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

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Conflicts of Interest/Disclosure

• 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
This report says medical errors such as indecipherable prescriptions cause the deaths of 98 patients a year, or is that 98,000? It's hard to read this. In any case, we're supposed to report them, or is that repeat them?
Medical Error Disclosure

Patient Safety Movement and Disclosure

• Disclosure Standards
• Legal Developments
• Prominent Disclosure Programs
Medical Error Disclosure

Disclosure Standards

• 2001 - The Joint Commission
  • 1st nationwide standard
  • Standard RI 2.90: “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


• 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.

Table 1. Key Elements of the Safe Practice for Disclosing Unanticipated Outcomes to Patients.*

<table>
<thead>
<tr>
<th>Content to be disclosed to the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide facts about the event</td>
</tr>
<tr>
<td>- Presence of error or system failure, if known</td>
</tr>
<tr>
<td>- Results of event analysis to support informed decision making by the patient</td>
</tr>
<tr>
<td>Express regret for unanticipated outcome</td>
</tr>
<tr>
<td>Give formal apology if unanticipated outcome caused by error or system failure</td>
</tr>
</tbody>
</table>

**Institutional requirements**

- Integrate disclosure, patient-safety, and risk-management activities
- Establish disclosure support system
  - Provide background disclosure education
  - Ensure 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.
Medical Error Disclosure

Disclosure Standards

• 2006 - National Quality Foundation (NQF)
  • Safe Practice 7 - Disclosure:
    Patient communication should include
    • The “facts”
    • Empathic communication of the “facts”
    • An explicit and empathic expression of regret
    • A commitment to investigate and as possible prevent future occurrences
    • Feedback of results of the investigation provided in sufficient detail to support informed decision making by the patient
    • “Timeliness”
Assessment Slide

• 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
Key Elements of COPIC's 3Rs Program.

<table>
<thead>
<tr>
<th>Key features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclosure linked to no-fault compensation for patient's out-of-pocket expenses (up to $30,000)</td>
</tr>
<tr>
<td>Disclosure training for physicians</td>
</tr>
<tr>
<td>Exclusion criteria: death, clear negligence, attorney involvement, complaint to state board, written demand for payment</td>
</tr>
<tr>
<td>Disclosure coaching for physician and case management for patient provided by 3Rs administrators</td>
</tr>
<tr>
<td>Payments not reportable to National Practitioner Data Bank</td>
</tr>
</tbody>
</table>

**Key outcomes (January 2000–October 2006)**

- 2853 Colorado physicians enrolled
- 3200 events handled in program
- 25% of patients received payments; average, $5,400 per case
- Seven paid cases subsequently litigated, two of which resulted in tort compensation
- 16 unpaid cases subsequently litigated, 6 of which resulted in tort compensation
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
Full disclosure of a medication error will increase the risk of litigation.

A. True
B. False
Medical Error Lit. Review

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
Medical Error Lit. Review

**Patients**

- 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**
Medical Error Lit. Review

Patients

- Want assurance
  - Won’t suffer financially
  - Clinician learned from the mistake
  - Prevention of future occurrences
Medical Error Lit. Review

Patients

• 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
Medical Error Lit. Review

Patients

• 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
Administrators

• Concerns
  • Mandatory reporting and making reports public will discourage disclosure within the organization
  • Favor disclosure to patients
  • Hesitant regarding disclosing minor or moderate injury to the state reporting systems

* 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
Clinicians

• Attitudes (cont.)
  • Agreed with patients that it’s natural for health care workers to want to hide the error

• What/how to disclose:
  • Put most positive “spin” on event
  • Choose words carefully-discuss adverse event but not explicitly state that an error occurred
Medical Error Lit. Review

**Clinicians**

- 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
Med Error Disclosure Study

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></td>
<td>23.3%</td>
</tr>
</tbody>
</table>

Results: Practice Setting

- Community pharmacists  n = 135
- Hospital pharmacists   n = 110
# Med Error Disclosure Study

## Results: Demographics

<table>
<thead>
<tr>
<th></th>
<th>Community</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F: 41.7%</td>
<td>M: 58.3%</td>
<td>F: 64.1%</td>
</tr>
<tr>
<td>M: 58.3%</td>
<td></td>
<td>M: 35.9%</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian: 7.1%</td>
<td></td>
<td>Asian: 10.1%</td>
</tr>
<tr>
<td>Caucasian: 80.4%</td>
<td></td>
<td>Caucasian: 83.7%</td>
</tr>
<tr>
<td>Other: 12.5%</td>
<td></td>
<td>Other: 6.3%</td>
</tr>
<tr>
<td><strong>Entry-level Degree</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.S. Pharm: 48.9%</td>
<td></td>
<td>B.S. Pharm: 16.4%</td>
</tr>
<tr>
<td>Pharm.D.: 26.7%</td>
<td></td>
<td>Pharm.D.: 56.3%</td>
</tr>
<tr>
<td><strong>Mean # of yrs since licensure</strong></td>
<td>28</td>
<td>22</td>
</tr>
</tbody>
</table>
## Med Error Disclosure Study

### 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>70.9%</td>
</tr>
<tr>
<td>Medication error training</td>
<td>69.9%</td>
<td>82%</td>
</tr>
<tr>
<td>Estimated # of medication errors/week</td>
<td>1.1</td>
<td>8.2</td>
</tr>
</tbody>
</table>
Med Error Disclosure Study

Results:
Error outcome of worst medication error

Community vs. Hospital

- Near miss
- No patient harm
- Patient harm
- Patient death
## Med Error Disclosure Study

### Results:
When disclosing, what did you include?

<table>
<thead>
<tr>
<th></th>
<th>Not in charge</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>55.5%</td>
<td>32.6%</td>
<td>35.6%</td>
<td>50.4%</td>
</tr>
<tr>
<td>Hospital</td>
<td>40%</td>
<td>40.9%</td>
<td>25.5%</td>
<td>20%</td>
<td>19.1%</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>56.3%</td>
<td>51.1%</td>
<td>32.6%</td>
<td>56.3%</td>
<td>23.7%</td>
<td>31.1%</td>
</tr>
<tr>
<td>Hospital</td>
<td>54.5%</td>
<td>60%</td>
<td>37.3%</td>
<td>60.9%</td>
<td>26.4%</td>
<td>36.4%</td>
</tr>
</tbody>
</table>
## Results: Attitudes

<table>
<thead>
<tr>
<th>Statement</th>
<th>Community</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication errors are inevitable</td>
<td>7.1%</td>
<td>20.2%</td>
</tr>
<tr>
<td>I will lose my colleague's respect</td>
<td>44.8%</td>
<td>25.9%</td>
</tr>
<tr>
<td>It is important to include all details</td>
<td>13.5%</td>
<td>8%</td>
</tr>
<tr>
<td>RPh should put the most positive spin on the event</td>
<td>40.1%</td>
<td>71.6%</td>
</tr>
<tr>
<td>RPh should address the patient’s emotions</td>
<td>0.9%</td>
<td>5.6%</td>
</tr>
<tr>
<td>If patient cannot communicate, RPh should disclose to the family</td>
<td>4.5%</td>
<td>3.4%</td>
</tr>
<tr>
<td>HCP most closely involved with error should disclose</td>
<td>34%</td>
<td>50%</td>
</tr>
<tr>
<td>RPh should disclose</td>
<td>8.1%</td>
<td>29.5%</td>
</tr>
</tbody>
</table>

Items listed above were found to be statistically significant (p<0.05).
*SD/D: Strongly Disagree, Disagree  **SA/A: Strongly Agree, Agree
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.
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
Medication Error Disclosure Framework

What the Literature tells us...

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


Might be the same for pharmacy...
Medication Error Disclosure Framework

What the Literature tells us...

• In the USA - NQF practices
• Review and summary of disclosure guidelines in:
  • Australia
  • Canada
  • United Kingdom
Medication Error Disclosure Framework

“Initial” Disclosure

• 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
  \[\text{Remorse expression}\]
• Include what is being apologized for, and what is being done to address the situation
Medication Error Disclosure Framework

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
Concluding Remarks

- 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.
Concluding Remarks

Disclosure of medication errors will lead us one step closer to enhancing patient safety and providing quality patient-centered care.
References


References


References


