

PII: S0959-8049(97)00016-6

The Use of National Registers of Radiation Exposure in Occupational Radiation Risk Assessment

J.M. Zielinski, D. Krewski, J.P. Ashmore and E. Cardis A

Environmental Health Directorate, Health Protection Branch, Health and Welfare Canada, Ottawa, Ontario, Canada K1A 0L2; Department of Mathematics & Statistics, Carleton University, Ottawa, Ontario, Canada K1S 5B6; Bureau of Radiation and Medical Devices, Environmental Health Directorate, Health Protection Branch, Health and Welfare Canada, Ottawa, Ontario, Canada K1A 0L2; and Office of the Director, International Agency for Research on Cancer, Lyon, France

RADIATION CARCINOGENESIS

KNOWLEDGE OF human cancer risks due to exposure to ionising radiation is based in large part on studies of atomic bomb survivors [1]. Because of the short-term high exposures experienced by atomic bomb survivors, there are difficulties in extrapolation of these results to long-term low-level exposures experienced by workers exposed to radiation by virtue of their occupation and by members of the general public who may be exposed to low levels of radiation from environmental, medical and other sources. Differences in cancer-incidence rates between Japan and other countries also raise questions about the general applicability of cancer-risk estimates derived from the follow-up of atomic bomb survivors to other populations.

Early occupational studies have focused on medical radiologists and radiological technicians [2–4], dial painters [5, 6], and underground miners [7–9]. Early studies of radiologists revealed excess mortality from leukaemia, multiple myeloma, and cancers of the pancreas, lung and skin. Radium dial painters early in the century were found to have excess osteocarcinomas and carcinomas of the paranasal sinus and mastoid. Underground miners exposed to the radioactive decay products of radon gas experienced elevated lung cancer rates.

The studies that provide the most information for quantifying the effect of exposure to low doses are those of nuclear industry workers. Nuclear workers represent relatively large cohorts exposed to low levels of radiation under well-described circumstances and whose doses are carefully monitored and recorded for regulatory control [10, 11]. Recently, in an attempt to increase statistical power, combined analyses of data from several cohorts in the U.S.A. [12] and in the U.K. [13] have recently been carried out. Because of differences in the study populations, combined analyses of data from different sources need to be con-

ducted carefully [14]. The International Agency for Research on Cancer (IARC) is currently conducting a combined analysis of nuclear workers in several countries [15].

CENTRALISED DOSE REGISTERS

For the purpose of this report, a centralised dose register is a repository of data on occupational radiation exposures maintained at a nations level. In principle, this allows worker exposure histories to be maintained in a single location as they change jobs. Registers contain cumulative radiation records that can be used for a variety of purposes including regulatory control of occupational radiation exposure and epidemiological studies of occupational radiation carcinogenesis.

The development of a comprehensive centralised radiation dose register is not a trivial undertaking [16]. Consideration needs to be given to the type and source of radiation to which workers are exposed, and to the type of dosimeters or monitoring systems required for each radiation type. Radiation exposures may be evaluated using personal dosimeters, bioassay or area monitoring.

The frequency with which data are submitted to the centralised register may vary with radiation type and employer. In the past, data have been provided to the registers in the form of written reports. If data are to be submitted using electronic media (floppy disks or direct transmission), highly standardised reporting formats will need to be developed.

Dosimeters used to determine occupational radiation exposures may be read in local laboratories or at a central location possibly affiliated with the centralised dose register. If either the same or different dosimeters are read in different laboratories, the compatibility of dose information obtained from different sources needs to be established.

THE WORKSHOP

In order to provide a basis for discussion of the issues involved in the use of centralised dose registers for epidemiological purposes, a number of the workshop participants were asked to prepare background papers based on their experience in this area. The initial paper by Professor A. Miller (Canada) provides an overview of the epidemiological literature on radiation cancer risks [17]. The remaining papers describe experiences in different countries in the development and use of centralised dose registers for epidemiological purposes. On the basis of these papers and subsequent discussions, the following recommendations were proposed.

RECOMMENDATIONS

Following the presentation of the background papers, participants at the meeting discussed ways of improving the use of registers and their data in epidemiological research. Consensus was reached on the recommendations given below. Each recommendation is followed by a brief summary of its underlying rationale and relevant points raised in the discussion.

The first eight recommendations deal with the design and content of radiation dose registers. The last recommendation calls for a legislative basis for centralised dose registers. Although this recommendation impacts upon regulatory policy, the participants felt it was important that a firm basis exists for development, implementation and maintenance of centralised registers.

Exposure data for different types of radiation should be recorded separately and it should include all basic data collected

This is necessary to ensure understanding of the basic dosimetric quantities recorded over time, taking into account the type of dosimeter, quality factors, calibration methods and dosimetric models in use at different times, thus ensuring the comparability of available dose estimates over time across facilities.

Inaccuracies in the dose measurements themselves should not be overlooked. The dosimeter is only monitoring a fraction of the surface area of the body and individuals do not always wear their dosimeters in the appropriate place.

There was considerable discussion on whether or not the data in the register should include information on confounding factors such as exposure to tobacco smoke. It was felt that a simple indicator of whether or not the individual had ever been a regular smoker would be useful. Most of the participants felt that this information could be readily incorporated into their registers. However, some concern was expressed over the accuracy of information obtained. For example, in a study of Ontario miners, union representatives expressed concerns that providing information on smoking may jeopardise potential compensation claims.

Other possible confounders discussed were background and medical radiation. In Canada and the U.K., corrections are made for background radioactivity. It was pointed out that collective doses from medical radiation are several times higher in Japan than they are in the U.K. In any international pooling of data, such confounders would have to be considered.

Cumulative annual doses should be retained whenever possible

There was an agreement that annual dose information should be retained whenever possible. Although annual doses will be adequate for most studies, a finer breakdown may be required in some studies. This was the case in a recent study conducted by Ontario Cancer Treatment and Research Foundation in collaboration with National Dose Registry of childhood leukaemia and parental exposures [18]. Discrete dosimeter records and three-month summaries were necessary to identify doses received by parents in the period prior to conception. A previous study by Gardner and colleagues [19] was criticised on the grounds that exposures occurring during the period six months prior to conception were estimated by amortisation of annual exposures.

Internal doses should be recorded

Internal doses of radionuclides such as caesium and tritium should be included in centralised dose registers. At a minimum, the date of measurement, the radionuclide and an estimate of intake should be provided. Although annual doses to specific organs are desirable for epidemiological purposes, demonstrations of legal compliance for internal dose are usually confined either to 'effective whole body dose' integrated over 50 years form the current year's intake of radioactivity, or to the fraction of permitted intakes for all nuclides in that year. Owing to the heterogeneous distribution of dose in the body from ingested radioactivity, none of these quantities permits useful calculations or organ dose. However, it should be possible for dosimetry services concerned to express their internal dosimetry information in terms of the quantity of specified materials (or nuclides) taken into the body for each year of exposure. This information is succinct, simple to record (albeit at the cost of significant computational effort), and sufficient to derive annual organ doses.

Accidental exposures should be recorded

Inclusion of accidental radiation exposures will ensure that coverage of exposure from all sources is as complete as possible. Since short-term accidental exposures may be relatively high, this information could be useful in assessing dose rate effects. At a minimum the date of measurement, type of radiation and an estimate of the dose should be recorded.

Multiple personal identifiers should be recorded

Multiple identifiers are necessary for studies involving computerised record linkage as well as ensuring the completeness of the records. Redundancy in the identifiers is highly recommended, and alternative identifiers such as names at birth or maiden names should be retained wherever possible. Suggested identifiers for centralised dose registers include: surname, first given names, previous surnames, second given name, sex, birth date, birth place, birth name, mother's maiden name, and father's given name. The use of such personal information should comply with any confidentiality and legal restraints in place in different countries.

If possible, a unique identifier should be used for subjects included in a centralised dose registry. The use of a national identification number can be very useful for linking records for research purposes. In Canada, it was necessary to obtain special permission to use the Social Insurance Number for the maintenance of radiation dose records.

Even if a unique identifier is available in the register, the use of additional personal identifiers is recommended. The unique identifier cannot be used to link registry data to other databases where that identifier is absent. In some cases, the use of unique identifiers may be restricted for confidentiality reasons.

Centralised dose registers should be designed to meet both regulatory monitoring and epidemiological needs

In most countries where the development of national dose registers was motivated by regulatory needs, a notable exception is the NRRW in the U.K., which was originally set up for epidemiological purposes. The participants felt that it should be possible to satisfy both regulatory and research needs using the same register.

It is not advisable to have two sets of records, one for each purpose for reasons of credibility and data integrity. A possible compromise would be to maintain a primary set of records for regulatory purposes, to be supplemented with additional information required in epidemiological investigations.

There was some discussion on the extent of coverage by central dose registers. In some countries all monitored workers are included, whereas in others coverage is limited to nuclear workers. The extent of coverage depends upon the purpose of the registry and the regulatory environment in which it must operate.

Indicators of socioeconomic status should be included

It was suggested that the occupational category could be used as a measure of a socioeconomic status, since most registers provide information on occupation. In the U.K., job categories are used for statistical purposes by regulatory authorities. Changes in the categorisation scheme by the regulatory bodies can cause difficulties in research studies.

IARC is considering job classification schemes for use in their study on nuclear workers. This is a difficult issue, requiring the development of an international classification based on disparate classifications in different countries.

The National Dose Registry of Canada has currently 80 different job categories. This is too fine a breakdown for most studies, and attempts are being made to collapse these into a smaller number of useful categories. From an epidemiological standpoint, broad job categories may not be useful, and could be highly correlated with radiation exposure.

Registers must be designed to be fully flexible

Registers must be able to adapt to new changes in regulations, types of dosimeters, dose models, etc. Data extraction and manipulation must be straightforward and economical so that the register can meet the wide variety of demands placed upon it.

There should be a legislative basis for a national register of occupational radiation exposure records

This legislation should require monitoring organisations to send data to the Registry, protect the confidentiality of the data, and ensure that it is accessible for research purposes. Depending upon the country, this legislation may also include specific regulatory requirements.

In the U.K., individuals have the right to refuse to participate in the NRRW, but experiences have shown that few people actually do. In some countries, such as Germany, information on cause of death is considered confidential. In such cases, individuals need to be contacted to secure permission to access death records.

CONCLUSIONS

This article reports on the current status of radiation dose registers in Canada, Japan, the United Kingdom and Sweden. Finland, Hungary and Switzerland also operate centralised dose registers. Over one million nuclear industry workers occupationally exposed to radiation are included in current registers.

Most of the centralised radiation exposure registers have been established to monitor worker exposure to ensure that occupational doses remain within established regulatory limits. However, once a centralised dose register is established, it affords a unique opportunity for epidemiological investigation of the health effects (including cancer) of ionising radiation.

Ideally, a centralised radiation dose register should include: annual dose estimates for each individual in the register, including estimates of internal doses, recorded by radiation type and accompanied by all basic data on the quantity recorded and the assumptions made for estimation of the doses; cumulative annual doses; and multiple personal identifiers. Sufficient personal identifiers should be included to permit linkage of radiation exposure data in the registry with data on health status, thereby facilitating the conduct of epidemiological investigations.

The first large-scale epidemiological study based on a centralised radiation dose register was reported by Kendall and colleagues [13]. This retrospective cohort mortality has served to strengthen the existing database on the cancer risks associated with occupational exposure to ionising radiation. A similar analysis based on the National Dose Registry of Canada will be completed this year.

Even though these studies involved large numbers of workers, most have been exposed to relatively small doses of radiation, and most of the exposed population is still alive. Individually, these studies may not be able to estimate precisely the risk associated with low doses of ionising radiation. In an attempt to overcome these difficulties, IARC is conducting combined analysis of data from Canada, the U.K. and the U.S.A. IARC has also started an international collaborative study of nuclear workers, which is being carried out simultaneously in 11 countries using a common core study protocol [15]. In the future, the co-ordinated assembly of additional data on occupational radiation exposures through central dose registers will be of great value in clarifying the extent of cancer risk associated with occupational radiation exposure.

- Shimizu Y, Kalo H, Schull WJ. Studies of the mortality of Abomb survivors 9. Mortality 1950–1985: Part 2, cancer mortality based on the recently revised doses. *Radiat Res* 1990, 121, 120–141.
- Matanoski GM, Seltser R, Sartwell PE, Diamond EL, Elliot EA. The current mortality rates of radiologists and other physician specialists: Specific causes of death. Am J Epidemiol 1975, 101, 199–210.
- Matanoski GM, Sartwell PE, Elliot EA, Tonascia J, Sternberg A. Cancer risk in radiologists and radiation workers. In Boice JD Jr, Fraumeni JF Jr, eds. Radiation Carcinogenesis: Epidemiology and Biological Significance. New York, Raven Press, 1984, 83–96.
- Smith PG, Doll R. Mortality from cancer and all causes among British radiologists. Br J Radiol 1981, 54, 187–194.
- Rowland RE, Lucas HF Jr. Radium-dial workers. In Boice JD Jr, Fraumeni JF Jr, eds. Radiation Carcinogenesis: Epidemiology

- and Biological Significance. New York, Raven Press, 1984, 231-240
- Rundo J, Keane AT, Lucas HF, et al. Current (1984) status of the study of Ra-226 and Ra-228 in humans at the Center of Human Radiobiology. In Gossner W, ed. The Radiobiology of Radium and Thorotrast. Munich, Germany, Urban and Schwarzenberg, 1986, 14-21.
- Morrison HI, Semenciw RM, Mao Y, Wigle DT. Cancer mortality among a group of flourspar miners exposed to radon progeny. Am J Epidemiol 1988, 128, 1266–1275.
- Whittemore AS, McMillan A. Lung cancer mortality among U.S. uranium miners: A reappraisal. J Natl Cancer Inst 1983, 71, 489-499.
- Kusiak RA, Springer JS, Ritchie AC, Muller J. Lung cancer mortality in Ontario gold miners: Possible etiological factors. Br J Ind Med 1991, 48, 808–817.
- Kneale GW, Mancuso TF, Stewart AM. Identification of occupational mortality risks of Hanford workers. Br J Ind Med 1984, 41, 6-8.
- 11. Checkoway H, Mathew RM, Shy CM, et al. Radiation, work experience, and cause specific mortality among workers at an energy research laboratory. Br J Ind Med 1985, 42, 525-533.
- Gilbert ES, Fry SA, Wiggs LD, et al. Analyses of combined mortality data on workers at the Hanford Site, Oak Ridge National Laboratory, and Rocky Flat Nuclear Weapon Plant. Radiat Res 1989, 120, 19–35.
- Kendall GM, Muirhead CR, MacGibbon BH, et al. Mortality and occupational exposure to radiation: First analysis of the National Registry for Radiation Workers. Br Med J 1992, 304, 220-225.
- Peto J. Meta-analysis of epidemiological studies. In Vainio H, Magee PN, McGregor DB, McMicheal AJ, eds. Mechanisms of

- Carcinogenesis in Risk Identification. Lyon, IARC, 1982, 571-577
- 15. Cardis E, Gilbert ES, Carpenter L, *et al.* Effects of low doses and low dose rates of external ionising radiation: Cancer mortality among nuclear industry workers in three countries. *Radiat Res* 1995, **142**, 117–132.
- Ashmore JP. The design of national dose registries. Eur J Cancer 1997, 33(Suppl. 3), S44–S47.
- Miller AB. Occupational radiation carcinogenesis (overview). Eur J Cancer 1997, 33(Suppl. 3), S7-S9.
- McLauglin JR, King W, Anderson T, Clarke E, Ashimore P. Paternal radiation exposure and leukaemia in offspring—The Ontario case-control study. Br Med 7 1993, 307, 959–966.
- Gardner MJ, Hall AJ, Snee MP, et al. Methods and basic data of case-control study of leukaemia and lymphoma among young people near Sellafield nuclear plant in West Cumbria. Br Med 7 1990, 300, 429-434.

Acknowledgements—This workshop was an initiative of the Environmental Health Directorate of Health and Welfare Canada. The Institute of Environment and Health of the University of Toronto and McMaster University in Canada collaborated with the Environmental Health Directorate in organising the workshop and hosted the meeting at the University of Toronto on 13-14 July, 1992. The International Agency for Research on Cancer (IARC), an independent agency within the World Health Organization and the Atomic Energy Control Board of Canada, cosponsored the meeting. The authors would like to acknowledge comments from the workshop participants that led to considerable improvement of this overview paper.