Influence of attitudes on pharmacists’ intention to report serious adverse drug events to the Food and Drug Administration

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WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT
• Attitude is an important factor impacting pharmacists’ reporting of adverse drug events (ADE) to pharmacovigilance centres.
• However, little is known about United States (US) pharmacists’ attitudes with respect to ADE reporting. No known study has assessed US pharmacists’ attitude to report serious ADEs to the FDA.

WHAT THIS STUDY ADDS
• This study results suggest that pharmacists hold favourable attitudes toward reporting serious ADEs to the FDA and there is an association between pharmacists’ attitude and intention to report serious ADEs.
• Pharmacists’ beliefs that reporting serious ADEs was time consuming and disrupted the normal workflow impact on reporting intentions.
• Pharmacists’ attitudes towards reporting need to be improved in order to enhance patient and drug safety.

AIM
To investigate the influence of pharmacists’ attitudes on intention to report serious adverse drug events (ADEs) to the Food and Drug Administration (FDA).

METHODS
This cross-sectional study used a mail survey to collect data from hospital and community pharmacists practicing in Texas, United States. Three and 16 items were used to measure intention and attitudes, respectively, using a seven-point bipolar scale. Pharmacists’ demographic and practice characteristics, and past reporting were also measured.

RESULTS
The response rate was 26.4% (n = 377/1500 pharmacists). Most pharmacists intended (n = 297, 78.8%) to report serious ADEs that they will encounter to the FDA through MedWatch. Overall, pharmacists held favourable attitudes towards reporting serious ADEs (mean = 24.5, SD = 6.7, possible range 1–49, neutral = 16). Pharmacists intending to report serious ADEs had more favourable attitudes than those who did not (P < 0.001). About 90% of the pharmacists believed that reporting serious ADEs would improve patient safety. However, 72.6% indicated that reporting serious ADEs was time consuming and over half (55.5%) of the respondents believed that reporting serious ADEs disrupted the normal workflow. Non-intenders held stronger beliefs that ADE reporting would disrupt the normal workflow and was time consuming compared with intenders. Years of experience, number of hours worked and practice setting were associated with pharmacists’ attitudes towards reporting (P < 0.05).

CONCLUSIONS
Most pharmacists held moderately favourable attitudes and high intentions toward reporting serious ADEs to the FDA. This study’s findings contribute to an increased understanding of individual factors that influence pharmacists’ attitude and intention towards reporting serious ADEs to the FDA.
Introduction

Little is known about the safety of a drug at the time of its approval. Inevitably, more is learned as the drug is widely used on the market. Rare, serious, uncommon and unpredictable events that may surface after approval may be reported through a voluntary reporting system [1]. In the United States (US), consumers and healthcare providers (HCPs) including pharmacists are encouraged to report serious adverse drug events (ADEs) that they encounter to the Food and Drug Administration (FDA) through MedWatch. ADE reports can be submitted to other providers, drug manufacturers or local risk management groups. However, reporting serious ADEs through MedWatch is standardized, anonymous and convenient. Reports can be submitted by phone (1-800-FDA-1088), fax (1-800-FDA-0178), internet (http://www.fda.gov/medwatch) and postage free mail.

Voluntary reports provide important drug risk information to the FDA, HCPs and patients and improve understanding of the drug’s risk profile. To ensure patient safety, these events need to be detected, monitored, counted, confirmed and investigated. ADE reporting is an important and critical aspect of pharmacovigilance or drug postmarketing surveillance. Pharmacists can promote the safe use of medications through identifying and reporting serious ADEs. However, most HCPs do not report the ADEs they encounter [2–4]. Less than 1% of serious adverse events are reported to the FDA [5]. A high rate of under-reporting delays or prevents identification of risks, confirmation of hypotheses, estimation of the magnitude of the risk and taking of possible regulatory action.

Several facilitators to ADE reporting have been identified/reported in the literature including improving education and information [6, 7], establishing an independent organization to receive ADE reports [8], provision of encouragement and motivation [9], legally mandating reporting [10], attention drawn to a particular drug, making reporting more convenient [6, 11], type and nature (severity, and novelty and seriousness) of the ADE [12]. However, concerns about malpractice litigation, lack of time, high workload, lack of trust and lack of economic inducements to report may impede pharmacists from reporting serious ADEs to voluntary reporting systems. Attitudes of HCPs have also been reported to influence reporting in many countries [13–15]. However, little is known about US pharmacists’ attitude with respect to ADE reporting. No known study has assessed US pharmacists’ attitude to report serious ADEs.

Attitude is the degree of positive or negative value placed on reporting serious ADEs by pharmacists. In several studies investigating voluntary behaviours using a theoretical framework, attitude has been consistently found to be a strong predictor of intentions among HCPs [16–20] and the general population [21–24]. In previous studies that predicted pharmacists’ intention to embark on various drug related behaviours, attitude emerged as a strong predictor of intention to perform the studied behaviours [25–29].

Reference to a well established theoretical framework such as the theory of planned behaviour can help in understanding the influence of attitudes on pharmacists’ intention to report ADEs. The theory of planned behaviour is a widely used psychosocial theory of behaviour. The theory of planned behaviour has been used successfully to predict many health-related behaviours and to predict the intentions of HCPs, including pharmacists [24, 25, 30–32]. According to the theory of planned behaviour, behaviour is predicted by intention, attitude, subjective norm and perceived behavioural control. Attitude is an important construct in the theory of the planned behaviour framework.

Study objectives

The aim of the study was to examine the influence of attitudes on pharmacists’ intention to report serious ADEs to the FDA through MedWatch. The specific objectives of the study were to (i) identify the main advantages and disadvantages of reporting serious ADEs to the FDA that underpin pharmacists’ attitudes, (ii) determine the differences in attitudes between intenders and non-intenders and (iii) determine the relationship between attitudes towards reporting serious ADEs to the FDA and pharmacists’ demographic and practice characteristics.

Method

Design, population and sample

This cross-sectional non-experimental study was part of a larger study to predict pharmacists’ intention to report serious ADEs to the FDA through MedWatch. This study reports on the relationship between attitudes and intention. The study was approved by The University of Texas at Austin’s Institutional Review Board. A sample of 1500 pharmacists was selected using simple random sampling from an electronic Texas State Board of Pharmacy list of registered Texas pharmacists. Only pharmacists working in community (independent, chain, clinic and other) and hospital pharmacy settings in Texas were included in the study. Data were collected through a self-administered anonymous mail survey.

Survey development and administration

As recommended by Ajzen & Fishbein [33], focus groups (n = 2) were conducted to identify pharmacists’ behavioural beliefs that form attitude. The two focus groups were conducted in Austin, Texas and were attended by six (6) and seven (7) practicing pharmacists, respectively. The following open-ended questions, adapted from Montano & Kasprzyk [34], were used in the focus groups:

1 What do you think are some of the advantages associated with pharmacists reporting serious ADEs to the FDA? and
What do you think are some of the disadvantages associated with pharmacists reporting serious ADEs to the FDA?

Each focus group lasted approximately 1 h. A content analysis was performed on the basis of the written transcriptions of the focus groups. The data were coded in order to facilitate the search for the main advantages and disadvantages associated with pharmacists reporting serious ADEs to the FDA. Many behavioural beliefs were identified from the responses of the focus group participants. Eight most commonly mentioned behavioural beliefs from the focus groups were formatted to develop the questionnaire items (n = 16) that were later used in the mail survey. This number is in line with the recommended minimum five to nine belief items [33].

Likert-type questions which were part of a larger survey were used to measure pharmacists’ attitudes toward reporting serious ADEs consisting of two factors: (i) behavioural beliefs (b) and (ii) outcome evaluations (e) [33]. The eight (8) modal salient beliefs (advantages and disadvantages) identified from the focus groups constituted the attitudes items. Each behavioural belief (b) item was rated using a bipolar semantic differential scale anchored by extremely unlikely (+1) and extremely likely (+7). A similar but separate scale was used to measure the outcome evaluations (the consequences) (e). Each of the evaluative outcomes associated with the respective behavioural belief was measured and rated using a semantic differential scale anchored by extremely bad (+1) and extremely good (+7).

For each respondent, the behavioural belief (b) and outcome evaluation (e) scores were multiplied. The attitude score was determined by summing these cross-products for all referents for each respondent (A = Σb*e), after reverse coding all the negatively worded items. Higher scores indicated a more favourable attitude towards reporting serious ADEs to the FDA.

Behavioural intention was defined as the degree of likelihood to report serious ADEs to the FDA through MedWatch. Pharmacists’ intention (three items) was measured using a seven-point bipolar scale ranging from extremely unlikely (1) to extremely likely (7). The following three question stems were used:

1. I intend to report serious ADEs that I will encounter to the FDA,
2. I will try to report serious ADEs that I will encounter to the FDA and
3. I plan to report serious ADEs that I will encounter to the FDA.

All the respondents who marked a 1, 2 or 3 on any of the three intention items were considered non-intenders for that item (re-coded with a −1). All responders who marked a 5, 6 or 7 on any of these three items were considered intenders for that item (re-coded with a +1). Those who marked 4 on any of the three intention items were considered to be neither intenders nor non-intenders (for that item) and the responses were re-coded with a zero. For each respondent, the dummy codes (−1 s, 0 s and +1 s) were added together across the three intention items. This composite score was then used to categorize respondents into intenders (i.e. positive total score), non-intenders (i.e. had a negative total score) and neither intenders nor non-intenders (i.e. had a total score of zero).

The study also collected the following demographic, practice and setting characteristics data: age (year of birth), gender, ethnic/racial background, type of practice setting (community vs. hospital/institutional), area/setting of primary place of employment, current job title, years of practice in pharmacy, 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 several 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 pharmacists. No identifying subject information was included on the survey. Respondents were asked to return the questionnaire within 2 weeks. A reminder packet was sent to pharmacists 3 weeks after the initial mailing. Questionnaires were collected over 2 months, June and July 2009.

Data analysis

Data analyses were conducted using PASW Statistics 18 (SPSS Inc., Chicago, IL). Descriptive statistics (e.g. means, frequencies, standard deviations) were computed for all study variables. Cronbach’s alpha was calculated to measure the reliability of the intention scale (three items). An independent groups t-test was used to compare the difference in pharmacists’ mean composite attitude scores between intenders and non-intenders, male and female pharmacists and community and hospital pharmacists. A Pearson correlation was used to test the relationship between the mean attitude composite scores and pharmacists’ years of experience, number of prescriptions/medication orders dispensed per day, and the number of hours worked by the pharmacist per week. A one way analysis of variance was run to compare the difference in mean composite attitude scores by ethnic/racial background, pharmacists’ current job title at their primary place of employment, area/setting of pharmacists’ primary place of employment. The a priori level of significance for all analyses was α < 0.05.
Results

From the 1500 survey packets sent out, a total of 69 letters were returned undeliverable. Thus, 1431 letters were considered delivered. A total of 399 surveys were received via mail for a response rate of 27.9% and of these, 377 responses (26.4%) were complete and usable. The intention scale (three items) had a reliability coefficient of 0.95.

Most respondents were Caucasian/non-Hispanic white (70.2%) and male (52.9%), with a mean age of 51.5 (SD = 12.7) years. The respondents worked for an average of 38.4 (SD = 10.6) h per week and had 25.0 (SD = 13.0) years of practice experience. They dispensed an average of 174.7 (SD = 119.7) prescriptions/medication orders per day. Many respondents were staff pharmacists (42.4%), worked with patients (mean = 26.4), 5.16 (SD = 1.51) 9 (2.4) 17 (4.5) 23 (6.1) 64 (17.0) 85 (22.5) 101 (26.8) 78 (20.7) 5.44 (SD = 1.42) 7 (1.9) 14 (3.7) 12 (3.2) 44 (11.7) 93 (24.7) 111 (29.4) 96 (25.5) 5.27 (SD = 1.50) 6 (1.6) 21 (5.6) 15 (4.0) 59 (15.6) 91 (24.1) 92 (24.4) 93 (24.7)

### Intention to report serious ADEs

Most pharmacists planned (n = 276, 73.2%) intended (n = 264, 70%) and would try (n = 300, 79.6%) to report serious ADEs that they would encounter to the FDA through MedWatch (Table 1). The pharmacists had high mean intention scores on these three items: 5.16 (SD = 1.51), 5.44 (SD = 1.42) and 5.27 (SD = 1.50) (Table 1). The mean aggregate intention score was 15.87 (SD = 4.22, possible range 3–21), neutral (3.70, SD = 1.62) or compromised their relationship with physicians (mean = 3.40, SD = 1.49) (Table 2).

The pharmacists evaluated three of the eight outcomes as being good: educates others about drug risks (mean = 6.02, SD = 1.03), personally beneficial/rewarding to the pharmacist (mean = 5.28, SD = 1.30) and improves patient safety (mean = 6.07, SD = 0.97) (Table 3).

The mean composite attitudes scores were moderately high (mean = 24.45, SD = 6.73; possible range: 1–49, neutral = 16), indicating that pharmacists had moderately favourable attitudes towards reporting serious ADEs to the FDA. Overall, hospital pharmacists had a higher mean attitude score than community pharmacists. The product of the item ‘Reporting serious ADEs to the FDA will improve patient safety’ and its behavioural outcome evaluation had the highest mean (mean = 35.77, SD = 10.57) (Table 4).

### Pharmacists’ attitudes towards reporting serious ADEs

Overall, the mean behavioural belief scores (b) were high. Improving patient safety (mean = 5.80, SD = 1.12) was rated as the most likely advantage (outcome), and breaking trust with patients (mean = 2.85, SD = 1.57) was the least likely outcome from reporting serious ADEs. Pharmacists also believed that reporting serious ADEs to the FDA educates others about drug risks (mean = 5.53, SD = 1.22), was personally beneficial/rewarding to the pharmacist (mean = 4.96, SD = 1.56), was time consuming (mean = 5.06, SD = 1.55) and disrupted the normal workflow (mean = 4.55, SD = 1.65). Respondents did not believe that reporting serious ADEs to the FDA increased the risk of malpractice (mean = 3.70, SD = 1.62) or compromised their relationship with physicians (mean = 3.40, SD = 1.49) (Table 2).

### Attitude differences between intenders and non-intenders

For the mean product scores (product behavioural outcome evaluations and behavioural beliefs) (2b, e) about reporting serious ADEs, intenders had a more favourable attitude (mean = 25.37, SD = 6.52) than non-intenders (mean = 21.01, SD = 7.13) (t = -4.122, d.f. = 339, P < 0.001). Intenders had higher product mean scores than non-intenders on the items: educates others about drug risks, is personally beneficial/rewarding to the pharmacist and improves patient safety (P < 0.05) (Figure 1).

### Relationship between attitude and demographic and practice characteristics

Attitude toward reporting serious ADEs was significantly negatively correlated with the pharmacists’ years of expe-

Table 1

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean (SD)</th>
<th>Non-intenders Extremely unlikely (1)</th>
<th>2</th>
<th>3</th>
<th>Neither likely nor unlikely (4)</th>
<th>Intenders 5</th>
<th>6</th>
<th>Extremely likely (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I intend to report serious ADEs that I will encounter to the FDA.</td>
<td>5.16 (1.51)</td>
<td>9 (2.4)</td>
<td>17 (4.5)</td>
<td>23 (6.1)</td>
<td>64 (17.0)</td>
<td>85 (22.5)</td>
<td>101 (26.8)</td>
<td>78 (20.7)</td>
</tr>
<tr>
<td>2. I will try to report serious ADEs that I will encounter to the FDA.</td>
<td>5.44 (1.42)</td>
<td>Strongly disagree (1)</td>
<td>14 (3.7)</td>
<td>12 (3.2)</td>
<td>44 (11.7)</td>
<td>93 (24.7)</td>
<td>111 (29.4)</td>
<td>96 (25.5)</td>
</tr>
<tr>
<td>3. I plan to report serious ADEs that I will encounter to the FDA.</td>
<td>5.27 (1.50)</td>
<td>6 (1.6)</td>
<td>21 (5.6)</td>
<td>15 (4.0)</td>
<td>59 (15.6)</td>
<td>91 (24.1)</td>
<td>92 (24.4)</td>
<td>93 (24.7)</td>
</tr>
<tr>
<td>Overall mean</td>
<td>15.87 (4.22)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Influence of attitudes on pharmacists’ intention to report ADEs

Table 2
Mean and frequency distribution of behavioural beliefs

<table>
<thead>
<tr>
<th>How likely do you think the following outcomes will be if you report serious ADEs to the FDA?</th>
<th>Frequency distribution of responses (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>1. Educates others about drug risks</td>
<td>377</td>
</tr>
<tr>
<td>2. Personally beneficial/ rewarding to the pharmacist</td>
<td>377</td>
</tr>
<tr>
<td>3. Improves patient safety</td>
<td>377</td>
</tr>
<tr>
<td>4. Increases risk of malpractice</td>
<td>377</td>
</tr>
<tr>
<td>5. Compromises relationship with physicians</td>
<td>377</td>
</tr>
<tr>
<td>6. Breaks trust with patients</td>
<td>377</td>
</tr>
<tr>
<td>7. Disrupts the normal workflow</td>
<td>377</td>
</tr>
<tr>
<td>8. Time consuming to report</td>
<td>377</td>
</tr>
</tbody>
</table>

Table 3
Mean and frequency distribution of behavioural outcome evaluations

<table>
<thead>
<tr>
<th>How good or bad do you feel each of the following outcomes would be if you reported serious ADEs to the FDA?</th>
<th>Frequency distribution of responses (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>1. Educates others about drug risks</td>
<td>376</td>
</tr>
<tr>
<td>2. Personally beneficial/ rewarding to the pharmacist</td>
<td>376</td>
</tr>
<tr>
<td>3. Improves patient safety</td>
<td>376</td>
</tr>
<tr>
<td>4. Increases risk of malpractice</td>
<td>373</td>
</tr>
<tr>
<td>5. Compromises relationship with physicians</td>
<td>375</td>
</tr>
<tr>
<td>6. Breaks trust with patients</td>
<td>376</td>
</tr>
<tr>
<td>7. Disrupts the normal workflow</td>
<td>376</td>
</tr>
<tr>
<td>8. Time consuming to report</td>
<td>376</td>
</tr>
</tbody>
</table>

Discussion

This study examined attitudes of Texas pharmacists towards reporting serious ADEs to the FDA. The overall mean attitude score was high, signifying that Texas pharmacists held favourable attitudes towards reporting serious ADEs to the FDA. The finding that pharmacists had a favourable attitude towards ADE reporting is consistent with previous studies conducted in other countries [13–15].

The beliefs that reporting serious ADEs to the FDA will improve patient safety and educate others about drug risks had the strongest influence on reporting intention (e.g. had highest mean product of behavioural belief and outcome evaluation scores). ADE reports contribute to patient safety through informing better and safer methods of using medicines. It is encouraging that pharmacists’ beliefs were in line with the primary advantages of ADE reporting – to improve patient safety and to educate others about drug risks. Similar findings have been reported elsewhere [13, 35, 36]. For example, Inman found that physicians believed that reporting ADEs informed their colleagues of the adverse experiences they have encountered [35].

Texas pharmacists did not believe that reporting serious ADEs to the FDA increased the risk of malpractice. This finding is contrary to previous research that reported that ADE reporting or self-identification is believed to result in repercussions, investigation and malpractice suits [37, 38]. In the literature, open reporting of ADEs is reported to be deterred by the threat of litigation, professional disciplinary action, investigation or reprisal [39–41]. For example, according to Inman, fear of possible involvement in litigation or investigation of prescribing costs by health departments was one of the seven main reasons why medical doctors did not report suspected ADRs [42]. This study’s finding is, however, consistent with other studies [9, 37].
43–47]. The passage of the Patient Safety and Quality Improvement Act of 2005 (PL. 109-41), which grants ‘peer review protection from report disclosure during legal proceedings, and protection of providers who report from professional retaliation’ [48], together with the confidentiality and anonymity of reporting accorded by MedWatch may explain our findings.

Pharmacists also believed that reporting serious ADEs to the FDA did not break trust with patients and did not compromise their relationship with physicians. Similarly, elsewhere reporting adverse drug events was found to build rather than destroy patient trust [15]. Furthermore, reporting adverse drug events was found to show that pharmacists took patients’ complaints seriously [15] and that they took greater responsibility for patient care [11].

In addition, pharmacists believed that reporting serious ADEs to the FDA is personally beneficial/rewarding to the pharmacist, time consuming and disrupted the normal workflow. However, they did not exhibit very strong support for these advantages and disadvantages (outcomes) with most of the responses to these items falling around 4 (neither agree nor disagree). The belief that ADE reporting disrupted the normal workflow, though not strong, is consistent with previous findings [9]. Similar to previous findings, it may be that pharmacists consider reporting ADEs as an additional duty or not to be an integral part of their professional duties [9]. Pharmacists could submit more reports if they considered reporting to be an integral part of their duties, as is the case in the Netherlands [14].

Results showed that those pharmacists who intended to report serious ADEs to the FDA were more likely to believe that reporting serious ADEs educated others about drug risks, was personally beneficial/rewarding to the pharmacist, and improved patient safety (P < 0.05) than those who did not intend to report. As a result, interventions that increase pharmacists’ awareness of the benefits of ADE reporting could be valuable. Pharmacists ought to be sensitized and educated on the benefits of reporting serious ADEs.

### Attitude and demographic and practice characteristics

This study found that hospital pharmacists had significantly more favourable attitudes than community pharmacists. This is consistent with previous studies that found that hospital pharmacists are more likely to report adverse drug events than community pharmacists [45, 49]. Practice setting was also found to be associated with reporting among medical practitioners [46, 50–52]. Hospital pharmacists had more favourable attitudes than community pharmacists as they may be more knowledgeable about clinical pharmacy and pharmacovigilance, have access to patient medical records and tend to see more patients with serious ADEs [53–56]. In addition, hospital pharmacists are more directly involved in patient care, and have access to state of the art computer systems which may not be available in the community setting [57, 58]. These factors increase their chances of detecting serious ADEs compared with community pharmacists.

Attitude was negatively associated with the pharmacists’ years of experience. Pharmacists with more years in pharmacy practice were more likely to have a less favourable attitude than those who had fewer years of experience. The pharmacists with more years of experience may be remembering the old and punitive way ADE reporting was conducted before the introduction of MedWatch in 1993. This is in contrast with other studies in Europe that reported a positive association between tendency to report ADEs and years of experience (seniority) [9, 13, 59–61].

Pharmacists’ attitudes were positively correlated with the number of hours worked. As observed by Sweis & Wong [9], pharmacists who worked more hours tended to have more favourable attitudes than those who worked less hours. In addition, pharmacists who were younger had more favourable attitudes towards reporting ADEs than other pharmacists. Focus should be given to the needs of more experienced pharmacists, those pharmacists practicing in community independent settings and those who work less hours when implementing activities aimed at positively increasing pharmacists’ attitude.

### Study limitations

The findings of this study should be interpreted in the light of its limitations as discussed below. The study used self-

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**Table 4**

Respondents’ composite attitude score

<table>
<thead>
<tr>
<th>Behavioural beliefs and outcome evaluation</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reporting serious ADEs to the FDA will educate others about drug risks</td>
<td>376</td>
<td>33.98</td>
<td>10.95</td>
</tr>
<tr>
<td>2. Reporting serious ADEs to the FDA is personally beneficial/rewarding to the pharmacist</td>
<td>376</td>
<td>27.50</td>
<td>12.87</td>
</tr>
<tr>
<td>3. Reporting serious ADEs to the FDA will improve patient safety</td>
<td>376</td>
<td>35.77</td>
<td>10.57</td>
</tr>
<tr>
<td>4. Reporting serious ADEs to the FDA will increase risk of malpractice</td>
<td>373</td>
<td>20.72</td>
<td>11.80</td>
</tr>
<tr>
<td>5. Reporting serious ADEs to the FDA will compromise relationship with physicians</td>
<td>375</td>
<td>22.53</td>
<td>11.21</td>
</tr>
<tr>
<td>6. Reporting serious ADEs to the FDA will break trust with patients</td>
<td>376</td>
<td>26.50</td>
<td>12.69</td>
</tr>
<tr>
<td>7. Reporting serious ADEs to the FDA will disrupt the normal workflow</td>
<td>376</td>
<td>15.59</td>
<td>9.90</td>
</tr>
<tr>
<td>8. Reporting serious ADEs to the FDA is time consuming</td>
<td>376</td>
<td>13.02</td>
<td>8.85</td>
</tr>
<tr>
<td>Composite attitude score</td>
<td>376</td>
<td>24.45</td>
<td>6.73</td>
</tr>
</tbody>
</table>

Scale: 1 = extremely unlikely; 4 = neither unlikely nor likely; 7 = extremely likely; possible range: 1 to 7. The belief and behavioural outcome evaluation ratings for items 4 to 8 were first reverse coded before being multiplied. Attitude composite score represents the composite score for the eight belief-based attitudes (sum of b1e1 through b8e8).
reports from pharmacists which are prone to inaccurate responses. The study could not verify the pharmacists' responses since the responses were anonymous. The pharmacists' responses could have been influenced by response bias, poor recall or social desirability factors associated with an expected behaviour. It has been reported that physicians overestimate their adherence to guidelines in their self-reports by as much as 20% [62]. Some pharmacists may have provided socially desirable responses to questions pertaining to attitudes and intentions. 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 accuracy of the data, it seems there was no incentive to be deceptive. Despite using a second mailing to improve the survey response rate, only 26.4% of the selected sample returned complete survey responses. This low response rate may limit the generalizability of the results from this study. In addition, since the study was anonymous, non-responders and responders could not be compared. Selection bias may be a problem. Furthermore, the study population consisted of Texas practicing pharmacists, and therefore, the results cannot be extrapolated to non-practicing pharmacists or to pharmacists in other states.

In addition, this study only focused on reporting serious ADEs to the FDA through MedWatch. Although reporting via MedWatch is the most common, there are several other ways pharmacists can report serious ADEs including reporting to pharmaceutical companies, provider (hospital) programmes or local risk management groups.

**Future research**

There are several issues that need further investigation. More empirical research should be conducted to confirm the study findings using a different population or pharmacists practicing in other states.

Future research should also pay more attention to the reporting context. The use of vignettes or hypothetical serious ADEs could help contextualize the performance of ADE reporting. Vignettes and hypothetical ADEs have been
successfully used to predict physician prescribing and reporting behaviour [51, 63] and pharmacists’ reporting behaviour [64]. Vignettes and hypothetical cases may be effective in predicting pharmacists’ attitude and intention towards reporting serious ADEs to the FDA. Public health officials, drug safety experts and pharmacy educators can gain insight from these findings for the development of strategies to increase ADE reporting by pharmacists. Pharmacy educators can also use results of this study to direct teaching strategies regarding pharmacovigilance activities.

**Competing Interests**

There are no competing interests to declare.

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Influence of attitudes on pharmacists' intention to report ADEs


Br J Clin Pharmacol / 72:1 / 151


