American Pharmacists Attitudes and Behaviors Regarding Medication Error Disclosure

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Abstract
Background: Patient safety places emphasis on full disclosure, transparency, and a commitment to prevent future errors. Studies addressing the disclosure of medication errors in the profession of pharmacy are lacking.
Objective: This study examined attitudes and behaviors of American pharmacists regarding medication errors and their disclosure to patients.
Methods: A 4-page questionnaire was mailed to a nationwide random sample of 2,002 pharmacists. It included items to assess pharmacists' knowledge of and experience with medication errors and their disclosure. The data was collected over three months and analyzed using IBM SPSS 22.0. The study received IRB exempt status.
Results: The response rate was 12.6% (n = 252). The average pharmacist respondent was a 57-year old (+ 12.1 years), Caucasian (79.8%), male (59.9%), with a BS Pharmacy degree (73.8%), and licensed for 33 years (+ 12.8 years). Most respondents were employed in a hospital (26.4%) or community (31.0 %) setting and held staff (30.9%), manager (29.1%), or clinical staff (20.6%) positions. Respondents reported having been involved in a medication error as a patient (31.0%) or a pharmacist (95.5%). The data suggest that full disclosure is not being achieved by pharmacists. Significant differences in some attitudes and behaviors were uncovered when community pharmacists were compared to their hospital counterparts.
Conclusion: There is room for improvement regarding proper medication error disclosure by pharmacists.

Keywords: Error disclosure, medication error, patient safety

BACKGROUND

Patient safety continues to be an area of focus across all healthcare disciplines in the United States. This emphasis on patient safety began in the late 1990s with the formation of the Quality of Health Care in America Committee of the Institute of Medicine (IOM), and its initial report aimed at assisting organizations in the prevention of medical errors. The publication, *To Err is Human: Building a Safer Health System,* acknowledged that individual actions are not typically the cause of medical errors, but "more commonly errors are caused by faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them." [1] This document only begins to address the importance of transparency, providing little guidance for how to disclose the error to the patient.

Despite the attention patient safety has received, medical errors remain inevitable. When an error occurs, patients and their families search for an explanation.[2-21] They want to know the details of what happened, yet a gap between the occurrence of an unexpected event while receiving care and its disclosure to the patient and/or their family still exists. The response of healthcare professionals involved requires a debated, yet important, decision of whether to disclose the error to the patient and how much detail to include.[4–8] Patient

safety places emphasis on full disclosure, transparency, and a commitment to prevent future errors. In the last two decades, disclosure standards, legislation, and programs have been developed in an effort to foster an environment where fear of disciplinary action is decreased, allowing healthcare professionals to be fully transparent when an error occurs.

The Joint Commission on Accreditation published the first nationwide standard addressing error disclosure in 2001. Standard RI 2.90 states, "Patients and, when appropriate, their families are informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes."[22] In 2006—and updated in 2009—the National Quality Foundation (NQF) Safe Practices were issued, with Safe Practice 7 stating, "Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient, and as appropriate, their family, should receive timely, transparent and clear communications concerning what is known about the event."[23] This standard further stipulated that patient communication should include the facts, empathic communication of the facts, an explicit and empathic expression of regret, and a commitment to investigate and, if possible, prevent future occurrences. Feedback of the results of the investigation should be provided to the patient and/or their family in sufficient detail to support informed decision making by the patient. This process should be done in a timely manner.

Other countries have developed similar disclosure frameworks for medical providers. *The Canadian Disclosure Guidelines: Being Open with Patients and Families* developed by the Canadian Patient Safety Institute promotes transparency, clear communication, and a strengthening of the provider-patient relationship.[24-25] It provides guidance on establishing a culture

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of transparency and a clear framework for the disclosure process. The *Australian Open Disclosure Framework—Better Communication, a Better Way to Care*, is a two-part program focused on providing institutions with tools to develop a culture of transparency and describing the procedure for full disclosure.[26] *Openness and Honesty When Things Go Wrong: The Professional Duty of Candour* was published by the United Kingdom's General Medical Council to provide guidance to medical professionals when a medical error occurs.[27] This document encourages both transparency and delivery of an apology to the patient. All of these programs were designed to recognize and address patient needs when an unintended outcome occurs and advocate for a full disclosure that includes an explicit account of what happened, an explanation of why it happened, a statement on how this will be prevented in the future, and an expression of regret.

Two primary approaches to disclosure programs exist in the United States. One focuses on properly training the physicians to disclose a medical error, while the other approach focuses on training risk managers and patient safety experts. With either approach, an apology and an offer to pay compensation is essential. As of 2017, laws mandating disclosure of unexpected medical outcomes existed in 10 of 50 U.S. states, while 37 states had apology laws.[28,29] Apology laws prohibit the use of empathetic or compassionate statements made by a provider handling a medical error situation to be used in court as evidence in a medical malpractice claim. Three prominent American disclosure programs include the Lexington VAMC Model, the Michigan Model, and the COPIC 3R's Program. [30-32] All three of these programs foster the provider-patient relationship by promoting open communication, full disclosure, an apology, and quality improvements.

Numerous articles on error disclosure have been published in the medical literature.[1-33] In evaluating the attitudes of patients, Gallagher and colleagues found that patients understand that medical errors are inevitable and that it is natural for healthcare workers to want to hide the error. [4, 6-8] When an error occurs, patients desire an explanation of what happened, how it will affect their health, how the problem will be corrected, how future errors will be prevented, acceptance of responsibility, and, above all, an apology. Patients also believe how the error is disclosed affects their emotions. If there is an incomplete disclosure of details or the clinician is evasive, the level of anger and anxiety increases. If the desired information is not provided, it may hinder the patient's ability to make decisions, decreases their trust in the provider, and possibly increases the risk of a lawsuit. These findings suggest that negative consequences are seen with a lack of transparency, but not with full disclosure.

Gallagher also surveyed healthcare professionals and found that, in theory, clinicians agree with patients that it is natural for healthcare workers to want to hide the error.[4, 6-8] Providers tend to put the most positive spin on the event and choose their words carefully. Emotions experienced by clinicians involved in an error include guilt, disappointment, fear of litigation, and anxiety about their reputation. Respondents also indicated that it was difficult to find emotional support as a clinician after an event occurred.

OBJECTIVE
The medical profession has been examined closely when it comes to disclosure, but studies addressing the disclosure of medication errors in the profession of pharmacy are lacking. The objective of this study was to examine the attitudes and behaviors of American pharmacists on medication errors and the disclosure of error information to patients involved. This national study represents an extension of a pilot study investigating the same research question in one midwestern state in 2014.[20] The pilot study found that pharmacists in this state agreed that errors should be disclosed to patients, yet it also saw significant differences in attitudes and behaviors when comparing community and hospital practitioners.

METHODS
A 4-page questionnaire was developed by modifying the survey used in the pilot study.[20] The instrument included 48 items on pharmacist demographics, work environment, personal experiences with errors and error disclosure, attitudes and behaviors on medication error and the disclosure process, and additional comments. The attitudinal items included several themes found in the literature on error disclosure in other health professions and by patients, previously mentioned in the introduction. Pharmacists were asked their level of agreement with each attitudinal item using a 5-point Likert scale (with 1 indicating strongly disagree and 5 indicating strongly agree). Some items were negatively worded to prevent a response set. Pharmacists were specifically asked about each of the components of an ideal error disclosure process (what happened, why it happened, how it could be prevented, and an apology). There were two sets of questions addressing the disclosure process: one asked pharmacists what they thought patients would like included in the disclosure, while the other asked what they included while disclosing an error. An additional question was added to the nationwide survey asking pharmacists if they have undergone error and/or safety training and what type.

A nationwide randomized sample of 2,002 pharmacists was obtained through the vendor Integrated Business Services, Inc.[34] The questionnaire, cover letter explaining the objectives of the study, and a postage-paid envelope were mailed to the sample in September 2016. One reminder postcard was sent to all potential respondents 4 weeks after the original mailing. Data collection ended after 3 months. Statistical analyses were performed on the collected data using IBM SPSS Statistics for Windows (version 22.0. IBM Corp. Armonk, NY). For analytical purposes, respondents in independent, chain, mass merchandiser, and supermarket pharmacies were recoded to represent the community pharmacy setting and compared with

hospital pharmacists. Interval variables were analyzed using single sample t-tests. Chi Square tests were used for comparisons between community and hospital pharmacists' agreement with attitudinal items. An alpha level of < 0.05 was used to test for statistically significant differences. This study received IRB exempt status.

RESULTS

The survey response rate was 12.6% (n = 252). Most respondents were employed as pharmacists (174, 69%) at the time of the survey. Respondents who reported not being employed as pharmacists were excluded from the data analysis. The average pharmacist respondent could be characterized as a 53-year old (± 9.9 years), Caucasian (80.4%), male (55.2%), with a Bachelor of Science in Pharmacy degree (70.6%), and licensed for 27.9 years (± 10.8 years). Respondents were more likely to be employed in a hospital setting (25.9%), independent community pharmacy (18.6%), or chain pharmacy (17.5%). Half of the reported job descriptions included staff positions: general staff (30.58%) and clinical staff (20.7%). About a third (31.0%) of respondents were managers, directors, or pharmacists-in-charge.

Community and hospital pharmacists were significantly different when compared by gender, entry-level degree earned, and holding managerial, clinical, or general staff positions. The average hospital pharmacist respondent was more likely to be a female (56.8%) and hold a clinical staff position (42.2%). Community pharmacists were more likely to have earned a Bachelor of Science degree as their first degree (80.7%) and hold managerial (40.5%) or general staff (36.9%) positions.

Findings for medication error disclosure environment and personal experiences for all pharmacists analyzed are included in Table 1. Tables 2 and 3 compare respondent attitudes on medication errors and their disclosure, and the disclosure process, respectively.

DISCUSSION AND CONCLUSION

Demographics
Demographic trends in this study were similar to those found in the pilot study—younger pharmacists were more likely to be female, have earned a Doctorate of Pharmacy, and work in hospitals where the number of available clinical positions is higher.[20] Older pharmacists were more likely to be male, have earned a Bachelor's Degree in Pharmacy, and work in community pharmacy. The similar results suggest reliability of methods and the survey instrument utilized.

Error Disclosure Environment and Experiences.
Pharmacists in the hospital reported a significantly higher number of medication errors per week (Table 1). This difference can be attributed to the healthcare setting. Hospitals are complex institutions often dealing with additional steps in the medication dispensing process, increasing the chances for mistakes. Regardless of setting, most pharmacists indicated that their workplace had policies on mandatory error reporting, yet only 44.4% of hospital pharmacists indicated that a policy on error disclosure to the patient exists at their institution. This significant difference may be related to who is responsible for disclosure in the hospital setting. More than half of hospital pharmacists responding to the survey indicated that they were not responsible for disclosing the error. Pharmacists in the community setting reported higher awareness of guidelines on disclosure to patients, as they are more likely to be involved in the process.

A small portion of respondents indicated experiencing a medication error as a patient themselves or as a family member of a patient. When asked to select which parts of the disclosure process patients would want to hear, the results showed some differences. Respondents were more likely to select an explicit statement of what happened (83.9%) and an apology (84.5%) over why the error happened (56.3%) and how the error might have been prevented (44.8%) in terms of what they expect patients want to hear. These trends where somewhat similar among community and hospital pharmacists. This is in stark contrast to the low portion of respondents who included these items when disclosing a serious error in their professional role.

An overwhelming majority of respondents (95.5%) reported being involved in a medication error as a pharmacist. Most of these events did not result in patient harm. Still, most pharmacists reported feeling upset, responsible, and/or disappointed after the event. When asked about the disclosure process that followed, pharmacists were more likely to include an apology (60.9%) and a statement of what happened (54.0%) rather than why the error happened (31.13%) and how the error might have been prevented (22.4%). Community and hospital pharmacists showed differences regarding the disclosure components included. Community pharmacists reported significantly higher percentages of including an apology (84.1%), what happened (68.3%), and how the error might have been prevented (28.0%). This further supports the notion that community pharmacists' increased likelihood to be involved with the error disclosure process makes them more prone to include additional information when disclosing. However, the data suggests that full disclosure is not being achieved, even by community pharmacists, with two parts of the process not being included as often: why the error happened (39%) and how the error might have been prevented 28%). The low percentage of hospital pharmacists reporting the inclusion of any of the disclosure steps is also of concern. Specifically, the lack of expression of regret is particularly troubling, considering the evidence that supports the inclusion of an apology.[22-32]

Attitudes on Medication Errors and their Disclosure.
Regardless of setting, and aligning with pilot study results, pharmacists agreed on the inevitability of errors (Table 2).

Several items in this survey section showed significant differences when comparing community and hospital pharmacists. Community pharmacists (82.1%) were more likely to agree that it is ethically imperative to disclose an error. This finding is consistent with numerous studies indicating healthcare practitioners' support of transparency in error reporting.[2-33] Moreover, community pharmacists (79.3%) disagreed with the notion that patients should be told only about an error that causes harm, and (57.1%) agreed that patients should be told about any error that relates to them. These findings reflect the more personal nature of the relationship between a community pharmacist and their patients and are consistent with other results in this study.

Hospital pharmacists (76.1%) were more likely to agree with the assertion that the average patient does not understand a true medication error. This is an unexpected result. Medication errors can be as simple as a near miss or very complex, potentially resulting in death. Hospital pharmacists in this study were less likely to be involved in error disclosure to patients, which could have an impact on their perceptions of patient knowledge and understanding of medication errors. When involved in an error, hospital pharmacists (54.5%) were more likely to fear the loss of respect from colleagues. In an interdisciplinary setting, it comes as no surprise that pharmacists fear that acknowledging involvement in a medication error may be perceived as a weakness or lack of confidence in practice.

Attitudes on Disclosure Process.
Community pharmacists (81%) strongly agreed that the pharmacist should disclose the error (Table 3). It is important to note that, in a community setting, the pharmacist is usually the only healthcare professional present to address the error. Hospitals tend to have strict error disclosure policies, specifying what can and cannot be disclosed to a patient and the process that must be followed. Thus, even though some hospital pharmacists reported being involved in error disclosure, their ability to fully disclose might have been impaired by hospital policy.

Most pharmacists agreed that it is important to include all details when disclosing a medication error, yet their reported previous actions seem to contradict this belief. The actions they took when disclosing an error showed that they did not include all components for a full disclosure. This finding suggests the need for additional training in error disclosure in pharmacy.

Limitations.
One limitation of this project was the low response rate and whether the results are applicable to the whole pharmacist population in the country. The pilot study had a better response rate, most likely because the researchers work at an educational institution within the state. Also, this study addressed pharmacist attitudes and behaviors, and there was the potential for social desirability bias. The fact that several

trends seen in this study were also seen in the pilot study provide some confirmation for the results presented and suggest that pharmacists were honest in their responses to the survey.

Conclusion
The results of this national study provide support for the disclosure of medication errors. They indicate room for improvement, especially as they relate to delivering full disclosure as opposed to addressing a few parts of the process. Providing pharmacists with additional medication error disclosure training and integrating it into the pharmacy school curriculum may bring pharmacists one step closer to full medication error disclosure.

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Table 1. Medication Errors: Work Environment and Experiences

Variable	Total	Community	Hospital
Mean + S.D. medication errors at workplace in the last week *	3.5 + 9.8	**0.8 + 1.8**	**9.2 + 15.7**
Primary workplace has policy on mandatory error reporting, no. (%)	135 (77.6)	71 (84.5)	33 (73.3)
Primary workplace has policy on error disclosure to the patient(s), no. (%) *	101 (58.0)	**59 (70.2)**	**20 (44.4)**
Personal Experience, no. (%)			
Had formal medication error and/or patient safety training	129 (74.1)	66 (78.6)	33 (73.3)
Voluntary continuing education program	74 (58.3)	38 (58.5)	19 (59.4)
Mandatory training at workplace	75 (59.1)	40 (61.5)	17 (53.1)
Coursework while in pharmacy school *	13 (10.2)	**3 (4.6)**	**6 (18.8)**
Self or family member been involved in a medication error as a patient *	54 (31.0)	**18 (21.4)**	**19 (42.2)**
What do patients want to hear?, no. (%)			
What happened *	146 (83.9)	**65 (77.4)**	**42 (93.3)**
Why the error happened	98 (56.3)	45 (53.6)	26 (57.8)
How error may have been prevented	78 (44.8)	38 (45.2)	19 (42.2)
Apology and/or expression of regret	147 (84.5)	73 (86.9)	35 (77.8)
Involved in a medication error as a pharmacist, no. (%)	161 (92.5)	82 (97.6)	42 (93.3)
Error Outcome, no. (%)			
Near miss	18 (11.2)	4 (4.9)	7 (16.7)
No patient harm	113 (70.2)	62 (75.6)	26 (61.9)
Patient harm	27 (16.8)	15 (18.3)	8 (19.0)
Patient death	3 (1.9)	1 (1.2)	1 (2.4)
Emotions after the error, no. (%)			
Upset	126 (78.3)	63 (76.8)	34 (81.0)
Responsible	116 (72.0)	59 (72.0)	32 (76.2)
Disappointed	100 (62.1)	53 (64.6)	22 (52.4)
Anxious	75 (46.6)	40 (48.8)	20 (47.6)
Guilty	69 (42.9)	35 (42.7)	17 (40.5)
Fearful	48 (29.8)	25 (30.5)	15 (35.7)
Disclosure components included, no. (%)			
What happened	87 (54.0)	**56 (68.3)**	**13 (31.0)**
Why the error happened	50 (31.1)	32 (39.0)	10 (23.8)
How error may have been prevented	36 (22.4)	**23 (28.0)**	**5 (11.9)**
Apology and/or expression of regret	98 (60.9)	**69 (84.1)**	**12 (28.6)**
Not in charge of disclosing, no. (%)	60 (37.3)	**16 (19.5)**	**28 (66.7)**

Numbers bolded denote statistically significant differences at alpha level ≤ 0.05.

Table 2. Attitudes on Medication Errors and Error Disclosure

	Total		Community		Hospital	
	SA/A	N/D/SD	SA/A	N/D/SD	SA/A	N/D/SD
I believe that…, no. (%)						
medication errors are inevitable.	145 (84.3)	27 (15.7)	70 (85.4)	12 (14.6)	39 (86.7)	6 (13.3)
there are different levels of severity of medication errors.	170 (98.3)	3 (1.7)	81 (97.6)	2 (2.4)	45 (100.0)	0 (0)
the average patient does not understand what a true medication error is.	98 (57.0)	74 (43.0)	**43 (52.4)**	**39 (47.6)**	**34 (75.6)**	**11 (24.4)**
patients should be told about any error that happens in a pharmacy that relates to them.	84 (48.3)	90 (51.7)	**48 (57.1)**	**36 (42.1)**	**15 (33.3)**	**30 (66.7)**
patients should only be told about errors that cause them harm.	54 (31.6)	117 (68.4)	**17 (20.7)**	**65 (79.3)**	**21 (47.7)**	**23 (52.3)**
patients should be told about errors that cause them no harm but require follow-up testing.	151 (87.3)	22 (12.7)	72 (86.7)	11 (13.3)	40 (88.9)	5(11.1)
the average patient does not want to know about an error that did not cause harm to them.	43 (24.7)	131 (75.3)	23 (27.4)	61 (72.6)	13 (28.9)	32 (71.1)
t is ethically imperative to disclose an error.	127 (73.0)	47 (27.0)	**69 (82.1)**	**15 (17.9)**	**27 (60.0)**	**18 (40.0)**
I worry regularly about making a medication error.	86 (49.7)	87 (50.3)	44 (52.4)	40 (47.6)	28 (62.2)	17 (37.8)
When I am involved in a medication error, I fear that… , no. (%)						
I will be sued.	92 (53.5)	80 (46.5)	41 (48.8)	43 (51.2)	23 (51.1)	22 (48.9)
my patients will lose trust in me.	126 (74.1)	44 (25.9)	63 (75.9)	20 (24.1)	30 (66.7)	15 (33.3)
I will lose confidence in my professional abilities.	79 (45.9)	93 (54.1)	35 (41.7)	49 (58.3)	24 (53.3)	21 (46.7)
I will lose my colleague's respect.	69 (40.4)	102 (59.6)	**23 (27.4)**	**61 (72.6)**	**24 (54.5)**	**20 (45.5)**
I will cause patient harm.	160 (93.6)	11 (6.4)	79 (94.0)	5 (6.0)	43 (97.7)	1 (2.3)
I will have my license revoked.	62 (36.0)	110 (64.0)	24 (28.6)	60 (71.4)	20 (44.4)	25 (55.6)

SA/A = Strongly agree/Agree, N/D/SD = Neutral;/Disagree/Strongly Disagree
Numbers bolded denote statistically significant differences at alpha level < 0.05.

Table 3. Attitudes on the Error Disclosure Process

	Total		Community		Hospital	
	SA/A	N/D/SD	SA/A	N/D/SD	SA/A	N/D/SD
When disclosing a medication error…, no. (%)						
it is important to include all details.	121 (69.9)	52 (30.1)	57 (67.9)	27 (32.1)	31 (68.9)	14 (31.1)
a pharmacist should put the most positive "spin" on the event.	36 (20.7)	138 (79.3)	24 (28.6)	60 (71.4)	7 (15.6)	38 (84.4)
a pharmacist should avoid using the word "error."	35 (20.1)	139 (79.9)	18 (21.4)	66 (78.6)	11 (24.4)	34 (75.6)
it is important to address the patient's emotions.	167 (96.0)	7 (4.0)	**83 (98.8)**	**1 (1.2)**	**41 (91.1)**	**4 (8.9)**
if a patient cannot communicate, then the pharmacist should disclose the information to the patient's family or caregiver.	164 (94.8)	9 (5.2)	79 (95.2)	4 (4.8)	43 (95.6)	2 (4.4)
the health care professional who was most closely involved with the error should be the person in charge of disclosing the error.	66 (38.2)	107 (61.8)	36 (43.4)	47 (56.6)	14 (31.1)	31 (68.9)
the pharmacist should be the person in charge of disclosing the error.	97 (55.7)	77 (44.3)	**68 (81.0)**	**16 (19.0)**	**10 (22.2)**	**35 (77.8)**
I believe that…, no. (%)						
training about medication error disclosure should be included in pharmacy education.	158 (91.9)	14 (8.1)	76 (90.5)	8 (9.5)	39 (90.7)	4 (9.3)
training about medication error disclosure should be included in continuing education.	155 (90.1)	17 (9.9)	77 (91.7)	7 (8.3)	38 (88.4)	5 (11.6)
there should be set guidelines for medication error disclosure.	121 (70.3)	51 (29.7)	58 (69.0)	26 (31.0)	31 (72.1)	12 (27.9)
a medication error disclosure process should be mandated by law.	53 (30.8)	119 (69.2)	25 (29.8)	59 (70.2)	17 (39.5)	26 (60.5)

SA/A = Strongly agree/Agree, N/D/SD = Neutral;/Disagree/Strongly Disagree
Numbers bolded denote statistically significant differences at alpha level ≤ 0.05.