
Adverse Events in Hospitals: “Swiss Cheese” Versus the “Hierarchal Referral Model of Care and Clinical Futile Cycles”

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Additional information is available at the end of the chapter

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Abstract

The James Reason ‘Swiss Cheese’ model of adverse event causation has been the predominant principle in the determination and prevention of health-care-associated adverse events for the last 20 years. This model was developed to understand the causation of large-scale organisational and industrial accidents. In principle, it looks for holes in the defence layers of a large organisation 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 or competency deficiencies within a background of an ever-changing micro socio-cultural environment. As such, using ‘Swiss Cheese’ methodology, there has been an over reliance on looking for system issues in health care that has led to a decreased focus on the individual performance of the health-care professional and avoidance of difficult cultural workplace issues. Clinical futile cycles (CFCs) are a model of adverse event causation that primarily focuses on the interaction between the immediate health-care professionals and patients and between health-care professionals. This focus allows for interventions that address issues such as clinical competency and the culture of the health-care environment.

Keywords: clinical futile cycles, health-care adverse events, Swiss cheese

Clinical vignette

Mrs. M, a fit 69-year-old, underwent an uncomplicated elective laparoscopic cholecystectomy [1]. The next morning (Day-1), upon review by the surgical team, it was decided that she should remain for

overnight observation due to some shoulder tip pain and nausea. That afternoon, she was transferred without the consultation of the surgical team from the surgical ward to a low dependency rehabilitation unit. By the following morning (Day-2), she was tachycardic, diaphoretic and had a distended abdomen. The ward medical officer reviewed Mrs. M and prescribed intravenous (IV) fluids and analgesia, ordered blood tests, and requested an urgent surgical review. The surgical team then saw Mrs. M as part of their usual morning ward round, and she still had generalised abdominal tenderness and abnormal vital signs. An abdominal X-ray and CT scan were ordered.

Mrs. M continued to deteriorate over the day. Another set of abnormal vital observations was taken sometime after the ward round, yet no doctor was informed. Mrs. M was seen by the two interns attached to the surgical unit. They were called to review her in the CT room due to concerning vital signs and contacted their registrar for assistance. They prescribed IV therapy and analgesia following their registrar's phone advice.

Upon discussion of the CT results between the consultant and registrar midday, it was decided that Mrs. M was to return to theatre later that day for explorative laparotomy, and then to transfer to ICU for post-operative observation. Mrs. M was therefore assessed by the intensivist on-duty who diagnosed peritonitis and renal failure, and prescribed triple antibiotics and rapid IV fluid therapy, and strict monitoring of fluid balance. She was concurrently seen by the anaesthetist on-duty for pre-anaesthetic assessment. As Mrs. M had single IV access, only one antibiotic was administered by the time she was called to the operating room.

Once in the operating theatre, surgery was delayed by an hour and ten minutes when Mrs. M becoming profoundly hypotensive upon anaesthetic induction. A bile leak was found intra-operatively and the abdomen lavaged. It was not discovered until her arrival in ICU later that evening that Mrs. M had only received one of the three prescribed antibiotics. By then, Mrs. M was severely septic, requiring inotropes, dialysis and mechanical ventilation. A second laparotomy, 2 days (Day-5) later found widespread bowel and hepatic ischaemia, and Mrs. M died the next day of multi-organ failure (Day-6).

Analysis of case

The death of Mrs. M, a fit 69-year-old lady, who underwent an elective procedure, is a classic case of clinical futile cycles (CFC) [1–3]. This term has been borrowed from biochemistry where two (or more) always on enzymatic systems change one chemical to another and then back to the original chemical with no net output but the use of much energy. In Mrs. M's case, there was certainly a lot of clinical activity from all levels of the medical and nursing hierarchy; yet, the net outcome was a preventable death. The ward doctor on day 2 did all the right things, IV fluids, ordered labs, and requested an urgent surgical review. The surgical team certainly had this patient on the radar, performed a CT scan, and got the theatre organised and the post op ICU bed. The surgical registrar gave good instructions over the phone and the consultant agreed with all of the above and undertook the re-operations.

However, if we 'scratch the surface' a bit more in this case sadly, Mrs. M found herself in the midst of an unintended CFC:

- nurses, doing the right thing, taking the observations and notifying the medical staff,
- interns with little knowledge and even less experience (too much time at med school learning ALS and CPR, but not enough time with real sick patients) of acutely deteriorating patients and certainly not enough emotional intelligence to manage all the players in a clinical scenario like Mrs. M's,
- a surgical registrar who would have all the competencies, but is too busy to attend the patient and direct the care at the bedside and instead delegates tasks to the interns above by phone and
- a consultant surgeon with the skill and ability to fix the problem but most commonly employed only on a sessional basis, so often not actually there in the hospital in question.

So, at four levels above in the traditional hierarchical referral model of care, everyone is doing the right thing. CFC is the explanation for all this activity, whilst appropriate for the individual practitioner concerned was not sufficient to get Mrs. M to theatre more urgently to have the problem fixed. In addition to the CFC, we have become accustomed to the naïve expectation that some sort of track and trigger system (Medical Emergency Team, Rapid Response System) will fix the problem by getting the patients deterioration alerted. However, that is all they do. The rest is up to the clinicians on the ground to make the right diagnosis, determine the level of severity of the condition, initiate management, notify the right people and with all pressures of the job to do this in a timely fashion to prevent patient catastrophe [4, 5]. All too often, it is only patient physiological reserve that defends patients from a system of care that is designed to fail them.

1. Introduction

The first chapter in this series of Patient Safety Vignettes [6] gives an overview of adverse events in health care and provides a standardised glossary of the various definitions that are used. An adverse event is defined as an injury resulting from a patient's medical management rather than a consequence of the patient's underlying medical condition or conditions [6–10]. Adverse events are common and costly to both the affected patients and the health-care system [6, 11–18]. In the last two decades, the incidence, aetiology and outcomes from adverse events have been documented mostly in the hospital setting [6, 11–23]. 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 such that they either die or are left with some sort of permanent disability as a result of the adverse event (**Table 1**) [37]. In 1995, the cost of adverse events to the Australian health-care system was estimated at \$2 (AUD) billion dollars [8]. Attempts to reduce the incidence of adverse events and make hospitals safer have been largely unsuccessful [38–41]. 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

Study (year of study)	Methodology	Setting	Sample	Incidence (%)	Outcome death	Outcome permanent disability	Preventability	Negligent care	Cost (annual)
California medical association (1977) [24]	Random sample retrospective case note review			4.2	N/A	N/A	N/A	19.1%	
Harvard medical practice study (1991) [25, 26]	Two-stage random sample retrospective case note review	51 acute-care New York State hospitals	30,121	3.7	13.6%	2.6%	58%	N/A	N/A
Utah and Colorado study (1992) [27]	Random sample retrospective case note review	28 general hospitals	15,000	2.9	6.6%	8.5%	53%	30%	
Quality in Australian Health Care Study (1992) [28]	Two-stage random sample retrospective case note review	28 acute-care hospitals of different sizes in 2 Australian states	14,179	16.6	4.9%	8.9%	51%	N/A	\$2 billion (AUD)
New Zealand public hospitals (1998) [29]	Two-stage random sample retrospective case note review	13 general acute hospitals	6579	11.2	15% for both categories		N/A	N/A	
United Kingdom (1999) [30]	Random sample retrospective case note review	2 acute-care London hospitals	1014	11.7	8.2%	6.3%	N/A	N/A	
Canadian health care study (2000) [31]	Two-stage random sample retrospective case note review	1 teaching, 1 large community and 2 small community hospitals	3745	7.5	20% for both categories		36.9%	N/A	
Brazilian hospitals (2003) [32]	Random sample retrospective case note review	3 teaching hospitals in Rio de Janeiro	1103	7.6	N/A	N/A	66.7%	N/A	
Dutch hospitals (2004) [33]	Three-stage random sample retrospective case note review	21 acute-care hospitals	7426	5.7	12.8% for both categories		40.3%	N/A	

Study (year of study)	Methodology	Setting	Sample	Incidence (%)	Outcome death	Outcome permanent disability	Preventability	Negligent care	Cost (annual)
Italian acute care hospitals (2008) [34]	Two-stage random sample retrospective case note review	1 acute-care hospital	1501	3.3					
Portuguese hospitals (2009) [35]	Two-stage random sample retrospective case note review	3 acute-care hospitals in Lisbon	1669	11.1	10.8%		53.2%		Euro 470,380 Direct costs
Swedish Hospitals (2009) [36]	Three-stage random sample retrospective case note review	28 acute-care hospitals	1967	12.3	3.0%	9.0%	70%	N/A	63,000 hospital bed days

Table 1. Epidemiology of adverse events.

theory to explain adverse events in health has been the ‘Swiss Cheese’ model developed by James Reason from his analysis of large-scale industrial and organisational accidents [42]. In this chapter, we examine the theory and, in particular, 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. We then propose an alternative called CFC within the traditional hierarchical referral system of care, to explain hospital setting adverse events which takes into account some of the unique cultural systems that exist in health care, but in hospitals in particular [43, 44]. Finally using this model, we then propose some fundamental reforms for the prevention of these adverse events in hospitals.

2. The ‘Swiss cheese’ model of health care and hospital setting adverse events

James Reason in his book ‘Managing the Risks of Organizational Accidents’ states that organisational accidents, as opposed to individual accidents, are predictable events [42]. An individual accident is one in which a person or a group of people makes an individual slip, lapse or error of judgement with the net 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, organisational accidents have ‘multiple causes involving many people at different levels of an organization’ [42]. These events, whilst usually infrequent, are often catastrophic. Analyses of such organisational accidents often reveal that the defences an

organisation 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 organisational 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 et al. published their 'Health Care Error Proliferation Model' of adverse health-care events [45]. This model takes the 'Swiss Cheese Model' and specifically adapts the various factors that exist in health care. Most notably, they place clinician vigilance as a key defence at the sharp end of the actual adverse event, in the form of clinical improvisation and localised workarounds. This clinician vigilance repairs gaps produced by actions, changes and adjustments that are made at the blunt end of the health-care organisation with its administrative and therefore higher level, layers of defence. A good example of this is the use of high-definition mobile telephone devices in rural and regional settings that allow almost an 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 organisations' patient privacy policies that have been developed at the blunt administrative end of the organisation.

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 organisation's administration [46]. These defences, in the hospital, 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 [46]. The aim of each of these blunt end defence layers is to continually decrease the size of the holes in each defence layer, by more audits, meetings and root cause analysis projects combined with the use of the quality improvement cycle. Inevitably, what are generated are recommendations, guidelines and more policy and procedure.

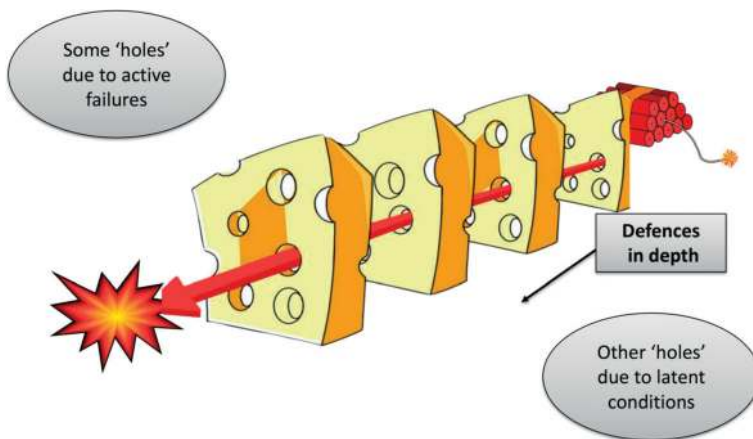


Figure 1. The reason 'Swiss cheese' model [37] (with kind permission from Ashgate Publishing).

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, the root cause analysis of these events often highlights holes in the 'Swiss Cheese', such as poor transcription of medication prescriptions and failure to do appropriate checks [47]. In the case of patient falls, there is failure to identify the 'at risk' patient and put appropriate preventative strategies in place. Fixing the holes or at least reducing the size of them can reduce the incidence of patient falls and medication errors. This can be done by and large with top-down policy and procedure and ensuring implementation of such [47]. The best example of this has been the reduction in the incidence of wrong-side surgery, with the implementation of time-out, with completion of a check list before surgery [48]. The Reason 'Swiss Cheese' model gives good explanation of the adverse event when there is a relatively tight temporal relationship, between the adverse event and the preventative strategies. The adverse event in these circumstances is itself evidence that a mistake or error was made. There is usually a series of clear errors with the 'Swiss Cheese' model that can be identified. This model then allows for 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 tight temporal relationship with the adverse event and the contributing errors. When the temporal relationship between the adverse event and the preventative strategies is not so tight, 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.

3. 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 organisational 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 study on the 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 [49]. In this analysis, cognitive failure included such errors as failure to synthesise, 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 [49]. In a two-hospital study from the United Kingdom that looked at 100 sequential admissions to the intensive care unit (ICU) from ward areas, it was found that 54 had sub-optimal care on the ward prior to transfer [50]. This group of patients had a mortality rate of 56%. Some of the

sub-optimal treatment factors included failure to seek advice, lack of knowledge, failure to appreciate clinical urgency and lack of supervision [50].

The adoption of the Reason 'Swiss Cheese' model for organisational accidents has led the whole Quality and Safety industry, and in particular hospitals, looking for 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. Nearly 20 years ago, Reason himself noted the folly of this approach in medicine 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 exploration and production – are shifting towards performance-based controls and away from prescriptive ones*' [42]. When Reason talks about human contribution to organisational accidents, he describes two schemas of control [42]. A 'Feed Forward' control system is one where human performance is determined by rules and procedures as determined by an organisational standards and objectives (**Figure 2**). In this schema, occasional accidents and incidents are analysed and then fed back into either an alteration of an existing rule or a procedure or the creation of a new one. At the other end of the control spectrum, there is the model where organisational output is largely determined by individual human performance (**Figure 3**). 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 a 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 schemas, 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, but yet with most of the actual clinical activity being undertaken by the 'Human Performance' schema.

Thus, what we have seen in the construction of hospital adverse event defences is an over-reliance on the administrative blunt end of the organisation, in terms of policy and procedures,

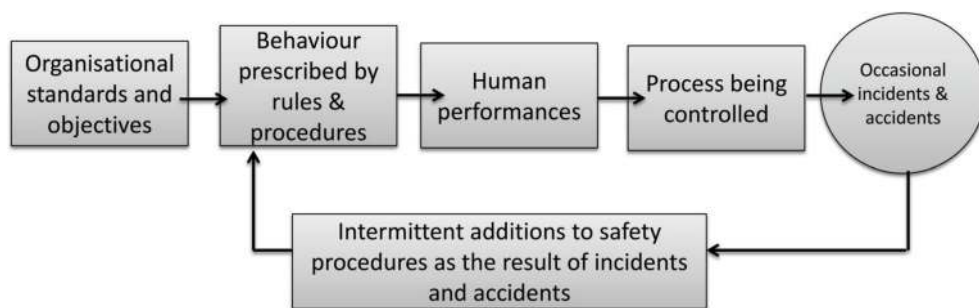


Figure 2. The reason 'feedforward' process control system [37] (with kind permission from Ashgate Publishing).

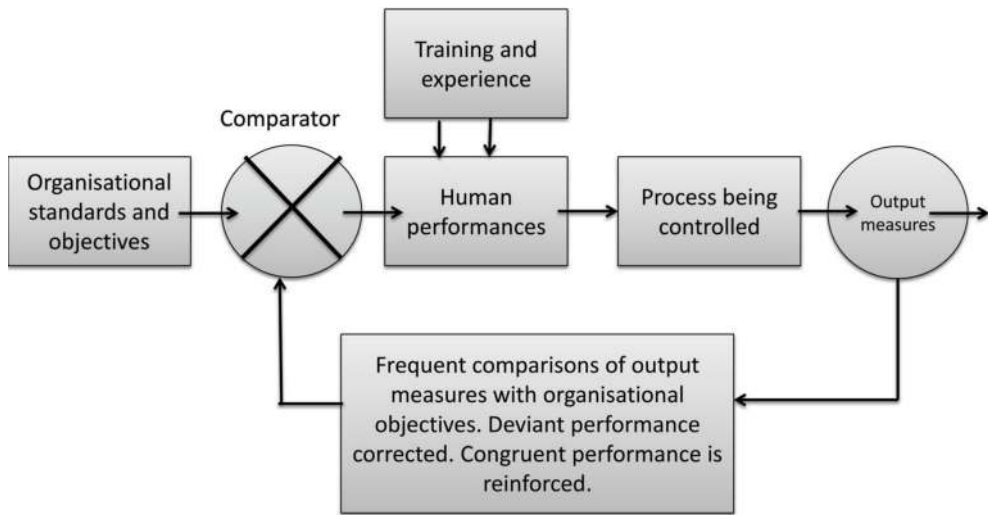


Figure 3. The reason feedback process control system [37] (with kind permission from Ashgate Publishing).

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. In Australia and the United Kingdom, several studies indicate that the medical undergraduate syllabus does not provide graduates with the basic knowledge, skills and judgement to manage acute life-threatening emergencies [51–53]. 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 [54–56].

The second fundamental problem with the 'Swiss Cheese' model and the Palmieri variation of this are 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, they enter a system where they 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 organisation. A patient's past medical history, family history, social

history, associated co-morbidities, drug regimen and allergies largely constitute their latent conditions. These conditions and their relation to the current presenting complaint that brings the patient into the hospital system are 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 [57]. 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 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 organisation. This is distinct from large-scale industrial accidents, where the impact of the event has a high degree of face validity, primarily due to 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 Health Care 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%) [14]. Seventy per cent of the deaths and 58% of the cases of significant disability were considered to have had a high degree of preventability [49]. 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) [14].

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 whilst valid and important has detracted from what is really needed: focussed attention on clinical competence and accountability at the patient interface.

4. CFC and the traditional hierarchical referral model of care

The term ‘Futile Cycle’ is a term used in cell biology and biochemistry to explain the conversion of one substance to another and back to the original substance by two always on enzymatic pathways. However, despite the enzymatic activity and energy utilisation, there is no net output or gain from this energy-consuming and active process. This is exactly what we see with hospital patient adverse events and in particular the deteriorating patient, a lot of clinical activity, none of which effectively alters the trajectory of the patient towards the adverse event. The clinical activity

occurs in a traditional hierarchical referral model of care that by its very nature is often either unresponsive or slowly responsive and where the exhaustive policy and procedures are often ignored.

In the hospital, the CFC usually starts with the most junior level of the 'traditional hierarchical referral model of care', at the bedside with the interaction between the junior nurse and the patient (Figure 4). With a clinical abnormality, be it an observation, a wrong drug order or a procedural failure, the junior nurse must make a decision as to the significance of the abnormality and the importance of reporting it to a more senior team member, either a senior nurse or the most available (usually junior) doctor. However, that decision to escalate the issue can be influenced in the workplace culture that exists in the particular micro-environment of that bedside and that ward at that time [58]. If the concern or abnormality is escalated, it is to the next person in the care hierarchy of the team looking after that patient. This is often the junior doctor who then needs to attend, assess and then also make a decision about whether or not to escalate the issue to the next person in the hierarchy. This is important because, for the most, the junior doctor does not have the skills or emotional intelligence to appropriately manage many of these clinical abnormalities [51–54]. If the issue is escalated, it is often to a middle-grade doctor, one who is often a specialist in training and who as such may be difficult to find. Unlike their juniors, usually this grade of doctor does have the technical and clinical abilities to deal with the particular issue. However, they are often over-committed with clinics, operating theatre, but more importantly often see themselves more like the consultants they aspire to be rather than a junior doctor having to deal with patient problems on

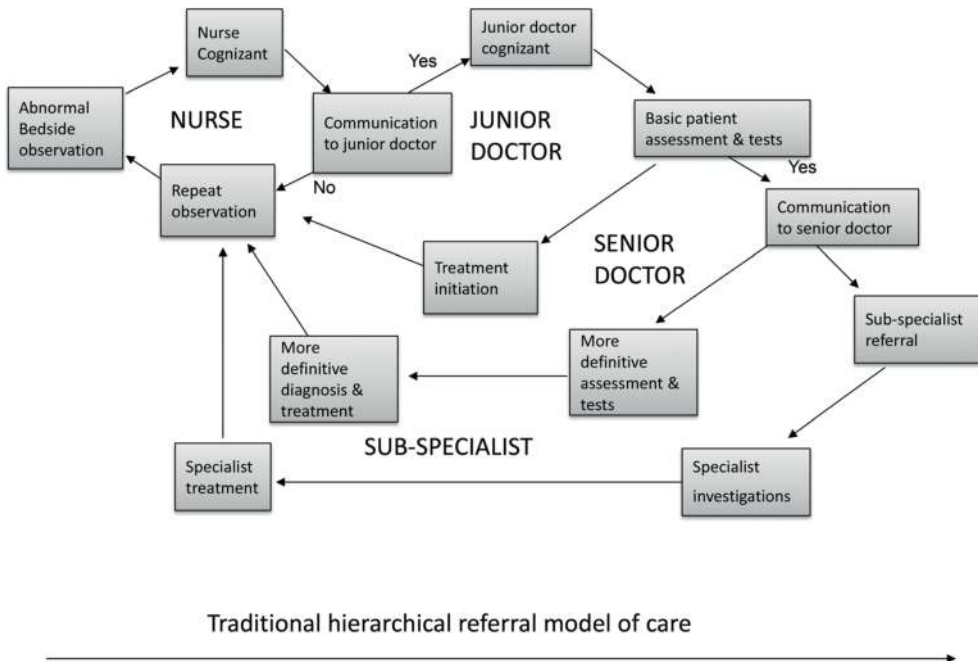


Figure 4. Clinical futile cycles [38, 39].

the ward. In addition, this grade of doctor is diagnosis-focused and often we see them giving instructions to their juniors (usually appropriately) to organise specialised investigations and other speciality consultations. There is nothing wrong with this, except for the fact that it is time-consuming [59].

In support of the CFC model is the study that has looked at the causation of adverse events in hospitals [13, 37, 49, 50]. All these studies can assign almost all causation to three human factor issues at the patient interface: competency, cognition (or failure thereof) and culture. Perhaps, the most disturbing example of this was described in the MERIT study, a randomised cluster control study of Medical Emergency Teams (MET) [60] in 23 Australian hospitals (including private and rural hospitals) in 2002. In the nearly 500 cardiac arrests that occurred during the study, in more than a third of instances staff took abnormal (that breached MET activation criteria) patient observations in the 15 min prior to the cardiac arrest, but did not activate an emergency response. The first thing of note with this phenomenon was that the incidence of not calling for help in an abnormal patient situation was high at 30% in the intervention hospitals and 40% in the control hospitals. Put in another way, in the average Australian hospital in 2002, if a patient had documented abnormal signs, in the 15 min before a cardiac arrest, in up to 40% of the time the staff did nothing about this. Another thing of note with these findings is that in intervention hospitals that had an intense education process on the new MET activation policy and procedure, the incidence of calling for help was only 10% greater than the control hospitals [60]. It is here at the bedside with the pre-cardiac arrest patient that the staff are trapped in a CFC, unable to get out of it due to either clinical incompetency (not able to recognise and act for the pre-arrest patient) and/or culture, whereby calling for help maybe considered not the norm in that ward, on that shift at that time [4, 5, 61–64].

The ‘Swiss Cheese’ response when RRS fails at the sharp end, for whatever reason, the response is to assume policy and procedure failure, despite the fact that there is no direct evidence for the benefit of Rapid Response Systems (RRS) [62–64]. However, it is well documented that there may be problem with the face validity of RRS due to the very low specificity of the activation criteria [65–67]. Furthermore, there may be problems around staff competency or cultural issues around staff losing face by calling for help. As a result, rather than trying to understand or deal with this very real issue of face validity, possible competency issues and probable cultural issues, the administrative response, all too often, is just to alter the policy and procedure and make the activation criteria mandatory for the bedside staff [68].

5. Using CFC to safety proof health from the sharp end back

If we accept the model of CFC, it becomes immediately apparent that no amount of activity away from the sharp end of the health-care adverse event will help, least of all the generation of a more policy and procedure. Instead, we need to focus attention on the health-care professional and the immediate socio-cultural environment in which they work [69].

Dealing first with the health-care worker, the selection of these individuals to undertake their chosen vocation is invariably done by consideration of various personal attributes, in the case of medicine academic achievement and individual performance in tests [69–73]. This process

and subsequent education takes no account of the fact that as soon as these people graduate, they will be working in a team environment.

The clinical care we deliver (and receive) is a function of the education and capability of our students who will eventually be our doctors and ultimately clinical leaders and decision-makers. What we teach and practise best is the point-of-care medicine and clinical interventions. Therefore, it is no surprise that what we examine and what students focus on are specific point-of-care clinical assessments and interventions [74]. This is best represented by the objective, structured, clinical, examination system (OSCE) that is now a widespread and common form of summative assessment [75]. In the OSCE, candidates undertake clinical assessment tasks at a number of specific stations for 5–8 min. Each station has a structured 'score card' that students must address to get the points. This system of examination in no way gives any indication on a student's ability and competency to comprehensively take a history, perform a physical examination, synthesise these findings into a meaningful problem list and finally and actually least importantly come up with a diagnosis [76]. It has got to the point now in the undergraduate curriculum that the clinical process of whole patient assessment is variably taught and certainly not examined, in a sufficiently stringent manner to motivate students to spend long hours doing patient histories and examinations. Having competent health-care professionals spend time with and understanding our patients is the single biggest step to making health care safe.

Second, priority needs to be given to the core business of hospital care, the interaction at the bedside and clinic between the patient and the various health-care professionals [4, 5, 61]. Clinical futile cycles give a practical platform to understand this culture. We need to accept that an abnormal or an inappropriate workplace culture is at the heart of every major inquiry into poor hospital care [77–82]. Every report into these enquiries recommends change. Yet, 30 years on from Bristol [81], we have mid-Staffordshire [80]. So, what have we really learned from the reports and thousands of pages of recommendations? Nothing. We need a different strategy: one that puts the patient and their well-being first. This should be followed by the implicit understanding that our core business is that of interaction with the patient from the most basic and junior levels. The bedside health-care team needs to be trained, credentialed and supported to deliver better health care, not as individual players, but as members of a team.

6. Conclusion

Despite the hundreds of millions of dollars spent on patient safety, we have very little to show for it except the fact that we know that the problem is real, common and universal to all health-care settings. In this chapter, we propose that the reason why we have not been able to improve patient safety is because we really do not understand what is going on at the point of clinical intervention.

The organisational response is based on mandated requirements, which look at system and operational issues. Rarely do we focus on the quality of the judgements made by the individual clinicians involved in adverse events and usually never do we question the clinical culture in which these events occur.

CFC provides an alternative framework to help understand adverse events and patient safety breaches, by forcing us to ask the question, 'they or she/he, knew that there was a problem, or that there might be a problem, why didn't they do something about it?' The question needs to be put to all the involved clinicians regardless of where they sit in the traditional clinical hierarchy. The answer to the question will usually fall into one of three broad categories, first those involved simply did not know what was going on, second, they did know what was going on and they tried to do something about it, and third they did know that there was a problem and for whatever reason did nothing. The answer to this one question then allows for appropriate interventions at the health-care workplace. If the involved individuals were simply oblivious to the situation, then retraining, re-credentialing and recertification are required for those clinicians. If the problem was recognised and attempts made to ameliorate it, then the more traditional root cause analysis should shed light on the issues that need resolution. Lastly, if the problem was recognised and nothing done, then cultural issues are at play. These may range from the obvious (e.g., an overall culture of not calling senior clinicians at night about problems) to more serious issues of workplace bullying and harassment (e.g., senior clinicians when called overnight about problems, being rude, belittling the caller, blaming and side-stepping the problem to avoid coming in after hours).

CFC also provides us with a term or a condition that describes the 'brain freeze' state of mind that can occur in stressful clinical situations. For the individual clinician, recognising and knowing that they have a moment of 'brain freeze' and that they are stuck in a CFC is the first step to getting out of that situation. The best way out is quite simply to ask for help, or to take time-out to reassess the problem.

In summary, we need to divert some of those hundreds of millions of dollars, away from committees, the quality and safety units, organisational and government mandatory-reporting systems back to understanding the core business of health care, the intervention between clinician and patient. Perhaps, then we will get the significant cultural change that needs to occur (and has occurred in other industries) that puts the saying 'first do no harm' at the centre of all clinical interactions.

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References

- [1] <http://www.vifmcommuniques.org/?p=5157>

- [2] Buist M, Middleton S. Aetiology of hospital setting adverse events 1: Limitations of the Swiss cheese model. *British Journal of Hospital Medicine* (London, England). 2016;**77**(11):C170-C174
- [3] Buist M, Middleton S. Aetiology of hospital setting adverse events 2: Clinical futile cycles. *British Journal of Hospital Medicine* (London, England). 2016;**77**(11):C175-C178
- [4] Kitto S, Marshall S, McMillan S, Shearer B, Buist M, Grant R, et al. Rapid response systems and collective (in) competence: An analysis of intra professional and inter professional activation factors. *Journal of Interprofessional Care*. 2015;**29**(4):340-346. DOI: 10.3109/13561820.2014.984021
- [5] Marshall S, Shearer W, Buist M, et al. What stops hospital clinical staff from following protocols? An analysis of the incidence and factors behind the failure of bedside clinical staff to activate the Rapid Response System (RRS) in a multi-campus Australian Metropolitan Health Care. *BMJ Quality and Safety*. 2012;**21**(7):569-575
- [6] Stawicki SP, Firstenberg MS. <https://www.intechopen.com/books/vignettes-in-patient-safety-volume-1/introductory-chapter-the-decades-long-quest-continues-toward-better-safer-healthcare-systems>
- [7] Cook R, Woods D, Miller C. *A Tale of Two Stories: Contrasting Views of Patient Safety*. Chicago: National Patient Safety Foundation; 1998
- [8] Cook R, Woods D. Operating at the sharp end: The complexity of human error. In: Bogner MS, editor. *Human Error in Medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994
- [9] Perrow C. *Normal Accidents*. New York: Basic Books; 1984
- [10] Reason J. *Human Error*. Cambridge: Cambridge University Press; 1990
- [11] California Medical Association. *Report of the Medical Insurance Feasibility Study*. San Francisco: California Medical Association; 1977
- [12] Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalised patients: Results of the Harvard Medical Practice Study I. *The New England Journal of Medicine*. 1991;**324**:370-376
- [13] Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalised patients: Results of the Harvard Medical Practice Study II. *The New England Journal of Medicine*. 1991;**324**:377-384
- [14] Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian Health Care Study. *The Medical Journal of Australia*. 1995;**163**:458-471
- [15] Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligence care in Utah and Colorado in 1992. *Medical Care*. 2000;**38**:261-271
- [16] Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: Preliminary record review. *BMJ*. 2001;**322**(7285):517-519

- [17] Davis P, Lay-Yee R, Briant R, Ali W, Schug S. Adverse events in New Zealand public hospitals. I: Occurrence and impact. *The New Zealand Medical Journal*. 2002;**115**(1167):U271
- [18] Baker GR, Norton PG, Flintoff V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. *CMAJ*. 2004;**170**:1678-1686
- [19] Soop M, Fryksmark U, Kooster M, Haglund B. The incidence of adverse events in Swedish hospitals: A retrospective medical record review study. *International Journal for Quality in Health Care*. 2009;**21**(4):285-291
- [20] Mendes W, Martins M, Rozenfeld S, Travassos C. The assessment of adverse events in hospitals in Brazil. *International Journal for Quality in Health Care*. 2009;**21**(4):279-284
- [21] Zegers M, de Bruijne MC, Wagner C, Hoonhut LH, Waaijman R, Smits M, et al. Adverse events and potentially preventable deaths in Dutch hospitals: Results of a retrospective study. *Quality & Safety in Health Care*. 2009;**18**(4):297-302
- [22] Sousa P, Uva AS, Serranheira F, Nunes C, Leite ES. Estimating the incidence of adverse events in Portuguese hospitals: A contribution to improving quality and safety. *BMC Health Services Research*. 2014;**14**:311
- [23] Sommella L, de Waure C, Ferriero AM, Biasco A, Mainelli MT, Pinnarelli, et al. The incidence of adverse events in an Italian acute care hospital: Findings of a two stage method in a retrospective cohort study. *BMC Health Services Research*. 2014;**14**:358
- [24] California Medical Association. Report of the Medical Insurance Feasibility Study. San Francisco: California Medical Association; 1977
- [25] Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalised patients: Results of the Harvard Medical Practice Study I. *The New England Journal of Medicine*. 1991;**324**:370-376
- [26] Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalised patients: Results of the Harvard Medical Practice Study II. *The New England Journal of Medicine*. 1991;**324**:377-384
- [27] Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligence care in Utah and Colorado in 1992. *Medical Care*. 2000;**38**:261-271
- [28] Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian Health Care Study. *The Medical Journal of Australia*. 1995;**163**:458-471
- [29] Davis P, Lay-Yee R, Briant R, Ali W, Schug S. Adverse events in New Zealand public hospitals I: Occurrence and impact. *The New Zealand Medical Journal*. 2002;**115**(1167):U271
- [30] Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: Preliminary record review. *BMJ*. 2001;**322**(7285):517-519
- [31] Baker GR, Norton PG, Flintoff V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. *CMAJ*. 2004;**170**:1678-1686

- [32] Mendes W, Martins M, Rozenfeld S, Travassos C. The assessment of adverse events in hospitals in Brazil. *International Journal for Quality in Health Care*. 2009;**21**(4):279-284
- [33] Zegers M, de Bruijne MC, Wagner C, Hoonhut LH, Waaijman R, Smits M, et al. Adverse events and potentially preventable deaths in Dutch hospitals: Results of a retrospective study. *Quality & Safety in Health Care*. 2009;**18**(4):297-302
- [34] Sommella L, de Waure C, Ferriero AM, Biasco A, Mainelli MT, Pinnarelli, et al. The incidence of adverse events in an Italian acute care hospital: Findings of a two stage method in a retrospective cohort study. *BMC Health Services Research*. 2014;**14**:358
- [35] Sousa P, Uva AS, Serranheira F, Nunes C, Leite ES. Estimating the incidence of adverse events in Portuguese hospitals: A contribution to improving quality and safety. *BMC Health Services Research*. 2014;**14**:311
- [36] Soop M, Fryksmark U, Kooster M, Haglund B. The incidence of adverse events in Swedish hospitals: A retrospective medical record review study. *International Journal for Quality in Health Care*. 2009;**21**(4):285-291
- [37] Buist M, Bernard S, Anderson J. Epidemiology and prevention of unexpected in hospital deaths. *The Surgeon: Journal of the Royal Colleges of Surgeons of Edinburgh and Ireland*. 2003;**5**:265-268
- [38] Landridge CP, Parry GJ, Bones CB, Hackbarth AD, Goldman DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. *The New England Journal of Medicine*. 2010;**363**:2124-2134
- [39] Classen DC, Resar R, Griffin F, Frederico F, Frankel T, Kimmel N, et al. Global trigger tool shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs (Millwood)*. 2011;**30**:581-589
- [40] Baines RJ, Langelaan M, de Bruijne MC, Spreeuwenberg P, Wagner C, et al. Changes in adverse events in hospitals overtime: A longitudinal retrospective patient record review study. *BMJ Quality and Safety*. 2013;**22**:290-298
- [41] Shojania KG, Thomas EJ. Trends in adverse events over time: Why are we not improving. *BMJ Quality and Safety*. 2013;**22**:273-277
- [42] Reason J. *Managing the Risks of Organizational Accidents*. Aldershot, Hampshire: Ashgate; 1997
- [43] Buist M, Harrison J, Abaloz E, Van Dyk S. Six year audit of cardiac arrests and medical emergency team calls in an outer metropolitan teaching hospital. *BMJ*. 2007;**335**(7631): 1210-1212
- [44] Buist M. How I nearly met my maker; A story of clinical futile cycles and survival. *The Joint Commission Journal on Quality and Patient Safety*. 2010;**36**(7):334-336
- [45] Palmieri PA, Delucia PR, Peterson LT, Ott TE, Green A. The anatomy and physiology of error in adverse health care events. *Advances in Health Care Management*. 2008;**7**:33-68
- [46] Buist M, Middleton S. What went wrong with the quality and safety agenda? An essay by Michael Buist and Sarah Middleton. *BMJ*. 2013;**347**:f5800

- [47] Australian Commission on Safety and Quality in Health Care. Safety and Quality Improvement Guide Standard 10. Preventing falls and harm from falls (October 2012). Sydney: ACSQHC; 2012
- [48] Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *The New England Journal of Medicine*. 2009;**360**: 491-499
- [49] Wilson RM, Harrison BT, Gibberd RW, Hamilton JD. An analysis of the causes of adverse events from the quality in Australian Health Care Study. *The Medical Journal of Australia*. 1999;**170**:411-415
- [50] McQuillan P, Pilkington S, Allan A. Confidential enquiry into the quality of care before intensive care unit admission. *BMJ*. 1998;**316**:1853-1858
- [51] Harrison GA, Hillman KM, Fulde GWO, Jacques TC. The need for undergraduate education in critical care. *Anaesthesia and Intensive Care*. 1999;**27**:53-58
- [52] Taylor D. Undergraduate procedural skills training in Victoria: Is it adequate? *The Medical Journal of Australia*. 1997;**171**:22-25
- [53] Buist M, Jarmolovski E, Burton P, McGrath B, Waxman B, Meek R. Can interns manage clinical instability in hospital patients? A survey of recent graduates. *Focus on health professional. Education*. 2001;**3**(3):20-28
- [54] Cooper N. Medicine did not teach me what I really needed to know. *BMJ*. 2003;**327**(Suppl): S190
- [55] McDonald R. New initiative to improve undergraduate teaching in acute care. *Student BMJ*. 2004;**12**:68
- [56] Stevens DP. Finding safety in medical education. *Quality & Safety in Health Care*. 2002;**11**:109-110
- [57] Buist M. In: DeVita M, Hillman K, Bellomo R, editors. *Predicting Hospital Crisis; Can we do it? The Challenge of Predicting In-Hospital Iatrogenic Deaths in Medical Emergency Teams*. New York, NY: Springer; 2011
- [58] Stewart J. To call or not to call: A judgement of risk by pre-registration house officers. *Medical Education*. 2008;**42**:938-944
- [59] Buist M, Burton P, Jarmolowski E, Bernard S, Waxman B. Recognising clinical instability in hospital patients before cardiac arrest or unplanned admission to intensive care: A pilot study. *The Medical Journal of Australia*. 1999;**171**:22-25
- [60] MERIT Study Investigators. Introduction of the medical emergency team (MET) system: A cluster randomised controlled study. *Lancet*. 2005;**365**:2091-2097
- [61] Buist M. The rapid response team paradox: Why doesn't anyone call for help? *Critical Care Medicine*. 2008;**36**(2):634-636

- [62] Jones DA, DeVita MA, Bellomo R. Rapid-response teams. *The New England Journal of Medicine*. 2011;**365**(2):139-146
- [63] Chan PS, Jain R, Nallmothu BK, Berg RA, Sasson C. Rapid response teams: A systematic review and meta-analysis. *Archives of Internal Medicine*. 2010;**170**:18-26
- [64] Cuthbertson BH, Smith GB. A warning on early-warning scores. *British Journal of Anaesthesia*. 2007;**98**:704-706
- [65] Edwards ED, Mason BW, Oliver A, Powell CV. Cohort study to test the predictability of the Melbourne criteria for the activation of the medical emergency team. *Archives of Disease in Childhood*. 2011;**96**:174-179
- [66] Edwards ED, Powell CV, Mason BW, et al. Prospective cohort study to test the predictability of the Cardiff and Vale paediatric early warning system. *Archives of Disease in Childhood*. 2009;**94**:602-606
- [67] Gao H, McDonnell A, Harrison DA, Moore T, Adam S, Daly K, et al. Systematic review and evaluation of physiological track and trigger warning systems for identifying at-risk patients on the ward. *Intensive Care Medicine*. 2007;**33**:667-679
- [68] Buist M, Shearer W. Rapid response systems: A mandatory system of care or an optional extra for bedside clinical staff. *Joint Commission Journal on Quality and Patient Safety*. 2010;**36**(6):263-265, 241
- [69] Bodenheimer T, Sinsky C. From triple to quadruple aim: Care of the patient requires care of the provider. *Annals of Family Medicine*. 2014;**12**:573-576
- [70] Barr DA. Science as superstition: Selecting medical students. *Lancet*. 2010;**376**:678-679
- [71] Parker MH, Turner J, McGurgan P, et al. The difficult problem: Assessing medical students' professional attitudes and behaviour. *The Medical Journal of Australia*. 2010;**193**:662-664
- [72] Bore M, Munro D, Powis D. A comprehensive model for the selection of medical students. *Medical Teacher*. 2009;**31**:1066-1072
- [73] Wilson IG, Roberts C, Flynn EM, Griffin B. Only the best: Medical student selection in Australia. *The Medical Journal of Australia*. 2012;**196**(5):357
- [74] Miller GE. The assessment of clinical skills/competence/performance. *Academic Medicine*. 1990;**65**(s9):S63-S67
- [75] Harden RM, Stevenson M, Downie WW, Wilson GM. Assessment of clinical competence using objective structured examinations. *BMJ*. 1975;**1**:447-451
- [76] Barman A. Critiques on the objective structured clinical examination. *Annals of the Academy of Medicine, Singapore*. 2005;**34**(8):478-482
- [77] Garling P. Final Report of the Special Commission of Inquiry: Acute Care Services in NSW Public Hospitals. Sydney: NSW Government; 2008. http://www.lawlink.nsw.gov.au/lawlink/Special_Projects/ll_splprojects.nsf/pages/acsi_finalreport

- [78] Walker B. Final Report of the Special Commission of Inquiry into Campbelltown and Camden Hospitals. Sydney: New South Wales Attorney General's Department; 2004
- [79] Hindle D, Braithwaite J, Travaglia J, Iedema R. Patient Safety: A Comparative Analysis of Eight Inquiries in Six Countries. Sydney: Centre for Clinical Governance Research, University of New South Wales; 2006. <http://www.ccc.health.nsw.gov.au/pdf/PatientSafetyreportWEB3.pdf>
- [80] Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. Volume 2: Analysis of Evidence and Lessons Learned (Part 2). London: The Stationery Office; 2013. www.midstaffpublicinquiry.com/report
- [81] Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1982-1995 (Department of Health, 2001). ISBN: 0101520727. Available from the Stationery Office
- [82] Davies G. Queensland Public Hospitals Commission of Inquiry. Brisbane: Queensland Public Hospitals Commission of Inquiry; 2005