CONSIDERATIONS AND PRELIMINARY DESIGN OF PATIENT EXPOSURE REGISTRY

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Received May 14 2010, revised August 6 2010, accepted September 2 2010

To aid in protecting patients from unnecessary exposures and to reduce radiation burdens to the public, a system for tracking a patient’s medical exposure history and related radiation doses would be a useful tool. A patient-centred exposure registry, the Patient Exposure Registry (PER), is a mechanism that provides this tracking. This article outlines the objectives of the proposed Canadian PER together with considerations and preliminary design of the registry. Implementation strategy is discussed. The strategy will allow many initiatives progressing in parallel such as backward data mining and forward development in order to make this important registry a reality in the near future.

INTRODUCTION

Technological advances and innovations in medicine have produced significant benefits to society. The use of radiology in diagnostic, interventional and therapeutic services is an essential component of health care. With a constantly improving health-care system, people live healthier and for long time. At the same time, the proliferation of advanced technologies has also led to an increased perception of the need for these technologies for many routine diagnostic procedures and therefore a remarkable increase in the utilisation of radiological imaging services (1–4).

In radiological procedures, the aim is not to deliver radiation dose, except in the case of radiation therapy, but rather to use the radiation to provide diagnostic information or to conduct an interventional procedure. In medical uses of radiation, there is an expectation of a health benefit to the patient. While providing many benefits, the inherent properties of ionising radiation may also cause potential harm. Therefore, decisions to recommend the use of such procedures should always include the potential risks associated with the radiation exposure (5–13).

Many studies have reported large variations in radiation exposure delivered to patients for many modalities (14–19). In addition to the variations in radiation doses received by patients due to their anatomical and physiological differences, variations in exposures delivered within a modality also have a large impact, as demonstrated, for example, in several Canadian studies (20–23). Recently, there has been a growing concern about the levels of radiation associated with many imaging procedures and the impact of this radiation exposure on the health of patients. This increased concern has created various national and international initiatives and actions (24–26), including actions of all major healthcare enterprises, such as the development of Radiation Exposure Monitoring profile for assessing and reporting dose indices in computed and digital radiography (27–29).

A system for tracking a patient’s medical exposure history and related radiation doses would be a useful tool to aid in protecting patients from unnecessary exposures, to reduce radiation burdens to the public and to assist health-care providers to make more informed decisions when considering any imaging procedure for a patient. Ultimately, it is the amount of radiation dose received by a patient that determines health effect. However, tracking exposure history itself will provide some estimate of doses to patients without knowing details of more accurate dose calculations. The tracking is valuable in providing a level of radiation protection to patients. A patient-centred exposure registry, the Patient Exposure Registry (PER), is a mechanism that provides this tracking.

In Canada, the methodology of tracking radiation doses for individuals has long been existing in occupational settings. Since 1951, the Canadian National Dose Registry (NDR) (30) has collected the dose records for over half a million radiation workers and has served to reduce occupational exposures during the past decades. Although there are different policies for regulating or controlling naturally occurring, workplace and medical exposures, the risk of radiation-induced cancer for a given dose is the same for an individual at a given age regardless of where or for what reason they have been exposed to ionising radiation. A centralised national registry will be able to provide better service and protection...
to individuals by tracking exposures from all radiation sources in homes, at workplaces and from health-care services. Therefore, since the integration of the NDR into the Radiation Health Assessment Division of the Radiation Protection Bureau, Health Canada in 2008, the discussion of extending the NDR to cover other radiation exposures was started. The proposed PER has been considered one of the important extensions of the existing NDR.

The development of a national PER is a highly ambitious and long-term undertaking. However, the rapid emergence of e-health systems worldwide and the introduction and implementation of electronic medical record (EMR) technology in Canada have shown great promise. The Canada Health Infoway (CHI) works with the provinces and territories to foster and accelerate the development and adoption of pan-Canadian electronic health information systems. The CHI is a health information highway—an infrastructure for health services and health information including its development, analysis, adaption, communication and use. The creation of a network of EMR systems will enable health-care providers to share, access, manage and safeguard the essential health information of millions of Canadians. The CHI initiative is built on the traditional excellence of Canada’s public health-care system and provides a vital link to the future by harnessing and employing new information and communication technologies. At the end of 2009, a total of 138 projects have been completed in 10 programme areas, such as infrastructure, interoperable EMR, diagnostic imaging system, registries and patient access to quality care. The concept of developing a PER for Canada seems to be a natural fit within this emerging e-health environment and the current trend of building evidence-based and patient-centred systems to improve health outcomes.

OBJECTIVES AND FUNCTIONS
The proposed PER would track and maintain records of the radiological procedures of individual patients for their lifetime. This includes assigning radiation doses to individual procedures with consideration of patient-specific parameters where possible and recording patient lifetime exposure histories. To achieve this basic function, the registry needs to collect dose-related exposure parameters for radiological procedures from service providers. Nowadays, many radiological procedures become very complicated, and in many cases it is hard to determine the accurate amount of doses delivered to patients. However, methods and software are currently available to compute typical patient doses for various modalities and for patients of various age groups, such as those summarised in Appendices B–F of the International Committee on Radiation Units and Measurements (ICRU) Report 74, ‘Patient dosimetry for X-rays used in medical imaging’. The typical dose values would be used as the starting point or the initial tools to assign radiation doses for the records in the registry. As more accurate and Canadian-specific dose estimations become available, doses in the registry could be updated as needed.

With this basic function, the proposed PER could provide:

- service providers or physicians with diagnostic examination histories; with the use of the registry, unnecessary imaging could be avoided ultimately helping to reduce wait times, a top priority of provincial governments and Health Canada;
- physicians with diagnostic examination histories, associated radiation doses and cumulative dose information for individual patients, allowing them to make more informed decisions on additional diagnostic procedures or on the need for follow-up screening or monitoring for radiation-induced secondary cancers in the best interest of the patient;
- patients with personal radiation dose health information to which they are entitled (depending on provincial legislation, since health care is a matter of provincial jurisdiction in Canada); summary data for health-care professionals and manufacturers to enhance their knowledge and expertise and flag emerging issues with some modalities and instruments;
- provinces/service providers with information on in- and out-of-province medical procedures received by residents to assess performance and use patterns of radiological procedures and make comparison across various jurisdictions;
- regulators with statistics (without the need for time-consuming patient dose survey and additional data collection) to refine existing standards or reference levels for optimisation of patient exposures and to maximise opportunity for good future outcomes;
- scientists with data from a wide population coverage for use in the development of better risk assessments and in epidemiological studies;
- research opportunities for assessing trends and patterns of population exposure which then provide a fundamental basis for health policy development.

Currently, radiation risk assessments are heavily based on data from A bomb survivors. Although valuable, the data represent high dose, acute exposures and are not necessarily applicable to the low-dose exposures most Canadians experience. Population doses collected in the proposed PER would largely increase the data pooling for radiation
risk assessment beyond A bomb survivors and provide a better understanding of radiation risk from prolonged low-dose exposures.

DESIGN CONSIDERATIONS

In health-care settings, ionising radiation is used for the screening, diagnostic and therapeutic purposes listed in Table 1. The scope of the PER extends to all medical procedures using ionising radiation.

The basic physical quantity used in radiological protection is the absorbed dose averaged over an organ or tissue. While the registry described here would have the ability to estimate radiation doses associated with various medical procedures, its primary objective is to track radiation exposures to individual patients. For practical reasons, especially in the early development phase, the registry should be designed to collect only the essential and a few basic exposure parameters of each radiological procedure.

The essential parameters are the same regardless of the type of radiological procedure: the ‘what’ and ‘when’, i.e. what procedure was performed and the date. These essential parameters enable the PER to track exposure histories of individual patients. Even this most basic information has value and can be used by medical professionals and patients to make informed decisions and to avoid unnecessary radiological procedures. The essential parameters could be the parameters to be recorded in the PER for complicated procedures, such as those in radiation therapy, before meaningful and basic exposure parameters be identified.

To truly improve decision-making, however, knowledge of radiation dose is needed, and this requires basic exposure parameters to be collected for each radiological procedure. During medical procedures using ionising radiation, absorbed doses in organs or tissues of the patient cannot usually be measured directly. Therefore, measurable quantities that characterise the radiation field or distribution, i.e. the exposure parameters, are used to assess radiation doses to the patient instead. Significant progress has been achieved in recent years in developing methods to derive absorbed doses in tissues and organs from a number of practical measurements or parameters, such as the PCXMC (a PC-based Monte Carlo program for calculating patient doses in medical X-ray examinations[34]). In addition, more and more manufacturers of medical equipment are now making those physical parameters available on various settings/displays[28, 29, 35, 36].

For most of the procedures in therapeutic radiology, although they can be quite complicated, proposed radiation doses to the patient are normally documented in the planned treatment and can serve as basic parameters to be recorded in the PER. For many screening or diagnostic procedures, and some therapeutic procedures, such as interventional treatment using angioplasty, radiation doses can be derived from exposure parameters used in describing a radiological procedure delivered to a patient. This requirement to calculate doses from exposure parameters is a key difference between the PER and Health Canada’s current NDR, where most records received and stored are the dose readings from radiation dosimetry badges worn by individual occupational radiation workers. This difference requires the PER to be capable of recording the basic parameters for various radiological procedures in order to calculate the associated radiation doses to the patient. Some procedures, such as chest X-rays, mammography and certain nuclear imaging procedures, can be described well by only a few parameters. However, there are many procedures, such as interventional angiograms, that are difficult to describe due to time-varying parameters. In those cases, time-integrated parameters, such as total dose–area product, need to be recorded.

The basic exposure parameters for some common procedures are given in Table 2. They are based primarily on a number of practical measurable quantities given in the ICRU Report 74. Those parameters differ by procedures and are subject to change with new developments and innovations in medical technology.

As indicated in the ICRU Report 74, in radiological imaging, several quantities are often used to quantify the magnitude of an exposure to the patient. However, there is some ambiguity, debate and even disagreement in quantity names and applications, such as kerma versus with absorbed dose, air versus water and free-in-air versus with backscatter. A similar situation exists in radiation therapy. Before arriving at international harmonisation of quantities and terminology, the recommended quantities in the
ICRU Report 74 were selected as the basic exposure parameters.

When stochastic radiation effects are of interest, the basic physical quantity used in radiological protection is the absorbed dose averaged over an organ or defined tissue—the mean organ/tissue dose, $D_T$. In medical X-ray imaging, more than one organ is often irradiated. To calculate the total radiation exposure, the effective dose has been introduced by the International Committee of Radiological Protection (9). The effective dose may or may not be a very rigorous parameter, but it still remains at the present time a useful single parameter to summarise the possible radiation-induced detriment and allow comparisons of radiation health risk among different medical procedures. Effective dose is the dose quantity used in current guidelines of various associations of radiologists (10–15). Patients or referring doctors occasionally ask for this information as well. With radiation weighting factor, $w_R$, taking account of the radiosensitivity of irradiated tissues, the effective dose, $E$, is determined as the sum of doses in various organs and tissues for a given radiation type, such as X-rays commonly used in diagnostic radiology:

$$ E = \sum_T w_T w_R D_T. $$

In radiation dosimetry, dose conversion coefficients have been established to link the basic exposure parameters with the mean organ/tissue doses for a given procedure. For patient-specific and more accurate dosimetry, those conversion coefficients are often established and modified using additional parameters describing the patient, characteristics of X-ray beams and exposure conditions, such as those summarised in the ICRU Report 74. Therefore,
more detailed exposure parameters should be included in the data flow to the PER whenever available. This can be achieved with the advancing information technology in health-care settings and standardisation of exposure parameters in medical equipment. Some examples of those additional parameters are given in Table 3. Possible dosimetric quantities are also given in Table 3.

Computed tomography (CT) scan and mammography are popular examinations using X-rays. Examples are given here to demonstrate how dosimetric quantities can be derived from a few basic exposure parameters.

For example, in mammography, the specified dosimetric quantity is the dose to breast—the mean glandular dose, \( D_G \), determined from the basic exposure parameter—the incident air kerma, \( K_{a,i} \):

\[
D_G = c_m \cdot K_{a,i},
\]

where \( c_m \) is the conversion coefficient that depends primarily on the total filtration in the unit of equivalent aluminium thickness (mm Al). As summarised in the ICRU Report 74, Appendix E, the dose conversion coefficient can further be modified by compressed breast thickness, fraction of glandular tissue in the breast (glandularity) and additional exposure parameters, such as peak tube voltage, tube current–time product and focal spot-to-image receptor distance.

For CT scans, the basic exposure parameter is the air kerma–length product, \( P_{KL} \), or the CT air kerma index, \( C_K \) (commonly called the CT dose index, CTDI):

\[
C_K = \frac{P_{KL}}{N \cdot T},
\]

where \( N \) is the number of slices and \( T \) the nominal slice thickness. Because of unique radiation exposure conditions in a CT scan, a number of special exposure quantities have been developed to characterise the doses associated with CT. They include the \( C_K \) determined in dosimetric phantoms at the centre (\( C_{K,\text{centre}} \)) and periphery locations (\( C_{K,\text{periphery}} \)), i.e. the weighted \( C_{K,w} \) and the volume \( C_{K,\text{vol}} \):

\[
C_{K,w} = \frac{1}{3} C_{K,\text{center}} + \frac{2}{3} C_{K,\text{periphery}},
\]

\[
C_{K,\text{vol}} = \frac{C_{K,w}}{P},
\]

where \( P \) is the pitch factor that equals the slice spacing divided by the number of slices and the slice thickness. Those CT exposure indices provide estimates of the radiation exposure to the region scanned for the entire series of slices. \( C_{K,w} \) or \( C_{K,\text{vol}} \) is often displayed on the CT operator’s console during setting of the scan parameters and recorded in imaging files. Actually, basic exposure parameters and many additional exposure parameters are stored and archived in the electronic Picture Archiving and Communication System and can be automatically extracted from the Digital Imaging and Communications in Medicine headers or the Structured Reporting for most digital procedures. With archiving these basic exposure parameters, radiation dose to the patient can be quickly estimated based on the best methodology available at the time, and re-calculated or updated when new risk factors and dose conversion coefficients, or a more accurate and patient-specific dose calculation formula become available.

The specified dosimetric quantity for a CT scan is the mean organ/tissue dose determined from the basic exposure parameter \( C_K \) or \( P_{KL} \):

\[
D_T = c_{CT} \cdot C_K \quad \text{or} \quad D_T = c_{KL} \cdot P_{KL},
\]
where $c_{CT}$ and $c_{KL}$ are the corresponding dose conversion coefficients. In the literature, conversion coefficients are also available for linking basic exposure parameters with the effective dose.\(^{39, 40}\)

Due to the relatively high radiation dose involved in interventional radiology using fluoroscopy, deterministic radiation effects may occur. Therefore, in addition to mean organ/tissue doses and the effective dose, the specified dosimetric quantity for interventional radiology should also include the peak skin dose which can be determined from the basic exposure parameter, such as the incident air kerma, $K_{a,i}$:

$$D_S = c_s \cdot K_{a,i},$$

Again $c_s$ is the corresponding conversion coefficient linking $K_{a,i}$ with $D_s$.

Dose conversion coefficients in varying details are available in the literature. Many more could be established as look-up tables built into the PER. Despite the wide range of organ doses in radiology, the cumulative effective dose provides a reasonably good indicator of the potential detriment for a patient exposed to diagnostic radiology and nuclear medicine. Using the concept of recording exposure parameters, radiation doses can be quickly estimated based on the best methodology available at the time, and re-calculated or updated when new risk factors or better patient-specific dose calculation formula become available.

With data received from various EMR systems, the PER could provide exposure histories together with estimated radiation doses for individual procedures as well as cumulative radiation doses (annual and/or lifetime doses) for individual patients. With those functions, the PER could serve as a service provider in the Provider Registry of the CHI\(^{41}\). Medical professionals and patients themselves could be the consumers of the PER. Many of the PER’s consumers may not be familiar with radiation doses expressed in the units of Gray or Sievert. To better communicate the risk to the public, the PER should have the capability of expressing radiation doses in relative dose levels, such as equivalent chest X-ray as used by the UK Royal College of Radiologists\(^{11}\).

In addition to patient identity and basic personal information, a registry for radiation exposures to patients requires recording of basic information on radiological procedures. This recording function would also make a proposed PER a client in the Client Registry in the CHI framework\(^{42}\), meaning it consumes patient health information in the pan-Canadian electronic health information system. As both a Client and a Provider in the CHI system, the rights to access patient information of the proposed PER would be subject to the Infoway’s established security requirements.

**DATA MODEL AND DATABASE STRUCTURE**

Three basic categories of information would be stored in a PER. These are patient information (an individual’s identity), radiation exposure information from various medical procedures received by the patient and information/identity of service providers. The relationship between these three different types of data is illustrated in Figure 1.

This data model is similar to that of the existing NDR for radiation workers. The NDR also has three data types: Employee, Radiation Dose and Employer. ‘EMPLOYEE’ in the NDR is replaced by ‘PATIENT’ in the PER and could be any individual in the Canadian public health-care system.

The three types of information in the PER are stored as keyed databases and are linked together by common keys. The details about patients and their radiation exposure information can be linked by the identifying number (a national identity number, unique to an individual). The radiation procedure information can be linked to the service providers by their identifying numbers, as registered in the Provider Registry within the CHI infrastructure.

The PER consists of 13 tables, as illustrated in Figure 2.

- The PATIENT table represents the primary entity in this patient-centred database. It contains all information necessary to identify an individual patient. The supporting tables provide updates on time-dependent information: Address, Surname and Pregnancy.
- The PROVIDER table contains all information necessary to identify a health-care provider where a radiological procedure was delivered to a patient.
- Radiation exposure history is recorded in the table RADIATION HISTOR Y. Radiation doses for individual patients in the PER are derived based on procedure-dependent exposure parameters as discussed above. These quantities are
listed in two supporting tables, PROCEDURE Type and EXPOSURE Parameter. An exposure due to a radiological procedure could result in different radiation doses, such as target organ dose, estimated effective dose or dose to the foetus for a pregnant patient. Two other supporting tables provide information on dose types and methods used in dose assessment.

- The PATIENT–PROVIDER table provides the linkage between radiation exposure and a patient who received a radiological procedure from a registered health-care provider.

Similar to employees registered in the NDR, individual patients are registered in the PER when they receive a medical radiological procedure for the first time. Individuals exposed to ionising radiation before birth would be registered in the database when they are born. Their initial radiation doses are the corresponding foetal doses previously recorded in the exposure histories of their mothers. Once individual patients are registered in the system, their medical exposures will be tracked for their lifetime. Such long-term monitoring will be terminated with the recording of the date of death. All data will be maintained in the registry for population risk assessment and research purposes.

DATA FLOW PROCESS

With the database structure in place, its data flow supports two basic functions: the data input to the registry from authorised service providers and responses to information requests from the clients of the registry. The clients could be patients themselves or their health-care providers. Data flow is subject to data security and access control, as outlined in Figure 3.

Unlike the existing NDR where the data flow is a regular process, such as monthly or quarterly readings of dosemeters, the data flow to and within the PER is triggered by a radiological procedure which can occur in any health-care facility, at any time and to any individual patient. However, a mechanism of routine data submission to the registry on daily or weekly basis could be established.

Data input or upload into the PER could initially be done by the Health Canada staff who will maintain the registry. With the advancement of information technology, authorised medical professionals could also have limited direct access to the registry. Automatic data extraction from radiological procedures and data submission to the registry can be developed and implemented, as is the case for many
Radiation protection for patients is not only important but is also becoming an urgent issue for a modern health-care system. For informed decision-making and evidence-based justification and risk assessment in delivering health services, there is no doubt that a PER is needed. However, the development of such a registry could take several years. To avoid any delay in the improvement of health outcomes, an implementation strategy should be considered in the design phase of the PER. The proposed PER should be able to quickly fulfil its primary objective while technologies and infrastructures for more sophisticated functions are developed. Thus, the implementation is embedded in the development of the registry.

- Start data collection while developing the database; safeguard existing data within the registry while simultaneously working to resolve information-sharing issues; data can be collected manually before automatic submission is developed.
- Begin with collecting essential parameters while identifying basic exposure parameters, especially for complicated radiological procedures and developing mechanisms to make those parameters available. The essential data (what and when) have existed in the health-care system for many years in every province and territory of Canada, making it possible to perform retrospective data collection in addition to acquiring new data. With the collection of these essential data on exposure histories for individual patients, the PER can quickly become a useful tool to assist in improving Canada’s health-care system.
- Begin with using the most up-to-date lookup table of typical or generic doses for various procedures based on nationally and internationally published values while developing detailed and patient-specific dose conversion coefficients and dose calculation tools for more accurate dose and risk assessment.

With this strategy in mind, the PER would benefit from the use of information from established EMR systems that exist in various communities and provinces or territories across the country. With the ongoing advances of EMR systems and fast developments in information technology, the functions of the PER are expected to be further enhanced with more automatic operations, resulting in less burdens to the service providers and up-to-date user-friendly information exchange with its clients (patients and medical professionals).

**CONCLUSION**

Ionising radiation is a known cause of cancer and other adverse effects. The risk of radiation-induced cancer increases with the dose. While radiology in diagnostic, interventional and therapeutic services is an essential component of the health-care system, increased use and over-use of ionising radiation has raised concerns for the quality of health outcomes. To aid in protecting patients from unnecessary exposures and to reduce radiation burdens to the public, a centralised PER is proposed as an important extension to the existing Canadian NDR. Although radiation dose is the key health determinant, tracking exposure history (the essential parameters: ‘what’ and ‘when’) itself will provide some estimate of radiation doses and is valuable in providing a level of radiation protection to patients. The PER is a mechanism that could provide this tracking. Using the concept of recording exposure parameters, radiation doses can be quickly estimated based on the best methodology available at the time, and re-calculated or updated when new risk factors and dose conversion coefficients, or more accurate and patient-specific dose calculation formula, become available.

Radiation protection for patients is not only important but also becomes an urgent issue due to increased use and sometimes unnecessary use of ionising radiation in the health-care system. For informed decision-making and evidence-based justification and risk assessment in delivering health services, there is no doubt that a PER is needed. To avoid any delay in the improvement of health outcomes, the proposed PER should be able to quickly fulfil its primary objective while technologies and infrastructures for more sophisticated functions are developed. Thus, the implementation will be embedded in the development of the registry.

The PER would benefit best from the use of information from established EMR systems that exist in various communities and provinces or territories across the country. With the ongoing advances in EMR systems and developments in information technology, the functions of the PER are expected to be further enhanced with more automatic operations, resulting in less burden to the service providers and up-to-date user-friendly information exchange with its clients, the patients and medical professionals.
The proposed PER is an evidence-based and patient-centred radiation exposure tracking system with the primary objective of patient safety and better health outcomes.

REFERENCES


