# Medical Harm and Medical Safety

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Greek healers in the 4th century B.C knew that treatment could cause unforeseen harm to the patient. Thus the Hippocratic Oath pledged to "prescribe regimens for the good of my patients according to my ability and judgment and never do any harm to anyone[1]. However despite an increasing emphasis on a scientific basis of medical practice, magnitude and the character of harm to the patient because of medical treatment is probably underestimated[2].

**Medical harm** is doing the wrong thing when meaning to do a right thing. In other words medical harm is failure of a planned action to achieve its intended outcome or a deviation between what was done and what actually should have been done.

It refers to any systemic failure in the health care systems that result in a negative psychological or physical consequence. Medical harm is not limited to iatrogenic illness. Thus, the Institute for Healthcare Improvement (IHI) defines medical harm as the "unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment), that requires additional monitoring, treatment or hospitalization, or that results in death. Such injury is considered harm whether or not it is considered preventable, whether or not it resulted from a medical error, and whether or not it occurred within a hospital." With this definition, IHI estimates that "15 million instances of medical harm occur each year in the United States". The term medical harm does not imply intent or negligence nor indicate the severity of the damage.

In 1999, in the US Institute of Medicine (IOM) of the National Academy of the Sciences released the report, "To Err is Human: Building a safer health system." It caused a furore, after the statistics it revealed were staggering: 44,000 to 98,000 preventable deaths occured due to medical errors annually; 7,000 deaths due to medicational errors alone[3]. Within two weeks of the report's release Congress a hearing on the subject and President Clinton ordered a government wide study of the feasibility of implementing the report[4].

Initial criticisms of the methodology of IOM estimates[5] focused on the statistical methods that amplified low number of incidents in the pilot studies to the general population[6]. However the subsequent reports emphasized the striking prevalence and consequences of medical errors.

Since the Harvard study in 1991 first described the extent of harm to patients, other countries (Australia, UK, New Zealand, Denmark and some other countries) have found similar results, notwithstanding the differences in their cultures and health systems[7,8,9,10]. The realization that health care actually harms patients has increased scrutiny of patient care in the context of an increasingly complex health system. This complexity has been intensified by rapidly changing medical technology and service demands[11,12] .

While less well documented, the scope of the patient safety problem in developing countries is believed to be far more serious. Based on existing information[13] .

- The risk of acquiring a health care-associated infection is estimated to be 2 to 20 times higher in developing countries than in industrialized ones.
- Neonatal infections among hospital born babies in developing countries were found to be 3 to 20 times higher than those reported in industrialized countries.
- WHO estimates that people residing in South East Asia receive more than 5 injections per year and 50% of the injections are 'unsafe'. Unsafe practices include reuse of syringes and needles and those practices which expose health care workers and the community to the risk of needle stick injuries.

- Over 1,000 metric tons of health care waste including injection-related waste every day which is not properly disposed of.
- South-East Asia is a large producer of medical devices that are exported all over the world. However, the devices sold in the domestic market are often manufactured outside the regulatory framework and may not meet international standards.
- Developing countries account for around 77% of all reported cases of counterfeit and substandard drugs in the world and that over 50% of all medicines prescribed are not justified.

We know that health care is a complex system and hence there is increased possibility of something going wrong. The same drugs and surgeries that can save lives have the potential to cause harm. Modern health care is delivered in teams, not by individuals. Modern clinicians rely on the support of intricate health-care systems to enable them to carry out their task. Errors can occur at each stage in any of these processes[14]. The human brain copes quite well with complexity. However regardless of their experience, intelligence, motivation or vigilance; human beings can make mistakes. One has to assume that errors will occur. We must design things in the workplace to try to minimize likelihood of the occurrence of error or its consequences. Utmost caution and adherence to protocols is needed.

The importance of human factors has long been realized in aviation. Carriers achieve nearly failure free record despite complexities. The aviation industry requires individual pilots to use a number of personal checklists to monitor their performance—an approach that health-care workers could easily emulate. For instance, if a wire that is vital for planes functioning is found defective in an airplane's preflight check, within 24 hours all the planes of that kind need to be checked for a similar defect. We have to reach similar level of security in medical care too.

## Medical Safety

After the landmark 1999 report of the Institute of Medicine, a great deal of interest has been generated in medical safety. Medical safety is defined as absence of medical harm. This goes much beyond the traditional Hippocratic Oath of "do no harm."

WHO has formed a World Alliance for Medical safety, which has done lot of ground work and published reports every two years, the latest being the WHO World Alliance for Patient Safety Forward report 2006-2008.

As the Alliance has undertaken work throughout the world, a series of common challenges have emerged[15].

1. Patient Safety is everyone's business. There is need to raise awareness of the scale of the patient safety problem and build political commitment to action. Without strong and committed leadership the patient safety movement cannot succeed.
2. We must solve safety problems for which we already have ample information about causes and solutions. It is striking that the same errors and system failures are repeated not only across but also within countries.
3. The problem of timely identification of new issues and their solutions. Despite increased effort, our systems to detect risk and patient safety problems are still primitive. Even when adverse events do occur, many of them are not reported by health-care workers. A culture of blame — rather than a culture of learning — is alive and well.
4. Developing open partnerships with patients. Health-care organizations are typically defensive in dealing with patients and carers.

## Why Medical Harm occurs[2]

There are some situations with increased likelihood of things going wrong. The most common of these have been identified in human, organizational and technical domains:

### Human

1. Fatigue
2. Distracting environment
3. High workload
4. First-time evolution and unfamiliarity with tasks
5. Vague or incorrect guidance
6. Poor Judgment and logical error
7. Imprecise communications
8. Poor procedures especially with no or inadequate supervision

### Organizational

1. Workplace design
2. Planning/policies
3. Administration/Finance
4. Leadership
5. Supply management

6. Handovers
7. Supervision/Feedback
8. Mismatch of personals

### Technical

1. Poor equipment
2. Poor maintenance
3. Lack of equipment
4. Complexity
5. Checklist unavilability

### Reporting of Medical Harm

The four core principles underlying the guidelines are:

1. Improve communication techniques and develop a safe culture of team work.
2. Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill effects from reporting.
3. Reporting should not be arduous, time consuming and prolonged.
4. Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of health care. In the end these recommended changes should be implemented.

### A suggested reporting format could be as follows:

1. The Discovery – Who, How
2. The Event – What, where, when, who, why
3. Risk assessment (severity, Preventability, Recurrence)
4. Narrative
5. Ancillary information – Product and Patient information
6. Analysis
7. Lessons Learned
8. Implementation

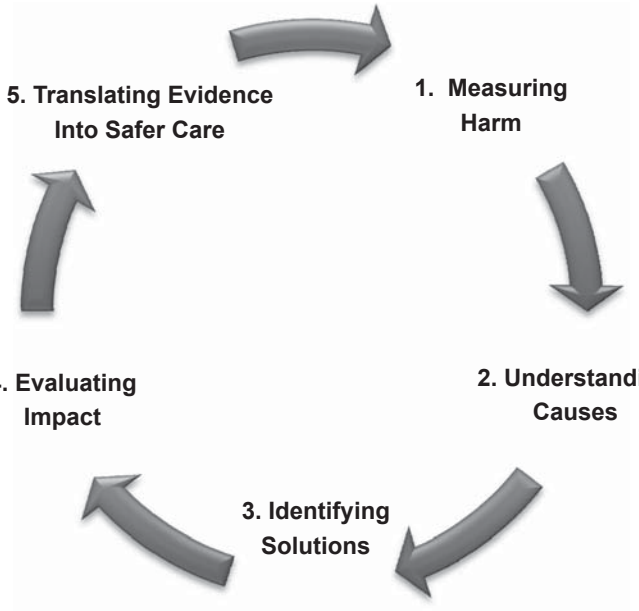
Unless we have reached the stage of Implementation, reporting is not complete. Implementation could be undertaken within the institute where the error occurred or may need wider dissemination for education.

### When Medical Error Occurs

There are two schools of thoughts regarding dealing with medical harm. The traditional one puts someone on the spot (blame culture) and asks that person to work harder. The newer view is to take a system approach [16].

The person approach sees an error as a product of carelessness and remedial measures of 'naming', 'blaming', 'shaming' and 'retraining' are directed towards the error maker. This approach does not work because only a very small minority of cases is deliberate violations. This approach does not solve the problem and only makes it worse. There is a false sense of security that something has been done and leads clinicians to hide future errors.

The system approach works better. The more we understand why the error occurred; the more checks can be put in place to reduce recurrence. An investigation typically follows the following schema:



## Case Study in Medical safety

1. Incident monitoring and measuring harm involves collecting and analysing information about any events that could have harmed or did harm anyone in the organization. This is a fundamental component of an organization's ability to learn from error.
2. After the harm has been identified and tackled in the best possible way, an investigation is made to try to understand underlying causes. The most common causes are identified by an acronym HALT.
   - H Hungry
   - A Angry
   - L Late
   - T Tired

## Limited memory capacity further reduced by:

- Stress
- Illness
- First day of work after a holiday
- Language or cultural factors
- Hazardous attitudes

Awareness of the most common types of breakdowns and factors could help efforts to identify and prioritize strategies to prevent diagnostic errors.

## The Staff Check List

**IMSAFE** is a mnemonic used by aircraft pilots to assess their fitness to fly. This can be recommended for medical workers too[17].

The staff should check with themselves- "**Am I safe to work today**?"

A performance-shaping factors "checklist" is as follows;

I Illness
M Medication- prescription and others
S Stress
A Alcohol
F Fatigue
E Emotion

3. Identifying solutions includes
   - Education
   - New protocols
   - New systems
4. The impact of these interventions should be evaluated and will form evidence based interventions, which can be used more widely.

Institutions that have created "blameless reporting systems" have had some success in increasing reporting, but these systems are not universally adopted. Currently no mandatory system exists in any country. At this point, the issue of reducing medical harm has not been adequately addressed and much more needs to be done.

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