Human Factor in Healthcare and Patient Harm
Part 5

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Recap

- Recap of previous presentation
  - ❖Hospitals and health care organizations are hazardous places.
  - ❖Also the hospitals of today are very complex.
  - ❖Errors are not infrequent in hospitals.
  - ❖There are many types of errors that occur in hospitals.
    - ➢Some may be minor in nature and go unnoticed or the effect of the error may be mild and do not harm anybody.
    - ➢But some errors may be disastrous for a patient.

Recap

- Contd.
  - Whenever a patient comes to a hospital, the minimum expectation the patient has is that the doctor shall provide a correct explanation for his/her symptoms in the form of an accurate diagnosis.
    - But that does not always happen.
  - There are various causes for the diagnostic errors.
  - Diagnostic process is complex and happens over a period of time.
  - The diagnostic process needs to synthesise diagnostic information from various sources, and needs to apply clinical reasoning to that synthesised information to arrive at the diagnosis.
  - Errors can happen at any stage of the diagnostic process.
    - Human cognitive factors can be a major cause of diagnostic errors.

Recap

- Contd.
  - Clinical laboratories are one of the major sources to provide diagnostic information.
  - However, in spite of the high degree of automation in clinical laboratories, errors still happen.
  - The clinical laboratory error can occur at any phase of the patient's sample processing, that is pre-analytical, analytical, and post-analytical.
  - However, almost seventy percent of the clinical laboratory errors occur in the pre-analytical phase.
  - Maximum human intervention also occurs in this phase.

Medication Safety

Medication Safety

Key Steps for ensuring medication safety

WHO

Medication Error

- Scope
  - ❖ Medications are offered by health services throughout the world
  - ❖ Medication use has increased considerably
    - ➢ As per the INN list there are over 8000 pharmaceutical products
  - ❖ With substantial and increasing medication use comes a growing risk of harm
    - ➢ This is compounded by the need to prescribe for an aging population with increasingly complex medical needs and introduction of many new medications

Medication Error

- Severity of the problem[23]
  - Unsafe medication practices and medication errors are a leading cause of avoidable harm in health care systems across the world
  - The scale and nature of this harm differs between low-, middle-, and high-income countries
  - Globally, the cost associated with medication errors has been estimated at US$ 42 billion annually.
  - Patients living in low-income countries experience twice as many disabilities-adjusted life years lost due to medication-related harm than those in high-income countries

Medication Error

- Medication errors occur when weak medication systems and/or human factors such as:
  - Fatigue
  - Poor environmental conditions, or
  - Staff shortages
- These factors affect:
  - Prescribing
  - Transcribing
  - Dispensing

Medication Error

- Administration, and
- Monitoring practices

- These factors can then result in severe harm, disability and even death
- Errors occur most frequently during administration
  - However, there are risks at different stages of the medication process

- Approaches to classifying medication errors
  - There are several methods:

Medication Error

- One approach is to base the classification on the stage in the sequence in the medication use process, such as:
  - Prescribing
  - Transcribing
  - Dispensing
  - Administration, or
  - Monitoring
- Another approach is to consider types of errors occurring, such as:

Medication Error

- Wrong medication
- Dose
- Frequency
- Administration route or patient

❖ A further approach

- This approach classifies errors according to whether they occur from mistakes made when planning actions
  - These are knowledge-based or rule-based mistakes, or
  - Errors in the execution of appropriately planned actions
    - ✓ Action-based errors known as “slips”, or
    - ✓ Memory-based errors known as “lapses”

Medication Error

- Errors may also be classified according to their level of severity
- These approaches are not mutually exclusive, and
  - There is no strong evidence to support particular methods of defining or classifying errors
  - The approach taken will depend on the setting and the purpose of the classification

- Undesirable outcomes
  - They include:
    - Adverse drug reactions,

Medication Error

- drug-drug interactions,
- lack of efficacy,
- Suboptimal patient adherence, and Poor quality life

- These undesirable outcomes have significant health and economic consequences. These include:
  - Increased use of health services
  - Preventable medication related hospital admissions, and death
  - In some countries 6-7% hospital admissions appear to be medication related
  - Of these, over two-thirds are avoidable
  - The problem is more pronounced in the elderly because of multiple risk factors one of which is Polypharmacy

Medication Error

- Definition of Medication Error
  - There is no consensus about the definition of a medication error
  - " Reporting and Prevention defines a medication error as:
    - *"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.*
    - *Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use"*

Medication Error

- Medication error has also been defined as:
  - *"Medication error has also been defined as a reduction in the probability of treatment being timely and effective, or an increase in the risk of harm relating to medicines and prescribing compared with generally accepted practice"*
- Causes of medication error:
  - Many studies have been conducted to determine factors associated with medication errors
  - A study showed that factors associated with medication errors included poor coordination of care, cost related barriers to medical services or medicines, multimorbidity and hospitalisation

Medication Error

- A summary of factors that may influence medication errors:
  - Factors associated with health care professionals
    - Lack of therapeutic training
    - Inadequate drug knowledge and experience
    - Inadequate knowledge of the patient
    - Inadequate perception of risk
    - Overworked or fatigued health care professionals
    - Physical and emotional health issues

Medication Error

- Contd.
  - Poor communication between health care professionals and with patients
  - Physical and emotional health issues
- Factors associated with patients
  - Patient characteristics (e.g., personality, literacy and language barriers)
  - Complexity of clinical cases, including multiple health conditions, Polypharmacy and high-risk medications
- Factors associated with work environment
  - Workload and time pressures

Medication Error

- Contd.
  - Distractions and interruptions
  - Lack of standardized protocols and procedures
  - Insufficient resources
  - Issues with the physical work environment
    - E.g. lighting, temperature and ventilation
- Factors associated with medicines
  - Naming of medicines
  - Labelling and packaging

Medication Error

- Factors associated with tasks
  - Repetitive systems for ordering, processing and authorization
  - Patient monitoring
    - Dependent on practice, patient, other health care settings, prescriber
- Factors associated with computerised information systems
  - Difficult processes for generating first prescription
    - E.g., drug pick lists, default dose regimens and missed alerts
  - Difficult processes for generating correct repeat prescriptions

Medication Error

- Contd.
  - Lack of accuracy of patient records
  - Inadequate design that allows for human error
- Primary-secondary care interface
  - Limited quality of communication with secondary care
  - Little justification of secondary care recommendations

- The Institute of Medicine publication, Preventing Medication Error cites a case, in 1994, of death of an one-day old baby born to a mother with prior history of syphilis[24]

Medication Error

- Infant's parents spoke only Spanish, making communication difficult
  - Treatment of the disease could not be verified easily
- Despite the constraints, a decision was taken to treat the infant for congenital syphilis
  - A single dose of "Benzathine penicillin G 150,000U IM" was prescribed
  - A nurse practitioner had documented a recommendation from the health department
  - The pharmacist filling the order consulted both the infant's progress notes and a drug reference book to determine the usual dose of the drug for an infant

Medication Error

- However the pharmacist misread the dose in both sources as 500,000 units/kilogram
  - This is the typical adult dose, the infant dose is 50,000 units/kg
- The pharmacist misread the order as 1,500,000, especially since the “U” for units appeared to add a zero to the dose – making it a ten fold overdose
- There was no procedure in the pharmacy for independent double check
  - As a result the error was not detected
- A pharmacy label on the bag indicated that 2.5 millilitres of medication to be administered IM equal to a dose of 1,500,000 units

Medication Error

- A nurse expressed her concern to some of her concerns that as a baby's muscle is so thin, only 0.5 ml per injections is allowed in infants
  - The labeled dose would require 5 injections
- Concerned for not causing pain, two nurses decided to investigate the possibility of administering the drug IV instead of IM
- They consulted with a popular medication reference book
  - The reference mentioned that aqueous penicillin G IV slow push or penicillin G procaine
  - There was no mention about penicillin G benzathine
  - Unfamiliar with various forms of penicillin, the nurse believed that benzathine is a brand name
- They administered the drug IV
- They also did not notice the ten fold increase in the dispensed dose

Medication Error

- The baby died
- The nurses were prosecuted for negligent homicide

- Expert testimony presented during the trial
  - While the nurse and her colleagues had played a part in the tragedy, more than 50 latent and active failures had occurred throughout the medication-use process
    - Most of these, such as poor labelling, the pharmacist's mistake and the confusing drug information, had not been under the control of the nurses
  - It was these failures that set the stage for the nurses' tragic mistakes
  - Had even one of these failures not occurred, either the accident would not have happened, or the error would have been detected before reaching the infant

Medication Error

- Since most of what people do is governed by the system and often lie outside the control of individuals, despite their best efforts
- This case illustrates that medication errors are almost never the fault of a single practitioner or caused by the failure or of a single element
- The analysis presented had a powerful influence on the jury
  - They acquitted the nurses
- The lesson learnt from the case study is that
  - We must look beyond blaming individuals, and
  - Focus on the multiple underlying system failures that shape individual behaviour and create the conditions under which errors occur

Medication Error

- Potential solutions:
  - There are many studies that tried to find out how the quality of prescribing can be improved.
    - The methods of prescribing that were arrived at were heterogeneous
    - There were not many study that tried to establish links between prescription of medication and patient harm
  - Reducing medication error and improving patient safety needs a system approach
  - Some strategies include:
    - Using clinical pharmacists

Medication Error

- Employing Computer technology more extensively, educational programme

- Multifaceted interventions for reducing medication error is recommended
- There is also an emphasis on the elderly population

- Some specific strategies identified in a meta study are:[25]
  - Twelve interventions types identified are:
    - Pharmacists-led medication reconciliation

Medication Error

- Computerised medication reconciliation
- Medication reconciliation by trained mentors
  - The trained mentors comprise physician with medication safety experience
- Computerised Physician Order Entry (CPOE)
  - The CPOE maybe with or without Clinical Decision Support System (CDS)
- Pharmacist partnership
  - The pharmacists participated on the medical team
  - They entered patient's pre-admission medications in a computerised tool
  - These were then integrated into patients' clinical history

Medication Error

- Pharmacists were involved in ward rounds

➢ Prescriber Education

- Junior doctors were involved in the education programme
- Targeted education by Pharmacists was imparted
- E-learning approach was also adopted by some hospitals
- Some hospitals adopted a method of detailed discussion regarding recently observed prescribing errors provided by pharmacists during three 10-minute session per week over a 4-week intervention period
  - ✓ Decreased prescribing errors were observed

➢ Patient education

- One study, where this was done by giving the patient a list of current medication along with a glossary of common medical terms upon discharge

Medication Error

- The study result did not find any difference in potential ADEs between the control and the interventional group
- However, there is growing awareness of the important role that patients and their carers can play in medication safety[26]
- A range of factors have been shown to affect patients' adoption of medication safety behaviours
- Evidence suggests that the best way to promote proactive patient involvement is through direct encouragement by health care providers
- Professional contact is more successful than other factors like marketing in engaging patients in medication safety behaviours

Medication Error

- Trained medication experts
  - Effect of these experts on medication administration was studied
  - It was found the administration errors were considerably less
- Medication dispensing
- Automated drug distribution along with electronic medication administration record
- Combining intervention types

- The study identified a number of single and combined intervention types that were effective in reducing medication errors
  - There was no effective intervention against dispensing error

Medication Error

- Medication reviews and reconciliation
  - ❖Medication review is a process of patients' medicines evaluation in order to improve the health outcomes and mitigate the drug-related problems
  - ❖Most successful interventions included a medication review conducted by a pharmacist or other clinicians, or focussed on multicomponent interventions
  - ❖Studies showed that pharmacist-led medication reviews reduced hospital admission due to Adverse Drug Events

Medication Error

- Medication reconciliation
  - It is the formal process of establishing and documenting a consistent, definitive list of medicines across transitions of care and then rectifying any discrepancies
  - Increased medication discrepancies at discharge are associated with an increased number of prescribed medications
    - This shows the importance of looking at Polypharmacy as a multifaceted threat to patient health
    - The accuracy of medication information on discharge summaries is generally poor

Medication Error

- A number of medication reconciliation systems have been tested
  - These systems deal with new medication changes, deletions and additions following hospital admissions
  - These systems reduce medication discrepancies, as well as potential and actual adverse drug events

- The National Institute of Clinical Excellence Guideline (UK) recommendations:
  - The medicines reconciliation process will vary depending on the care setting that the person has just moved into
    - For example:
      - From primary care into hospital, or from hospital to care home

Medication Error

- Flow chart (NICE) Medication Reconciliation
  - ❖In an acute setting
    1. Accurately list all of the person's medicines
       - This should include prescribed, over-the-counter (OTC) and complementary medicines
       - Carry out medicine medicines reconciliation within 24 hours or sooner if clinically necessary, when the person moves from one care setting to another
       - E.g., if they are admitted to hospital

Medication Error

2. Recognise that medicines reconciliation may need to be carried out on more than one occasion during the hospital stay
   - E.g., when the person is admitted, transferred between wards and discharged
3. In primary care, carry out medicines reconciliation for all people who have been discharged from hospital or another care setting
   - This should happen as soon as is practically possible
   - Before a prescription or new supply of medicines is issued and within one week of the GP practice receiving the information
4. In all care settings organisation should ensure that a designated health professional has overall organisational responsibility for the medicines reconciliation process

Medication Error

- The process should be determined locally and include:
- Organisational responsibilities
- Responsibilities of health and social care practitioners involved in the process (including who they are accountable to)
- Individual training and competency needs

5. Organisations should ensure that medicines reconciliation is carried out by a trained and competent health professional
   - Ideally a pharmacist, pharmacy technician, nurse or doctor
   - They should have necessary knowledge, skills and expertise, including:

Medication Error

- Effective communication skills
- Technical knowledge of process for managing medicines
- Therapeutic knowledge of medicines use

6. Involve patient and their family members or carers, where appropriate, in the medicines reconciliation process
7. When carrying out medicines reconciliation, record relevant information on an electronic or paper based form

- Automated Information System
  - ❖Computerised intervention can reduce medication error
  - ❖Computerised Provider Order Entry (CPOE) with decision support may be effective

Medication Error

- Provided the CPOE is targeted at a limited number of potentially inappropriate medications, and
  - Is designed to reduce alert burden by focussing on clinically relevant warning
- Substantial evidence is available which supports use of CPOE to decrease the frequency medication errors in the in-patient setting
  - CPOE has the potential to reduce medication errors by 48%
- CPOE can reduce dosing errors in some specific groups of medicines such as anticoagulants and aminoglycoside antibiotics

Medication Error

- Education
  - Educating health care providers is a key element to improve safety in primary care
  - This is true even when education is a part of multicomponent interventions
  - Studies have shown that
    - Educational interventions improves adherence to guidance for prescription of antibiotics
  - Engaging and empowering patients have a positive impact on medication safety

Medication error : case scenario

- *Mrs Poly, a 65-year-old woman, came to the outpatient clinic complaining of abdominal pain and dark stools. She had a heart attack five years ago.*
- *At her previous visit three weeks ago she was complaining of muscle pain, which she developed while working on her farm. She was given a non-steroidal anti-inflammatory drug (NSAID), diclofenac.*
- *Her other medications included aspirin, and three medicines for her heart condition (simvastatin, a medicine to reduce her serum cholesterol; enalapril, an angiotensin-converting enzyme (ACE) inhibitor; and atenolol, a beta blocker).*
- *She was admitted to hospital as she developed symptoms of blood loss (such as fatigue and dark stools). She was provisionally diagnosed as having a bleeding peptic ulcer due to her NSAID, and her doctor discontinued diclofenac and prescribed omeprazole, a proton pump inhibitor.*

Medication error : case scenario

- *Following her discharge, her son collected her prescribed medicines from the pharmacy. Among the medicines, he noticed that omeprazole had been started and that all her previous medicines had been dispensed, including the NSAID*
- *As his mother was slightly confused and could not remember exactly what the doctor had said, the son advised his mother that she should take all the medications that had been supplied.*
- *After a week, her abdominal pain continued and her son took her to the hospital. The clinic confirmed that the NSAID, which should have been discontinued (deprescribed), had been continued by mistake.*
- *This time Mrs Poly was given a medication list when she left the hospital which included all the medications she needed to take and was advised about which medications had been discontinued and why.*

- WHO: Medication Safety in Polypharmacy

Medication safety process

- The WHO figure in the previous slide shows medication safety process cycle
- The process is composed of 5 steps

1. Appropriate prescribing and risk assessment
   - This is the first step in the process
   - Before prescribing a risk-benefit analysis should be done
   - It should be remembered that no medicine is absolutely free from risk
   - In the case scenario, the patient was prescribed two potentially gastro ulcerative agents
   - But no gastro protective medication was prescribed
   - NSAID can also cause cardiovascular events

Medication safety process

- The case presented is a high scenario situation
- The situation requires medical professionals to prescribe responsibly after analysing the risks and benefits

2. Medication review

- A comprehensive medication review is a multidisciplinary activity
  - In the review risks and benefits of each medicines are considered
  - Patient is involved in the process of review and decisions made future therapy
  - This process optimises the use of medicines for each individual process
- Multiple morbidities usually require treatment with multiple medications

Medication safety process

- Multiple medication use for treating multiple morbidities is called Polypharmacy
  - Polypharmacy when not used properly can put the patient at risk of:
    - ✓ Adverse drug events
    - ✓ Drug interactions
- In the case described, there was haemodynamic changes due to blood loss
  - So a temporary stoppage of the ACE inhibitor was warranted before restarting ACE inhibitor once the blood loss has been resolved

Medication safety process

3. Dispensing, preparation and administration

- The case depicted is a high risk situation
- Even then diclofenac was prescribed which can cause harm
- This medication was continued after discharge when the patient transitioned from hospital to home
  - At home, the medications and their adverse events cannot be supervised
  - Thus continuation of improper and unsupervised medication can cause harm to patient specially where health literacy is poor

Medication safety process

4. Communication and patient engagement

- For preventing medication errors, proper communication between the provider and patient as well as between providers is important
- When Mrs Poly was severely ill due to gastric bleeding, the NSAID was discontinued
- But, the decision to discontinue the medicine was not adequately communicated either to other health care workers or to the patient
- Initial presenting symptoms due to adverse effects could have been identified earlier if she had been warned about the risks

Medication safety process

5. Medication reconciliation is a formal process in which health care professionals engage patients to communicate medication at transfer of patients from one care setting to another
   - Diclofenac can cause gastrointestinal bleeding and increases the risk of cardiac problems
   - This drug led to the hospitalization of the patient
   - The medication was discontinued
   - These information was not communicated to the patient
   - Had the information been communicated to the patient at the time of discharge
   - The communication form could have been a medication list or patient-held medication record. This would have helped her in determining what the newly added and discontinued medications needed to be

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End of Part 5

(To be continued .....)