Original Research

Examination of pharmacists’ intention to report serious adverse drug events (ADEs) to the FDA using the theory of planned behavior

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Abstract

Background: Adverse drug event (ADE) reporting by pharmacists is an indispensable part of the drug safety system. U.S. pharmacists may submit reports of serious ADEs that they encounter to the Food and Drug Administration (FDA) through MedWatch. However, underreporting of serious ADEs is a common problem. Little is known about pharmacists’ decision making with respect to ADE reporting.

Objectives: This study explored the utility of the theory of planned behavior (TPB) model in predicting Texas pharmacists’ intention to report serious ADEs to the FDA.

Methods: Data were collected from practicing Texas pharmacists using a mail questionnaire. A total of 1500 surveys were mailed, and 377 usable responses were obtained for a response rate of 26.4%.

Results: A majority (70.2%) of the 377 respondents were white/Caucasian, and 52.9% were male. Overall, pharmacists intended to report serious ADEs (mean = 15.87 ± 4.22; possible range: 3-21), had a positive attitude toward reporting (mean = 4.62 ± 4.92; possible range: −15 to +15), perceived that important others wanted them to report (subjective norm [SN] score = 5.65 ± 2.99; possible range: −9 to +9), and believed that they had control over their reporting behavior (perceived behavioral control [PBC] score = 3.54 ± 2.69; possible/actual range: −6 to +6). Attitude (β = 0.221, P < .001) and SN (β = 0.438, P < .001) significantly predicted intent; however, PBC (β = 0.028, P > .05) did not. Attitude, SN, and PBC together accounted for 34.0% of the variance in intention to report serious ADEs (P < .001). The addition of past reporting behavior (P = .021) and perceived moral obligation (P < .001) significantly increased the variance in intention explained by the TPB model.

Conclusions: Pharmacists showed a strong positive intent to report serious ADEs to the FDA. Strategies to increase pharmacists’ intentions to report serious ADEs should focus on helping them see the value of

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reporting and altering their perception of social pressure toward reporting. The TPB may have utility in predicting ADE-reporting behavior. © 2011 Elsevier Inc. All rights reserved.

Keywords: Adverse drug events; ADR reporting; Pharmacists; Attitude; Drug and patient safety; Pharmacovigilance; Spontaneous reporting

Introduction

At the time a drug is approved, little is known about rare and serious adverse events associated with its use. Consequently, these events are identified as the drug is widely used by the population. Voluntary adverse drug events (ADEs) reports are an important source of information to the Food and Drug Administration (FDA), health care professionals (HCPs), and patients concerning drug risks. New drug risks identified through serious ADE reports are added to the drug's label, and the information is communicated to HCPs. ADE reports inform better and safer ways of using available drugs, facilitate the identification and elimination/withdrawal of unsafe products from the market, and educate HCPs on the safe use of medications. Additionally, this information improves understanding of the drug's risk profile. By reporting serious ADEs, pharmacists can promote the safe use of medications and contribute toward public health and drug safety. ADE reporting by HCPs is an indispensable part of pharmacovigilance and postmarketing surveillance.

Pharmacists, doctors, nurses, and dentists in the United States can report serious ADEs directly to the FDA through MedWatch. MedWatch is the national adverse event reporting program in the United States that is administered by the FDA. ADE reports are submitted using the MedWatch form (form 3500) and can be submitted online or by mail, by fax, or over the phone. However, most HCPs do not report the ADEs that they encounter. An estimated 50-96% of all ADEs are not reported annually in the United States. Less than 1% of serious adverse events are reported to the FDA. Reporting rates have also been found to be as low as 1.5%.

As primary providers of drug therapy, pharmacists are particularly well suited to promote safe and effective use of medicines. Their comprehensive knowledge on drugs and training in therapeutics enable them to make a valuable contribution toward ADE-reporting systems. There is guidance in the literature on what shapes HCPs reporting of adverse events and medication errors. Several factors that have been shown to impact reporting include perceived usefulness, fatigue, busyness, lack of time, fear of malpractice litigation, perceived ease of use, subjective norm (SN), lack of knowledge about the reporting system, lack of economic inducements to report, and attitudes toward reporting.

However, pharmacists' decision making with respect to ADE reporting and the role and impact of pharmacists' beliefs toward ADE reporting are largely unknown. In addition, little is known about the main drivers of pharmacists' intention to report ADEs and the actual contribution of these factors in explaining intention and behavior. In ADE-reporting literature, there is an absence of a theoretically grounded organizing framework. In one of the few instances of using a theory to guide ADE reporting, Wu et al used the technology acceptance model to evaluate HCPs' intention to use an adverse event reporting system.

A better understanding of HCPs' behavior can be attained through using theories to investigate these behaviors. The theory of planned behavior (TPB), an extension of the theory of reasoned action, is a psychological model of purposive behavior and deliberative decision making. It is one of the widely used theoretical models of individual behavior. The TPB has been used successfully to predict many health-related behaviors and to predict the intentions of HCPs including pharmacists. Reviews of the TPB have supported its utility with the TPB explaining 27% and 39% of the variance in behavior and intention, respectively. Thus, the TPB is a promising framework for predicting pharmacists' intention and behaviors and was used as the guiding theoretical framework in the present study (Fig. 1). The main constructs of the TPB are behavior, intention (dependent variable), A, SN, and perceived behavioral control (PBC) (independent variables). Each of the independent variables is driven by beliefs (Fig. 1). This study focused on the direct measures of the TPB and their effect on intention.
Pharmacists' attitudes, their perceptions of the beliefs of significant others on their behavior (e.g., physicians, other pharmacists, pharmacy managers, and patients), and their perceived control over their reporting behavior may influence their intentions to report serious ADEs. However, no known study has used the TPB to assess pharmacists' decision making regarding ADE reporting. The literature shows that the predictive power of the TPB can be improved by adding other variables, such as past behavior and moral norm or perceived moral obligation (PMO). In fact, Beck and Ajzen24 and Fishbein25 incorporated moral norms in early theory of reasoned action/TPB work, and a meta-analysis demonstrated the importance of moral norm as an addition to the TPB.30 In addition, Fishbein31 recently added past behavior as a "background influence" variable in his updated model of behavior. Some researchers have proposed that moral norm and past behavior be added to the model.32,33 The addition of past behavior and moral norm was found to improve the ability to predict many health-related intentions and behaviors.24,34,35 and these variables were hypothesized to impact reporting intentions in the present study. Thus, in addition to the 3 key TPB constructs (A, SN, and PBC), the study model also included PMO and past reporting behavior (PRB).

**Objectives**

The aim of the study was to explore the utility of the TPB model in explaining Texas pharmacists' intention to report serious ADEs to the FDA. The specific objectives of the study were to determine (1) the pharmacists' A, SN, PBC, and intention, (2) the relative contribution of A, SN, and PBC toward the prediction of intention, (3) the amount of variance in pharmacists' intention to report serious ADEs explained by the TPB, and (4) if the PRB and PMO constructs contribute toward the prediction of pharmacists' intention to report serious ADEs over and above the TPB constructs.

**Study hypotheses**

The study hypotheses are as follows:

H1: Favorable attitude (A) is a positive and significant predictor of intention to report serious ADEs controlling for SN and PBC.

H2: SN supporting ADE reporting is a positive and significant predictor of intention to report serious ADEs controlling for A and PBC.

H3: Strong PBC is a positive and significant predictor of intention to report serious ADEs controlling for A and SN.
H4: A + SN + PBC constructs explain a significant amount of variance in pharmacists’ intention to report serious ADEs.
H5: PRB significantly increases the explanatory power of the regression model compared with using only the A + SN + PBC to explain pharmacists’ intention to report serious ADEs.
H6: PMO significantly increases the explanatory power of the regression model compared with using only the A + SN + PBC to explain pharmacists’ intention to report serious ADEs.

Methodology

Design, population, and sample

This cross-sectional descriptive study was approved by The University of Texas at Austin’s Institutional Review Board. An electronic Texas State Board of Pharmacy list of licensed pharmacists was used as the sampling frame. The study population consisted of all licensed pharmacists working in community and hospital pharmacies in Texas (N = 12,904). The sample was generated by first stratifying the database by first names and then selecting the sample of 1500 using simple random sampling. Only pharmacists working in community (independent, chain, clinic, and other) and hospital pharmacies were included in the study. Data were collected through a self-administered anonymous mail survey.

Survey development and administration

Intention was defined as the degree of expected likelihood to report serious ADEs to the FDA through MedWatch. Attitude toward the behavior was defined as the degree of positive or negative value placed on reporting serious ADEs by pharmacists, SN was defined as the perception of social pressure to report serious ADEs, and PBC was defined as the perceived control over reporting serious ADEs or confidence in the ability to implement the reporting plans. PRB was defined as the frequency with which ADE reporting has been performed in the past. PMO was defined as an individual’s self-assessment of the level of moral obligation to report serious ADEs.

Intention (3 items) was measured using a 7-point bipolar scale ranging from extremely unlikely (1) to extremely likely (7). The possible total score ranged from 3 to 21 (neutral = 12). The following 3 question stems were used: “I intend to report serious ADEs that I will encounter to the FDA;” “I will try to report serious ADEs that I will encounter to the FDA;” and “I plan to report serious ADEs that I will encounter to the FDA.”

Attitude was measured through 3 items. The strength of attitude was assessed using bipolar semantic differential scales anchored by worthless (-3) and valuable (+3), unpleasant (-3) and pleasant (+3), bad (-3) and good (+3), unenjoyable (-3) and enjoyable (+3), and harmful (-3) and beneficial (+3). The total score from these 3 statements represents the pharmacist’s overall positive or negative feeling toward reporting serious ADEs.

SN was assessed by a 3-item scale. The pharmacists rated their agreement with 3 statements using a 7-point bipolar scale ranging from -3 to +3. The total possible scores ranged from -9 to +9. The 3 questions used to measure SN are as follows:

Most people who are important to me think that I should: _3_ _2_ _1_ _0_ _-1_ _-2_ _-3_ I should not report serious ADEs that I encounter to the FDA.

The people in my life whose opinions I value would approve: _3_ _2_ _1_ _0_ _-1_ _-2_ _-3_ I disagree with reporting of serious ADEs that I encounter to the FDA.

The pharmacists whose opinions I value report: _3_ _2_ _1_ _0_ _-1_ _-2_ _-3_ I do not report serious ADEs to the FDA.

The study used 2 items to measure PBC over reporting serious ADEs. The PBC items were measured using a 7-point bipolar semantic differential scale anchored by -3 (eg, strongly disagree) and +3 (eg, strongly agree). The following questions were used:

1. How much control do you believe you have over reporting serious ADEs that you encounter to the FDA? no control: _-3_ _-2_ _-1_ _0_ _1_ _2_ _3_ complete control.

2. It is mostly up to me whether or not I report serious ADEs to the FDA. strongly disagree: _-3_ _-2_ _-1_ _1_ _2_ _3_ strongly agree.

The scores from the 2 items were then summed with the total possible score ranging from -6 to +6. Higher scores indicate that pharmacists perceive greater control reporting serious ADEs to the FDA.

The PRB measure was developed based on similar measures used in previous studies.21,24,35
PRB was measured using the following 2 dichotomous (yes/no) questions:

1. Have you ever reported any ADEs to the FDA through MedWatch?
2. Have you reported any ADEs to the FDA through MedWatch in the previous 12 months?

A total score was obtained by summing the scores from these 2 items with higher scores indicating higher PRB.

PMO was measured using a single item adapted from Randall and Gibson26 and Gorsuch and Ortberg28 and was stated as follows: I believe I have a moral obligation to report serious ADEs that I will encounter to the FDA. The item was measured using a bipolar Likert response scale anchored by 1 = strongly disagree and 7 = strongly agree.

All the items are shown in Table 1. The following demographic as well as practice and setting characteristics data were also collected: age (year of birth), sex (male/female), ethnic/racial background, type of practice setting, area/setting of primary place of employment, current job title, years of practice, hours worked per week, number of prescriptions/medication orders dispensed per day, and hours spent dispensing medication and/or interacting with patients.

The survey was pilot tested on a convenience sample of 13 hospital and community pharmacists in Austin, Texas. The respondents were asked to complete the questionnaire and then give comments and feedback on the relevance and clarity of items. Minor modifications were made to improve the clarity of some of the items, and the order of questions was also changed after the pilot test.

A self-addressed postage-paid questionnaire and a cover letter explaining the purpose of the project was sent to each of the 1500 randomly selected pharmacists. No identifying respondent information was included on the survey. Respondents were asked to return the questionnaire within 2 weeks. A reminder packet was sent to all pharmacists 3 weeks after the initial mailing. Questionnaires were collected over 2 months, June and July 2009.

Data analysis

Data were analyzed using Statistical Package for Social Sciences® Version 14.0 (SPSS Inc., Chicago, IL). Summated scales for intention, A, SN, PBC, and PRB were created. Descriptive statistics (e.g., means, frequencies, and standard deviations [SDs]) were computed for all study variables. Cronbach's alpha was used to measure the reliability of the scales with at least 3 items. To test study hypotheses, multiple regression analysis was used to regress intention on the independent variables. First, intention was regressed on the TPB predictors (A, SN, PBC). Then we added PRB to the model containing the 3 TPB predictors. Lastly, we added PMO to the model containing the 3 TPB predictors. Statistical tests were 2-sided with alpha set at $P < .05$.

Results

Response rate

A total of 69 packets were returned undeliverable from the 1500 survey packets sent out. Thus, 1431 packets were considered delivered. A total of 399 surveys were received via mail for an overall response rate of 27.9% and, of these, 377 responses were complete and usable, yielding a final response rate of 26.4%. The study's usable response rate of 26.4% is comparable to 1 other mail survey involving pharmacists in Texas (27.0%) and other studies of HCPs (HCPs): 21%, 25%, 40%, and 19.7%. The response rate was higher than 21% obtained in a mail survey of pharmacists in Iowa and lower than those of other studies involving pharmacists in Texas that reported response rates ranging from 35.1% to 58.4%. In addition, the response rate was lower than the mean response rate of 60% obtained among 321 distinct mail surveys published in medical journals.

Demographic and practice setting characteristics

Most respondents were Caucasian/non-Hispanic white (70.2%) and male (52.9%) with a mean age of 51.5 (SD = 12.7) years. On average, pharmacists worked for 38.4 (SD = 10.6) hours per week and had 25.0 (SD = 13.0) years of practice experience. Respondents dispensed an average of 174.7 (SD = 119.7) prescriptions/medication orders per day. Many pharmacists worked in an urban area (46.7%) and practiced in community chain setting (42.2%). Many respondents were staff pharmacists (42.4%) and dispensed medication/interacted with patients.
Table 1
Survey statements and descriptive statistics by construct

<table>
<thead>
<tr>
<th>Construct</th>
<th>Survey statement</th>
<th>Mean (SD)</th>
<th>N</th>
<th>Percent who disagreed&lt;sup&gt;a,b,c&lt;/sup&gt;</th>
<th>Percent who agreed&lt;sup&gt;b,d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitude</td>
<td>Valuable</td>
<td>1.83 (1.26)</td>
<td>376</td>
<td>22 (5.9)</td>
<td>328 (87.2)</td>
</tr>
<tr>
<td></td>
<td>Pleasant</td>
<td>0.0 (1.11)</td>
<td>374</td>
<td>113 (30.2)</td>
<td>113 (30.2)</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>1.37 (1.49)</td>
<td>374</td>
<td>127 (34.0)</td>
<td>262 (70.1)</td>
</tr>
<tr>
<td></td>
<td>Enjoyable</td>
<td>-0.24 (1.40)</td>
<td>374</td>
<td>94 (25.1)</td>
<td>291 (77.4)</td>
</tr>
<tr>
<td></td>
<td>Beneficial</td>
<td>1.67 (1.45)</td>
<td>376</td>
<td>291 (77.4)</td>
<td>291 (77.4)</td>
</tr>
<tr>
<td>SN</td>
<td>Most people who are important to me think that I should report serious ADEs that</td>
<td>1.84 (1.15)</td>
<td>376</td>
<td>4 (1.1)</td>
<td>308 (81.9)</td>
</tr>
<tr>
<td></td>
<td>I encounter to the FDA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The people in my life whose opinions I value would approve my reporting of</td>
<td>2.19 (0.99)</td>
<td>376</td>
<td>2 (0.5)</td>
<td>342 (91.0)</td>
</tr>
<tr>
<td></td>
<td>serious ADEs that I encounter to the FDA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The pharmacists whose opinion I value report serious ADEs to the FDA</td>
<td>1.62 (1.34)</td>
<td>375</td>
<td>16 (4.3)</td>
<td>298 (79.2)</td>
</tr>
<tr>
<td>PBC</td>
<td>It is mostly up to me whether or not I report serious ADEs to the FDA</td>
<td>1.83 (1.51)</td>
<td>375</td>
<td>32 (8.5)</td>
<td>319 (85.1)</td>
</tr>
<tr>
<td></td>
<td>I have much control over reporting serious ADEs that I encounter to the FDA</td>
<td>1.71 (1.46)</td>
<td>374</td>
<td>29 (7.8)</td>
<td>317 (84.8)</td>
</tr>
<tr>
<td>PRB</td>
<td>Have you ever reported any ADEs to the FDA through MedWatch?</td>
<td>—</td>
<td>377</td>
<td>NO: 256 (67.9)</td>
<td>YES: 121 (32.1)</td>
</tr>
<tr>
<td></td>
<td>Have you reported any ADEs to the FDA through MedWatch in the previous 12 mo?</td>
<td>—</td>
<td>377</td>
<td>NO: 256 (67.9)</td>
<td>YES: 121 (32.1)</td>
</tr>
<tr>
<td>PMO</td>
<td>I believe I have a moral obligation to report serious ADEs that I will</td>
<td>5.90 (1.27)</td>
<td>376</td>
<td>8 (2.1)</td>
<td>325 (86.4)</td>
</tr>
<tr>
<td></td>
<td>encounter to the FDA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intention</td>
<td>I intend to report serious ADEs that I will encounter to the FDA</td>
<td>5.16 (1.51)</td>
<td>377</td>
<td>49 (13.0)</td>
<td>264 (70.0)</td>
</tr>
<tr>
<td></td>
<td>I will try to report serious ADEs that I will encounter to the FDA</td>
<td>5.44 (1.42)</td>
<td>377</td>
<td>33 (8.8)</td>
<td>300 (79.9)</td>
</tr>
<tr>
<td></td>
<td>I plan to report serious ADEs that I will encounter to the FDA</td>
<td>5.27 (1.50)</td>
<td>377</td>
<td>42 (11.2)</td>
<td>276 (73.2)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Percent stating they disagreed or strongly disagreed.
<sup>b</sup> Scales ranged from -3 (eg, strongly disagree, worthless) to +3 (strongly agree, valuable).
<sup>c</sup> Percents were calculated using the number of surveys with valid responses (N) as the denominator.
<sup>d</sup> Percent stating that they agreed or strongly agreed.
Table 2: Demographic and practice characteristics of the respondents

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td></td>
<td>51.46 (12.69)</td>
</tr>
<tr>
<td>Practice experience (in years)</td>
<td></td>
<td>24.98 (13.0)</td>
</tr>
<tr>
<td>Number of hours worked per week</td>
<td></td>
<td>38.43 (10.6)</td>
</tr>
<tr>
<td>Number of hours spent dispensing medication/interacting with patients</td>
<td></td>
<td>30.79 (14.8)</td>
</tr>
<tr>
<td>per week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescriptions/medication orders dispensed per day</td>
<td></td>
<td>174.67 (119.7)</td>
</tr>
<tr>
<td>Sex</td>
<td>199 (52.9)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>177 (47.1)</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian/non-Hispanic white</td>
<td>262 (70.2)</td>
<td></td>
</tr>
<tr>
<td>Asian American/Pacific Islander</td>
<td>37 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Mexican American/Hispanic</td>
<td>33 (8.8)</td>
<td></td>
</tr>
<tr>
<td>African American/non-Hispanic black</td>
<td>27 (7.2)</td>
<td></td>
</tr>
<tr>
<td>Other&lt;sup&gt;a&lt;/sup&gt;</td>
<td>11 (2.9)</td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaskan Native</td>
<td>3 (0.8)</td>
<td></td>
</tr>
<tr>
<td>Current job title at primary place of employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff pharmacist</td>
<td>160 (42.4)</td>
<td></td>
</tr>
<tr>
<td>Pharmacy manager</td>
<td>102 (27.1)</td>
<td></td>
</tr>
<tr>
<td>Pharmacy owner/partner</td>
<td>44 (11.7)</td>
<td></td>
</tr>
<tr>
<td>Clinical pharmacist</td>
<td>37 (9.8)</td>
<td></td>
</tr>
<tr>
<td>Relief pharmacist</td>
<td>24 (6.4)</td>
<td></td>
</tr>
<tr>
<td>Other&lt;sup&gt;b&lt;/sup&gt;</td>
<td>10 (2.7)</td>
<td></td>
</tr>
<tr>
<td>Area/setting of primary place of employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>175 (46.7)</td>
<td></td>
</tr>
<tr>
<td>Suburban</td>
<td>126 (33.6)</td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>74 (19.7)</td>
<td></td>
</tr>
<tr>
<td>Practice setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community: multiple/chain</td>
<td>159 (42.2)</td>
<td></td>
</tr>
<tr>
<td>Community: independent</td>
<td>74 (19.6)</td>
<td></td>
</tr>
<tr>
<td>Hospital: multiple/chain</td>
<td>58 (15.4)</td>
<td></td>
</tr>
<tr>
<td>Hospital: independent</td>
<td>44 (11.7)</td>
<td></td>
</tr>
<tr>
<td>Other&lt;sup&gt;c&lt;/sup&gt;</td>
<td>42 (11.1)</td>
<td></td>
</tr>
</tbody>
</table>

Counts per item may not total 377 because of item nonresponse.

<sup>a</sup> Other category included Spanish, Anglo-white Caucasian, Czech-German, and Asian.

<sup>b</sup> Other category included assistant pharmacy manager, pharmacy informatics, consultancy, general manager, clinical pharmacy coordinator, pharmacist in charge, and vice president.

<sup>c</sup> Other category included government hospital, veterans affairs, community health center/clinic, home infusion, long-term care/institutional, army/military, county hospital/clinic, surgery center/surgical day hospital, city health department, mail order, home health care, and worksite pharmacy.

for an average of 30.8 (SD = 14.8) hours per week (Table 2).

Most respondents (67.9%) had never reported any ADEs to the FDA through MedWatch, whereas 93.4% had not reported any ADEs in the previous 12 months. About 45% of pharmacists indicated that they had encountered reportable ADEs in their practice in the past. There was no statistically significant difference between the demographic characteristics of the study sample, and all pharmacists registered in Texas.

Scale reliability and correlations

Intention, A, and SN were all internally consistent with Cronbach’s alpha scores greater than 0.70 (Table 3). Intention had the highest reliability (alpha = 0.95). The 2 items comprising the PBC were also highly correlated (Spearman’s rho = 0.71).
Table 3
Reliability and descriptive statistics for the TPB scales

<table>
<thead>
<tr>
<th>Scale</th>
<th>No. of items</th>
<th>Mean (SD)</th>
<th>Min</th>
<th>Max</th>
<th>Cronbach’s alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitude</td>
<td>5</td>
<td>4.62 (1.92)</td>
<td>−12</td>
<td>15</td>
<td>0.75</td>
</tr>
<tr>
<td>SN</td>
<td>3</td>
<td>5.65 (2.99)</td>
<td>−5</td>
<td>9</td>
<td>0.91</td>
</tr>
<tr>
<td>PBC</td>
<td>2</td>
<td>3.54 (2.69)</td>
<td>−6</td>
<td>6</td>
<td>0.71</td>
</tr>
<tr>
<td>Intention</td>
<td>3</td>
<td>15.87 (4.22)</td>
<td>3</td>
<td>21</td>
<td>0.95</td>
</tr>
</tbody>
</table>

* Spearman’s rho for the 2 items was calculated instead of the Cronbach’s alpha.

TPB model constructs

**Attitude toward reporting serious ADEs**

Pharmacists believed that reporting serious ADEs to the FDA was valuable (mean = 1.83 ± 1.26), neither pleasant nor unpleasant (mean = 0.0 ± 1.41), good (mean = 1.37 ± 1.49), unenjoyable (mean = −0.24 ± 1.40), and beneficial (mean = 1.67 ± 1.45) (Table 1). Overall, pharmacists had a moderate and positive attitude toward reporting (mean = 4.62 ± 4.92; range: −12 to +15) (Table 3).

**Subjective norm**

Pharmacists believed that most people who were important to them thought that they should report serious ADEs that they encounter to the FDA (mean = 1.84 ± 1.15). Pharmacists also believed that the people in their lives whose opinions they valued would approve of their reporting of serious ADEs that they encounter to the FDA (mean = 2.19 ± 0.99). They also indicated that the pharmacists whose opinions they valued report serious ADEs to the FDA (mean = 1.62 ± 0.99) (Table 1). Overall, pharmacists had a strong and positive SN (mean = 5.65 ± 2.99; range: −5 to +9) (Table 3).

**PBC over reporting serious ADEs**

Most pharmacists (n = 319, 85.1%) believed that it was mostly up to them whether or not they report serious ADEs to the FDA (mean = 1.83 ± 1.51) and that they had control over reporting serious ADEs that they encounter to the FDA (n = 317, 84.8%, mean = 1.71 ± 1.46) (Table 1). Overall, pharmacists had a moderately high and positive PBC (mean = 3.54 ± 2.69; range: −6 to +6) (Table 3).

**Intention**

The mean scores for the 3 intention items were 5.16 ± 1.51, 5.44 ± 1.42, and 5.27 ± 1.50 (Table 1). Overall, pharmacists intended to report ADEs (mean = 15.87 ± 4.22; range: 3-21) (Table 3). For example, 300 pharmacists indicated that they will try to report serious ADEs that they encounter to the FDA (Table 1).

**Predictors of intention**

Attitude (β = 0.221, P < .001) and SN (β = 0.433, P < .001) were statistically significant predictors of intention to report serious ADEs. Therefore, H1 and H2 were supported. However, PBC (β = 0.028, P = .526) was not a significant predictor of intention controlling for A and SN (Table 4). Therefore, H3 was not supported. A, SN, and PBC together accounted for 34.0% (R = 0.583, adjusted R² = 0.335) of the variance in intention to report serious ADEs to the FDA (F = 63.60, df = 3, 370, P < .001) (Table 4). Therefore, H4 was supported.

The addition of PRB to the model increased the proportion of variance in intention explained from 34.0% to 35.0% (R² change = 0.009, F (1, 369) change = 5.39, P = .021). The regression weight of the PRB construct was significant (β = 0.100, P = .021) (Table 5). Therefore, H5 was supported.

The addition of PROMO to the TPB constructs (A, SN, and PBC) increased the proportion of variance in intention explained by the model from 34.0% to 37.6%. The change in R² was statistically significant (R² change = 0.036, F (1, 369) change = 21.21, P < .001) (Table 6). The regression coefficient of the PROMO construct was statistically significant (β = 0.244, P < .001). Therefore, H6 was supported.

**Discussion**

As hypothesized, pharmacists’ attitudes and SNs were significant predictors of intention to report serious ADEs, but PBC was not a significant predictor of intention. Thus the study data partially supported the TPB explaining a significant amount of variance in ADE-reporting intentions. The combination of A, SN, and PBC explained 34.0% of the variance in intention to report...
Table 4
Results of multiple regression analysis for the TPB constructs

<table>
<thead>
<tr>
<th>Predictor variable</th>
<th>B</th>
<th>SE</th>
<th>β</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>11.302</td>
<td>0.408</td>
<td>27.73</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Attitude</td>
<td>0.190</td>
<td>0.041</td>
<td>0.221</td>
<td>4.64</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SN</td>
<td>0.620</td>
<td>0.069</td>
<td>0.438</td>
<td>8.95</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PBC</td>
<td>0.044</td>
<td>0.070</td>
<td>0.028</td>
<td>0.64</td>
<td>.526</td>
</tr>
</tbody>
</table>

SE, Standard Error; B, Unstandardized regression coefficients; Beta (β), Standardized regression coefficients.
N = 374 pharmacists, F = 63.60, df = 3, 370, P < .001, R = 0.583, R² = 0.340, adjusted R² = 0.335.

Serious ADEs to the FDA. The explanation of 34.0% of the variance in pharmacists' reporting intentions is worthwhile from a practical viewpoint, given the small number of predictors. In some previous studies of HCPs and health behaviors (not ADE reporting), comparable proportions of variance in intention (eg, 33.7% and 40%) were predicted. The data were consistent with the predicted relationships among the TPB model components (A, SN, PBC, and I). The TPB may be well suited to better understanding ADE-reporting intentions of pharmacists and possibly reporting behaviors.

Pharmacists had a strong intention to report serious ADEs to the FDA. This supports previous studies based on the TPB that found that pharmacists had high intentions to provide medication-related services. For example, Odedina and Segal found that community pharmacists had high intention to provide pharmaceutical care.

The study results show that pharmacists expressed positive and strong attitudes toward reporting serious ADEs to the FDA. The study respondents thought that ADE reporting was valuable, good, and beneficial (ie, for the profession and patients). Previous studies also found that pharmacists had positive attitudes toward ADE reporting. However, this study's respondents also thought that ADE reporting was unenjoyable and was neither pleasant nor unpleasant. This may discourage them from making reports despite the operational value they attach to ADE reporting.

SN was the strongest (TPB) predictor of intention after controlling for A and PBC. This concurs with findings from previous research on ADE reporting. For example, Wu et al found that SN was the most important predictor of professionals' intention to use an adverse event reporting system. Similarly, other studies on HCPs' (including pharmacists) behaviors found that SN was the most important predictor of intention. SN has been found to be stronger than A in the prediction of intentions of behaviors that affect others compared with behaviors that do not and is of greater importance in the formation of intention about a behavior that carries implications for others. Thus, the importance of SN in the formulation of intentions to report serious ADEs may be explained by the fact that ADE reporting is perceived to have implications for other people (eg, doctors, patients, and colleagues). Taken together, these findings imply that SN is a critical antecedent for ADE-reporting intentions and should be targeted in

Table 5
Regression coefficients after adding PRB to the TPB constructs

<table>
<thead>
<tr>
<th>Predictor variable</th>
<th>B</th>
<th>SE</th>
<th>β</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>14.015</td>
<td>1.237</td>
<td>—</td>
<td>11.33</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Attitude</td>
<td>0.184</td>
<td>0.041</td>
<td>0.215</td>
<td>4.53</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SN</td>
<td>0.600</td>
<td>0.069</td>
<td>0.424</td>
<td>8.65</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PBC</td>
<td>0.030</td>
<td>0.069</td>
<td>0.019</td>
<td>0.43</td>
<td>.666</td>
</tr>
<tr>
<td>PRB</td>
<td>0.093</td>
<td>0.301</td>
<td>0.100</td>
<td>2.32</td>
<td>.021</td>
</tr>
</tbody>
</table>

SE, Standard Error; B, Unstandardized regression coefficients; Beta (β), Standardized regression coefficients.
N = 374 pharmacists, F = 49.61, df = 4, 369, P < .001, R = 0.591, R² = 0.350, adjusted R² = 0.343.
Table 6
Regression coefficients after adding PMO to the TPB constructs

<table>
<thead>
<tr>
<th>Predictor variable</th>
<th>B</th>
<th>SE</th>
<th>$\beta$</th>
<th>$t$</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>7.742</td>
<td>0.869</td>
<td>0.193</td>
<td>8.908</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Attitude</td>
<td>0.166</td>
<td>0.040</td>
<td>0.300</td>
<td>4.127</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SN</td>
<td>0.424</td>
<td>0.080</td>
<td>0.029</td>
<td>5.314</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PBC</td>
<td>0.045</td>
<td>0.068</td>
<td>0.244</td>
<td>0.671</td>
<td>.503</td>
</tr>
<tr>
<td>PMO</td>
<td>0.809</td>
<td>0.176</td>
<td></td>
<td>4.605</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

SE, Standard Error; B, Unstandardized regression coefficients; $\beta$, Beta (B), Standardized regression coefficients.

$N = 374$ pharmacists, $F = 55.61$, $df = 4$, $369$, $P < .001$, $R = 0.613$, $R^2 = 0.376$, adjusted $R^2 = 0.369$.

Interventions aimed at improving ADE reporting among pharmacists.

In this study, PBC was not a significant predictor of intent to report serious ADEs after controlling for A and SN, a finding also reported elsewhere in the pharmacy literature. Also in the literature, problems have been reported concerning directly measuring the PBC construct. The small number of items (n = 2) used to measure the construct may have contributed to nonsignificance. In addition, the PBC construct was operationalized in this study as controllability (the degree of volition or control over reporting). However, other aspects such as ease/difficulty, facilitating conditions, and self-efficacy were not measured and could have changed the significance of the construct in the model. The measurement of PBC and its role in ADE reporting warrant further study.

Adding the PRB construct to the TPB model significantly increased the power of the regression model. Thus, providing pharmacists (nonreporters) with real (or practiced) experiences with completing and submitting ADE reports for actual (or hypothetical) serious ADEs may significantly increase their intentions to report serious ADEs in the future. In addition, interventions to improve ADE reporting should focus on those who have not reported ADEs in the past. Similar findings have been reported in the literature. Taken together, these findings indicate that past behavior is an important predictor and, thus, should be included in models of ADE-reporting intentions among pharmacists.

In this study, only 7% of the respondents had reported ADEs in the previous 12 months and 32% had reported ADEs to the FDA in the past. The proportion of pharmacists who had ever reported ADEs (32%) in this study is comparable to the proportion of reporters found in previous studies: 33.2% obtained among Dutch doctors and 33.7% obtained among Swedish general practitioners and hospital pharmacists. Other studies found lower percentages of HCPs who had ever reported adverse drug reactions (ADRs): 25.6%, 23.3%, and 19.4%, whereas some studies reported higher percentages of HCPs who had ever reported ADRs.

Importantly, this shows that a large proportion of respondents were not fully engaged in reporting ADEs to the FDA, despite them having favorable intention, A, SN, and PBC toward reporting. Similar findings were reported in the nonpharmacy and pharmacy literature. For example, Lee et al. reported that 93% of pharmacists indicated that ADR reporting was important, yet only 14.7% had done so in the previous year. These results seem to indicate the existence of challenges that impede the translation of intentions into behavior. Several factors may moderate the intention-behavior link and consistency, including 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 (eg, perceptions of the efficacy and costs), strength of the respective intentions, time interval between intention and behavior, type of behavior measure (objective vs self-report), and type of sample. Because of the above factors, other measures besides behavioral intention and its antecedents need to be taken into consideration in predicting behavior.

Finally, PMO independently improved the prediction of intention thereby corroborating previous research showing that PMO is an important predictor of intention especially in moral situations. Findings from a recent systematic review of studies based on social cognitive theories among HCPs also support these findings. Moral norm (equivalent of PMO) was significant ($P < .05$) in 10 of the 14 studies assessed. This study was the first to examine the direct path of
moral norm to intention to report serious ADEs by pharmacists. In this study, a large number of pharmacists indicated that they had a moral obligation to report serious ADEs that they encounter to the FDA. This finding suggests that ADE reporting is perceived as a moral issue or a professional responsibility for U.S. pharmacists. Similarly, pharmacists in other countries also feel that they have a professional obligation to report ADRs\textsuperscript{56,83,84} and that ADE reporting is their professional duty.\textsuperscript{85} Similar beliefs about professional duty have been reported among physicians as well. Importantly, the World Health Organization considers ADE reporting as a part of HCPs' duties.\textsuperscript{85,86}

Limitations

The study has several limitations. First, it was impossible to validate the pharmacists' responses with the actual ADE reports given the anonymity of the study and of ADE reporting. Second, this nonexperimental cross-sectional study cannot make causal inferences because it did not control for all appropriate confounding variables. However, the use of a theory and prior research to guide this study makes the inferences plausible. Third, the study is unable to test the relationship between study factors and actual reporting behavior given its cross-sectional design. Testing this relationship would require a study using a prospective study design. Fourth, only 26.4% of the sample responded. This low response rate makes nonresponse bias a concern and may limit the generalizability of the study.

Conclusions

Pharmacists showed a positive intention, attitude, SN, and PBC over reporting serious ADEs to the FDA. Attitude and SN were significant and positive predictors of intention. Together, attitude, SN, and PBC accounted for 34.0% of the variance in pharmacists' intention to report serious ADEs, and the addition of PRB and PMO to the TPB improved the prediction of intention. The TPB with the addition of PRB and PMO is a useful framework for predicting pharmacists' reporting intentions. Strategies to improve pharmacists' reporting intentions should focus on these predictors and the removal of obstacles that impede the translation of intentions into behavior.

Acknowledgments

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