

風險管理 與RCA基本概念

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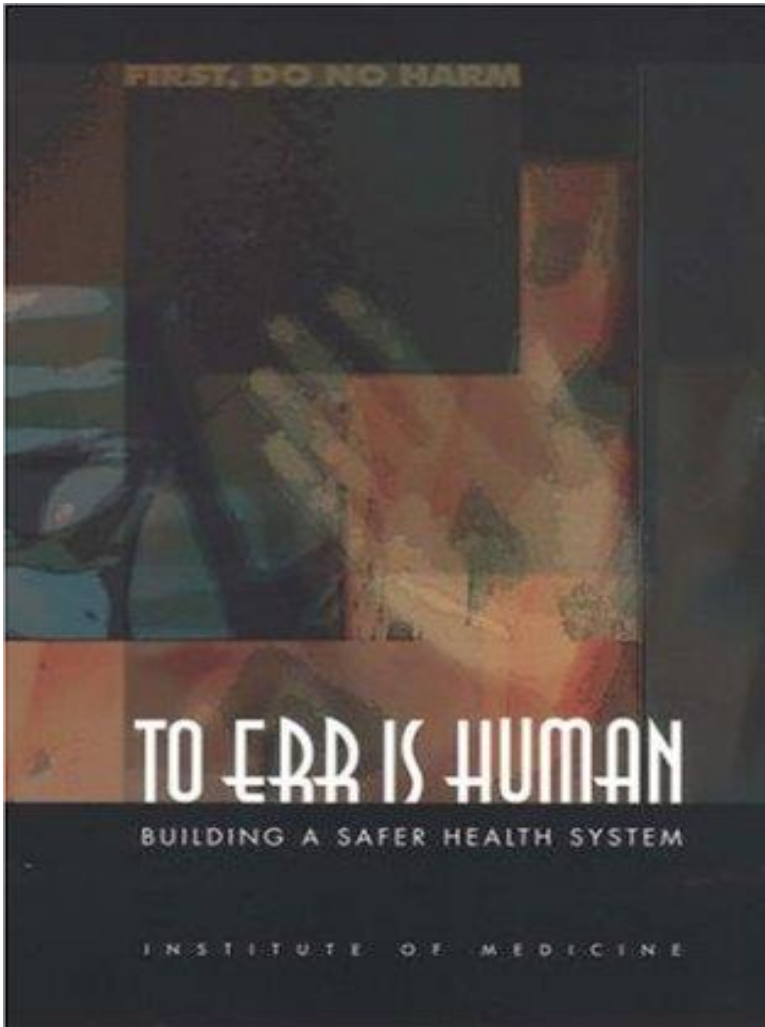


Outline

- 風險管理
- 通報與安全文化
- RCA基本原理與概念
- RCA進階-RCA²



To Err is Human



- Errors in medical management lead to between **44,000-98,000 deaths** in the **US each year.**

--IOM

- **One in every 10 patients** admitted to a hospital is the **victim** of at least one mistake.

--National Public Radio (NPR) November 21, 2000.



風險管理計畫

- 風險的**偵測**：意外事件通報系統(Risk Identification)
- 風險的**通報**(Risk Reporting)：
 - ◆ 採取**無懲罰**、**可匿名**的方式。
 - ◆ 主管簽核後，送交院方醫療品質主管單位，並對意外事件進行評估、建議與追蹤。
- 風險的**優先順序**：異常風險矩陣 SAC (Risk Prioritization)
- 風險**預先管理**(Risk Proactive Management)：**FMEA**、**HVA**
- 不良**事件的調查**(Investigation of Adverse Events)：**RCA**
 - ◆ 相關要求的管理(Management of Related Claims)：如，輸血反應、藥物不良事件、術前與術後診斷的重大差異、麻醉或中重度鎮靜時發生的不良事件、院內感染和傳染病爆發

註：FMEA (Failure Mode and Effects Analysis)
HVA (Hazard Vulnerability Assessment)
RCA (Root Cause Analysis)



風險管理手法

管理手法	構面	矩陣圖
FMEA	Severity 嚴重度 Probability 機率 Detection 偵測	Risk Probability Number (RPN)
HVA	Severity 嚴重度 Probability 機率	Risk (Relative Threat)
RCA	Severity 嚴重度 Probability 機率	Risk Matrix (SAC)



FMEA--Ratings

Ranking	Severity (S)	Probability (P)	Detection (D)
10	Death	More than once a day	Impossible to detect
9	↓	3 – 4 times a day	Remote
8	Permanent injury	Once a week	Very slight
7	↓	Once a month	Slight
6	Temporary injury	Once in three month	Low
5	↓	Once in half – one year	Medium
4	Reported/ dissatisfied	Once a year	Moderately high
3	↓	Once in 1 – 3 years	High
2	Notice/ no report	Once in 3 – 5 years	Very High
1	↓	Less than once in 5 years	Virtually certain



FMEA Format

FMEA document general format / TABLE 1

May be a product, assembly, subassembly or part

Initial development of the FMEA									Improvement activities		Post-improvement activities				
Process step/ input	Potential failure mode	Potential failure effects	SEV	Potential causes	OCC	Current controls	DET	RPN	Actions recommended	Resp.	Actions taken	SEV	OCC	DET	RPN
①	②	③	④	⑤	⑥	⑦	⑧	⑨	⑩	⑪	⑫	⑬			

DET = detection

FMEA = failure mode and effects analysis

OCC = occurrence

Resp = responsible

RPN = risk priority number

SEV = severity



HVA Tool--Category 1

自然災害事件 (Naturally Occurring Events)

事件 Event	發生機率 Probability	嚴重度 = (嚴重—輕微)						風險 Risk
	發生可能性 Likelihood this will occur	人員影響 Human Impact	資產影響 Property Impact	企業影響 Business Impact	準備程度 Preparedness	內部反應 Internal Response	外部反應 External Response	相對威脅 Relative threat*
分數Score	0 = 不適用N/A 1 = 低Low 2 = 中Moderate 3 = 高High	0 = 不適用N/A 1 = 低Low 2 = 中Moderate 3 = 高High	0 = 不適用N/A 1 = 低Low 2 = 中Moderate 3 = 高High	0 = 不適用N/A 1 = 低Low 2 = 中Moderate 3 = 高High	0 = 不適用N/A 1 = 高High 2 = 中Moderate 3 = 低或無Low or none	0 = 不適用N/A 1 = 高High 2 = 中Moderate 3 = 低或無Low or none	0 = 不適用N/A 1 = 高High 2 = 中Moderate 3 = 低或無Low or none	0-100%
旱災 Drought	1	2	2	2	2	2	2	22%
>6級之地震 Earthquake, >6 Local	3	3	3	3	3	3	2	94%
流行病 Epidemic/Natural	2	3	2	3	3	3	2	58%
洪水 Flood, Local	2	3	3	3	3	3	2	62%
颱風 Hurricane	3	2	1	3	3	1	1	61%
平均分數 Average Score	2.20	2.60	2.20	2.80	2.80	2.40	1.80	59%



HVA Tool--Category 2

技術事件 (Technologic Events)

事件 Event	發生機率 Probability	嚴重度 = (嚴重—輕微)						風險 Risk
	發生可能性 Likelihood this will occur	人員影響 Human Impact	資產影響 Property Impact	企業影響 Business Impact	準備程度 Preparedness	內部反應 Internal Response	外部反應 External Response	相對威脅 Relative threat*
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商用航空器墜毀 Air Plane Crash, Commercial	1	3	2	3	2	2	1	24%
生物事件 Biological Incident	1	3	2	3	3	3	2	29%
化學事件 Chemical Incident	2	2	2	3	3	3	3	59%
水壩/潰堤 Dam/Levee Failure	1	3	3	3	3	3	2	31%
放射性炸彈 Dirty Bomb	1	3	3	3	3	3	2	31%
平均分數 Average Score	1.20	2.80	2.40	3.00	2.80	2.80	2.00	35%



HVA Tool--Category 3

人員相關事件 (Human Related Events)

事件 Event	發生機率 Probability	嚴重度 = (嚴重—輕微)						風險 Risk
	發生可能性 Likelihood this will occur	人員影響 Human Impact	資產影響 Property Impact	企業影響 Business Impact	準備程度 Preparedness	內部反應 Internal Response	外部反應 External Response	相對威脅 Relative threat*
分數Score	0 = 不適用N/A 1 = 低Low 2 = 中Moderate 3 = 高High	死亡或受傷之 可能性 Possibility of death or injury	實際物品損失 及破壞 Physical losses and damages	中斷服務 Interruption of services	事前準備 Preplanning	時間、效能、 資源 Time, effectiveness, resources	社區/聯防工作 人員與支援 Community/ Mutual Aid staff and supplies	0-100%
青少年綁架 Adolescent Kidnap	1	3	0	3	2	2	1	20%
攻擊性行為 Assaultive Behavior	3	2	0	1	2	2	1	45%
武器攻擊 Assaultive Behavior w/Weapon	1	3	1	1	3	3	1	22%
炸彈威脅 Bomb Threat	3	1	1	1	3	2	1	50%
內部炸彈爆炸 Bomb Explosion, Internal	1	3	3	3	3	3	2	31%
平均分數 Average Score	1.80	2.40	1.00	1.80	2.60	2.40	1.20	38%



HVA Tool--Category 4

危害物質之事件 (Events involving Hazardous Materials)

事件 Event	發生機率 Probability	嚴重度 = (嚴重—輕微)						風險 Risk
	發生可能性 Likelihood this will occur	人員影響 Human Impact	資產影響 Property Impact	企業影響 Business Impact	準備程度 Preparedness	內部反應 Internal Response	外部反應 External Response	相對威脅 Relative threat*
分數Score	0 = 不適用N/A 1 = 低Low 2 = 中Moderate 3 = 高High	死亡或受傷之 可能性 Possibility of death or injury	實際物品損失 及破壞 Physical losses and damages	中斷服務 Interruption of services	事前準備 Preplanning	時間、效能、 資源 Time, effectiveness, resources	社區/聯防工作 人員與支援 Community/ Mutual Aid staff and supplies	0-100%
就地避難 Shelter in Place	1	1	2	3	3	3	2	26%
小至中度規模之 內部潑灑 Small-Medium Sized Internal Spill	2	1	2	2	3	3	1	44%
生物恐怖攻擊 Terrorism, Biological	1	3	1	3	3	3	1	26%
爆炸恐怖攻擊 Terrorism, Blast	1	2	0	3	3	3	2	24%
平均分數 Average Score	1.25	1.75	1.00	2.75	3.00	3.00	1.50	30%



執行弱點強化--擬定應變計畫

尺度	風險	行動
1	風險性極高	需要立即進行應變計畫擬定，並進行相關教育、演習
2	高風險	需要進行應變計畫擬定
3	中度風險	可考量進行應變計畫擬定
4	低風險	不需進行應變計畫擬定



每項計畫主要工作內涵

Standard Formula of Each Plan

- 計畫 (Plans)
- 教育 (Teaching)
- 執行 (Implementation)
- 應變 (Response)
- 監測 (Monitoring)
- 改善 (Improvement)



CCH-HVA規劃與討論





FMEA vs HVA

FMEA	HVA
皆非統計性方法	
皆 前瞻性(proactive) 預防分析	
皆要找出造成危害的情況	
與統計型分析相較，主觀易有分析偏差，因此需要歷史資料佐證與專家提供意見	
$RPN = S \times O \times D$	HVA Value (Risk) = Pro \times S

S: Severity 為風險衝擊嚴重程度

O: Occurrence ↔ Pro: Probability 均為風險發生頻率、機率

D: Detection 風險檢測難易度

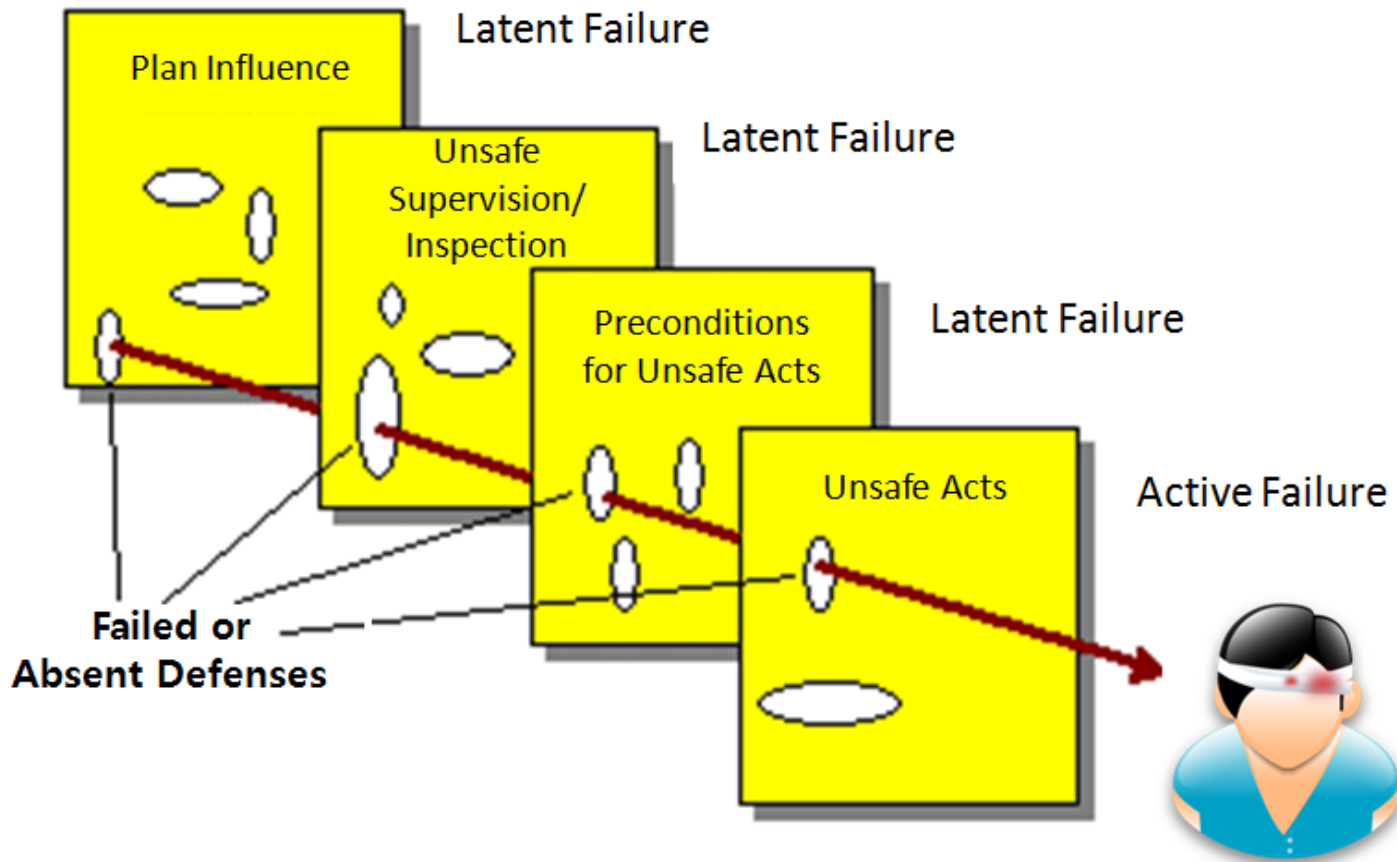


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錯誤理論 (Swiss Cheese Theory)





通報與安全文化

○ 通報理由：

- ◆ 發掘系統性問題
- ◆ 從錯誤中學習
- ◆ 預防事件再發生

○ 通報範圍：

- ◆ 跡近錯誤(near miss)：未發生於病人身上
- ◆ 無傷害事件(no harm event)
- ◆ 不良事件(adverse event)：輕度、中度、重度、極重度、死亡



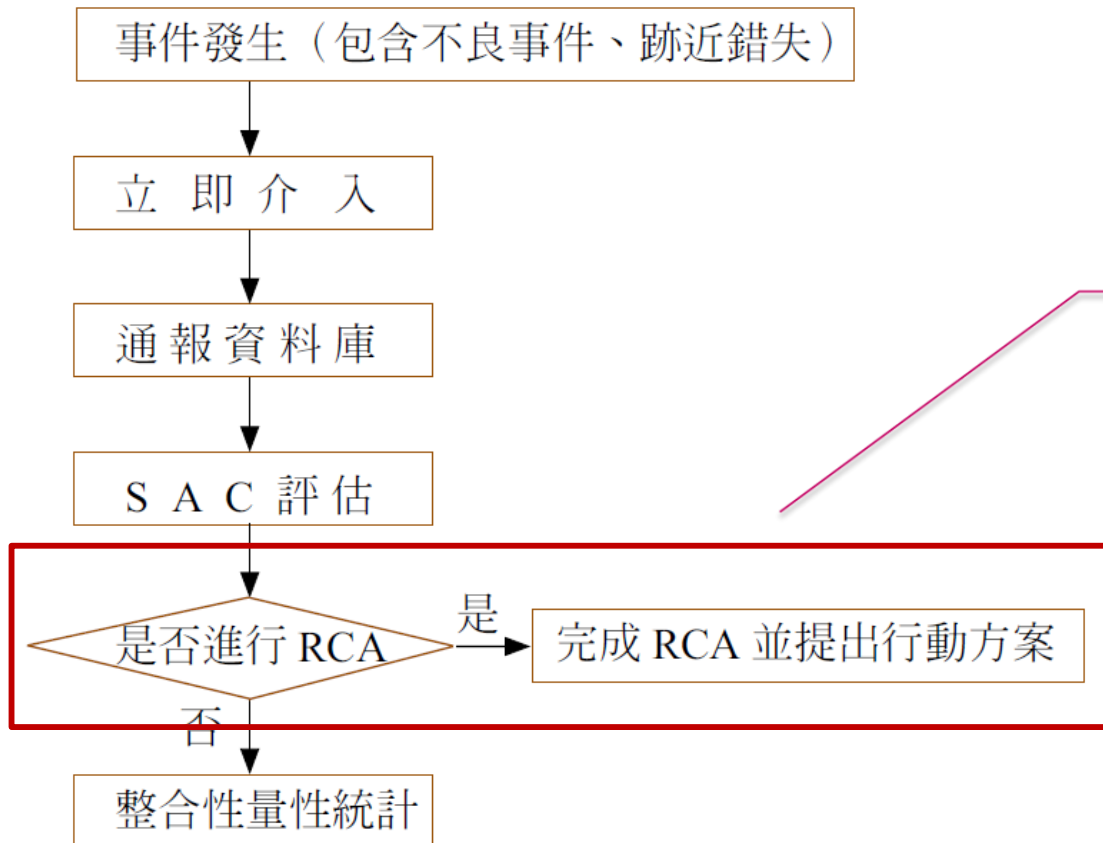
不良事件分類

- **輕度傷害**：雖然造成傷害，但不需額外處理
- **中度傷害**：需額外的探視、評估或觀察，僅需簡單的處理
- **重度傷害**：除需額外的探視、評估或觀察外，需住院治療或因而延長住院處理
- **極重度傷害**：造成病人永久性殘障或功能障礙
- **死亡**：病人死亡





事件分析流程



1.SAC1/SAC2
2.Sentinel Events
3.Systematic Problems
4.Hospital defined



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RCA基本概念 (1)

○ 什麼是RCA？

- ◆ 即：根本原因分析(Root Cause Analysis)
- ◆ 發掘潛在性、基本的執行偏差或因果關係
- ◆ 找出事件近端原因，追究系統化根本原因

➤ 近端原因：

暫時消除異常，無法避免再次發生！

➤ 根本原因：

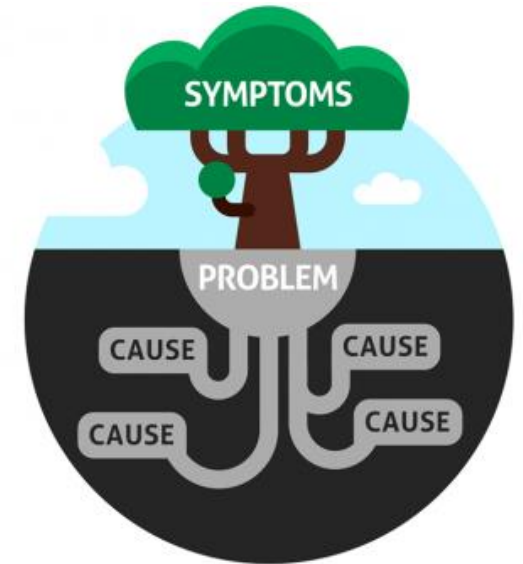
偵測體制上實際的風險，進行系統性改造



RCA基本概念 (2)

○ 進行RCA的目標：

1. 了解**發生什麼事**
2. 調整事情**為何會進行到此地步**
3. 如何**預防類似事件再發生**



○ 執行RCA的好處：

1. 改善只針對解決單一事件，治標不治本的缺點
2. 找出**流程或系統的風險**，採取正確行動
3. 透過組織分享或資訊分析，**預防不良事件再發生**
4. 協助**建置完整資料庫**



RCA基本概念 (3)

○ 什麼狀況須進行RCA？

1. SAC=1 or 2的事件
2. 嚴重後果的異常事件或警訊事件
3. 系統性問題 (經IDT分析)
4. 醫院自行規定的事件



1. SAC評估矩陣

安全性 (嚴重度) 評估級數, Safety (Severity) Assessment Code, SAC) :

Probability and Severity	Catastrophic	Major	Moderate	Minor
Frequent	1	1	2	3
Occasional	1	2	3	3
Uncommon	1	2	3	3
Remote	1	2	3	3

When you pair a severity category with a probability category for either an actual event or Close Call, you will get a ranked **matrix score (1= highest risk, 2= intermediate risk, 3= lowest risk)**. These ranks, or SACs can then be used for doing comparative analysis and for deciding who needs to be notified about the event.



SAC評估矩陣--發生率

Probability Categories(發生率)

1. The probability categories **apply to actual Adverse Events and Close Calls.**
不良事件和跡近錯誤案例都適用
2. In order to assign a probability rating for an Adverse Event or Close Call, it is ideal to know how often it occurs at your facility. Sometimes the data will be easily available because it is **routinely tracked** (e.g., falls with injury, ADEs, etc.). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for **a quick or informal opinion from staff** most familiar with those events. Sometimes it will have to be your **best educated guess**.
依實際發生次數、或詢問熟悉類似事件的員工、或以經驗估算
 - a. **Frequent** – Likely to occur immediately or within a short period (may happen **several times in 1 year**).
 - b. **Occasional** – Probably will occur (may happen **several times in 1 to 2 years**).
 - c. **Uncommon** – Possible to occur (may happen **sometime in 2 to 5 years**).
 - d. **Remote** – Unlikely to occur (may happen **sometime in 5 to 30 years**).



SAC評估矩陣--嚴重度

Severity Categories(嚴重度)

1. Key factors : **extent of injury, length of stay, level of care required for remedy, and actual or estimated physical plant costs.** These four categories apply to actual Adverse Events and potential events (Close Calls). For actual Adverse Events, assign severity based on the patient's actual condition.
 - 評估重點：傷害程度、住院天數、治療等級、實際或預估的設備花費
 - 不良事件之嚴重度的評估要以病人實際狀況為基礎
2. If the event is a Close Call, assign severity based on **a reasonable "worst case"** systems level scenario.

跡近錯誤案例之嚴重度要以在合理的狀態下，最壞的情境來評估



2. 警訊事件 (Sentinel Events)

Standard QPS.7

The hospital uses a defined process for identifying and managing sentinel events. ⑥

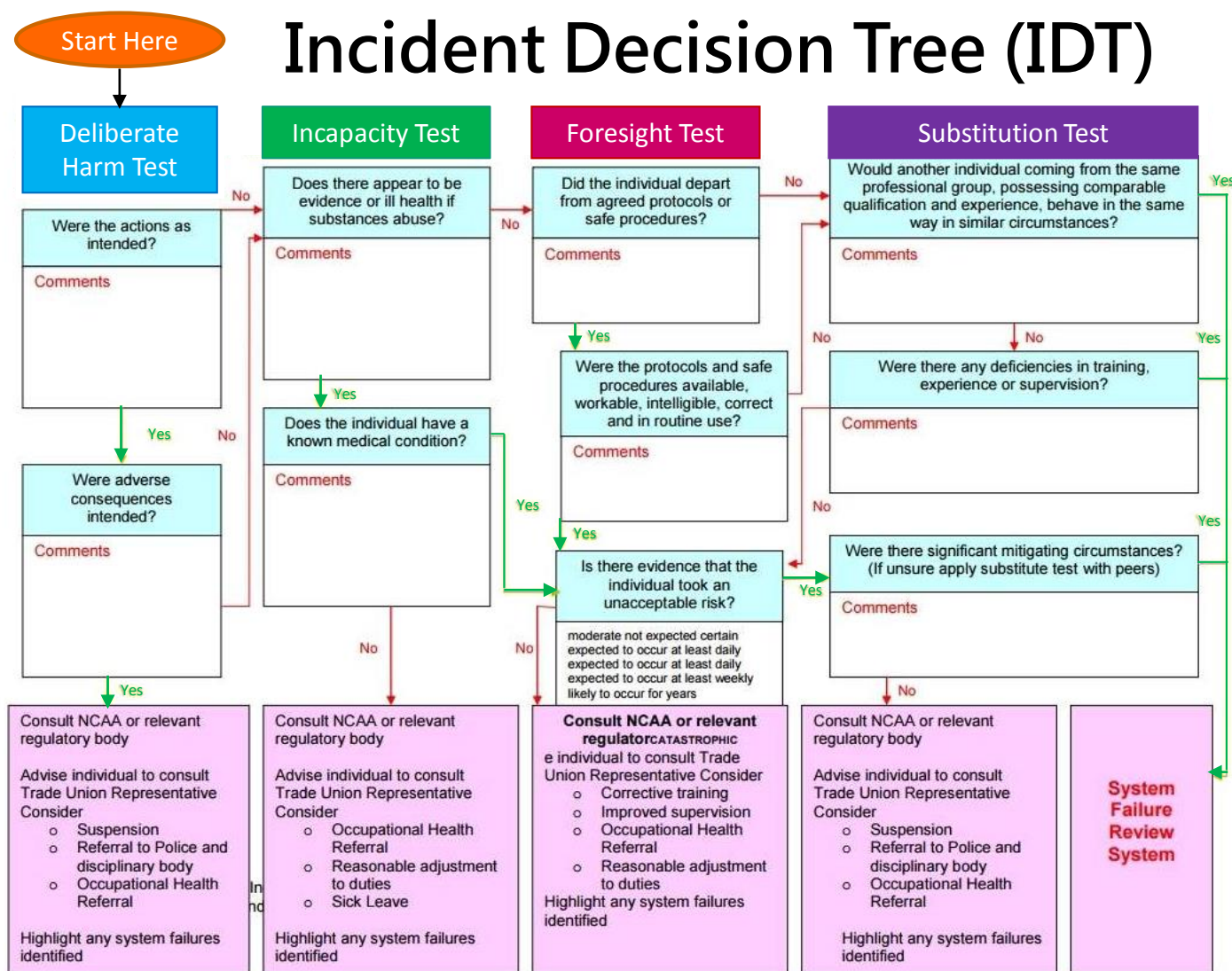
Intent of QPS.7

A *sentinel event* is an unanticipated occurrence involving death or serious physical or psychological injury. Serious physical injury specifically includes loss of limb or function. Such events are called *sentinel* because they signal the need for immediate investigation and response. Each hospital establishes an operational definition of a sentinel event that includes at least

- a) an unanticipated death, including, but not limited to,
 - death that is unrelated to the natural course of the patient's illness or underlying condition (for example, death from a postoperative infection or a hospital-acquired pulmonary embolism);
 - death of a full-term infant; and
 - suicide;
- b) major permanent loss of function unrelated to the patient's natural course of illness or underlying condition;
- c) wrong-site, wrong-procedure, wrong-patient surgery;
- d) transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;
- e) infant abduction or an infant sent home with the wrong parents; and
- f) rape, workplace violence such as assault (leading to death or permanent loss of function); or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor while on hospital property. (Also see SQE.8.2)



3. 系統性問題 (IDT分析)





異常事件決策樹 (IDT)--四大構面

- 刻意傷害檢視 (Deliberate Harm test)
 - ◆ 是指此傷害是否為蓄意造成？
- 能力檢視 (Incapacity test)
 - ◆ 是否因個人健康或其他原因而造成病人傷害？
- 外部檢視 (Foresight test)
 - ◆ 是否違反安全規範或標準作業規範而造成錯誤？
- 情境檢視 (Substitution test)
 - ◆ 換成另一個人是否會犯同樣的錯誤？



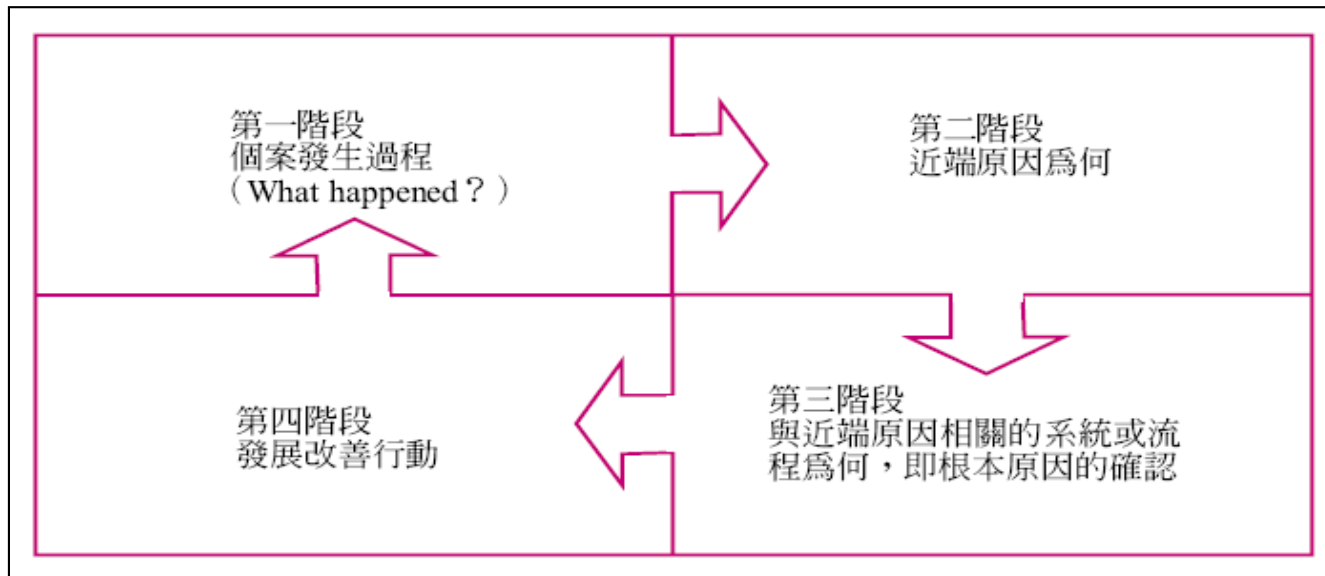
RCA進行步驟

一. 事件調查

二. 找出近端原因

三. 確認根本原因

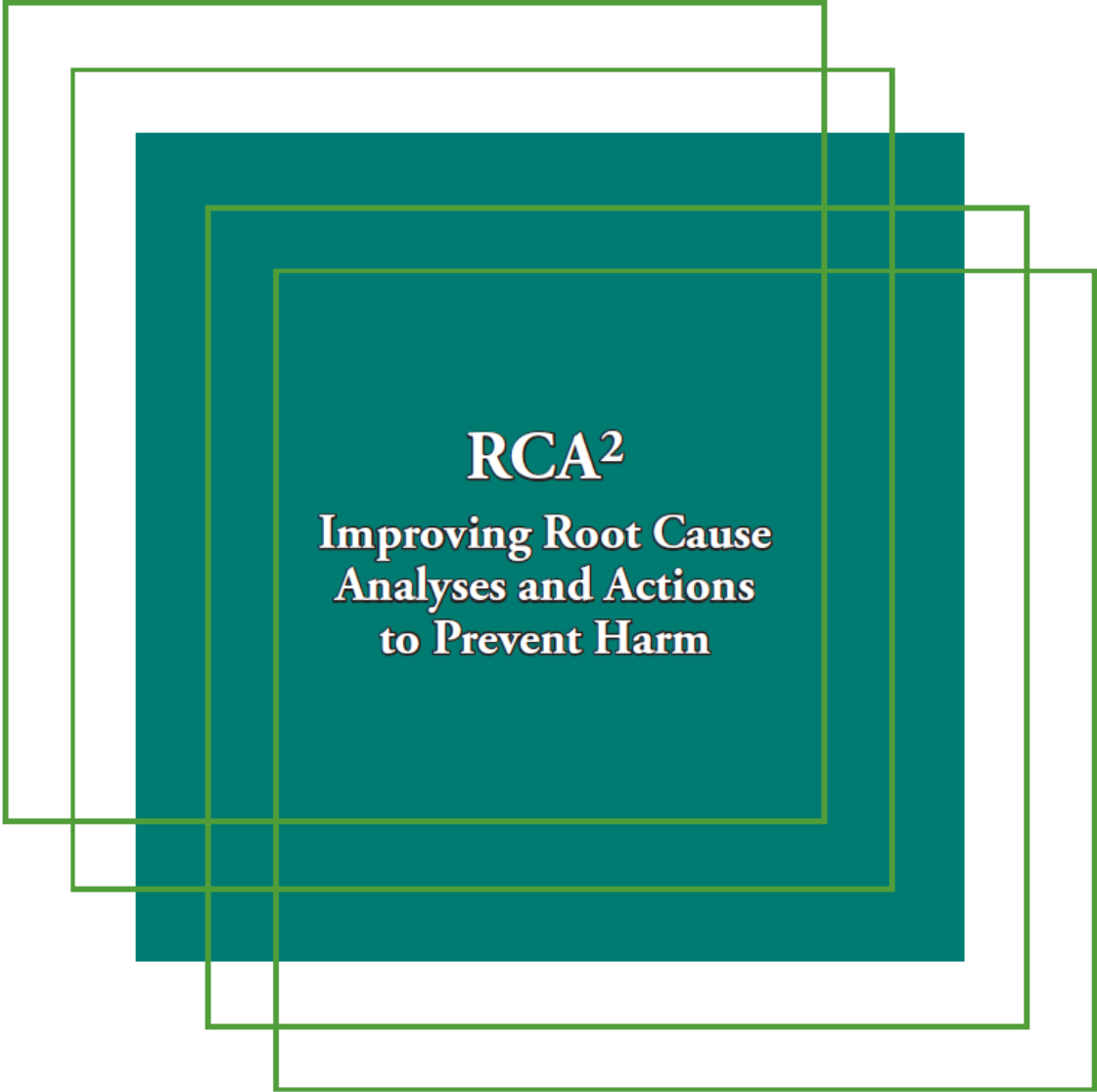
四. 設計及執行改善計畫





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RCA²

**Improving Root Cause
Analyses and Actions
to Prevent Harm**



NPSF National Patient Safety Foundation

268 Summer Street | Boston, MA 02210 | 617.391.9900 | www.npsf.org



Why RCA² ?

- The process employed to accomplish this learning has been called root cause **analysis** (RCA), but it has had inconsistent success.

過去常只停留在『分析』，無有效的改善措施

- To improve the effectiveness and utility of these efforts, we have concentrated on the ultimate objective: **preventing future harm**.

RCA²是要強調預防未來再發生類似的傷害

- Prevention requires actions to be taken, and so we have renamed the process **Root Cause Analysis and Action, RCA²** (RCA “squared”) to emphasize this point.

因此更名為RCA²以強調action的重要



Purpose and Goal of RCA²

Purpose:

- Identification and implementation of sustainable **systems-based** improvements.
 - ◆ An RCA² review is to **identify system vulnerabilities** so that they can be **eliminated or mitigated**.
 - ◆ Root cause analysis and action team findings **must not be used to discipline or punish staff**.
- Make patient care safer in settings across the **continuum of care**.

Goal:

- Identify methodologies and techniques that will lead to more **effective and efficient** RCA².
- Provide **tools to evaluate individual RCA² reviews** so that significant flaws can be identified and remediated to achieve the ultimate objective of improving patient safety.



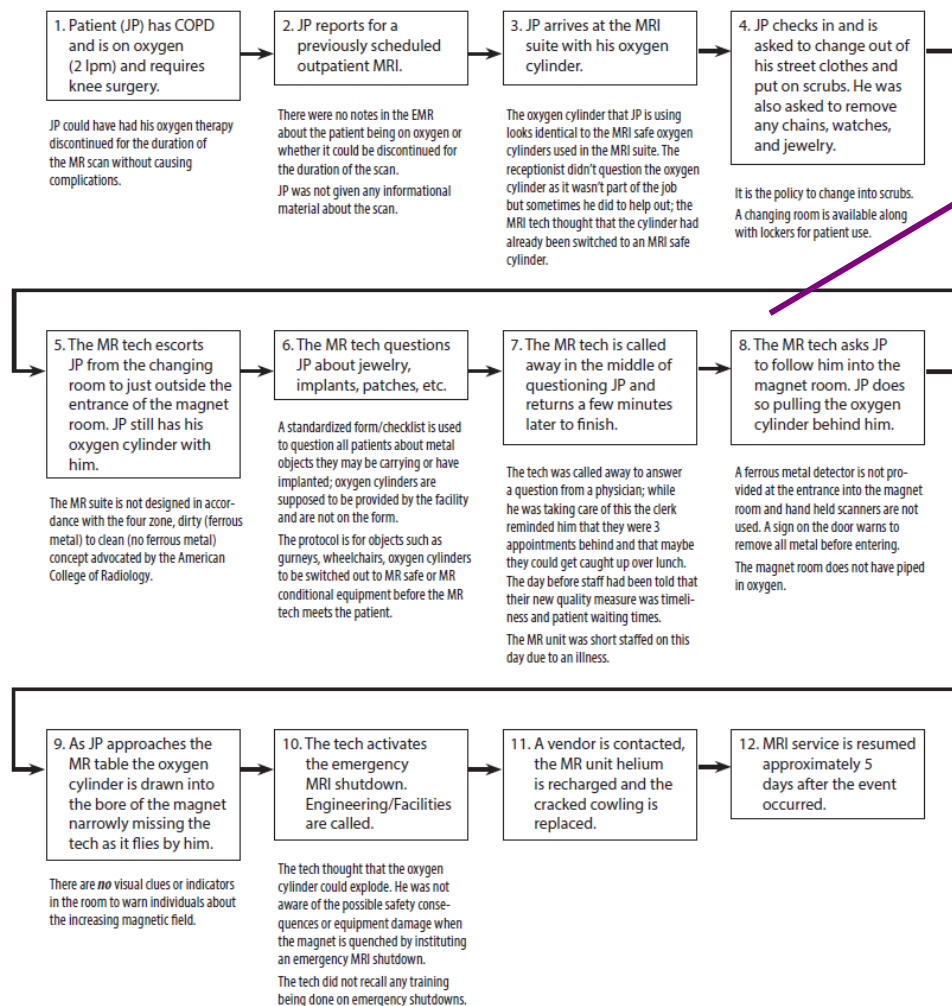
Process of RCA²

1. **Triage** adverse events and close calls/near misses
2. Identify the **appropriate RCA² team size and membership**
3. Establish RCA² **schedules for execution**
4. **Use tools provided** here to facilitate the RCA² analysis
5. **Identify effective actions** to control or eliminate system vulnerabilities
6. Develop **Process/Outcome Measures** to verify that actions worked as planned
7. Use tools provided here for leadership to **assess the quality of the RCA² process**



RCA²輔助工具--流程圖

○ 運用於事件還原與調查



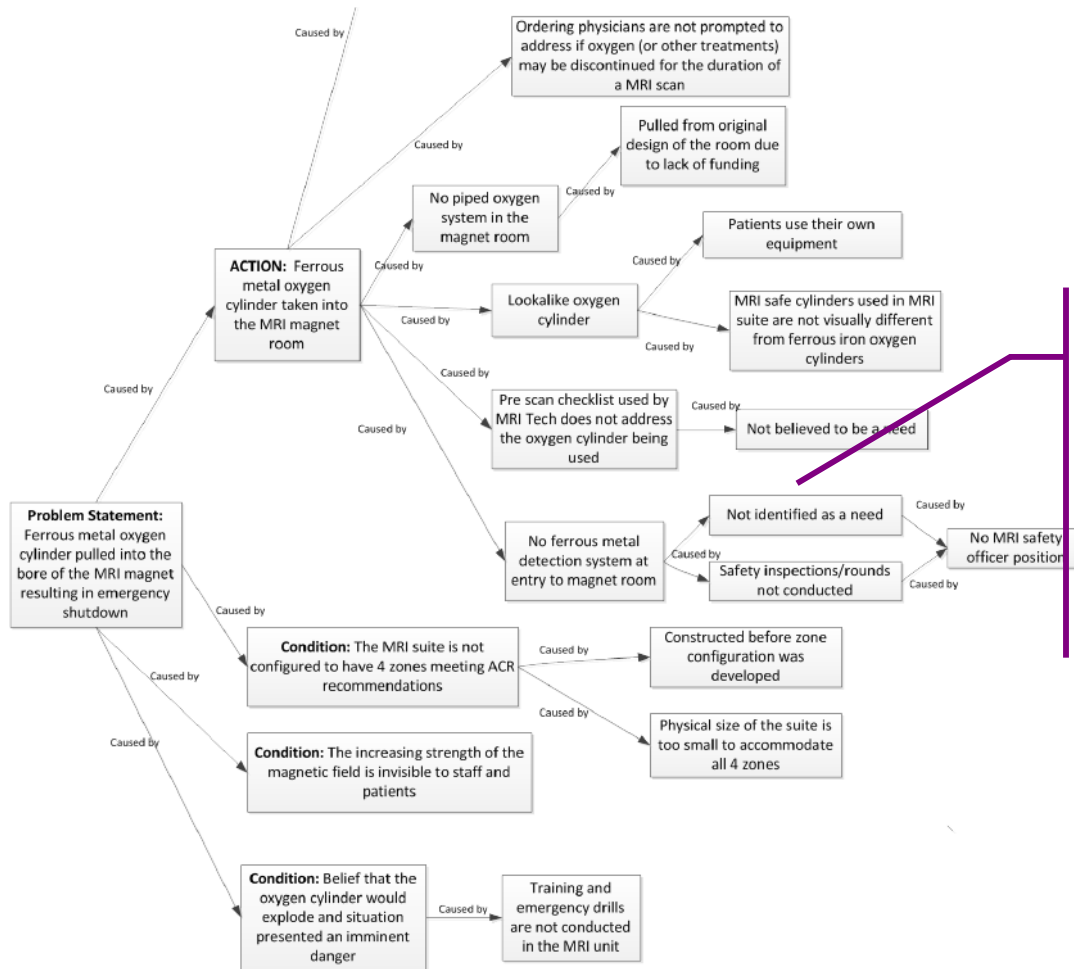
□ 流程圖：

- ◆ 將每個流程依例寫出
- ◆ 團隊成員於下方各自列出可能之問題點



RCA²輔助工具--因果圖

○ 運用於事件調查 / 原因找尋



因果圖：

- ◆ 將問題列出，逐次往下探究原因
- ◆ 找出各個項目導致的因素，持續追查



RCA²輔助工具--因果關係五規則 (1)

○ 運用於找尋根本原因

原則1：清楚呈現“因果”關係

錯誤範例：住院醫師疲勞

正確範例：住院醫師每周排班80小時，造成疲勞程度增加，提高了誤看劑量標示的可能性。

原則2：使用特定且明確的描述方式來說明事件的發生，不要使用負面和模糊不清的字句，避免負面的描述，如不佳、不適當、錯誤、不好、未能、疏忽。

錯誤範例：手冊寫的不好

正確範例：Pumps使用手冊字體大小8點，沒有範例說明，所以護理同仁很少使用，增加了Pump設定錯誤可能性。

原則3：人為錯誤一定是有原因造成

錯誤範例：住院醫師選錯劑量，導致病人劑量過高。

正確範例：醫囑系統螢幕沒有足夠的空間顯示不同劑量的藥物，增加藥物劑量選錯的可能性，導致病人劑量過高。



RCA²輔助工具--因果關係五規則 (2)

○ 運用於找尋根本原因

原則4：違反 SOP不是根本原因，一定是有原因造成

錯誤範例：放射技師沒有依照CT SOP，導致病人經空針被灌入空氣，造成致命性氣栓。

正確範例：準備室環境吵雜混亂，伴隨作業壓力，增加CT SOP步驟遺漏執行的可能性，導致以空針將空氣注進病人體內。

原則5：當有既定的執行職責時，未能執行僅是因果關係

錯誤範例：護士沒有每半小時確核STAT orders，造成抗凝血治療延誤，增加血栓的可能性

正確範例：沒有在特定的時間指派特定的護理人員去確核order，會提高STAT order遺漏或延遲執行的機會，而導致治療延誤。

Causal statements are written to describe (1) Cause, (2) Effect, and (3) Event. Something (Cause) leads to something (Effect) which increases the likelihood that the adverse Event will occur.

某事（原因）造成某個結果（影響），提高了不良（事件）發生的可能性

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