Practical safety measures

Proactive Ways of Mitigating Patient Safety Risk

Application of FMEA & SERAE

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Hong Kong

Similarities of FMEA and RCA

- **Aim to reduce harm to patients**
- **Use non-statistical tools**
- **Review process to ID conditions that lead to harm**
- **Require team activities : people, time, material & other support**

Difference between FMEA and RCA

Characteristics	FMEA	RCA
Analysis	Proactive	Reactive
Questions	Hypothetical	Actual
Approach	Prospective	retrospective

What is FMEA?

Failure :when a system or part of a system performs in a way that is not intended or desirable

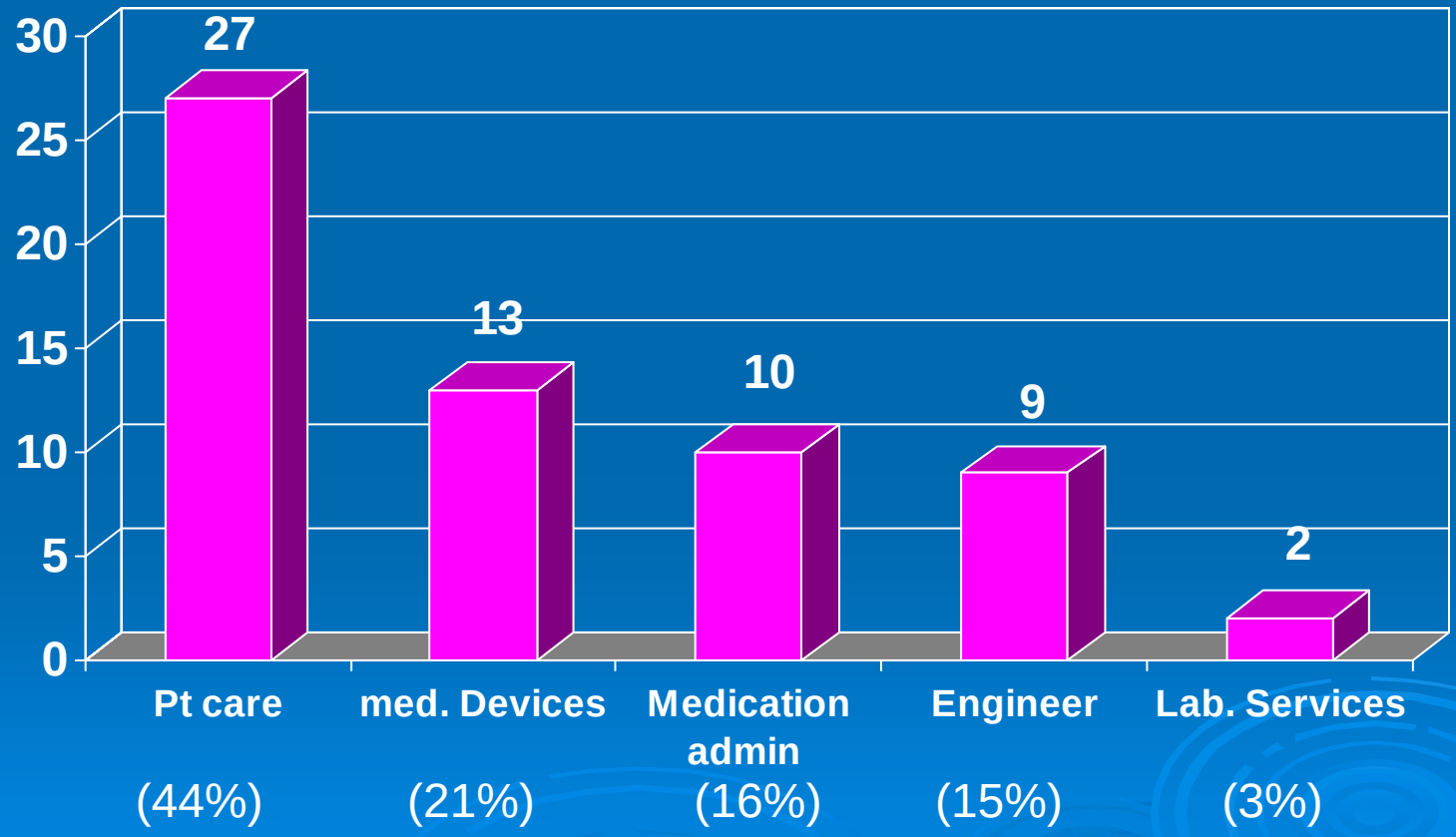
Mode :the way or manner in which something can fail

Effects :the result or consequences of a failure mode

Analysis :detailed examination of the elements or structure of a process

Involve 4-10 steps

"'Pubmed" review
A total of 61 abstracts with the key word "FMEA"



Google search on FMEA

- Yielded 150,000 hits
- Combined with “engineering” yielded 40,000
- Combined with “medicine” yielded 3,000 only

Senders Qual Saf Health Care 2004

MILITARY STANDARD

PROCEDURES FOR PERFORMING
A FAILURE MODE,
EFFECTS AND CRITICALITY ANALYSIS

Since 1974

MIL-STD-1629A
24 NOVEMBER 1980

SUPERSEDING
MIL-STD-1629 (SHIPS)
1 NOVEMBER 1974
MIL-STD-2070 (AS)
12 JUNE 1977

Institute for Safe Medication Practices (ISMP) became interested in FMEA around 1990

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Timing of FMEA (in Aviation, engineer industry)

The FMEA should be updated whenever:

- At the beginning of a cycle (new product / process)
- Changes are made to the operating conditions
- A change is made in the design
- New regulations are instituted
- Customer feedback indicates a problem

Failure Modes & Effects Analysis in Healthcare

JCAHO Standard LD.5.2

In July 2001, the United States Joint Commission on Accreditation of Health Care Organizations adopted a new leadership standard that requires department heads to perform at least one FMEA per year.

Joint Commission

Failure Modes & Effects Analysis

"FMEA is a team-based, systematic, proactive technique that is used to prevent process and product problems before they occur."

Joint Commission

Can assess severity but not possibility of occurrence

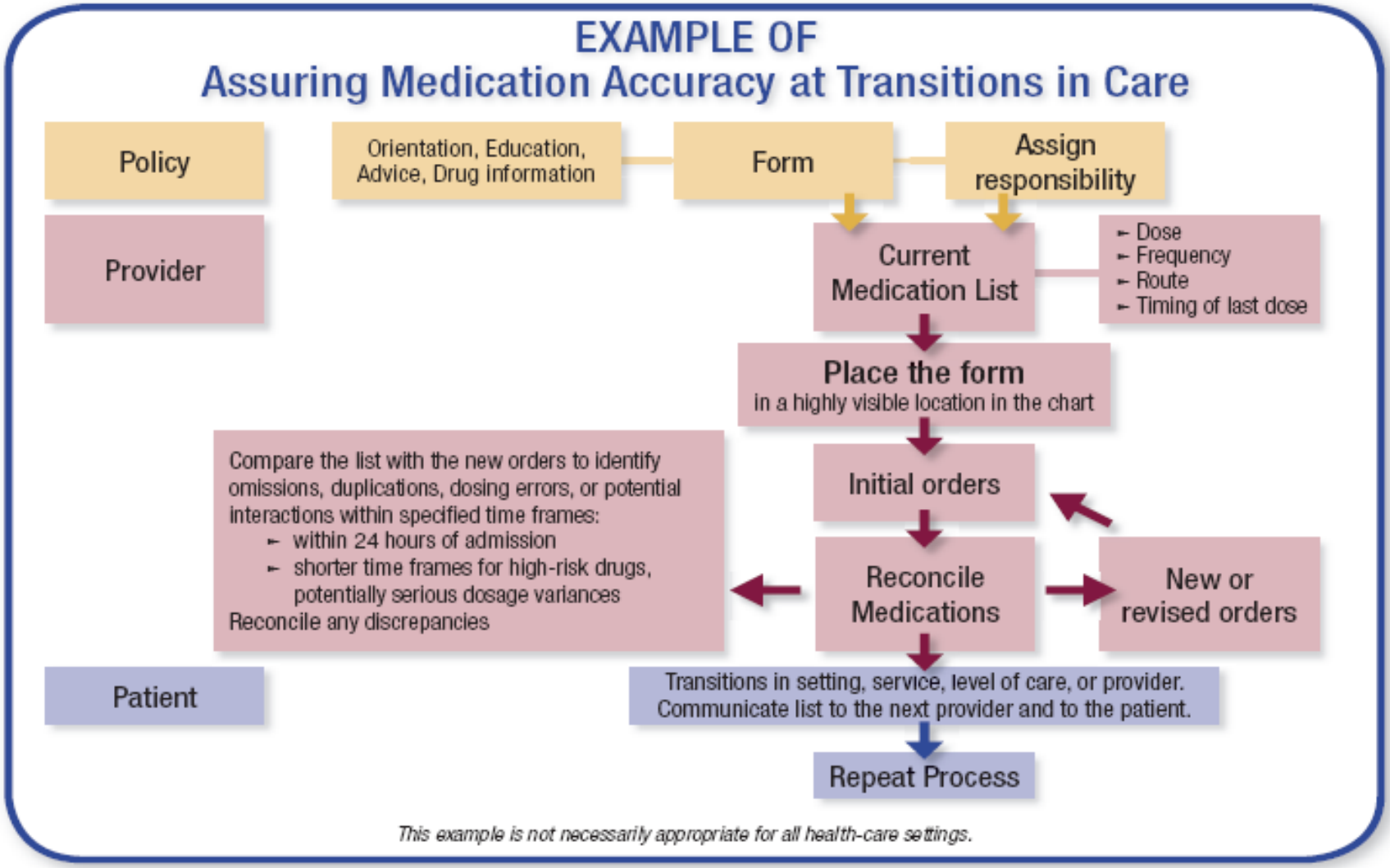
The 8 steps FMEA

1. Select a high-risk process* and assemble a team
2. Diagram the process - "is map"
3. Brainstorm failure modes (as many as 40 FM)
4. Prioritize failure modes (using RPN)
5. Identify root causes of failure modes
6. Redesign process – "should map"
7. Analyze and test new process
8. Implement and monitor

*** Mainly from performance data, staff and customer feedback**

Sample Failure Mode, Effect, and Criticality Analysis for Hypothetical Medication Use Process in O.R.

Process	Pharmacy	Dispense	O.R.	Transfer	Sterile field	Administer	Patient
Potential failure modes	Look-alike drugs Multiple concentrations	Wrong drug Wrong concentration		Switched drugs Contamination		Wrong drug Wrong dose	
Potential effect on patient	8	8		10		10	
Frequency of failure mode	7	3		2		3	
Likelihood of reaching patient	3	4		6		10	
Criticality of failure mode	168	96		120		300	
Root causes	Open formulary Ambiguous labels	Alphabetical storage Ambiguous labels		Unnecessarily complex process Approved procedure not consistently followed		No means of verifying drug/dose after transfer to sterile field	
Strategies	P&T Committee review/redesign of formulary content & process	Redesign storage system. Introduce bar coding.		Simplify procedure. Eliminate open-vessels for IV drugs. Monitor compliance.		No action needed. Risk eliminated earlier in process.	


EXAMPLE OF
Assuring Medication Accuracy at Transitions in Care
Policy
Orientation, Education, Advice, Drug information
Form
Assign responsibility
Provider
Current Medication List
Dose
Frequency
Route
Timing of last dose
Place the form
in a highly visible location in the chart
Initial orders
Compare the list with the new orders to identify omissions, duplications, dosing errors, or potential interactions within specified time frames:
within 24 hours of admission
shorter time frames for high-risk drugs, potentially serious dosage variances
Reconcile any discrepancies
Reconcile Medications
New or revised orders
Patient
Transitions in setting, service, level of care, or provider. Communicate list to the next provider and to the patient.
Repeat Process
This example is not necessarily appropriate for all health-care settings.

Failure Mode, Effect, and Criticality Analysis (FMECA) Worksheet

1. Flow chart the selected process as it is designed (the intended process)
2. Flow chart the selected process as it is routinely conducted (the actual process)
3. List each step and each link between steps of the intended process in Column 5 below
4. Include discrepancies between the flow charts (steps 1 & 2) in Column 6 below

5. Step or Link in process	6. List all potential Failure Modes	7. Potential effect	8. Severity of effect	9. Probability of failure-effect	10. Invisibility of failure	11. Criticality (8x9x10)	12 RPN Sum (11)	13 Rank (Order 12)

Joint Commission on Accreditation of Healthcare Organizations

Adapted, with permission, from model used by Good Samaritan Hospital, Dayton, Ohio

Risk priority number

Rating	Severity	Occurrence	Detectability
1	Minor – No effect	Remote 1 in 10,000	Certain 10 out of 10
2	Minor injury	Low 1 in 5000	High 7 out of 10
3	Moderate injury	Moderate 1 in 200	Moderate 5 out of 10
4	Major injury	High 1 in 100	Low 2 out of 10
5	Catastrophic or death	Certain to occur 1 in 20	Certain not to detect 0 out of 10

Risk Priority Number - RPN

Severity X Occurrence X Detectability

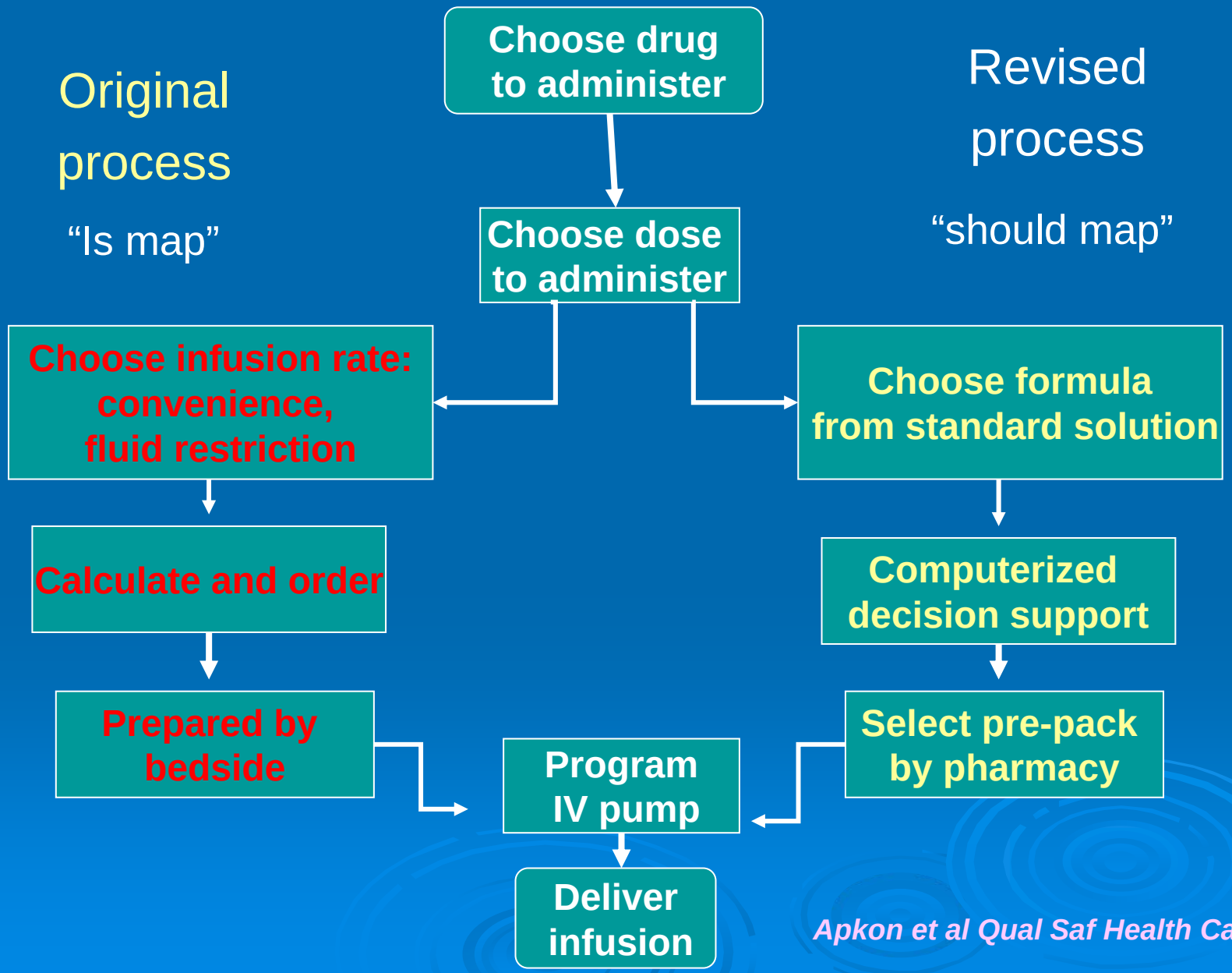
Most critical failure mode

Failure mode	Effect	Sev	Prob	Det	RPN	Crit	Rank
FM #1	Effect 1a	3	6	7	126		
	Effect 1b	7	4	7	196	322	1
FM #2	Effect 2a	3	3	2	18		
	Effect 2b	7	3	2	42	60	3
FM #3	Effect 3a	10	5	3	150		
	Effect 3b	3	5	3	45	195	2

Most severe effect

Table 4-5. Determining Risk and Criticality for Priority Ranking

Flowchart of drug infusion process steps



Apkon et al Qual Saf Health Care 2004

Failure Modes & Effects Analysis

Apkon et al Qual Saf Health Care 2004

- Original processes

	S	O	D	RPN
1. Select drug	7.3	2.8	2,5	51
2. Select dose	8.8	2.8	2.3	57
3. Select route	6.8	5	4	136
4. Calculate	8.8	7	3.8	234
5. Prepare	8.8	4.3	8.3	314
6. Program pump	8.8	4.5	6.8	269

- Revised processes

	S	O	D	RPN
1. Select drug	7.3	2.5	2,5	46
2. Select dose	7.3	2.8	2.3	42
3. Select route	8.8	1.5	2	26
4. Calculate	8.8	2	2.8	49
5. Prepare	8.8	2	5	88
6. Program pump	8.8	2.8	4	99

Limitations of FMEA

1. No confidence on possibility of occurrence.
2. No data on interaction of failures.
3. Theoretical analysis and difficult to be integrated into overall organization processes.
4. “Find and fix” mind set.

Limitations of FMEA

"Even when FMEA or RCA are performed flawlessly, these qualitative tools are not designed to identify risk point combinations in complex systems".

Combination of events that leads to error – cheese hole theory

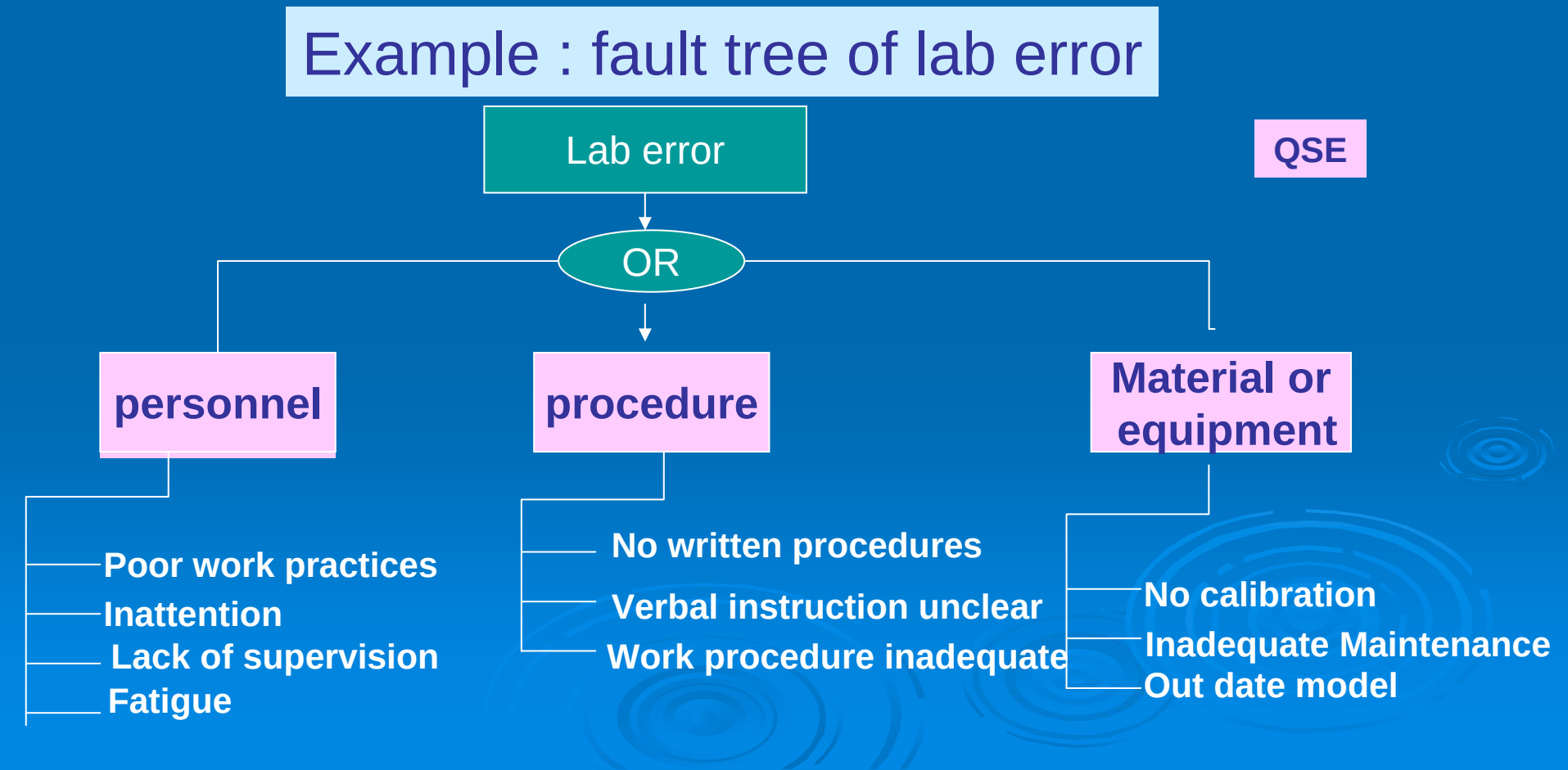
"If members inappropriately assess the risk associated with a particular process, the institution may expend considerable resources correcting a problem that in fact may have little to do with the risk of a recurrent event"

Marx et al Qual Saf Health Care 2003

Recommended improvement of FMEA

Krouwer Archives of Pathology & Laboratory Medicine 2004

1. Additional use of fault tree and quality system essentials (QSE) to ID failure mode effects & causes



Recommended improvement of FMEA

- Avoid over emphasis on improving RPN while neglecting mitigations for failure mode that have never occurred

1. A failure event leads to patient death with rare occurrence RPN 10X2X10=200
2. A failure event leads to an added high cost with frequent occurrence RPN 10X10X2=200

1 should be the first priority

Krouwer Archives of Pathology & Laboratory Medicine 2004

Most critical failure mode

Failure mode	Effect	Sev	Prob	Det	RPN	Crit	Rank
FM #1	Effect 1a	3	6	7	126		
	Effect 1b	7	4	7	196	322	1
FM #2	Effect 2a	3	3	2	18		
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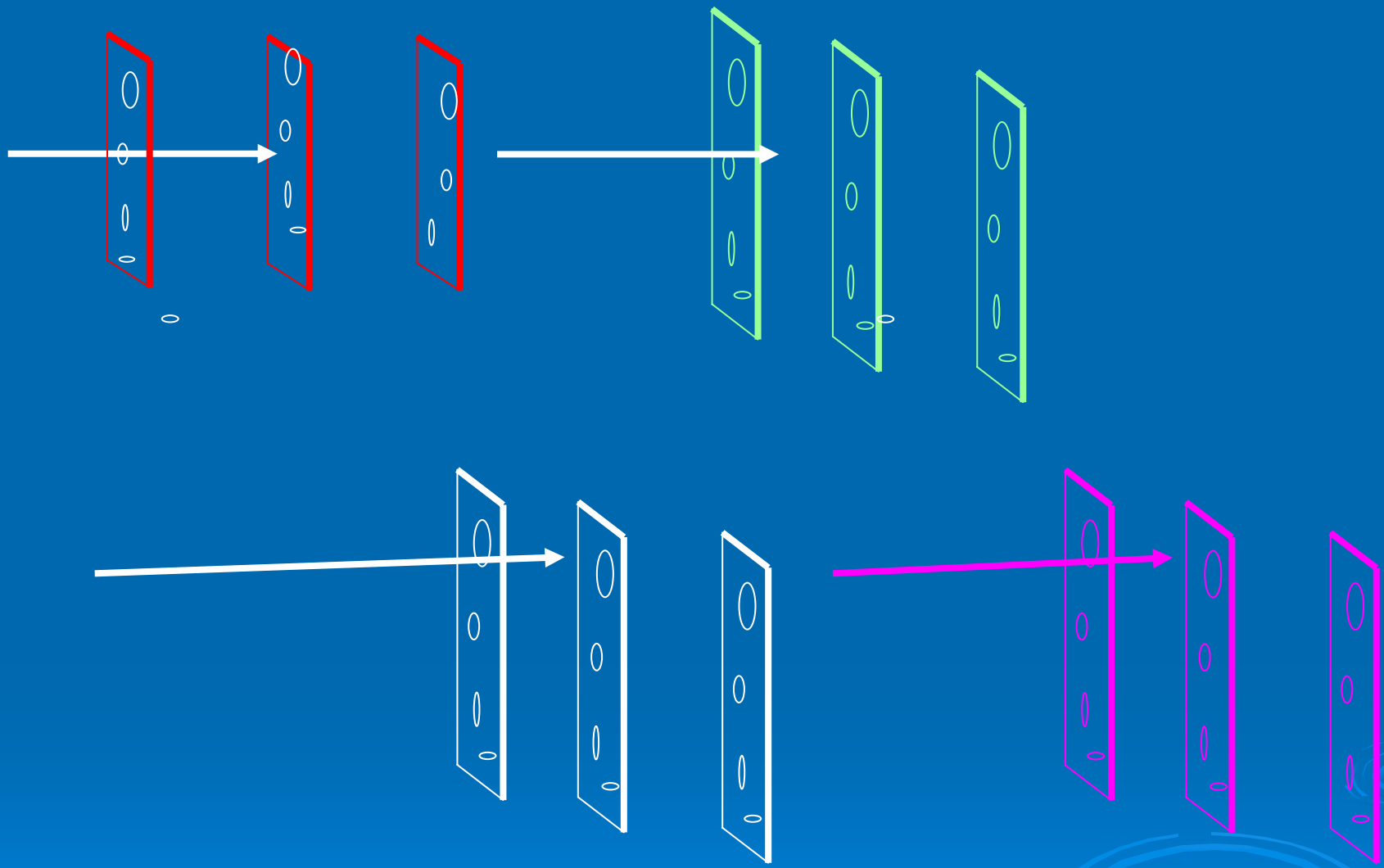
FM #3	Effect 3a	10	5	3	150		
	Effect 3b	3	5	3	45	195	2

Most severe effect

Table 4-5. Determining Risk and Criticality for Priority Ranking

Adverse outcome - Death



Mindful to avoid creating cheese holes from cheese holes

Limitations of FMEA

1. No confidence on possibility of occurrence.
2. No data on interaction of failures.
3. Theoretical analysis and difficult to be integrated into overall organization processes.
4. “Find and fix” mind set.

An innovative approach

Between RCA and FMEA

System Evaluation of Reported Adverse Events

(SERAE)

System Evaluation of Reported Adverse Events (SERAE)

SERAE is a team-based, systematic, proactive technique that is used to prevent process and system problems before they occur

- by timely analysis of adverse events occurred and reported in other hospitals.

Limitations of FMEA

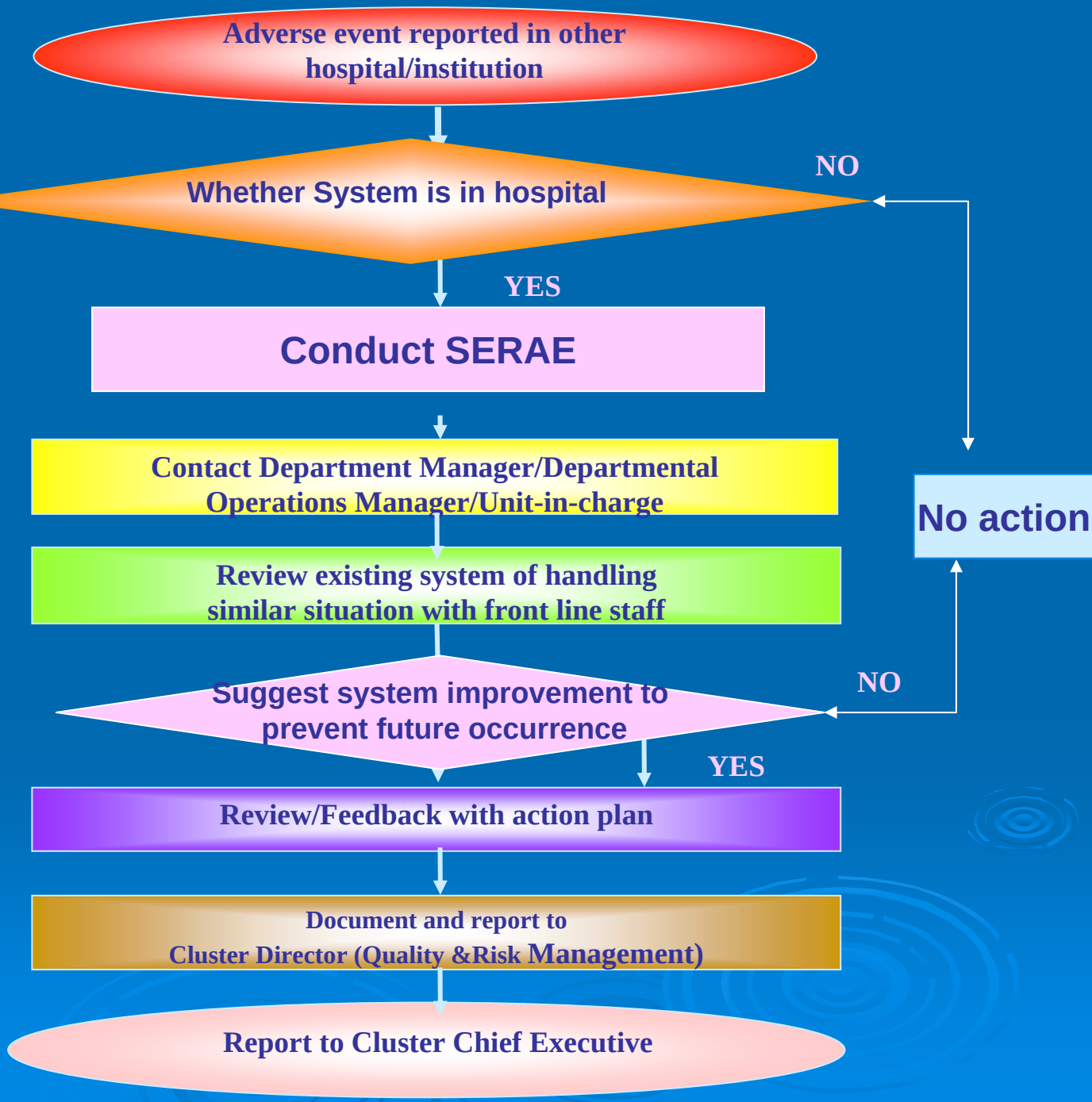
1. No confidence on probability of occurrence.
2. No data on interaction of failures.
3. Theoretical analysis and difficult to be integrated into overall organization processes.
4. “Find and fix” mind set.

Advantage of SERAE

- Actual occurrence has transpired.
- Actual data on interaction of failures can be obtained
- Actual reference point and not just purely theoretical exercise
- As in RCA, a “learn and prevent” mindset can prevail

The boss (CCE) likes to know anyway…..

Flowchart of the SERAE



System Evaluation of Reported Adverse Events (SERAE)

Would similar AE be happening in our hospital?

Why did it happen? → **proximate causes**

Underlying causes

Why did that happen? → **processes**

Why did that happen? → **systems**

8 key questions to ask in SERAE

- Would similar AE be happening in our hospital?
- Is there any SOP in your department? **written document**
- How are the processes done? Direct review on-site
- Are there non-compliance and failure modes?
  - evidence of similar AE
  - other failure modes

  } **Review past record**
- What are the severity ratings of possible AE?
- Which are the failure modes to address?
- What are the corrective actions?
- What improvement is planned for corrective actions?

Stratification of RAE for different approaches

- Inappropriate / inadequate resources
- Suboptimal system problem
  - SSPI single party
  - SSPII multiple parties

Stratification of RAE

- Inappropriate / inadequate resources

Usually need simple corrective action

Example

Retention of laryngoscope light bulb in patient's airway :

Cause – detachable light bulb

Remedy – change to fiber-optic laryngoscope

Stratification of RAE

- Suboptimal system problem

SSPI - single party

Example : **Sharing of mortuary compartment leading to mixing up of dead body** – involve mortuary

SSPII multiple parties

Example : **Mixing up of intrathecal & intravenous administration of cytotoxic drugs – multidisciplinary team meeting including adult and paediatric oncology and haematology, pharmacy, physicians and nursing staff**

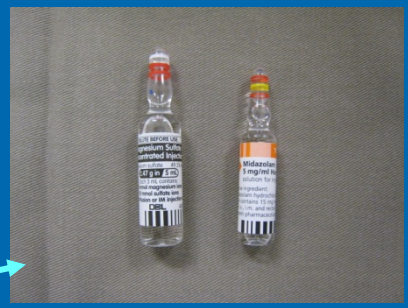
Piloted SERAE in QMH

- 18 incidents were reviewed since April 2007

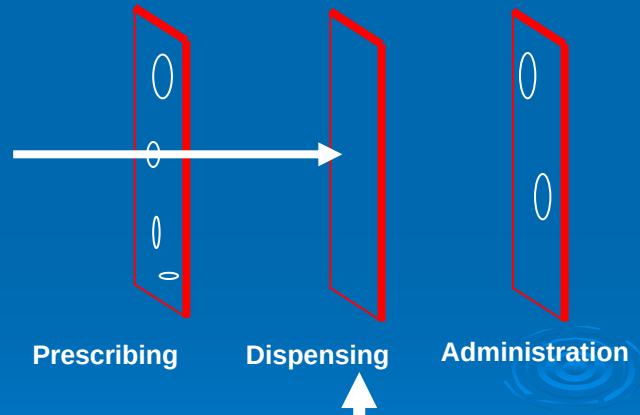
Look Alike Drugs - Dormicum Vs Magnesium Sulphate ($MgSO_4$)

- Pitfalls:
  - Look alike drugs
- Focus on clinical areas:
  - A&E
  - AICU
  - CCU
  - COD
  - DR
  - OTS
  - PAM

adults



- Review on Dormicum Vs $MgSO_4$:
  - Drug supply:
    - HA 277 for DDA Vs Ward Stock or via MAR
  - Drug storage:
    - Organized manner: DD cupboard Vs Medication Trolley
  - Drug administration:
    - Handling of DD Vs 3C5R principles of AOM
- Remove all ward stock of $MgSO_4$
- Reinforce constant vigilance



Mortuary*

- Current status of the mortuary service was checked on 11 April 2007

Hospital	No. of cold chambers available	No. of cold chamber in-use	Occ. Rate (%)
DKCH	-	-	-
FYKH	24	16	66.67
GH	43	35	81.40
QMH	87	76	87.36
MMRC	-	-	-
TWH	24	22	91.67
Total	**178**	**149**	**83.71**

- Guidelines on 'Release of Bodies' in place

*Will ↑10-15 boxes

- Undertakers are not allowed to directly take body from body box
- Body is checked by mortuary staff and put in a viewing room
- Then mortuary staff, relatives/reps after viewing with call out procedure. Only completed undertakers come for removal .
- Checks include identification bracelet, sheet ID card and "Memo for Identification and Collection of Body" before moving the deceased.

Mortuary Utilization Report on : 13/02/2008 12:37:32

Cluster	Capacity	Occupied	Utilization
HKE	196	204	104%
HKW	194	152	78%
KC	305	316	104%
KE	244	202	83%
KW	432	500	116%
NTE	239	287	120%
NTW	201	257	128%
Total	1811	1918	106%

Mortuary Utilization Report on : 10/03/2008 11:15:58`

Cluster	Capacity	Occupied	Utilization
HKE	239	251	105%
HKW	194	197	102%
KC	305	368	121%
KE	244	270	111%
KW	432	565	131%
NTE	239	335	140%
NTW	201	301	150%
Total	1854	2287	123%

Piloted SERAE in QMH

- 18 incidents were reviewed since April 2007
- An average of 4 – 6 hours was spent on review
- 27 possible failure modes were identified
- 37 corrective actions identified
- 31 (84 %) of measures were corrected with immediate effects
- The remaining six completed within a year

  (eg. lock for “hot” laboratory; compartments to mortuary).
- Severity rating reduced from 15-40 to 5-9

Severity rating of failure mode

RISK QUANTIFICATION MATRIX

醫院管理局
HOSPITAL AUTHORITY

Consequence

Likelihood	Insignificant 1	Minor 2	Moderate 3	Major 4	Extreme 5
Almost certain - 5					
Likely - 4					
Possible - 3					
Unlikely - 2					
Remote - 1					

RISK Low Medium High

Top 5 RAESE with Corrective Measures Taken (I)

Incident SSPI	Possible Failure Mode Identified	Severity Rating	Defects Identified in QMH	Corrective Measures	Severity Rating after Corrective Measures
Sharing of mortuary compartment leading to mixing up of dead body	◆ Two bodies were stored in one compartment ◆ Misidentification of the dead bodies by the mortuary staff	15 10	Two bodies were stored in one compartment during the peak season, i.e., Chinese New Year	◆ Store 2 bodies of the same sex temporarily in one compartment if required ◆ Strengthen the body identity checking by mortuary staff and the 2D-Barcode Scanning System ◆ Reinforce the Guidelines on 'Release of Bodies' ◆ Monitor the utilization rate of mortuary in QMH as well as cluster hospital	5

Top 5 RAESE with Corrective Measures Taken (II)

Incident SSPII	Possible Failure Mode Identified	Severity Rating	Defects Identified in QMH	Corrective Measures	Severity Rating after Corrective Measures Done
Mixing up of intrathecal & intravenous administration of cytotoxic drugs	◆ Labeling of the drugs was not distinct ◆ IV and IT were administered at the same time for the same patient ◆ Doctor and nurse did not perform checking	15 10 15	◆ Inexperienced House Officer (HO) reconstituted IV chemotherapy over week-ends and public holidays without supervision ◆ Some chemotherapy drugs were kept as ward stock items ◆ Chemo drugs were prescribed in Medication Administration Record (MAR) form	◆ Perform chemotherapy reconstitution by Medical Officer (MO) who has appropriate experience. Supervise HO by MO if required ◆ Provide daily IV chemotherapy reconstitution service by Pharmacy ◆ Use standardized chemotherapy protocol, handwritten MAR forms are not accepted ◆ Remove all ward stocks of chemotherapy ◆ Dilute high risk IV chemotherapy drugs to a volume or store in an IV infusion minibag that cannot be normally given intrathecally	9

Top 5 RAESE with Corrective Measures Taken (III)

Incident SSPII	Possible Failure Mode Identified	Severity Rating	Defects Identified in QMH	Corrective Measures	Severity Rating after Corrective Measures Done
Mix up of biopsy specimen	◆ Checking was not performed ◆ Pre-fix of specimen bottles	15 10	◆ Patients were disorientated ◆ Many procedures were scheduled at a session	◆ Provide wristbands for those out-patients who are mentally incapacitated ◆ Reinforce 'time-out' for all operations and procedures, as well as those minor ones	5

Top 5 RAESE with Corrective Measures Taken (IV)

Incident SSPI	Possible Failure Mode Identified	Severity Rating	Defects Identified in QMH	Corrective Measures	Severity Rating after Corrective Measures Done
Inappropriate use of OPA/cidex	◆ Same colored trays were used for containing different detergents ◆ No labeling of the trays	15 15	◆ Same coloured trays were used for containing "OPA" and "Sterile Water" ◆ Varied practices were found in different departments	◆ Distinguish and label the containers for "OPA" and "Sterile Water" ◆ Perform minimal effective concentration (MEC) test by Cidex solution test strip when solution is prepared for starting a session ◆ Renew rinsing agent, i.e., sterile water for every case	9

Top 5 RAESE with Corrective Measures Taken (V)

Incident SSPII	Possible Failure Mode Identified	Severity Rating	Defects Identified in QMH	Corrective Measures	Severity Rating after Corrective Measures Done
Adverse transfusion reaction	◆ Difference in temperatures leading to growing of bacteria	15	◆ Blood and blood components were put in the same containers after collecting from the Blood Bank	◆ Different containers for different types of blood components as each requires different temperatures ◆ Discontinue the practice of putting a towel between components with different storage conditions ◆ Clean and disinfect the inside surfaces of the insulated container with alcohol pads every time before collecting blood/blood components from the Blood Bank	5

Advantage of SERAE:

- Proactive
- Timely
- Less labor intensive
- Meet standard
- Less threatening to staff

Meeting a Challenge

Perhaps the best thing to do

is to smile

Just don't smile at the wrong time……..