**Course:** Fundamentals in Patient Safety

**Topic:** What is Patient Safety?

Patients can be harmed from health care, resulting in permanent injury, increased lengths of stay in hospital and even death. Over the past 15 years, we have learned that adverse events occur not because people intentionally hurt patients, but rather due to the complexity of health-care systems, where treatment and care depend on many factors, in addition to the competence of health-care providers. When so many and varied types of health-care providers, such as dentists, dieticians, doctors, midwives, nurses, surgeons, pharmacists, social workers, and others are involved, it can be difficult to ensure safe care, unless the system is designed to facilitate the delivery of quality and safe services.

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**Patient Safety:** the reduction of risk of unnecessary harm associated with health care to an acceptable minimum. *(WHO-ICPS, 2009)*

**The burden of unsafe care**

Health care is one of the most unsafe industries. Studies show that about 10% of hospital patients suffer an adverse event (AE) and the incidence of AE in developing countries is higher than 10%.

| Health care - associated infection (HCAI) | ■ Hundreds of millions of patients are affected by HCAI worldwide each year, leading to significant mortality and financial losses for health systems and patients  
■ Of every 100 hospitalized patients at any given time, 7 in developed and 10 in developing countries will acquire at least one HCAI  
■ 5-15% of hospitalized patients acquire HCAI - about 40% in ICUs - mortality from HCAI is 12%-80% (WHO)  
■ 5 million HCAI estimated to occur in hospitals in Europe/year (WHO) |
| Medication errors | Leading cause of injury in developed-developing countries  
■ 1.5 million harmed and thousands killed in USA/year (2006)  
■ In some countries, 70% of patients’ medication histories contain errors (2005) |
| Unsafe surgery | ■ 234 million surgical procedures/year worldwide (more than childbirths)  
■ 7 million complications, 1 million deaths worldwide each year (WHO) |
| Clinical handovers | Communication between units/health-care team/hospital facilities/community  
■ 15% handovers result in adverse events (Australia, 2007) |
| Injection safety | ■ Over 70% of injections in primary health-care are unnecessary  
■ Unsafe injections account for 33% of new HBV infections, 42% of HCV and 2% of all new HIV infections worldwide |

- “Adverse events,” include missed and delayed diagnoses, mistakes during treatment, medication mistakes, delayed reporting of results, miscommunications during transfers and transitions in care, inadequate postoperative care, mistaken identity and others.
- Patient safety is an issue in all countries that deliver health services, whether these services are privately commissioned or funded by the government.
- In developing countries, the poor state of infrastructure and equipment, unreliable supply and quality of drugs, shortcomings in infection control and waste management, poor performance of personnel, low motivation or insufficient skills and severe under-financing of the health services makes the probability of adverse events much higher.
- Many of the features of patient safety programmes do not require financial resources, but rather the commitment of individuals to practise safely.
• Health-care providers can improve patient safety by engaging with patients, checking procedures, learning from errors and communicating effectively within the health-care team.
• Such simple activities can help minimize costs, while minimizing the harm caused to patients too.
• Reporting and analysis of errors can help identify the contributing factors. Understanding the factors that lead to errors is essential in order to develop changes that will prevent future errors.

Economic costs
Studies have shown that there are significant economic costs associated with unsafe care.

<table>
<thead>
<tr>
<th>Medical errors and adverse events (litigation, settlements etc)</th>
<th>USA: annual impact, $19.5 billion (2008)</th>
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<tbody>
<tr>
<td></td>
<td>UK: £400 million in settlements every year</td>
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<tr>
<td></td>
<td>Australia: $18 million (1997-1998)</td>
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<tr>
<td>Health care-associated infections</td>
<td>Europe: 13-24 billion Euros/year (or an average of 25 million extra days hospital stay)</td>
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<td>USA: annual impact, $6.5 billion (2004)</td>
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<tr>
<td>Medication errors</td>
<td>USA: annual impact, $3.5 billion (2006)</td>
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Challenges related to unsafe care can be categorized into:
• Unsafe medical care, e.g.: unsafe medication, injection practices, unsafe blood practices, health care-associated infection, unsafe care related to mothers and neonates or the elderly, patient falls.
• Structural factors contributing to unsafe care, such as no regulation or accreditation, no culture of safety, poor training and education of health-care workers (HCW), environment pressures.
• Poor processes contributing to unsafe care, such as misdiagnosis, poor test follow-up, counterfeit drugs, poor involvement of patients in their care.

Lessons from other industries
• Large-scale technological disasters involving spacecraft, offshore oil platforms, railway networks, nuclear power plants led to the development of frameworks for safer workplaces.
• Accidents are usually the result of multiple factors. Individual situational factors, workplace conditions and latent organizational factors and management decisions are often involved.
• The more complex the organization, the greater potential for a large number of system errors.
• J. Reason analysed many large-scale disasters 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 negative outcomes.
• An analysis of the Chernobyl catastrophe showed that organizational errors and violations of operating procedures that were viewed as evidence of a “poor safety culture” at the Chernobyl plant were really organizational characteristics that contributed to the incident.
• The lesson learnt from the Chernobyl and ‘Challenger’ accident investigations was the significant importance of the extent to which an organizational culture tolerates violations of rules and procedures.

The blame culture
• The way health care has managed errors has been based on the “person approach”- the individuals involved in the care at the time of the incident are held accountable.
• “Blaming” in health care is common for resolving problems; referred to as the “blame culture”.
• Systemic improvements cannot be made as long as we focus on blaming individuals. This willingness to assign blame is thought to be one of the main constraints on the health system’s ability to manage risk and improve care.
Why do we blame?

- It is human nature to blame someone and it is emotionally satisfying for everyone involved in investigating an incident if there is someone to blame.
- It is a human belief that punitive action sends a message to others that errors are unacceptable and that those who make them will be punished. This assumption is based on a belief that the offender somehow chose to make the error instead of adopting the correct procedure.
- Health-care providers 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 treatment than to those at managerial level.
- i) Human actions are almost always constrained and governed by factors beyond the control of the individual; ii) people cannot easily avoid actions that they did not intend to perform (J. Reason).

Errors have multiple causes

- These are: personal, task-related, situational and organizational. Within a skilled, experienced and well-intentioned workforce, situations are more amenable to improvement than people.
- Today, most complex industrial/high-technological managers realize that a blame culture will not bring safety issues to the surface.
- While many health-care systems are beginning to recognize this, thinking has not yet moved away from the person approach—in which finger-pointing or cover-ups are common—towards an open culture in which processes are in place to identify and rectify failures.
- Organizations that place a premium on safety, examine all aspects of their system in the event of an accident, including equipment design, procedures, training and organizational features.
- Almost 80% of errors or adverse events are system derived.

Violations

- In all cultures, health-care professionals are required to be accountable for their actions, maintain competence and practise ethically. In learning about systems thinking, health-care providers should appreciate that they are accountable for their actions.
- Many health-care professionals break professional rules daily, such as using incorrect hand hygiene techniques or letting inexperienced providers work without proper supervision.
- J. Reason studied the role of violations in systems and argued that, in addition to a systems approach to error management, effective regulators with the appropriate legislation, resources and tools are needed to sanction unsafe clinician behaviour.

A violation is a deviation from safe operating procedures, standards or rules (J. Reason)

Routine violations: Professionals who fail to practise hand hygiene because they feel they are too busy is an example of a routine violation. These violations are common and often tolerated.

Optimizing violations: Senior professionals who let students perform a procedure without proper supervision because they are busy with their private patients.

Necessary violations: Time-poor nurses and doctors who knowingly skip important steps in administering (or prescribing) medication, or a midwife who fails to record a woman's progress because of time constraints, are examples of necessary violations.

- Using a systems approach, the entire system of care can be examined 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 actually responsible.

A model for patient safety

Leaders in patient safety have defined patient safety as: “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.”
This definition provides the scope for the conceptual model of 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. methods for feedback and continuous improvement.

The WHO International Conceptual Patient Safety (ICPS) framework

- The ICPS conceptual framework addresses 48 key concepts and preferred terms.
- It aims to represent a continuous learning and improvement cycle emphasizing identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience; all of which occur throughout any point, within the conceptual framework. The 10 high-level classes are: 1. Incident type; 2. Patient outcomes; 3. Patient characteristics; 4. Incident characteristics; 5. Contributing factors; 6. Organizational outcomes; 7. Detection; 8. Mitigating factors; 9. Ameliorating actions; 10. Actions taken to reduce risk.

The ICPS framework is a convergence of international perceptions of the main issues of patient safety, to facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care.

How to apply patient safety thinking to all health-care activities

**Develop relationships with patients:** Every health-care provider should relate with patients as unique human beings with their own experience of their disease. The application of knowledge and skills alone will not necessarily result in the best outcomes for patients. Safe and effective care depends on patients disclosing their experiences of their illnesses, their circumstances, their attitudes to the risks involved, and their values and preferences on how they wish to be treated.

**Understand the multiple factors involved in failures:** There are many factors associated with an adverse event. Consider errors from a systems perspective. Questions about the underlying factors and causes of errors should be asked: ‘what happened?’ rather than ‘who was involved?’. The “whys” (why something happened when given an answer) is a method used to investigate the causes focused on the system rather than the health-care provider involved.

**Avoid blaming when an error occurs:** Health-care providers must support each other when they are involved in an adverse event. Unless they are open about errors, there will be little opportunity to learn from them. Conduct meetings or peer-review forums, such as morbidity and mortality meetings, to review such events.

**Practise evidence-based care:** Health-care providers should learn how to apply evidence-based practices and be aware of the role of protocols/guidelines and how important it is to follow them.

**Maintain continuity of care for patients:** The health-care system is made up of many parts that interrelate to produce a continuum of care. Understanding the journey that patients make through this system is necessary in understanding how failures arise. Important information can be missed, outdated or be incorrect, leading to inadequate care or errors.

**Be aware of the importance of self-care:** Health-care providers should be responsible for their own well-being and that of their colleagues.

**Act ethically every day:** Health-care providers should be aware of their legal and ethical obligations to put the interests of their patients first.

The delivery of safe health care

The success of a patient’s care depends on understanding the entire health system available to that particular patient. An understanding of systems (Topic 3) will help the health-care providers 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 in an effective and timely manner.

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