To disclose, or not to disclose (a medication error) – that is the question

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- Faculty declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.
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Pharmacist and Technician Objectives

At the conclusion of this program, the pharmacist will be able to:
1. Review the recent medical literature on how to approach disclosure of a medical error.
2. Describe the results of a survey of Illinois pharmacists’ attitudes and behaviors on medication errors and their disclosure.
3. Identify a framework for dealing with the disclosure of medication errors.

Assessment Slide
- Health care professionals must disclose medical errors to patients and/or their family?
  A. Yes
  B. No

Medical Error Disclosure
- Why the increased interest?
  → Institute of Medicine’s report
    • Errors in health care are very common
    • “Patient Safety Movement” Emphasis on:
      → full disclosure / transparency
Disclosure as a patient safety concern

Prominent Disclosure Programs

2001 - The Joint Commission
Safe Practice 7 - Disclosure

- Patients and, when appropriate, their families are informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes.
- Does not require an apology

Medical Error Disclosure

Disclosure Standards

- 2006 - National Quality Foundation (NQF)
  Safety Practices (updated 2009)
  - Safe Practice 7 - Disclosure: “Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.”
  - Disclosure as a patient safety concern

Key Elements of the Safe Practice for Disclosing Unanticipated Outcomes to Patients.

- Provide facts about the event
- Anticipate the impact on patients, families, and caregivers
- Results of event analysis and support informed decision making by the patient
- Express regret for unanticipated outcome
- Formal apology if unanticipated outcome caused by error or system failure
- Testify to the institution’s commitment to patient safety
- Integrate disclosure, patient safety, and risk management activities
- Establish disclosure support systems
- Provide background information and education
- Encourage that disclosure coaching is available at all times
- Provide emotional support for health care workers, administrators, patients, and families
- Use performance improvement tools to track and enhance disclosure

* Data are from the National Quality Forum.

Is disclosure of medical errors to patients required by law?

A. Yes
B. No
Medical Error Disclosure

Legal Developments
As of 2010
• 34 states + DC have apology laws
• 25 with specific medical laws
• 9 states have disclosure laws
• 6 states have both
• 16 have nothing...

What about IL? NO

Medical Error Disclosure

Disclosure Programs
• Great variability
  • VA Hospital – Lexington, KY (1999)
    • No significant changes after implementation
  • University of Michigan
    • Decrease in claims and litigation expenses
  • COPIC 3Rs Program – CO (2000)
    • Recognize, Respond, and Resolve
    • Data thus far suggest claims can be resolved less adversarially than when using traditional litigation

Medical Error Disclosure

Key Elements of COPIC’s 3Rs Program.

<table>
<thead>
<tr>
<th>Key Elements of COPIC’s 3Rs Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclosure training for physicians</td>
</tr>
<tr>
<td>Disclosures linked to no-fault compensation for patient's out of pocket expenses (up to $15,000)</td>
</tr>
<tr>
<td>Disclosures linked to risk management for patients</td>
</tr>
<tr>
<td>Disclosure linked to physician and case managers for patient provided to 3Rs administrators</td>
</tr>
<tr>
<td>Payments not reportable to National Practitioner Data Bank</td>
</tr>
<tr>
<td>Key outcomes (January 2006 - October 2009)</td>
</tr>
<tr>
<td>2013 Colorado physicians enrolled</td>
</tr>
<tr>
<td>3911 events handled in program</td>
</tr>
<tr>
<td>21% of patients received payments, average, $1,429 per case</td>
</tr>
<tr>
<td>Severely impaired cases subsequently liganded, two of which resulted in not compensation</td>
</tr>
<tr>
<td>34 impaired cases subsequently liganded, 6 of which resulted in tort compensation</td>
</tr>
</tbody>
</table>

Medical Error Disclosure

Disclosure Programs
• Two approaches in American institutions:
  • Train the physicians
  • Train the risk managers or patient safety experts
• Full disclosure (including an apology) + an offer (to pay?) is probably most effective

Medical Error Disclosure

Literature Review
• No article related to pharmacy
• Medical literature
  • Patients
    • Attitudes and preferences
  • Administrators
  • Clinicians
    • Physicians attitudes
    • Barriers to disclosure

Assessment slide

Full disclosure of a medication error will increase the risk of litigation.
A. True
B. False
**Patients**
- **Attitudes**
  - Understand medical errors are inevitable
  - Want to be told about an error that caused harm
  - Believe disclosure will increase trust
  - Believe it’s natural for health care workers to want to hide the error

- **What do patients want if an error occurs?**
  - Explanation of what happened
  - Why it happened
  - How will it affect their health
  - How the problem will be corrected
  - How future errors will be prevented
  - Accept responsibility
  - **APOLOGY**

- **Emotions**
  - Sadness, anxiety, depressed, traumatized
  - Fear of additional errors
  - Anger
  - Believe that how the error is disclosed affects emotions
    - Disclosed honestly and with empathy = less anger
    - Incomplete or evasive = increased anger and anxiety

- **If desired information is not provided:**
  - Hinder patients’ clinical decision making
  - Decrease trust in physician
  - Possibly increased risk of lawsuit
  - Overall, no evidence of full disclosure having negative consequences

*Findings above from one study surveying administrators in 6 states:
  - 2 mandatory reporting and public disclosure
  - 2 mandatory reporting w/out public disclosure
  - 2 w/out mandatory reporting*
Medical Error Lit. Review

**Clinicians**

- **Attitudes**
  - Worry regularly about errors
    - Lawsuits, loss of patients trust, loss of colleague’s respect, decreased self-confidence
  - Concerned an apology will lead to liability
  - Agreed errors that caused harm should be disclosed to the patient

- **Emotions**
  - Upset, guilty, disappointed
  - Fearful of a lawsuit
  - Anxious about reputation
  - Difficult to find emotional support post event

Assessment Slide

- Regardless of practice site, pharmacists in Illinois have similar attitudes and behaviors regarding the disclosure of medication errors.
  - A. Yes
  - B. No

Medication Error Disclosure Study

"Pharmacists’ attitude on disclosure of harmful medication errors to patients"
ChungYun (Christina) Kim, PharmD candidate

Research proposal funded by the Chicago College of Pharmacy Student Research Program at Midwestern University

Results from Poster: Kim C, Mazan J, Quiñones-Boex A, "Pharmacist Attitudes and Behaviors on Medication Errors and their Disclosure"

Medication (Med) Error Disclosure Study

**Objective**

- To examine attitudes and behaviors related to medication errors and their disclosure
- Compare community and hospital pharmacists
Assessment Slide

- Pharmacist agree that medication errors are inevitable.
  A. True
  B. False

Med Error Disclosure Study

Methods
- Online questionnaire (SurveyMonkey®
- Pharmacist knowledge of medication error
- Past experiences with medication errors
- Disclosure process
- Demographics
- 2 state associations (ICHP, IPhA)
- Follow-up email 4 weeks after initial message
- Fall 2014
- Statistical analyses performed using SPSS 19.0

Results: Response Rate

<table>
<thead>
<tr>
<th></th>
<th>ICHP</th>
<th>IPHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total e-mailed</td>
<td>715</td>
<td>1100</td>
</tr>
<tr>
<td>Total responses</td>
<td>422</td>
<td></td>
</tr>
<tr>
<td>Net Response rate</td>
<td>23.3%</td>
<td></td>
</tr>
</tbody>
</table>

Results: Practice Setting
- Community pharmacists $n = 135$
- Hospital pharmacists $n = 110$

Results: Disclosure Environment

<table>
<thead>
<tr>
<th></th>
<th>Community</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory error reporting</td>
<td>84.4%</td>
<td>80.0%</td>
</tr>
<tr>
<td>Medication error training</td>
<td>69.9%</td>
<td>82.0%</td>
</tr>
<tr>
<td>Estimated # of medication errors/week</td>
<td>1.1</td>
<td>8.2</td>
</tr>
</tbody>
</table>

Results: Demographics

<table>
<thead>
<tr>
<th></th>
<th>Community</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>M: 41.7%</td>
<td>M: 50.0%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian:</td>
<td>60.1%</td>
<td>70.1%</td>
</tr>
<tr>
<td>Caucasian:</td>
<td>35.7%</td>
<td>20.1%</td>
</tr>
<tr>
<td>Other:</td>
<td>4.3%</td>
<td>6.8%</td>
</tr>
<tr>
<td>Entry-level Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R. S. Pharm:</td>
<td>45.5%</td>
<td>48.4%</td>
</tr>
<tr>
<td>Pharm.D.:</td>
<td>56.7%</td>
<td>51.6%</td>
</tr>
<tr>
<td>Mean # yrs since licensure</td>
<td>20</td>
<td>22</td>
</tr>
</tbody>
</table>

Results: Error outcome of worst medication error
Med Error Disclosure Study

Results: When disclosing, what did you include?

<table>
<thead>
<tr>
<th>Not In</th>
<th>What happened</th>
<th>Why it happened</th>
<th>How it could have been prevented</th>
<th>An apology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community</td>
<td>16.3%</td>
<td>56.6%</td>
<td>32.6%</td>
<td>36.6%</td>
</tr>
<tr>
<td>Hospital</td>
<td>10%</td>
<td>0%</td>
<td>0%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Med Error Disclosure Study

Results: What were your emotions afterwards?

<table>
<thead>
<tr>
<th></th>
<th>Upset</th>
<th>Responsible</th>
<th>Guilty</th>
<th>Disappointed</th>
<th>Fearful</th>
<th>Anxious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community</td>
<td>58.3%</td>
<td>51.1%</td>
<td>32.8%</td>
<td>58.3%</td>
<td>23.7%</td>
<td>31.1%</td>
</tr>
<tr>
<td>Hospital</td>
<td>51.5%</td>
<td>60%</td>
<td>37.3%</td>
<td>60.8%</td>
<td>26.1%</td>
<td>38.1%</td>
</tr>
</tbody>
</table>

Med Error Disclosure Study

Results: Attitudes

<table>
<thead>
<tr>
<th></th>
<th>Community</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SD</td>
<td>A</td>
</tr>
<tr>
<td>Medication errors are inevitable</td>
<td>41.1%</td>
<td>21.3%</td>
</tr>
<tr>
<td>It would make my colleagues respect me</td>
<td>41.9%</td>
<td>19.2%</td>
</tr>
<tr>
<td>It is important to include all errors</td>
<td>4.5%</td>
<td>51.9%</td>
</tr>
<tr>
<td>Importance</td>
<td>Community</td>
<td>Hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SD</td>
</tr>
<tr>
<td>Medication errors are inevitable</td>
<td>84%</td>
<td>43.1%</td>
</tr>
<tr>
<td>It would make my colleagues respect me</td>
<td>41.1%</td>
<td>21.3%</td>
</tr>
<tr>
<td>It is important to include all errors</td>
<td>4.5%</td>
<td>51.9%</td>
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</table>

Med Error Disclosure Study

Limitations

- Convenience sample
- Only 1 state
- Social desirability bias

Med Error Disclosure Study

Conclusions

- Pharmacist attitudes on medication errors and their disclosure were slightly different when comparing the community and hospital setting.
- Regardless of practice setting, pharmacists agreed that medication errors are inevitable and that disclosure is necessary.

Assessment Slide

- When disclosing an error, what do you think patients want to hear?
  A. An explicit statement of what happened
  B. An explicit statement of why the error happened
  C. An explicit statement of how it may have been prevented
  D. An apology
  E. All of the above
Medication Error Disclosure Framework

What the Literature tells us...

- "Disclosure Gap"
- Error disclosure rates vary greatly
- Physicians support disclosure but don’t do so because of perceived barriers:
  - Fear of lawsuit
  - Emotions
  - Lack of training - not knowing what to say
    - Who, what, when, and how
  - Whether or not to use the word error

Might be the same for pharmacy...

Medication Error Disclosure Framework

What the Literature tells us...

- “Being more open with patients about errors represent a paradigm shift for the medical profession.”

In the USA - NQF practices
- Review and summary of disclosure guidelines in:
  - Australia
  - Canada
  - United Kingdom

Medication Error Disclosure Framework

What the Literature tells us...

- ASAP after discovering error (even if all the facts are not yet known)
- Acknowledge error to the patient and their family
- Provide an apology / expression of regret
- Describe all known facts and consequences
  - Will require additional disclosure meeting(s) in case of a serious event

Medication Error Disclosure Framework

How to Disclose - Communication:

- Use simple, lay terms
- Use active listening skills
- Use an open approach
- Provide time for discussion/questions
- Verify that information is understood
- Consider language/cultural differences

The Apology

- One must say “I am sorry”
- All directly involved in the error should apologize
- Sincerity is key!
  - Tone of voice
  - Body language
  - Facial expressions
- Remorse expression
- Include what is being apologized for, and what is being done to address the situation
Additional Disclosure Considerations

- Acknowledge that something didn’t go according to plan
- Acknowledge patient’s feelings
- Provide known clinical facts and discuss ongoing care
- Indicate that action is being (or will be) taken to prevent the event from happening again
- Agree to provide feedback, when available

Medication Error Disclosure Framework

- Pharmacists should disclose medication errors
- IL pharmacists agreed!
- Learn about your workplace disclosure guidelines
- Consider sharing what you learned here!
- Disclosure requires preparation and should include
  - Who, what, when, how + an apology
  - Disclosure helps everyone
  - Patients, pharmacists, pharmacies, hospitals, etc.