Risk Management I
Patient Safety

Case Discussion:
Dana Farber Cancer Institute

SANIT Management in the Health Sector 2004

10 November 2004

Prof. M Rosenmöller

Assignment Questions

1. Who, or what caused the death of Betsy Lehman?
2. What was the Dana-Farber’s system for ensuring patient safety?
3. How should the Dana-Farber respond to the Globe story of March 23 1995?
4. What are the key issues that must be addressed in the first few days after the error was discovered?
5. How should the Dana-Farber reduce the risk of future errors?
DOCTOR'S ORDERS KILLED CANCER PATIENT
Published on March 23, 1995
Author(s): Richard A. Knox, Globe Staff

When 39-year-old Betsy A. Lehman died suddenly last Dec. 3 at Boston's Dana-Farber Cancer Institute, near the end of a grueling three-month treatment for breast cancer, it seemed a tragic reminder of the risks and limits of high-stakes cancer care.

Aftermath at the Dana Farber

Responding to the Error – open and aggressively
- Information to Lehman's family + open attitude to MEDIA
- Private settlement with Lehman family ($2.4 Mill)
  - donation Lehman's husband – breast cancer research fund – 'Betsy Lehman'.

• Personal Changes
  - resigned: chief Pharmacy, Physician in chief, oncology fellow no practice for 3 yrs.
  - New CEO
  - Principal investigator – laid off as she filed suit agains DFCI for scapegoating

• Census of Nurses (18 RNs)
• Process of Redesign
• Structural Changes
  - Executive Director for Nursing
  - Patient and Family Council
  - From 25 to 5 research departments

• A new hospital culture
  - "we carry the burden (of the error), the responsibility (to learn from it) and the power (to inform others)"
  - Accept the possibility of error & openly discuss failure
  - from front runner in Cancer Research to foremost institutions in Patient Safety
BETSY AMANDA LEHMAN FUND  
Published on March 27, 1995

A fund has been established at Brown University in memory of Betsy A. Lehman, who created the Health Sense column in the Globe’s Health/Science section. Ms. Lehman died on Dec. 3. The fund will be used to encourage and reward excellence in journalism, providing an annual prize to an undergraduate and ultimately, it is hoped, a scholarship.

DANA-FARBER PROBE WIDENS THREE SUSPENDED FROM PATIENT CARE  
Published on April 1, 1995

Author(s): Richard A. Knox, Globe Staff

Acting on the basis of “new evidence,” the Dana-Farber Cancer Institute yesterday initiated disciplinary proceedings against two physicians and one pharmacist involved in the chemotherapy overdose of two breast cancer patients, one of whom died. Dr. David M. Livingston, the institute’s physician-in-chief, declined to divulge the names of the individuals involved, the charges they face or the nature of the “new evidence.”

DANA-FARBER ON PROBATION AGENCY DOWNGRADES ACCREDITATION  
Published on April 15, 1995

Author(s): Richard A. Knox, Globe Staff

The nation’s leading agency for certifying hospital quality has put Boston’s Dana-Farber Cancer Institute on probation after two recent cases involving overdoses of potent anticancer drugs. In the jargon of the Joint Commission on the Accreditation of Healthcare Organizations, Dana-Farber’s accreditation was downgraded from “full” to “conditional.” The commission is giving the cancer institute six months to correct its lapses.
Patient Errors = Killer!!

- 1991 Harvard Medical Practice Study, 4% injury resulting in disability
- New York State: 98,609 patients in 1984
  - 14% fatal outcome
- US: 180,000 death each year as result of iatrogenic injury
  - (3 jumbo-jet crashes/2days)
Medical Errors

- **Diagnostic**
  - Error or delay in diagnosis
  - Failure to employ indicated tests
  - Failure to act on results/monitoring/tests
- **Treatment**
  - Error in the performance of an operation, procedure or test
  - Error in administering the treatment
  - Error in the dose of method of using a drug
  - Avoidable delay in treatment or in responding to an abnormal test
  - Inappropriate (not indicated) care
- **Preventive**
  - Failure to provide prophylactic treatment
  - Inadequate monitoring of follow up treatment
- **Other**
  - Failure of Communication
  - Equipment failure
  - Other system failure

Source: Kohn et al. (eds), 'To Err is Human. Building a Safer Health System' National Academy Press. Washington DC

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Cause effect:
**Individual – System/Process – Organisation**

- **Human Factors** – individual responsibility
  - Slip / mistake (rule based / knowledge based)
  - Training simulators
- **System Complexity**
  - System design
  - Elements of the system
  - Management of the system
- **Organisational Factors**
  - External factors
  - Organisational culture
  - Organisational structure
Type of Human Error

- **SLIP**
  - Action deviates from current intention
    - Double capture
    - Perceptual confusion
    - Omissions associated with interruptions

- **MISTAKES**
  - Rules based
    - Wrong rules
    - Wrongly applied
  - Knowledge based
    - New situation, change, lack of knowledge

Human Error - Individual Failure

- Failure to notice the error
  - Success erodes vigilance and fosters complacency and routinization
  - Use to high risk environment
- Failure to raise concern
  - Hospital atmosphere prevents from talking about mistakes
  - Culture not supportive to error reporting
  - Professional culture: perfect individuals
    - error = personal failure
    - “how can there be error without negligence?”
    - => retraining or removing / deregistration
System Level Failure

"same set of circumstances provoking similar errors regardless of people involved"

"we assumed that if we are all wonderful - our pharmacy safety would be wonderful"

(Stephen Sallan, Dana Farber Cancer Institute)

- Active failures vs. latent conditions
- Systems design
  - Research protocols, protocol location
  - Order communication, Order execution
  - Transition to outpatient care
  - Staff discontinuity and multiple handoffs
  - Non Standard Language
  - The nature of the chemotherapy
- Preventing Harm
  - Drug doses and delivery checking
  - Staff familiarity
  - Retrospective adverse events monitoring (Quality Assurance Process)

Organisational Context

"an organisation that does not recognize the possibility of error does not create systems and processes to prevent errors or correct them when they occur"

- Little Data on Errors
  - No reporting
  - At frontiers of clinical science – risk of failure are high
- Limited Senior Oversight
  - Board of Trustees, Patient Care Assessment Committee
- Psychological Safety
  - Not easy for a nurse to challenge a physician’s order
  - Research physicians – the most important in the organisation
  - No Senior Nurse – nurses not important?
Can Harm be Prevented?

- Computer Automation
- Team Composition
- Nurse Staffing Composition
- High Risk Systems
- Disclosing Error

Levels of Analysis of Medical Error

[Diagram showing levels of analysis: Clinical Processes, "Meta" Processes, Culture, Leadership]
Knowledge of the Processes of Medication Use

- **Prescribing**
  - Assessing the need for and selecting the correct drug
  - Individualizing the therapeutic regimen
  - Designating the desired therapeutic response

- **Dispensing**
  - Reviewing / processing the order
  - Compounding and preparing the drug
  - Dispensing the drug in a timely manner

- **Administering**
  - The right medication to the right patient when indicated
  - Informing / including the patient

- **Monitoring**
  - Monitoring / Documenting the patient’s response
  - Identifying and reporting ADE – **Adverse Drug Events**
  - Reevaluating drug selection, regimen, frequency and duration

- **System and Management Control**
  - Collaborating and communicating
  - Reviewing and managing patient’s complete therapeutic drug regimen

Understand the causality to prevent errors

- Some systems are more prone to accidents than others
- Make systems more reliable and safe!
- Human error – learn from industry
- Latent errors / system failures
- Systems focus on active errors!
- Application of human factors in other industries has successfully reduced errors
Official Reporting Systems

- Mandatory External Reporting
  - State Adverse Event Tracking
  - Food and Drug Administration (FDA)
- Voluntary External Reporting
  - Joint Commission on Accreditation of Health Organisations (JCAHO)
  - Medication Errors Reporting (MER) Programme
  - US Pharmacopoeia
  - Aviation Safety Reporting System at NASA
  - Mandatory Internal Reporting with Audit
- Key Points Existing Reporting Systems

Hierarchy of Reporting

- Serious Preventable Adverse Events
- Near Misses or Lesser Injuries
- Mandatory Reporting
  - Public Disclosure
- Voluntary Reporting
  - Confidentiality protected
Performance Standards and Expectations for Health Care Organisations

- Licensing and Accreditations
- Purchaser Requirements and Demands
- Licensing, Certifications and Accreditations
- The Role of Health Professionals and Groups
- Standards for Drugs and Devices

Creating Safety Systems in Health Care Organisations

- Implement proven Medication Safety Practices
- Safety Systems in High-risk-industries
- Principles for Design of Safety Systems in Health Care Organisations
Principles for **Design of safety systems I** in Health Care Organisations

– **Provide Leadership**
  - Make patient safety a priority corporative objective
  - Make patient safety Everyone’s responsibility
  - Make clear assignments and Set Expectations for Safety
  - Priced Human and Financial Resources for Error Analysis and System Redesign
  - Develop Effective Mechanism for Identifying and Dealing with Unsafe Practitioners

– **Respect Human Limits In Process Design**
  - Design Jobs for Safety
  - Avoid Reliance on Memory
  - Use Constraints and Forcing Functions
  - Avoid Reliance on Vigilance
  - Simplify Key Process
  - Standardise Work Processes

Principles for **Design of safety systems II** in Health Care Organisations

- **Promote Effective Team Functioning**
  - Train in Teams Those Who are Expected to Work In Teams
  - Include the Patient in Safety Design and the Process of Care

- **Anticipate the Unexpected**
  - A proactive Approach
  - Design for Recovery
  - Improve Access to Accurate Timely Information

- **Create a Learning Environment**
  - Use Simulations whenever possible
  - Encourage reporting of errors and hazardous conditions
  - Ensure no reprisals for reporting of errors
  - Develop of working culture in which communion flows freely regardless of authority gradient
  - Implement mechanisms of feedback and learning from error
Thank you very much for your interest!

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