Effect of social influences on pharmacists’ intention to report adverse drug events

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Abstract

Objectives: To identify the groups or individuals that influence pharmacists’ decision making to report adverse drug events (ADEs), determine the differences in social influence or subjective norm between intenders and nonintenders, and determine the relationship between subjective norm toward reporting serious ADEs and practice and demographic characteristics.

Design: Nonexperimental cross-sectional study.

Setting: Texas during June and July 2009.

Participants: 1,500 Texas pharmacists.

Intervention: As part of a larger survey, 3 and 18 items were used to assess pharmacists’ intentions and subjective norm, respectively, to report serious ADEs to the Food and Drug Administration (FDA).

Main outcome measure: Pharmacists’ subjective norm toward reporting serious ADEs.

Results: The survey had a response rate of 26.4% (n = 377). Most pharmacists intended to report serious ADEs that they would encounter (15.87 ± 4.22 [mean ± SD], possible range 3–21, neutral = 12). The mean subjective norm scores were moderately high and positive (28.75 ± 9.38, 1–49, 16), indicating that the referents had a moderate influence on pharmacists regarding reporting serious ADEs to FDA. FDA had the greatest (34.82 ± 12.16) and drug manufacturers the lowest (21.55 ± 13.83) social influence. The most important salient referents (important others) in pharmacists’ decisions to report serious ADEs were FDA, patients, pharmacy associations, pharmacy managers/bosses, and hospitals and hospital groups. Gender (female equals higher), pharmacists’ years of experience (negative correlation), and knowledge of ADE reporting (positive correlation) were associated with subjective norm.

Conclusion: Pharmacists had a moderately high subjective norm, suggesting that ADE reporting intentions is influenced by others and that the opinions of others are of great importance in pharmacists’ intentions regarding ADE reporting. The main drivers of subjective norm were FDA, patients, pharmacy associations, and managers/bosses.

Keywords: Subjective norm, pharmacists, adverse drug events, adverse drug event reporting, pharmacovigilance, safety.
The reporting of adverse drug events (ADEs) to pharmacovigilance centers is an integral part of postmarketing surveillance and promotes the safe use of medications. In the United States, ADEs are reported mainly to the Food and Drug Administration (FDA). FDA is responsible for protecting the public health by ensuring the efficacy and safety of all drugs sold within U.S. borders. Drug safety is an essential component of FDA’s mission, and the agency expects all pharmacists to report serious ADEs. Through reporting ADEs, health professionals, including pharmacists, may contribute toward preventing unnecessary and avoidable patient harm from drug use. However, low ADE reporting is a serious problem, as less than 1% of serious ADEs are reported to FDA.1–4

Many factors have been shown to affect ADE reporting. These include lack of time, attitude, access to reporting forms, knowledge of reporting, knowledge of ADEs and what to report, heavy workload, and fear of malpractice suit.5,6 ADE reporting can also be explained by an individual's social influences. Human beings, including pharmacists, tend to conform to the expectations of others with whom they interact (e.g., patients, physicians, peers and colleagues, pharmacy associations, family/spouses, FDA, pharmacy managers, hospitals and hospital groups, lawyers, third-party payers, boards of pharmacy, drug manufacturers). Studies investigating voluntary behaviors of health professionals such as nurses’ use of physical restraints with older people,7 physicians’ prescribing of emergency contraception,8 and education of patients concerning sexually transmitted diseases by physicians9 found that social influence significantly predicted behavioral intention.

The importance of social influence on health professionals’ behaviors and intentions can be understood by reference to a regarded and compelling theoretical framework: the theory of planned behavior (TPB).10 TPB’s constructs are believed to be involved in different behaviors. TPB has been used successfully to predict many health-related behaviors and to predict the intentions of health professionals, including pharmacists.9,11–14 TPB is one of the most widely used psychosocial theories of behavior and posits that behavior is influenced by intention, attitude toward the behavior, subjective norm (or social influence), perceived behavioral control, and behavioral, normative, and control beliefs (Figure 1).10 Subjective norm is an important construct in the TPB framework and is main focus of the current study.

The results of a survey assessing Texas pharmacists’ subjective norm toward adverse drug event (ADE) reporting found that the pharmacists had a moderately high subjective norm, suggesting that ADE reporting intention is influenced by others and that the opinions of others are of importance to pharmacists’ intentions regarding ADE reporting. The Food and Drug Administration (FDA) had the greatest influence and drug manufacturers the lowest influence on intention to report. The most important salient referents (important others) in pharmacists’ decisions to report serious ADEs were FDA, patients, pharmacy associations, pharmacy managers/bosses, and hospitals and hospital groups.

Interventions that enhance pharmacists’ positive social norms may be effective in changing ADE reporting intentions, and all relevant stakeholders (e.g., FDA, employers, patients) should support ADE reporting by pharmacists. Similar to previous findings, the current study found that drug manufacturers had a weak but positive influence on pharmacist reporting of serious ADEs to FDA, perhaps because pharmacists did not consider them trustworthy sources regarding drug safety. The reasons for female respondents having significantly higher subjective norm scores than men are unclear, and the association between gender and subjective norm of pharmacists, and gender and ADE reporting in general, requires further study.

Subjective norm is the perceived social pressure to engage or not engage in a behavior. Subjective norm has been found to be an important and the strongest predictor of health profes-
tionals’ intentions and behaviors in several studies using theoretical models, especially in behaviors that affect or involve others. Meta-analyses and systematic review have confirmed the importance of subjective norm when using a conceptual model. Subjective norm is stronger in the prediction of behaviors that affect others compared with behaviors that do not. In other words, when an individual forms an intention about a behavior that carries implications for others, the perceived views of significant others are of greater importance.

However, few studies have investigated the role of social influences or subjective norm in ADE reporting using a theoretical framework. Two notable exceptions are a study of Texas pharmacists’ intentions to report serious ADEs and a study of health professionals’ intention to use an adverse event reporting system. These studies found subjective norm to be the strongest predictor of reporting intentions. Wu et al. reported that subjective norm “had the most contribution (total effect) on a professional’s intention to use an adverse event reporting system” and Gavaza et al. found that subjective norm was the strongest positive predictor of Texas pharmacists’ intention to report serious ADEs to FDA after controlling for attitude and perceived behavioral control. This indicates that social influence to report ADEs is an important antecedent for ADE reporting intentions and behavior. Thus, pharmacists who are motivated to comply with important others (groups or individuals) perceived as supporting the behavior should intend to report serious ADEs to FDA.

However, no known study has investigated the main (salient) stakeholders (referents) who influence pharmacists’ decision-making processes with respect to ADE reporting intentions and behaviors using a theoretical framework.

Objectives
The objectives of the study were to (1) identify the main groups or individuals that influence pharmacists’ decision making to report ADEs, (2) determine the differences in subjective norm between pharmacists who intended to report serious ADEs and those who did not, and (3) determine the relationship between subjective norm toward reporting serious ADEs and practice and demographic characteristics.

The study hypotheses were that (1) pharmacists who intend to report serious ADEs will have higher subjective norm than those who do not intend to report and (2) demographic (e.g., age, gender, ethnicity) and practice characteristics (e.g., practice setting, pharmacists’ knowledge of ADE reporting, number of prescriptions/medication orders filled, practice location) will be related to subjective norm.

Methods
A nonexperimental cross-sectional survey design was used. The study population consisted of all community (independent, chain, clinic, and other) and hospital pharmacists with an active pharmacy license in Texas. A mail questionnaire was developed to assess pharmacists’ subjective norm toward ADE reporting. Data were collected through a self-administered anonymous mail survey. The study was approved by the University of Texas at Austin Institutional Review Board. A sample of 1,500 pharmacists was selected using simple random sampling from the Texas State Board of Pharmacy electronic list of registered Texas pharmacists.

Survey development and administration
As recommended by Ajzen and Fishbein, focus groups were conducted to identify pharmacists’ normative beliefs that form subjective norm and to develop the subjective norm measure used in the survey. Two focus groups, each lasting approximately 1 hour, were conducted in Austin, TX. The following two open-ended questions were used in the focus groups to identify the important groups or individuals: (1) What individuals or groups would approve pharmacists reporting serious ADEs to the FDA? (2) What individuals or groups would not approve pharmacists reporting serious ADEs to the FDA?

Responses to these questions were content analyzed based on the written transcriptions of the focus groups. The data were coded in order to facilitate the search for key groups or individuals who were likely to apply social pressure on pharmacists with respect to reporting serious ADEs. Identified salient referents or groups/individuals were used to develop the questionnaire items (18 items). Likert-type questions that were part of a larger survey were used to measure pharmacists’ subjective norm toward reporting serious ADEs consisting of two factors: (1) normative beliefs (n; 9 items), and (2) motivation to comply (m; 9 items). The nine modal salient referents (groups/individuals) identified from the focus groups constituted the subjective norm items. Each normative belief
item was rated using a bipolar semantic differential scale anchored by extremely unlikely (1) and extremely likely (7). For example, the normative belief question pertaining to physicians was asked as follows: How likely is it that physicians would think that you should report serious ADEs to the FDA? (1, extremely unlikely, to 7, extremely likely).

A similar but separate scale was used to measure the motivation to comply (m). Each of the motivation to comply items associated with its respective normative belief were measured and rated using a semantic differential scale anchored by extremely unlikely (1) and extremely likely (7). For example, the following question pertaining to physicians was asked: Generally speaking, how likely are you to do what the physicians want you to do when it comes to ADE reporting? (1, extremely unlikely, to 7, extremely likely).

For each respondent, the normative belief (n) and motivation to comply (m) scores were multiplied. The subjective norm composite score was determined by summing these cross products for all referents for each respondent (subjective norm = Σnimi). Higher scores indicated a more favorable subjective norm toward reporting serious ADEs to FDA.

In addition, three items were used to measure pharmacists’ intention to report serious ADEs to FDA using a seven-point bipolar scale ranging from extremely unlikely (1) to extremely likely (7). Respondents were later categorized as intenders (score >12), nonintenders (<12), or neither intenders nor nonintenders (12).

The following demographic and practice characteristic data also were collected: number of prescriptions/medication orders dispensed per day, hours spent dispensing medication and/or interacting with patients, ethnic/racial background, age, gender, type of practice setting, area/setting of primary place of employment, current job title, years of practice in pharmacy, and hours worked per week.

A cover letter and a postage-paid self-addressed questionnaire were sent to all 1,500 pharmacists, and the survey was resent 2 weeks later. Completed questionnaires were collected for a period of 2 months (June and July 2009).

Data analysis
Descriptive statistics (e.g., means, frequencies, SDs) were computed for all study variables, and Pearson correlation, t tests, and analysis of variance were also computed to address study objectives. The α priori level of significance for all analyses was α ≤ 0.05. Data analyses were conducted using PASW Statistics 18 (SPSS, Chicago).

Results
The survey had a 26.4% response rate (n = 377 pharmacists). The mean ±SD age of pharmacists was 51.5 ± 12.7 years, and most pharmacists were men (52.9%) and white (70.2%). These pharmacists dispensed 174.7 ± 119.7 prescriptions/medication orders per day. Only 32.1% of pharmacists had ever reported ADEs to FDA, and 6.6% (n = 25) had reported ADEs to FDA in the previous 12 months.

Intention to report serious ADEs
Most pharmacists indicated that they intended to report serious ADEs to FDA. The pharmacists had high mean intention scores on the three items: 5.16 ± 1.51, 5.44 ± 1.42, and 5.27 ± 1.50. The mean of the composite intention score was 15.87 ± 4.22 (possible range = 3–21, neutral = 12). A total of 297 pharmacists were categorized as intenders and 45 as nonintenders.

Pharmacists’ subjective norm toward reporting serious ADEs
The mean subjective norm scores were moderately high and positive (28.75 ± 9.38, possible range = 1–49, neutral = 16), indicating that the referents had a moderate influence on pharmacists regarding reporting serious ADEs to FDA. FDA appeared to be the most prominent social influence (highest mean of 34.82 ± 12.16), whereas drug manufacturers appeared to be the least influential (21.55 ± 13.83) (Table 1). Subjective norm was positively correlated with pharmacists’ intention to report serious ADEs (r = 0.43, n = 376, P < 0.001).

Table 1. Respondents’ subjective norm composite score

<table>
<thead>
<tr>
<th>Product of normative beliefs/motivation to comply concerning reporting serious ADEs by intenders and nonintenders</th>
<th>n</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
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<tr>
<td>Physicians (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
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<tr>
<td>Drug manufacturers (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
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<tr>
<td>Food and Drug Administration (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
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<tr>
<td>Pharmacy associations (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
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<tr>
<td>Pharmacy managers/bosses (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
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<tr>
<td>Other pharmacists (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
</tr>
<tr>
<td>Average overall mean (Σnimi)</td>
<td>374</td>
<td>26.43 ± 12.57</td>
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</tbody>
</table>

The pharmacists who intended to report ADEs (intenders) were more likely to believe that referents or important groups/individuals expected them to report serious ADEs than those who did not intend to report (nonintenders; P < 0.05) (Table 2). Overall, intenders had higher mean subjective norm scores (30.24 ± 9.17, n = 297) than nonintenders (22.39 ± 8.03, n = 45; t = −5.433, df = 338, P < 0.001).

Table 2. Product of normative beliefs and motivation to comply concerning reporting serious ADEs by intenders and nonintenders
subjective norm by demographic and practice characteristics

Female pharmacists (29.85 ± 9.32, n = 177) had significantly higher mean subjective norm scores than male pharmacists (27.83 ± 9.35, n = 197; t = −2.097, df = 372, P = 0.037).

Subjective norm was negatively and significantly correlated with pharmacists’ years of experience (r = −0.164, n = 373, P = 0.001). Pharmacists who had been in practice longer were more likely to think that important others did not support ADE reporting than those who had been in practice for fewer years. In addition, pharmacists with higher knowledge of ADE reporting had higher subjective norm scores than those with lower knowledge (r = 0.200, n = 374, P < 0.001). No other significant differences in subjective norm were found.

Discussion

The study found a positive association between subjective norm and intention. In addition, as hypothesized, those pharmacists intending to report serious ADEs had higher subjective norm than those who did not intend to report. This may indicate that social influence is an important antecedent for ADE reporting intentions and behaviors. The perceived views of important individuals or groups influence pharmacists’ intentions to report serious ADEs to FDA. Interventions that incorporate such important others to enhance or promote positive subjective norm may be effective in changing ADE reporting intentions.

Although some studies have reported the existence of a good correspondence between intentions and the subsequent behavior,31,32,33,34 behavioral intention is limited in its prediction of behavior. The relationship between intended and actual behavior is fairly low, making it difficult to know if referents actually change behavior. Several factors may moderate the intention–behavior link and consistency.35,36,37 Some of the factors include the presence of facilitating conditions, (perceived) control over the behavior, the extent to which the behavior is habitual, stability and context of performance, frequency of behavior performance, coping appraisals (e.g., perceptions of efficacy and costs), strength of the respective intentions, time interval between intention and behavior, type of behavior measured (objective versus self-report), and type of sample.38–40 Owing to the above factors, behavioral intention may prove to be a poor predictor of behavior.

The study results showed that pharmacists had a moderately high and positive subjective norm, indicating that the important individuals or groups had a moderate influence on pharmacists when it comes to reporting serious ADEs to FDA. Pharmacists felt moderately high social pressure to report serious ADEs to FDA. The most important salient referents (groups/individuals affecting ADE reporting) were FDA, patients, pharmacy associations, pharmacy managers/bosses, and hospitals and hospital groups. Pharmacists believed that these salient referents were interested in whether they reported serious ADEs to FDA. The results also showed that pharmacists were likely to comply with what these groups or individuals wanted them to do concerning ADE reporting. These referents should be used to communicate with pharmacists about the need to report serious ADEs to FDA.

FDA had the most prominent social influence on pharmacists regarding reporting ADEs to FDA. This result is not surprising and is in agreement with opinion poll results showing that FDA commands the respect of more than two-thirds of the American adult population.39 Most pharmacists seem to accept the role of FDA in drug safety. However, several barriers impede FDA from capitalizing on this influence, including lack of funding, multiple and competing priorities, and understaffing.

Patients also had a strong social influence on pharmacists. Most respondents were likely to comply with patients’ viewpoints regarding the reporting of serious ADEs. Pharmacists, especially community pharmacists, obtain most information about serious ADEs directly from patients.40 Because of direct-to-consumer advertising and the widespread availability of health information on the Internet and other sources, patients are becoming increasingly more knowledgeable and engaged in their treatment.

Physicians were another strong social influence in pharmacists’ intent to report serious ADEs. Most respondents were likely to comply with physicians’ viewpoints regarding reporting serious ADEs. Reports have shown that physicians have varied reactions to pharmacists reporting serious ADEs to
FDA. A study in Utah found that physicians were less willing to allow pharmacists to help patients manage ADEs or suggest alterations in patients’ drug regimens.40 The study also found a negative correlation between physicians’ attitude toward community pharmacists acting as patient advocates on drug-related matters and age.40 The negative attitude of physicians toward pharmacists’ drug therapy recommendations and difficulty in making direct contact with physicians41,42 may limit the interprofessional liaison between pharmacists and physicians.10

Similar to the findings of Cosentino et al.43 and Irujo et al.,44 the current study found that drug manufacturers had a weak but positive influence on pharmacist reporting of serious ADEs to FDA. Irujo et al. reported that few pharmacists communicated the occurrence of ADEs to drug manufacturers. Pharmaceutical companies did not appear to have much influence on pharmacist reporting of serious ADEs, perhaps because pharmacists did not consider them trustworthy sources regarding drug safety. This may be explained by the fact that drug companies do not always reveal all they know about their products’ safety profiles to FDA, health professionals, and the public15–47 and have little economic incentive to search and publicize information about ADEs associated with their products.40 In addition, the sponsoring of false and misleading drug advertisements (making unsubstantiated claims and misrepresenting drug risks) by drug manufacturers may also play a role.45 However, drug manufacturing companies are required by law to forward FDA all ADEs that are reported to them by health professionals or patients.

Partially supporting our second hypothesis, subjective norm was associated with knowledge, years of experience, and gender. Female respondents had significantly higher subjective norm scores than men. It is unclear why this was the case and whether this was clinically significant, but other studies have found a similar association between gender and ADE reporting.49,50 One study conducted in Spain, however, found that male physicians were more likely to report ADEs than female physicians.51 More research on the association between gender and subjective norm of pharmacists, and gender and ADE reporting in general, should be conducted.

Consistent with previous studies, knowledge of ADEs and ADE reporting was associated with reporting.44,52,53 Education programs have been shown to increase ADE reporting and the quality of ADE reports.45–56 By improving pharmacists’ knowledge of ADEs and ADE reporting, education programs can increase subjective norm and potentially the reporting of intentions and behavior. Given the current study’s findings, professional education campaigns that use role models, peer educators, and patient advocates to encourage reporting may be effective. The use of peer-led education interventions (led by peer educators or role models) has been reported to be effective in improving participants’ attitude and knowledge57–61; however, such programs have not been tested empirically for the promotion of ADE reporting. Pharmacists may be more likely to change if the message is presented by someone to whom they can relate or who they perceive as important to their reporting decisions.

**Limitations**

This study has several limitations. First, it used a cross-sectional study design. Second, the study used anonymous self-reporting by pharmacists and therefore the information provided could not be verified. Response bias, poor recall, or social desirability factors associated with an expected behavior cannot be completely ruled out. However, responses in this study were anonymous and a majority of those who responded admitted that they had never reported ADEs. Although this is no guarantee of the accuracy of the data, it seems that participants had no incentive to be deceptive. Finally, only 26.4% of the sample responded despite a second mailing. As a result, selection bias may be a concern and the results of this study may not be generalizable to all pharmacists in Texas or the United States.

**Conclusion**

Pharmacists had a moderately high subjective norm, suggesting that ADE reporting influence is influenced by others and that the opinions of others are of importance to pharmacists’ intentions regarding ADE reporting. Interventions that enhance pharmacists’ positive social norms may be effective in changing ADE reporting intentions. All relevant stakeholders (e.g., FDA, employers, patients) should support ADE reporting by pharmacists.

**References**


