Why is patient safety relevant to health care?

There is now overwhelming evidence that significant numbers of patients are harmed from their health care either resulting in permanent injury, increased length of stay (LOS) in hospitals and even death. We have learnt over the last decade that adverse events occur not because bad people intentionally hurt patients but rather that the system of health care today is so complex that the successful treatment and outcome for each patient depends on a range of factors, not just the competence of an individual health-care provider. When so many people and different types of health-care providers (doctors, nurses, pharmacists, social workers, dieticians and others) are involved this makes it very difficult to ensure safe care, unless the system of care is designed to facilitate timely and complete information and understanding by all the health professionals.

Patient safety is an issue for all countries that deliver health services, whether they are privately commissioned or funded by the government. Prescribing antibiotics without regard for the patient’s underlying condition and whether antibiotics will help the patient, or administering multiple drugs without attention to the potential for adverse drug reactions, all have the potential for harm and patient injury. Patients are not only harmed by the misuse of technology, they can also be harmed by poor communication between different health-care providers or delays in receiving treatment.

Patient safety is a broad subject incorporating the latest technology such as electronic prescribing and redesigning hospitals and services to washing hands correctly and being a team player. Many of the features of patient safety do not involve financial resources; rather, they involve commitment of individuals to practise safely. Individual doctors and nurses can improve patient safety by engaging with patients and their families, checking procedures, learning from errors and communicating effectively with the health-care team. Such activities can also save costs because they minimize the harm caused to patients. When errors are reported and analysed they can help identify the main contributing factors. Understanding the factors that lead to errors is essential for thinking about changes that will prevent errors from being made.

Keywords
Patient safety, system theory, blame, blame culture, system failures, person approach, violations and patient safety models.

Learning objective
The objective of this module is to understand the discipline of patient safety and its role in minimizing the incidence and impact of adverse events, and maximizes recovery from them.

Learning outcomes: knowledge and performance
Patient safety knowledge and skills covers many areas: medication safety, procedural and surgical skills, effective teamwork, accurate and timely communication and more. The topics in this Curriculum Guide have been selected based on the evidence of relevance and effectiveness. This topic takes an overview of patient safety and sets the scene for deeper learning in some of these areas. For example, we introduce the term “sentinel event” in this topic but we go deeper into its meaning and relevance to patient safety in topic 6.

What students need to do (performance requirements):
• apply patient safety thinking in all clinical activities;
• demonstrate ability to recognize the role of patient safety in safe health-care delivery.
What students need to know (knowledge requirements):

- the harm caused by health-care errors and system failures;
- the lessons about error and system failure from other industries;
- the history of patient safety and the origins of the blame culture;
- the difference between system failures, violations and errors;
- a model of patient safety.

WHAT STUDENTS NEED TO KNOW (KNOWLEDGE REQUIREMENTS)

The harm caused by health-care errors and system failures

Even though the extent of adverse events in the health system has long been recognized [1-8], the degree to which they are acknowledged and managed varies greatly across health systems and across health professions. Poor information and understanding about the extent of harm, and the fact that most errors do not cause any harm at all, may explain why it has taken so long to make patient safety a priority. In addition, mistakes affect one patient at a time and staff working in one area may only experience or observe an adverse event infrequently. Errors and system failures do not all happen at the same time or place, which can mask the extent of errors in the system.

The collection and publication of patient outcome data is not yet routine for all hospitals and clinics. However, the significant number of studies that have relied upon patient outcome data [7,9,10] show that most adverse events are preventable. In a landmark study by Leape et al. [10] found that more than two thirds of the adverse events they studied were preventable, 28% were due to the negligence of a health professional and 42% were caused by other factors not related to such negligence. They concluded that many patients were injured as a result of poor medical management and substandard care. Bates et al. [11] found that adverse drug events were common and that serious adverse drug events were often preventable. They further found that medications harmed patients at an overall rate of about 6.5 per 100 admissions in large US teaching hospitals. Although most resulted from errors at the ordering stage, many also occurred at the administration stage. They suggested that prevention strategies should target both stages of the drug delivery process. Their research, based on self-reports by nurses and pharmacists and daily chart review, is a conservative figure because doctors do not routinely self-report medication errors.

Many studies confirm that medical error is prevalent in our health system and that the costs are substantial. In Australia [13], medical error in one year resulted in as many as 18,000 unnecessary deaths and more than 50,000 disabled patients. In the United States [14], medical error resulted in at least 44,000 (and perhaps as many as 98,000) unnecessary deaths each year and one million excess injuries.

In 2002, WHO Member States agreed on a World Health Assembly resolution on patient safety because they saw the need to reduce the harm and suffering of patients and their families and the compelling evidence of the economic benefits of improving patient safety. Studies show that additional hospitalization, litigation costs, infections acquired in hospitals, lost income, disability and medical expenses have cost some countries between US$ 6 billion and US$ 29 billion a year [12,14].
The extent of patient harm from health care has been exposed by the publication of the international studies listed in Table 10. They confirm the high numbers of patients involved and show the adverse event rate in four countries.

### Table 10: Data on adverse events in health care from several countries

<table>
<thead>
<tr>
<th>Study</th>
<th>Study focus (date of admissions)</th>
<th>Number of hospital admissions</th>
<th>Number of adverse events</th>
<th>Adverse event rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>United States (Harvard Medical Practice Study)</td>
<td>Acute care hospitals (1984)</td>
<td>30 195</td>
<td>1 133</td>
</tr>
<tr>
<td>2</td>
<td>United States (Utah–Colorado study)</td>
<td>Acute care hospitals (1992)</td>
<td>14 565</td>
<td>475</td>
</tr>
<tr>
<td>3</td>
<td>United States (Utah–Colorado study)</td>
<td>Acute care hospitals (1992)</td>
<td>14 565</td>
<td>787</td>
</tr>
<tr>
<td>4</td>
<td>Australia (Quality in Australian Health Care Study)</td>
<td>Acute care hospitals (1992)</td>
<td>14 179</td>
<td>2 353</td>
</tr>
<tr>
<td>5</td>
<td>Australia (Quality in Australian Health Care Study)</td>
<td>Acute care hospitals (1992)</td>
<td>14 179</td>
<td>1 499</td>
</tr>
<tr>
<td>6</td>
<td>United Kingdom</td>
<td>Acute care hospitals (1999–2000)</td>
<td>1 014</td>
<td>119</td>
</tr>
<tr>
<td>7</td>
<td>Denmark</td>
<td>Acute care hospitals (1998)</td>
<td>1 097</td>
<td>176</td>
</tr>
</tbody>
</table>


a Revised using the same methodology as the Quality in Australian Health Care Study (harmonising the four methodological discrepancies between the two studies).
b Revised using the same methodology as Utah–Colorado Study (harmonising the four methodological discrepancies between the two studies). Studies 3 and 5 present the most directly comparable data for the Utah–Colorado and Quality in Australian Health Care studies.

The studies listed in Table 10 used retrospective medical record reviews to record the extent of patient injury as a result of health care [15-18]. Since then, Canada, England and New Zealand have published similar adverse event data [19]. While the rates of injury differ in the countries that publish data, there is unanimous agreement that the harm is of significant concern. The catastrophic deaths that are reported in the media, while horrific for the families and health professionals involved, are not representative of the majority of adverse events in health care. Patients are more likely to suffer less serious but nevertheless debilitating events such as wound infections, decubitus ulcers and unsuccessful back operations [19]. Surgical patients are more at risk than others [20].

To assist management of adverse events many health systems categorize adverse events by level of seriousness. The most serious adverse events are called sentinel events, which cause serious injury or death. Some countries call these the “should never be allowed to happen” events. Many countries now have or are putting in place systems to report and analyse adverse events. Some countries have even mandated reporting of sentinel events. The reason for categorizing adverse events is to ensure that the most serious ones with the potential to be repeated are uncovered and steps taken to prevent another incident. These methods are covered in topic 7.
Table 11 sets out the types of sentinel events that are required reporting by governments in Australia and the United States.

Table 11. Sentinel events reported in the Australia and the United States [19]

<table>
<thead>
<tr>
<th>Type of adverse event</th>
<th>USA (% of 1579)</th>
<th>Australia (% of 175)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suicide of in patient or within 72 hours of discharge</td>
<td>29</td>
<td>13</td>
</tr>
<tr>
<td>Surgery on wrong patient or body part</td>
<td>29</td>
<td>47</td>
</tr>
<tr>
<td>Medication error leading to death</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Rape/assault/homicide in an in patient setting</td>
<td>8</td>
<td>N/A</td>
</tr>
<tr>
<td>Incompatible blood transfusion</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Maternal death (labour, delivery)</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Infant abduction/wrong family discharge</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Retained instrument after surgery</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>Unanticipated death of a full-term infant</td>
<td>-</td>
<td>N/A</td>
</tr>
<tr>
<td>Severe neonatal hyperbilirubinaemia</td>
<td>-</td>
<td>N/A</td>
</tr>
<tr>
<td>Prolonged fluoroscopy</td>
<td>-</td>
<td>N/A</td>
</tr>
<tr>
<td>Intravascular gas embolism</td>
<td>N/A</td>
<td>-</td>
</tr>
</tbody>
</table>

N/A indicates that this category is not on the official reportable Sentinel Event list for that country

**Human and economic costs**

There are significant economic and human costs associated with adverse events. The Australian Patient Safety Foundation estimated for the state of South Australia the costs of claims and premiums on insurance for large medical negligence suits to be about $18 million (Australian) in 1997–1998 [21]. The National Health Service in the United Kingdom pays out around £400 million in settlement of clinical negligence claims every year [22]. The US Agency for Healthcare Research and Quality (AHRQ) reported in December 1999 that preventing medical errors has the potential to save approximately US$ 8.8 billion per year [23]. Also reporting in 1999, the Institute of Medicine report, *To err is human—building a safer health system*, estimated that between 44 000 and 98 000 people die each year from medical errors in hospitals alone, thus making medical errors the eighth leading cause of death in the United States. The Institute of Medicine also estimated that preventable errors cost the nation about US$ 17 billion annually in direct and indirect costs.

The human costs of pain and suffering include loss of independence and productivity for both patients and the families and carers remains un-costed. While debates [24-27] within the medical profession about the methods used to determine the rates of injury and their costs to the health system continue, many countries have accepted that the safety of the health-care system is a priority area for review and reform.

**Lessons about error and system failure from other industries**

The large-scale technological disasters in spacecraft, ferries, off-shore oil platforms, railway networks, nuclear power plants and chemical
installations in the 1980s led to the development of organizational frameworks for safer workplaces and safer cultures. The central principle underpinning efforts to improve the safety in these industries was that accidents are caused by multiple factors, not single factors in isolation: individual situational factors, workplace conditions and latent organizational and management decisions were commonly involved.

Analysis of these disasters also showed that the more complex the organization, the greater potential for a larger number of system errors in the organization or operation.

Sociologist Barry Turner, who examined organizational failures in the 1970s was the first to appreciate that tracing the “chain of events” was critical to an understanding of the underlying causes of accidents [28,29]. Reason’s work on the cognitive theory of latent and active error types and risks associated with organizational accidents built on his work [30,31]. Reason analysed the features of many of the large-scale disasters occurring in the 1980s and noted that latent human errors were more significant than technical failures. Even when faulty equipment or components were present, he observed that human action could have averted or mitigated the bad outcome.

An analysis of the Chernobyl catastrophe [32] showed that organizational errors and violations of operating procedures that were typically viewed as evidence of a “poor safety culture” [33] at Chernobyl were really organizational characteristics that contributed to the incident. The lesson learnt from the Chernobyl investigation was that the extent to which a prevailing organizational culture tolerates violations of rules and procedures is critical. This was a feature present in the events preceding the Challenger crash* [3]. That investigation showed how violations had become the rule rather than the exception. Vaughan analysed the Challenger crash findings and described how violations are the product of continued negotiations between experts searching for solutions in an imperfect environment with incomplete knowledge**. This process of identifying and negotiating risk factors, he suggested, leads to the normalization of risky assessments.

Reason [35] took these lessons from industries to make sense of the high number of adverse events inside health care. He stated that only a systems approach (as opposed to the more common “person” approach—of blaming an individual doctor or nurse) will create a safer health-care culture because it is easier to change the conditions people work in than change human actions. To demonstrate a systems approach he used examples from the technological hazard industries that show the benefits of built-in defences, safeguards and barriers***. When a system fails, the immediate question should be why it failed rather than who caused it to fail; e.g. which safeguards failed? Reason created the “Swiss cheese” Model [36] to explain how faults in the different layers of the system can lead to accidents/mistakes/incidents.

Figure 3 uses Reason’s Swiss cheese model and shows the steps and multiple factors (latent factors, error producing factors, active failures and defences) that are associated with an adverse event.

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*The viton O-ring seals failed in the solid rocket boosters shortly after launch. The Rogers Commission also found that other flaws in shuttle design and poor communication may have also contributed to the crash.

**For nearly a year before the Challenger’s last mission the engineers were discussing a design flaw in the field joints. Efforts were made to redesign a solution to the problem but before each mission, both NASA and Thiokol officials (a company that designed and built the boosters) certified the solid rocket boosters were safe to fly. (See Challenger: a major malfunction by Malcolm McConnell, Simon & Schuster, 19877. Challenger had previously flown nine missions before the fatal crash.

***Engineered defensive systems include automatic shut-downs (alarms, forcing functions, physical barriers). Other defensive mechanisms are dependent on people such as pilots, surgeons, anaesthetists, control room operators. Procedures and rules are also defensive layers.
The diagram shows that a fault in one layer of the organization is usually not enough to cause an accident. Bad outcomes in the real world usually occur when a number of faults occur in a number of layers (for example, rule violations, inadequate resources, inadequate supervision, inexperience) and momentarily line up to permit a trajectory of accident opportunity. For example, if a junior doctor was properly supervised in a timely way, then a medication error may not occur. To combat errors at the sharp end, Reason invoked the “defence in-depth” principle [36]. Successive layers of protection (understanding, awareness, alarms and warnings, restoration of systems, safety barriers, containment, elimination, evacuation, escape and rescue) are designed to guard against the failure of the underlying layer. The organization is designed to anticipate failure thus minimizing the hidden “latent” conditions that allow actual or “active” failures to cause harm.

Figure 3. Swiss cheese model


History of patient safety and the origins of the blame culture

The way we have traditionally managed failures and mistakes in health care has been called the person approach—we single out the individuals directly involved in the patient care at the time of the incident and hold them accountable. This act of “blaming” in health care has been a common way for resolving health-care problems. We refer to this as the “blame culture”. Since 2000, there has been a dramatic increase in the number of references to the “blame culture” in the health literature [37]. This is possibly due to the realization that system improvements cannot be made while we focus on blaming individuals. Our willingness to “blame” is thought to be one of the main constraints on the health system’s ability to manage risk [36,38-41] and improve health care. Putting this into the context of health care, if a patient is found to have received the wrong medication causing an allergic reaction we look for the person—be they medical student, nurse or doctor—who gave the wrong drug and blame that person for the patient’s condition. Individuals who are identified as responsible are also shamed. The person responsible may receive remedial training, a disciplinary interview or told never to do it again. We know that simply insisting the health-care workers just “try harder” does not work. Policy and procedures may also change to tell health-care workers how to avoid an allergic reaction in a patient. The focus is still on the individual staff members rather than on how the system failed to protect the patient and prevent a wrong medication being administered.

Why do we blame?

A demand for answers as to why “the event” occurred is not an uncommon response. It is human nature to want to blame someone and far more “satisfying” for everyone involved in investigating an incident if there is someone to blame. Social psychologists have studied how people make decisions about what caused a particular event, explaining it as attribution theory. The premise of this theory is that people naturally want to make sense of the world, so when unexpected events happen, we automatically start figuring out what caused it.
Pivotal to our need to blame is the belief that punitive action sends a strong message to others that errors are unacceptable and that those who make them will be punished. The problem with this assumption is that it is predicated on a belief that the offender somehow chose to make the error rather than adopt the correct procedure: that the person intended to do the wrong thing. Because individuals are trained and/or have professional/organizational status, we think that they “should have known better” [42]. Our notions of personal responsibility play a role in the search for the guilty party. Expressions such as “the buck stops here” or “carrying the can” are widely used. Professionals accept responsibility for their actions as part of their training and code of practice. It is easier to attribute legal responsibility for an accident to the mistakes or misconduct of those in direct control of the operation then on those at the managerial level [42].

Charles Perrow [43] in 1984 was one of the first to write about the need to stop “pointing the finger” at individuals when he observed that between 60% and 80% of system failures were attributed to “operator error” [1]. The prevailing cultural response to mistakes, at that time, was to punish individuals rather than address any system problems that may have contributed to the error(s). Underpinning this practice was the belief that, since individuals are trained to perform tasks, then a failure of that task must relate to the failure of individual performance, thus deserving punishment. Perrow believed that these sociotechnical breakdowns are a natural consequence of complex technological systems [31]. Others [44] have added to this theory by emphasizing the human factor at an individual and institutional level.

Reason [36], building on the earlier work of Perrow [43] and Turner [29], provided this rationale for managing human error:

- Human actions are almost always constrained and governed by factors beyond an individual’s immediate control. (A medical student working in a surgical ward is constrained by the hospital’s management of the theatres.)
- People cannot easily avoid those actions that they did not intend to perform. (A medical student may not have intended to obtain consent from a patient for an operation but was unaware of the rules in relation to informed consent.)
- Errors have multiple causes: personal, task-related, situational and organizational factors. (If a medical student entered the theatre without correct scrubbing it may be because the student was never shown the correct way, has seen others not comply with scrubbing guidelines, the cleaning agent had run out, there was an emergency that the student wanted to see and there was no time, etc.)
- Within a skilled, experienced and largely well-intentioned workforce, situations are more amenable to improvement than people. (If staff were prevented from entering theatres until appropriate cleaning techniques were followed, then the risk of infection would be diminished.)

Reason warned against being wise after the event—so-called “hindsight bias”—because most people involved in serious accidents do not intend something to go wrong and generally do what seems like the “right” thing to do at the time, though they “may be blind to the consequences of their actions” [31].

Today most complex industrial/high technological managers realize that a blame culture will not bring safety issues to the surface [45]. While many health-care systems are beginning to recognize this we are yet to move away from the person
approach—in which finger pointing or cover-ups are common—to an open culture where processes are in place to identify failures or breaks in the “defences”. Organizations that place a premium on safety routinely examine all aspects of the system in the event of an accident, including equipment design, procedures, training and other organizational features [46].

**Difference between system failures, violations and errors**

Using a systems approach to errors and failures in the system does not mean that system thinking implies a “blame-free” culture. In all cultures, individual health professionals are required to be accountable for their actions and to maintain competence and practise ethically. In learning about systems thinking, students should appreciate that they as trusted health professionals are still required to act responsibly and are accountable for their actions [47]. Part of the difficulty is that many health professionals daily break professional rules such as using proper handwashing techniques, or letting junior and inexperienced providers work without proper supervision. Students may see doctors on the wards or in the clinics who cut corners and think that it is the way things are done. Such behaviours are not acceptable. Reason studied the role of violations in systems and argued that, in addition to a systems approach to error management, we need effective regulators with the appropriate legislation, resources and tools to sanction unsafe clinician behaviour [48].

**Violations**

Reason defined a violation as a deviation from safe operating procedures, standards or rules [48]. He linked the categories of routine and optimizing violations to personal characteristics and necessary violations to organizational failures.

**Routine violation**

Doctors who fail to wash their hands in between patients because they feel they are too busy is an example of a routine violation. Reason stated that these violations are common and often tolerated. Other examples in health care would be inadequate handovers, not following a protocol and not attending on-call requests.

**Optimizing violation**

Doctors who let a medical student perform a procedure unsupervised because they are with their private patients is an example of an optimizing violation. This category involves a person being motivated by personal goals such as greed or thrills from risk taking, performing experimental treatments and performing unnecessary procedures.

**Necessary violation**

Nurses and doctors who knowingly miss out important steps in medication dispensing because of time constraints and the number of patients to be seen is an example of a necessary violation. A person who deliberately does something they know to be dangerous or harmful does not necessarily intend a bad outcome but poor understanding of professional obligations and a weak infrastructure for managing unprofessional behaviour in hospitals provide fertile ground for aberrant behaviour to flourish.

By applying systems thinking to errors and failures, we can ensure that when such an event occurs we do not automatically rush to blame the people closest to the error—those at the so called “sharp” end of care. Using a systems approach we can examine the entire system of care to find out what happened rather than who did it. Only after careful attention to the multiple factors associated with an incident can there be an assessment as to whether any one person was responsible.
A model of patient safety

The urgency of patient safety was raised over a decade ago when the US Institute of Medicine convened the National Roundtable on Health Care Quality. Since then the debate and discussions about patient safety worldwide have been informed by lessons learnt from other industries, the application of quality improvement methods to measure and improve patient care and the development of tools and strategies to minimize errors and failures. All of this knowledge has strengthened the place of the safety sciences in the context of medical practice and health-care services generally. The need to improve health care through redesigning processes of care has been acknowledged by WHO and its representative countries as well as by most health professions.

The emergence of patient safety as a discipline in its own right has been made possible because of other disciplines such as cognitive psychology, organizational psychology, engineering and sociology. Applying the theoretical knowledge from these disciplines has led to the development of postgraduate courses in quality and safety and patient safety education in prevocational and vocational medical programmes.

Applying patient safety principles and concepts in the workplace does not mean that a health provider has to have formal qualifications in quality and safety. Rather, it requires one to apply a range of skills and be wary of patient safety considerations in every situation and recognizing that things can go wrong. Reason, a cognitive psychologist, emphasized that practitioners should make a habit of sharing their experiences of adverse events. Being an effective team member has risen in importance as we better understand the role of accurate and timely communication in patient safety. Training to become an excellent team member starts in medical school. Learning how to substitute roles and appreciate the other’s perspective is central to effective teamwork.

As the health professions have gained more confidence with the evidence and the steps that are required to make the health-care system safer, it is timely that patient safety as a discipline in its own right should be defined and conceptualised. Emanuel and other patient safety leaders defined patient safety as follows:

A discipline in the health-care sector that applies safety science methods towards the goal of achieving a trustworthy system of health-care delivery. Patient safety is also an attribute of health-care systems; it minimizes the incidence and impact of, and maximizes recovery from adverse events [49].

This definition provides the scope for the conceptual model for patient safety. Emanuel et al. [49] designed a simple model with which to see patient safety. It divides health-care systems into the following four main domains:

1. those who work in health care;
2. those who receive health care or have a stake in its availability;
3. the infrastructure of systems for therapeutic interventions (health-care delivery processes);
4. the methods for feedback and continuous improvement.

This model shares fifty similar features with other models [50] of quality design including:

- understanding the system of health care;
- recognizing that performance varies across services;
- the methods for improvement including how to implement and measure a change;
- understanding the people who work in the system and their relationships with one another and the organization.
WHAT STUDENTS NEED TO DO (PERFORMANCE REQUIREMENTS)

Apply patient safety thinking in all clinical activities

There are many opportunities for students in their clinical work to incorporate patient safety knowledge into practice.

Relationships with patients

Relate and communicate with each individual patient as a unique human being who has their own experience of their disease or illness. Applying clinical skills alone will not necessarily achieve the best outcomes for patients. In addition, the student needs information from the patient about how they view their illness or condition and its impact on them and their families. Safe and effective care depends on the patient disclosing their experience of the illness, their social circumstances, their attitudes to the risk involved and their values and preferences for how they wish to be treated.

Students and clinical teachers must ensure that patients understand that medical students are not qualified doctors. When introduced to patients or their families a medical student should always be described as “medical students”. It is important not to describe students as “junior doctors”, “student doctors”, “young doctors”, “assistants” or “colleagues” as this can lead the patient to thinking that the student is qualified. An important aspect of patient safety is honesty to patients so it is important that students advise patients of their correct status, even if that means correcting what their clinical teacher has said.

Sometimes clinical teachers introduce students in a way that is designed to instil confidence in the student and the patient, without realizing that they may “stretch the truth” in doing so. As it can be awkward trying to correct what the clinical teacher has said at this point, it is a good idea to check with a clinical teacher how they usually introduce students to patients beforehand, especially the first time you are working and learning with a particular clinical teacher. Students must explain and make it clear to patients and their families that they are medical students studying to become doctors.

Understand the multiple factors involved in failures

Students should look beyond a medical mistake or failure in care and understand that there may be many factors associated with an adverse event. This will involve the student asking questions about the underlying factors and encouraging others to consider an error from a systems perspective. They could be the first in a team meeting or discussion group to ask questions about possible causes of errors by using the phrase, for example, “What happened” rather than “Who was involved”. The five “whys” (keep on asking why something happened when given an answer) is a method used to keep discussions about causes focused on the system rather than the people.

Statement: The nurse gave the wrong drug.
Why?
Statement: Because she misheard the name of the drug ordered by the doctor.
Why?
Statement: Because the doctor was tired and it was in the middle of the night and the nurse did not want to ask him to repeat the name.
Why?
Because she knew that he was known to have a temper and would shout at her.
Why?
Because he was very tired and had been operating for the last 16 hours …
Why?
Because…
Avoid blaming when an error occurs
It is important that medical students support each other and health professionals when they are involved in an adverse event. Unless students are open about errors there will be little opportunity to learn from them. However, often medical students are excluded from meetings where discussions about adverse events occur. Also, the hospital or clinic may not hold such meetings to discuss adverse events. This does not necessarily mean that clinicians want to hide their errors; it may mean they are unfamiliar with patient safety strategies to learn from them. They may also worry about medico-legal fears and possible interference from administrators. Even so, as patient safety concepts become more widely known and discussed in health care, more opportunities are arising for reviewing care and making the improvements necessary to minimize errors. Students can ask their supervisors if the hospital conducts mortality and morbidity meetings or other peer review forums where adverse events are reviewed. Students, irrespective of level of training and education must appreciate the importance of reporting their own errors to their supervisors.

Practise evidence-based care
Students should learn how to apply evidenced-based practice. They should be aware of the role of guidelines and appreciate how important it is to follow them. When a student is placed in a clinic or hospital they should seek out information about the common guidelines and protocols that are used.

Maintain continuity of care for patients
The health system is made up of many parts that interrelate to produce a continuum of care for patients and families. Understanding the journey that patients make through the health-care system (of which a hospital or clinic is just a part) is necessary to understand how the system can fail. Important information can be missed or incorrect. This can lead to inadequate care or errors. The continuity of care chain is broken, leaving the patient vulnerable to a poor outcome.

Student awareness of the importance of self-care
Students should be responsible for their own well-being and that of their peers and colleagues. Medical students should be encouraged to have their own doctor and be aware of their own health status. If a student is in difficulty (mental illness or drug or alcohol impairment), they should be encouraged to seek professional help.

Act ethically everyday
Learning to be a good doctor requires observation of respected senior clinicians as well as practical clinical experience involving patients. One of the privileges medical students have is the opportunity as students to learn medicine “at the bedside” and treating “real patients”. Most patients understand that medical students have to learn and that the future of medicine depends on training. Yet, it is also important that students remember that their opportunity to interview and examine patients is a privilege that is granted by each individual. In most situations, patients cannot be examined by a student unless they give their consent. Students should always ask permission from each patient before they physically touch or seek personal information from them. They should also be aware that patients may withdraw this privilege at any time and request that the student stop what they doing.

It is important that clinical teachers advise patients that their cooperation in educational activities is entirely voluntary. Clinical teachers and medical students must obtain verbal consent from patients before students interview or examine them. When a patient is being asked to allow a student to examine them they should be told that the
examination is primarily for educational purposes. An appropriate form of words is, “Would you mind if these students ask you about your illness and/or examine you so that they can learn more about your condition?”

It is important that all patients understand that their participation is voluntary and that a decision not to participate will not compromise their care. Verbal consent is sufficient for most educational activities but there will be times when a written consent is required. Students should be requested to make inquiries if they are in doubt about the type of consent required.

Particular care should be taken when involving patients in teaching activities because the benefit to the patient is secondary to the educational needs of the students. Patient care and treatment is usually not dependent on student engagement.

Explicit guidelines for clinical teachers and medical students provide protection for everyone. If no guidelines exist it is a good idea to request that the faculty develop a policy on the relationship between students and the patients they are allowed to treat in their role as students. Properly designed guidelines will protect patients, promote high ethical standards and avoid misunderstandings.

Most medical schools are aware of the problem of the “hidden curriculum” in medical education. Studies show that students on clinical placements have felt pressured to act unethically [52], and they report that these situations are difficult to resolve. All students and doctors in training potentially face similar ethical dilemmas. On the rare occasion in which a clinical supervisor directs medical students to participate in patient management that is perceived to be unethical or misleading to the patient, faculty staff should deal with the matter. Many students may not even be confident enough to raise such matters with their supervisors and are unsure of how to act. Raising this in teaching about patient safety is very important. This role confusion can lead to student stress and can have a negative impact on morale and the development of the students’ professionalism. It can also place patients at risk. Learning how to report concerns about unsafe or unethical care is fundamental to patient safety and relates to the capacity of the system to support reporting.

Students should be aware of their legal and ethical obligations to put the interests of patients first [8]. This may include refusal to comply with an inappropriate instruction or direction. The best way to resolve the conflict (or at least gain a different perspective) is for the student to speak privately with the clinician or responsible staff person concerned. The patient concerned should not be part of this discussion. The student should explain the problem(s) and why they are unable to comply with the instruction or direction. If the clinician or responsible staff person ignores the issues raised and continues to instruct the medical student to proceed, then discretion should be used to proceed or withdraw from the situation. If it is decided to continue, then patient consent must be confirmed. If the patient does not consent, the student must not proceed. If a patient is unconscious or anaesthetized, the student should explain why they cannot proceed. It may be necessary to point out the requirement of the faculty to comply with these guidelines. It may also be appropriate to discuss the situation with another person in the faculty or clinical school. If medical students are uncertain about the appropriateness of any behaviour by any other person involved in patient care, they should discuss the matter with a senior colleague of choice, usually the associate dean.
All students who feel that they have been subjected to unfair treatment because of a refusal to do something that seems to be wrong should seek advice from senior colleagues.

**Demonstrates ability to recognize the role of patient safety in safe healthcare delivery**

The timing of a medical student’s entry into a hospital or clinical environment varies across universities—some medical students are exposed from their first year, other students are exposed later in their medical training and education. Prior to entering a clinical environment students should:

- **Ask questions about other parts of the health system that are available to the patient**
  The success of a patient’s care and treatment depends on understanding of the total health system available to the particular patient. If a patient comes from a poor area where there is no refrigeration, then sending a patient home with insulin that needs refrigeration will not assist the patient. An understanding of systems (topic 3) will help the student appreciate how different parts of the health system are connected and how continuity of care for the patient is dependent on all parts of the system communicating effectively and in a timely way.

- **Ask for information about the hospital or clinic processes that are in place to identify adverse events**
  Most hospitals or clinics will have a reporting system to identify adverse events. It is important that students are aware of these events and understand how the hospital manages them. If there are no reporting requirements in the hospital, then the student can ask the appropriate people how the hospital manages such events. At the least, this may generate some interest in the topic. (Reporting and incident management are covered in topics 3, 4 and 6.)

**HOW TO TEACH THIS TOPIC**

**Teaching strategies/formats**

The prevalence data used in this topic have been published in the literature and cover a number of countries but not all of them. Some teachers may wish to put the case for patient safety using prevalence data from their country. If it is not available, then another way would be to access databases maintained by the health service and see if some of the data can be used to demonstrate the potential or real harm to patients from their health care. For example, the Institute for Healthcare Improvement (IHI) in the United States has published *Trigger tool for measuring adverse events*, which is designed to assist health-care professionals measure their adverse event rates. If there are no measures available to a country or hospital, then try to obtain data for one area of care such as infection rates. Infection rates in a particular country may be available and this could be used to demonstrate the extent of transmission of infection that is a potentially preventable.

This topic can be broken up into sections to be included in existing curricula or can be taught in small groups or as a stand alone lecture. If the topic is being delivered as a lecture, then the slides at the end of the topic may be helpful for presenting the information.

Part A of the Curriculum Guide sets out a range of teaching methods for patient safety since giving a lecture is not always the best approach.

**A small group discussion session**

A teacher could use any of the activities listed below to stimulate discussion about patient safety. Another way is to have one or more
students prepare a seminar on the topic of patient safety using the information in this topic. They could then lead a discussion about the areas covered in the topic. The students could follow the headings as outlined below and use any of the activities below to present the material. The tutor facilitating this session should also be familiar with the content so information can be added about the local health system and clinical environment.

Harm caused by health-care errors and system failures:
- use examples from the media (newspapers and television) that have been published/broadcasted;
- use de-identified case examples from your own hospitals and clinics;
- use a case study to construct a flowchart of the patient’s journey;
- use a case study to brainstorm all of the things that went wrong and the times when an action might have prevented the adverse outcome for the patient;
- invite a patient who has experienced an adverse event to talk to the students.

Difference between system failures, violations and errors:
- use a case study to analyse the different avenues for managing an adverse event;
- participate or be an observer in a root cause analysis.

An interactive/didactic session
Invite a respected senior clinician and/or other health-care professionals from within your country to talk about health-care errors in the workplace. If no one is available, then use a video of an influential and respected physician talking about errors and how the system of health care exposes everyone to them. A search of the internet will locate video clips of speeches that have been made by patient safety leaders. Having someone talk about errors and how they impact on patients and staff is a powerful introduction of patient safety to students. Students can react to the presentation. The teacher can then go through the information in this topic to demonstrate to students how and why attention to patient safety is essential for safe clinical practice. The slides can be PowerPoint or converted to overhead slides for a projector. Start the session with the case study and get the students to identify some of the issues presented in the story. Use the accompanying slides at the end of this topic as a guide.

Other ways to present different sections in this topic are listed below.

Lessons about error and system failure from other industries:
- invite a staff member from another discipline such as engineering or psychology to talk about system failures, cultures of safety and role of error reporting in safety;
- invite someone from the aviation industry to talk about their response to human errors.

History of patient safety and the origins of the blame culture:
- invite a senior respected clinician to talk about the damage of “blaming” in the context of medical care;
- invite a quality and safety officer to talk about systems in place to minimize errors and manage adverse events.

Simulation
Different scenarios could be developed about adverse events and the need to report and analyse errors.

Teaching and learning activities
There are many other opportunities for students to learn about patient safety such as during their clinical placements in hospitals or clinics. The
following are some examples of activities that students could perform, either alone or in pairs:

- follow a patient on their journey through the health-care service;
- ask students to spend a day with another health professional (nurse, physiotherapist, social worker, pharmacist, dietician and interpreter) and to identify the main role and functions of that profession;
- ask students when they have student–patient encounters to routinely seek information about the illness or condition from the patient’s perspective;
- ask students to make inquiries of their hospital or health service about whether there are processes or teams to investigate and report on adverse events—if there are avenues, ask the students to seek permission from the relevant supervisor for them to observe or take part;
- ask students to find out if the hospital conducts mortality and morbidity meetings or other peer review forums where adverse events are reviewed;
- require the students to talk among themselves about errors they have observed in the hospital using a no blame approach;
- ask the students to select a ward or clinic where they are placed and inquire about a main protocol used by the staff; get the students to ask how the guideline was written and how staff know about it and how to use it and when to deviate from it.

**CASE STUDIES**

**Caroline’s story**

*This case illustrates the importance of attention to continuity of care and how a system of care can go badly wrong.*

On 10 April 2001, Caroline, aged 37, was admitted to a city hospital and gave birth to her third child in an uncomplicated caesarean delivery. Dr A was the obstetrician and Dr B was the anaesthetist who set the epidural catheter. On 11 April, Caroline reported that she felt a sharp pain in her spine and on the night before the epidural was removed she accidentally bumped the epidural site. During this time, Caroline repeatedly complained of pain and tenderness in the lumbar region. The anaesthetist, Dr B, examined her and diagnosed “muscular” pain. Still in pain and limping, Caroline was discharged (transferred) from the city hospital on 17 April.

For the next seven days Caroline remained at her home in the country. She telephoned her obstetrician, Dr A, about her fever, shaking, intense low back pain and headaches. On 24 April, the local medical officer, Dr C, examined Caroline and her baby and recommended they both be admitted to the district hospital for back pain and jaundice, respectively.

The admitting doctor at the district hospital, Dr D, recorded that Caroline’s back pain appeared to be situated at the S1 joint rather than at the epidural site. On 26 April, the baby’s jaundice had improved, but Caroline had not yet been seen by the general practitioner, Dr E, who admitted he had forgotten about her. The medical registrar, Dr F, examined Caroline and diagnosed sacroiliitis. He discharged her with prescriptions for oxycodone, paracetamol and diclofenac. He also informed Caroline’s obstetrician, Dr A, of his diagnosis.

Caroline’s pain was assisted by the medications until 2 May when her condition deteriorated. Her husband then took Caroline, who was in a delirious state, to the local country hospital. Shortly after arriving at the hospital on 3 May she started convulsing and mumbling incoherently. The local medical officer, Dr C, recorded in the medical records “? excessive opiate usage, sacroiliitis”.
Her condition was critical by this stage and she was rushed by ambulance to the district hospital.

By the time she arrived at the district hospital, Caroline was unresponsive and needing intubation. Her pupils were noted to be dilated and fixed. Her condition did not improve and on 4 May she was transferred by ambulance to a second city hospital. At 13:30 on Saturday, 5 May, she was determined to have no brain function and life support was withdrawn.

A postmortem examination revealed an epidural abscess and meningitis involving the spinal cord from the lumbar region to the base of the brain with cultures revealing a methicillin-resistant staphylococcus aureus (MRSA) infection. Changes to the liver, heart and spleen were consistent with a diagnosis of septicaemia. The coronial investigation concluded that Caroline’s abscess could and should have been diagnosed earlier than it was.

The following discussion of the coroner’s report into the death of Caroline highlights many of the issues addressed in the topics outlined in this Curriculum Guide. The observation that surfaced again and again in this story was the inadequacy in recording detailed and contemporaneous clinical notes and the regular incidence of notes being lost. The anaesthetist, Dr B, was so concerned about Caroline’s unusual pain that he consulted the medical library, but he did not record this in her clinical notes. He also failed to communicate the risk of what he now thought to be “neuropathic” pain to Caroline or ensure that she was fully investigated before being discharged. There were also concerns that evidence-based guidelines were not followed with respect to Dr B scrubbing prior to the epidural insertion as it was the view of an independent expert that the bacteria that caused the abscess was most likely to have originated from the staff or environment at the city hospital.

It was clear that Caroline would be managed by others after her discharge; however, she was not involved as a partner in her health care by being given instructions about the need to seek medical attention if her back pain worsened. Similarly, no referral letter or phone call was made to her local medical officer, Dr C.

It was the coroner’s opinion that each of the doctors who examined Caroline after she returned to the country was hasty in reaching a diagnosis, mistakenly believing that any major problem would be picked up by someone else down the track. Her local medical officer, Dr C, only made a very cursory examination of Caroline as he knew she was being admitted to the district hospital. The admitting doctor, Dr D, thought there was a 30% chance of Caroline having an epidural abscess but did not record it in the notes because he believed it was obvious. In a major departure from accepted medical practice, Dr E agreed to see Caroline and simply forgot about it.

The last doctor to examine Caroline at the district hospital was the medical registrar, Dr F, who discharged her with prescriptions for strong analgesics without fully investigating his provisional diagnosis of sacroiliitis, which he thought could have been postoperative or infective. With regards to medicating safely, Dr F’s handwritten notes to Caroline were considered vague and ambiguous in instructing her to increase the dose of oxycodone if the pain increased, while at the same time monitoring specific changes. The notes Dr F made on a piece of paper detailing his examination and the possible need for magnetic resonance imaging (MRI) were never found.

The one doctor who the coroner believed could have taken global responsibility for Caroline’s care...
was her obstetrician, Dr A. He was phoned at least three times after her discharge from the city hospital with reports of her continuing pain and problems, but failed to realize the seriousness of her condition.

From the birth of her child to her death 25 days later, Caroline was admitted to four different hospitals and there was a need for proper continuity of care in the handover of responsibilities from each set of medical and nursing staff to another. The failure to keep adequate notes with provisional/differential diagnoses and investigations and provide discharge summaries and referrals led to a delay in the diagnosis of a life-threatening abscess and ultimately Caroline’s death.

Reference
Inquest into the death of Caroline Barbara Anderson, Coroner’s Court, Westmead, Sydney Australia, 9 March 2004. (Merrilyn Walton was given written permission by Caroline’s family to use in teaching medical students and other health professionals so that they could learn about patient safety from the perspective of patients and families.)

TOOLS AND RESOURCES


*Crossing the quality chasm: a new health system for the 21st century*. Washington, DC, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, 2001

HOW TO ASSESS THIS TOPIC

A range of assessment methods are suitable for this topic including essay, MCQ paper, short best answer question paper (SBA), case-based discussion and self-assessment. Students can be encouraged to develop a portfolio approach to patient safety learning. The benefit of a portfolio approach is that at the end of the student’s medical training they will have a collection of all their patient safety activities. Students will be able to use this to assist job applications and their future careers.

The assessment of knowledge of the potential harm to patients, the lessons from other
industries, violations and the blame free approach and models for thinking about patient safety is all assessable using any of the following method:

- portfolio;
- case-based discussion;
- OSCE station;
- written observations about the health system and the potential for error (in general);
- reflective statements (in particular) about:
  - the hospital and clinical environment and the potential for patient harm;
  - the consequences of adverse events on patient trust in health care;
  - the systems in place for reporting medical errors;
  - the role of senior clinicians in managing adverse events;
  - the role patients have in the health-care system.

The assessment can be either formative or summative; rankings can range from unsatisfactory to giving a mark. See examples of some of these assessment methods in Appendix 2.

**HOW TO EVALUATE THIS TOPIC**

Evaluation is important in reviewing how a teaching session went and how improvements can be made. See the Teacher’s Guide (Part A) for a summary of important evaluation principles.

**References**


41. Walton M. *Creating a ‘no blame’ culture: have we got the balance right?*. Quality and Safety in Health Care 2004;13:163-4.
47. Walton M. *Creating a “no blame” culture: have we got the balance right?*. Quality and Safety in Health Care 2004;13:163-4.

**SLIDES FOR TOPIC 1: WHAT IS PATIENT SAFETY?**

Didactic lectures are not usually the best way to teach students about patient safety. If a lecture is being considered, it is a good idea to plan for student interaction and discussion during the lecture. Using a case study is one way to generate group discussion. Another way is to ask the students questions about different aspects of health care that will bring out the issues contained in this topic such as the blame culture, nature of error and how errors are managed in other industries.

The slides for topic 1 are designed to assist the teacher deliver the content of this topic. The slides can be changed to fit the local environment and culture. Teachers do not have to use all of the slides and it is best to tailor the slides to the areas being covered in the teaching session.