Response to a Medication Error Tragedy and the Development of a Patient Safety Program

Dana-Farber Cancer Institute

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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 Situation

- 2 patients affected
- High-dose, stem cell supported chemotherapy protocol – designed to deliver maximum tolerated doses of drug
- Drugs to be delivered over a 4 day period – total dose to be delivered over that 4 day period given daily for 4 days – therefore a 4 fold overdose
- Orders written by a fellow without attending review
- Error not picked up by pharmacist who mixed the drugs, or nurses who administered the drugs
- Analysis of patient demise not done systematically
The Culture

• Leadership unclear on their responsibility for the events that occurred, and on their role in the investigation and evaluation of the situation

• Evaluation focused on individual performances rather than systems issues

• Lines of “accountability” not clear
New Perspectives

• Acknowledgement that Trustees and Leadership are responsible for quality and safety at DFCI

• Acknowledgement that systems issues contribute greatly to medical errors

• Acknowledgement that a fair and just culture is needed to identify areas of vulnerability and to work on solutions

• Creation of a Trustee run quality and risk management committee where all quality issues are discussed, and all errors and events are discussed
Changes that Occurred

• Fellow’s orders must be reviewed and co-signed by attending physicians

• Nurses and pharmacists have full and shared responsibility for all medication orders – they must review the orders for:
  – Appropriateness to clinical situation
  – Accuracy against regimen or protocol sets
  – Parameters to treat (blood counts, renal function, etc)
  – Clinical status of patient – performance status, toxicity assessment, etc
  – They can “reject” orders, which results in live-time P&T review

• Initiation of “Interventions” program – analysis of all orders questioned or changed by pharmacy review

• Implementation of computerized chemotherapy order entry system by 1997
Electronic Health Record Development

- Critical component of safety – continually enhanced based on experience, to improve performance and safety

- Diagnosis linked templated regimens – defined by P&T and literature supported
  - Regimens with well defined nomenclature, schedules and doses, and max doses
  - BSA, AUC calculations automated
  - Ambiguity and lack of clarity eliminated

- Protocol ordering hard-wired by Protocol Office – registered patients linked to specific orders, including dose or arm for dose escalation, or randomized trials

- Ordering privileges defined – attendings must be credentialed, and fellows must have all orders co-signed. NP/PA have first doses co-signed. All research protocol orders require attending co-signature

- Nursing and Pharmacy must review orders, critical parameters, and “activate” orders

- Critical information (history, labs, etc) universally available in EHR for everyone’s review

- All treatments documented in oncology flow sheets in EHR
Interventions Committee – Error Review

• Fair and Just Culture required

• All “errors” tracked and catalogued, regardless of whether they reach the patient or cause harm

• Errors viewed as systems failures, with examination of policies, EHR functionality, workflow issues, etc

• Recommendations made for change in chemotherapy templates, policies, workflow, and EHR functionality

• 47,566 infusion room visits - 218 interventions (0.5%) (during 6 month period)

• Mechanism for dealing with individuals with performance issues
Cisplatin/Hydration Error

- Patient with lymphoma ordered for cisplatin by attending, received the drug without hydration and developed permanent renal failure

- Immediate Root Cause Analysis performed (< 48 hrs)
  - Attending wanted pt to receive hydration but assumed housestaff would write order
  - Housestaff assumed attending didn’t want hydration
  - Nursing assumed no hydration was indicated because of pleural effusions and respiratory distress
  - Pharmacy did not check for presence of hydration orders
  - Viewed as systems problem rather than poor physician performance

- Result – EHR re-programmed within 48 hrs with “hard stop” screen requiring ordering clinician to declare hydration intention prior to accessing chemo orders. Hydration templated into all appropriate order sets.

- Pt and family informed of error by attending physician with sincere apology, backed up by institute administration. Pt and family grateful for honesty and timeliness. No legal action.
Institute for Safe Medication Practice (ISMP)

- Contracted by DFCI in 2007 to review chemotherapy practice
- Report issued in Feb 2008 with 48 high level practices needing attention
- Committee formed, overseen by trustee subcommittee, to work on issues
- ISMP asked back in October 2010 for follow-up. Report pending
Role of Patients in Safety Work

- Patient safety is about “patient safety”
- Patients and families have unique perspectives on processes that involve them
- Patients and families can play an active role in safety initiatives – “Just Ask”, etc
- Patient advisors sit on Trustee level quality committee, and all quality and process improvement working groups
Full disclosure of errors to patients and families

- Institute policy
- Must be timely
- Must be complete
- Institute support for those involved
- Positive outcomes