醫療儀器的安全使用與風險管理

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醫療器材不利事件 年度新增案例與議題

- Baxter 血液透析器
  - --氟化物導致猝死
  - --廠商與醫院之責任?
- 榮總心導管感染事件
  - -- Disposable & Single-use device的重複使用
  - --只是感染管控的課題?

IOM Report

- **The IOM report "To Err Is Human***: Building a Safer Health System"* used extrapolations of a study of hospitals in Colorado and Utah and another in New York.
- **Adverse events --2.9% in Colorado and Utah**
  3.8% in New York
- **Death -- 6.6% in Colorado and Utah hospitals**
  13.6% in New York hospitals
- **Report concluded, "over half these adverse events resulted from medical errors and could have been prevented."**

IOM Report(cont.)

- **Much of the attention has focused on medical equipment failures.**
- **The IOM report cited a case involving infusion pumps that failed to shut off properly in an operating room, resulting in a free flow of excess medication that nearly resulted in a patient's death.**
- **Experts who have studied the issues say that communications and systems problems are more significant than equipment failures.**

FDA related Report

- **根據Congress(Gardner and Flack, 1999)的報告，美國FDA於1998年從儀器設備製造商所通報疑似與儀器設備有關之死亡報告有980筆**
- **The [U.S.] Food and Drug Administration gets reports of approximately 500 technology-related deaths a year.**
- Medical devices as they relate to errors in medicine are not a major component.

ECRI Evaluate Report

- **3% ~ 5% of medical errors in general are related to technology in some fashion**
- **Deaths about 2,700 / year**
- **Maybe 70% of health care technology-related errors are user errors**

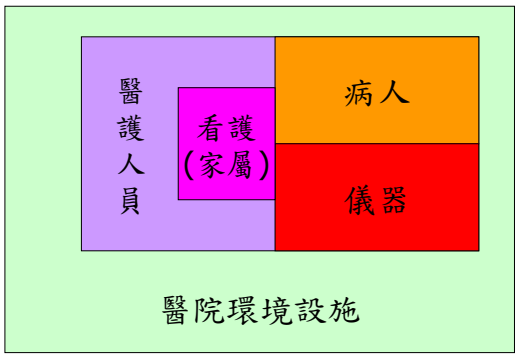
User & Device

- **In many hospitals, there are numerous different brands of devices (e.g., pump, monitor, ventilator)**
- **Knowing how to work one does not mean knowing how to work others.**
- **You have to worry about float nurses, technicians -- these are all people who have to be cross-trained. It's not easy.**

Risk analysis of Use-related hazards

- Chemical hazards(e.g., toxic chemical)
- Mechanical hazards
- Thermal hazards(e.g., High, Cool)
- Electrical hazards(e.g., Shock, EMI)
- Radiation hazards
- Biological hazards(e.g., SARS, Infection)

Interactional Interface



採購作業

- 進行醫療儀器相關規格、安全等級之評估，篩選出符合規定之廠商進入議價投標程序，例如是否需衛生署輸入許可證、有無通過EMC檢測、IEC601-1、FDA…等等認證。
- 收集相關警訊

交機安裝

- 在採購時，須就儀器本身所需使用之環境進行規劃，例如空調、水源、電力、氣源....等等，以營造一適合儀器擺放及安全之環境。

交機驗收

- 需實地做電性安全檢測，包含機殼漏電流、電極漏電流、接地阻抗、電壓規格、插頭型式等及儀器功能進行驗收，以確認儀器設備之安全性。

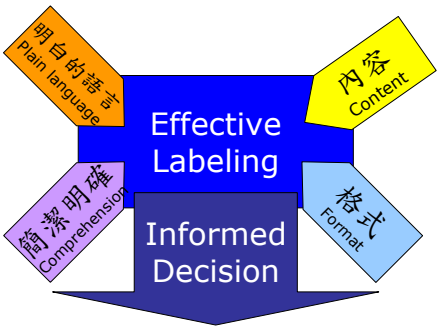
準備使用

在將設備使用於病人之前

- Checking List—防止device failure
- 針對儀器設備進行操作訓練，以使醫療人員能對儀器設備之功能、注意事項及操作熟悉，避免因操作不當而對病人造成傷害。

儀器生命週期內

- 規劃「儀器使用之評核」，以使儀器使用者能熟悉儀器之操作，避免人機介面因操作不當所引發之不良事件，以維護病人之安全。
- 為使儀器能正常運轉順利，平常之保養及定期之校正維護也需規劃時程施作，避免儀器設備故障，對病人所造成之傷害。



歷年來之統計

項目 / 年度	人為疏忽			
	操作不當	撞擊進水	小零件遺失	統計
90	341	175	82	598
91	164	102	65	331
92	167	136	41	344

HFE VS Risk Management

- 人因工程(HFE-Human Factor Engineering)
  Identify
  Understand
  Control
  Prevent failure

行動電話功率比較

	PHS	GSM	3G
手機發射功率	10mW	600-1000mW	1000-2000mW
基地台發射功率	0.5W	20W	20W

HF of Use Environment

- 光線(Light)、喧鬧聲(Noise)
- 分心(Distraction) 、注意力分散
- 移動、顫動(Motion/Vibration)
- 工作量(Workload)

HF of User

- 知識(Knowledge)
- 能力(Abilities)
- 期待(Expectations)
- 限制(Limitations)

HF of Device

- 操作的需要及程序
- 儀器的複雜度
- 特殊的使用者介面的特性

Human Factors

在medical device考慮人因的設計

- 直覺的操作對手冊的依賴性低
- 顯示值容易讀
- 控制容易使用
- 確定和安全的連接—愚巧法
- 有效的警報系統
- 容易維修和保養

Human Factors

Human Factors-Related Standards under Development

- **ANSI/AAMI HEXX: 2000 2CDV:** *Volume 1, HF Design Process and Volume 2, HF Design Principles and Specifications*
- **IEC 60601** *Safety Standard for Electrical Medical Devices*
- **IEC 60601-1-6** *Collateral Standard: Usability: analysis, test, and validation of human factors compatibility*
- **ISO 14791** *Risk Management*

FDA Report System

- MedWatch -- for reporting problems with medical products, including devices.
- In 2000, five device-related issues were posted on the MedWatch Web site.
- The FDA also reviews all new products before they are released to market.

FDA Report System

- Each company has to show that their devices are safe and effective.
- Authority to remove an unsafe product from the market
- Inspect manufacturing firms on a regular basis, and we have a problem-reporting system."

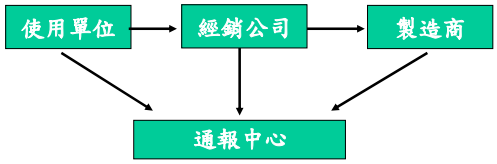
國際間的醫療器材不利事件通報系統

- Europe– Vigilance System
- USA– Medical Device Reporting(MDR) system
- Canada– Mandatory Problem Reporting(MPR)
- Australia– Incident Reporting & Investigation Scheme(IRIS)
- Japan– some guidelines
- Taiwan--

通報的效益

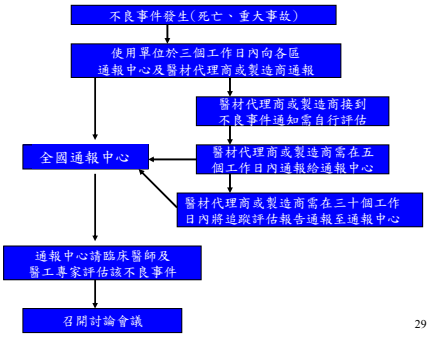
- 醫療院所
  - --建立醫療器材風險管理系統
    - *擬定管理策略，依據風險分類建立不同管理手段之管理系統
    - *檢討調整採購評估之審查流程與門檻
  - --建立通報系統
    - *整合國際通報系統，主動提供院內與國內相關訊息
  - --建立資料庫，累積專業知識、人才
    - *通報資料的累積是醫療器材技術提升的重要來源
    - *問題與風險分析技術是醫療器材高階技術的核心

醫療器材不良反應通報作業



使用單位:如醫療院所，療養院等
經銷公司:如代理商，經銷商

醫療器材不良反應通報流程



結論

- 科技始終來自於人性，因此醫療科技的成功與失敗，也是取決於人
- 如何去防範這人機介面上所發生之失誤，以降低醫療風險，促進病人之就醫安全，也是當前所需注意之重要課題。

Reference

- FDA Medical Device Reporting data files (http://www.fda.gov/cdrh/mdrfile.html)
- FDA Manufacture and User Facility Device Experience Database(http://www.fda.gov/cdrh/maude.html)
- CDRH Safety Alerts, Public Health Advisories, and Notices(http://www.fda.gov/cdrh/safety.html)
- FDA Enforcement Reports recalls and legal actions (http://www.fda.gov/opacom/Enforce.html)
- ECRI Medical Device Safety Reports (http://www.mdsr.ecri.org/index.asp)
- The Institute of Safe Medical Practices(ISMP's) Medication Safety Alert(http://www.ismp.org/MSAarticles/Calendar/calendar.html)
- Joint Commission on Accreditation of Healthcare Organizations(JCAHO) Sentinel Events (http://www.jcaho.org/sentinel/sentevnt_main.html)