Establishing National Medical Imaging Incident Reporting Systems: Issues and Challenges

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Radiology incident reporting systems provide one source of invaluable patient safety data that, when combined with appropriate analysis and action, can result in significantly safer health care, which is now an urgent priority for governments worldwide. Such systems require integration into a wider safety, quality, and risk management framework because many issues have global implications, and they also require an international classification scheme, which is now being developed. These systems can be used to inform global research activities as identified by the World Health Organization, many of which intersect with the activities of and issues seen in medical imaging departments. How to ensure that radiologists (and doctors in general) report incidents, and are engaged in the process, is a challenge. However, as demonstrated with the example of the Australian Radiology Events Register, this can be achieved when the reporting system is integrated with their professional organization and its other related activities (such as training and education) and administered by a patient safety organization.

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INTRODUCTION

Sir Liam Donaldson, chair of the World Alliance for Patient Safety of the World Health Organization (WHO), makes a particularly apt analogy between safety in the aviation industry and health care [1]. He asks the reader to imagine a jet aircraft that contains an orange-colored wire essential for its safe functioning. An airline engineer in one part of the world doing a preflight inspection spots that the wire is frayed in a way that suggests a critical fault rather than routine wear and tear. What would happen next? It is likely that, probably within days, most similar jet engines in the world would be inspected, and their orange wires, if faulty, would be renewed. An important question is, can health care pass the orange wire test? In medical imaging, these issues are highly relevant. The orange wire could easily represent an interventional catheter or implanted device, a batch of intravenous contrast medium, a PACS or image-processing software, a test result, or a CT component or parameter setting. How effective and reliable are the reporting of the failure, its analysis, and the delivery of the alert to the sector of health care that most needs to know about the failure, that is, the clinical interface?

In this paper, we describe the need for incident reporting systems in health care, their value in improving patient safety, and issues and challenges that exist globally. Their role in medical imaging is specifically addressed, drawing on clinical examples and the experience of the Radiology Events Register (RaER) project in Australia and New Zealand. We review where medical imaging currently stands in relation to patient safety and its future direction and consider how a medical imaging incident reporting system can integrate successfully into a wider framework that addresses safety, quality, and risk in health care.

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Table 1. Definitions and concepts

Event: something that happens to or involves a patient.

Patient safety incident: an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The term *incident* is used interchangeably.

Near miss: an incident that did not reach a patient.

Harmful incident or adverse event: an incident that resulted in harm to a patient.

Error: the failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or the execution phase. Errors are by definition unintentional. It is important to note that not all incidents are due to error. The term *failure* can be used to describe a process defect, irrespective of whether there is an underlying error.

BACKGROUND: PATIENT SAFETY AND INCIDENT REPORTING

Before any discussion of patient safety, it is important that the fundamental concepts and terminology be understood. The International Classification for Patient Safety [2] offers the definitions and concepts listed in Table 1.

A recent WHO report noted that unsafe patient care is ubiquitous and associated with significant morbidity and mortality throughout the world, much of which might be amenable to intervention [3]. Although precise estimates of the size of the problem are not available, it is likely that millions of people suffer disabling injuries or death directly as a result of medical care. Runciman et al [4] considered it among the top 4 or 5 public health problems in the developed world. Injuries can occur in association with many health care interventions, including those that involve diagnostic and therapeutic aspects of medical imaging. Many of these are preventable and therefore challenge the long-standing medical principle of "First, do no harm" [5].

The issue of patient safety is truly global. Some major international reports are often cited as providing the wake-up call to the extent and severity of the issue and the need for urgent action [6-8]. National studies have reported rates of adverse events associated with hospital admissions in the United States [9-11], Australia [12-14], Great Britain [15], New Zealand [16], Denmark [17], Canada [18], France [19], Spain [20], Sweden [21], and the Netherlands [22]. In general, these retrospective studies from around the globe, using medical chart review, show some similarities. The rate of adverse events is approximately 10% of hospital admissions. The rate of serious adverse events, defined as those resulting in permanent disability or as contributors to or causes of death, is approximately 2% of hospital admissions. Importantly, most of these studies show that about 40% to 50% of these adverse events are preventable, although the "preventability" of deaths has been questioned [23].

Incident reporting is one of a number of methods for collecting information about safety problems in health care and is widely used in hospital settings. In terms of optimal monitoring of safety issues, no single approach adequately detects the full range of target events. These methods often detect different types of events; some experts suggest using more than one approach to monitor for patient safety problems [24,25].

Incident reporting is an integral component of high-risk and high-reliability organizations. Understanding what is going wrong with a process, and why, is a basic requirement for improving the quality of the process. However, health care, possibly with the exception of the field of anesthesiology [26-29], has been slow to adopt and implement this principle [30]. As noted by the Agency for Healthcare Research and Quality [31], there is

> an obvious lack of information about the prevalence and etiology of medical errors, as well as the effects of these errors. It is impossible to design intelligent systems, protocols, or processes to reduce errors if we do not first know where errors are occurring and why.

Every defect should lead to improvement processes that make care safer. It is now time to deliver on the promise of reporting systems in patient safety [30]. Table 2 shows the ideal characteristics of a successful reporting and learning system that enhances patient safety [32].

If legal protection of reported incident data cannot be ensured, then it is important that the information is not "reidentifiable," that is, that it is not possible to identify an individual incident in a specific facility on the basis of the information provided. The important component of an incident is the narrative [33]. It should be appreciated by the reporter that no identifiable information is required for the value of the report to be extracted. Ensuring the confidentiality of both the incident data and the person who provided the report is of major importance when designing reporting and learning systems. It has also been suggested that reports submitted anonymously may be of less reliability and value compared with their confidential counterparts. However, although an anonymous system could be criticized for its lack of accountability and transparency, it may be more important to provide anonymity early in the evolution of an incident reporting system until trust is developed and clinical staff members are able to see practical feedback and outcomes, at which time confidential reporting may be introduced.