“Dana-Farber Cancer Institute, Boston – the interaction of provider and regulator in pursuit of quality improvement.”

Jim Conway, SVP, Institute for Healthcare Improvement
previously EVP & COO, Dana-Farber Cancer Institute

Nancy Ridley, Director,
Betsy Lehman Center for Patient Safety,
Massachusetts Department of Public Health

Objectives

- Understanding the Lehman overdose
- Learning for DFCI and DPH, individually and together
- Impact of a “sentinel” event in MA and beyond
- Role of the media – then and now
- Applicable lessons for *all* healthcare systems
- Key Opportunities and Issues – past, present and future

Presentation Outline

- The incident – what and how did it happen?
- Immediate issues and responses
- DFCI and DPH coming together around the incident
- Key Learning
- Leadership at the local, state and national level—driving learning and improvement
- Applications of learning going forward

Betsy Lehman

- 39 year old mother of two
  - Wife off DFCI cancer researcher
  - Boston Globe Health Reporter
- Advanced breast cancer
- Experimental bone marrow transplant - “standard of care”
- Overdose of chemotherapy x 4
- Suddenly died the day before discharge
- No one had any idea that there was an error, or the cause of death

DFCI Discovery of the Incident….

- Data manager discovers error 2 months later
- Immediate Issues…
  - Who was guilty?
  - Several staff suspended!
- Organizational decision to disclose

Immediate Responses….

- Response by Boston Globe
- Response by leaders (internal and external)
- Response by the DFCI board

Immediate Responses….

Government accountability?

- Response by the state (DPH) and federal (HCFA) agencies
- Response by Boards of Registration (medical, pharmacy, nursing)

How Did DFCI Respond?

- We were afraid of error and disclosure
- No processes were in place
- Few knew their role and responsibilities
- No one knew their reporting responsibilities
- Board took control
- Goal was to find the guilty - and later improvement

DANA-FARBER ADMITS DRUG OVERDOSE CAUSED DEATH OF GLOBE COLUMNIST, DAMAGE TO SECOND WOMAN

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. In fact, it was something very different. The death of Lehman, a Boston Globe health columnist, was due to a horrendous mistake: a massive overdose of a powerful anticancer drug that ravaged her heart, causing it to fail suddenly….

The Boston Globe

3/23/1995

Immediate Reactions to the Incident

Internal and External Reviews

- Investigation and Assessment
- Internal
  - Committee of Peers
  - Root Cause Analysis
- External
  - DPH
  - JCAHO
  - NIH
  - Professional Boards

IMPACT OF THE ERROR

- Internally demanding & disruptive
  - staff
  - patients
  - families
  - community
- Significant external interest
  - media
  - clinical

DFCI SYSTEMS RESPONSE

Leadership

- Board & Executive Management committed to comprehensive improvement
  - Joint Committee QI and RM
- Restructured executive leadership to support care and improvement
- Set expectation for full compliance with JCAHO & State standards
- Provided leadership, resources, and accountability required

SYSTEMS RESPONSE

Assessment & Improvement

- Teams
  - Board: Pharmacy, Protocol, Medical Record
  - Leadership: JCAHO standards
- Interdisciplinary and collaborative with MD leadership
- Comprehensive review
- JCAHO standards as roadmap for improvement
  - survey reports also guided efforts
- Open
- Opportunities identified & prioritized
- Rigorous attention to develop, implement, and monitor each improvement effort; significant role of training

SYSTEMS RESPONSE

Focused, Comprehensive, Effective Expertise

- Nationally respected consultants
  - QI
  - Standards and accreditation
  - ADE and medical errors
- Built internal expertise
  - Support QI and organizational learning
  - Sustain efforts and continually improve

SYSTEMS RESPONSE

Communication to Patients, Families, Staff, Other Care Partners

- Honest
- Frequent updates
- Education as a priority
- Focused on continuous improvement

SYSTEMS RESPONSE

HARD WORK!!!

- Over 100 staff involved
- Extraordinary personal commitment
  - improvement
  - learn everything they can to prevent similar error
  - unacceptability of errors
- Systematic assessment leads to seemingly endless improvement opportunities

Key Findings of Investigations

- Failure of Governance and leadership
  - Arrogance of excellence
  - Quality, Safety, Risk priorities and focus
- Overdependence on “perfect” people in broken systems
- Punitive culture
- “Virtuoso performers” with neither conductor nor score
- Clinical practice “lost” in the organization
- Voice of the patient wasn’t respected
- No systems for error discovery, communication, support, resolution, learning for all parties

1996 DFCI QI Goal

Develop and support initiatives to solidify DFCI's position as a leader in utilizing quality improvement techniques to achieve demonstrated continuous improvement at every level and in every area of the Institute.

This commendation is important but it is only just the beginning... The only way to ensure quality is to be ever vigilant.

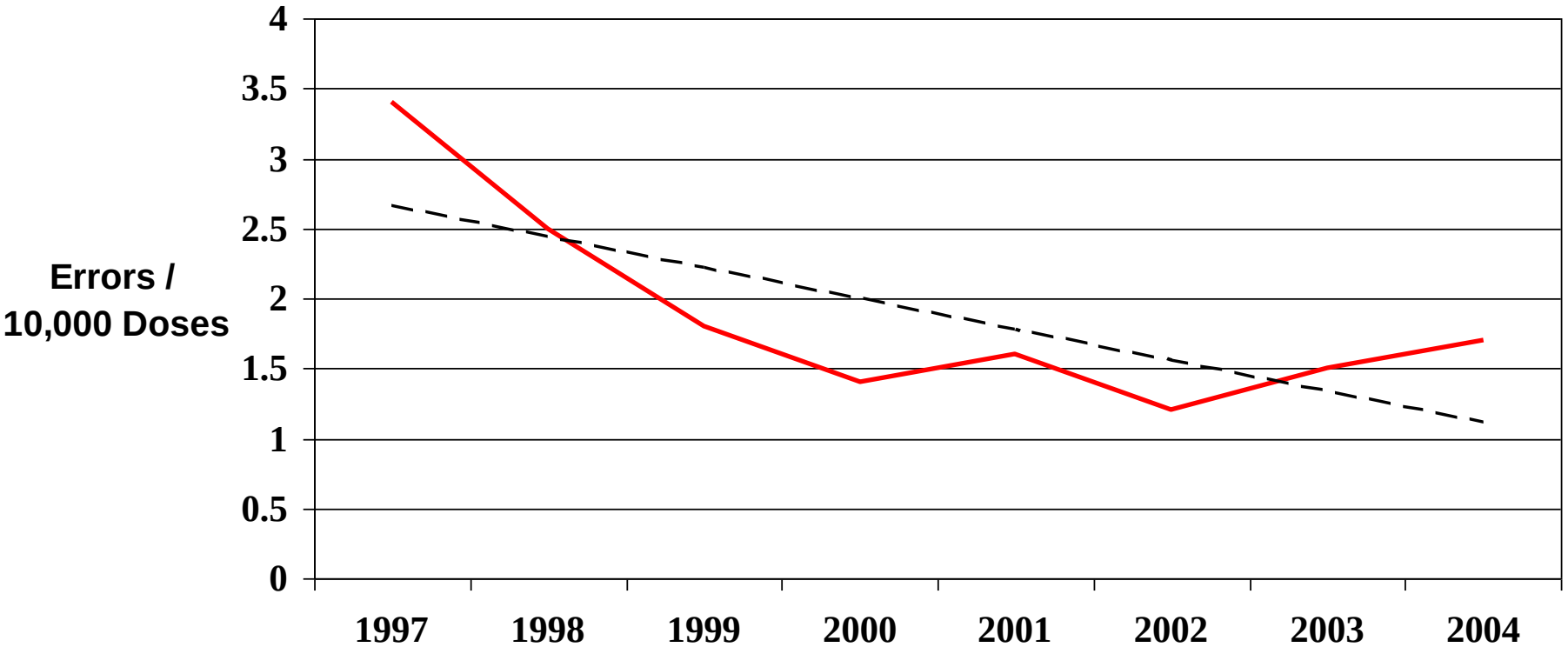
– David Nathan, M.D., President of DFCI, on the Institute receiving Accreditation with Commendation, May 1996

DFCI Challenges… for the state agency

- Media knew before we did
- Historical perspectives on reporting
- On-site investigation team
- Systems vs individual accountability
  - Health Professions Boards not in DPH (then)
  - Turf
  - Condition-level deficiencies
- Subsequent cases – media involvement

Medication Safety at DFCI

Outpatient Errors Reaching Patients



Courtesy L. Leape

WITH WORK, DANA-FARBER LEARNS FROM '94 MISTAKES

Author(s): **Scott Allen**

A decade after Lehman's death, on Dec. 3, 1994, Dana-Farber has emerged as one of the most safety- conscious hospitals in America, with computers that trigger alarms at potential overdoses, a hyper-vigilant error-reporting system, and a top executive who pushes measures in pursuit of the old physician's promise to "first do no harm." Once a symbol of medicine's dark side, Dana-Farber's experience is now used in instructional brochures and videos.

The Boston Globe

11/30/2004

Key Learning in DFCI Journey

Applicable Across Healthcare

- The responsibility and power of all leadership [trustee, clinical and administrative] over safety throughout the past 14 years
- The need for relentless vigilance to safety, risk, error, near-miss, harm
- Addressing the multiple victims of error
- The crucial role the design of systems and application of technology play in support of safe practice by excellent staff
- The synergy of interdisciplinary practice and team work
- Patient and Family Centered Care

DFCI legacy…. State perspective

- Communications between healthcare facility and DPH when questions as to reporting occur
- Health professional boards now in DPH
- Public/private partnerships (Coalition) formed
- AHRQ funded collaborative research on patient safety

The State Journey

Pre-DFCI, Post-DFCI

- Reporting of medical errors – public vs confidential
- HCFA (CMS) and state perspectives on roles of federal/state agencies
- Accountability – system vs individuals
- Public/private partnerships
- Creating a culture of *safety* and a culture of *trust*

Massachusetts History of Patient Safety Movement

- 1994: Death of Betsy Lehman at Dana Farber Cancer Institute
- 1997-1998: Establishment of the Massachusetts Coalition for the Prevention of Medical Errors
- 1999: IOM Report *To Err is Human,* estimating 44,000-98,000 Americans are killed each year by medical error.
- 2001: Enactment of the Betsy Lehman statute
- 2004: Launch of the Lehman Patient Safety Center
- 2006: Health Care Reform – Part 1
- 2008: Heath Care Reform – part 2

Reporting of Serious Incidents

- DPH and Board of Medicine
- Public availability vs confidentiality
- Health Care Reform – new DPH requirements
  - The 28 NQF SREs
    - Public reporting
    - Hospitals may not bill
  - Healthcare Associated Infections
    - Public reporting
    - ? billing

Health Care Reform –

Additional initiatives for DPH and Lehman Center

- End of Life Expert Panel
- Patient Family advisory Councils
- Rapid Response systems
- Revision of Determination of Need statute (ambulatory surgery clinics)
- Pharmaceutical and Medical Device Manufacturer codes of conduct
- Electronic Medical Records and CPOE
- Academic detailing for pharmaceuticals
- Healthcare Workforce Center

1997-1998 Establishment of the

Massachusetts Coalition for the Prevention of Medical Errors

Initial Coalition Barriers/Fears

- Concerns about liability exposure, sanctions, and disciplinary actions.
- The group acknowledged early on, the very real tension that exists between providers and the agencies that regulate them.
- This was the first time in this state that health care providers and government agencies had sat down together to talk openly about medical errors and what they could do together to prevent them.

MCPME Principles

- Make the health care system as safe as possible for patients, family members, and staff. This provides the "glue" that holds the Coalition together in spite of the differing and sometimes adversarial views.

- Obtain leadership "buy-in" and support from a broad-based group. The Massachusetts initiative has the commitment and support from the leadership and boards of provider, professional and regulatory organizations.

- Promote unrelenting communication between the key parties, particularly in the early stages to build trust and credibility.

- Establish a system that allows for input from clinicians to enlist their support for any practice and/or system changes that are recommended.

MCPME Principles (cont.)

- Consider including consumers or consumer organizations in the process early on to get their input and feedback. Recognition and acknowledgement that patient safety is everyone's responsibility is an important step in the error reduction process.

- Do not reinvent the wheel. Recognize that there is a wealth of experience and knowledge in your state and nationally in the area of error prevention. Build on the expertise of others in developing interventions that work.

- Strike a balance between the desire for quick solutions and broad based "buy-in" from all parties. Find a way to build consensus.

- Consider when and how to engage the media but do not let the media drive the process.

Betsy Lehman Center for Patient Safety

- Legislative History - Betsy Lehman Center - MGL Chapter 6A, Section 16E
- The Lehman Center shall “serve as a clearinghouse for the development, evaluation and dissemination, including, but not limited to, the sponsorship of training and education programs, of best practices for patient safety and medical error reduction.”
- Non-regulatory, confidential
- Patient Safety and Medical Errors Reduction Board

LEHMAN CENTER - PUBLIC/PRIVATE COLLABORATION

- Massachusetts Coalition for the Prevention of Medical Errors
- Health Care Quality and Cost Council
- Partnership for HealthCare Excellence
- Health Care for All - Consumer Health Quality Council

LEHMAN CENTER INITIATIVES

- Healthcare Associated Infections - Expert Panel
- Weight Loss Surgery - Expert Panel
- Patient Safety in Obstetrics Expert Panel
- Betsy Lehman Conference and Awards

Lehman/MCPME Coalition Initiatives

- Accountability Project
- Nursing Home Medication Safety
- Ambulatory Medication Safe Practices
- Hospital Safe Practices – Reconciling Medications and Communicating Critical Test Results
- Massachusetts Infection Prevention initiatives

Lehman Center Activities for 2008/2009

- Technical Advisory Group on HAI – Prevention-Oriented Implementation strategies
    - 3 Tier Reporting to DPH, Lehman, internal QI
    - Strategies for patients & families: materials for hospitals to provide to patients and families to be active partners in care, and sharing successful strategies
    - Engagement of hospital leadership
    - Toolkits based on local and national programs
- Updates for Expert Panel on Weight Loss Surgery – dissemination
- 2008/2009 Expert Panel on Obstetrics
- Hospital Standardized Mortality Rates (HSMR)
- Potentially Preventable Readmissions to hospitals
- Support HCQCC and DPH initiatives

14-Years Later: What's the Long View? Organization and the State

- The patient / family / consumer always front and center
- Continuous focus on learning and improvement
- Individual and shared accountability for quality and safety
- The only risk greater than disclosure is the risk to have known it and not disclosed.
- "A small group of thoughtful people could change the world. Indeed, it's the only thing that ever has." **Margaret Mead**
- Error: the Burden, the Responsibility, the Power

"Do not go where the path may lead; go instead where there is no path and leave a trail”

Ralph Waldo Emerson

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