Aetiology of hospital setting adverse events 1: limitations of the 'Swiss cheese' model

Introduction

An adverse event in health care is an injury resulting from a patient's medical management rather than a consequence of the patient's underlying medical condition or conditions. Adverse events are common and costly to the affected patients and the health-care system.

In the last two decades, the incidence, aetiology and outcomes from adverse events have been documented mostly in the hospital setting (*Table 1*). Taking these studies together, approximately 10% of hospital patient admissions have some sort of adverse event. Of these, half result in no long-term harm to the patient. However, 10% (of the 10%, i.e. 1% of all hospital admissions) of the affected patients suffer significant harm; they either die or are left with some sort of permanent disability as a result of the adverse event (*Table 1*) (Buist et al, 2003).

In 1995 the cost of adverse events to the Australian health-care system was estimated at $2 billion (AUD) dollars (Wilson et al, 1995). Attempts to reduce the incidence of adverse events and make hospitals safer have been largely unsuccessful (Shojania and Thomas, 2013). Like other diseases and conditions, an understanding of the underlying aetiology or pathophysiology of adverse events is important for the development of preventative strategies.

To date the predominant theory to explain adverse events in health has been the 'Swiss cheese' model developed by James Reason (1997) from his analysis of large scale industrial and organizational accidents. This article examines that theory and its limitations when applied to hospital systems, with specific reference to the deteriorating patient – the final common pathway for most adverse events when patients suffer harm. A second article (p. C175) proposes an alternative model called clinical futile cycles to explain hospital setting adverse events which takes into account some of the unique cultural systems that exist in hospitals (Buist and DeVita, 2010).

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The 'Swiss cheese' model and hospital setting adverse events

In *Managing the Risks of Organizational Accidents* James Reason (1997) states that organizational accidents, as opposed to individual accidents, are predictable events. An individual accident is one in which a person or group of people makes an individual slip, lapse or error of judgment with the result being an adverse outcome either to the person or the people who erred, or to the person or people in the immediate vicinity. As such there is usually a relatively tight, simple explanation for cause and effect in an individual accident. On the other hand, organizational accidents have 'multiple causes involving many people at different levels of an organization' (Reason, 1997).

These events, while usually infrequent, are often catastrophic. Analyses of such organizational accidents often reveal that the defences an organization has to prevent such catastrophes are breached by a unique series of sequential hazards that play out in an environment of latent conditions, the so-called Swiss cheese. It follows that, one can decrease the incidence of these organizational accidents by increasing the number of defences (more cheese slices) and/or by shrinking the size of the holes in each of the defences (*Figure 1*).

In 2008, Palmieri and colleagues published their 'health care error proliferation model' of adverse health-care events. This takes the Swiss cheese model and specifically adapts it to various factors that exist in health care (*Figure 2*). Most notably, they place clinician vigilance as a key defence at the 'sharp' or clinical end of the actual adverse event, in the form of clinical improvisation and localized workarounds. This clinician vigilance repairs gaps produced by actions, changes and adjustments that are made at the 'blunt' or administrative end of the health-care organization. A good example of this is the use of high definition mobile telephone devices in rural and regional settings that allow almost immediate transfer of clinical information to an appropriate clinician at a referral centre. However, this clinical workaround and improvisation is clearly at odds with most organizations' patient privacy policies that have been developed at the blunt administrative end of the organization (Palmieri et al, 2008).

Having for the most part accepted the Reason Swiss cheese model of adverse events and adapted variations, most hospitals' response to adverse events has been to increase defences at the blunt end of the health-care organization's administration (Buist and Middleton, 2013). In the hospital, these defences take the form of dedicated quality and safety units and committees, electronic event reporting systems, and the development of appropriate standards linked to hospital accreditation (Australian Commission on Safety and Quality in Health Care, 2015). Each of these blunt end defence layers aims to continually decrease the size of the holes in each layer, by more audits, meetings and root cause analysis projects, combined with the use of the quality improvement cycle. Inevitably what is generated is recommendations, guidelines, and more policy and procedure.

The Swiss cheese model does explain well some types of hospital adverse events, in particular patient falls, wrong side surgery and medication errors. In the case of medication errors, root cause analyses of these often highlight 'holes', such as poor transcription of medication prescriptions, and failure to do appropriate checks (Australian Commission on Safety and Quality in Health Care, 2013). In the case of patient falls, there is failure to identify the at-risk patient and put in place appropriate preventative strategies (Australian Commission on Safety and Quality in Health Care, 2012). Fixing the holes or at least reducing their size can reduce the incidence of patient falls and medication errors. This can be done with top-down policy and procedure and ensuring implementation of such. The

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Table 1. Epidemiology of adverse events

Study (year)	Reference	Methodology	Setting	Sample	Incidence (%)	Outcome death	Outcome permanent disability	Preventability	Negligent care	Cost (annual)
California Medical Association (1977)	California Medical Association (1977)	Random sample retrospective case note review			4.2%	N/A	N/A	N/A	19.1%	
Harvard medical practice study (1991)	Brennan et al (1991), Leape et al (1991)	Two-stage random sample retrospective case note review	51 acute care New York State hospitals	30121	3.7%	13.6%	2.6%	58%	N/A	N/A
Utah and Colorado study (1992)	Thomas et al (2000)	Random sample retrospective case note review	28 general hospitals	15000	2.9%	6.6%	8.5%	53%	30%	
Quality in Australian health care study (1992)	Wilson et al (1995)	Two-stage random sample retrospective case note review	28 different-sized acute care hospitals in two Australian states	14179	16.6%	4.9%	8.9%	51%	N/A	$2 billion (AUD)
New Zealand public hospitals (1998)	Davis et al (2002)	Two-stage random sample retrospective case note review	13 general acute hospitals	6579	11.2%	15% for both categories		N/A	N/A	
UK (1999)	Vincent et al (2001)	Random sample retrospective case note review	Two acute care London hospitals	1014	11.7%	8.2%	6.3%	N/A	N/A	
Canadian health care study (2000)	Baker et al (2004)	Two-stage random sample retrospective case note review	One teaching, one large community and two small community hospitals	3745	7.5%	20% for both categories		36.9%	N/A	
Brazilian hospitals (2003)	Mendes et al (2009)	Random sample retrospective case note review	Three teaching hospitals in Rio de Janeiro	1103	7.6%	N/A	N/A	66.7%	N/A	
Dutch hospitals (2004)	Zegers et al (2009)	Three-stage random sample retrospective case note review	21 acute care hospitals	7426	5.7%	12.8% for both categories		40.3%	N/A	
Italian acute care hospitals (2008)	Sommella et al (2014)	Two-stage random sample retrospective case note review	One acute care hospital	1501	3.3%					
Portuguese hospitals (2009)	Sousa et al (2014)	Two-stage random sample retrospective case note review	Three acute care hospitals in Lisbon	1669	11.1%	10.8%		53.2%		Euro 470 380 direct costs
Swedish hospitals (2009)	Soop et al (2009)	Three-stage random sample retrospective case note review	28 acute care hospitals	1967	12.3%	3.0%	9.0%	70%	N/A	630 000 hospital bed days

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Figure 1. The Reason 'Swiss cheese' model. From Reason (1997).

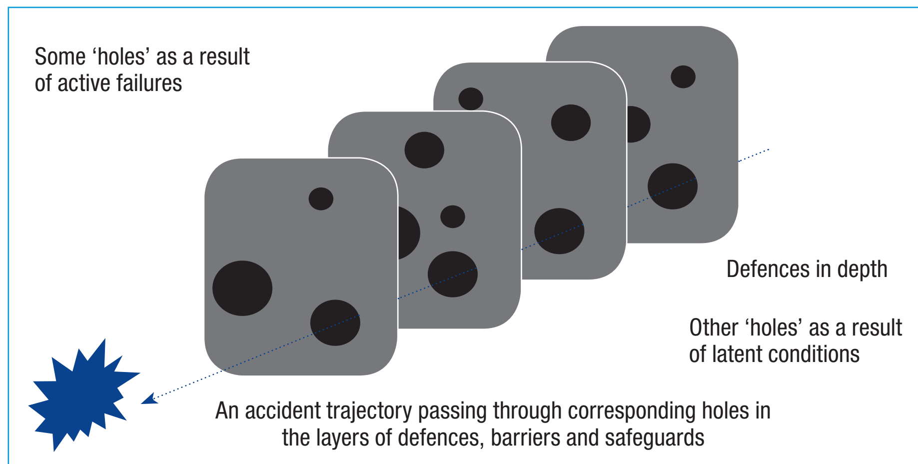
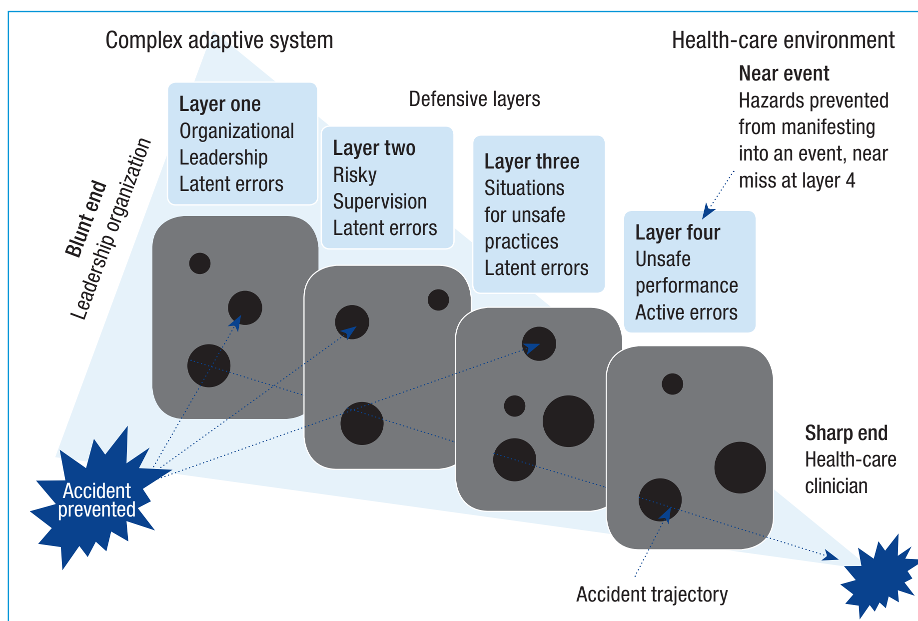


Figure 2. Health-care error proliferation model (Palmieri, 2008).



best example of this has been the reduction in incidence of wrong side surgery, with the implementation of time out and completion of a checklist before surgery (Haynes et al, 2009).

The Reason Swiss cheese model gives a good explanation of the adverse event when there is a high degree of face validity, usually when there is a relatively tight temporal relationship between the adverse event and possible preventative strategies. The adverse event itself in these circumstances is itself evidence that a mistake or error was made. With the Swiss cheese model there is usually a series of clear errors that can be identified. This model then allows preventative strategies to be implemented and, with the increasing move back to professional responsibility for compliance, in theory at least the 'holy grail' of the perfectly safe hospital should be attainable.

However, most adverse events in hospital, particularly the more serious ones, often do not have such clear errors with a high degree of face validity and obvious temporal relationships with the adverse event and the contributing errors. When the temporal relationship between the adverse event and the preventative strategies is not so obvious, hospital cultural factors start to be more significant, and the potential for policy and procedure to help is much less so, simply because it can be and often is ignored.

Problems with the Swiss cheese model: why are hospitals different from other industries?

There are three fundamental problems with the application of the Swiss cheese model to adverse events in hospitals. First, in the hospital, the distinction between individual and organizational accidents is not clear. The entire premise of the Swiss cheese model was the investigation of causation factors of large industrial accidents as opposed to individual accidents. In the hospital we do not have large scale accidents but, instead, multiple little accidents or adverse events daily, if not hourly, and in almost every setting.

The literature on causation of adverse events in hospitals overwhelmingly points to failures at the sharp end of care delivery to the patient by frontline staff. Analysis of the causative factors associated with the adverse events in the Quality in Australian Health Care Study found that cognitive failure was a factor in 57% of these adverse events (Wilson et al, 1999). In this analysis, cognitive failure included such errors as:

- Failure to synthesize, decide and act on available information
- Failure to request or arrange an investigation, procedure or consultation
- Lack of care or attention
- Failure to attend
- Misapplication of, or failure to apply, a rule, or use of a bad or inadequate rule (Wilson et al, 1999).

A two-hospital study from the UK, that looked at 100 sequential admissions to the intensive care unit from ward areas, found that fifty four had sub-optimal care on the ward before transfer (McQuillan et al, 1998). This group of patients had a mortality rate of 56%. Some sub-optimal treatment factors included failure to seek advice, lack of knowledge, failure to appreciate clinical urgency, and lack of supervision (McQuillan et al, 1998).

Adoption of the Reason Swiss cheese model for organizational accidents has led the whole quality and safety industry, and in particular hospitals, to focus almost exclusively on system solutions to what can be explained by individual competency and micro-environment cultural issues at the patient interface. In particular, a major rationale of Reason's philosophy is to avoid individual accountability for errors and the culture of blame and shame. However, Reason himself noted the folly of this approach in the medical setting when he stated:

> **'It is curious that such a bastion of discretionary action as medicine should be moving towards a "feed forward" mode of control when many other hitherto rule dominated domains – notably railways and oil**

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exploration and production – are shifting towards performance-based controls and away from prescriptive ones' (Reason, 1997).

When Reason talks about human contribution to organizational accidents he describes two schemas of control. A 'feed forward' control system is one where human performance is determined by rules and procedures as determined by organizational standards and objectives. In this schema occasional accidents and incidents are analysed and then fed back into either an alteration of an existing rule or procedure or the creation of a new one. At the other end of the control spectrum there is the model where organizational output is largely determined by individual human performance.

The basis for this model is that, in the first instance, the humans are generally highly trained and that performance is controlled by continual performance reinforcement against a known or standard comparator. The best example of this, in hospitals, is specialist medical practice. To even start specialist training there have been many years of training and experience (medical school, house officer jobs, and pre-specialty registrar placements) followed by a period of mentoring and, in essence, apprenticeship to learn the specialty to the known standard of the comparator; the standard of practice as maintained by the specialty colleges. Taking these two schema one can immediately see the trouble with health care in hospitals. It is a large industry with community and political expectations that are more congruent with the 'feed forward' schema (*Figure 3*), yet with most of the actual clinical activity being undertaken by the 'human performance' schema (*Figure 4*).

Figure 3. The Reason 'feed forward' process control system. From Reason (1997).

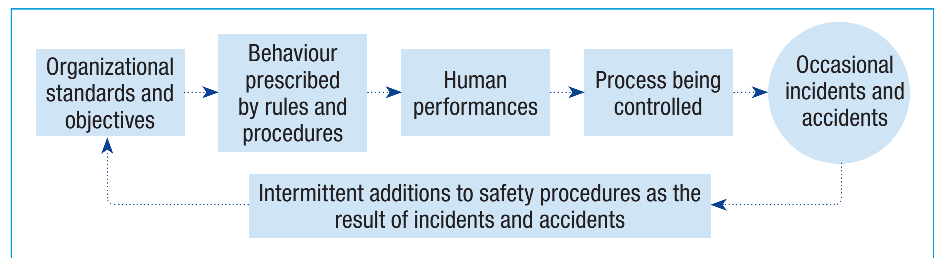
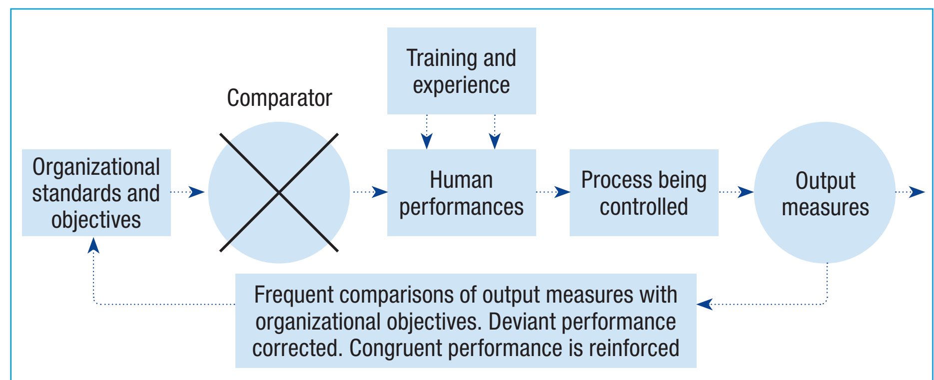


Figure 4. The Reason feedback process control system. From Reason (1997).



Thus what we have seen in the construction of hospital adverse event defences is an over-reliance on the administrative blunt end of the organization, in terms of policy and procedures, with the assumption that the health-care professionals at the patient end are competent and will be compliant. The shift to looking for hospital-wide problems has come at the cost of avoiding the issue of individual professional accountability and associated issues, most notably the education and certification of health care professionals. Several studies in Australia (Buist et al, 1999, 2001; Harrison et al, 1999) and the UK (McQuillan et al, 1998), indicate that the medical undergraduate syllabus does not provide graduates with the basic knowledge, skills and judgment to manage acute life-threatening emergencies. These studies identified deficiencies in cognitive abilities, procedural skills and communication. Despite this, undergraduate and postgraduate curricula have been slow to embrace a patient safety culture (Stevens, 2002; Cooper, 2004).

The second fundamental problem with the Swiss cheese model and the Palmieri variation of this is that they are overly simplistic and do not take into account the complexity of the patient and the hospital system. When a patient enters a hospital system, he/she enters a system where the patient will be exposed to a variety of hazards which, in turn, have numerous defences in place to prevent an adverse patient outcome. Operations, anaesthesia, medical interventions and procedures, drugs and fluids and even oxygen therapy constitute the hazards.

Most defences in health care are reliant on the competence of the health-care professional and as such are 'soft.' 'Hard' defences are those that are impossible to overcome, for example in anaesthesia where the administration of hypoxic gas mixtures is physically prevented. The soft defences in health care include treatment policies and procedures, manual alarm systems, and ad-hoc hierarchical and lateral human checking systems. Soft defences are very reliant on the training and education that health-care workers receive and the culture of compliance.

Superimposed on these layers of hazards and defences that confront a patient, there are the latent conditions that exist, most obviously within the patient, but more insidiously within the hospital as an organization. A patient's past medical history, family history, social history, associated comorbidities, drug regimen and allergies largely constitute his/her latent conditions. These conditions, and their relation to the current presenting complaint that brings the patient into the hospital system, is territory that individual health-care workers are usually extremely well trained in and familiar with. Hospital latent conditions are not so explicit, particularly to the patient or the frontline health-care worker. They are made up of a complex matrix of production and cultural imperatives such as the financial operating environment, political and societal imperatives, medico-legal and insurance concerns, compliance issues imposed by various regulatory bodies (often with associated financial incentives or disincentives) and workforce and work-practice issues. Thus in the hospital system, unlike any other industry, we have a high degree of ever-changing complexity; complex patients and a complex system where adverse events are essentially prevented by a whole host of predominantly soft defences (Buist, 2011). The Swiss cheese model is a static model with fixed defences in terms of the layers and the size of holes in each layer. This

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KEY POINTS

- The 'Swiss cheese' model was developed to understand causation of large scale organizational and industrial accidents. In principle it looks for holes in the defence layers of a large organization that are largely administrative and not the fault of individuals that may be directly involved with the accident.
- This model has limitations when applied to health care, where most of the errors or accidents are individual technical errors or competency deficiencies.
- The use of the Swiss cheese methodology has led to an over-reliance on looking for system issues in health care. This has resulted in decreased focus on the individual performance of the health-care professional and avoidance of difficult cultural workplace issues.

translates well into most industries, but in health care, the complexity is dynamic and ever changing, the number of holes and layers change with every patient and each and every different health-care professional.

The third problem with the Swiss cheese model is that adverse events in hospitals occur so insidiously that they become normalised into the operating behaviour and practice of the organization. This is distinct from large-scale industrial accidents, where the impact of the event has a high degree of face validity, primarily as a result of the immediacy and scale of the event. Therefore, in terms of numbers, patient adverse events may constitute a crisis. However, to the individual practitioner or even hospital these events may not appear to be a problem. On the whole, such events are infrequent and occur, over a long time frame. For example, the Quality in Australian Healthcare Study looked at a random sample of 14 179 admissions to 28 hospitals in two states of Australia in 1992 and documented 112 deaths (0.79%) and 109 cases where the adverse event caused greater than 50% disability (0.77%) (Wilson et al, 1995). Seventy per cent of the deaths and 58% of the cases of significant disability were considered to have had a high degree of preventability (Wilson et al, 1999). Thus, for the individual clinicians, treating departments and units, and even the 28 study hospitals themselves, their actual experience of these outcomes, over the year would be minimal (one or two cases).

Conclusions

The Swiss cheese model gives a poor explanation of the multitude of insidious individual accidents that occur in hospitals and is too simplistic for the complexity of most patients and the complex matrix of health care that is provided in a hospital. Most importantly, the focus on system issues while valid and important, has detracted from what is really needed; focussed attention on clinical competence and accountability at the patient interface. **BJHM**

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Conflict of interest: Professor M Buist is a shareholder in Patientrack. He was the founder and has been a director of this company; Dr S Middleton: none.

Australian Commission on Safety and Quality in Health Care (2012) *Safety and Quality Improvement Guide Standard 10: Preventing Falls and Harm from Falls.* Australian Commission on Safety and Quality in Health Care, Sydney

Australian Commission on Safety and Quality in Health Care (2013) *Literature Review: Medication Safety in Australia.* Australian Commission on Safety and Quality in Health Care, Sydney

Australian Commission on Safety and Quality in Health Care (2015) *Guide to the National Safety and Quality Health Service Standards for health service organisation boards.* Australian Commission on Safety and Quality in Health Care, Sydney

Baker GR, Norton PG, Flintoff V et al (2004) The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. *CMAJ* **170**: 1678–86 (doi: 10.1503/cmaj.1040920)

Brennan TA, Leape LL, Laird NM et al (1991) Incidence of adverse events and negligence in hospitalised patients: results of the Harvard Medical Practice Study I. *N Engl J Med* **324**: 370–6 (doi: 10.1056/NEJM199102073240604)

Buist M (2011) The challenge of predicting in-hospital cardiac arrests and deaths. In: Bellomo R, DeVita M, Hillman K, eds *Textbook of Rapid Response Systems*. Springer, New York

Buist M, DeVita M (2010) How I nearly met my maker; A story of clinical futile cycles and survival. *Jt Comm J Qual Patient Safety* **36**(7): 334–6

Buist M, Middleton S (2013) What went wrong with the quality and safety agenda? An essay by Michael Buist and Sarah Middleton. *BMJ* **347**: f5800 (doi: 10.1136/bmj.f5800)

Buist M, Burton P, Jarmolowski E, Bernard S, Waxman B (1999) Recognising clinical instability in hospital patients before cardiac arrest or unplanned admission to Intensive Care: A pilot study. *Med J Aust* **171**: 22–5

Buist M, Jarmolovski E, Burton P, McGrath B, Waxman B, Meek R (2001) Can Interns manage clinical instability in hospital patients? A survey of recent graduates. *Focus on Health Professional Education* **3**(3): 20–8

Buist M, Bernard S, Anderson J (2003) Epidemiology and prevention of unexpected in hospital deaths. *Surg J R Coll Surg Edinb Irel* **5**: 265–8 (doi: 10.1016/S1479-666X(03)80042-2)

California Medical Association (1977) *Report of the Medical Insurance Feasibility study.* California Medical Association, San Francisco

Cooper N (2004) Medical training did not teach me what I really needed to know. *Student BMJ* **12**: February (doi: 10.1136/sbmj.040287)

Davis P, Lay-Yee R, Briant R, Ali W, Schug S (2002) Adverse events in New Zealand public hospitals I: occurrence and impact. *N Z Med J* **115**(1167): U271

Harrison GA, Hillman KM, Fulde GWO, Jacques TC (1999) The need for undergraduate education in critical care. *Anaesth Int Care* **27**: 53–8

Haynes AB, Weiser TG, Berry WR et al (2009) A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* **360**: 491–9 (doi: 10.1056/NEJMsa0810119)

Leape LL, Brennan TA, Laird N et al (1991) The nature of adverse events in hospitalised patients: results of the Harvard Medical Practice Study II. *N Engl J Med* **324**: 377–84 (doi: 10.1056/NEJM199102073240605)

McQuillan P, Pilkington S, Allan A et al (1998) Confidential enquiry into the quality of care before intensive care unit admission. *BMJ* **316**: 1853–8

Mendes W, Martins M, Rozenfeld S, Travassos C (2009) The assessment of adverse events in hospitals in Brazil. *Int J Qual Health Care* **21**(4): 279–84 (doi: 10.1093/intqhc/mzp022)

Palmieri PA, Delucia PR, Peterson LT, Ott TE, Green A (2008) The anatomy and physiology of error in adverse health care events. *Advances in Health Care Management* **7**: 33–68 (doi: 10.1016/s1474-8231(08)07003-1)

Reason J (1997) *Managing the Risks of Organizational Accidents.* Ashgate, Aldershot, Hampshire

Shojania KG, Thomas EJ (2013) Trends in adverse events over time: why are we not improving. *BMJ Qual Saf* **22**: 273–7 (doi: 10.1136/bmjqs-2013-001935)

Sommella L, de Waure C, Ferriero AM et al (2014) The incidence of adverse events in an Italian acute care hospital: findings of a two stage method in a retrospective cohort study. *BMC Health Serv Res* **14**: 358 (doi: 10.1186/1472-6963-14-358)

Soop M, Fryksmark U, Kooster M, Haglund B (2009) The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care* **21**(4): 285–91 (doi: 10.1093/intqhc/mzp025)

Sousa P, Uva, AS, Serranheira F, Nunes C, Leite ES (2014) Estimating the incidence of adverse events in Portuguese hospitals: a contribution to improving quality and safety. *BMC Health Serv Res* **14**: 311 (doi: 10.1186/1472-6963-14-311)

Stevens DP (2002) Finding safety in medical education. *Qual Saf Health Care* **11**: 109–10 (doi: 10.1136/qhc.11.2.109)

Thomas EJ, Studdert DM, Burstin HR et al (2000) Incidence and types of adverse events and negligence care in Utah and Colorado in 1992. *Med Care* **38**: 261–71

Vincent C, Neale G, Woloshynowych M (2001) Adverse events in British hospitals: preliminary record review. *BMJ* **322**(7285): 517–19 (doi.org/10.1136/bmj.322.7285.517)

Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD (1995) The Quality in Australian Health Care Study. *Med J Aust* **163**: 458–71

Wilson RM, Harrison BT, Gibberd RW, Hamilton JD (1999) An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Med J Aust* **170**: 411–15

Zegers M, de Bruijne MC, Wagner C et al (2009) Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective study. *Qual Saf Health Care* **18**(4): 297–302 (doi: 10.1136/qshc.2007.025924)

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