Australian Government

Australian Radiation Protection and Nuclear Safety Agency

ARPANSA NATIONAL CONFERENCE ON RADIATION PROTECTION IN MEDICINE

ADDRESS BY CEO OF ARPANSA

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The prime purpose of this Conference is to promote further the dialogue between Australia's radiation regulators and the medical professions about the proposed Code of Practice and Safety Guides on the medical applications of ionising radiation.

I am going to talk about the fundamental rationale for radiation protection in medicine. I will talk about radiation protection as it applies to the medical exposure of patients. Of course, the Code and safety guides also deal with occupational and public exposures arising from medical applications. These are important but do not raise any new issues of principle for radiation protection – in this regard medical practice needs to apply the same approaches as used in any other application of ionising radiation.

For the sake of simplicity, I will focus on the exposure of 'ordinary' patients and avoid issues associated with medical exposures to carers, volunteers etc. Nor will I deal with the specific issues of exposure of pregnant patients, though I am sure that this is an issue that will arise during the day.

After talking about the need for radiation protection of patients and the system for radiation protection that is intended to be embodied in the Code and safety guides, I will conclude with a brief description of ARPANSA's role in radiation protection in medicine and some international developments in the field.

Is there a need for radiation protection of patients?

The question as to whether there is a need for radiation protection of patients must be faced. Occasionally, I have a sense that some in the medical professions are of the view that administration of radiation does good for patients in diagnostic and therapeutic terms and worries about radiation related risks to patients are a marginal issue that should not distract us from doing this good.

Of course, in the practice of medicine involving procedures that expose patients to radiation, there is a need for the practice to be professionally managed and organised so as to ensure that the right procedures are appropriately administered to the right patients. In this sense, radiology, nuclear medicine and radiotherapy are no different from other medical disciplines. Patients need to be protected from wrong administration of doses of radiation, just as they need to be protected from wrong prescription of pharmaceutical drugs. This can be done through the established processes of medical practice regulation. Radiation protection regulation can support this good practice, but does not have a central role.

At the levels of dose involved in radiotherapy, the need for radiation protection so as to avoid accidents is acute. And I shall speak more about this.

But even when we know that the correct radiation procedure - and here I focus on diagnostic radiation procedures - is being performed upon the correct patient, is there still a need for radiation protection of the patient? The answer to that question turns

upon the answer to the question as to whether ionising radiation at low doses provides a risk of subsequent development of cancer.

The debate about radiation risks at low doses

A wide range of evidence, and most particularly the data from the Japanese atomic bomb survivors, establishes unequivocally that exposure to ionising radiation at levels providing a dose of greater than something like 50-100mSv increases a person's risk of contracting a cancer later in life. And it seems that this risk increases linearly with dose, at least for solid cancers.

Does this linear relationship continue down effectively to zero dose – or at some level, is there a threshold below which radiation does not increase cancer risk; or even is there a threshold below which radiation has a protective effect?

You will certainly find credible people who believe in the latter propositions in this country and others – especially the United States. And at least one eminent medical body, the French National Academy of Medicine has adopted the position, based largely on evaluation of radiobiological evidence, that the 'linear non threshold' assumption should not be used without precaution for evaluating risks associated with low (< 100 mSv) and even more so with very low (<10mSv) doses. They make this argument explicitly in the context of the European Directive on radiation protection in radiology.[i]

There are inherent difficulties in reaching a conclusion on this matter – because the risk at low doses appears is almost certainly low, it is beyond the scope of any feasible epidemiological study to establish it definitively. Cellular studies, as is often the case, provide results that could be interpreted as tending either way.

But it is not that there is no evidence supporting this 'linear non threshold' hypothesis. It is not the time or place to go through the evidence in detail. But I shall point to the conclusions of several authoritative reviews of the science.

The US National Research Council published its very extensive 'BEIR VII' study on Health Risks from Exposure to Low Levels of Ionizing Radiation in 2005[ii]. After a typically American exhaustive study conducted with public processes and including all the epidemiological and radiobiological evidence, the summary conclusion is stated as:

> *'Despite the challenges associated with understanding the health effects of low doses of low LET radiation, current knowledge allows several conclusions. The BEIR VII Committee concludes that the current scientific evidence is consistent with the hypothesis that there is a linear dose-response relationship between exposure to ionizing radiation and the development of radiation-induced solid cancers in humans. The Committee further judges that it is unlikely that a threshold exists for the induction of cancers but notes that the occurrence of radiation-induced cancers at low doses, will be small.'*

In its report to the UN General Assembly in 2006, the UN Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reported on its most recent examination of the epidemiological studies of radiation and cancer[iii]. In particular, the report

reviewed the most up to date analysis of the Japanese atomic bomb survivor survey. The report observes:

> *The results from analysing the data on the Japanese atomic bombing survivors are consistent with a linear dose-response relationship for the risk of all solid cancers together and with a linear-quadratic dose response relationship for leukaemia.*

The UNSCEAR 2006 report also looks at the cellular evidence for non-targeted and delayed effects of ionizing radiation, including radiation induced genomic instability and bystander effects. UNSCEAR agreed that the implications of these effects needed more study but stated that:

> *the Committee stresses that the estimation of the health effects of radiation is based on epidemiological and experimental observations where there is a statistically significant dose-related increase in disease incidence. These direct observations of adverse health outcomes implicitly take account of mechanistic elements relating not only to the targeted (direct) effects of irradiation but also to the non-targeted and delayed effects*

In a 2006 publication on low dose extrapolation of radiation related cancer risk[iv], the ICRP considered:

> *the evidence relating to cancer risk associated with exposure to low doses of low-LET radiation, and particularly doses below current recommended limits for protection of radiation workers and the general public.* [The report] *looks at the possibility of establishing a universal threshold dose below which there is no risk of radiation-related cancer. The focus is on evidence regarding linearity of dose response for all cancers considered as a group, but not necessarily individually, at low doses (the so-called linear, no-threshold (LNT) hypothesis). The report* [covered]*: • Epidemiological studies of exposed human populations • DNA damage, and cellular consequences of radiation-induced damage • Experimental approaches using animal models • Quantitative uncertainty analysis. The report concludes that while existence of a low-dose threshold does not seem unlikely for radiation-related cancers, it does not favour the existence of a universal threshold. The LNT hypothesis, combined with an uncertain dose and dose rate effectiveness factor (DDREF) for extrapolation from high doses, remains a prudent basis for radiation protection at low doses and low dose rates.*

What is the risk?

For overall radiation protection, people usually use a risk factor of around 5% increase in risk of a cancer per Sievert of dose. But this is a figure that is averaged over ages and between sexes and refers to effective whole body dose. For considering the risk in use of radiation in medicine, one needs to take into account that the dose is delivered to particular organs and especially that there are age and sex related differences in risk.

At all ages women face a greater risk than men. The table[v] shows values calculated for age groups and females/males of risk of incidence of cancer after exposure to an effective dose of 20mSv of radiation.

Age at Exposure	Female	Male
0-9 years	0.56%	0.32%
10-19 years	0.41%	0.23%
20-29 years	0.30%	0.17%
30-39 years	0.20%	0.12%
40-49 years	0.14%	0.08%
50-59 years	0.08%	0.05%
60+ years	0.04%	0.02%

These are small risks – low doses have low risk. But when this low risk is aggregated across the population that receives doses of radiation for medical purposes it does mean that there are numbers of cases of cancer arising from medical applications of radiation and these numbers can be estimated.

In a paper published in The Lancet some years ago[vi], Berrington de Gonzalez and Darby did a quite sophisticated, albeit broad scale, analysis of the risk of cancer from diagnostic X-rays. Their study took into account – most directly for the UK but also for 14 other countries – the organ doses and age and sex of those exposed. For Australia, they suggested 431 cancer cases per year from diagnostic X ray use, representing an attributable risk of 1.3% overall. Some of the parameters assumed in this study are no doubt out-dated and the study does of necessity make some reasonably heroic extrapolations, but I think it does establish something of a 'ballpark' figure for the risk arising from the application of diagnostic X rays in Australia.

Some newer procedures using CT result in quite substantial doses and thus present quite measurable risks on an individual basis. A recent article in the Journal of the American Medical Association[vii] reports on CT coronary angiography involving doses from 42 to 91 mSv for the lungs and 50 to 80 mSv for the female breast. The lifetime cancer risk estimates calculated by the authors for standard cardiac scans varied from 1 in 143 for a 20 year old woman to 1 in 3261 for an 80 year old man.

The radiation protection system applying to patients

I hope you are convinced that radiation protection of patients is needed. Moderate reductions in dose that do not weaken the diagnostic outcomes will save lives.

How is radiation protection of patients achieved? The overall system of radiation protection is established for the world (outside the US) by the International Commission on Radiological Protection - ICRP. Interestingly, this body was established under the auspices of the International Congresses of Radiology in 1928 and its parent organisation is still the International Society of Radiology. In 1928, the primary issue was the radiation protection of radiologists, rather than the patients. The radiologists were often being exposed excessively as the science and art of radiology developed. In these early days, the issue was how to set limits to avoid acute radiation burns – knowledge of the stochastic and delayed impacts of radiation on risk of cancer was yet to come.

Over the years the system has developed as new knowledge and new practices have emerged. Every decade or so, the ICRP has published revised Recommendations for

radiation protection. When its publishing company gets around to it, the ICRP will publish its 2007 Recommendations, being the distillation of its most current thinking on radiation protection for occupational, public and medical exposures and for planned exposures, existing situations and emergency situations.

The 2007 ICRP Recommendations relating to medical exposures are very much a matter of 'steady as she goes'. The three pillars of radiation protection continue to be justification – do more good than harm; optimisation – the doses received should be as low as readily achievable, economic and social factors being taken into account; and limitation – no one should receive a dose above a certain limit. This last concept is not applied to medical exposures, that is, the exposures of patients in the course of diagnosis or therapy, though it does of course apply to doses received by occupationally exposed persons and the public exposed as a result of the medical uses of radiation.

Justification for medical procedures

The ICRP continues to talk about three levels of justification for application of radiation in medicine. The first can be dispensed with simply: the 'planned exposure' of patients to radiation in medicine is justified generally. Second, however, is the justification of a defined radiation procedure. This level of justification is usually be broadly established by national and international professional bodies, most directly through the training they provide to members of the professions. Sometimes, those bodies explicitly choose to taker a public position on an application of radiation as the RANZCR has done with regard to asymptomatic whole body CT scanning.

And finally, the third level of justification is justification of a particular procedure for an individual patient. Here the circumstances of the individual need to be taken into account – including age and sex. Of course, for very many simple diagnostic radiology procedures with very low doses and very well established benefits, this level of justification need not be a big deal. As the complexity and dose arising from a procedure increase and where there is the possibility of there being alternative modalities, then individual justification needs consideration that goes beyond being mere custom and practice.

Optimisation of protection in medical exposures

Having established arrangements that allow for sensible processes to establish that a procedure on a certain patient is necessary, then attention must be paid to the optimisation of the procedure to produce the exposure and dose necessary to achieve the clinical objective, but no more.

The optimisation of protection in medicine can involve both the design and construction of equipment and installations and the day to day methods of working. It can extend from the application of simple common sense to complex quantitative processes.

It must be emphasised that in and of itself, the optimisation of protection in medical exposure does not necessarily mean the reduction of doses to the patient. If, for example, doses could be reduced by removing an anti-scatter grid but that this removal would result in an unacceptable loss of image quality for a certain examination, then the removal is not warranted by the optimisation process.

In radiation therapy, it is necessary to distinguish between the dose to the target tissue and the dose to other parts of the body. Unless the dose to the target tissue meets the therapy objective, then the procedure is not justified and the question of optimisation does not even begin. The protection of tissue outside the target area is, of course, an integral part of radio therapy dose planning, which thus has the same aims as optimisation of protection.

In diagnostic radiology and nuclear medicine, there is an important role to be played in optimisation of protection by the appropriate utilisation of diagnostic reference levels. Such levels – DRLs – should be established so as to be consistent with national practice. They should be simple to measure. They do not apply to individual patient dose – but comparison with DRLs should be built into a practice. Where it is found that exposure levels in a practice significantly exceed DRLs, there should be a review of procedures and equipment to determine if protection has been adequately optimised. If not, measures aimed at reduction of dose should be taken. On the other hand, it may well be found that protection is optimised and the higher levels of dose than suggested by the DRLs reflects the particular case load of the practice.

It is vital to stress that, while application of DRLs should be a regulatory requirement, the levels themselves do not in any way represent a regulated level or a dose constraint. They do not represent a dividing line between good and bad medicine. Exceeding a DRL is not a matter for regulatory action – but having a program to appropriately apply DRLs is proposed as a regulatory requirement.

Preventing accidents and emergencies in medicine

In view of the doses being administered in the therapeutic applications of radiation, it is obviously vital that accidents be prevented. This is not just the matter of optimising the administration of a radiation dose to a correctly identified patient; but of being sure that the procedures are in place and are checked and checked again, as is the planning and dose delivery equipment, to ensure that the right dose is administered to the right patient.

Some prescriptive regulation can play a role here. But by far the most important factors are overall safety management systems and quality assurance that are applied in a practice and the safety culture of the practice. Regulators can try to ensure that there is evidence for there being proper safety management systems and quality assurance activities and can audit these activities. The regulator can encourage a strong safety culture by engaging with those responsible for the practice. Finally, however, the responsibility for achieving these things lies with the person who would be called ‘the operator’ in international nuclear safety parlance and is called the ‘Responsible Person’ in the draft Code.

In many ways, the prevention of accidents in radiotherapy is more akin to a ‘nuclear safety’ paradigm than to a ‘radiation protection’ one. People involved in nuclear safety are focussed primarily on the prevention of accidents – and the defence in depth, management systems and safety culture that contribute to the prevention of accidents.

Two weeks ago, I was at a meeting of international nuclear and radiation regulators at the IAEA in Vienna. There was a presentation from an official from the French

nuclear safety authority, which has the responsibility for the regulation of medical practices in France, as well as overseeing its 55 nuclear power plants. There have been several recently identified radiotherapy accidents in France with a number of deaths being attributed to them. I was interested to note that the French authority is in discussion with the radiotherapy profession to develop an extension of the international nuclear events scale to allow for classification and reporting of radiotherapy accidents in a manner akin to the reporting of incidents in nuclear installations.

Role of ARPANSA
The functions of the CEO of ARPANSA that are relevant to the radiation protection of patients include the promotion of national uniformity in radiation protection, the provision of advice on radiation protection and the carrying out of research and provision of services for radiation protection. The latter two functions include direct reference to medical exposures to radiation.

In May 2006, I received advice that I had sought from the Radiation Health and Safety Advisory Council, a body established under the ARPANS Act, which included a number of recommendations about strengthening ARPANSA's role in relation to medical exposures. In particular, the Council recommended a stronger engagement of ARPANSA with the medical professions with regard to training and information related to the improvement of the management of radiation dose to patients and the issues relating to radiation protection of patients. In my reply to the Council, I said that I supported the thrust of the Council recommendations but would need additional resources to address them properly. I could not and cannot divert resources from ARPANSA's 'traditional' activities in medical radiation, including such fundamentals as maintaining the relevant Australian standards and disseminating them through calibration services.

In its 2007 Budget, the Government rode to the rescue with an allocation of new funding to ARPANSA to promote the safer and better use of radiation in medicine. A centrepiece of this program will be our acquisition of a medical linac. This will allow ARPANSA to research and develop direct megavoltage dosimetry methods and will be an invaluable training tool to support radiotherapy in Australia. The funding will also support out forthcoming survey of doses from CT and other steps to increase our engagement with the medical professions. As I see it, this enhanced engagement is to improve the 'selling' of the message of the optimisation of the use of radiation in medicine.

I hope to talk to many of you here about how we might achieve greater engagement and improved achievement of this message.

International action plan on radiation protection of patients
ARPANSA's work in supporting radiation protection in medicine is part of a world-wide effort in both developed and developing countries. We are not alone in seeking a greater degree of regulatory and professional commitment to this subject. There is an international program promoted by the IAEA on the protection of patients. This is centred around implementing an 'action plan' that was agreed by the IAEA Board of Governors in 2002 following an international conference in Spain in 2001. The aim of

the action plan is to support IAEA member states (and especially developing member states) in the education, training and services needed to establish systems for radiation protection of patients. The IAEA cooperates with the WHO, and regional health bodies, the EC and the ICRP in this work.

Conclusion

The application of ionizing radiation in medicine continues to be an important part of diagnosis and treatment in very many important parts of health care. Continued technological change promises to increase the good that can be done by radiation – while also likely to increase the numbers of procedures and doses per procedure.

There are risks of radiation related cancers in patients following on from use of radiation in medicine. It is incumbent of the medical professions to ensure that medical exposures are justified and that protection is optimised. Also, that there management systems and a strong safety culture in medical practices.

The draft Code of Practice aims to provide the regulatory framework to assist the professions to maintain radiation protection of patients. Equally as important as the regulatory framework is the higher level of engagement between the medical community and the radiation protection community represented by this Conference.

Thank you for your attention.

References

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