

# Clinical decision making and Medical errors

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## Clinical decision making lectures 2021



❑ A number of **major challenges to delivering high quality healthcare** are now widely recognized:

1. unknowing **variation** in clinical practice and service delivery;

2. **errors** of commission and omission;

3. **failure** to implement new knowledge and technology systematically and appropriately;

4. **over-use and under-use of services** – inappropriate care;

5. unsatisfactory patient experience;

6. **poor quality** clinical practice;

7. **waste.**



- ❑ There is a **serious gap** between the **medical care patients should receive** and that which they actually receive, leading to the observation that the “application of what is known already will have a **greater impact on health and disease** than any single drug or technology likely to be introduced .
- ❑ The **scale and complexity of modern healthcare systems** is increasing.
- ❑ The sheer **quantity of medical information**, is frequently beyond the power of one person to comprehend.
- ❑ Evidence is accumulating that **failing to provide appropriate treatment** is a problem of epidemic proportions.
- ❑ Some patients admitted to hospitals experienced an “**adverse event**” (something that actually or potentially causes significant **patient harm**); around half of these events were judged **preventable with “ordinary standards of care**



❑ Patients die in hospitals each year as a result of **medical errors**.

Deaths due to **preventable adverse** events exceed the deaths attributable to motor vehicle accidents ,breast cancer ,or AIDS .

**Six performance characteristics** that, if improved, **would reduce the gap** between the **quality of healthcare actually received** and the **quality of healthcare that it should be possible to achieve** given the current state of medical knowledge: “

1. **Safety** —**avoiding injuries** to patients from the care that is intended to help them.
2. **Effectiveness** —**providing services based on scientific knowledge** to all who could benefit and **refraining from providing services to those not likely to benefit** (avoiding under use and overuse).



3. *Patient-centered*— providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
4. *Timeliness* —reducing waits and sometimes harmful delays for both those who receive and those who give care.
5. *Efficiency* —avoiding waste, in particular waste of equipment, supplies, ideas, and energy.
6. *Equitability*—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status."



- ❑ **Medical errors** and other causes of **departures** from “best clinical practice” are known to have a major impact on the quality and safety of patient care.
- ❑ Improving the **effectiveness** of clinical services and increasing **safety** while **also reducing costs** is a massive challenge facing all healthcare services.
- ❑ **Clinical practice depends on human skills and organizations**, and these are subject to **human error and system failures**.
- ❑ However **informatics systems** can significantly **reduce**, and in some cases **eradicate**, many errors and service delivery problems.
- ❑ **Standards and regulations** for medical malpractice **vary by country and authority** within countries.
- ❑ Medical professionals may obtain **professional liability insurances** to compensate the risk and costs of lawsuits based on medical malpractice. **Medical defense**



# Clinical error

## Definition and patterns of error

The **clinical error is defined** as ‘the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim’. In other words, errors can **arise in planning actions** or in **executing them**.

As examples of the types of clinical error , adverse drug events and improper transfusions, surgical injuries and wrong–site surgery, suicides, restraint–related injuries or death, falls, burns, pressure ulcers and mistaken patient identity.

They commented that high error rates with serious consequences are most likely to occur **in intensive care units, operating rooms and emergency departments**.



# Types of clinical error

## *Diagnostic*

- Error or delay in diagnosis
- Failure to use indicated investigations
- Use of inappropriate investigations
- Failure to act on results of investigations

## *Treatment*

- Error in the performance of a procedure
- Error in administering a treatment
- Error in the dose of drug
- Avoidable delay in treatment

## *Preventive*

- Failure to provide prophylactic treatment
- Inadequate follow-up

## *Other*

- Failure of communication
- Equipment failure
- System failure





## ❖ List of Medication Errors

- Incomplete patient information
- Unavailable drug information (warnings)
- Miscommunication of medication order
- Confusion between drugs with similar names
- Lack of appropriate drug labeling
- Environmental conditions that distract health care providers  
Click to add text
- Failure to **adjust dosage** in response to a change in hepatic/renal function
- History of **allergy** to the same or related medication
- Wrong drug name, dosage form, or **abbreviation on order**
- **Incorrect dosage calculation i.e. in pediatrics**



## ❖ Treatment errors

### Error in administering treatment

- ❑ The use of combinations of treatments that are recognized as likely to result in an adverse event is often the subject of litigation.
- ❑ For example, the combination of lithium and diuretics can result in elevated and toxic lithium levels.
- ❑ Most negligence claims regarding these drugs arise when a doctor prescribes a diuretic to a patient who is on lithium and no one adequately monitors lithium levels or acts on the results of monitoring. It is not unusual for the patient to continue to attend a psychiatric clinic following the prescription of a diuretic, and psychiatrists may become involved in the litigation because of unclear arrangements between the doctor and the psychiatrists about who should monitoring lithium levels .

- ❑ Error in the continuing prescription of treatments that are indicated for brief use
- ❑ These claims can arise from the continuing prescription of drugs such as clomethiazole and diazepam.
- ❑ In the case of the prescription of a drug during an **in-patient episode** is continued indefinitely by the doctor and/or is **not stopped during subsequent out-patient** appointments.



## ❖ Surgical Events

- ❑ Surgery performed on the **wrong body part**  
Surgery performed on the **wrong patient** .
- ❑ **Wrong surgical procedure** on a patient
- ❑ **Retention of a foreign object** in a patient  
after surgery or other procedure
- ❑ Intraoperative or immediately post-operative **death** in a normal healthy patient



## ❖ Product or Device Events

- ❑ Patient death or serious disability associated with the use of **contaminated drugs, devices**, or biologics provided by the healthcare facility
- ❑ Patient death or serious disability associated with the **use or function of a device in patient care in which the device is used or functions other than as intended**
- ❑ Patient death or serious disability associated with **intravascular air embolism** that occurs while being cared for in a healthcare facility



## ❖ Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with **patient disappearance for more than four hours**
- Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility



## ❖ Care Management Events

- ❑ Maternal death or serious disability associated with labor or delivery on a low-risk pregnancy while being cared for in a healthcare facility.
- ❑ Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- ❑ Death or serious disability (*kernicterus*) associated with failure to identify and treat jaundice in newborns
- ❑ Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- ❑ Patient death or serious disability due to spinal manipulative therapy
- ❑ Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products (transfusion of the wrong blood group )



# ❖ Environmental Events

- ❑ Patient death or serious disability associated with an **electric shock while being cared for in a healthcare facility**
- ❑ Any incident in which a line designated **for oxygen or other gas to be delivered to a patient contains the wrong gas** or is contaminated by **toxic substances**
- ❑ Patient death or serious disability associated with a burn incurred **from any source while being cared for in a healthcare facility**
- ❑ Patient death associated with a **fall** while being cared for in a healthcare facility
- ❑ Patient death or serious disability associated with the **use of restraints or bedrails** while being cared for in a healthcare facility





## ❖ Criminal Events

- ❑ Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- ❑ **Abduction** of a patient of any age
- ❑ **Sexual assault** on a patient within or on the grounds of a healthcare facility
- ❑ Death or significant injury of a patient or staff member resulting from a **physical assault** that occurs within or on the grounds of a healthcare facility



## ■ Explanatory models of human error

There are two models of causation of human error.

1. The **person approach** focuses on **the errors of individuals**, and is apt to accuse them of forgetfulness, inattention or moral failure.
2. The **system approach** identifies the conditions and systems under which **individuals work as the source of the error**, with the aim of both understanding the origins of error and building defenses to avert errors or to mitigate their effects .

The system approach acknowledges that the majority of clinical errors **do not result from individual irresponsibility or the actions of a particular group** .

The most common systems deficiencies identified as underlying clinical errors are :

- **failures in dissemination of drug knowledge and**
- **inadequate availability of patient information** such as test results necessary for safe treatment



# Strategies for reducing clinical error

1. Reduce the complexity of tasks.
2. Optimize information processing by the use of protocols or aids
3. Automate (computerize ) wisely and as necessary.
4. Use of constraints, as in the delivery system of anaesthetic gases
5. Diminish unwanted side-effects of change, particularly when new techniques or treatments are first introduced



# Six Sigma has been shown to improve patient care by:

- Reducing the number of errors made by physicians, nurses and technicians
- Improving lab turnaround times
- Reducing appointment wait times
- Decreasing steps in the supply chain
- Accelerating reimbursement for insurance claims
- Improving patient outcomes



## ❖ Public attitudes to medical error

- ❑ The most worrying aspect of the recent changes in public attitude to clinical error is the **increased criminalization of fatal medical errors.**
- ❑ It is reported that the increase in the charge of assassination against doctors **globally.**
- ❑ The increase is attributed to society's changed attitude towards the notion of gross negligence.



## ❖ **The Four Ds of Negligence.** The American Medical Association

assign the following four Ds of negligence:

- 1. Duty.** Patients must show that a physician-patient relationship existed in which the **physician owed the patient a duty.**
- 2. Derelict.** Patients must show that **the physician failed to comply with the standards of the profession.** For example, a gynecologist has routinely taken Pap smears of a patient and then, for whatever reason, does not do so. If the patient then shows evidence of cervical cancer, the physician could be said to have been derelict.
- 3. Direct cause.** Patients must show that **any damages were a direct cause of a physician's breach of duty.** For example, if a patient fell on the sidewalk and damaged her cast, she could not prove that the cast was damaged because it was incorrectly or poorly applied by her physician. It would be clear that the damage to the cast resulted from the fall. If, however, the patient's leg healed incorrectly because of the way the cast had been applied, she might have a case.
- 4. Damages.** Patients must prove that they suffered injury



# Proving Fault in Medical Malpractice Cases

Legal liability for injuries caused by medical malpractice can be established under a number of legal theories:

## **Negligence (carelessness , inattention )**

Most medical malpractice cases proceed under the **theory** that a **medical professional was negligent in treating the patient.**

To establish medical negligence, an injured patient must prove (**Elements of the case**)



# Negligent Prescription of Medications or Medical Devices

- ❑ A medical professional may be held liable for the negligent prescription of a medication or medical device if he or she ignored the manufacturer's instructions, or prescribed an incorrect medication or dosage, which resulted in injury to the patient.
- ❑ In some cases, a pharmaceutical manufacturer may be liable where a drug caused a patient injuries, but only if the manufacturer failed to warn of potential side effects or dangers of the drug..





- ❑ In most cases, the prescribing physician is considered a "learned intermediary," which means that because of his or her superior medical knowledge, and the fact that he or she has been given adequate information from the manufacturer, he or she is in the best position to determine whether a particular drug or device is appropriate for a patient.
- ❑ Thus, the physician has the primary duty of advising the patient of the risks and side effects of a medication or medical device he or she prescribes



# Informed Consent

- ❑ In many situations, the **failure to obtain a patient's "informed consent"** relative to a procedure or treatment is a form of medical negligence, and may even give **rise to a cause of action for battery**.
- ❑ Although the specific definition of informed consent may vary from state to state, it means essentially that a physician (or other medical provider) **must tell a patient all of the potential benefits, risks, and alternatives involved in any surgical procedure, medical procedure, or other course of treatment, and must obtain the patient's written consent to proceed.**



## Breach of Contract or Warranty

- ❑ Although doctors very rarely promise specific results from procedures or treatments, in some cases they do, and the **failure to produce the promised results may give rise to an action for breach of contract or breach of warranty.**
- ❑ For example, a **plastic surgeon** may promise a patient a certain result, which result may be judged more easily than other types of medical results, simply by viewing the patient.
- ❑ Similarly, if a patient is not satisfied with the outcome of a procedure, and the physician had guaranteed or warranted a certain result, the patient may attempt to recover under a theory of breach of **warranty.**



# Methods to improve safety and reduce error

❑ Medical care is frequently compared adversely to aviation: while many of the factors that lead to errors in both fields are similar, aviation's error management protocols are regarded as much more effective.

1. patient's **informed consent** policy
2. patient's getting a **second opinion** from another independent practitioner with similar qualifications
3. voluntary reporting of errors (to obtain valid data for cause analysis)
4. Electronic or paper reminders to help patients maintain medication adherence
5. systems for ensuring review by experienced or specialist practitioners
6. -hospital accreditation



# What influences patients to make malpractice claims?

- A **poor relationship** with the healthcare provider or clinician before the alleged (unproven )injury
- Television advertising by law firms
- Explicit recommendations by health providers or professionals to seek legal advice
- The impression of **not being kept informed** by the healthcare provider or clinician
- **Financial concerns**



## Prevention

There are numerous proposed strategies for :

- ❑ reducing the incidence of clinical errors and
- ❑ enhance patient safety,

❑ It also advocated a nationwide public mandatory system for **reporting errors** that would help managers and clinicians **to identify and learn from them.**

❑ Furthermore, it called for **improvement in safety** through the actions of overseeing organizations, professional groups and others.

❑ Finally, it directly asked healthcare organizations **to ensure safe practices** at the level of delivery.

