRP Report No. 178, Deriving Organ Doses and their Uncertainty for

Epidemiologic Studies with a focus on the One Million U.S. Workers and Veterans Study of Low-Dose Radiation Health Effects (NCRP 2018b). The dose reconstruction and uncertainty methods of these guidance documents will be employed for the MSK deceased sub-cohort.

The conditions of exposure are critical for the dose reconstruction process. In general, the approach for determining annual organ doses for individuals in the MSK deceased sub-cohort will be to normalize available annual dose values (from historical personal monitoring and dosimetry data) to $H_P(10)$, and then to convert these to mean annual organ doses, D_T. With D_T and $H_P(10)$ each being related to common fundamental dosimetry quantities, the NCRP (NCRP, 2018b) has generated tables of conversion factors that directly relate $H_P(10)$ to D_T for the various irradiation geometries, as well as methodologies for initially normalizing early exposure data to $H_P(10)$. In addition, more specific guidance on dosimetry (including considerations for the use of protective aprons and/or thyroid shields and monitoring practices) and associated uncertainties is addressed by the NCRP (NCRP, 2018b) (e.g., 2D Monte Carlo approaches, probability distribution of estimated doses, etc.) and is being specifically developed for the multicenter medical radiation worker cohort of the MPS (Yoder et al. 2018) and will be applied to this feasibility study.

Conclusions

MSK has been at the forefront of novel radiation diagnostic and therapeutic approaches (including initial work with x-rays, radium and radon), and radiation worker exposure scenarios include: radiology x-ray, radiology fluoroscopy, nuclear medicine, radiation oncology, radiation protection, radiochemistry, medical physicists, research laboratories, inpatient nursing, brachytherapy, imaging and localization procedures, and others. The results of this feasibility sub-cohort of deceased workers, and associated lessons learned may potentially be applied to an expanded multicenter study of about 170,000 medical radiation worker component of the MPS.

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Disclosure statement

The authors declare no personal conflicts of interest. The views expressed in this paper represent collective opinions of the authors and are not necessarily those of their professional affiliations.

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Michael Bellamy is a Staff Scientist at the Oak Ridge National Laboratory (ORNL). His research is currently concentrated on the development of accurate dosimetric assessements of organ and effective dose for both occupational and clinically exposed populations, as well as understanding fundamental micro and macro effects of radiation on the body.

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Craig Yoder directed Landauer's technical activities relating to radiation dosimetry, particularly for applications in radiation protection for over 30 years. An internationally known expert in radiation monitoring, he led the development of optically stimulated luminescence. He is a member of NCRP and former President of the Council on Ionizing Radiation Measurements and Standards.

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Xiaolin Liang is a Senior Program Analyst at Memorial Sloan Kettering Cancer Center in the Department of Epidemiology & Biostatistics. Her primary collaboration is the Women's Environmental, Cancer, and Radiation Epidemiology Study group and has served as an informatics specialist at the coordinating center of the study since its inception.

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