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Review article

Australian regulatory framework and reporting entities are hindering the lessons to be learned from adverse radiation events

G. Denham

Hunter New England Health, Manning Rural Referral Hospital, 26 York Street, Taree, New South Wales, Australia

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ABSTRACT

When adverse radiation events occur in the medical radiation science profession in Australia they are reported to the relevant state or territory authority. The details and cause of the incident are forwarded to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to be included in the Australian Radiation Incident Register. The aim of any error reporting system is to learn from previous errors and to prevent them occurring again. The information obtained from past errors is one of the most invaluable tools to prevent future adverse events.

This article examines the current regulatory framework, reporting systems and radiation protection authorities in Australia and their effectiveness at improving patient safety. Several obstacles must be overcome if the systems and organisations responsible for radiation safety are to meet the expectations of both the community and the medical radiation science profession.

Introduction

Sir Liam Donaldson, Chair of the World Alliance for Patient Safety states that "the fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system".[1] Many adverse events are likely to have similarities that can be identified and applied in many settings. When errors are reported and investigated, the lessons learned can be shared with other individuals and organisations to help prevent similar errors occurring.

It is what occurs after an error has been reported that is more important than the act of reporting itself. Australia has eight separate jurisdictions that are responsible for radiation protection with reporting requirements and systems varying in each. What happens after radiation incidents are reported in each jurisdiction determines the ability of that reporting system to be an effective learning system.[2]

This article examines the current regulatory framework, reporting systems and radiation protection authorities in Australia and their effectiveness at improving patient safety.

Error reporting in Australia

Adverse radiation incidents are reported to the relevant state or territory government radiation safety authority in which the incident occurred. Details of the incident and any findings of a root cause analysis are forwarded to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) for inclusion in the Australian Radiation Incident Register (ARIR). The ARIR was established in 1971 by the National Health and Medical Research Council with the reporting of incidents originally being voluntary.[3]

In 1999 the Australian Health Ministers' Conference agreed to the development of the National Directory for Radiation Protection (NDRP) as a way of achieving uniformity in radiation protection practices in the various jurisdictions of Australia. The Conference agreed that "the regulatory elements of the Directory shall be adopted in each jurisdiction as soon as possible, using existing Commonwealth/State/Territory regulatory frameworks."[4] Edition 1.0 of the NDRP that was published in 2004 included Schedule 13 – National incident reporting framework, a schedule of incidents that must be reported to ARPANSA for inclusion in the ARIR. The types of incidents reportable under Schedule 13 include diagnostic procedures on the incorrect patient or those resulting in observable acute radiation effects and therapeutic treatment that differs from differs from that prescribed by 10% and 15% by way of radiotherapy or radioactive substance respectively.[5] Twelve years later this has still not occurred with only New South Wales (NSW), Victoria (VIC) and Western Australia (WA) enacting legislation to conform with of the NDRP.[6–13]

Reporting requirements vary from state to state due to the variations in legislation in the various jurisdictions (Table 1). There is evidence to suggest that specific reporting requirements in

E-mail address: Gary.Denham@hnehealth.nsw.gov.au.

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Table 1
Various radiation protection legislation and reporting requirements in Australia.

State	Authority	Legislation	Reporting requirements
Australian Capital Territory (ACT)	Health Protection service	Radiation Protection Act 2006	Non-specific: "A person who uses a regulated radiation source to carry out a diagnostic or therapeutic procedure involving the irradiation of a person (the ***treated person***) at the request of a doctor must ensure that the treated person does not receive a dose of radiation from the procedure that is not in accordance with the request"[6]
New South Wales (NSW)	Environment Protection Authority (NSW)	Radiation Control Regulation 2013 under the Radiation Control Act 1990	Specific: Section 37 lists the occurrences that are defined as radiation accidents that are reportable to the Authority.[7]
Northern Territory (NT)	Environmental Health Branch	Radiation Protection Act	Non-specific: "The person must ensure the treated person does not receive a dose of radiation from the carrying out of the procedure in an amount or a way that does not comply with the request for the diagnostic procedure or prescription for the therapeutic procedure"[8]
Queensland (QLD)	Health Protection Unit	Radiation Safety Act 1999	Non-specific: "A use licensee who, under the licence, uses a radiation source to carry out a diagnostic or therapeutic procedure involving the irradiation of a person (the ***treated person***) must ensure the treated person does not receive a radiation dose from the carrying out of the procedure in an amount, or a way, that does not comply with the request for the diagnostic procedure or prescription for the therapeutic procedure"[9]
South Australia (SA)	Environment Protection Authority (SA)	Radiation Protection and Control Act 1982	Non-specific: "any other person must, in carrying on an activity related to radioactive substances or ionising radiation apparatus, endeavour to ensure that exposure of persons to ionising radiation is kept as low as reasonably achievable, social and economic factors being taken into account". This does not apply to radiotherapy[10]
Tasmania (TAS)	Public Health Services	Radiation Protection Act 2005	Non-specific: "that the treated person does not receive a dose of radiation from the carrying out of the procedure in an amount or a way that does not comply with the request for the diagnostic procedure or the prescription for the therapeutic procedure"[11]
Victoria (VIC)	Public Health	Radiation Act 2005	Specific: The Department of Health document titled 'Mandatory reporting of radiation incidents' sets out the mandatory reporting requirements[12]
Western Australia (WA)	Radiological Council	Radiation Safety (General) Regulations 1983 under the Radiation Safety Act 1975	Specific: Section 19A lists the occurrences that are defined as radiation accidents that are reportable to the Council.[13]

legislation result in a greater number of incidents being reported. The states with specific reporting requirements; NSW, VIC and WA all have annual radiation incident reports available to the public that provide detailed descriptions of all reported incidents.[14–16] Details of radiation incidents in Australian Capital Territory (ACT) and Tasmania (TAS) can be accessed in the ACT Health Annual Reports and Operation of the Radiation Protection Act 2005 Annual reports respectively. In an 11-year period (2004–2014) the ACT Health Annual Reports detail 3 incidents of radiation dose due to equipment malfunction, 2 misalignment of treatment area incidents in radiotherapy and 1 incident of a misadministration of a radiopharmaceutical.[17–27] In a 5-year period (2011–2015) the TAS Annual Report on the Operation of the Radiation Protection Act 2005 detail 3 incidents of radiation dose due to equipment malfunction, 2 incidents of procedures performed on the incorrect patient and 1 incident of radiation exposure to a member of the public.[28–32] The states with the specific reporting requirements have many more incidents listed in their annual reports every year.

The ARIR as a learning system

Leape[2] identified the characteristics of successful reporting systems (Table 2) which result in improvements in patient safety. As the national radiation incident reporting system the ARIR should strive to achieve these characteristics.

Reinforcement remains the top preventative measure for incidents in the 2014 ARIR Annual Summary Report[33] and one could assume that a number of these will be in the form of counselling or disciplinary action. The fear of blame and retaliation has often been reported as a cause of underreporting of errors[34–36] and reporters may feel this is the case when dealing with the local authorities that carry out the initial investigation. This may be a difficult culture to eliminate due to the public's desire for accountability and practitioners' fear of liability.[2] For any error reporting system to work all parties involved must feel comfortable and safe sharing information about mistakes. This facilitates to create a culture of safety within an organisation.[37,38]

Table 2
Characteristics of successful incident reporting systems.[2]

Non-punitive	Reporters are free of fear of retaliation or punishment from others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed to a third party
Independent	The program is independent of any authority with power to punish the reporter or organization
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and who are trained to recognize underlying systems causes
Timely	Reports are analysed promptly, and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than on individual performance
Responsive	The agency that receives reports is capable of disseminating recommendations, and participating organizations agree to implementing recommendations when possible