

# Patient safety

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## Abstract

Hospitals, though essential for healing, are fraught with risks, and errors are more common than previously thought. In high-income countries, about 1 in 10 patients experience adverse events, while low- and middle-income nations face 134 million unsafe care incidents annually, contributing to 2.6 million deaths. Traditional thinking blames individual errors, but this hinders open learning and accountability.

Patient safety is the discipline focused on preventing harm through systems, procedures, and a culture that minimizes risks and fosters recovery from errors. It involves improving healthcare delivery by addressing safety issues at the "sharp end" (where care is provided) and the "blunt end" (upstream factors like system design and organization).

Common sources of harm include medication errors, surgical mistakes, healthcare-associated infections, diagnostic errors, patient falls, venous thromboembolism, pressure ulcers, unsafe transfusions, patient misidentification, and unsafe injection practices. Patient harm is often due to a combination of system flaws, technological issues, human error, and patient-related factors.

Achieving patient safety involves creating a culture of transparency, learning from adverse events, and implementing frameworks like the Swiss Cheese Model, which visualizes how errors pass through multiple layers of safety. Tools like root cause analysis (RCA) and Failure Modes and Effects Analysis (FMEA) help identify systemic issues and

prevent future harm. Healthcare workers must collaborate in teams, emphasizing continuous learning and system redesign to improve patient safety. Building accountability, ensuring safe practices, and supporting healthcare professionals are essential for creating a safe, trustworthy healthcare system.

**Key words:** patient safety, patient harm, medication, surgical and diagnostic errors, Swiss Cheese Model, health care associated infections

## Introduction

*'To err is human' – Alexander Pope (1688-1744),  
Poet of Enlightenment*

**Case report:** In the mid-1970s, House Officers (HOs) in Sri Lanka's Cardiology Unit of the General Hospital Colombo were trained to perform right heart catheterization. During one procedure, an HO mistakenly entered the femoral artery instead of the saphenous vein, causing the catheter to travel up the carotid artery. Fortunately, the femoral artery went into spasm, preventing bleeding. The HO quickly called for assistance, and pressure was applied to the incision site. The patient was transferred to the Cardiothoracic Unit, which was close by, where a surgeon repaired the artery promptly. The patient recovered and was able to walk home a few days later, thanks to prompt intervention, prevention of further harm and immediate repair of the damaged artery.<sup>1</sup>

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The above incident which occurred around 50 years ago was a serious medical error. Although seriousness to the patient was minimized by timely intervention, the worse outcomes could have been death from haemorrhage, gangrene, septicaemia or the loss of a lower limb. The HO concerned was the author who was a young inexperienced doctor, and he may have committed this error due to a combination of factors such as inexperience, lack of self-awareness, work volume overload and poor supervision. This incident was preventable and it illustrates that hospitals are fraught with risks and dangers.

### **How big is the problem of unsafe care in hospitals?**

On average, an estimated one in 10 patients is subject to an adverse event while receiving hospital care in high-income countries. Available evidence suggests that 134 million adverse events due to unsafe care occur in hospitals in low- and middle-income countries, contributing to around 2.6 million deaths every year.<sup>2</sup> According to recent estimates, the social cost of patient harm can be valued at 1-2 trillion US dollars a year.

Thinking about patient safety began to change in the 1990s in response to several kinds of new information. First, medical injury was acknowledged as occurring far more often than thought before, with most of these injuries deemed preventable followed by various changes in the healthcare industry to make patient care safer.

### **What is patient safety?**

A short definition given by the Institute of Medicine (IOM) is freedom from accidental injury. Long definition of patient safety: it is a discipline in healthcare sector that is based on safety sciences with a goal of achieving a trustworthy system for health delivery and it is an attribute of healthcare systems which minimizes the incidence or impact of adverse effects and maximizes the recovery from adverse effects which are widespread and preventable.<sup>3</sup> Another definition is that it is a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that

consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur – WHO definition.<sup>2</sup> Patient safety in itself, is a discipline, and discrimination should be made between safety and quality. Definition of quality of care: quality of care is the degree to which healthcare services for individuals and populations increases the likelihood of desired health outcome and is consistent with current professional knowledge.<sup>4</sup>

Patient safety is dependent on open learning, learning from errors and adverse effects, as main source of understanding. It is a continuous cycle [as in Kolb's cycle, Figure 2].<sup>5</sup> Reporting adverse effects or near misses, and lessons learned and establishment of culture away from casting unfair blame provides a background for patient safety. The concept of patient safety turns away from the societal status and privileged knowledge which shielded doctors and other practitioners from accountability in the past with conscious concern and effects leading to minimizing extent and severity of adverse effects by well-designed systems, consensus, personal attention and by seeking ways to repair damage honestly and respectfully, when it occurs.<sup>3</sup> When illness begins care is necessarily for something which has already gone wrong. Harm to patient can occur due to omission or action, as well as due to inaction. Confidentiality and physical privacy of patient care interfere with transparency and vigilance that is required for patient safety.

### **Where should 'patient safety' take place?**

It occurs in the microsystem that is the immediate surroundings where patient care happens, for example, operating theatre, emergency treatment unit etc. These are some of the sharp ends where failures of safety are bound to happen. Patient care has two poles, the blunt end and the sharp end. Blunt end is the upstream, which has several components – design of systems, organization, management, training and equipment – whereas the sharp end, which is the downstream, has patients, practitioners and equipment.

**What are the common sources of patient harm?**  
Refer Table 1.

**Table 1. Common sources of patient harm**

| <b><i>What are the common sources of patient harm?</i></b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Medication errors</i>                                   | Medication-related harm affects 1 out of every 30 patients in health care, with more than a quarter of this harm regarded as severe or life threatening. Half of the avoidable harm in health care is related to medications. <sup>6</sup>                                                                                                                                                                                                                                                             |
| <i>Surgical errors</i>                                     | Over 300 million surgical procedures are performed each year worldwide. <sup>7</sup> Despite awareness of adverse effects, surgical errors continue to occur at a high rate; 10% of preventable patient harm in health care was reported in surgical settings with most of the resultant adverse events occurring pre- and post-surgery. <sup>8</sup>                                                                                                                                                  |
| <i>Healthcare-associated infections</i>                    | With a global rate of 0.14% (increasing by 0.06% each year), health care-associated infections result in extended duration of hospital stays, long-standing disability, increased antimicrobial resistance, additional financial burden on patients, families and health systems, and avoidable deaths. <sup>9</sup> Of all sepsis cases managed in hospitals, 23.6% were found to be health care associated, and approximately 24.4% of affected patients lost their lives as a result. <sup>10</sup> |
| <i>Diagnostic errors</i>                                   | These occur in 5-20% of physician-patient encounters. <sup>11,12</sup> According to reviews by treating doctors, harmful diagnostic errors were found in a minimum of 0.7% of adult admissions. <sup>13</sup> Diagnostic errors affect at least 1 in 20 US adults. <sup>14</sup>                                                                                                                                                                                                                       |
| <i>Patient falls</i>                                       | Patient falls are the most frequent adverse events in hospitals. <sup>15</sup> Their rate of occurrence ranges from 3 to 5 per 1000 bed-days, and more than one third of these incidents result in injury thereby worsening clinical outcomes <sup>16</sup> and increasing the financial burden. <sup>17</sup>                                                                                                                                                                                         |
| <i>Venous thromboembolism</i>                              | Venous thromboembolism is a highly burdensome and preventable cause of patient harm, which contributes to one third of the complications attributed to hospitalization. <sup>18</sup>                                                                                                                                                                                                                                                                                                                  |
| <i>Pressure ulcers</i>                                     | Pressure ulcers are injuries to the skin or soft tissue. If not promptly managed, they can have fatal complications. Pressure ulcers affect more than 1 in 10 adult patients admitted to hospitals despite being highly preventable. <sup>19</sup> They have a significant impact on the mental and physical health of individuals, and their quality of life.                                                                                                                                         |
| <i>Unsafe transfusion practices</i>                        | Unnecessary transfusions and unsafe transfusion practices expose patients to the risk of serious adverse transfusion reactions and transfusion-transmissible infections. Data on adverse transfusion reactions from a group of 62 countries show an average incidence of 12.2 serious reactions per 100,000 distributed blood components. <sup>20</sup>                                                                                                                                                |
| <i>Patient misidentification</i>                           | Failure to correctly identify patients can be a root cause of many problems and has serious effects on health care provision. It can lead to catastrophic adverse effects, such as wrong-site surgery. A report of the Joint Commission published in 2018 identified 409 sentinel events of patient identification out of 3326 incidents (12.3%) between 2014 and 2017. <sup>21</sup>                                                                                                                  |
| <i>Unsafe injection practices</i>                          | Each year, 16 billion injections are administered worldwide, and unsafe injection practices place patients and health care workers at risk of infectious and non-infectious adverse events. <sup>22</sup>                                                                                                                                                                                                                                                                                              |

**What are the factors leading to patient harm?** There are multiple and interrelated factors that can lead to patient harm, and more than one factor is usually involved in any single patient safety incident<sup>23</sup> Refer Table 2.

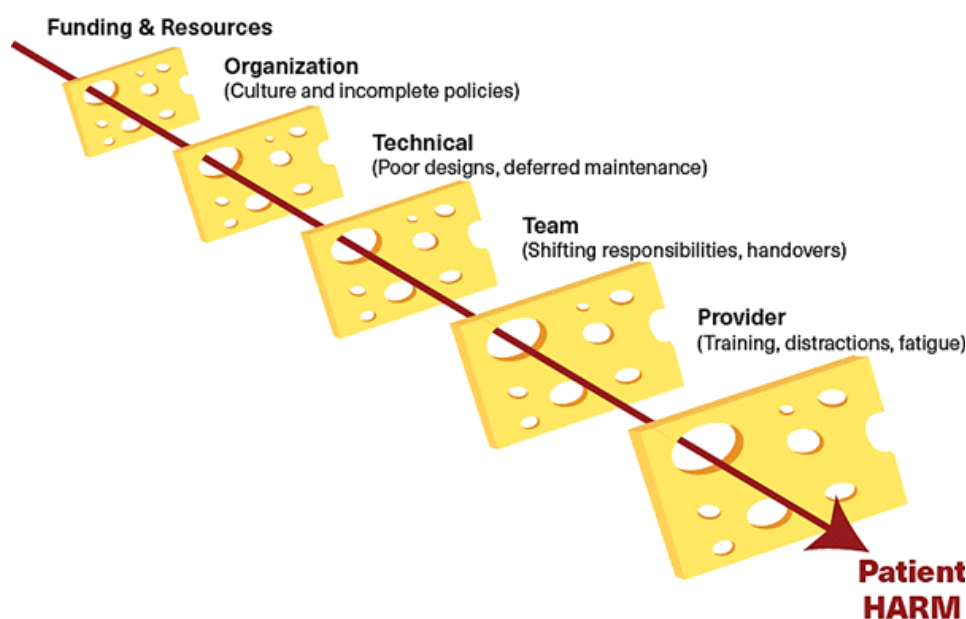
**Table 2. Factors leading to patient harm**

| <b>What are the factors leading to patient harm?</b> |                                                                                                                                                                                                    |
|------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>System and organizational factors</i>             | The complexity of medical interventions, inadequate processes and procedures, disruptions in workflow and care coordination, resource constraints, inadequate staffing and competency development. |
| <i>Technological factors</i>                         | Issues related to health information systems, such as problems with electronic health health records or medication administration systems, and misuse of technology.                               |
| <i>Human factors and behaviour</i>                   | Communication breakdown among health care workers, within health care teams, and with patients and their families, ineffective teamwork, fatigue, burnout, and cognitive bias.                     |
| <i>Patient-related factors</i>                       | Limited health literacy, lack of engagement and non-adherence to treatment.                                                                                                                        |
| <i>External factors</i>                              | Absence of policies, inconsistent regulations, economic and financial pressures, and challenges related to natural environment.                                                                    |

#### **How is patient safety achieved?**

Health systems are multi-layered. In the realm of patient safety, the Swiss Cheese Model (Figure 1) helps to visualize how errors may slip through the gaps of human and technological vigilance.<sup>24</sup> As the chain of healthcare delivery is complex and interacts with the outside world, 'error-traps' can occur leading to patient harm.

If one applies the concept of Swiss Cheese Model to healthcare delivery services, safety layers can operate at layers at institution, organization, team, individual and technology levels. Each slice of the Swiss Cheese Model represents an obstacle or a checkpoint that may prevent an error or incident from occurring.



**Figure 1. Swiss cheese model.**

As such the ideal design of a system of care should allow operator to perform only correctly. Therefore, it is loaded with several barriers that prevent wrong doings that require to be broken before causing patient harm.<sup>25</sup> Sharing stories of adverse events and reflective thinking give useful insights and drive adjustments to optimize safe delivery of patient care. Another way to learn patient safety is simulation which is a safe method where demonstrations of scenarios can be repeated endlessly with modifications enabling accurate feedback to be given to the learners.<sup>26</sup> Trials and error to test various procedures with patients is obviously not acceptable for ethical and safety reasons. As an analytic method in patient safety, root cause analysis (RCA) shows that immediate cause at the sharp-end /patient end is often not the cause for blame as it happens as a result of multiple system failures.<sup>27</sup> Another but similar process to improve delivery of safe health care is 'Failure Modes and Effective Analysis' [FMEA].<sup>28</sup> It is a prospective strategy where analysis of every aspect of the system design is carried out. FMEA is an engineering approach, usually taken early in the development of a product, that seeks to imaginatively identify potential failures and their effects. Knowledge from past failures might contribute to a designer's ability to foresee potential failures in their design. FMEA is used in analysing every aspect of a system's design, including the system's global

functioning, its components and their interactions, the functioning of equipment, the programming of equipment and the procedures for activities. The errors could also be reduced by redesigning systems and processes using human factors principles – standardization, simplifications and use of constraints. One such constraint is a "forcing function," which is a design characteristic that makes error impossible [e.g., incompatible connectors that prevent connecting an anaesthetic gas to the oxygen port of an anaesthesia machine].<sup>3</sup> It is similar to a principle adopted in petrol pumping stations, where the petrol pump cannot fit the inlet of tanks of diesel vehicles.

In patient safety, unlike in education sciences, there is no gold standard for comparison. In developing patient safety standards, protocols and guidelines contributions from engineering, social sciences, psychology, psychometrics, health services research, epidemiology, statistics, philosophy, ethics, education, computer science, etc., can contribute, depending on the procedure. To avoid issues due to systems failure, look at the gap between standards and actual practice. In order to get the best practice, carry out rapid cycles of feedback to clinicians and obtain responses to improve the practice and arrive at a consensus for institutional development.<sup>5</sup>

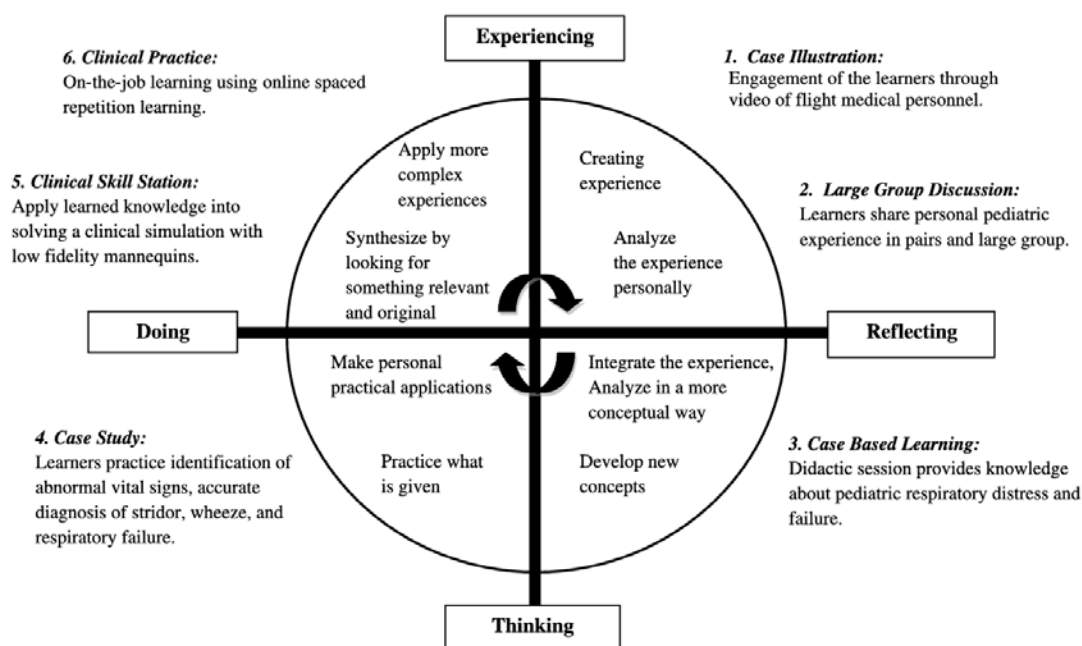


Figure 2. Experiential learning (Kolb's learning cycle): experience as a source of learning and development. (Adapted from reference 5).

Doctors and other practitioners work in teams. Often healthcare delivery is not by individuals alone, but as teams with patients and care environment interacting. An array of such interactions to facilitate patient safety can happen during teaching ward rounds, grand rounds, clinicopathological conferences, postmortems, and mortality and morbidity meetings. There should be transparency in the healthcare environment with learning happening with each patient experience – adverse effects could derive new information which is error related. Such instances always give better lessons for the healthcare industry to write and improve patient safety.

Culture and professionalism within the healthcare institutions is that there is high reliability and trust across the staff ranging from administrators, clinicians, nurses, paramedical staff to ancillary staff thereby instead of assigning blame for sharp-end mistakes causing patient harm to one individual is by fully disclosing mistakes, failures, near misses due to system failures upstream (blunt end) and carrying out a root-cause-analysis (RCA). In addition, providing support for clinicians who inherently carry out risky work is also a desirable trait in the institutional culture. Another step is disclosure of relevant facts to injured parties and maintaining the principle of no harm and non-maleficence all the time. To overcome the bias due to unequal power structure of the provider-patient relationship, system-wide honesty and full disclosure of all facts are required.

Accountability for delivering effective and safe patient care and avoiding substandard care is important to avoid litigation. Once agreed upon by stakeholders, these modalities of care are applied to clinical practices as clinical guidelines. One of the main reasons for such a long lapse to address accountability to patients was that patient confidentiality was maintained at the cost of lack of transparency, as the practice of medicine was considered a revered profession. Anaesthesiology which was one of the medical disciplines to break this barrier adopted an application of aviation industry – application of checklist and other safety checks.

### Who then is the patient safety practitioner?

For some it can be a primary professional identity. Universities award Masters of Science degree in patient safety which has become a credential in that area of speciality. Some go up to the doctoral level but for most, patient safety is a personal commitment. For practitioners with special interest in patients who have become patient-safety savvy, the practical wisdom grows from experience and ability to recognize that

something is not right. Adverse effects about to unfold can be averted or the impact can be minimized by those who have awareness in patient safety.

## Conclusions

Most mistakes leading to harm in healthcare result from system or process failures, rather than individual healthcare workers' actions. These errors often stem from poorly designed systems and the stressful, complex environments healthcare workers operate in. Shifting from a blame-based approach to a systems-based perspective allows for a better understanding of these errors, acknowledging the human nature of workers under pressure. However, negligence and misconduct still need to be addressed. A safe healthcare system involves leadership commitment to safety, creating a safety-first culture, ensuring safe procedures, and building workforce competencies. Additionally, improving teamwork, communication, and engaging patients and families in decision-making are essential for safety. Establishing systems for reporting incidents fosters continuous learning and improvement. Investing in patient safety enhances health outcomes, reduces costs, boosts system efficiency, and restores public trust in healthcare. Traditional approaches often link errors to incompetence, punishing individuals rather than promoting learning. The blame game discourages reporting mistakes, keeping crucial issues hidden. Moving away from this model is key to fostering openness. The ultimate goal should be a world where no one is harmed in healthcare, ensuring that all patients receive safe, respectful care every time, everywhere.

**End-piece: 'Primum non nocere' (First, do no harm) – Hippocrates (c. 460 BC-c. 370 BC), Greek Physician and Philosopher.**

### Author declaration

### Conflict of interests

None.

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