

Patient Safety

Principle of Risk Assessment & Adverse Events

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Why clinical risk is relevant to patient safety

- Risk management-routine-industries-associated with limiting litigation costs.
- Hospitals and HCO-variety of methods-managing risks. The success - risk management programme-depends-creating and maintaining safe systems of care, designed-reduce adverse events-improve human performance.
- Allows identification potential errors. Health care-inherently risky-impossible to eradicate all harm-many activities and actions-introduced-will minimize opportunities for errors.

Why clinical risk is relevant to patient safety

Contd..

- Many hospitals-well established systems-reporting adverse event.
- HCW-responsibility-take the correct action-see an unsafe situation or environment.
- In the event of a patient falling on a slippery floor or receiving the wrong medication-equally important for a HCW to report-events-steps can be taken-avoid future incidents.

Why clinical risk is relevant to patient safety

Contd..

- Effective risk management involves every level of the health service, so it is essential that all HCW understand the objectives and relevance of the risk management strategies and their relevance to their own workplace.

Unfortunately, even though a hospital may have a policy of reporting incidents such as medication errors, the actual reporting of them is often sporadic.

Why clinical risk is relevant to patient safety

Contd..

- The following simple four-step process is commonly used to manage clinical risks:
 1. Identify the risk;
 2. Assess the frequency and severity of the risk;
 3. Reduce or eliminate the risk;
 4. Assess the costs saved by reducing the risk

Incident Monitoring

- Incident reporting - existed - decades. Many countries-national databases -events pertaining to different specialties
 - WHO defines an incident as an event or circumstance that could have or did lead to unintended and/or unnecessary harm to a person and/or a complaint, loss or damage.
1. **Near Miss Events**
 2. **Adverse Events**
 3. **Sentinel Events**

Incident Monitoring

Contd..

Near Miss Event

- **Definition:** An unexpected incident related to system or process failure which could have caused damage, but didn't.
- **Examples:**
- Medication error causing no harm
- Plaster falling from ceiling. No injuries.
- Short circuit detected, fire prevented.
- Fungus in the IV bottle detected just in time.
- Sudden equipment failure but no damage done.
- **Reporting Time Frame:** – Same day, may be next morning.

Incident Monitoring

Contd..

Adverse Event

- **Definition:** An unexpected incident related to system or process failure which caused damage that was not serious / lasting.
- **Examples:**
- Medication error causing minor allergy.
- Plaster falling on the patient minor injuries.
- Slip/Trip/Fall causing minor injuries.
- Theft of patient's / hospital's property.
- **Reporting Time Frame:** – Same day, within 6-8 hours.

Incident Monitoring

Contd..

Sentinel Event

- **Definition:** An unexpected incident related to system or process failure which caused death / major enduring loss of function lasting at least two weeks.
- **Examples:**
- Medication error causing death/ severe complications.
- Plaster falling on the head causing death.
- Wrong site/ wrong patient/ wrong surgery.
- Instrument/sponge left in the surgical site by mistake.
- **Reporting Time Frame:** Immediate, within < 2 hours.

Incident Monitoring

Contd..

- Key to an effective reporting system - staff routinely reporting incidents or near misses.
- However, unless staff trust that the organization will use the information for improvement and not to blame individuals, they will not report.
- Trust includes the belief that the organization will also act upon the information.

The role of complaints in improving care

- Complaints from patients – uncomfortable - good opportunity-improve - clinical practice - process of care - restores - trusting relationship - patient, family and the health-care team.
- The information from complaints - used - educate and inform - HCW - about problem areas.
- Benefits of complaints
 - Assist to maintain standards;
 - Reduce the frequency of litigation;
 - Help maintain trust in the profession;
 - Encourage self-assessment;
 - Protect the public.

The role of complaints in improving care

Contd..

- Complaints – highlights – problems - poor communication or suboptimal clinical decision-making.
- HCW - receive complaints - careers - not an indication of incompetence.
- Medical error - subset of human error; all humans make mistakes.

Complaints and concerns where the individual is responsible

- System thinking – system processes are considered more likely to be cause of problem than are individuals
- After investigation - the treating doctor or health-care team may also have been at fault—for example by cutting corners and breaching accepted protocols.
- Standard of care may be low resulting in suboptimal care.

Understanding and Learning from Errors

Errors

- **Definition:** An error occurs “when someone is trying to do the right thing, but actually does the wrong thing
- Errors may occur by doing the wrong thing (commission) or by failing to do the right thing (omission).
- “Slip” - accidentally pushing the wrong button on a piece of equipment.
- “Lapse” - memory failure such as failing to administer a medication

Mistake

- **Definition:** A mistake is a failure of planning, i.e. the plan is wrong.
- Be either rule based, because a “wrong” rule is applied, or knowledge based.
- E.g. of a rule-based mistake - Getting the diagnosis wrong and so embarking on an inappropriate treatment plan.
- Knowledge-based mistakes - Tend to occur when HCW are confronted with what is for them a “new” clinical situation

Violation

- **Definition:** A violation is different from errors caused by the system. Violations are errors caused by a deliberate deviation from an accepted protocol or standard of care.

Understanding and Learning from Errors

- Inevitability of error as a fundamental facet of the “human condition”- “silly mistake”-everyday life
- The challenging reality for HCW is that the same mental processes that lead us to make “silly mistakes” away from the workplace are also in play when we are at work.
- However, the work context makes the consequences vastly different.

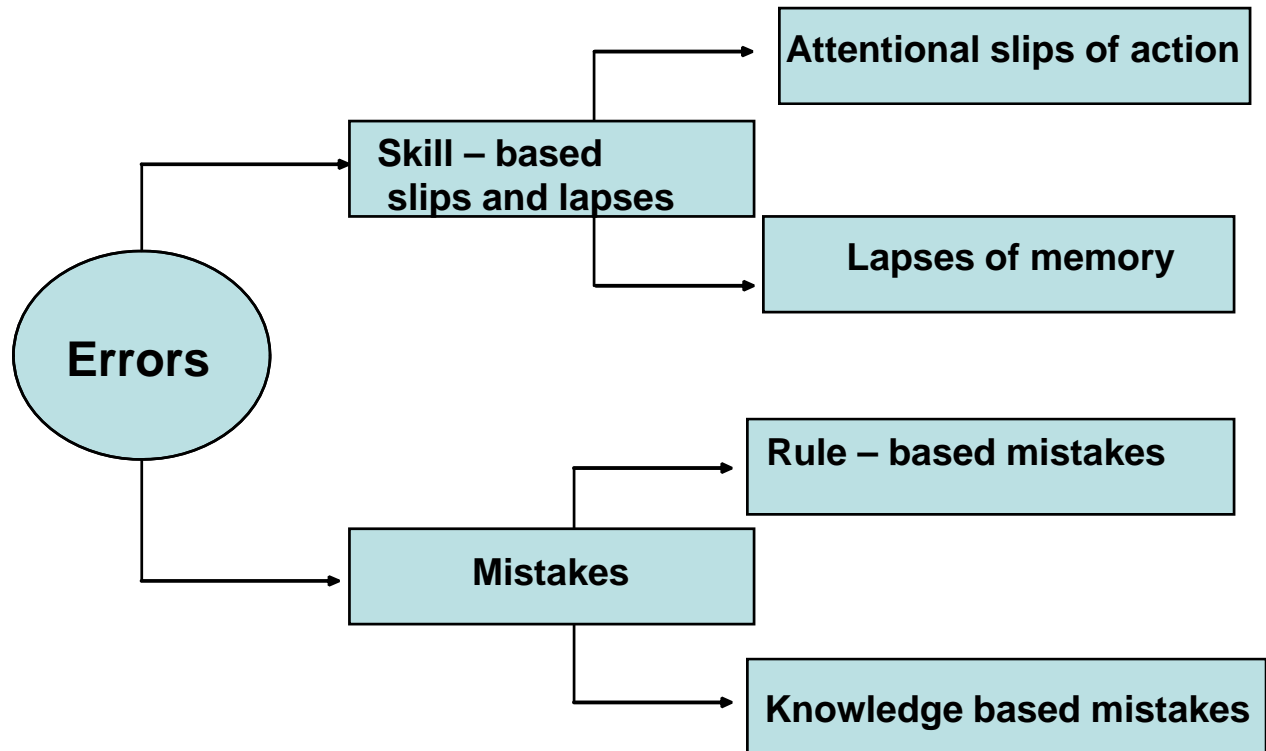
Understanding and Learning from Errors

Contd..

- The unique feature in health care-associated errors - failure occurs (omission or commission) - patient suffers.

Slips, lapses and mistakes are all serious and can potentially harm patients.

Principal Error Types



Situations associated with an increased risk of error

HCW unfamiliar with a task / inexperience

- It is very important that HCW do not perform a procedure for their very first time on a patient.
- They need to first understand what they are doing and to practice on a mannequin or other prop in a simulated environment.
- If it is the first time, the HCW should be properly supervised and watched while they perform the procedure.

Situations associated with an increased risk of error

Contd..

Shortage of Time

- Time pressures make people cut corners and take shortcuts when they should not. Not washing hands properly is an example.

Inadequate Checking

- The simple act of checking has saved thousands of patients receiving the wrong medications.

Situations associated with an increased risk of error

Contd..

Poor Procedures

- This can relate to a number of factors— inadequate preparation, inadequate staffing and inadequate attention to the particular patient.
- Before using any equipment-HCW familiarize themselves with it.

Individual Factors predispose HCW to errors

Limited Memory Capacity

- Learning to ask for help is an essential skill for all HCW who have inadequate knowledge and skills.
- The amount of information that a HCW is required to know today is far beyond that which is capable of being memorized.
- Educational outcomes-more about performance than retention of information.
- Human brain-limited organ-capable of remembering a finite amount of information.

Individual Factors predispose HCW to errors

Contd..

- HCW should not rely on memory, particularly when there are a number of steps involved.
- Guidelines and protocols were developed to assist clinicians to provide care following the best available evidence.

HCW should get into the habit of using checklists and not relying on their memory.

Individual Factors predispose HCW to errors

Contd..

Fatigue

- Memory is affected by fatigue.
- In recognition of the problems caused by fatigue many countries have or are reforming the excessive hours worked by HCW.

Stress, hunger, illness

- If HCW are feeling unwell, stressed and hungry they are more likely to make errors.

Individual Factors predispose HCW to errors

Contd..

Language or cultural factors

- The potential for communication errors caused by language and cultural factors is obvious

Hazardous attitudes

- HCWs who perform procedures on patients without supervision might be said to display a hazardous attitude.

Practice strategies to reduce errors – Personal Errors

Personal error reduction strategies:

- Know yourself (eat well, sleep well and look after yourself):
- Know your environment;
- Know your task (s);
- Preparation and planning (What if...);
- Build checks into the routine;
- Ask if you do not know.

Practice strategies to reduce errors – Personal Errors

Contd..

- There are many easy to remember mnemonics to assist HCW monitor themselves. HALT is one such aid.

- Do not forget if you are

H Hungry

A Angry

L Late

or

T Tired

Practice strategies to reduce errors – Personal Errors

Contd..

- **IM SAFE**

I Illness

M Medication (prescription alcohol and others)

S Stress

A Alcohol

F Fatigue

E Emotion

Practice strategies to reduce errors – Personal Errors

Contd..

- Assume that errors will be made and that they should prepare for them;
- Identify those circumstances most likely to lead to errors;
- Have contingencies in place to cope with problems, interruptions and distractions;
- Always mentally rehearse complex procedures or if it is the first time you are doing an activity involving a patient.

Practice strategies to reduce errors – Human Errors

Tips to limit the potential errors caused by humans

- Avoid reliance on memory;
- Simplify processes;
- Standardize common processes and procedures;
- Routinely use checklists;
- Decrease the reliance on vigilance.

Adverse Event Analysis & Corrective & Preventive Action (CAPA)

Adverse Event Analysis & Corrective & Action Prevention (CAPA)

- There are a number of examples of quality improvement methods in health care but the two most relevant are:
 - **Clinical Practice Improvement (CPI)**
 - **Root Cause Analysis (RCA)**

Clinical Practice Improvement (CPI)

- CPI methodology improves the quality and safety through a detailed examination of the processes and outcomes in clinical care.
- There are 5 phases
 1. Project Phase
 2. Diagnostic Phase
 3. Intervention Phase
 4. Impact and Implementation Phase
 5. Sustaining and Improvement Phase

Clinical Practice Improvement

Contd..

1. Project Phase

- The team needs to ask themselves what it is they wish to fix or achieve.

Clinical Practice Improvement

Contd..

2. Diagnostic Phase

- The team needs to ask if the problem they have identified is worth solving.
- The team should establish the full extent of the problem as possible.
- A brainstorming exercise by the team will generate possible changes that could lead to an improvement.
- A decision about how to measure the improvement needs to be resolved during this phase.

Clinical Practice Improvement

Contd..

3. Intervention Phase

- The team will work out what the problem are and their possible solutions.
- Each of the solutions have to be tested through a trial and error process by using the PDSA cycle to test changes, observe them and keep the ideas which will work.

Clinical Practice Improvement

Contd..

4. Impact and Implementation Phase

This is the time to measure and record the result of the trials of the interventions.

Did they make any difference?

Clinical Practice Improvement

Contd..

5. Sustaining and Improvement Phase

The final phase requires the team to develop and agree upon a monitoring process and plans for continuous improvement.

Improvements made now will become failures in the future if there are no plans to sustain the improvements

**Process and Outcome Surveillance plus
Education & Performance feedback Effect
on Rates of
Ventilator Associated Pneumonia (VAP),
Catheter Associated Urinary Tract Infections
(CA-UTI) &
Mortality Rate in Intensive Care Unit (ICU)**

AIM

To ascertain the effect of an infection control program utilizing process and outcome surveillance plus education and performance feedback on ICU rates of VAP and CA-UTI

Methods

- Prospective study— surgical ICU.
 - Phase 1— Rates of VAP and CA-UTI were determined during a period of active process and outcome surveillance without education and performance feedback.
 - Phase 2 – Rates of VAP and CA-UTI after implementation of an infection control program utilizing education and performance feedback.
- HAI – Defined as per CDC.
- Standard laboratory methods for identification of micro-organism (Mini-API, BioMerieux, Lyon)

Control of Key Issues in Infection Control

Hand Washing

Hand washing compliance was observed and monitored. Randomized evaluation 3 times a week during one hour each time, during all working shifts and in all healthcare workers.

Vascular Catheter Care

Vascular catheter care compliance was observed and monitored.

The correct catheter care included :-

- i). Presence of sterile gauze or transparent sterile dressing.
- ii). Clean, no humidity, well coated.
- iii). Presence of the date of insertion.

Urinary Catheter Care

Urinary catheter care compliance was observed and monitored.

The correct catheter care included :-

- i). Presence of catheter upon the thigh.
- ii). Presence of urine collecting bag underneath the bladder level and no floor contact.

Mechanical Ventilator Care

Mechanical Ventilated Patient care was observed and monitored.

The correct ventilated patient care included :-

- i). Absence of liquids in the tubes.
- ii). Absence of mucous in the tubes.
- iii). Head of patients bed at 30-45 grades.
- iv). Well inflated intra-tracheal balloon.

Results

VAP

- Phase 1 – 1340 MV days.
Phase 2 – 904 MV days.
- Phase 1 – 29.1 VAP per 1000 MV days (39\1340)
Phase 2 – 14.4 VAP per 1000 MV days (13\904)
(RR=0.49, 95% CI=0.26-0.93, P-value=0.0246)
- VAP rate reduction was 50.6%.

Results

CA-UTI

- Phase 1 – 2863 UC days.
Phase 2 – 1969 UC days.
- Phase 1 – 4.5 CA-UTI per 1000 UC days (13\2863)
Phase 2 – 0.5 CA-UTI per 1000 UC days (1\1969)
(RR=0.11, 95% CI=0.01-0.86, P-value=0.0104)
- CA-UTI rate reduction was 88.8%.

Results

Mortality

- Phase 1 – 1.9% (17\908).

 - Phase 2 – 0.4% (3\741).

(RR=0.22, 95% CI=0.06-0.74, P-value=0.0071)

Root Cause Analysis

Root Cause Analysis

- Root Cause Analysis structured approach-evaluate, analyze and develop system improvements-the adverse events.
- Reporting an incident requires the following basic information:
 - What happened?
 - Who was involved?
 - When did it happen?
 - Where did it happen?
 - The severity of the actual or potential harm.
 - The likelihood of recurrence.
 - The consequences.

Root Cause Analysis

Contd..

- Defining characteristics of root cause analysis include:
 - Review by an inter-professional team knowledgeable about the processes involved in the event;
 - Analysis of systems and processes rather than individual performance;
 - Deep analysis using “what” and “why” probes until all aspects of the process are reviewed and contributing factors are considered;
 - Identification of potential improvements that could be made in systems or processes to improve performance and reduce the likelihood of such adverse events or close calls in the future.

Adverse Event Analysis & CAPA

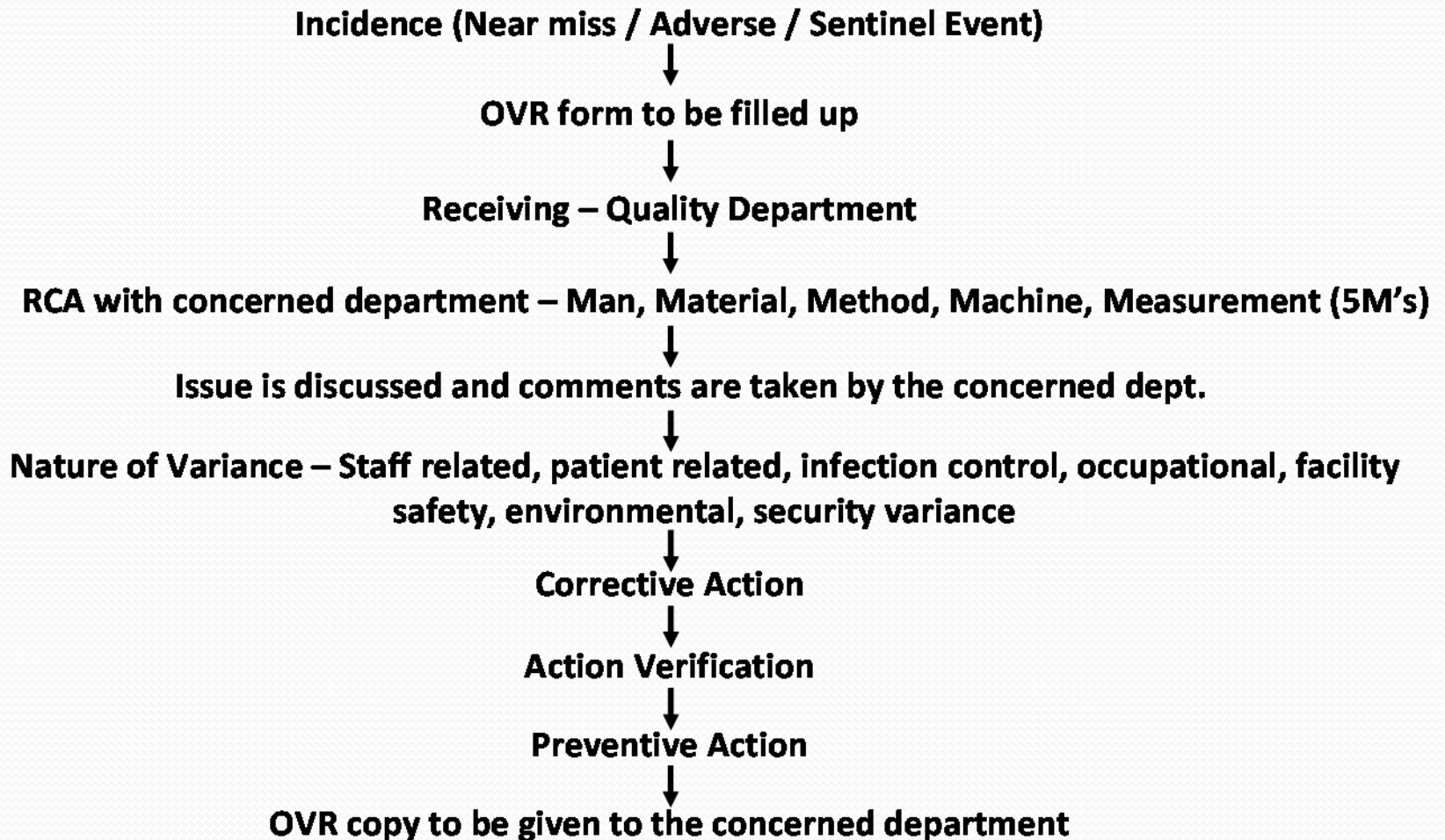
Quality Improvement Tools

- ✓ **Flowchart**
- ✓ **Cause and Effect Diagrams (Ishikawa/Fishbone)**
- ✓ **Pareto Charts**
- ✓ **Run Charts**

Flow Charts

- A flow chart is a pictorial method for showing all the steps or parts of a process that makes up the system.

Flow Chart – Occurrence of Variance Report (OVR) Process

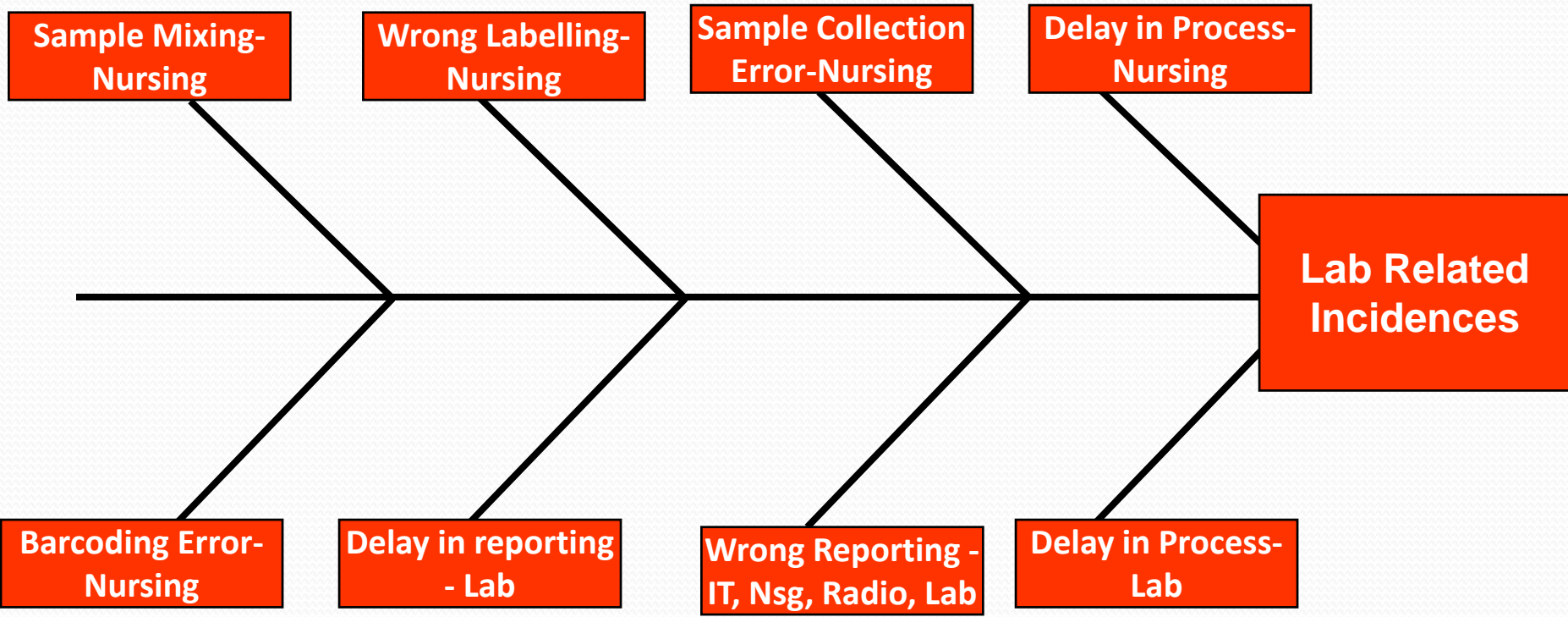


Cause and Effect Diagram

- It is a tool for solving problems. Possible causes of a certain effect are explored and displayed.
- This diagram is also called an Ishikawa or fishbone diagram.

Ishikawa Diagram

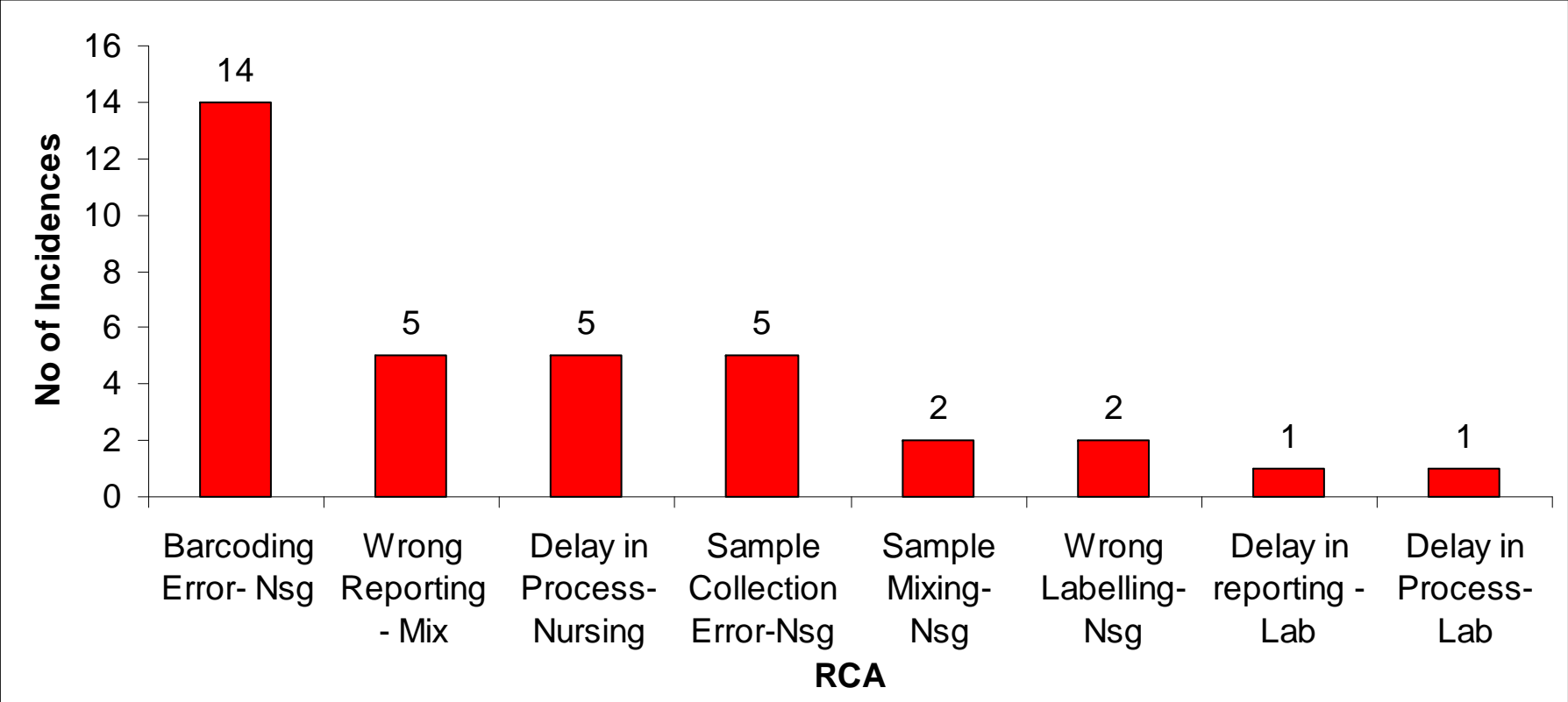
Root Causes:



Pareto Charts

- It is a bar chart in which the multiple factors that contribute to the overall effect are arranged in descending order according to the magnitude of their effect.
- The ordering is an important step because it helps the team concentrate its efforts on the factors that have the greatest impact
- It also assist them to explain the rationale for concentrating on particular areas.

Pareto Chart

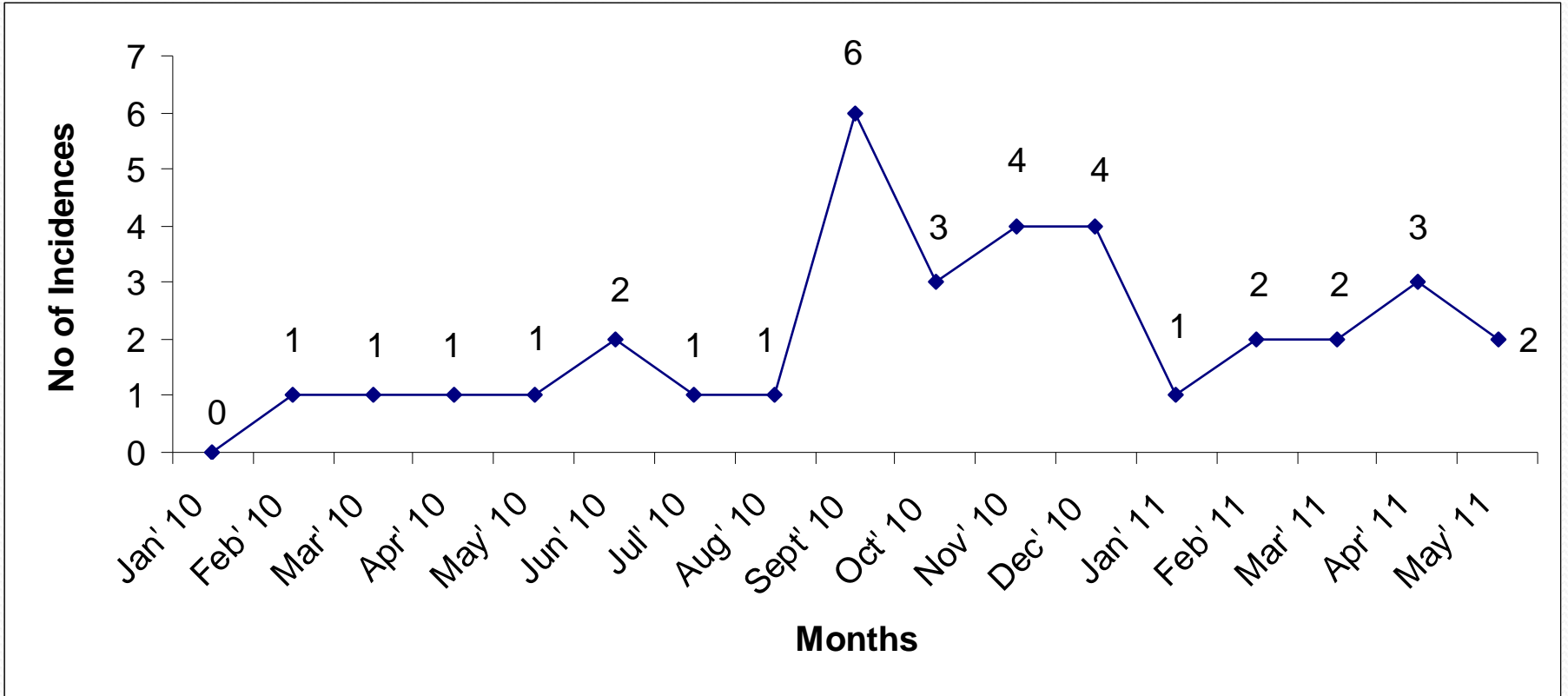


Run Chart

- Run charts or time plots are graphs of data over time.
- It helps the team know if a change is an improvement over time or just a random fluctuation wrongly interpreted as significant improvement.
- It helps identify if there is a trend. A trend is formed when a series of consecutive points continually fall or rise.

The benefits of using run charts include helping the team judge how a particular process is performing.

Run Chart



Conclusion

A broadly based system approach is required for organizational learning and the possibility of system change to occur.

The proactive intervention of a systems approach to minimizing the opportunities for errors can prevent adverse events. Individuals can also maintain a safe clinical working environment by looking after their own health and responding appropriately to concerns from patients and colleagues.

Thank you