Summary of the first meeting of the Smart Card (Smart Access) Project of the IAEA held in VIC, IAEA, Vienna on 27-29 April 2009

According to the latest estimates of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), as many as four billion diagnostic X-ray examinations are carried out worldwide each year. Medical exposure remains by far the largest man-made source of exposure to ionizing radiation and continues to grow at a substantial rate. In the period 1997–2007, the estimated annual collective effective dose to the world population from medical diagnostic and dental X-ray examinations was estimated to be 4,000,000 man Sv.

During the last 100 years, improvements in technology have resulted in dose reductions for radiographic examinations by a factor more than ten-fold. But the same is not true for computed tomography (CT). Since its introduction in 1972, CT technology has improved substantially, making it possible to obtain better quality CT examinations. However, patterns of use have been continuously changing, with increased utilization, and the percentage contribution of medical radiation dose from CT has continued to increase. For example, in report number 160, the National Council on Radiation Protection and Measurements (NCRP), noted that medical radiation currently accounts for 48% of the radiation exposure to the population of the United States, an approximately 7-fold increase from the early 1980's. CT is the largest single contributor from medical imaging, and is responsible for nearly 25% of the dose to this population.

In another recently published study in the April 2009 issue of *Radiology* conducted at a tertiary care academic medical center in USA, results indicated that 33% of the patients had undergone 5 or more lifetime CT exams and 5% had undergone between 22 and 132 exams. Fifteen percent of the patients received a cumulative effective dose from CT exams of greater than 100 mSv, and 4% received between 250 and 1375 mSv.

Although medical exposure constitutes nearly 95% of the exposure to population from non-natural sources, *there is no standard methodology to follow the long-term radiation exposure for the individual patient*. The entitlement of the patient for this information is becoming more and more recognized. Such methodology has long existed for recording occupational (eg medical technologist) exposures and has served to reduce exposures during the past few decades. Procedural dose information may also afford guidance for health care providers when making decisions about diagnostic imaging for patients, echoing the words of Robert Glass, "Managing in the presence of data is far better and easier than managing in its absence".

In addition to the growth in diagnostic imaging examinations, interventional procedures have also increased. Angiography and CT fluoroscopy to guide interventions are replacing many surgical procedures. A typical example is angioplasty, which has reduced the need for coronary bypass surgery in many situations. Thus, we are now in an era when patient exposure continues to rise. Much of this increase is due to the beneficial role of x-ray examinations in improving diagnosis, but there is still a responsibility to have some method that accounts for cumulative radiation doses to patients.

One of the guiding principles of radiation protection is to limit exposure to reduce the known and potential health effects that result from radiation. For diagnostic imaging, such as X ray studies and CT scans, the radiation dose is relatively low level and the potential health effect is primarily cancer in future years. The risk from one or few procedures is small. However, with repeated examinations, the risk will increase.

The IAEA, in discharge of its responsibility towards its mandate of establishing Standards of radiation safety and providing for application of these Standards had established a program on radiation protection of patients in 2001 and launched an international action plan that involves a number of international organizations such as WHO, PAHO, UNSCEAR, ICRP, EC, IEC, ISO and professional societies in the field of radiology (ISR), medical physics (IOMP), nuclear medicine (WFNMB), radiographers (ISRRT), radiation protection (IRPA) and radiation oncology (ESTRO). The approach is not regulatory but promoting radiation protection through training, provision of guidance, projects in Member States that assess radiation dose to patients and attempt dose reduction without compromising image quality. The IAEA has enjoyed considerable success in its program and the most visible example is the dedicated website on radiation protection of patient (http://rpop.iaea.org) that is becoming a popular resource for credible information from an international source, currently evidenced from half a million hits per month on the website.

What needs to be done?

Because of increasing use of diagnostic imaging in medical care worldwide, a record of radiation exposure is warranted. Up to now there are no systems widely available for tracking dose to patients. This is highly ambitious plan, but developments in IT in health care show promise for conveying important measures of radiation dose with individual's electronic health care record. Much of information management currently, both within and outside medicine, is through "Smart Card" technology. Tracking dose information through this technology may provide consistency in medical care. While the name "Smart Card" has been attached to this project, this is really more "Smart Access", taking advantage of developing technology which will unify medical care.

What is proposed?

There are number of possibilities in the project:

1. A Smart Card that contains a patient's information including as well radiation dose data, whether with or without images

2. A Smart Card only as a digital signature to access the data that is actually available online. A patient-accessible website can serve as a 'virtual' card

3. The information about radiation dose is made available in e-health records in a manner that can help track individual patient's exposure over time. With interoperability, it should provide possibility of access from anywhere.

4. In countries where neither an electronic card nor e-health record is feasible, a methodology to achieve information on tracking all radiological procedures, such as radiation passport, somewhat like vaccination card could be initiated.

What outcome is expected?

The primary benefit of this project is improved safety and quality of care for the individual patient. Availability of information to the physicians and other healthcare providers about previous radiological examinations and resultant radiation dose estimates will help to make informed management decision, potentially avoiding unnecessary radiation exposures. The availability of this information will also help to secure the healthcare provider-patient relationship so discussions about past procedures, and the potential benefit versus risk of the proposed examination can ensue. The recording of radiation dose can also inculcate sensitivity to radiation protection of patients.
It must be emphasized that the decision whether to undergo a radiological examination is a trusted agreement between patient and his or her physician or health care provider. To this end, it is the responsibility of the healthcare team to understand what examinations that provide a radiation exposure to the patient have been performed in the past, the potential risks of these examinations, and make a decision about further imaging that is based on this information and is in the best interests of the patient. Moreover, cumulative information on recording diagnostic imaging dose estimates will enhance the knowledge and expertise of radiologists, medical physicists, technologists, health physicists and manufacturers.

As with any medical record information, the dose record would be subject to all requirements for protected health information and patient privacy.

Secondary benefits of the project are also anticipated:

- Dose data may be used in registries. Service providers may use these data to assess patterns of use for modalities and across health enterprises
- The data could eventually be used to investigate potential health effects by low level radiation exposure in a large population
- It will result in development and refinement of existing Standards on radiation dosimetry

What are challenges?

There are essentially two types of challenges. The first pertains to including radiation dose information in the record system and the other to transporting the information to different media. It was realized that e-health is emerging rapidly and many more challenges are likely.

Many modern digital imaging systems have currently DICOM (Digital imaging and communication) structured dose reports and that will facilitate archiving the dose information. Conceivably, current dose quantities may undergo change in coming years that will require versatility and robustness of stored dose estimation data to provide for adaptability to changing needs and understanding.

IHE-REM (Integrating the Health Enterprise- Radiation Exposure Monitoring) profile will be the starting point as method of communicating dose information to enable interoperability across health care enterprises

- The dose information will be integrated into electronic health record system, emerging as the standard of care.
- Interoperability standards such as DICOM are needed for data storage format and data interpretation/display
- Security/confidentiality issues including authorization steps (for example, in the case of emergency care), levels of access (whether the dose record should be in a separate access class from the rest of the patient's electronic health care record) need to be settled.

Further actions:

1. To prepare detailed report by September 2009.
2. Hold the next meeting in January 2010 with involvement of representatives of e-health, referring physician, public health information, ACR , ICRP, IOMP, ISR, EC, IRPA and also European radiologist

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Contributors in the above meeting:
Donald Frush, USA (Chair), Madan Rehani (IAEA, Scientific Secretary)
Heinz Blendinger, Germany (IHE), Andrew Casertano (USA), Steven Sutlief (USA), Jing Chen (Canada).